Aanvraag voor procedure voor ontheffing voor antigeen sneltest als zelftest

[redacted] Beheer B.V.

Overbekkingsweg 12A
7273 PW, Haarlo, Nederland

Contactpersoon voor de aanvraag:
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Tel: [redacted]
Email: [redacted]

Contactadres:
Albert Cuyplaan 6a
7482 JA, Haaksbergen

Fabrikant:
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10028 Sokak No:11 A.O.S.B 35620 Cigli / IZMIR / TURKEY
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Website: www.chil.com.tr

AUTHORIZATION LETTER

As Chil Tıbbi Malzemeler San. ve Tic. Ltd. Şti., we manufacture Covid-19 Antigen rapid test. We authorize, 5.1.2e BV with Dutch exemption application of our Covid-19 Antigen Rapid Test.

5.1.2e

5.1.2e

CHİL TIBBİ MAL. SAN. VE TİC. LTD. ŞTİ.

5.1.2e

CHİL TIBBİ MAL. SAN. TİC. LTD. ŞTİ.
10028 sok. No:11 AOSB 35620 Çiğli-İzmir/TURKEY
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info@chil.com.tr www.chil.com.tr

09.04.2021

Manufacturer: Chil Tıbbi Mal. San ve Tic. Ltd. Şti.

Address : 10028 Sok. No:11 AOSB 35620 Çiğli/İzmir-Turkey

Product Name: CHIL COVID-19 Antigen Rapid Test (Home Test- Nasal Swab-Cassette)

File number of the special approval of the BfArM: 5640-S-078/21

We, herewith declare that the above mentioned product CHIL COVID-19 Antigen Rapid Test(Home Test-Nasal Swab-Cassette) is analytically same as our product CHIL COVID-19 Antigen Rapid Test(Nasopharyngeal/Oropharyngeal Swab-Cassette).

CHIL COVID-19 Antigen Rapid Test(Nasopharyngeal/Oropharyngeal Swab-Cassette) is listed in the BfArM list with the AT337/20 AT number; and its performance is evaluated by Paul-Ehrlich-Institut (PEI) with the product name **COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette**).

5.1.2e

CHIL TIBBİ MAL. SAN. TİC. LTD. ŞTİ.
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Ministerie van Volksgezondheid,
Welzijn en Sport

Procedure voor ontheffing voor antigeen sneltest als zelftest

Sinds 4 maart 2021 kunnen fabrikanten en leveranciers van een antigeen sneltest een tijdelijke ontheffing aanvragen zodat hun product als zelftest op de Nederlandse markt mag worden gebracht. Op dit moment zijn er nog geen antigeen sneltesten CE-gemarkeerd voor het gebruik als zelftest, maar de overheid wil toch op een veilige en verantwoorde manier de (versnelde) beschikbaarheid en het gebruik van zelftesten mogelijk maken. Daarom krijgen fabrikanten de mogelijkheid om via een tijdelijke ontheffing hun antigeen sneltest, onder voorwaarden, versneld op de Nederlandse markt te brengen als zelftest. De verleende ontheffingen gelden in eerste instantie tot en met 31 december 2021. Alle ontheffingen worden openbaar gemaakt via Rijksoverheid.nl.

Voorwaarden en criteria ontheffingsprocedure Om een ontheffing te kunnen krijgen voor uw antigeen sneltest moet u aan onderstaande voorwaarden en criteria voldoen:

Specifiek:

- De antigeen sneltest heeft al een CE-markering voor professioneel gebruik als antigeen sneltest en u kunt dit aantonen. **(Zie Declaration of Conformity, Klik hier)**
- U bent al gestart met de conformiteitsbeoordelingsprocedure tot het verkrijgen van een CE-certificaat voorhet gebruik van deze antigeen sneltest als zelftest via een notified body, en u kunt dit aantonen. **(Zie NB procedure, er is contact opgenomen met 3 Notified Bodies. Klik hier)**
- De antigeen sneltest is aantoonbaar geschikt voor gebruik als zelftest voor een specifiek omschreven doelgroep. **(Ja)**
- De antigeen sneltest voldoet aan de vereisten voor zelftesten zoals genoemd in het besluit IVD's en beschikbare normen op het gebied van zelftesten (met uitzondering van het door het Notified Bodyafgegeven certificaat voor gebruik als zelftest). **(Ja, zie onder andere Declaration of Conformity, Klik hier)**

Algemeen:

- Lever alle documentatie in het Engels of Nederlands aan. **(Ja)**
- De aanvraag bevat de gegevens van een contactpersoon voor vragen over de aanvraag en de documentatie. **(Zie titelpagina, Klik hier)**
- Geef in de aanvraag aan of de antigeen sneltest staat opgenomen in de meest recente versie van de op 17februari 2021 vastgestelde lijst van de Health Security Committee *"A common list of COVID-19 rapidantigen tests"*[1] **(Nee, de test is niet opgenomen in de bovenstaande lijst)**
- Geef in de aanvraag aan of een andere Europese lidstaat al een ontheffing heeft verleend voor het gebruik van de antigeen sneltest als zelftest. **(Ja, Duitsland heeft de ontheffing al verleend, Zie Algemene informatie, Klik hier)**
- Het ingediende dossier moet duidelijk gestructureerd zijn, een inhoudsopgave bevatten en eenvoudig te doorzoeken zijn. **(Ja)**
- U heeft een systeem waarin u de ervaringen met het gebruik van de antigeen sneltest als zelftest bijhoudt en beoordeelt, en waarmee u indien nodig maatregelen kunt nemen.[2] Een dergelijk systeem wordt tegenwoordig aangeduid met de term Post-Market Surveillance. **(Ja, dit wordt hoofdzakelijk uitgevoerd door de fabrikant (Chil), met ondersteuning van Rob Huisman Beheer B.V. Zie PMS Procedure en Plan, Klik hier)**

1 https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

2 Besluit IVD, artikel 8 lid 5 inzake conformiteitsbeoordelingsprocedures en Annex III, artikel 5, Annex IV, artikel 3 lid 1 en Annex VI, artikel 3

- Signalen over calamiteiten en veiligheidskwesties, gerelateerd aan het zelfafname aspect van de betreffende test, rapporteert u onmiddellijk aan de IGJ. **(Ja)**
- U volgt de reguliere wettelijke procedures ten aanzien van vigilantie voor veiligheidskwesties die zijn gerelateerd aan de algemene veiligheids- en prestatie eisen. **(Ja)**
- Als u een CE-certificering heeft verkregen voor het gebruik van de antigeen sneltest als zelftest, moet u de IGJ en VWS/GMT op de hoogte brengen via 5.1.2e minvws.nl. **(Ja)**
- Een verleende ontheffing wordt openbaar gemaakt via www.rijksoverheid.nl/ontheffingen-antigeentesten.
- Tijdens het aanvraagproces kan het ministerie van VWS om aanvullende documentatie vragen of wijzigingen doorvoeren indien nodig. U wordt tijdig op de hoogte gesteld en krijgt de mogelijkheid om de aanvraag aan te passen als dat nodig is.

Benodigde documentatie **(Zie Inhoudsopgave, Klik hier)**

Voeg bij de aanvraag voor een ontheffing minimaal de volgende documenten toe:

- Bewijs dat de antigeen sneltest een CE-markering heeft voor professioneel gebruik, inclusief daarbij behorende onderliggende documentatie.
- Bewijs dat voor de antigeen sneltest een aanvraag is ingediend bij een EU27 Notified Body voor het verkrijgen van het CE-certificaat voor gebruik als zelftest. Of bewijs dat al een contract is gesloten voor de conformiteitbeoordelingsprocedure via een EU27 Notified Body voor gebruik als zelftest, en een bevestigd plan van aanpak met tijdslijnen voor het verkrijgen van het CE-certificaat (indien beschikbaar).
- Productinformatie:
    - Productnaam/handelsnaam en catalogusnummer.
    - Algemene beschrijving van de test, inclusief het werkingsmechanisme.
    - Bedoeld gebruik van de test, inclusief type monster/monstername en beschrijving van de te testen doelgroep.
    - Duidelijke (digitale) afbeeldingen/foto's van de verschillende componenten en voorbeeld foto's van alle zijden verpakking en etikettering.
    - Validatiestudies: rapportage over analytische en klinische validatie (methode en resultaten)waaruit de prestaties van de test bij zelfgebruik zonder begeleiding volgen (sensitiviteit en specificiteit).
    - Als bij de validatie gebruik wordt gemaakt van gegevens uit een studie die buiten Nederland is uitgevoerd, moet u onderbouwen hoe deze gegevens te extrapoleren zijn naar de Nederlandsesituatie.
    - Validatiestudies: rapportage over analytische en klinische validatie (methode en resultaten)waaruit de prestaties van de test bij professioneel gebruik volgen (sensitiviteit en specificiteit).
    - Gebruiksvriendelijkheidstudie voor de zelftest, rekening houdend met de eisen uit EN-IEC62366-1.
    - Gebruiksaanwijzing in het Nederlands. Dit is een vereiste bij zelftesten. Indien beschikbaar: ook Nederlandstalige instructievideo's, een link of verwijzing naar waar deze video's te bekijken zijn.
    - Beschrijving van de samenstelling van de testkit (device, reagentia, accessoires) die nodig zijn voor de zelftest met beschrijving van afwijkingen ten opzichte van de oorspronkelijke professional use kit, inclusief toeleveranciers van componenten.
    - De CE Declaration of Conformity voor het professioneel gebruik van de antigeen sneltest.
    - De CE Declaration of Conformity voor nieuwe componenten ten opzichte van professional usekit, indien van toepassing.

  - Checklist essentiële eisen
  - Documentatie voor risk management met overzicht risk estimation, risk control measures enresidual risks in overeenstemming met EN ISO 14971. Geef specifieke risico's in verband met het gebruik als zelftest duidelijk aan, bijvoorbeeld door gebruik van highlight.
- Indien van toepassing: bewijs dat een andere Europese lidstaat al een ontheffing heeft verleend voor het gebruik van de antigeen sneltest als zelftest.
- De gebruiksaanwijzing moet de door de overheid vastgestelde instructies bevatten. Daarin moet uitgelegd worden wat de vervolgstappen zijn bij een negatieve of positieve testuitslag. De door de overheid vastgestelde instructies vindt u op Rijksoverheid.nl via de volgende link: https://www.rijksoverheid.nl/documenten/publicaties/2021/03/22/informatie-voor-gebruiker-corona-zelftest

Stuur de aanvraag voor een ontheffing per e-mail naar [redacted] minvws.nl Vermeld daarbij dat u een ontheffing aanvraagt voor het **aanbieden van een antigeen sneltest als zelftest op basis van artikel 8 van de Wet op de medische hulpmiddelen**. De aanvraag moet inclusief de gevraagde documentatie zijn.

Inhoudsopgave

*Zie ook de bladwijzers voor een gemakkelijk en snel overzicht

CHIL COVID-19 ANTIGEN RAPID TEST

Product Name:

CHIL COVID-19 Antigen Rapid Test (Nasal/Nasopharyngeal/Oropharyngeal Swab-Casette)

Reference Number:

CCOV-201(For Professional Use), CCOV-206 (For Lay User)

Product Intended Use:

CHIL COVID-19 Antigen Rapid Test is an in vitro diagnostic test intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus that causes COVID-19 in a nasal swab from individuals age 2 years and older individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

Product Content:

Test cassette contains SARS-CoV-2 antibody-coated in the test region and Goat anti-Chicken IgY polyclonal antibody-coated in the control region on the membrane. The test cassette consists of the SARS-CoV-2 antibody, Chicken IgY, and Colloidal gold conjugate coated in the conjugate pad. The specimen extraction solution is a phosphate solution.

Materials Supplied

1. Swab 2. Tube with antigen extraction buffer
3. Test cassette 4. Instruction for Use (IFU)

Test Pirinciple:

This kit by immune chromatography test, the sample will be under the capillary action to move forward along the test cassette. If the sample contains SARS-CoV-2 N antigens, these antigens will be with colloidal gold labeled coronavirus monoclonal antibody. This immune complex will be membrane fixed by coronavirus monoclonal antibody capture, form the purple line which reveals a positive result. If the line does not show any color, the negative result will be displayed. The test cassette also contains a quality control line (C), which shall appear in purple regardless of whether there is a test line.

Storage Condition:

The kit is stored at 2-30°C and stable for 12 months in its aluminium sealed pouch. The test cassette should be used within 15 minutes after removed from its aluminium pouch, at the specified environment (temperature 2°C - 35°C, humidity 40% - 60%).

Performance Summary:

Sensitivity: 98.55% (95% CI: 96.33%- 99.60%) * Specificity: 99.57% (95% CI: 98.46%- 99.95%) *

Precision: 99.49% (95% CI: 98.67%- 99.87%) *

* 95% confidence interval: (%-%)

The prevalence of the disease was assumed to be 5%. Experiment results on twenty SARS CoV-2 antigen negative specimens of healthy people have confirmed as all negative for the concentration of microorganisms or viruses mentioned above. These tested pathogens have no cross reaction effect on the detection performance of the COVID-19

Antigen Rapid Test and common substances have no interference effect on the detection performance of the COVID-19 Antigen Rapid Test.

Differences Between Home Use and Professional Use

Between professional use and home use, a shorter nasal swab is used instead of the nasopharyngeal swab as the product content. In order to make sampling more convenient at home, the user manual and box labeling are differentiated with applications such as the procedure pictures and the QR code of the application video. Apart from these, the test for professional use and the test for home use are exactly the same.

Extra informatie betreft algemene punten uit de procedure

– Geef in de aanvraag aan of de antigeen sneltest staat opgenomen in de meest recente versie van de op 17 februari 2021 vastgestelde lijst van de Health Security Committee "A common list of COVID-19 rapid antigen tests"
CHIL COVID-19 Antigen Rapid Test (Home Test) is niet opgenomen in de bovengenoemde lijst.
Wel is de test te vinden in de volgende databases onder de naam: CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette) of COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette):

- Covid-19 in Vitro Diagnostic Devices and Test Methods Database
https://covid-19-diagnostics.jrc.ec.europa.eu/devices/detail/1691

- Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, nummer AT337/20 AT.
https://antigentest.bfarm.de/ords/f?p=101:100:20244072733506:::::&tz=2:00

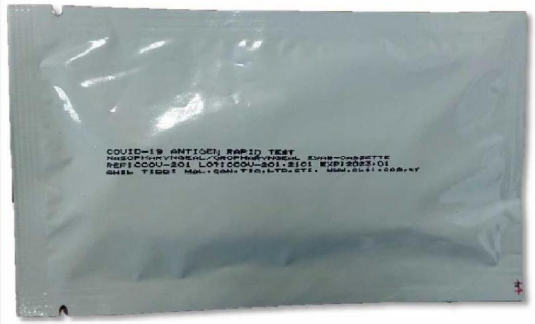
De prestaties van de test zijn door het Paul-Ehrlich-Institut (PEI) geëvalueerd met de productnaam COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)

– Geef in de aanvraag aan of een andere Europese lidstaat al een ontheffing heeft verleend voor het gebruik van de antigeen sneltest als zelftest.

Het "Bundesinstitut für Arzneimittel und Medizinprodukte" heeft op basis van "§11 Absatz 1 Medizinproduktegesetz (MPG)" de goedkeuring gegeven voor COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette) als zelftest door leken.

Dossiernummer van de speciale goedkeuring van het BfArM: 5640-S-078/21
(Zie bijlage)

Foto's/Afbeeldingen van componenten, (Let op: niet op ware grootte)



Gebruiksaanwijzing

CHIL COVID-19 ANTIGEN RAPID TEST
HOME TEST / LEKENTEST
(neusuitstrijkje - test strip)

STAP 1
Snuit uw neus voordat u de test uitvoert.

STAP 2
HANDEN WASSEN
Was of desinfecteer uw handen en droog ze daarna goed af

STAP 3
VERPAKKINGSINHOUD CONTROLEREN

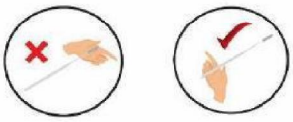
Test Strip | Buisje met Testvloeistof | Steriel Wattenstaafje

STAP 4
UITPAKKEN VAN DE TESTSTRIP

Haal de teststrip uit de verpakking en leg hem op een vlakke droge ondergrond.

STAP 5
HET STERIELE WATTENSTAAFJE

Haal het wattenstaafje voorzichtig uit de verpakking. Zorg ervoor dat u het bovenste deel van het wattenstaafje niet aanraakt.

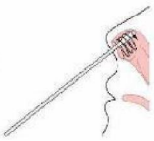


STAP 6
MONSTERAFNAME

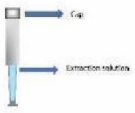
a) Houd het wattenstaafje halverwege het handvat vast en steek het voorzichtig ongeveer 1,5 cm tot 2,5 cm in het neusgat, afhankelijk van de grootte van de neus van de persoon.

b) Draai het wattenstaafje langzaam 5 keer rond de binnenwand van het neusgat. Zorg ervoor dat er een uitstrijkje/ monster op het wattenstaafje zit.

c) Herhaal met hetzelfde wattenstaafje de procedure van monsterafname in het andere neusgat. Neem ongeveer 15 seconden om het monster te verzamelen.



STAP 7
PLAATS HET WATTENSTAAFJE IN HET BUISJE MET DE TESTVLOEISTOF



Open de schroefdop van het buisje.

Plaats het wattenstaafje in het buisje en draai het wattenstaafje 5-6 keer rond.

STAP 8
MENGEN VAN HET WATTENSTAAFJE MET DE TESTVLOEISTOF

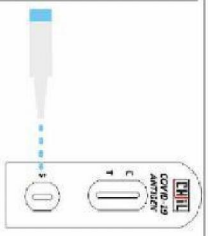
Druk de kop van het wattenstaafje tegen de wand van het buisje om het antigeen in het wattenstaafje vrij te maken. Terwijl het wattenstaafje in het flesje zit, knijpt u in het flesje en verwijdert u zoveel mogelijk vloeistof uit het wattenstaafje.

STAP 9
HET OPENBREKEN EN WEER VASTMAKEN VAN DE BOVENSTE SLUITING

Sluit de schroefdop van het buisje weer. Breek, scheur of knip het bovenste deel van het buisje af met een schaar. Houd het buisje verticaal, aangezien het brekende gedeelte naar boven wijst, om te voorkomen dat de monsteroplossing wordt gemorst. Zorg ervoor dat de vloeistof in het kegelvormige gedeelte naar beneden valt. Indien nodig, kunt u er lichtjes op tikken om de vloeistof te laten vallen.

STAP 10
VOEG 4 DRUPPELS TOE

Het toevoegen van de juiste hoeveelheid druppels is cruciaal voor een betrouwbaar resultaat. Daarom moet u precies 4 druppels op de teststrip laten vallen. Zorg ervoor dat de sluitingsopening groot genoeg is en vrij van vreemde voorwerpen.



STAP 11
LEESTIJD

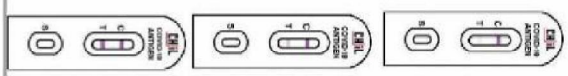
Lees het resultaat af na 15- 30 minuten. De resultaten na 30 minuten zijn niet meer geldig.

STAP 12
WEGGOOIEN

Doe alle onderdelen in de geleverde verpakking en gooi het in de daarvoor bestemde prullenbak

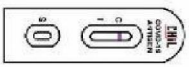
INTERPRETATIE VAN DE RESULTATEN

POSITIEF RESULTAAT



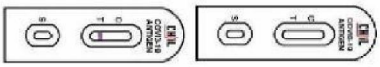
Als zowel de kwaliteitscontrolelijn (C) als de testlijn (T) worden weergegeven, betekent dit dat het SARS-CoV-2-antigeen is opgespoord en dat het resultaat positief is. De kleurintensiteit van de testlijn (T) kan variëren, afhankelijk van de dichtheid van het verzamelde monster. Binnen de gespecificeerde waarnemingstijd moet echter zelfs een zeer vage lijn als een positief resultaat worden geïnterpreteerd, ongeacht de dichtheid van de gekleurde lijn.

NEGATIEF RESULTAAT



Als er slechts één kwaliteitscontrolelijn (C) aanwezig is en de testlijn (T) kleurloos is, betekent dit dat het SARS-CoV-2-antigeen niet is opgespoord en dat het resultaat negatief is.

ONGELDIG RESULTAAT



Als de kwaliteitscontrolelijn (C) niet wordt weergegeven, is de test ongeldig, of er nu een testlijn (T) is of geen lijn. De test moet vernieuwd worden.

Issued Date & Revision 2021.04.01/1 COM.RIFU.236

CKS-114

CHIL COVID-19 ANTIGEN RAPID TEST
HOME TEST / LEKENTEST
(neusuitstrijkje - test strip)

INSTRUCTIES VOOR DE GEBRUIKER EN DOEL VAN DE TEST

De CHIL COVID-19-antigeensneltest is een in-vitrodiagnostische test voor de snelle kwalitatieve opsporing van nucleocapsideproteïne-antigeen van het SARS-CoV-2-virus bij personen van 2 jaar en ouder met of zonder symptomen. Door middel van een uitstrijkje van de menselijke voorste neusstreek, bijvoorbeeld bij verdachte gevallen met of zonder symptomen of om andere epidemiologische redenen, kan de mogelijke besmetting met COVID-19 aldus worden opgespoord.
COVID-19 is een zeer besmettelijke en acute ziekte van de luchtwegen met deels een zeer ernstig ziektebeloop.
De gebruiksaanwijzing (IFU) moet vóór gebruik zorgvuldig worden gelezen en opgevolgd. Personen die positief reageren op de CHIL COVID-19-antigeensneltest moeten onmiddellijk contact opnemen met hun arts of de plaatselijke gezondheidsdienst (telefonisch), zichzelf in quarantaine plaatsen en contact vermijden om zichzelf en anderen te beschermen. Ook sluiten positieve resultaten een bacteriële infectie of een co-infectie met andere virussen niet uit. Zelfs mensen die negatief testen kunnen asymptomatisch besmet zijn, aangezien de incubatieperiode 1-14 dagen kan bedragen, maar gewoonlijk 3-7 dagen. Als u COVID-19-symptomen krijgt, zoals koorts, hoest en/of kortademigheid, verlies van reuk- en/of smaakzin of iets dergelijks, ondanks een eventuele negatieve zelftest, neem dan (telefonisch) contact op met uw arts of uw plaatselijke gezondheidsinstantie.
De CHIL COVID-19 antigeensneltest is bedoeld voor zelftoediening bij personen van 2 jaar en ouder. Personen tussen 2 en 12 jaar moeten worden getest door een volwassene van de wettelijke leeftijd.

GELEVERDE MATERIALEN

1. Steriele wattenstaafje
2. Teststrip
3. Buisje met antigeenextractievloeistof
4. Gebruiksaanwijzing

NOODZAKELIJKE HULPMIDDELEN, NIET INBEGREPEN IN DE LEVERING

- Stopwatch
- Persoonlijke beschermingsmiddelen

WAARSCHUWINGEN EN VOORZORGSMAATREGELEN

1. Voor in-vitrodiagnostiek en voor eenmalig gebruik.
2. Buiten bereik van kinderen bewaren. Niet gebruiken bij personen jonger dan 2 jaar. CHIL-COVID 19 - Antigeensneltestkit bij kinderen tussen 2-12 jaar mag alleen worden gebruikt door een meerderjarige volwassene.
3. De test is een in-vitrodiagnostische wegwerptest die uitsluitend wordt gebruikt voor het opsporen van anterieure neusswabs. Het moet strikt volgens de gebruiksaanwijzing worden gebruikt. Gebruik geen vervallen of beschadigde producten. Bewaar de testkit op een droge plaats, bij 2-30 °C. Stel het niet bloot aan straling, koude- of warmtebronnen of direct zonlicht.
4. Zoals bij alle diagnostische tests, moet worden opgemerkt dat een identificatiediagnose niet kan worden gebaseerd op één testresultaat. De diagnose kan alleen worden gesteld door een deskundige na evaluatie van alle klinische en laboratoriumresultaten.
5. De test moet tegen vocht worden beschermd. Tests of monsters die bij lage temperatuur worden bewaard, moeten op kamertemperatuur worden gebracht voordat ze kunnen worden gebruikt.
6. De tests moeten zo spoedig mogelijk na verwijdering uit de aluminium zakken worden uitgevoerd om onnodige blootstelling aan vochtigheid te voorkomen, die de testresultaten kan beïnvloeden.
7. Gebruik een schoon wattenstaafje voor ieder individueel om kruisbesmetting te voorkomen. Een onjuiste bediening kan de nauwkeurigheid van de resultaten beïnvloeden, zoals onvoldoende monstervolume, onvoldoende menging van het monster, onnauwkeurige detectietijd, enz.
8. Gebruik voor testen onmiddellijk na het verzamelen van het monster. Met uitzondering van het neusswabje, mogen andere testonderdelen niet in het lichaam worden gebruikt.
9. Er moet een passende bioveiligheidsprocedure zijn voor stoffen die besmet kunnen zijn en vermoedelijke bronnen van infectie zijn.

- Raak monsters en tests alleen aan met beschermende handschoenen.
- Zuig of slik geen specimens door de mond.
- Niet eten, drinken of roken tijdens de behandeling. Vermijd contact van ogen, neus en mond met besmette voorwerpen.
- Desinfecteer alle oppervlakken en uw handen voor en na het testen.
- Behandel uw specimens en gebruikte testkits met zorg omdat ze mogelijk besmettelijk zijn. De gebruikte testkits kunnen met het huisvuil worden weggegooid.
- Elk onderdeel van de test blijft werkzaam tot de vervaldatum bij juiste hantering en opslagomstandigheden.

VEELGESTELDE VRAGEN (FAQS)

1. Wat is COVID-19?

COVID-19 (Novel Corona Virus Disease) is een infectieziekte die wordt veroorzaakt door het nieuwe coronavirus. Dit nieuwe virus en deze nieuwe ziekte waren onbekend voordat de uitbraak in Wuhan, China, in december 2019 begon. Veel voorkomende symptomen van COVID-19 zijn koorts, hoest/droge hoest en/of kortademigheid, verlies van reuk- en/of smaakzin, keelpijn, diarree, vermoeidheid, hoofdpijn, pijn in de ledematen, of iets dergelijks. Deze symptomen zijn meestal mild en beginnen geleidelijk. Sommige mensen raken besmet maar ontwikkelen geen symptomen (asymptomatisch beloop) en voelen zich niet ziek. De meeste mensen (ongeveer 80%) herstellen van de ziekte zonder dat ze een speciale behandeling nodig hebben. Ongeveer 1 op de 6 mensen die COVID-19 krijgen, wordt ernstig ziek en heeft symptomen op naam. Ouderen en mensen met medische problemen zoals hoge bloeddruk, hartproblemen of diabetes zullen waarschijnlijk een ernstig verloop hebben. Ongeveer 2% van de met SARS-CoV-2 besmette personen heeft tot dusver het leven verloren. Mensen met de bovenstaande symptomen moeten zeker contact opnemen met hun arts. COVID-19 is overdraagbaar van persoon op persoon als druppel- en/of smeerinfectie of via aërosolen bij het inademen of uitademen, opgepikt door anderen met het virus. Dit betekent dat besmetting via voorwerpen en oppervlakken ook mogelijk is. Vermijd daarom het aanraken van uw ogen, neus of mond. De meeste schattingen van de incubatieperiode voor COVID-19 zijn 1 dag tot 14 dagen.

2. Wat is de CHIL COVID-19 antigeen sneltest (neusswab) teststrip?
De CHIL COVID-19 antigeensneltest is een test die een antigeensneltest wordt genoemd. Antigeensneltesten worden gebruikt voor de snelle kwalitatieve opsporing van eiwitten van het SARS-CoV2-virus.

3. Waarom is mijn monster getest?
U bent getest omdat u mogelijk bent blootgesteld aan het virus dat COVID-19 veroorzaakt (op basis van uw tekenen en symptomen (bv. koorts, hoest, ademhalingsmoeilijkheden) en/of andere risicofactoren) en u zich in de eerste twaalf dagen van de symptomen bevindt. U kunt de test ook doen zonder symptomen of door contact met een positief persoon.

4. Wat zijn de bekende en potentiële risico's en voordelen van de test?
Potentiële risico's zijn onder andere:

- - Mogelijke ongemakken of andere complicaties die zich tijdens de monsterafname kunnen voordoen.
- - Mogelijk foutief testresultaat (lees ook het gedeelte "interpretatie" in het gedeelte over de resultaten).
- Mogelijke voordelen zijn:
- - De resultaten, samen met andere informatie, kunnen u en/of uw zorgverleners helpen bij het vaststellen van een mogelijke COVID-19-infectie en, indien nodig, helpen bij het doen van verdere aanbevelingen over uw behandeling.
- - De resultaten van deze test kunnen helpen voorkomen dat de COVID-19-infectie zich onder uw familie en anderen verspreidt.

5. Doet het pijn om monsters te nemen met een wattenstaafje?
Nee, het wattenstaafje heeft geen scherpe randen en zou dus geen pijn moeten doen. Het afnemen van monsters met een wattenstaafje kan in sommige omstandigheden als ongemakkelijk worden ervaren. Als u bijvoorbeeld pijn voelt, stop dan met de test en vraag zo mogelijk uw medisch adviseur (arts of apotheker) om contactloos advies.

6. Ik heb een verstopte neus. Kan ik het neusmonster goed nemen?
Ja, deze testprocedure neemt een monster van de voorkant van de neus. Om deze reden heeft een verstopte neus geen invloed op de procedure voor het nemen van monsters.

7. Wat zijn de verschillen tussen antigeentests en andere COVID-19-tests?
Er zijn verschillende soorten tests om de diagnose COVID-19 te stellen. Moleculaire tests (ook bekend als PCR-tests) detecteren genetisch materiaal van het virus. Antigeentests detecteren eiwitten van het virus. Antigeentests zijn zeer specifiek voor het virus, maar zijn niet zo gevoelig als moleculaire tests. Dit betekent dat een positief resultaat zeer nauwkeurig is, maar dat een negatief resultaat een infectie niet uitsluit. Als het resultaat van de test negatief is, moet u met uw arts bespreken of verdere tests nodig zijn en of u zich thuis moet blijven isoleren.

8. Hoe nauwkeurig is de CHIL COVID-19-antigeen-sneltest?
Op basis van tussentijdse resultaten van een klinische studie waarin de CHIL COVID-19-antigeensneltest werd vergeleken met een RT-PCR-methode, identificeerde de CHIL COVID-19-antigeensneltest 98,55% van de positieve monsters en 99,57% van de negatieve monsters

PRESTATIEKENMERKEN

1. Detectiegrens: de detectiegrens is 30 TCID50 / ml
2. Kruis-Reactiviteit:
Deze kruisreactiviteitsstudie is uitgevoerd om de invloed van veel voorkomende respiratoire pathogenen op de detectieprestaties van de CHIL Covid-19 antigeentest te evalueren. De volgende respiratoire pathogenen werden geselecteerd voor kruisreactiviteitstests: Influenza A-virus H1N1, Influenza B-virus, Mycoplasma pneumoniae, Rhinovirus A, Rotavirus, Colon Escherichia, Respiratoir Syncytieel Virus, Adenovirus, enz.

De concentratie van de bacteriële monsters wordt vastgesteld op 106 CFU (kolonievormende eenheden) / ml of hoger en de concentratie van de virale monsters wordt vastgesteld op 105 pfu (plaquevormende eenheden) / ml of hoger. De testresultaten zijn weergegeven in de volgende tabel.

Pathogeen	Concentratie	Test Resultaten
HKU1	10^5 pfu/mL	Negatief
OC43	10^5 pfu/mL	Negatief
NL63	10^5 pfu/mL	Negatief
229E	10^5 pfu/mL	Negatief
MERS-coronavirus	10^5 pfu/mL	Negatief
Human Metapneumovirus	10^5 pfu/mL	Negatief
Influenza A virus H1N1	10^5 pfu/mL	Negatief
Influenza A virus H3N2	10^5 pfu/mL	Negatief
Influenza A virus H5N1	10^5 pfu/mL	Negatief
Influenza A virus H7N9	10^5 pfu/mL	Negatief
Influenza B virus	10^5 pfu/mL	Negatief
Rhinovirus A	10^5 pfu/mL	Negatief
Rhinovirus B	10^5 pfu/mL	Negatief
Rhinovirus C	10^5 pfu/mL	Negatief
Adenovirus 1	10^5 pfu/mL	Negatief
Adenovirus 2	10^5 pfu/mL	Negatief
Adenovirus 3	10^5 pfu/mL	Negatief
Adenovirus 4	10^5 pfu/mL	Negatief
Adenovirus 5	10^5 pfu/mL	Negatief
Adenovirus 7	10^5 pfu/mL	Negatief
Adenovirus 55	10^5 pfu/mL	Negatief
Enterovirus A	10^5 pfu/mL	Negatief
Enterovirus B	10^5 pfu/mL	Negatief
Enterovirus C	10^5 pfu/mL	Negatief
Enterovirus D	10^5 pfu/mL	Negatief
EB Virus	10^5 pfu/mL	Negatief
Measles virus	10^5 pfu/mL	Negatief
Human cytomegalovirus	10^5 pfu/mL	Negatief
Rotavirus	10^5 pfu/mL	Negatief
Norovirus	10^5 pfu/mL	Negatief
Mumps virus	10^5 pfu/mL	Negatief
Varicella-zoster virus	10^5 pfu/mL	Negatief
Respiratory syncytial virus	10^5 pfu/mL	Negatief
Mycoplasma pneumoniae	10^5 cfu/mL	Negatief
Escherichia coli	10^5 cfu/mL	Negatief

De experimentele resultaten op twintig SARS-CoV-2-antigeen-negatieve monsters van gezonde personen hebben bevestigd dat alle monsters negatief zijn voor de concentratie van micro-organismen of virussen. Deze geteste pathogenen hebben geen kruisreactie-effect op de detectieprestaties van de COVID-19 Antigen Rapid Test.

3. Storende stoffen

Er zullen interferentietests worden uitgevoerd om de prestaties van de CHIL COVID-19-antigeensneltest met algemeen gebruikte stoffen te evalueren. In de studie zullen de volgende stoffen worden toegevoegd aan negatieve en zwak-positieve monsters om het interferentie-effect op de resultaten van de COVID-19 Antigen Rapid

Stoffen	Concentratie	CHIL COVID-19 Antigen Rapid Test Resultaten van negatieve Monsters	CHIL COVID-19 Antigen Rapid Test Resultaten van positieve Monsters
Mucin	200 mg/ml	Negatief	Positief
Hemoglobin	10 mg/ml	Negatief	Positief
Histamine Hydrochloride	4.0mg/L	Negatief	Positief
Human albumin	60 mg/ml	Negatief	Positief
α-interferon	2 ng/ml	Negatief	Positief
Lopinavir	2 µg/ml	Negatief	Positief
Tobramycin	10 mg/L	Negatief	Positief
Ribavirin	40 mg/L	Negatief	Positief
Tramadol	12 µg/ml	Negatief	Positief
Azithromycin	5 µg/ml	Negatief	Positief
Meropenem	10 mg/ml	Negatief	Positief
Oseltamivir	1000 ng/ml	Negatief	Positief
Benzocaine	1.5 mg/ml	Negatief	Positief
Peramivir	20 µg/ml	Negatief	Positief

Uit de testresultaten blijkt dat de bovengenoemde veelvoorkomende stoffen geen effect hebben op de detectieprestaties van de COVID-19 Antigen Rapid Test.

High Dose Hook Effect

Het met SARS-CoV-2 gekweekte virus werd aan het monster toegevoegd. Het met SARS-CoV-2 gekweekte virus vertoonde geen haakeffect bij 9,73 × 106 TCID50 / ml.

Klinische studies

Analyse van de mate van overeenstemming tussen de COVID-19 antigeensneltest en de PCR-test in neusmonsters.

		PCR Test		Totaal
		Positief	Negatief	
CHIL COVID-19 Antigen Rapid Test	Negatief	4	464	468
	Positief	272	2	274
Totaal		276	466	742

Gevoeligheid: 98.55% (95%CI: 96.33% - 99.60%)*
Specificiteit: 99.57% (95%CI: 98.46% - 99.95%)*

Precisie: 99.49% (95%CI: 98.67% - 99.87%)*
*95 % Betrouwbaarheidsinterval : (%-%)
De prevalentie van de ziekte werd verondersteld 5% te zijn.

Symbolen

	Raadpleeg de gebruikershandleiding		Droog bewaren
	Bewaren tussen temperaturen	LOT	Partij nummer
	Voor eenmalig gebruik	IVD	In-Vitro-Diagnose Kit
	Fabrikant		Omvat <n> Tests
	Vervaldatum	CE	CE Keurmerk
	Let op! Voorzorgsmaatregelen in acht nemen.		Toestel / Middel voor zelfbehoud

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Informatie voor gebruikers van zelftesten

Let op, doe in de volgende gevallen geen zelftest maar maak een afspraak bij een GGD testlocatie:

- u heeft coronaklachten
- u heeft contact gehad met een besmet persoon
- u bent de afgelopen 10 dagen teruggekomen uit een oranje gebied

Met deze zelftest kunt u testen of u op dit moment corona heeft. Hieronder leest u wat de uitslag betekent en wat u met de uitslag moet doen.

➔ De testuitslag is **positief**

Dit betekent dat u waarschijnlijk corona heeft.

Wat moet u doen?
- Ga in isolatie, dus blijf thuis en vermijd zoveel mogelijk contact met uw huisgenoten.
- Ontvang geen bezoek.
- Maak direct een afspraak voor een hertest bij de GGD via **0800-1202** of via www.coronatest.nl. Tot de uitslag van de hertest bekend is blijft u thuis in isolatie.
- Als de hertest ook positief is start de GGD samen met u het bron- en contactonderzoek.
- Vragen? Ga naar www.rijksoverheid.nl/uitslag-coronatest voor meer informatie of bel met 0800-1351.

Waarom een hertest?
Een zelftest is minder betrouwbaar dan de test op de GGD testlocatie. Hierdoor is er kans dat uw positieve uitslag vals alarm is. Als de hertest bij de GGD negatief is dan mag u uit isolatie.

➔ De testuitslag is **negatief**

Dit betekent dat u waarschijnlijk geen corona heeft.
Let op! Een negatieve uitslag van een zelftest is niet 100% betrouwbaar. Blijf dus voorzichtig.

Wat moet u doen?
- Blijf de corona regels volgen. Houd afstand, draag een mondkapje, was vaak je handen en blijf letten op klachten.
- Als u klachten krijgt of contact heeft gehad met een besmet persoon, laat u dan zo snel mogelijk testen bij de GGD.
- Vragen? Kijk voor meer informatie op www.rijksoverheid.nl/uitslag-coronatest of bel met 0800-1351.

➔ De testuitslag is **niet duidelijk**

De test is dan niet geldig, doe een nieuwe test

Meer informatie:
Meer weten over het testen op corona? Kijk op **www.rijksoverheid.nl/coronatest**
De regels voor isolatie vindt u op **www.rijksoverheid.nl/quarantaine**
Hulp of ondersteuning nodig tijdens de isolatie- of quarantaineperiode? Ga naar **www.rijksoverheid.nl/quarantainegids**

De zelftesten waar de Rijksoverheid een ontheffing voor heeft verleend, vindt u op **www.rijksoverheid.nl/ontheffingen-antigeentesten**

CHIL COVID-19 Antigen Rapid Test Clinical Study Report

COVID-19 Antigen Rapid Test

Clinical Study Report

1. TABLE OF CONTENT

2. INTRODUCTION

The objective of this evaluation is to establish the clinical specimen's performance of the Novel Coronavirus (COVID-19) Antigen, including performance on clinical specimens.

The purposes of the study are to evaluate the performance of the CHIL Medical Devices COVID-19 Antigen Rapid Test with Nasal swab specimens and to compare the consistency between Nasal swab and Nasophyrngeal swab, which are tested by Chil's Kit.

3. ADMINISTRATIVE INFORMATION

The protocol should be read carefully, the protocol and 'Test Procedure' supplied with the reagents must be followed exactly unless explicitly stated. The assays during the period of the evaluation should be double checked by another method. The results for both Novel Coronavirus (COVID-19) Antigen and any alternative assay methods must be properly identified. The data should be clearly legible and marked with the name of the laboratory and initialed by Coordinator. All original raw data must be made available for further information.

4. CLINICAL STUDY

4.1. Time Scale of Evaluation

The evaluation is planned as to be completed within 2 weeks.

4.2. Materials Used

Target reagent: A lot of qualified (COVID-19) Antigen produced based on technological process and the outputted Standard Operating Procedure. The Polymerase Chain Reaction (PCR) method was used for reference method.

4.3. Specimens to Be Tested

All the specimens used in this evaluation were supplied from hospitals, laboratories and clinics.

4.3.1. Specimen types

Nasal swab specimens were used.

4.3.2. Specimen quantity

Specimens above should be collected from known PCR positive and known PCR negative patients.

4.4. Data Storage and Reporting

All data will be filed both on hard copy and in electronically files. Data will be stored for at least 5 years. All laboratory results are strictly confidential. Copies of raw data were retained under the internal R&D and Regulatory Affairs departments of CHIL Tıbbi Malzemeler San. ve Tic. Ltd. Şti. and Özel İzmir Ege Laboratories for future reference.

4.5. MATERİAL AND METHOD

- COVID-19 Antigen Rapid Test produced by CHIL Medical Devices is used to screen 102 PCR positive patient specimens and 280 PCR negative patient specimens. Nasal swab specimens collected according to proper procedure.
- For each type, four kinds of specimens from the same person were tested by Company's Kit. We selected 25 positive and 25 negative specimens. POS1-POS25 of specimens are from infected people, and NEG1-NEG25 are from uninfected people. POS21-POS25 are weekly positive.
- The test kits were used from three different Lot (CCOV-201.20C1, CCOV-201.20C2 and CCOV-201.20C3) for evaluation.

4.6. RESULTS

4.6.1. Limit of Detection (LOD)

The LOD for COVID-19 Antigen Rapid Test was established using dilutions of an inactivated virus culture. The starting material was supplied at a concentration of 3.84 x 10^5 TCID50/mL. Studies were designed to estimate the LOD of the assay using nasal swab specimens, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for COVID-19 Antigen to obtain a series of different concentrations.

Table 1. Limit of detection

COVID-19 Titer	$3.84x10^5$TCID50/mL								
Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200	1/6400	1/12800	1/25600
Concentration in Dilution tested (TCID50/mL)	$3.84x10^3$	$1.92x10^3$	$9.6x10^2$	$4.8x10^2$	$2.4x10^2$	$1.2x10^2$	6x 10	3x 10	1.5x10
Detection rates of 5 replicates	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	80% (4/5)
Detection rates of 20 replicates near cut-off	NA	NA	NA	NA	NA	100% (20/ 20)	100% (20/2 0)	95% (19/2 0)	75% (15/2 0)
Lowest Concentration with Uniform Positivity per Analyte	30 TCID50/mL								
Limit of detection(LOD) per inactivated virus culture	30 TCID50/mL								

4.6.2. Statistical Table of Clinical Trial Data

Table 2. Statistical table of clinical trial data

Specimens	Specimen types	Gender	Age	PCR results	PCR CT Range	CHIL COVID-19 Antigen Rapid Test Results	Specimen collected time	Duration of symptoms	Symptoms
1	Nasal Swab	F	2	Positive	24-27	Positive	4.01.2021	1-3 days	Cough, fever
2	Nasal Swab	F	3	Positive	27-30	Positive	8.01.2021	1-3 days	Fever, crozy
3	Nasal Swab	F	8	Positive	24-27	Positive	5.01.2021	1-3 days	Reduced appetite, fever
4	Nasal Swab	F	6	Positive	30-33	Positive	8.01.2021	1-3 days	Fever, diarrhea
5	Nasal Swab	M	5	Positive	21-24	Positive	11.01.2021	1-3 days	Fever, reduced appetite
6	Nasal Swab	M	9	Positive	24-27	Positive	6.01.2021	1-3 days	Fever, cough
7	Nasal Swab	M	4	Positive	30-33	Positive	5.01.2021	4-7 days	Coryza, cough
8	Nasal Swab	M	7	Positive	24-27	Positive	8.01.2021	4-7 days	General malaise, coryza
9	Nasal Swab	M	12	Positive	18-21	Positive	7.01.2021	4-7 days	Altered smell or taste, reduced appetite
10	Nasal Swab	M	14	Positive	21-24	Positive	14.01.2021	4-7 days	Altered smell or taste, chill
11	Nasal Swab	M	18	Positive	21-24	Positive	4.01.2021	4-7 days	Headache
12	Nasal Swab	M	19	Positive	18-21	Positive	6.01.2021	1-3 days	General malaise
13	Nasal Swab	M	23	Positive	21-24	Positive	5.01.2021	1-3 days	Headache, reduced appetite, altered smell or taste
14	Nasal Swab	M	17	Positive	30-33	Positive	12.01.2021	Asymptomatic	Contact with confirmed positive
15	Nasal Swab	F	20	Positive	30-33	Negative	4.01.2021	7>	Joint ache, headache
16	Nasal Swab	F	15	Positive	18-21	Positive	7.01.2021	4-7 days	Reduced appetite, sore throat
17	Nasal Swab	F	22	Positive	<18	Positive	6.01.2021	1-3 days	Altered smell or taste, headache
18	Nasal Swab	F	63	Positive	27-30	Positive	11.01.2021	1-3 days	Joint ache, altered smell or taste, headache, sore throat
19	Nasal Swab	F	49	Positive	21-24	Positive	8.01.2021	4-7 days	Altered smell or taste, headache, cough
20	Nasal Swab	F	60	Positive	21-24	Positive	11.01.2021	1-3 days	Headache, altered smell or

									taste, joint ache, fever
21	Nasal Swab	F	57	Positive	24-27	Positive	13.01.2021	4-7 days	Sore throat, cough, headache, joint ache
22	Nasal Swab	M	24	Positive	21-24	Positive	7.01.2021	4-7 days	Headache, joint ache
23	Nasal Swab	M	28	Positive	18-21	Positive	12.01.2021	1-3 days	Altered smell or taste, headache
24	Nasal Swab	M	31	Positive	21-24	Positive	14.01.2021	4-7 days	Tiredness, sore throad, altered smell or taste
25	Nasal Swab	M	55	Positive	21-24	Positive	6.01.2021	1-3 days	General malaise, altered smell or taste, sore throat, fever
26	Nasal Swab	M	64	Positive	30-33	Positive	7.01.2021	4-7 days	Altered smell or taste, headache, cough
27	Nasal Swab	M	72	Positive	18-21	Positive	13.01.2021	1-3 days	Joint ache, altered smell or taste, sore throat, cough, fever
28	Nasal Swab	M	73	Positive	30-33	Positive	11.01.2021	1-3 days	Cough, fever, shortness of breath
29	Nasal Swab	M	65	Positive	30-33	Positive	4.01.2021	4-7 days	Headache, joint ache, sore throat
30	Nasal Swab	F	69	Positive	24-27	Positive	6.01.2021	1-3 days	Chill, fever, joint ache, cough, sore throat
31	Nasal Swab	F	74	Positive	30-33	Positive	14.01.2021	1-3 days	Fever, cough, shortness of breath
32	Nasal Swab	F	67	Positive	27-30	Positive	8.01.2021	1-3 days	Muscle ache, reduced appetite, fever, shortness of breath
33	Nasal Swab	F	70	Positive	27-30	Positive	13.01.2021	1-3 days	Cough, fever, sore throat, muscle ache
34	Nasal Swab	F	11	Positive	21-24	Positive	4.01.2021	1-3 days	Reduced appetite, altered smell or taste
35	Nasal Swab	F	7	Positive	24-27	Positive	11.01.2021	4-7 days	Sore throat, altered smell or taste

36	Nasal Swab	F	12	Positive	18-21	Positive	5.01.2021	1-3 days	Altered smell or taste, coryza
37	Nasal Swab	F	5	Positive	24-27	Positive	8.01.2021	1-3 days	Cough, fever, reduced appetite
38	Nasal Swab	M	3	Positive	21-24	Positive	13.01.2021	1-3 days	Fever, coryza
39	Nasal Swab	M	2	Positive	27-30	Positive	6.01.2021	1-3 days	Fever, cough
40	Nasal Swab	M	13	Positive	21-24	Positive	12.01.2021	1-3 days	Fever, sore throat, tiredness
41	Nasal Swab	F	14	Positive	24-27	Positive	7.01.2021	1-3 days	Reduced appetite, general malaise
42	Nasal Swab	F	21	Positive	21-24	Positive	13.01.2021	1-3 days	Cough, fever, joint ache
43	Nasal Swab	F	22	Positive	30-33	Positive	4.01.2021	4-7 days	Chill, joint ache, altered smell or taste
44	Nasal Swab	F	17	Positive	18-21	Positive	5.01.2021	1-3 days	Sore throat, tiredness, headache
45	Nasal Swab	F	17	Positive	27-30	Positive	12.01.2021	1-3 days	Fever, joint ache
46	Nasal Swab	F	18	Positive	24-27	Positive	5.01.2021	4-7 days	Tiredness, cough, altered smell or taste
47	Nasal Swab	F	15	Positive	30-33	Positive	6.01.2021	Asymptomatic	-
48	Nasal Swab	F	22	Positive	27-30	Positive	14.01.2021	Asymptomatic	-
49	Nasal Swab	F	23	Positive	30-33	Positive	8.01.2021	1-3 days	Tiredness, altered smell or taste
50	Nasal Swab	F	18	Positive	21-24	Positive	14.01.2021	1-3 days	Altered smell or taste, tiredness
51	Nasal Swab	M	18	Positive	27-30	Positive	11.01.2021	4-7 days	Headache, joint ache
52	Nasal Swab	M	18	Positive	<18	Positive	14.01.2021	1-3 days	Muscle ache, cough, sore throat
53	Nasal Swab	M	16	Positive	30-33	Positive	12.01.2021	Asymptomatic	-
54	Nasal Swab	M	21	Positive	<18	Positive	7.01.2021	1-3 days	Headache, cough, altered smell or taste, tiredness
55	Nasal Swab	M	20	Positive	33-36	Positive	4.01.2021	4-7 days	Tiredness, joint ache, headache
56	Nasal Swab	M	14	Positive	24-27	Positive	13.01.2021	1-3 days	Fever, altered smell or taste, cough, sore throat

57	Nasal Swab	M	19	Positive	33-36	Positive	6.01.2021	4-7 days	Coryza, altered smell or taste, headache
58	Nasal Swab	M	20	Positive	18-21	Positive	8.01.2021	1-3 days	Chill, fever, joint ache, cough, sore throat
59	Nasal Swab	M	21	Positive	18-21	Positive	12.01.2021	1-3 days	Sore throat, cough, altered smell or taste, headache
60	Nasal Swab	M	20	Positive	27-30	Positive	5.01.2021	1-3 days	Joint ache, cough, coryza
61	Nasal Swab	M	16	Positive	21-24	Positive	4.01.2021	1-3 days	Sore throat, altered smell or taste
62	Nasal Swab	M	17	Positive	18-21	Positive	6.01.2021	1-3 days	Headache, altered smell or taste, tiredness
63	Nasal Swab	M	17	Positive	27-30	Positive	14.01.2021	Asymptomatic	-
64	Nasal Swab	M	18	Positive	33-36	Positive	12.01.2021	1-3 days	Joint ache, headache
65	Nasal Swab	F	25	Positive	27-30	Positive	6.01.2021	4-7 days	Tiredness, altered smell or taste, sore throat
66	Nasal Swab	F	25	Positive	30-33	Positive	13.01.2021	4-7 days	Tiredness, joint ache, altered smell or taste, headache
67	Nasal Swab	F	41	Positive	18-21	Positive	4.01.2021	1-3 days	Tiredness, cough, altered smell or taste, sore throat, headache
68	Nasal Swab	F	35	Positive	<18	Positive	14.01.2021	1-3 days	Joint ache, fever, altered smell or taste, headache
69	Nasal Swab	F	28	Positive	33-36	Negative	7.01.2021	4-7 days	Headache, altered smell or taste
70	Nasal Swab	F	37	Positive	18-21	Positive	5.01.2021	1-3 days	Fever, joint ache, cough, reduced appetite, altered smell or taste
71	Nasal Swab	F	56	Positive	21-24	Positive	4.01.2021	1-3 days	Fever, shortness of breath, cough, joint ache
72	Nasal Swab	F	49	Positive	30-33	Positive	12.01.2021	4-7 days	Altered smell or taste,

									cough, headache
73	Nasal Swab	F	29	Positive	27-30	Positive	14.01.2021	4-7 days	Tiredness, altered smell or taste, sore throat
74	Nasal Swab	F	36	Positive	18-21	Positive	8.01.2021	4-7 days	Cough, tiredness, sore throat, headache
75	Nasal Swab	F	50	Positive	30-33	Positive	6.01.2021	4-7 days	Tiredness, cough, altered smell or taste, sore throat
76	Nasal Swab	F	38	Positive	21-24	Positive	14.01.2021	1-3 days	Shortness of breath, chill, fever, joint ache, cough, sore throat
77	Nasal Swab	F	47	Positive	30-33	Positive	4.01.2021	1-3 days	Joint ache, fever, reduced appetite, altered smell or taste
78	Nasal Swab	F	33	Positive	24-27	Positive	5.01.2021	1-3 days	Fever, joint ache, cough, sore throat, headache
79	Nasal Swab	F	64	Positive	27-30	Positive	13.01.2021	1-3 days	Tiredness, diarrhea, reduced appetite, shortness of breath
80	Nasal Swab	M	26	Positive	27-30	Positive	12.01.2021	3-4 days	Headache, reduced appetite, altered smell or taste
81	Nasal Swab	M	61	Positive	18-21	Positive	14.01.2021	1-3 days	Chill, fever, joint ache, cough, sore throat
82	Nasal Swab	M	57	Positive	27-30	Positive	15.01.2021	1-3 days	Cough, chill, diarrhea, joint ache
83	Nasal Swab	M	30	Positive	27-30	Positive	6.01.2021	3-4 days	Reduced appetite, sore throat
84	Nasal Swab	M	45	Positive	<18	Positive	13.01.2021	1-3 days	Cough, sore throat, joint ache, shortness of breath
85	Nasal Swab	M	55	Positive	18-21	Positive	4.01.2021	1-3 days	Headache, cough, sore throat, shortness of breath
86	Nasal Swab	M	34	Positive	30-33	Positive	8.01.2021	Asymptomatic	-

87	Nasal Swab	M	31	Positive	24-27	Positive	14.01.2021	4-7 days	Tiredness, diarrhea, reduced appetite
88	Nasal Swab	M	53	Positive	27-30	Positive	12.01.2021	1-3 days	Chill, fever, joint ache, cough
89	Nasal Swab	M	32	Positive	30-33	Positive	8.01.2021	Asymptomatic	-
90	Nasal Swab	M	27	Positive	27-30	Positive	6.01.2021	4-7 days	Tiredness, reduced appetite, headache
91	Nasal Swab	M	34	Positive	33-36	Positive	6.01.2021	4-7 days	Tiredness, altered smell or taste
92	Nasal Swab	F	74	Positive	24-27	Positive	14.01.2021	1-3 days	Fever, cough, shortness of breath
93	Nasal Swab	F	65	Positive	24-27	Positive	11.01.2021	1-3 days	Joint ache, reduced appetite, sore throat, fever, altered smell or taste
94	Nasal Swab	F	69	Positive	21-24	Positive	5.01.2021	1-3 days	Fever, joint ache, reduced appetite, sore throat, shortness of breath
95	Nasal Swab	F	80	Positive	27-30	Positive	4.01.2021	1-3 days	Fever, altered smell or taste, shortness of breath
96	Nasal Swab	F	72	Positive	24-27	Positive	13.01.2021	1-3 days	Sore throat, cough, headache, joint ache, fever, shortness of breath
97	Nasal Swab	F	68	Positive	30-33	Positive	12.01.2021	1-3 days	Fever, sore throat, cough, headache, joint ache, shortness of breath
98	Nasal Swab	M	66	Positive	33-36	Positive	7.01.2021	4-7 days	Altered smell or taste, joint ache, fever
99	Nasal Swab	M	70	Positive	30-33	Positive	4.01.2021	1-3 days	Muscle ache, reduced appetite, fever, shortness of breath
100	Nasal Swab	M	71	Positive	24-27	Positive	15.01.2021	1-3 days	Joint ache, altered smell or taste, sore throat, cough, fever

101	Nasal Swab	M	65	Positive	30-33	Positive	6.01.2021	4-7 days	General malaise, headache, cough, headache
102	Nasal Swab	M	66	Positive	33-36	Positive	5.01.2021	4-7 days	Joint ache, coryza, altered smell or taste, cough, sore throat
103	Nasal Swab	M	11	Negative	-	Negative	6.01.2021	4-7 days	Fever, cough
104	Nasal Swab	M	2	Negative	-	Negative	7.01.2021	1-3 days	Fever, coryza, reduced appetite
105	Nasal Swab	M	6	Negative	-	Negative	12.01.2021	1-3 days	Reduced appetite, diarrhea
106	Nasal Swab	M	13	Negative	-	Negative	6.01.2021	4-7 days	Sore throat, cough, fever
107	Nasal Swab	M	11	Negative	-	Negative	8.01.2021	4-7 days	Diarrhea
108	Nasal Swab	M	9	Negative	-	Negative	14.01.2021	1-3 days	Fever, cough, chill
109	Nasal Swab	M	7	Negative	-	Negative	13.01.2021	4-7 days	Altered smell or taste, coryza
110	Nasal Swab	M	5	Negative	-	Negative	4.01.2021	1-3 days	Fever, cough, reduced appetite
111	Nasal Swab	M	13	Negative	-	Negative	8.01.2021	1-3 days	Fever, joint ache, cough, sore throat
112	Nasal Swab	M	10	Negative	-	Negative	11.01.2021	1-3 days	Reduced appetite, cough, sore throat
113	Nasal Swab	M	2	Negative	-	Negative	4.01.2021	1-3 days	Fever, cough, reduced appetite, coryza
114	Nasal Swab	M	3	Negative	-	Negative	8.01.2021	1-3 days	Coryza, fever
115	Nasal Swab	M	7	Negative	-	Negative	5.01.2021	1-3 days	Fever, sore throat
116	Nasal Swab	M	7	Negative	-	Negative	12.01.2021	Asymptomatic	Contact with confirmed positive
117	Nasal Swab	M	7	Negative	-	Negative	6.01.2021	1-3 days	General malaise
118	Nasal Swab	M	12	Negative	-	Negative	15.01.2021	1-3 days	Chill, reduced appetite
119	Nasal Swab	M	8	Negative	-	Negative	6.01.2021	1-3 days	Cough, reduced appetite
120	Nasal Swab	M	13	Negative	-	Negative	7.01.2021	1-3 days	Cough, sore throat
121	Nasal Swab	M	6	Negative	-	Negative	5.01.2021	1-3 days	Fever, coryza
122	Nasal Swab	M	3	Negative	-	Negative	8.01.2021	Asymptomatic	Contact with confirmed

									positive
123	Nasal Swab	M	9	Negative	-	Negative	13.01.2021	>7 days	General malaise
124	Nasal Swab	M	5	Negative	-	Negative	6.01.2021	1-3 days	Fever, cough, reduced appetite
125	Nasal Swab	M	10	Negative	-	Negative	15.01.2021	Asymptomatic	Contact with confirmed positive
126	Nasal Swab	M	9	Negative	-	Negative	14.01.2021	1-3 days	Sore throat, chill, cough
127	Nasal Swab	M	5	Negative	-	Negative	4.01.2021	1-3 days	Fever, cough, sore throat
128	Nasal Swab	M	11	Negative	-	Negative	6.01.2021	Asymptomatic	Contact with confirmed positive
129	Nasal Swab	F	13	Negative	-	Negative	8.01.2021	1-3 days	Tiredness, chill
130	Nasal Swab	F	8	Negative	-	Negative	12.01.2021	1-3 days	Fever, joint ache, cough, sore throat
131	Nasal Swab	F	4	Negative	-	Negative	5.01.2021	1-3 days	Fever, reduced appetite
132	Nasal Swab	F	4	Negative	-	Negative	14.01.2021	1-3 days	Diarrhea
133	Nasal Swab	F	5	Negative	-	Negative	7.01.2021	4-7 days	General malaise
134	Nasal Swab	F	5	Negative	-	Negative	8.01.2021	4-7 days	Cough, sore throat
135	Nasal Swab	F	2	Negative	-	Negative	11.01.2021	1-3 days	Fever
136	Nasal Swab	F	7	Negative	-	Negative	8.01.2021	1-3 days	Cough
137	Nasal Swab	F	6	Negative	-	Negative	12.01.2021	1-3 days	Chill, altered smell or taste
138	Nasal Swab	F	13	Negative	-	Negative	13.01.2021	1-3 days	Cough, reduced appetite
139	Nasal Swab	F	11	Negative	-	Negative	14.01.2021	Asymptomatic	-
140	Nasal Swab	F	9	Negative	-	Negative	8.01.2021	Asymptomatic	-
141	Nasal Swab	F	12	Negative	-	Negative	4.01.2021	Asymptomatic	-
142	Nasal Swab	F	5	Negative	-	Negative	6.01.2021	1-3 days	Chill, fever, sore throat
143	Nasal Swab	F	9	Negative	-	Negative	8.01.2021	4-7 days	Headache, cough
144	Nasal Swab	F	4	Negative	-	Negative	5.01.2021	Asymptomatic	-
145	Nasal Swab	F	2	Negative	-	Negative	6.01.2021	Asymptomatic	-
146	Nasal Swab	F	6	Negative	-	Negative	15.01.2021	1-3 days	General malaise
147	Nasal Swab	F	10	Negative	-	Negative	14.01.2021	4-7 days	Reduced appetite
148	Nasal Swab	F	12	Negative	-	Negative	7.01.2021	1-3 days	Diarrhea
149	Nasal Swab	F	4	Negative	-	Negative	4.01.2021	Asymptomatic	-

150	Nasal Swab	F	2	Negative	-	Negative	7.01.2021	Asymptomatic	-
151	Nasal Swab	F	7	Negative	-	Negative	6.01.2021	1-3 days	Cough
152	Nasal Swab	F	7	Negative	-	Negative	12.01.2021	Asymptomatic	-
153	Nasal Swab	F	10	Negative	-	Negative	7.01.2021	1-3 days	Sore throat, cough
154	Nasal Swab	F	3	Negative	-	Negative	13.01.2021	1-3 days	General malaise
155	Nasal Swab	F	5	Negative	-	Negative	8.01.2021	>7 days	Coryza
156	Nasal Swab	F	2	Negative	-	Negative	12.01.2021	4-7 days	Coryza, cough
157	Nasal Swab	F	12	Negative	-	Negative	5.01.2021	>7 days	Sore throat, tiredness
158	Nasal Swab	F	16	Negative	-	Negative	7.01.2021	>7 days	Joint ache
159	Nasal Swab	F	21	Negative	-	Negative	15.01.2021	1-3 days	Joint ache, reduced appetite
160	Nasal Swab	F	14	Negative	-	Negative	4.01.2021	>7 days	Tiredness
161	Nasal Swab	F	22	Negative	-	Negative	5.01.2021	1-3 days	Coryza
162	Nasal Swab	F	20	Negative	-	Negative	6.01.2021	1-3 days	Muscle ache
163	Nasal Swab	F	18	Negative	-	Negative	12.01.2021	1-3 days	Chill
164	Nasal Swab	F	15	Negative	-	Negative	14.01.2021	Asymptomatic	-
165	Nasal Swab	F	15	Negative	-	Negative	8.01.2021	Asymptomatic	-
166	Nasal Swab	F	23	Negative	-	Negative	12.01.2021	1-3 days	General malaise
167	Nasal Swab	M	17	Negative	-	Negative	7.01.2021	1-3 days	Muscle ache
168	Nasal Swab	M	18	Negative	-	Negative	4.01.2021	1-3 days	Cough, sore throat
169	Nasal Swab	M	18	Negative	-	Negative	5.01.2021	1-3 days	General malaise
170	Nasal Swab	M	18	Negative	-	Negative	14.01.2021	1-3 days	Tiredness
171	Nasal Swab	M	21	Negative	-	Negative	15.01.2021	1-3 days	Joint ache
172	Nasal Swab	M	20	Negative	-	Negative	6.01.2021	1-3 days	Cough, tiredness
173	Nasal Swab	M	19	Negative	-	Negative	5.01.2021	1-3 days	Muscle ache, cough, sore throat
174	Nasal Swab	M	19	Negative	-	Negative	7.01.2021	4-7 days	General malaise
175	Nasal Swab	M	16	Negative	-	Negative	8.01.2021	4-7 days	Chill, cough
176	Nasal Swab	M	22	Negative	-	Negative	4.01.2021	1-3 days	Cough, sore throat
177	Nasal Swab	M	23	Negative	-	Negative	6.01.2021	4-7 days	Tiredness
178	Nasal Swab	M	20	Negative	-	Negative	14.01.2021	4-7 days	Coryza
179	Nasal Swab	M	14	Negative	-	Negative	8.01.2021	1-3 days	Fever, cough, sore throat
180	Nasal Swab	M	19	Negative	-	Negative	5.01.2021	4-7 days	Headache, tiredness, altered

									smell or taste
181	Nasal Swab	M	21	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
182	Nasal Swab	M	15	Negative	-	Negative	13.01.2021	4-7 days	Joint ache, sore throat
183	Nasal Swab	M	15	Negative	-	Negative	14.01.2021	1-3 days	Tiredness, fever, cough
184	Nasal Swab	M	31	Negative	-	Negative	7.01.2021	4-7 days	Chill, sore throat
185	Nasal Swab	M	24	Negative	-	Negative	14.01.2021	1-3 days	Fever, cough, tiredness
186	Nasal Swab	M	47	Negative	-	Negative	11.01.2021	4-7 days	Muscle ache, reduced appetite
187	Nasal Swab	M	50	Negative	-	Negative	8.01.2021	1-3 days	Cough, fever, joint ache
188	Nasal Swab	M	28	Negative	-	Negative	15.01.2021	7>days	Cough
189	Nasal Swab	M	53	Negative	-	Negative	14.01.2021	7> days	Reduced appetite
190	Nasal Swab	M	25	Negative	-	Negative	5.01.2021	4-7 days	Chill
191	Nasal Swab	M	29	Negative	-	Negative	13.01.2021	4-7 days	Tiredness, cough
192	Nasal Swab	M	36	Negative	-	Negative	8.01.2021	4-7 days	Altered smell or taste
193	Nasal Swab	M	42	Negative	-	Negative	5.01.2021	4-7 days	Coryza
194	Nasal Swab	M	58	Negative	-	Negative	12.01.2021	4-7 days	General malaise
195	Nasal Swab	M	63	Negative	-	Negative	6.01.2021	4-7 days	Chill, tiredness
196	Nasal Swab	M	51	Negative	-	Negative	7.01.2021	7>days	Joint ache
197	Nasal Swab	M	27	Negative	-	Negative	15.01.2021	7>days	Headache, chill
198	Nasal Swab	M	30	Negative	-	Negative	8.01.2021	4-7 days	Tiredness, cough
199	Nasal Swab	M	31	Negative	-	Negative	4.01.2021	7>days	Tiredness,
200	Nasal Swab	M	46	Negative	-	Negative	14.01.2021	Asymptomatic	Contact with Confirmed Positive
201	Nasal Swab	M	27	Negative	-	Negative	7.01.2021	1-3 days	Tiredness, fever, cough
202	Nasal Swab	M	54	Negative	-	Negative	13.01.2021	1-3 days	Coryza
203	Nasal Swab	M	33	Negative	-	Negative	5.01.2021	4-7 days	Tiredness, cough
204	Nasal Swab	M	39	Negative	-	Negative	12.01.2021	7>days	Headache
205	Nasal Swab	M	60	Negative	-	Negative	8.01.2021	4-7 days	General malaise
206	Nasal Swab	M	55	Negative	-	Negative	4.01.2021	4-7 days	Tiredness, headache
207	Nasal Swab	M	38	Negative	-	Negative	5.01.2021	1-3 days	Altered smell or taste
208	Nasal Swab	M	38	Negative	-	Negative	12.01.2021	4-7 days	Tiredness, cough
209	Nasal Swab	M	25	Negative	-	Negative	5.01.2021	4-7 days	Coryza
210	Nasal Swab	M	41	Negative	-	Negative	8.01.2021	4-7 days	Joint ache, chill

211	Nasal Swab	M	45	Negative	-	Negative	15.01.2021	Asymptomatic	Contact with Confirmed Positive
212	Nasal Swab	M	30	Negative	-	Negative	8.01.2021	1-3 days	Altered smell or taste
213	Nasal Swab	M	62	Negative	-	Negative	7.01.2021	1-3 days	Reduced appetite, coryza
214	Nasal Swab	M	61	Negative	-	Negative	6.01.2021	4-7 days	Muscle ache
215	Nasal Swab	M	26	Negative	-	Negative	7.01.2021	4-7 days	Tiredness
216	Nasal Swab	M	24	Negative	-	Negative	5.01.2021	1-3 days	Tiredness, fever, cough
217	Nasal Swab	M	32	Negative	-	Negative	12.01.2021	1-3 days	Diarrhea
218	Nasal Swab	M	44	Negative	-	Negative	13.01.2021	4-7 days	General malaise
219	Nasal Swab	M	43	Negative	-	Negative	7.01.2021	4-7 days	General malaise, coryza
220	Nasal Swab	M	33	Negative	-	Negative	8.01.2021	Asymptomatic	Contact with Confirmed Positive
221	Nasal Swab	M	60	Negative	-	Negative	5.01.2021	1-3days	Tiredness, fever
222	Nasal Swab	M	59	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
223	Nasal Swab	M	49	Negative	-	Negative	6.01.2021	4-7 days	Joint ache, chill
224	Nasal Swab	M	56	Negative	-	Negative	7.01.2021	1-3 days	Tiredness, cough, shortness of breath
225	Nasal Swab	M	25	Negative	-	Negative	15.01.2021	4-7 days	General malaise, coryza
226	Nasal Swab	M	40	Negative	-	Negative	7.01.2021	Asymptomatic	Contact with Confirmed Positive
227	Nasal Swab	M	39	Negative	-	Negative	5.01.2021	4-7 days	General malaise, coryza
228	Nasal Swab	M	24	Negative	-	Negative	11.01.2021	4-7 days	Joint ache, chill
229	Nasal Swab	M	31	Negative	-	Negative	8.01.2021	4-7 days	Tiredness, cough
230	Nasal Swab	M	51	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
231	Nasal Swab	M	60	Negative	-	Negative	5.01.2021	1-3 days	Coryza
232	Nasal Swab	M	54	Negative	-	Negative	13.01.2021	Asymptomatic	Contact with Confirmed Positive
233	Nasal Swab	M	26	Negative	-	Negative	7.01.2021	4-7 days	General malaise, coryza
234	Nasal Swab	M	25	Negative	-	Negative	8.01.2021	1-3 days	Joint ache, chill
235	Nasal Swab	M	39	Negative	-	Negative	5.01.2021	Asymptomatic	Contact with Confirmed Positive
236	Nasal Swab	F	25	Negative	-	Negative	7.01.2021	1-3 days	Tiredness, cough
237	Nasal Swab	F	63	Negative	-	Negative	15.01.2021	1-3 days	Shortness of breath, joint ache, cough

238	Nasal Swab	F	34	Negative	-	Negative	6.01.2021	4-7 days	Coryza
239	Nasal Swab	F	29	Negative	-	Negative	12.01.2021	4-7 days	Tiredness
240	Nasal Swab	F	27	Negative	-	Negative	7.01.2021	4-7 days	Coryza, shortness of breath
241	Nasal Swab	F	35	Negative	-	Negative	8.01.2021	1-3 days	Altered smell or taste
242	Nasal Swab	F	33	Negative	-	Negative	13.01.2021	1-3 days	Tiredness, fever, cough
243	Nasal Swab	F	40	Negative	-	Negative	7.01.2021	4-7 days	Joint ache, chill
244	Nasal Swab	F	57	Negative	-	Negative	5.01.2021	Asymptomatic	Contact with Confirmed Positive
245	Nasal Swab	F	52	Negative	-	Negative	14.01.2021	4-7 days	Coryza
246	Nasal Swab	F	49	Negative	-	Negative	8.01.2021	Asymptomatic	Contact with Confirmed Positive
247	Nasal Swab	F	50	Negative	-	Negative	14.01.2021	4-7 days	Joint ache, chill
248	Nasal Swab	F	26	Negative	-	Negative	11.01.2021	4-7 days	General malaise, coryza
249	Nasal Swab	F	36	Negative	-	Negative	7.01.2021	Asymptomatic	Contact with Confirmed Positive
250	Nasal Swab	F	33	Negative	-	Negative	5.01.2021	1-3 days	Altered smell or taste
251	Nasal Swab	F	33	Negative	-	Negative	8.01.2021	4-7 days	Chill, sore throat
252	Nasal Swab	F	48	Negative	-	Negative	5.01.2021	1-3 days	Tiredness, fever, cough
253	Nasal Swab	F	45	Negative	-	Negative	15.01.2021	4-7 days	Coryza, tiredness
254	Nasal Swab	F	51	Negative	-	Negative	5.01.2021	4-7 days	Joint ache, chill
255	Nasal Swab	F	62	Negative	-	Negative	12.01.2021	Asymptomatic	Contact with Confirmed Positive
256	Nasal Swab	F	60	Negative	-	Negative	15.01.2021	4-7 days	Chill, sore throat
257	Nasal Swab	F	63	Negative	-	Negative	12.01.2021	4-7 days	General malaise, coryza
258	Nasal Swab	F	44	Negative	-	Negative	7.01.2021	4-7 days	Coryza
259	Nasal Swab	F	23	Negative	-	Negative	8.01.2021	1-3 days	Altered smell or taste
260	Nasal Swab	F	45	Negative	-	Negative	4.01.2021	4-7 days	Muscle ache
261	Nasal Swab	F	36	Negative	-	Negative	14.01.2021	Asymptomatic	Contact with Confirmed Positive
262	Nasal Swab	F	53	Negative	-	Negative	8.01.2021	Asymptomatic	Contact with Confirmed Positive
263	Nasal Swab	F	48	Negative	-	Negative	5.01.2021	4-7 days	General malaise, coryza
264	Nasal Swab	F	24	Negative	-	Negative	7.01.2021	4-7 days	Joint ache, chill
265	Nasal Swab	F	49	Negative	-	Negative	15.01.2021	1-3 days	Tiredness, fever, cough

266	Nasal Swab	F	52	Negative	-	Negative	14.01.2021	4-7 days	Joint ache, chill
267	Nasal Swab	F	39	Negative	-	Negative	12.01.2021	4-7 days	General malaise, coryza
268	Nasal Swab	F	24	Negative	-	Negative	5.01.2021	Asymptomatic	Contact with Confirmed Positive
269	Nasal Swab	F	28	Negative	-	Negative	12.01.2021	4-7 days	Coryza
270	Nasal Swab	F	27	Negative	-	Negative	14.01.2021	4-7 days	Joint ache, chill
271	Nasal Swab	F	61	Negative	-	Negative	8.01.2021	4-7 days	Chill, sore throat
272	Nasal Swab	F	59	Negative	-	Negative	14.01.2021	4-7 days	General malaise, coryza
273	Nasal Swab	F	45	Negative	-	Negative	7.01.2021	Asymptomatic	Contact with Confirmed Positive
274	Nasal Swab	F	40	Negative	-	Negative	14.01.2021	4-7 days	Coryza
275	Nasal Swab	F	57	Negative	-	Negative	13.01.2021	Asymptomatic	Contact with Confirmed Positive
276	Nasal Swab	F	32	Negative	-	Negative	14.01.2021	4-7 days	Cough
277	Nasal Swab	F	30	Negative	-	Negative	12.01.2021	1-3 days	Tiredness, fever, cough
278	Nasal Swab	F	35	Negative	-	Negative	8.01.2021	4-7 days	Joint ache, chill
279	Nasal Swab	F	66	Negative	-	Negative	14.01.2021	4-7 days	Reduced appetite, muscle ache
280	Nasal Swab	F	70	Negative	-	Negative	5.01.2021	1-3 days	Shortness of breath, cough
281	Nasal Swab	F	65	Negative	-	Negative	14.01.2021	4-7 days	Tiredness, cough
282	Nasal Swab	F	67	Negative	-	Negative	6.01.2021	1-3 days	Tiredness, fever, cough
283	Nasal Swab	F	66	Negative	-	Negative	12.01.2021	4-7 days	Chill, sore throat
284	Nasal Swab	F	71	Negative	-	Negative	7.01.2021	4-7 days	Joint ache, chill
285	Nasal Swab	F	69	Negative	-	Negative	12.01.2021	1-3 days	Diarrhea
286	Nasal Swab	F	71	Negative	-	Negative	5.01.2021	Asymptomatic	Contact with Confirmed Positive
287	Nasal Swab	F	65	Negative	-	Negative	14.01.2021	4-7 days	Headache
288	Nasal Swab	F	73	Negative	-	Negative	8.01.2021	1-3 days	Altered smell or taste
289	Nasal Swab	F	69	Negative	-	Negative	15.01.2021	4-7 days	Tiredness, cough
290	Nasal Swab	F	65	Negative	-	Negative	4.01.2021	4-7 days	Joint ache, chill
291	Nasal Swab	F	67	Negative	-	Negative	12.01.2021	1-3 days	Tiredness, fever, cough, shortness of breath
292	Nasal Swab	F	73	Negative	-	Negative	11.01.2021	4-7 days	Coryza, reduced appetite
293	Nasal Swab	F	70	Negative	-	Negative	7.01.2021	4-7 days	Cough, joint ache

294	Nasal Swab	F	65	Negative	-	Negative	12.01.2021	Asymptomatic	Contact with Confirmed Positive
295	Nasal Swab	F	70	Negative	-	Negative	13.01.2021	4-7 days	Coryza
296	Nasal Swab	F	69	Negative	-	Negative	4.01.2021	4-7 days	Headache, reduced appetite
297	Nasal Swab	F	66	Negative	-	Negative	5.01.2021	4-7 days	Joint ache, cough
298	Nasal Swab	F	67	Negative	-	Negative	7.01.2021	1-3 days	Fever
299	Nasal Swab	F	71	Negative	-	Negative	6.01.2021	1-3 days	Diarrhea
300	Nasal Swab	F	65	Negative	-	Negative	12.01.2021	1-3 days	Joint ache, chill
301	Nasal Swab	F	69	Negative	-	Negative	8.01.2021	4-7 days	Sore throat, coryza
302	Nasal Swab	F	66	Negative	-	Negative	14.01.2021	Asymptomatic	Contact with Confirmed Positive
303	Nasal Swab	F	73	Negative	-	Negative	5.01.2021	4-7 days	General malaise
304	Nasal Swab	F	70	Negative	-	Negative	4.01.2021	1-3 days	Fever, sore throat
305	Nasal Swab	F	69	Negative	-	Negative	4.01.2021	4-7 days	Coryza
306	Nasal Swab	F	66	Negative	-	Negative	13.01.2021	4-7 days	Cough
307	Nasal Swab	F	65	Negative	-	Negative	8.01.2021	4-7 days	Joint ache, chill
308	Nasal Swab	F	70	Negative	-	Negative	12.01.2021	Asymptomatic	Contact with Confirmed Positive
309	Nasal Swab	F	69	Negative	-	Negative	8.01.2021	4-7 days	Joint ache
310	Nasal Swab	F	66	Negative	-	Negative	5.01.2021	4-7 days	Coryza
311	Nasal Swab	F	72	Negative	-	Negative	7.01.2021	4-7 days	Joint ache, chill
312	Nasal Swab	F	74	Negative	-	Negative	12.01.2021	4-7 days	General malaise
313	Nasal Swab	F	73	Negative	-	Negative	15.01.2021	4-7 days	Sore throat
314	Nasal Swab	F	65	Negative	-	Negative	5.01.2021	4-7 days	Joint ache
315	Nasal Swab	F	68	Negative	-	Negative	11.01.2021	1-3 days	Altered smell or taste
316	Nasal Swab	F	65	Negative	-	Negative	8.01.2021	4-7 days	Cough
317	Nasal Swab	F	65	Negative	-	Negative	12.01.2021	1-3 days	Fever, chill
318	Nasal Swab	F	69	Negative	-	Negative	4.01.2021	4-7 days	General malaise, coryza
319	Nasal Swab	F	72	Negative	-	Negative	13.01.2021	1-3 days	Fever, cough
320	Nasal Swab	F	65	Negative	-	Negative	12.01.2021	4-7 days	Chill, sore throat
321	Nasal Swab	F	68	Negative	-	Negative	8.01.2021	4-7 days	Reduced appetite
322	Nasal Swab	F	71	Negative	-	Negative	5.01.2021	1-3 days	Diarrhea, tiredness
323	Nasal Swab	F	66	Negative	-	Negative	8.01.2021	4-7 days	Joint ache, chill
324	Nasal Swab	F	73	Negative	-	Negative	4.01.2021	1-3 days	Fever

325	Nasal Swab	F	68	Negative	-	Negative	12.01.2021	1-3 days	Chill
326	Nasal Swab	F	69	Negative	-	Negative	7.01.2021	4-7 days	Reduced appetite
327	Nasal Swab	F	65	Negative	-	Negative	8.01.2021	4-7 days	Chill, sore throat, cough
328	Nasal Swab	F	65	Negative	-	Negative	4.01.2021	4-7 days	Sore throat, cough
329	Nasal Swab	F	71	Negative	-	Negative	6.01.2021	4-7 days	Coryza
330	Nasal Swab	F	73	Negative	-	Negative	15.01.2021	4-7 days	Chill, sore throat
331	Nasal Swab	F	70	Negative	-	Negative	8.01.2021	1-3 days	Altered smell or taste
332	Nasal Swab	F	66	Negative	-	Positive	13.01.2021	1-3 days	Fever
333	Nasal Swab	F	69	Negative	-	Negative	4.01.2021	4-7 days	Chill, sore throat
334	Nasal Swab	F	65	Negative	-	Negative	12.01.2021	4-7 days	Coryza
335	Nasal Swab	F	68	Negative	-	Negative	8.01.2021	1-3 days	Diarrhea
336	Nasal Swab	F	70	Negative	-	Negative	5.01.2021	4-7 days	Joint ache, chill
337	Nasal Swab	F	72	Negative	-	Negative	12.01.2021	Asymptomatic	Contact with Confirmed Positive
338	Nasal Swab	M	66	Negative	-	Negative	7.01.2021	4-7 days	Sore throat, cough
339	Nasal Swab	M	73	Negative	-	Negative	13.01.2021	4-7 days	General malaise
340	Nasal Swab	M	71	Negative	-	Negative	7.01.2021	1-3 days	Fever
341	Nasal Swab	M	69	Negative	-	Negative	8.01.2021	4-7 days	Chill, sore throat
342	Nasal Swab	M	97	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
343	Nasal Swab	M	70	Negative	-	Negative	11.01.2021	4-7 days	Sore throat
344	Nasal Swab	M	73	Negative	-	Negative	4.01.2021	1-3 days	Diarrhea
345	Nasal Swab	M	68	Negative	-	Negative	12.01.2021	4-7 days	Joint ache, cough
346	Nasal Swab	M	66	Negative	-	Negative	5.01.2021	Asymptomatic	Contact with Confirmed Positive
347	Nasal Swab	M	74	Negative	-	Negative	14.01.2021	1-3 days	Altered smell or taste
348	Nasal Swab	M	66	Negative	-	Negative	6.01.2021	4-7 days	General malaise
349	Nasal Swab	M	69	Negative	-	Negative	12.01.2021	4-7 days	Cough
350	Nasal Swab	M	70	Negative	-	Negative	13.01.2021	4-7 days	Joint ache
351	Nasal Swab	M	68	Negative	-	Negative	14.01.2021	1-3 days	Altered smell or taste
352	Nasal Swab	M	72	Negative	-	Negative	12.01.2021	4-7 days	Chill
353	Nasal Swab	M	69	Negative	-	Negative	12.01.2021	1-3 days	Joint ache, fever
354	Nasal Swab	M	68	Negative	-	Negative	4.01.2021	4-7 days	General malaise
355	Nasal Swab	M	71	Negative	-	Negative	15.01.2021	4-7 days	Sore throat

356	Nasal Swab	M	67	Negative	-	Negative	7.01.2021	4-7 days	Coryza
357	Nasal Swab	M	68	Negative	-	Negative	5.01.2021	4-7 days	Coryza
358	Nasal Swab	M	70	Negative	-	Negative	4.01.2021	Asymptomatic	Contact with Confirmed Positive
359	Nasal Swab	M	67	Negative	-	Negative	13.01.2021	4-7 days	Chill, sore throat
360	Nasal Swab	M	66	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
361	Nasal Swab	M	73	Negative	-	Negative	15.01.2021	4-7 days	Chill, sore throat
362	Nasal Swab	M	66	Negative	-	Negative	14.01.2021	1-3 days	Reduced appetite, fever, cough
363	Nasal Swab	M	71	Negative	-	Negative	6.01.2021	4-7 days	Chill, sore throat
364	Nasal Swab	M	66	Negative	-	Negative	15.01.2021	4-7 days	General malaise
365	Nasal Swab	M	70	Negative	-	Negative	5.01.2021	1-3 days	Cough, shortness of breath
366	Nasal Swab	M	72	Negative	-	Negative	12.01.2021	1-3 days	Altered smell or taste
367	Nasal Swab	M	68	Negative	-	Negative	13.01.2021	1-3 days	Diarrhea, tiredness
368	Nasal Swab	M	73	Negative	-	Negative	14.01.2021	4-7 days	Joint ache, chill
369	Nasal Swab	M	68	Negative	-	Negative	7.01.2021	1-3 days	Joint ache, fever
370	Nasal Swab	M	70	Negative	-	Negative	12.01.2021	4-7 days	Chill, sore throat
371	Nasal Swab	M	69	Negative	-	Negative	6.01.2021	Asymptomatic	Contact with Confirmed Positive
372	Nasal Swab	M	72	Negative	-	Negative	12.01.2021	4-7 days	Joint ache, headache
373	Nasal Swab	M	68	Negative	-	Negative	11.01.2021	4-7 days	Coryza, sore throat
374	Nasal Swab	M	66	Negative	-	Negative	7.01.2021	1-3 days	Fever
375	Nasal Swab	M	65	Negative	-	Negative	8.01.2021	4-7 days	Joint ache, chill
376	Nasal Swab	M	70	Negative	-	Negative	13.01.2021	1-3 days	Tiredness, fever
377	Nasal Swab	M	65	Negative	-	Negative	15.01.2021	4-7 days	Joint ache
378	Nasal Swab	M	65	Negative	-	Negative	5.01.2021	4-7 days	Cough
379	Nasal Swab	M	68	Negative	-	Negative	4.01.2021	4-7 days	Muscle ache
380	Nasal Swab	M	65	Negative	-	Negative	15.01.2021	4-7 days	Coryza
381	Nasal Swab	M	72	Negative	-	Negative	13.01.2021	4-7 days	Sore throat, shortness of breath
382	Nasal Swab	M	69	Negative	-	Negative	6.01.2021	1-3 days	Tiredness, fever, cough

Table 3. Patient Demographics

Age Group	Total	PCR results		Prevalence	CHIL COVID-19 Antigen Rapid Test Results		Prevalence
		Positive	Negative		Positive	Negative	
<14	71	16	55	22.54 %	16	55	22.54 %
14-24	58	32	26	55.17%	31	27	53.45%
24-64	130	35	95	26.92 %	34	96	26.15%
>65	123	19	104	15.45 %	20	103	16.26 %

Table 3. Analysis of coincidence rate of COVID-19 Antigen rapid test and PCR Test in nasal specimens

		PCR Test		Total
		Positive	Negative	
CHIL COVID-19 Antigen Rapid Test	Negative	2	279	281
	Positive	100	1	101
Total		102	280	382

Sensitivity: 98.04% (95%CI: 93.10% - 99.76%) *
Specificity: 99.64% (95%CI: 98.03% - 99.99%) *
Accuracy: 99.56% (95%CI: 98.26% - 99.96%) *
*95 % Confidence Interval: (%-%)
The results above showed that there was a good consistency between the CHIL COVID-19 Antigen Rapid Test and the PCR results on the clinical specimens.

4.6.3. Different Specimens Consistency Study

The study is designed to evaluate different specimens (Nasal swab/ Nasopharyngeal swab) performance for CHIL COVID-19 Antigen Rapid Test.

Table 4. The consistency of different specimens (Result specification: "+" Positive "-" Negative)

Specimen No.	Nasal swab	Nasopharyngeal swab
POS1	+++	+++
POS2	+	+
POS3	++	+++
POS4	+	++
POS5	++	++
POS6	+	+
POS7	++	++

POS8	+	+
POS9	++	++
POS10	+	+
POS11	+++	+++
POS12	+	+
POS13	++	++
POS14	++	++
POS15	+	++
POS16	+++	+++
POS17	+	++
POS18	+++	+++
POS19	++	++
POS20	+++	+++
POS21	+	+
POS22	+	+
POS23	+	+
POS24	+	+
POS25	+	+
NEG1	-	-
NEG2	-	-
NEG3	-	-
NEG4	-	-
NEG5	-	-
NEG6	-	-
NEG7	-	-
NEG8	-	-
NEG9	-	-
NEG10	-	-
NEG11	-	-
NEG12	-	-
NEG13	-	-
NEG14	-	-
NEG15	-	-

NEG16	-	-
NEG17	-	-
NEG18	-	-
NEG19	-	-
NEG20	-	-
NEG21	-	-
NEG22	-	-
NEG23	-	-
NEG24	-	-
NEG25	-	-

The study show that the same results are obtained in Nasal and Nasopharyngeal Swab specimens by using CHIL COVID-19 Antigen Rapid test.

4.6.4. Cross reaction testing

This cross-reaction study is performed to verify the influence of common respiratory pathogens on the detection performance of CHIL COVID-19 Antigen Test. The following respiratory pathogens are selected for cross-reactivity tests: Influenza A virus H1N1, influenza B virus, Mycoplasma pneumoniae, Rhinovirus A, Rotavirus, Large intestine Escherichia, respiratory syncytial virus, adenovirus, etc.

The concentration of bacterial specimens is set to 10^6 cfu/mL or higher, and the concentration of virus specimens is set to 10^5 pfu/mL or higher. The test results are shown in the table 5 below.

Table 5. Cross reaction (cfu: colony-forming unit, pfu: plaque-forming unit)

Pathogen	Concentration	CHIL COVID-19 Antigen Rapid Test Results
HKU1	10^5 pfu/mL	Negative
OC43	10^5 pfu/mL	Negative
NL63	10^5 pfu/mL	Negative
229E	10^5 pfu/mL	Negative
MERS-coronavirus	10^5 pfu/mL	Negative
Human Metapneumovirus	10^5 pfu/mL	Negative
Influenza A virus H1N1	10^5 pfu/mL	Negative

Influenza A virus H3N2	10^5 pfu/mL	Negative
Influenza A virus H5N1	10^5 pfu/mL	Negative
Influenza A virus H7N9	10^5 pfu/mL	Negative
Influenza B virus	10^5 pfu/mL	Negative
Mycoplasma pneumoniae	10^6 cfu/mL	Negative
Rhinovirus A	10^5 pfu/mL	Negative
Rhinovirus B	10^5 pfu/mL	Negative
Rhinovirus C	10^6 pfu/mL	Negative
Adenovirus 1	10^5 pfu/mL	Negative
Adenovirus 2	10^5 pfu/mL	Negative
Adenovirus 3	10^5 pfu/mL	Negative
Adenovirus 4	10^5 pfu/mL	Negative
Adenovirus 5	10^5 pfu/mL	Negative
Adenovirus 7	10^5 pfu/mL	Negative
Adenovirus 55	10^5 pfu/mL	Negative
Enterovirus A	10^5 pfu/mL	Negative
Enterovirus B	10^5 pfu/mL	Negative
Enterovirus C	10^5 pfu/mL	Negative
Enterovirus D	10^5 pfu/mL	Negative
EB Virus	10^5 pfu/mL	Negative
Measles virus	10^5 pfu/mL	Negative
Human cytomegalovirus	10^5 pfu/mL	Negative
Rotavirus	10^5 pfu/mL	Negative

Norovirus	10^5 pfu/mL	Negative
Mumps virus	10^5 pfu/mL	Negative
Varicella-zoster virus	10^5 pfu/mL	Negative
Respiratory syncytial virus	10^5 pfu/mL	Negative
Mycoplasma pneumoniae	10^6 cfu/mL	Negative
Escherichia Coli	10^6 cfu/mL	Negative

Experiment results on twenty COVID-19 Antigen negative specimens of healthy people have confirmed as all negative for the concentration of microorganisms or viruses mentioned above. These tested pathogens have no cross-reaction effect on the detection performance of the COVID-19 Antigen Rapid Test.

4.6.5. Interference testing

Interference testing is performed to evaluate CHIL COVID-19 Antigen Rapid Test performance with common substances. The study is designed as to add the following substances to negative and weakly positive specimens to evaluate the interference effect on the COVID-19 Antigen Rapid Test results (see the table below).

Table 6. Interference testing

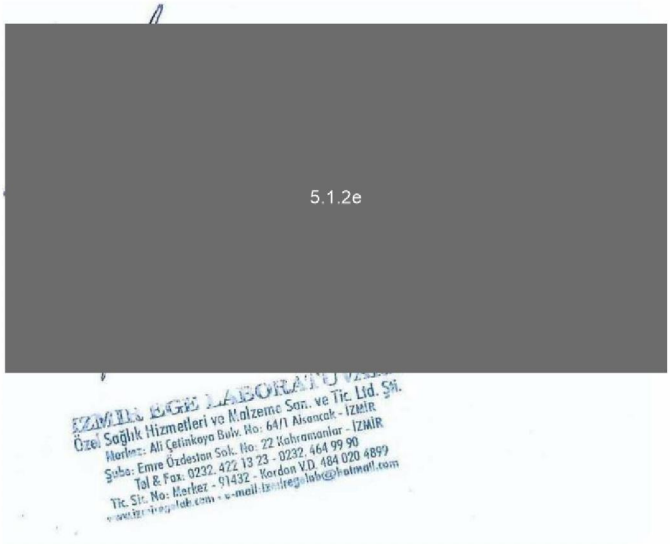
Substances	Concentratios	CHIL COVID-19 Antigen Rapid Test Results on Negative specimens	CHIL COVID-19 Antigen Rapid Test Results on Positive specimens
Mucin	200 mg/ml	Negative	Positive
Hemoglobin	10 mg/ml	Negative	Positive
Histamine Hydrochloride	4.0mg/L	Negative	Positive
Human albumin	60 mg/ml	Negative	Positive
α- interferon	2 ng/ml	Negative	Positive
Lopinavir	2 µg/ml	Negative	Positive
Tobramycin	10 mg/L	Negative	Positive
Ribavirin	40 mg/L	Negative	Positive
Tramadol	12 µg/ml	Negative	Positive
Azithromycin	5 µg/ml	Negative	Positive

Meropenem	10 mg/ml	Negative	Positive
Oseltamivir	1000 ng/ml	Negative	Positive
Benzocaine	1.5 mg/ml	Negative	Positive
Peramivir	20 µg/ml	Negative	Positive

The test results show that the above-mentioned common substances have no interference effect on the detection performance of the COVID-19 Antigen Rapid Test. However, high concentrations of Hemoglobin may affect the test performance. In accordance with this possibility, hemolyzed specimens should not be used for avoiding having false test results.

5. DISCUSSION

As an overall conclusion, CHIL COVID-19 Antigen Rapid Test has a good clinical performance according to performed studies.



Extrapolating the performance of the test on self-application to the Dutch situation

Clinical validation studies were made in Turkey. Used specimens were examples of people of different races living in Turkey. Also, the comparative validation study was conducted at the Paul Ehrlich Institut (PEI), Germany with 120 tests, and this study was positively concluded (Refer BfArM SARS-CoV-2 Antigen Test List AT337/20). Since the test detects nucleocapsid protein and Covid-19 variants do not mutate on this protein, the variant profile in the country has no effect on the test result. For these reasons, there will be no significant difference between Dutch, Turkish and German population results.

Regulatory Affairs Responsible

Mert Hadimoğulları

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CHIL COVID-19 Antigen Rapid Test Clinical Study Report

COVID-19 Antigen Rapid Test

Clinical Study Report

1. TABLE OF CONTENT

2. INTRODUCTION

The objective of this evaluation is to establish the clinical specimen's performance of the Novel Coronavirus (COVID-19) Antigen, including performance on clinical specimens.

The purposes of the study are to evaluate the performance of the CHIL Medical Devices COVID-19 Antigen Rapid Test with Nasal swab specimens and to compare the consistency between Nasal swab and Throat swab, which are tested by Chil's Kit.

3. ADMINISTRATIVE INFORMATION

The protocol should be read carefully, the protocol and 'Test Procedure' supplied with the reagents must be followed exactly unless explicitly stated. The assays during the period of the evaluation should be double checked by another method. The results for both Novel Coronavirus (COVID-19) Antigen and any alternative assay methods must be properly identified. The data should be clearly legible and marked with the name of the laboratory and initialed by Coordinator. All original raw data must be made available for further information.

4. CLINICAL STUDY

4.1. Time Scale of Evaluation

The evaluation is planned as to be completed within 2 weeks.

4.2. Materials Used

Target reagent: A lot of qualified (COVID-19) Antigen produced based on technological process and the outputted Standard Operating Procedure. The Polymerase Chain Reaction (PCR) method was used for reference method.

4.3. Specimens To Be Tested

All the specimens used in this evaluation were supplied from hospitals, laboratories and clinics.

4.3.1. Specimen types

Nasopharyngeal swab and oropharyngeal swab should be used.

4.3.2. Specimen quantity

Specimens above should be collected from known PCR positive and known PCR negative patients.

4.4. Data Storage and Reporting

All data will be filed both on hard copy and in electronically files. Data will be stored for at least 5 years. All laboratory results are strictly confidential. Copies of raw data were retained under the internal R&D and Regulatory Affairs departments of CHIL Tıbbi Malzemeler San. ve Tic. Ltd. Şti. and Özel İzmir Ege Laboratories for future reference.

4.5. MATERİAL AND METHOD

- COVID-19 Antigen Rapid Test produced by CHIL Medical Devices is used to screen 405 PCR positive patient specimens and 466 PCR negative patient specimens. Nasal swab specimens collected according to proper procedure.
- For each type, four kinds of specimens from the same person were tested by Company's Kit. We selected 25 positive and 25 negative specimens. POS1-POS25 of specimens are from infected people, and NEG1-NEG25 are from uninfected people. POS21-POS25 are weekly positive.
- The test kits were used from three different Lot (CCOV-201.20C1, CCOV-201.20C2 and CCOV-201.20C3) for evaluation.

4.6. RESULTS

4.6.1. Limit of Detection (LOD)

The LOD for COVID-19 Antigen Rapid Test was established using dilutions of an inactivated virus culture. The starting material was supplied at a concentration of 3.84 x 10^5 TCID50/mL. Studies were designed to estimate the LOD of the assay using nasal swab specimens, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for COVID-19 Antigen to obtain a series of different concentrations.

Table 1. Limit of detection

COVID-19 Titer	3.84x10^5TCID50/mL								
Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200	1/6400	1/12800	1/25600
Concentration in Dilution tested (TCID50/mL)	3.84x 10^3	1.92 x 10^3	9.6x 10^2	4.8x 10^2	2.4x 10^2	1.2x 10^2	6x 10	3x 10	1.5x 10
Detection rates of 5 replicates	100% (5/5)	100 % (5/5)	100 % (5/5)	100 % (5/5)	100% (5/5)	100 % (5/5)	100% (5/5)	100% (5/5)	80% (4/5)
Detection rates of 20 replicates near cut-off	NA	NA	NA	NA	NA	100 % (20/ 20)	100% (20/2 0)	95% (19/2 0)	75% (15/2 0)
Lowest Concentration with Uniform Positivity per Analyte	30 TCID50/mL								
Limit of detection(LOD) per inactivated virus culture	30 TCID50/mL								

4.6.2. Statistical Table of Clinical Trial Data

Table 2. Statistical table of clinical trial data

Specimens	Specimen types	Gender	Age	PCR results	PCR CT Range	CHIL COVID-19 Antigen Rapid Test - Testing Results	Specimen collected time
CT0001	Nasopharyngeal swab	Male	55	Positive	21-24	+++	2020.4.10
CT0002	Nasopharyngeal swab	Male	44	Positive	30-33	+	2020.4.10
CT0003	Nasopharyngeal swab	Male	37	Positive	<18	+++++	2020.4.10
CT0004	Nasopharyngeal swab	Female	27	Positive	<18	+++++	2020.4.10
CT0005	Nasopharyngeal swab	Female	48	Positive	<18	++++	2020.4.10
CT0006	Nasopharyngeal swab	Male	38	Positive	<18	+++++	2020.4.10
CT0007	Nasopharyngeal swab	Male	56	Positive	<18	+++++	2020.4.10
CT0008	Nasopharyngeal swab	Female	88	Positive	<18	+++++	2020.4.10
CT0009	Nasopharyngeal swab	Female	56	Positive	<18	++++	2020.4.10
CT0010	Nasopharyngeal swab	Female	87	Positive	<18	+++++	2020.4.10
CT0011	Nasopharyngeal swab	Male	48	Positive	18-21	++++	2020.4.10
CT0012	Nasopharyngeal swab	Female	48	Positive	18-21	++++	2020.4.10
CT0013	Nasopharyngeal swab	Male	65	Positive	18-21	++++	2020.4.10
CT0014	Nasopharyngeal swab	Female	24	Positive	18-21	++++	2020.4.10
CT0015	Nasopharyngeal swab	Male	36	Positive	18-21	++++	2020.4.10
CT0016	Nasopharyngeal swab	Female	16	Positive	18-21	+++	2020.4.10
CT0017	Nasopharyngeal swab	Female	34	Positive	18-21	++++	2020.4.10
CT0018	Nasopharyngeal swab	Male	54	Positive	18-21	++++	2020.4.10
CT0019	Nasopharyngeal swab	Male	66	Positive	18-21	++++	2020.4.10
CT0020	Nasopharyngeal swab	Female	30	Positive	18-21	++++	2020.4.10

CT0021	Nasopharyngeal swab	Male	18	Positive	21-24	+++	2020.4.10
CT0022	Nasopharyngeal swab	Female	65	Positive	21-24	++++	2020.4.10
CT0023	Nasopharyngeal swab	Female	51	Positive	<18	+++++	2020.4.10
CT0024	Nasopharyngeal swab	Female	84	Positive	21-24	+++	2020.4.10
CT0025	Nasopharyngeal swab	Male	50	Positive	21-24	+++	2020.4.10
CT0026	Nasopharyngeal swab	Female	89	Positive	21-24	+++	2020.4.10
CT0027	Nasopharyngeal swab	Female	62	Positive	21-24	+++	2020.4.10
CT0028	Nasopharyngeal swab	Male	56	Positive	21-24	+++	2020.4.10
CT0029	Nasopharyngeal swab	Male	48	Positive	21-24	+++	2020.4.10
CT0030	Nasopharyngeal swab	Male	43	Positive	21-24	+++	2020.4.10
CT0031	Nasopharyngeal swab	Male	23	Positive	24-27	++	2020.4.10
CT0032	Nasopharyngeal swab	Female	50	Positive	24-27	++	2020.4.10
CT0033	Nasopharyngeal swab	Male	39	Positive	24-27	+++	2020.4.10
CT0034	Nasopharyngeal swab	Female	54	Positive	24-27	++	2020.4.10
CT0035	Nasopharyngeal swab	Male	34	Positive	24-27	+++	2020.4.10
CT0036	Nasopharyngeal swab	Male	36	Positive	24-27	++	2020.4.10
CT0037	Nasopharyngeal swab	Female	43	Positive	24-27	++	2020.4.10
CT0038	Nasopharyngeal swab	Male	67	Positive	24-27	++	2020.4.10
CT0039	Nasopharyngeal swab	Female	37	Positive	24-27	++	2020.4.10
CT0040	Nasopharyngeal swab	Male	26	Positive	24-27	++	2020.4.10
CT0041	Nasopharyngeal swab	Male	35	Positive	27-30	++	2020.4.10
CT0042	Nasopharyngeal swab	Male	39	Positive	27-30	++	2020.4.10
CT0043	Nasopharyngeal swab	Male	35	Positive	27-30	++	2020.4.10

CT0044	Nasopharyngeal swab	Female	70	Positive	27-30	++	2020.4.10
CT0045	Nasopharyngeal swab	Male	53	Positive	27-30	++	2020.4.10
CT0046	Nasopharyngeal swab	Male	65	Positive	27-30	++	2020.4.10
CT0047	Nasopharyngeal swab	Female	25	Positive	27-30	++	2020.4.10
CT0048	Nasopharyngeal swab	Male	62	Positive	27-30	++	2020.4.10
CT0049	Nasopharyngeal swab	Male	65	Positive	27-30	++	2020.4.10
CT0050	Nasopharyngeal swab	Male	63	Positive	27-30	++	2020.4.10
CT0051	Nasopharyngeal swab	Female	32	Positive	30-33	+	2020.4.10
CT0052	Nasopharyngeal swab	Female	11	Positive	30-33	+	2020.4.10
CT0053	Nasopharyngeal swab	Male	85	Positive	30-33	++	2020.4.10
CT0054	Nasopharyngeal swab	Female	65	Positive	21-24	++++	2020.4.10
CT0055	Nasopharyngeal swab	Female	30	Positive	30-33	+	2020.4.10
CT0056	Nasopharyngeal swab	Male	66	Positive	30-33	+	2020.4.10
CT0057	Nasopharyngeal swab	Female	22	Positive	30-33	+	2020.4.10
CT0058	Nasopharyngeal swab	Female	31	Positive	30-33	+	2020.4.10
CT0059	Nasopharyngeal swab	Female	33	Positive	30-33	+	2020.4.10
CT0060	Nasopharyngeal swab	Female	34	Positive	30-33	+	2020.4.10
CT0061	Nasopharyngeal swab	Female	33	Positive	30-33	++	2020.4.10
CT0062	Nasopharyngeal swab	Female	32	Positive	30-33	+	2020.4.10
CT0063	Nasopharyngeal swab	Female	47	Positive	30-33	+	2020.4.10
CT0064	Nasopharyngeal swab	Female	30	Positive	30-33	+	2020.4.10
CT0065	Nasopharyngeal swab	Male	53	Positive	30-33	+	2020.4.10
CT0066	Nasopharyngeal swab	Male	28	Positive	33-36	+	2020.4.10

CT0067	Nasopharyngeal swab	Male	37	Positive	33-36	+	2020.4.10
CT0068	Nasopharyngeal swab	Female	29	Positive	33-36	+	2020.4.10
CT0069	Nasopharyngeal swab	Male	29	Positive	33-36	+	2020.4.10
CT0070	Nasopharyngeal swab	Male	36	Positive	33-36	+	2020.4.10
CT0071	Nasopharyngeal swab	Female	25	Positive	33-36	+	2020.4.10
CT0072	Nasopharyngeal swab	Female	56	Positive	33-36	+	2020.4.10
CT0073	Nasopharyngeal swab	Female	58	Positive	33-36	+	2020.4.10
CT0074	Nasopharyngeal swab	Male	30	Positive	33-36	-	2020.4.10
CT0075	Nasopharyngeal swab	Female	32	Positive	33-36	+	2020.4.10
CT0076	Nasopharyngeal swab	Male	44	Positive	>36	-	2020.4.10
CT0077	Nasopharyngeal swab	Male	28	Positive	>36	-	2020.4.10
CT0078	Nasopharyngeal swab	Female	59	Positive	>36	-	2020.4.10
CT0079	Nasopharyngeal swab	Male	51	Positive	>36	+	2020.4.10
CT0080	Nasopharyngeal swab	Male	57	Positive	>36	+	2020.4.10
CT0081	Nasopharyngeal swab	Male	50	Positive	-	+	2020.4.10
CT0082	Nasopharyngeal swab	Female	57	Positive	-	+	2020.4.10
CT0083	Nasopharyngeal swab	Male	69	Positive	-	+	2020.4.10
CT0084	Nasopharyngeal swab	Male	31	Positive	-	+	2020.4.10
CT0085	Nasopharyngeal swab	Female	64	Positive	-	+	2020.4.10
CT0086	Nasopharyngeal swab	Male	57	Positive	-	+	2020.4.10
CT0087	Nasopharyngeal swab	Female	59	Positive	-	+	2020.4.10
CT0088	Nasopharyngeal swab	Male	49	Positive	-	+	2020.4.10
CT0089	Nasopharyngeal swab	Female	62	Positive	-	+	2020.4.10

CT0090	Nasopharyngeal swab	Male	28	Positive	-	+	2020.4.10
CT0091	Nasopharyngeal swab	Female	31	Positive	-	+	2020.4.10
CT0092	Nasopharyngeal swab	Male	67	Positive	-	+	2020.4.10
CT0093	Nasopharyngeal swab	Male	36	Positive	-	+	2020.4.10
CT0094	Nasopharyngeal swab	Male	58	Positive	-	+	2020.4.10
CT0095	Nasopharyngeal swab	Female	82	Positive	-	+	2020.4.10
CT0096	Nasopharyngeal swab	Female	42	Positive	<18	+++++	2020.4.24
CT0097	Nasopharyngeal swab	Male	65	Positive	<18	+++++	2020.4.24
CT0098	Nasopharyngeal swab	Female	80	Positive	18-21	++++	2020.4.24
CT0099	Nasopharyngeal swab	Male	54	Positive	18-21	++++	2020.4.24
CT0100	Nasopharyngeal swab	Female	61	Positive	18-21	++++	2020.4.24
CT0101	Nasopharyngeal swab	Male	61	Positive	21-24	+++	2020.4.24
CT0102	Nasopharyngeal swab	Female	61	Positive	21-24	++++	2020.4.24
CT0103	Nasopharyngeal swab	Female	52	Positive	21-24	+++	2020.4.24
CT0104	Nasopharyngeal swab	Male	70	Positive	24-27	++	2020.4.24
CT0105	Nasopharyngeal swab	Female	51	Positive	24-27	++	2020.4.24
CT0106	Nasopharyngeal swab	Male	70	Positive	24-27	+++	2020.4.24
CT0107	Nasopharyngeal swab	Male	26	Positive	24-27	++	2020.4.24
CT0108	Nasopharyngeal swab	Male	23	Positive	24-27	++	2020.4.24
CT0109	Nasopharyngeal swab	Female	34	Positive	30-33	++	2020.4.24
CT0110	Nasopharyngeal swab	Male	59	Positive	30-33	+	2020.4.24
CT0111	Nasopharyngeal swab	Female	56	Positive	30-33	+	2020.4.24
CT0112	Nasopharyngeal swab	Male	32	Positive	33-36	+	2020.4.24

CT0113	Nasopharyngeal swab	Female	9	Positive	33-36	+	2020.4.24
CT0114	Nasopharyngeal swab	Female	61	Positive	>36	+	2020.4.24
CT0115	Nasopharyngeal swab	Female	24	Positive	>36	+	2020.4.24
CT0116	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.03
CT0117	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0118	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.04
CT0119	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0120	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.06
CT0121	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0122	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0123	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0124	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0125	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0126	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0127	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0128	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0129	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0130	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0131	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0132	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0133	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0134	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0135	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09

CT0136	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0137	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0138	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0139	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.01
CT0140	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0141	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0142	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0143	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0144	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0145	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0146	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0147	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0148	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0149	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0150	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0151	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0152	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0153	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0154	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0155	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0156	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0157	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0158	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11

CT0159	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0160	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0161	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0162	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.14
CT0163	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0164	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0165	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0166	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0167	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0168	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0169	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0170	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.03
CT0171	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0172	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.04
CT0173	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0174	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.06
CT0175	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0176	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0177	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0178	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0179	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0180	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0181	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0182	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0183	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0184	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0185	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0186	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0187	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0188	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0189	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0190	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0191	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0192	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0193	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.01
CT0194	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0195	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0196	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0197	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0198	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0199	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0200	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0201	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0201	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0203	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0204	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0205	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0206	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0207	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0208	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0209	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0210	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0211	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0212	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0213	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0214	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0215	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0216	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.14
CT0217	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0218	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0219	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0220	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0221	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0222	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0223	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0224	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.03
CT0225	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0226	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.04
CT0227	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09

CT0228	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.06
CT0229	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0230	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.05
CT0231	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0232	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0233	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0234	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0235	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0236	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0237	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0238	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0239	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0240	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0241	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0242	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0243	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0244	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0245	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.09
CT0246	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0247	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.01
CT0248	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0249	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0250	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11

CT0251	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0252	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.10
CT0253	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0254	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0255	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0256	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0257	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.12
CT0258	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0259	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0260	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0261	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0262	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0263	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0264	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0265	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0266	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0267	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0268	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0269	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0270	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.14
CT0271	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0272	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0273	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11

CT0274	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0275	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.11
CT0276	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0277	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0278	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0279	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0280	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0281	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0282	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0283	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0284	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0285	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0286	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0287	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0288	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0289	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0290	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0291	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0292	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0293	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0294	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0295	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0296	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0297	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0298	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0299	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0300	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0301	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0302	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0303	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0304	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0305	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0306	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0307	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0308	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0309	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0310	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0311	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0312	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0313	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0314	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0315	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0316	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0317	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0318	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0319	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0320	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0321	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0322	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0323	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0324	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0325	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0326	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0327	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0328	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0329	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0330	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0331	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0332	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0333	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0334	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0335	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0336	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0337	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0338	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0339	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0340	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0341	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0342	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0343	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0344	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0345	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0346	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0347	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0348	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0349	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0350	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0351	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0352	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0353	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0354	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0355	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0356	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0357	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0358	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0359	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0360	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0361	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0362	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0363	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0364	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0365	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0366	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0367	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0368	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0369	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0370	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0371	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0372	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0373	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0374	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0375	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0376	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0377	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0378	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0379	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0380	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0381	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0382	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0383	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0384	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0385	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0386	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0387	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0388	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13

CT0389	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0390	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0391	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0392	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0393	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0394	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0395	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0396	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0397	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0398	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0399	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0400	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0401	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0402	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0403	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0404	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0405	Nasopharyngeal/ Oropharyngeal Swab	-	-	Positive	-	+	2020.11.13
CT0406	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0407	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.03
CT0408	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0409	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.04
CT0410	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0411	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.06

CT0412	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0413	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0414	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	+	2020.11.09
CT0415	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0416	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0417	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0418	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0419	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0420	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0421	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0422	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0423	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	+	2020.11.09
CT0424	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0425	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0426	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0427	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0428	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0429	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0430	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0431	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0432	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0433	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0434	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12

CT0435	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0436	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0437	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0438	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0439	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0440	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0441	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0442	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0443	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0444	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0445	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0446	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0447	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0448	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0449	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0450	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0451	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0452	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0453	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0454	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0455	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0456	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0457	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0458	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0459	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0460	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0461	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0462	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0463	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0464	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0465	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0466	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0467	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0468	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0469	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0470	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0471	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0472	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0473	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0474	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0475	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0476	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0477	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0478	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0479	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0480	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12

CT0481	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0482	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0483	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0484	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0485	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0486	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0487	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0488	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0489	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0490	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0491	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0492	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0493	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0494	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0495	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0496	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0497	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0498	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0499	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0500	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0501	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0502	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0503	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0504	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0505	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0506	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0507	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.03
CT0508	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0509	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.04
CT0510	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0511	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.06
CT0512	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0513	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0514	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0515	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0516	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0517	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0518	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0519	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0520	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0521	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0522	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0523	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0524	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0525	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0526	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09

CT0527	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0528	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0529	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0530	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0531	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0532	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0533	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0534	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0535	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0536	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0537	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0538	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0539	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0540	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0541	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0542	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0543	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0544	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0545	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0546	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0547	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0548	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0549	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0550	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0551	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0552	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0553	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0554	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0555	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0556	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0557	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0558	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0559	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0560	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0561	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0562	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0563	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0564	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0565	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0566	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0567	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0568	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0569	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0570	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0571	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0572	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09

CT0573	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-		2020.11.09
CT0574	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0575	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0576	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0577	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0578	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0579	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0580	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0581	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0582	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0583	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0584	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0585	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0586	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0587	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0588	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0589	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0590	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0591	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0592	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0593	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0594	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0595	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0596	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0597	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0598	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0599	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0600	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0601	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0602	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0603	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0604	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0605	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0606	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0607	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.03
CT0608	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0609	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.04
CT0610	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0611	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.06
CT0612	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0613	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0614	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0615	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0616	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0617	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0618	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0619	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0620	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0621	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0622	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0623	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0624	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0625	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0626	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0627	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0628	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0629	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0630	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0631	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0632	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0633	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0634	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0635	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0636	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0637	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0638	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0639	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0640	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0641	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0642	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0643	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0644	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0645	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0646	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0647	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0648	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0649	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0650	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0651	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0652	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0653	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0654	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0655	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0656	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0657	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0658	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0659	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0660	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0661	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0662	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0663	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0664	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0665	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0666	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0667	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0668	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0669	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-		2020.11.11
CT0670	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0671	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0672	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0673	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0674	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0675	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0676	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0677	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0678	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0679	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0680	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0681	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0682	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0683	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0684	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0685	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0686	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0687	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0688	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0689	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0690	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0691	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0692	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0693	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0694	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0695	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0696	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0697	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0698	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0699	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0700	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0701	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0702	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0703	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0704	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0705	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0706	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0707	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.03
CT0708	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0709	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.04
CT0710	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09

CT0711	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.06
CT0712	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0713	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0714	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0715	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0716	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0717	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0718	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0719	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0720	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0721	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0722	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0723	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0724	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0725	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0726	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0727	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0728	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0729	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0730	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0731	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0732	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0733	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0734	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0735	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0736	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0737	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0738	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0739	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0740	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0741	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0742	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0743	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0744	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0745	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0746	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0747	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0748	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0749	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0750	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0751	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0752	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0753	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0754	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0755	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0756	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0757	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0758	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0759	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0760	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0761	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0762	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0763	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0764	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0765	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0766	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0767	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0768	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0769	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0770	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0771	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0772	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0773	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0774	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0775	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0776	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0777	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0778	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0779	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0780	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0781	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0782	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0783	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0784	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0785	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0786	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0787	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0788	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0789	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0790	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0791	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0792	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0793	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0794	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0795	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0796	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0797	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0798	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0799	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0800	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0801	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0802	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

CT0803	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0804	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0805	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0806	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0807	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.03
CT0808	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0809	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.04
CT0810	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0811	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.06
CT0812	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0813	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.05
CT0814	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0815	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0816	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0817	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0818	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0819	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0820	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0821	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0822	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0823	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0824	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0825	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09

CT0826	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0827	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0828	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0829	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0830	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.01
CT0831	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0832	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0833	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0834	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0835	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0836	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0837	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0838	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0839	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0840	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.12
CT0841	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0842	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0843	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0844	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0845	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0846	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0847	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0848	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13

CT0849	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0850	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0851	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0852	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0853	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.14
CT0854	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0855	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0856	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0857	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0858	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0859	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0860	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0861	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0862	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.10
CT0863	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0864	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0865	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0866	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.13
CT0867	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0868	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0869	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11
CT0870	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.09
CT0871	Nasopharyngeal/ Oropharyngeal Swab	-	-	Negative	-	-	2020.11.11

Table 3. Analysis of coincidence rate of COVID-19 Antigen rapid test and PCR Test in nasal specimens

		PCR Test		
		Positive	Negative	**Total**
COVID-19 Antigen Rapid Test	Positive	401	2	**403**
	Negative	4	464	**468**
	Total	**405**	**466**	**871**

*Sensitivity: 99.01% (95%CI: 97.49% - 99.73%) **
*Specificity: 99.57% (95%CI: 98.46% - 99.95%)**
*Accuracy: 99.54%** (95%CI: 98.83% - 99.88%) **
**95 % Confidence Interval : (%-%) ** Disease Prevalance %5 accepted*

The results above showed that there was a good consistency between the CHIL COVID-19 Antigen Rapid Test and the PCR results on the clinical specimens.

4.6.3. Different Specimens Consistency Study

The study is designed to evaluate different specimens (Nasopharyngeal swab/ Oropharyngeal swab) performance for CHIL COVID-19 Antigen Rapid Test.

Table 4. The consistency of different specimens (Result specification: "+" Positive "-" Negative)

Specimen No.	Nasal swab	Throat swab
POS1	+++	+++
POS2	+	+
POS3	++	+
POS4	+	+
POS5	++	++
POS6	+	+
POS7	++	+
POS8	+	+
POS9	++	++
POS10	+	+
POS11	+++	++
POS12	+	+
POS13	++	++
POS14	++	+
POS15	+	+
POS16	+++	+++

POS17	+	+
POS18	+++	+++
POS19	++	++
POS20	+++	++
POS21	+	+
POS22	+	+
POS23	+	+
POS24	+	+
POS25	+	+
NEG1	-	-
NEG2	-	-
NEG3	-	-
NEG4	-	-
NEG5	-	-
NEG6	-	-
NEG7	-	-
NEG8	-	-
NEG9	-	-
NEG10	-	-
NEG11	-	-
NEG12	-	-
NEG13	-	-
NEG14	-	-
NEG15	-	-
NEG16	-	-
NEG17	-	-
NEG18	-	-
NEG19	-	-
NEG20	-	-
NEG21	-	-
NEG22	-	-
NEG23	-	-

NEG24	-	-
NEG25	-	-

The study show that the same results are obtained in Nasopharyngeal/ Oropharyngeal Swab specimens by using CHIL COVID-19 Antigen Rapid test.

4.6.4. Cross reaction testing

This cross reaction study is performed to verify the influence of common respiratory pathogens on the detection performance of CHIL COVID-19 Antigen Test. The following respiratory pathogens are selected for cross-reactivity tests: Influenza A virus H1N1, influenza B virus, Mycoplasma pneumoniae, Rhinovirus A, Rotavirus, Large intestine Escherichia, respiratory syncytial virus, adenovirus, etc.
The concentration of bacterial specimens is set to 10^6 cfu/mL or higher, and the concentration of virus specimens is set to 10^5 pfu/mL or higher. The test results are shown in the table 5 below.

Table 5. Cross reaction (cfu: colony-forming unit, pfu: plaque-forming unit)

Pathogen	Concentration	CHIL COVID-19 Antigen Rapid Test Results
HKU1	10^5 pfu/mL	Negative
OC43	10^5 pfu/mL	Negative
NL63	10^5 pfu/mL	Negative
229E	10^5 pfu/mL	Negative
MERS-coronavirus	10^5 pfu/mL	Negative
Human Metapneumovirus	10^5 pfu/mL	Negative
Influenza A virus H1N1	10^5 pfu/mL	Negative
Influenza A virus H3N2	10^5 pfu/mL	Negative
Influenza A virus H5N1	10^5 pfu/mL	Negative
Influenza A virus H7N9	10^5 pfu/mL	Negative
Influenza B virus	10^5 pfu/mL	Negative
Mycoplasma pneumoniae	10^6 cfu/mL	Negative

Rhinovirus A	10^5 pfu/mL	Negative
Rhinovirus B	10^5 pfu/mL	Negative
Rhinovirus C	10^6 pfu/mL	Negative
Adenovirus 1	10^5 pfu/mL	Negative
Adenovirus 2	10^5 pfu/mL	Negative
Adenovirus 3	10^5 pfu/mL	Negative
Adenovirus 4	10^5 pfu/mL	Negative
Adenovirus 5	10^5 pfu/mL	Negative
Adenovirus 7	10^5 pfu/mL	Negative
Adenovirus 55	10^5 pfu/mL	Negative
Enterovirus A	10^5 pfu/mL	Negative
Enterovirus B	10^5 pfu/mL	Negative
Enterovirus C	10^5 pfu/mL	Negative
Enterovirus D	10^5 pfu/mL	Negative
EB Virus	10^5 pfu/mL	Negative
Measles virus	10^5 pfu/mL	Negative
Human cytomegalovirus	10^5 pfu/mL	Negative
Rotavirus	10^5 pfu/mL	Negative
Norovirus	10^5 pfu/mL	Negative
Mumps virus	10^5 pfu/mL	Negative
Varicella-zoster virus	10^5 pfu/mL	Negative
Respiratory syncytial virus	10^5 pfu/mL	Negative

Mycoplasma pneumoniae	10^6 cfu/mL	Negative
Escherichia Coli	10^6 cfu/mL	Negative

Experiment results on twenty COVID-19 Antigen negative specimens of healthy people have confirmed as all negative for the concentration of microorganisms or viruses mentioned above. These tested pathogens have no cross reaction effect on the detection performance of the COVID-19 Antigen Rapid Test.

4.6.5. Interference testing

Interference testing is performed to evaluate CHIL COVID-19 Antigen Rapid Test performance with common substances. The study is designed as to add the following substances to negative and weakly positive specimens to evaluate the interference effect on the COVID-19 Antigen Rapid Test results (see the table below).

Table 6. Interference testing

Substances	Concentratios	CHIL COVID-19 Antigen Rapid Test Results on Negative specimens	CHIL COVID-19 Antigen Rapid Test Results on Positive specimens
Mucin	200 mg/ml	Negative	Positive
Hemoglobin	10 mg/ml	Negative	Positive
Histamine Hydrochloride	4.0mg/L	Negative	Positive
Human albumin	60 mg/ml	Negative	Positive
α- interferon	2 ng/ml	Negative	Positive
Lopinavir	2 µg/ml	Negative	Positive
Tobramycin	10 mg/L	Negative	Positive
Ribavirin	40 mg/L	Negative	Positive
Tramadol	12 µg/ml	Negative	Positive
Azithromycin	5 µg/ml	Negative	Positive
Meropenem	10 mg/ml	Negative	Positive
Oseltamivir	1000 ng/ml	Negative	Positive
Benzocaine	1.5 mg/ml	Negative	Positive
Peramivir	20 µg/ml	Negative	Positive

The test results show that the above mentioned common substances have no interference effect on the detection performance of the COVID-19 Antigen Rapid Test. However, high concentrations of Hemoglobin may affect the test performance. In accordance with this possibility, hemolyzed specimens should not be

used for avoiding to have false test results.

5. DISCUSSION

As an overall conclusion, CHIL COVID-19 Antigen Rapid Test has a good clinical performance according to performed studies.

TRANSLATION FROM TURKISH INTO ENGLISH

T.R.

IZMIR GOVERNORSHIP

PROVINCIAL HEALTH DIRECTORATE

Tire State Hospital

Number : 56480858-503.03.02

Subject : Covid-19 Rapid Test Results

TO WHOM IT MAY CONCERN

As a result of test workouts which were conducted in Covid-19 Polyclinic of our hospital; it is observed that the results of antigen Covid-19 rapid tests with CHIL Brand, conforms to the PCR results in the ratio of 100%. These tests were conducted with 50 patients.

Kindly submitted for your information.

Electronically signed

5.1.2e

This document has been translated by me from its Turkish into English.

5.1.2e

T.C.
İZMİR VALİLİĞİ
İL SAĞLIK MÜDÜRLÜĞÜ
Tire Devlet Hastanesi

Sayı : 56480858-503.03.02
Konu : Covid-19 Hızlı Test Sonuçları Hk.

İLGİLİ MAKAMA

Hastanemiz Covid-19 Polikliniğinde yapılan test amaçlı denemeler sonucunda; CHİL marka antijen Covid-19 hızlı testinin sonuçlarının PCR sonuçları ile %100 uyumlu olduğu gözlemlenmiştir. Bu denemeler 50 hasta ile yapılmıştır.

Bilgilerinize arz / rica ederim.

5.1.2e

5.1.2e

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Bilgi için: ÜMİT KAHRAMANLI
Veri Hazırlama ve Kontrol İşlt.
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INTRODUCTION

CHIL Tıbbi Mal. San. ve Tic. Ltd Şti. conducted Usability Study to evaluate CHIL COVID-19 Antigen Rapid Test usability performance for participants at the observation of the independent laboratory.

Rapid Tests are supplied with Instructions for Use, box which provided Quick Reference Instructions and and QR code for the Operation Video on it, nasal swab and extraction tube by the manufacturer CHIL Tıbbi Mal. San. ve Tic. Ltd Şti.

A usability Study is intended to determine the extent to an interface facilitates a user's ability to complete routine tasks. Typically the test is conducted with a group of potential users on-site with portable Rapid Test Kits. Users are asked to complete a series of routine tasks. Results are recorded and analyzed whether needed improve on the test design or not.

The 100 participants applied the CHIL COVID-19 Antigen Rapid Test by using given Instructions for Use and Quick Reference Instructions, QR Code for Operation Video on the box with the given tasks by the independent Laboratory Staff. According to this procedure, participant's task completion rates, comments, overall satisfaction ratings, questions, and feedback were recorded in Annex I.

EXECUTIVE SUMMARY

The CHIL Tıbbi Mal. San. ve Tic. Ltd. Şti. conducted with Ege Laboratory an onsite usability study in Turkey on Feb 9th and Feb 10th, 2021.

100 participants, including individuals (n=50), caregivers (n=30) and age of 2-11 years individuals(n=20) participated in the study. Each individual or caregiver pair participated in a 30-minute session with a single proctor. The usability evaluation session included one simulated use of the CHIL Tıbbi Mal. San. ve Tic. Ltd. Şti. in which a user was already connected with a laboratory staff, knowledge tasks, and opportunities to provide feedback.

The purpose of this study was to assess the usability of the CHIL COVID-19 Antigen Rapid Test, the comprehensibility and applicability of the provided instructions.

In general, all participants found the given Instructions for Use and Quick Reference Instructions on the box to be clear, straightforward. 97% (97 out of 100) participants thought that the CHIL COVID-19 Antigen Rapid Test was easy to use. All of the participants (100) used Instructions for Use and thought that the instructions were comprehensible.

This Usability Study identified only a few minor problems including:

- Insufficient amount of specimen due to not tightening the Extraction Tube sufficiently.
- Insufficient sampling because the swab is not rotated enough in the nose.
- Problem with breaking the top of the extraction tube.
- Reading the test results early or late than advised in Instructions for Use because the timer is not started on time. Late or early start of timer was not a level that would affect the test result.

This document contains the participants' feedback, satisfaction ratings, task completion rates, ease or difficulty of completion ratings, errors, and recommendations for improvements. The scenarios and questionnaires is included in the Annex I and II section.

METHODOLOGY

The staff from Ege Laboratory have contacted participants, necessary information regarding the usability study was provided, and appropriate dates and times were determined to start usability study.

Each individual and caregiver session lasted approximately 30 minutes. During the session, the laboratory staff explained the test session and asked the participant to fill out a brief questionnaire (see Annex I). Participants read the task scenarios and tried to perform the CHIL COVID-19 Antigen Rapid Test according to the given Instructions for Use, and Quick Reference Instructions on the box.

- 20 Caregivers also applied the test to people aged 2-11 years and evaluated the questionnaire accordingly.

After the tasks, the laboratory staff asked the participant to rate the test kit on a 5-point Likert Scale with measures ranging from Strongly Disagree to Strongly Agree (see Annex I):

Questionnaire was prepared for answers that assess below example questions,

- Were the Quick Reference Instructions on the box and Instructions for Use clear enough?
- How easy it was to find the information from the Instructions for Use and Quick Reference Instructions on the box?
- Were the visual instructions clear or enough when performing the test?
- Have you had difficulty using the QR code on the box fort he Operation Video?

After the tasks were completed, the laboratory staff asked the participant to rate the CHIL COVID-19 Antigen Rapid Test overall for below subjective measures including:

- Ease of use
- Ergonomic design of the CHIL COVID-19 Antigen Rapid Test
- Frequency of use
- Difficulty to following test procedure in Instructions for Use
- Learn ability- how easy it would be for most users to learn to use the CHIL COVID-19 Antigen Rapid Test
- Information facilitation – how quickly participant could find information
- Look & feel appeal – Box design makes me want to use the test further

In addition, the test laboratory staff asked the participants the following overall test questions:

- What the participant liked most?
- What the participant liked least?
- Recommendations for improvement.

See Annex I for the overall questionnaires.

PARTICIPANTS

100 participants, including Individuals (n=50), caregivers (n=30), and age of 2-11 years individuals(n=20) completed the usability study in the two testing dates. 50 participants were involved in testing on Feb 9th and 50 on Feb 10th. Of the 100 participants, 50 were male and 50 were female. 97 of the 100 participants performed the CHIL COVID-19 Antigen Rapid Test correctly. Usability Study Focus groups prepared according to IEC 62366-1 and 'Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use' Usability Study Recommendations are shown in the table 1.

Table 1. *Focus Grups*

	Caregivers 1*	Caregivers 2**	Individuals
Sex n (%) Male Female	 10 10	 8 2	 32 38
Age	21-64	21-64	2-73*
Education n (%) ≤High School Bachelors' degree Post-graduate/Specialty PhD degree	 2 7 3 1	 6 5 4 2	 23 25 12 10

*Caregivers 1 applied the tests to the individuals at the age of 2-11 years old.

** Caregivers 2 applied the tests only for themselves.

EVALUATION TASKS/SCENARIOS

Test participants attempted completion of the following tasks (see Table 2. for complete test scenarios/tasks)

- Obtain information about the performing of the CHIL COVID-19 Antigen Rapid Test by examining the box.
- Check the contents of the box according to the information on the box.

Table 2. Tasks

User Task	Task Requirements	Potential Use Errors
1.Clean your hands before starting the test.	Wash or disinfect your hands before you start testing and make sure your hands are dry.	Failure to clean and dry the hands may result in contamination that can affect the test result.
2.Check the expiration date on the box	Compare today's date with expiry date on the box	Failure to notice expired product
3.Check the box content	Compare the instructions for use and the contents of the box	Failure to notice the damaged or missing materials
4.Remove the swab from the pouch.	Remove without touching the head of the swab that advised in Instructions for Use	Failure to notice the warning
5.Collect the nasal specimen by using swab	Insert the swab 1,5-2,5 cm (0,6-1 inch) into the patient's nostrils and rotate the swab around the inside wall of the nostril 5-6 times.	Failure to sufficient sampling because the swab is not rotated enough in the nose
6.Place swab in the extraction tube	Put the swab into the extraction tube, rotate the swab for about 10 seconds.	Failure to keep and rotate the swab sufficiently in the tube.
7.Take swab out from the extraction buffer tube.	Squeeze the bottle when taking the swab out to remove as much liquid as possible from the swab.	Failure to squeeze the extraction buffer tube sufficiently.

8.Break the top part of the extraction tube	Keep the extraction tube vertical as the breaking part will be upward to avoid specimen solution spills and break the top part of the extraction tube.	Failure to break the top part of the extraction tube correctly.
9. Add 4 drops of the specimen from the extraction buffer tube to the sample well of the test cassette.	Carefully add 4 drops of sample from the extraction buffer tube to the sample well of the test cassette without spilling around.	Failure to add insufficient drops to the sample well can affect the test result.
10. Start the timer and read the test result in 15 minutes.	Do not read the test results before 15 minutes or after 30 minutes.	Reading the test results early or late than advised in Instructions for Use.

RESULTS

Most of the participants completed all tasks correctly. 99 of the 100 (99%) completed Task 5(Collect the nasal specimen by using swab), 99 of the 100 (99%) completed Task 7(Take swab out from the extraction buffer tube) and 99 of the 100 (99%) completed Task 8(Break the top part of the extraction tube). The user who had problems with Task 5 was a 25-year-old female from the Individual group with bachelor degree. The user who had problems with Task 7 was the caregiver who tested his 8-year-old individual. The caregiver was a 43-year-old male with post graduate/specialty. The user who had problems with Task 8 is a 67-year-old male retired from the Individual group.

Table 3. Summary of the Results

Number of participant who completed the task correctly	100	100	100	100	99	100	99	99	100	100
Completion Rates	100%	100%	100%	100%	99%	100%	99%	99%	100%	100%

According to IEC 62366, questions were prepared for the Usability Study and a questionnaire was created. Refer to Annex I

LIKES, DISLIKES, PARTICIPANT RECOMMENDATIONS

Upon completion of the tasks, participants provided feedback for what they liked most and least about the CHIL COVID-19 Antigen Rapid Test, and recommendations for improving the instructions.

LIKED MOST

The following comments capture what the participants liked most:

- Easy to use
- Reading results in a short time
- Easy to interpret the the test result
- Portable device
- Visual instructions to be effective and helpful
- Clear demonstration of the performing the test with the Operation Video

LIKED LEAST

Most of the participants found CHIL COVID-19 Antigen Rapid Test to be very useful and easy to use but the following comment capture what the some of participants liked the least:

- Collection of the specimen from the nostril with a nasal swab

RECOMMENDATIONS FOR IMPROVEMENT

Participants were generally satisfied with the use of the CHIL COVID-19 Antigen Rapid Test and the instructions but the following comments capture what the some of participants recommended for improvement:

- Mobile application can be developed.
- Customer services hotline can be provided on the box.

CONCLUSION

Most of the participants found CHIL COVID-19 Antigen Rapid Test to be well-organized, very useful, and easy to use. Having a more than one instructions like Instruction for Use and Operation Video to find information is key to many of the participants. All participants thought the instructions were straightforward and easy to understand and follow. Caregivers did not have any problems while testing individuals aged 2-11 years.

CHIL	USABILITY STUDY QUESTIONNAIRE	Doküman Kodu/ Document Code:	US-A1
		Yayın Tarihi/ Issues Date:	05.02.2021
		Prepared By:	QA Department
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ANNEX I

Sex: **Date:**

Age: **Nationality:**

Educational Status:

Please fill in the following questionnaire related to CHIL COVID-19 Antigen Rapid Test based on your experience while performing the CHIL COVID-19 Antigen Rapid Test.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
CHIL COVID-19 Antigen Rapid Test is easy to use.					
CHIL COVID-19 Antigen Rapid Test can be preferred to use frequently					
Instructions for Use is straightforward, easy to understand and follow.					
Quick Reference Instructions and shown on the box is straightforward, easy to understand and follow.					
Operation Video QR Code is easy to scan.					
Operation Video is descriptive and helpful to perform the test.					
Most people would learn to use CHIL COVID-19 Antigen Rapid Test easily.					
CHIL COVID-19 Antigen Rapid Test can be performed correctly just by reading the Instructions for Use.					
The test result is easy to interpret.					
The warnings and precautions prevent mistakes that could be made while performing the test.					
It is easy as shown in the instructions to use the swab and collect nasal specimen from the nostril.					
It is easy to remove the swab from the extraction buffer tube.					
The top part of the extraction tube can be broken easily.					
It is easy to add 4 drops of specimen to the sample well of the test cassette.					

	USABILITY STUDY QUESTIONNAIRE	Doküman Kodu/ Document Code:	US-A1
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The test result is clear within 15 minutes.					
It is clearly visible to see line conditions when interpreting the test results.					
The labels and symbols on the box is understandable.					
CHIL COVID-19 Antigen Rapid Test has ergonomic design.					
Box design is appeal to the eye.					

Please answer the following questions related to CHIL COVID-19 Antigen Rapid Test based on your experience while performing the CHIL COVID-19 Antigen Rapid Test.

What did you like most when performing the test?	
What did you like least when performing the test?	
What do you recommend to improve CHIL COVID-19 Antigen Rapid Test?	

CHiL	USABILITY STUDY TASKS AND SCENARIOS	Doküman Kodu/ Document Code:	US-A2
		Yayın Tarihi/ Issues Date:	05.02.2021
		Prepared By:	QA Department
		Sayfa No / Page No:	9/ 9

Annex II

Please read the tasks and scenarios carefully and perform the test accordingly.

User Tasks and Scenarios
1.Clean your hands before starting the test and read the instructions for use.
2.Check the expiration date on the box.
3.Check the box content.
4.Remove the swab from the pouch.
5.Collect the nasal specimen by using swab.
6.Place swab in the extraction tube.
7.Take swab out from the extraction buffer tube.
8.Break the top part of the extraction tube.
9. Add 4 drops of the specimen from the extraction buffer tube to the sample well of the test cassette.
10. Start the timer and read the test result in 15 minutes.

	RISK MANAGEMENT FOR CHIL COVID-19 ANTIGEN RAPID TEST	Doküman Kodu/ Document Code:	RA
		Yayın Tarihi/ Issues Date:	27.12.2020
		İçerik Rev. Tarihi – No/ Date of Content Rev.- No	23.03.2021-2
		Sayfa No / Page No:	1 / 27

1. OVERVIEW OF RISK MANAGEMENT ACTIVITIES AS APPLIED TO MEDICAL DEVICES

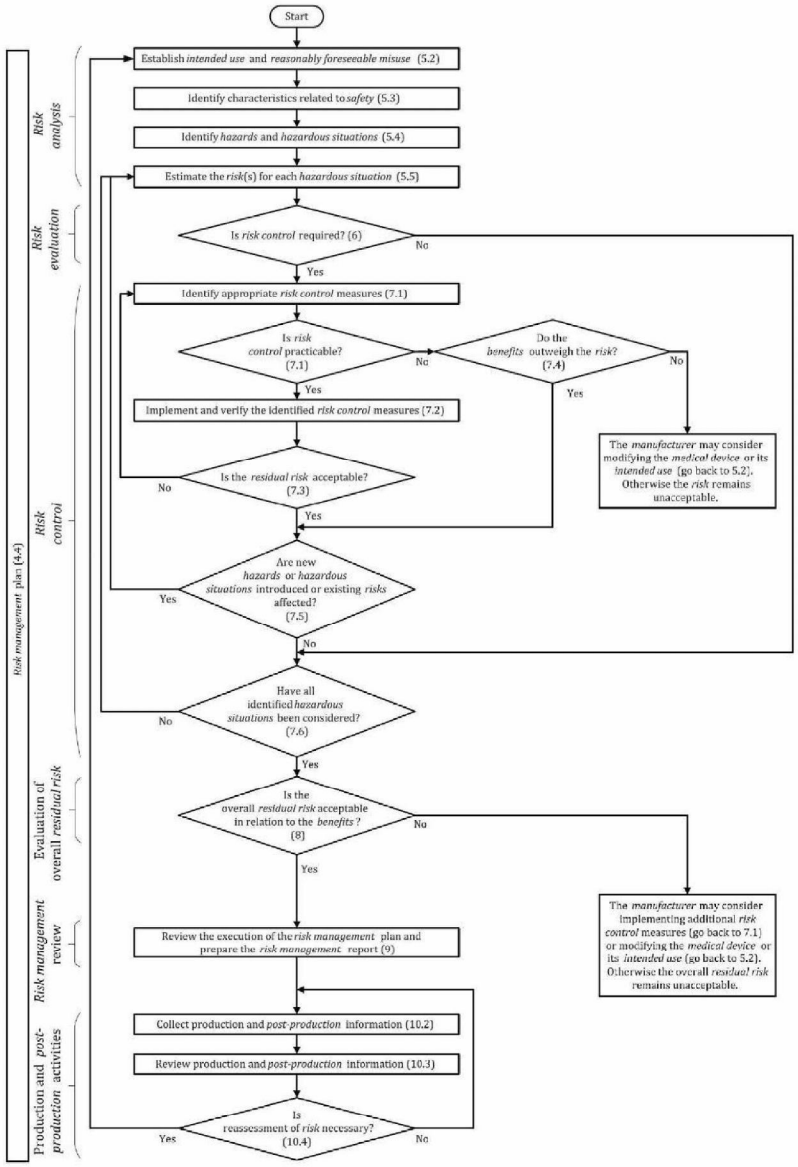

Figure 1 Overview of Risk Management Activities As Applied To Medical Devices

2. RISK MANAGEMENT

This section conforms : EN ISO 14971:2019

This section takes into consideration all hazards having possible influence on:

- Test Results
- Safety of the patient
- Safety of the user(s)
- Impact on the environment with attention to:
- Handling suitability of the device for its intended purpose.

1.1 National or Regional Regulatory Requirements

Refer to EN ISO 13485:2016 Quality System, 98/79/EC Directive and internal references.

1.2 Risk Management Process

In Chil a risk management process is created defining dangers related with medical devices, forecasting related risks and evaluate them, controlling these risks and screening efficiency of this control. This process concerns the articles mentioned below:

- Risk analysis;
- Risk evaluation;
- Risk control;
- Evaluation of overall residual risk
- Risk management review
- Production and post-production activities.

Refer to Risk Management File.

The following are established, implemented, documented and maintained in Annex I Medical Device Risk Evaluation Table.

a. Identifying hazards and hazardous situations associated with the CHIL COVID-19 Antigen Rapid Test;
b. Estimating and evaluating the associated risks;
c. Controlling these risks, and
d. Monitoring the effectiveness of the risk control measures.

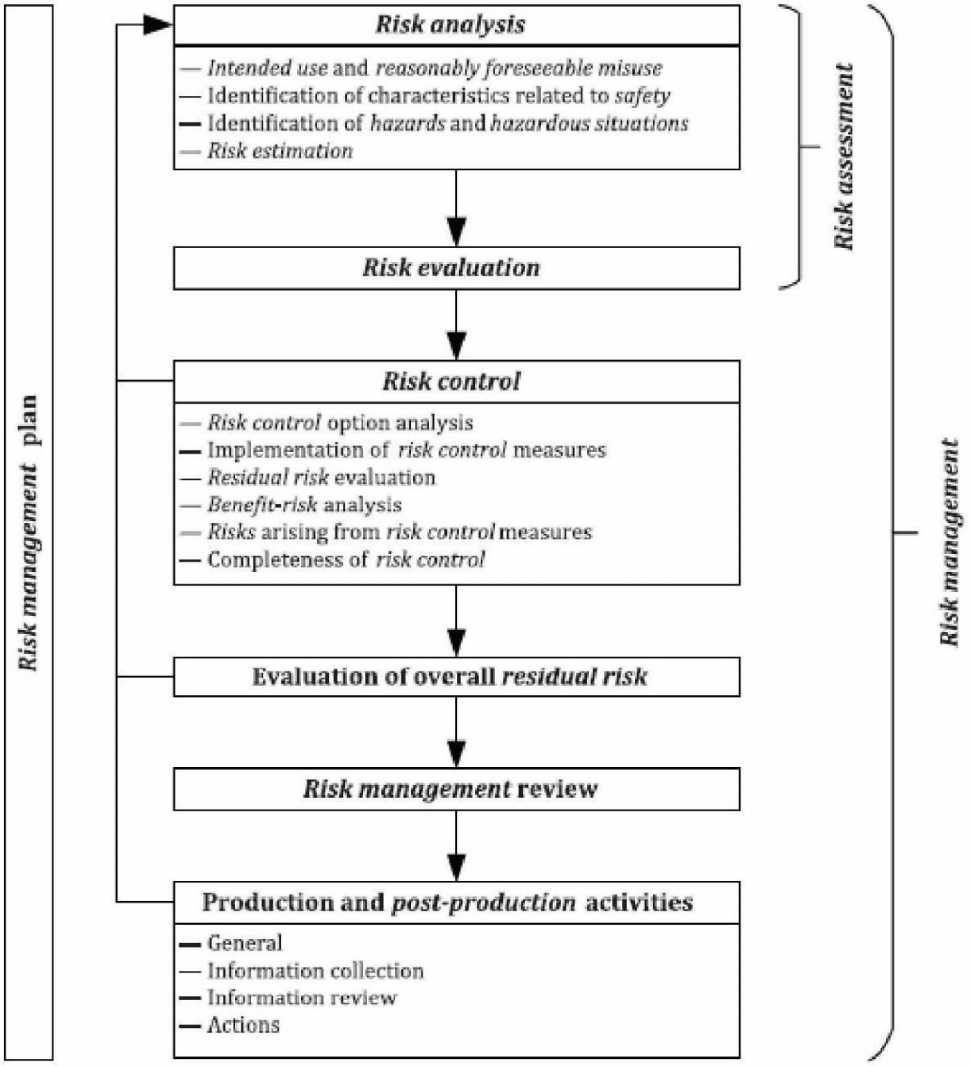

Figure 2 *A Schematic Representation of the Risk Management Process*

2.3 Management Responsibilities

Top management undertakes to implement the risk management process by providing sufficient resources and assigning competent personnel for risk management. Top management defines and documents a policy to establish criteria for risk acceptability.

Refer to Risk Management File.

2.4 Competence of Personnel

Persons performing risk management tasks shall be competent on the basis of education, training, skills and experience appropriate to the tasks assigned to them. Where appropriate, these persons shall have knowledge of and experince with the particular medical device (or similar medical devices) and its use, the technologies involved or the risk management techniques emloyed. appropriate records shall be maintaned.

Refer to Risk Management File

2.5 Risk Management Plan

Risk management plan is part of the risk management plan and include followings:

a. The scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable;
b. Assignment of responsibilities and authorities;
c. Requirements for review of risk management activities;
d. Criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurance of harm cannot be estimated;
e. A method to evaluate the overall residual risk, and criteria for acceptability of the overall residiual risk based on the manufacturer's policy for determining acceptable risk;
f. Activities for verification of the implementation and effectiveness of risk control measures;
g. Activities related to collection and review of relevant production and post-production information

Refer to Risk Management File

2.6 RISK MANAGEMENT FILE

As manufacturer, CHIL creates and maintains a risk management file for specific medical devices under consideration. The risk management file provides traceability for each identified hazard for:

- the risk analysis;
- the risk evaluation;
- the implementation and verification of the risk control measures; and
- the results of the evaluation of the residual risks.

Refer to EN ISO 13485:2016 system files

3. RISK ANALYSIS

3.1 Risk Analysis Process

The risk management file contains the risk management plan and risk analysis results specific to the relevant medical device. The risk analysis included in the risk management file as an attachment is including the following:

a. The definition and description of the analyzed medical device, all factors that may affect the operation of the product are presented in the form of product components and factors affecting the product (Annex III)
b. The persons and the organization of the risk team performing the risk analysis are specified in the form of Annex III product components and factors affecting the product (Annex III)
c. Risk analysis, scope and date of analysis are given in Risk Evaluation Table of Medical Devices (Annex I)

Refer to Risk Management Procedure and EN ISO 13485:2016 system files

3.2 Intended Use and Reasonably Foreseeable Misuse

CHIL COVID-19 Antigen Rapid Test is an in vitro diagnostic test intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus that causes COVID-19 in a nasal swab. İntended use and foreseeable misuse is recorded in Annex II form by taking account the intended medical indication, patient population, part of body or type

of tissue interacted with the device and its accessories, user profile, user environment and operating principle.The risk team lists the foreseeable misuse, possible causes and measures to be taken with the brainstorming method in the same form.

Refer to Risk Management File and IEC 62366-1:2015

3.3 Device Description

CHIL COVID-19 Antigen Rapid Test is manual and used alone to produce examination results.

CHIL COVID-19 Antigen Rapid Test contains sterile nasal swab, test cassette and buffer extraction tube. Timer and personal protective equipments are necessary but not provided accessories.

3.3.1 Limitation

- The result of the product should not be taken as a confirmed diagnosis, but for clinical reference only. Diagnosis should be made along with RT-PCR results, clinical symptoms, epidemic conditions, and further clinical data.
- In the early stage of infection, the test result might be negative due to the the low SARS-CoV-2 antigen level or antigen has not yet appeared in the specimen.
- Due to the limitation of the detection method, the negative result cannot exclude the possibility of an infection. The positive result should not be taken as a confirmed diagnosis.
- This Test can only qualitatively detect SARS-CoV-2 antigens in human anterior nasal and/or nasopharyngeal and/or oropharyngeal swab. It cannot determine the certain antigen level in the specimens.
- The accuracy of the test depends on the specimen collection process. Improper specimen collection, improper specimen transportation, and storage or freezing and thawing of the specimen would affect the test results.
- It is needed when diluting swab specimens with the matched extraction buffer supplied. Using other extraction buffers may cause wrong results.
- The extraction buffer and test cassette must be equilibrated to room temperature (18℃ - 26℃) before the use, otherwise, the results may be incorrect.
- Sensitivity may decrease if the specimen was not tested directly. Please test the specimen as soon as possible.

- Cross-reactions may exist due to the N protein in SARS which has high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS infection.

3.4 Questions

REF: ISO/TR 24971:2020 Annex A

I. What is the intended use/intended purpose and how is the device to be used?

Refer to 3.2 Intended Use and Reasonably Foreseeable Misuse

II. Is the medical device intended to be implanted?

No, it is not inttended to be implanted.

III. Is the medical device intended to be in contact with the patient or other persons?

No. COVID-19 Antigen Rapid Test is a *in vitro* diagnostic medical device.

IV. What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?

The materials used are compitible with SARS-CoV-2 nucleocapsid antigen. The substances in the extraction buffer are irritating to the skin and harmful to the environment. This information is specified in the instructions for use.

V. Is energy delivered to or extracted from the patient?

No.

VI. Are substances delivered to or extracted from the patient?

No.

VII. Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?

No.

VIII. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

Only swab is sterile and no sterilization needed by the user.

IX. Is the medical device intended to be routinely cleaned and disinfected by the user?

No. COVID-19 Antigen Rapid Test is single use test.

X. Is the medical device intended to modify the patient environment?

The product is used in room conditions, but can be stored between 2-30°C. Studies have verified that it can work under different humidity conditions, but an optimum humidity of 50% is recommended.

XI. Are measurements taken?

No.

XII. Is the medical device interpretative?

Yes If the C line appears, it means negative result. If T and C appear together, it means a positive result. Results other than these combinations are invalid.

XIII. Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?

No.

XIV. Are there unwanted outputs of energy or substances?

No.

XV. Is the medical device susceptible to environmental influences?

Only susceptibility is temperature. The device should be stored at 2-30 °C.

XVI. Does the medical device influence the environment?

No.

XVII. Does the medical device require consumables or accessories?

No.

XVIII. Is maintenance or calibration necessary ?

No.

XIX. Does the medical device contain software ?

No.

XX. Does the medical device have a restricted shelf-life?

Yes, COVID-19 Antigen Raip Test's shelf life is 24 months after the date of manufacturing.

XXI. Are there any delayed or long-term use effects?

No. COVID-19 Antigen Rapid Test is a single use test.

XXII. To what mechanical forces will the medical device be subjected?

None.

XXIII. What determines the lifetime of the medical device?

Deterioration of mobilizing agent, gold nanoparticles and stabilization of used antibodies.

XXIV. Is the medical device intended for single use?

Yes. COVID-19 Antigen Rapid Test is a single use test.

XXV. Is safe decommissioning or disposal of the medical device necessary?

The medical device should dispose carefully.

XXVI. Does installation or use of the medical device require special training or special skills?

No.

XXVII. How will information for safety be provided?

Usability study conducted for safety usage according to IEC 62366:2015. Also safe usage is ensured with detailed warnings written in the instructions for use, warnings specified in labeling and instructions on the box (such as application video with QR code).

XXVIII. Will new manufacturing processes need to be established or introduced?

No.

XXIX. Is successful application of the medical device critically dependent on human factors such as the user interface?

Yes. Usability study conducted for safety usage according to IEC 62366:2015. Label, instructions for use, symbols used, ergonomic features, physical design and layout parameters are assesed by users.

XXIX.1 Can the user interface design features contribute to use error?

Refer to Annex II and usability study. These records created according to Risk Managment Procedure, Usability Procedure and Usability Instruction.

XXIX.2 Is the medical device used in an environment where distractions can cause use error?

Refer to usability study

XXIX.3 Does the medical device have connecting parts or accessories?

No

XXIX.4 Does the medical device have a control interface?

CHIL COVID-19 Antigen Rapid Test has a visual interface that users can interpret the results with reddish color lines.

XXIX.5 Does the medical device display information?

Environments, orientation, the visual capabilities of the user, clarity of the presented information, colour coding, and the accessibility of critical information are assesed by users who contributed to usability study.
Refer to usability study.

XXIX.6 Is the medical device controlled by a menu?

No

XXIX.7 Will the medical device be used by persons with special needs?

COVID-19 Antigen Rapid Test should keep out of reach of children. Do not use in anyone CHIL COVID-19 Antigen Rapid Test under 2 years of age. Children aged 2-12 years must be tested by an adult (+18 years old).

XXX. Does the medical device use an alarm system?

No

XXXI. In what ways might the medical device be misused (deliberately or not)?

Refer to Annex II for misuses of CHIL COVID-19 Antigen Rapid Test.

XXXII. Is the medical device intended to be mobile or portable ?

CHIL COVID-19 Antigen Rapid Test is intended to mobile test.

XXXIII. Does the use of the medical device depend on essential performance?

No.

XXXIV. Does the medical device produce an output that is used as an input in determining clinical action?

Yes. CHIL COVID-19 Antigen Rapid Test is a pre-diagnosis in vitro medical device. What the users should do according to the possible results of the test are specified in the instructions for use.

3.5 Identification Of Characteristics Related To Safety

Qualitative and quantitative characteristics that could affect the safety of the medical device are documented in product components, factors affecting the product and performance characteristics. (Refer to Performance Evaluation Report)

3.6 Identification of Hazards and Hazardous Situations

Known hazards and foreseeable hazards based on the intended use, foreseeable misuse (Annex II), Failure Mode and Effects Analysis (Annex IV), and safety-related properties of the relevant medical device are identified and documented in the Medical Device Risk Evaluation Table Annex I. In this form, the hazardous situation created by reasonably foreseeable sequences or combinations for each events is identified and documented. CHIL COVID-19 Antigen Rapid Test can examine as positive, negative or invalid results. Examination results are either correct, incorrect or indeterminate.

3.7 Risk Estimation

The associated risks are estimated for each hazardous situation using available data. Possible consequences for hazardous situations of damages whose probability of occurrence cannot be predicted are listed in the Medical Device Risk Assessment Table Annex I for risk assessment and risk control, again in the same form, if applicable the probability and severity of the damage are recorded, risk evaluation is made and risk control measures are determined.

Information and data for risk estimation can be obtained from:

- Published standards
- Scientific or technical investigations
- Field data from similar devices already in use, including publicly available reports of incidents

- Usability tests employing typical users
- Clinical evidence
- Result of relevant investigations or simulations
- Expert opinions
- External quality assessment schemes for in vitro diagnostic medical devices

4. Risk Evaluation

For each identified hazardous situation, the estimated risks are evaluated and whether the risk is acceptable is decided by using the criteria for risk acceptability in the risk management plan.

If the risk is Acceptable, there is no need to apply requirements for risks arising from risk control option analysis and risk control measures. The estimated risk is now treated as risk.

If the risk is not acceptable, risk control activities are carried out.

Risk assessment results are recorded in the Medical Device Risk Evaluation Table Annex I and documented in the risk management file. Compliance is reviewed by auditing the risk management file.

5. Risk Control

5.1 Risk control option analysis

Risk control measures reduce the risks to an acceptable level. One or more of the risk control options listed below are used:

a. inherently safe design and manufacture;
b. protective measures in the medical device itself or in the manufacturing process;
c. information for safety and, where appropriate, training to users.

Selected risk control measures are recorded in the Medical Device Risk Evaluation Table Annex I / Annex III and documented in the risk management file.

5.2 Implementation of Risk Control Measures

The selected risk control measures are implemented and verificated. This verification is recorded in risk control verification report which is in risk management file.

Refer to Risk Management File.

5.3 Residual Risk Evaluation

Residual risk evaluation results are recorded in the Medical Device Risk Evaluation Table Annex I and documented in the risk management file. If the risk is no longer acceptable according to the criteria, further risk control measures are considered. And the form is revised.

5.4 Benefit-Risk Analysis / Evaluation of Overall Residual Risk

This device is a single use in vitro diagnostic medical device which never comes into contact with human body. Under certain circumstances however. Indirect risk of achieving wrong result due to major reasons of:

a. misuse
b. deterioration of device due to storage.

Are carefully re-evaluated below:

- Precautions against 'misuse' are broadly taken by improvements in IFU and by providing 'Customer Support Service'.
- Precautions against 'deterioration' are broadly taken by improvements

In device desing such as to give 'invalid test result' instead of a wrong result in case of deterioration.

As an overall conclusion; The balance between medical benefit and residual risks is acceptable.

6. Production and Post-Production Activities

Chil installed and has been continuing a systematic procedure for evaluation of information related with post production stages of medical or similar devices. Information, probable relations with safety are evaluated for the articles especially mentioned below:

- If there are hazards present that are not realized before.
- If risk (risks) are not acceptable at present that forecasted for a danger.
- If original evaluation is made invalid by different way.

If any of these conditions are provided results of evaluation are used as data for feedback to risk management process.

Scientific data and field data of this device and millions of similar devices sold world-wide with broad public acceptance. There are no malfunction of the device or any harm to the user.(Refer to EN ISO 13485:2016 system files ; The QC controls,customer complaints, etc.)

CHIL, prepares post market surveillance report every year as taking data from several sources such as customer complaints, customer feedback, recalls, sales and marketing information, etc.

7. Risk Management Report

Refer to Risk Managament file.

To the best of our skill and knowledge, we hereby concluded that:

a. All hazards are clearly identified.
b. All identified hazards are adequately reduced.
c. This device carries no unacceptable risk for the professional user or the personnel or the performance of its-self or to the environment.

- Quality management elements are related to the elements of risk Management (refer to Quality Assurance System Files – EN ISO 13485:2016)
- Other International Standards that may be related to the elements of risk management ISO 10993-1, ISO 14969, IEC 60300, IEC 60812, IEC 61025, ISO 22442, ISO 19001, ISO 18113-1.

8. Risk Analysis Performed By :

Risk Analysis is performed by CHIL Tıbbi Mal. San. ve Tic. Ltd. Şti. under coordination of Quality Assurence and Regulatory Affairs Departmant.

ANNEX I

O/P: Olasılık/Probability, E/S: Etki/Severety, RD/RC: Risk Derecesi/ Risk Category
Kırmızı/Red:Feci/Catastrophic, Sarı/ Yellow: İstenmeyen/Undesirable, Yeşil/Green: Kabul edilir/ Acceptable

KAPSAM / SCOPE	CHiL	TIBBİ CİHAZ RİSK DEĞERLENDİRME TABLOSU/ RISK EVALUATION TABLE OF MEDICAL DEVICES			İlk Yayın/ First Issue	
					İçerik Revizyon Tarihi-No/ Content Revision Date - No	17.12.2020
	Ürün Ref No/ Product Ref No:	CCOV-201CCOV-201, CCOV-202, CCOV-203,CCOV-206	Cihazın Adı/ Name of Device:	COVID-19 ANTİJEN HIZLI TEST/ COVID-19 ANTIGEN RAPID TEST	Doküman No/ Document No:	TCRD-21/01
	Kullanım Amacı/ Intended Use:	COVID-19 Antijen Hızlı Testi, insanların nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.				
	Hazırlayan/ Prepared by:		5.1.2e ☐		Onaylayan / Approved by:	5.1.2e ☐

	Tehlike/ Hazard	Tehlikeli Durum / Hazard Situation	Olası zarar/ Potantial Harm	Risk Tahmini ve Değerlendirmesi/ Risk Estimation and Evaluation				Risk Kontrol Tedbiri/ Risk Control Measures	Kayıtlar/ Records	Sorumlu/ Responsible	Artık Risk/ Residual Risk	Artık Risk Değerlendirmesi/ Residual Risk Evaluation			Tıbbi Yarar/ Medical Benefit
				O/P	E/S	RD/RC	Açıklama/ Explanation					O/P	E/S	RD/RC	
ÜRETİM ÖNCESİ / P	Nemlenme/ Humidity	Fiziksel faktör / Physical Factor	Neme doymuş silikaların nem çekme özelliğini kaybetmesi/Moisture-saturated silicas lose their moisture absorption ability	3	4	12	Testin çalışmaması/ Test not running	Silika stok poşetlerinin içinde nem indikatörü ile kontrolünün sağlanması/Ensuring control of silica stock bags with moisture indicator	x	Depo Sorumlusu/ Warehouse Responsible	x				x
	Voltaj/ Voltage	Yetersiz güç beslemesi/ Insufficient power supply	Makinelerin arızalanması/Machinery breakdown	1	5	5	Makine arızası nedeniyle üretimin yavaşlaması/ Production slowdown due to machine breakdown	Çalışma ve sosyal güvenlik bakanlığından onaylı yetkili firma tarafından periyodik kontrol ettirilmektedir./It is periodically inspected by an authorized firm approved by the Ministry of Labor and Social Security.	x	Bakım Onarım Sorumlusu/ Maintenance and Repair Responsible	x				x
	Kontaminasyon/ Contamination	Yetersiz dezenfeksiyon ve stabilizasyon/Inadequate disinfection and satibilization	Ürünlerin kontamine olması/ Contamination of products	1	5	5	Testin çalışmaması/ Test not running	Günlük temizliğin eksiksiz uygulanması/Complete application of daily cleaning	Günlük temizlik çizelgesi/Daily cleaning schedule record	Bakım Onarım Sorumlusu/ Maintenance and Repair Responsible	x				x

O/P: Olasılık/Probability, E/S: Etki/Severety, RD/RC: Risk Derecesi/ Risk Category
Kırmızı/Red:Feci/Catastrophic, Sarı/ Yellow: İstenmeyen/Undesirable, Yeşil/Green: Kabul edilir/ Acceptable

KAPSAM / SCOPE	CHiL	TIBBİ CİHAZ RİSK DEĞERLENDİRME TABLOSU/ RISK EVALUATION TABLE OF MEDICAL DEVICES			İlk Yayın/ First Issue	
					İçerik Revizyon Tarihi-No/ Content Revision Date - No	29.03.2021
	Ürün Ref No/ Product Ref No:	CCOV-201CCOV-201, CCOV-202, CCOV-203,CCOV-206	Cihazın Adı/ Name of Device:	COVID-19 ANTİJEN HIZLI TEST/ COVID-19 ANTIGEN RAPID TEST	Doküman No/ Document No:	TCRD-21/01
	Kullanım Amacı/ Intended Use:	COVID-19 Antijen Hızlı Testi, insanların nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.				
	Hazırlayan/ Prepared by:		5.1.2e ☐		Onaylayan / Approved by:	5.1.2e ☐

					Risk Tahmini ve Değerlendirmesi/ Risk Estimation and Evaluation								Artık Risk Değerlendirmesi/ Residual Risk Evaluation			
	Tehlike/ Hazard	Tehlikeli Durum / Hazard Situation	Olası zarar/ Potantial Harm	O/P	E/S	RD/RC	Açıklama/ Explanation	Risk Kontrol Tedbiri/ Risk Control Measures	Kayıtlar/ Records	Sorumlu/ Responsible	Artık Risk/ Residual Risk	O/P	E/S	RD/RC	Tıbbi Yarar/ Medical Benefit
PRODUCTION	Sıcaklık/ Temperature	Ürünü oluşturan komponenetlerin optimum sıcaklıkta stoklanmaması/ Not stocking the components that make up the product at the optimum temperature	Ürünlerin sıcaklıktan etkilenip performansının bozulması/ Products affected by temperature and their performance deteriorate	2	5	10	Testin çalışmaması/ Test not running	Gün içerisinde sık sık yapılan sıcaklık kontrolleri/Frequent temperature checks during the day	Günlük sıcaklık takip formu/Daily temperature tracking form	Depo Sorumlusu/ Warehouse Responsible	x				x
	Performans Sonucu/ Performance Result	Yeterli örneklem alınmaması/ Insufficient sample size	Hatalı çıkabilecek ürün üretimi/Product production that may be faulty	1	10	10	Müşteriden olumsuz geri dönüş, mali kayıp /Negative feedback from the customer, financial loss	Yeteri kadar örneklem alınması/ Taking enough samples	Giriş Kalite Kontrol-Final Kalite Kontrol Raporları/Entry Quality Control - Final Quality Control Reports	Kalite Kontrol Sorumlusu/ Quality Control Responsible	x				x
	Kimyasal /Chemical	Tampon çözeltisinin hazırlanma esnasında dökülmesi/Spilling of the buffer solution during preparation	Tampon çözeltisinin içindeki bileşenlerin kimyasal yaranlanmalara sebep olması/Chemical damage to the components in the buffer solution	2	5	10	Kişide alerjik reaksiyon gözlenmesi/An allergic reaction to the person	Tampon hazırlama esnasında kişilerin koruyucu ekipman kullanması/ People using protective equipment during buffer preparation	x	Kalite Güvence Sorumlusu/ Quality Assurence Responsible	x				x

O/P: Olasılık/Probability, E/S: Etki/Severety, RD/RC: Risk Derecesi/ Risk Category
Kırmızı/Red:Feci/Catastrophic, Sarı/ Yellow: İstenmeyen/Undesirable, Yeşil/Green: Kabul edilir/ Acceptable

KAPSAM / SCOPE	CHiL	TIBBİ CİHAZ RİSK DEĞERLENDİRME TABLOSU/ RISK EVALUATION TABLE OF MEDICAL DEVICES			İlk Yayın/ First Issue	
					İçerik Revizyon Tarihi-No/ Content Revision Date - No	29.03.2021
	Ürün Ref No/ Product Ref No:	CCOV-201CCOV-201, CCOV-202, CCOV-203,CCOV-206	Cihazın Adı/ Name of Device:	COVID-19 ANTİJEN HIZLI TEST/ COVID-19 ANTIGEN RAPID TEST	Doküman No/ Document No:	TCRD-21/01
	Kullanım Amacı/ Intended Use:	COVID-19 Antijen Hızlı Testi, insanların nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.				
	Hazırlayan/ Prepared by:	Ece SÖKMEN YILMAZ ☐		Onaylayan / Approved by:	Hilda ÇİL KAYA ☐	

	Tehlike/ Hazard	Tehlikeli Durum / Hazard Situation	Olası zarar/ Potantial Harm	Risk Tahmini ve Değerlendirmesi/ Risk Estimation and Evaluation				Risk Kontrol Tedbiri/ Risk Control Measures	Kayıtlar/ Records	Sorumlu/ Responsible	Artık Risk/ Residual Risk	Artık Risk Değerlendirmesi/ Residual Risk Evaluation			Tıbbi Yarar/ Medical Benefit
				O/P	E/S	RD/RC	Açıklama/ Explanation					O/P	E/S	RD/RC	
ÜRETİM / PR	Ölçüm /Measurement	Malzeme uyumluluk bilgisi/ Material Compitibility	Maddi zarar/ Financial Loss	2	8	16	Kaset ölçüsüyle strip ölçüsünün uyuşmaması/Casette size and strip size do not match	Makine ayarlarının kontrol edilmesi ve kumpas cihazı ile doğrulanma/ Checking machine settings and verifying with caliper device	Makine bakım ve onarım formu, yıllık kalibrasyon listesi/ Machine maintenance and repair form, annual calibration list	Bakım Onarım Sorumlusu/ Kalite kontrol sorumlusu /Maintenance and Repair Responsible/ Quality control responsible	x				x
	Radyasyon enerjisi/Radiation Energy	Üretim personelinin dijital baskı makinesinde kasete baskı yapımı sırasında UV ışığa maruz kalması/ Production personnel are exposed to UV light during cassette printing on a digital printing machine	Üretim personelinin sağlığı/ Health of production personnel	3	5	15	Koruyucu gözlük kullanılmaması durumunun önüne geçilmesi/Prevention of not wearing protective glasses	Üretim personelinin gerekli koruyucu ekipmanı kullanıp kullanmadığını kontrol etmek./Checking whether the production personnel are using the necessary protective equipment.	x	Üretim Sorumlusu/ Production responsible	x				x
	Kimyasal/ Chemical	Zehirlenme/ Poisoning	Üretim personelinin sağlığı/ Health of production personnel	3	5	15	Tampon dolumu esnasında üretim personelinin koruyucu ekipman kullanmasının sağlanması/ Ensuring that production personnel use protective equipment during buffer filling	Üretim personelinin gerekli koruyucu ekipmanı kullanıp kullanmadığını kontrol etmek/ checking whether the production personnel are using the necessary protective equipment	x	Üretim Sorumlusu/ Production responsible	x				x

O/P: Olasılık/Probability, E/S: Etki/Severety, RD/RC: Risk Derecesi/ Risk Category
Kırmızı/Red:Feci/Catastrophic, Sarı/ Yellow: İstenmeyen/Undesirable, Yeşil/Green: Kabul edilir/ Acceptable

KAPSAM / SCOPE

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TIBBİ CİHAZ RİSK DEĞERLENDİRME TABLOSU/ RISK EVALUATION TABLE OF MEDICAL DEVICES

İlk Yayın/ First Issue			
İçerik Revizyon Tarihi-No/ Content Revision Date - No	29.03.2021		
Ürün Ref No/ Product Ref No:	CCOV-201CCOV-201, CCOV-202, CCOV-203,CCOV-206	Cihazın Adı/ Name of Device:	COVID-19 ANTİJEN HIZLI TEST/ COVID-19 ANTIGEN RAPID TEST
Doküman No/ Document No:	TCRD-21/01		
Kullanım Amacı/ Intended Use:	COVID-19 Antijen Hızlı Testi, insanların nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.		
Hazırlayan/ Prepared by:	5.1.2e ☐	Onaylayan / Approved by:	5.1.2e ☐

LIFE CYCLE / YA		Tehlike/ Hazard	Tehlikeli Durum / Hazard Situation	Olası zarar/ Potantial Harm	Risk Tanımını ve Değerlendirmesi/ Risk Estimation and Evaluation O/P	E/S	RD/RC	Açıklama/ Explanation	Risk Kontrol Tedbiri/ Risk Control Measures	Kayıtlar/ Records	Sorumlu/ Responsible	Artık Risk/ Residual Risk	Artık Risk Değerlendirmesi/ Residual Risk Evaluation O/P	E/S	RD/RC	Tıbbi Yarar/ Medical Benefit
	ÜRETİM SONU	Miktar/ Quantitiy	Ürün komponentlerinin hatalı miktarda kutuya yerleştirilmesi/ Placing the product components in the wrong amount of box	Maddi zarar , müşteriden olumsuz geri dönüş/ Financial damage, negative feedback from the customer	1	5	5	Hatalı kutulamanın önüne geçilmesi için kontrol sıklığının önüne geçilmesi gerekmektedir/ Control frequency should be avoided in order to prevent incorrect boxing.	Kutuların tartılarak koliye yerleştirilmesi/Weighing the boxes	Final kalite kontrol raporu/ Final Quality Control Report	Üretim Sorumlusu / Kalite kontrol Sorumlusu /Production Responsible / Quality Control Responsible	x				x
		Stok alanı/ Stock Area	Olumsuz ortam koşulları/Adverse ambient conditions	Ürünlerin zarar görmesi/ Damage to products	2	4	8	Olumsuz ortam koşullarına karşı stok alanının ortam koşulları ürün stoklanmasına uygun şekilde tutulmalıdır/Against adverse environmental conditions, the ambient conditions of the stock area should be kept in accordance with product stocking.	Günlük Stok alanı sıcaklık-nem kontrolleri /Daily Stock area temperature-humidity controls	Ortam koşulları kontrol formu/Ambient conditions control form	Depo sorumlusu/ Warehouse Responsible	x				x

O/P: Olasılık/Probability, E/S: Etki/Severety, RD/RC: Risk Derecesi/ Risk Category
Kırmızı/Red:Feci/Catastrophic, Sarı/ Yellow: İstenmeyen/Undesirable, Yeşil/Green: Kabul edilir/ Acceptable

KAPSAM / SCOPE	CHiL	TIBBİ CİHAZ RİSK DEĞERLENDİRME TABLOSU/ RISK EVALUATION TABLE OF MEDICAL DEVICES			İlk Yayın/ First Issue	
					İçerik Revizyon Tarihi-No/ Content Revision Date - No	29.03.2021
	Ürün Ref No/ Product Ref No:	CCOV-201CCOV-201, CCOV-202, CCOV-203,CCOV-206	Cihazın Adı/ Name of Device:	COVID-19 ANTİJEN HIZLI TEST/ COVID-19 ANTIGEN RAPID TEST	Doküman No/ Document No:	TCRD-21/01
	Kullanım Amacı/ Intended Use:	COVID-19 Antijen Hızlı Testi, insanların nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.				
	Hazırlayan/ Prepared by:		Ece SÖKMEN YILMAZ ☐		Onaylayan / Approved by:	Hilda ÇİL KAYA ☐

AŞAMA DÖNGÜSÜ		Tehlike/ Hazard	Tehlikeli Durum / Hazard Situation	Olası zarar/ Potantial Harm	Risk Tahmini ve Değerlendirmesi/ Risk Estimation and Evaluation				Risk Kontrol Tedbiri/ Risk Control Measures	Kayıtlar/ Records	Sorumlu/ Responsible	Artık Risk/ Residual Risk	Artık Risk Değerlendirmesi/ Residual Risk Evaluation			Tıbbi Yarar/ Medical Benefit
					O/P	E/S	RD/RC	Açıklama/ Explanation					O/P	E/S	RD/RC	
	NRASI/POST	Transfer/Transfer	Uygunsuz ortam, olumsuz koşullar;/Inappropriate environment, adverse conditions	Ürünlerin zarar görmesi deforme olması/Damage to the products being deformed	2	4	8	Transfer aşamasındaki olumsuz ortam koşullarından etkilenme/Affected by adverse environmental conditions during the transfer phase	Kutulama işleminin ürünün ortam koşullarından en az etkilenecek şekilde sağlanması ve kontrolünün yapılması/Ensuring and controlling the packaging process in a way that the product is least affected by ambient conditions.	Final kalite kontrol raporu/ Final Quality Control Report	Kalite kontrol sorumlusu/ Quality Control Responsible	x				x

ANNEX II

CHIL	**AMAÇLANAN KULLANIM VE ÖN GÖRÜLEBİLİR YANLIŞ KULLANIM / INTENDED USE AND FORESEEABLE MISUSE**				İlk Yayın/ First Issue	19.12.2020
					İçerik Revizyon Tarihi-No/ Content Revision Date - No	05.02.2021-0
Ürün Ref No/ Product Ref No:	CCOV-206 / CCOV - 201 / CCOV-202 / CCOV 203	Cihazın Adı/ Name of Device:	CHIL COVID-19 ANTIGEN RAPID TEST		Doküman No / Document No	FM-21/01
Amaçlanan Tıbbi Gösterge/ Intended Medical Indication:		Covid-19 Ön Teşhisi/Covid-19 Pre-Diagnosis			Hasta populasyonu/ Patient population:	Covid-19 Şüphesi Olan Kişiler/Covid-19 Suspected Persons
Cihazın ve aksesuarlarının etkileşimde olduğu vücut veya doku tipi:		Nazal Bölge/Nasal Area			Kullanıcı profili/ User Profile:	Amatör Kullanıcı/Amateur User
Kullanılan Çevresi/ User Environment		Evde Kullanım/Lay User	Çalışma Prensibi / Operating Principle:		Yanal Akışlı immunokromatografik Test/Immunochromatographic lateral flow test	
Kullanım Amacı/ Intended Use:	CHIL® COVID-19 Antijen Hızlı Testi, insanların nazal, nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir./ This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.				Risk Ekibi/ Risk Team:	Mert Hadimoğulları İpek Uludağ Ece Sökmen Yılmaz Ayça Sürengöz

Ön Görülebilir Yanlış Kullanım / Foreseeable Misuse	**Riskler / Risks**					
	Tehlikeli Durum/ Hazardous Situation	**O/P**	**E/S**	**RD/RE**	**Olası Sebepleri/ Possible Cause**	**Tedbir / Measure**
Okuma Zamanı/Reading Time	Reading Results before 10 minutes (False Result)	3	2	6	Zamanlayıcı olmaması/Absence of timer	Kullanım Talimatlarında zamanlayıcı kullanılması önerisi ve Kullanım Talimatlarında a uyarısı: Optimum okumalar için 10 dakikalık bir zaman aralığı önerilir. Test ve kontrol çizgileri görünse bile 10 dakikadan önce veya 30 dakikadan sonra okuma yapılmamalıdır./Recommendation of using timer in the Instructions for use and warning a on Instructions for Use: For optimum readings, a 10 minute time interval is recommended. Readings should not be taken before 10 minutes or after 30 minutes, even when test and control lines are visible.
	Reading Results after 30 minutes (False Result)	3	2	6	Zamanlayıcı olmaması/Absence of timer	
Hatalı Örnek Hacmi /Wrong Specimen Volume	Over specimen volume than advised (False Result)	3	3	9	Damlaları yanlış saymak/Counting drops wrong	Kullanım Talimatlarında Uyarı: 4 damla numune kullanma ve ekstraksiyon şişesini iyice sıkma konusunda uyarı./Warning on Instructions for Use: to use 4 drops of specimen and warning about squeezing the extraction bottle well.
	Lower specimen volume than advised (False Result)	3	2	6	Sürüntü çubuğunun çektiği numuneyi geri alamama/Not being able to take the sample drawn by the swab	

Düşük-Yüksek Sıcaklık-Nem/Low-High Temperature-Humidity	2°C altındaki sıcaklık/Temperature below 2°C	4	3	12	Aşırı koşullar/ Extreme Conditions	Kullanım Talimatlarına İlişkin Uyarı: - Test kasetinin, numunenin, tamponun ve / veya kontrollerin oda sıcaklığına (15-30 ° C) ulaşmasına izin verin - Kit, oda sıcaklığında veya buzdolabında (2-30 ° C) saklanabilir. Test kaseti, kapalı poşet üzerinde yazılı olan son kullanma tarihine kadar stabildir. Test kaseti, kullanıma kadar kapalı poşet içinde kalmalıdır. DONDURMAYIN. Yanlış okuma sonucunu önlemek için geçersiz test sonucunu göstereceğinden kontrol hattı üretilemez./ Warning on Instructions for Use: - Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) - The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. -Control line can not be produced as it will indicate invalid test result
	30°C üzerindeki sıcaklık/Temperature over 30°C	4	3	12		
	%60'ın üzerinde nem değeri/Humidity over 60%	4	3	12		
Test Sonucuna Işık etkisi/Light Effect on Reading Results	Insufficient Light Source	3	1	3	Different Environment Conditions	Test performansı üzerinde ışığın etkisi yoktur/There is no effect of light for test performance
	Different Light Source	3	1	3		
Tekrar Kullanım/Re-use	Re-using the Test	1	5	5	Maliyeti azaltma/To Reduce Cost	Kullanım Talimatları ile İlgili Uyarı: Test cihazı asla tekrar kullanılmamalıdır./Warning on Instructions for Use: The test device should never be reused.
Yanlış Kullanım/Abnormal Use (e.g Eating, Throwing the test)	Testi Amacı Dışında Kullanmak/Using the Test Other Than Testing Purposes	1	5	5		Warning about abnormal using in the Instructions for Use
Yanlış Örnek Tipi/Wrong Specimen Type	Nazal, Nazofarengeal veya Orofarengeal Dışında bir örnek tipi kullanmak (serum,plasma gibi)/ Using other than nasal, nasopharyngeal or oropharyngeal specimen (e.g serum,plasma)	2	5	10	Possible incomfort about specimen collection	Numune türleri ve yanlış numune türü ile ilgili uyarı, kullanım talimatında belirtilmiştir. /Specimen types and warning about wrong specimen type are specified in the instruction for use.
	Tampon, nazal çubuk gibi					

Üçüncü Parti Malzeme kullanmak/ Using Unverified third-party reagent	[illegible] malzemeleri farklı yerlerden temin etmek./ Obtaining materials such as tampons and nasal swabs from different brand or company.	3	5	15	Maliyeti Azaltmak/To Reduce Cost	Sadece valide edilmiş CHIL ürünlerinin kullanımı için uyarı/Warning for use of validated CHIL products only

ANNEX III

CHIL	HIZLI TEST ÜRÜN BİLEŞENLERİ VE ÜRÜNE ETKİ EDEN ETMENLER/RAPID TEST PRODUCT COMPONENTS AND PRODUCT AFFECTING FACTORS	Tarih/ Date:	12.11.2020
		Doküman No/ Document No:	P-CCOV-201/01
		İçerik Revizyon Tarihi-No/ Revision Date of Contents -No:	20.11.2020-0

	Hazırlayan/Prepared by:	5.1.2e		
Ürün Adı/ Name of Product:	COVİD-19 Antijen Hızlı Test/ COVID-19 Antigen Rapid Test			
Ürün Amacı/Intended Use:	CHIL® COVID-19 Antijen Hızlı Testi, insanların nazal, nazofarenks ve orofarenks sürüntülerinden SARS-CoV-2 nükleokapsid protein antijeninin kalitatif tespiti için immünokromatografik bir in-vitro testtir. /This product is used for in vitro diagnostic test for the qualitative detection of the antigen of SARS-CoV-2 (novel coronavirus) in human nasal swab. Instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use.			
Bir paket kaç test içeriyor?/How many tests does a package contain?:	1,25,40	REF	CCOV-201, CCOV-202, CCOV-203, CCOV-206, CCOV-207	

A. KULLANILAN VEYA ÜRETİLEN MAZLEME VE BUNLARIN REAKTİFLİĞİ/THE MATERIAL USED OR PRODUCED AND THEIR REACTIVITY

A.1. Tabaka/Sheet

Tabaka Komponent Kodu/Sheet Component Code:	COM.RUS-PS.14	
Amacı/Purpose	Testin kromatografik immunoserolojik parçasını oluşturur. Esas işi yapan kısmdır./It forms the chromatographic immunoserological part of the test. It is the part that does the main work.	
Malzeme ÖzellikleriMaterial Properties:	Neme duyarlı. Nemden korunacak şekilde depolanır ve işlemlenir./Sensitive to moisture. It is stored and processed in a way that is protected from moisture.	
Tabaka Bileşenleri/Sheet Components	**Dikkate Alınması Gereken Güvenlik Bilgileri/Safety Information to Be Considered**	
	Malzemenin Zarar Gördüğü Durumlar/Cases where the material is damaged	**Çevre ve İnsana Zarar/Environmental and Human Harm**
Bileşen 1: Örnek pedi/Component 1: Sample pad	Nem alması/Humicity	x
Bileşen 2: Konjugat ped/Component 2: Conjugate pad	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	x
Bileşen 3: NC membran/Component 3: NC membrane	Nem alması/Humicity	x
Bileşen 4 : Emici ped/Component 4: Absorbent pad	Nem alması/Humicity	x
Bileşen 5: Altın nano partikül	Işığa maruz kalması, NaCl ile reaksiyona girmesi/Exposure to light, reaction with NaCl	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 6: SARS-CoV-2 antikoru	Oda sıcaklığında bırakılması, kirlilik karışması/Leaving at room temperature and contamination	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 7: Keçi anti-tavuk IgY poliklonal antikoru	Oda sıcaklığında bırakılması, kirlilik karışması/Leaving at room temperature and contamination	Kimyasal ve toksik içerikli madde/Chemical and toxic substance

A.2. Tampon/Buffer

Amacı/Purpose:	Örneğin testte ilerlemesine yardımcı olmak/Helping the specimen to complete the running	
Malzeme Özellikleri/Material Properties:	Çevreye toksik malzeme içerir. Çökelmesi, ışıktan etkilenmesi, etkilendiği fiziksel koşullar bilinmemektedir./Contains environmentally toxic material. Its precipitation, exposure to light, physical conditions affecting it are unknown.	
Komponent Kodu/Component Code:	COM.RBUF06-21/001	
Tampon Bileşenleri/Buffer Component	**Dikkate Alınması Gereken Güvenlik Bilgileri/Safety Information to Be Considered**	
	Malzemenin Zarar Gördüğü Durumlar/Cases where the material is damaged	**Çevre ve İnsana Zarar/Environmental and Human Harm**
Bileşen 1/ Component 1	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 2 / Component 2	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 3 / Component 3	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 4 / Component 4	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 5 / Component 5	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 6 / Component 6	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 7 / Component 7	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 8 / Component 8	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bielşen 9 / Component 9	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance
Bileşen 10 / Component 10	Nem alması, ışığa maruz kalması/Humicity and Exposure to Light	Kimyasal ve toksik içerikli madde/Chemical and toxic substance

A.3. Tampon Şişesi/Buffer Bottle	
Komponent Kodu/Component Code:	COM.RBB.02
Amacı/Purpose:	Tamponu saklamak ve teste damlatmak/Store the buffer and as dropper for the test
Malzeme Özellikleri/Material Properties:	1 ml'lik, Bir damlası ~ 20 µl/1 ml, One drop~ 20 µl
Dikkat edilmesi gerekenler/Things to pay attention:	Damla hacmi 18-20 µl olmalı. Sızdırmamalı./Drop volume should be 18-20 µl. It should not leak.
A.3. Varsa Kaset Kapakları veya Stripi Yüzeyden İzole Eden Materyal/A.3. Cassette Covers, if any, or Material Isolating the Strip from the Surface	
Komponent Kodu/Component Code:	Üst kapak COM.RCAS-T.03, alt kapak COM.RCAS-T.03/Top cover COM.RCAS-T.03, bottom cover COM.RCAS-T.03
Amacı/Purpose:	Stripi dış ortamdan izole ederek kaset tipi hızlı testi oluşturmak. /Creating a cassette type quick test by isolating the strip from the external environment.
Malzeme Özellikleri/Material Properties:	Beyaz Chil Tasarımı (Yarım daire ile bütünleşik diktörtgen şekilli), Pin et kalınlığı 1.57mm Lot:CCOV200.20C3 Daha sonra Pin et kalınlığı %2-3 azaltıldı. 1.52mm./"White Chil Design (rectangular shape integrated with semicircle), Pin wall thickness 1.57mm Lot: CCOV200.20C3 Later, Pin wall thickness was reduced by 2-3%. 1.52mm."
Dikkat edilmesi gerekenler/Things to pay attention:	Stripte numunenin yürümesine izin vermeyin./Allowing the specimen to walk on the strip.
A.4. Varsa Sürüntü Çubuğu/ Swab (if appliciable)	
Komponent Kodu/Component Code:	COM.SW.02
Amacı/Purpose:	Nazal,Nazofarengeal veya orofarengeal yolla örnek almak için kullanılan materyaldir./Materials used for nasal, nasopharyngeal or oropharyngeal sampling.
Malzeme Özellikleri/Material Properties:	Silindirik fırça tipi, toplam boyu 150mm, 21 mm silgici mevcuttur. Steril çubuklardır./Cylindrical brush type, total length 150mm, 21mm eraser available. Swabs are sterile.
Dikkat edilmesi gerekenler/Things to pay attention:	Sürüntü çubukları steril malzemeler oldukları için paketinin açılmamış olmasına dikkat edilmelidir./Since the swabs are sterile materials, care should be taken not to open their packaging.
A.5. Kullanım Kılavuzu / Instructions For Use	
Komponent Kodu/Component Code:	COM.RIFU.236, COM. RIFU.247
Amaç/Purpose:	Kullanıcıya ürün ile alakalı tüm ayrıntıları açık bir şekilde vermek./To give the user all the details about the product clearly.
Dil/Language:	Türkçe,İngilizce,Almanca/Turkish,English,German
İçerik Başlıkları/Content:	Kullanım amacı, Giriş, Prensip, Ürün İçeriği, Temin Edilen Malzemeler, Gereken Fakat Sağlanmayan Malzemeler, Saklama ve Kararlılık, Uyarılar ve Önlemler, Örnek Toplama ve Hazırlama, Test Prosedürü, Sonuçların Yorumlanması, Kalite Kontrol, Kısıtlamalar, Performans Karakteristikleri, Referanslar (Profesyonel Kullanım İçin) Test Prosedürü, Sonuçların Açıklanması, Kullanım Amacı, Temin Edilen Malzemeler, Gereken Fakat Sağlanmayan Malzemeler, Uyarılar ve Önlemler, ,Sıkça Sorulan Sorular (Amatör Kullanım) / Intended Use, Introduction, Principle, Product Content, Materials Provided, Materials Required But Not Provided, Storage and Stability, Warnings and Precautions, Sample Collection and Preparation, Test Procedure, Interpretation of Results, Quality Control, Limitations, Performance Characteristics, References (Professional Use) Test Procedure, Interpretation of Results, Intended Use, Materials Provided, Materials Required But Not Provided, Warnings and Precautions, Frequently Asked Questions (Lay Use)
Tablolar/Tables:	Performans karakteristikleri- Tespit limiti, Çapraz Reaksiyon, Girişim maddeleri./Performance characteristics- Detection limit, Cross-reaction, Interference substances.(Professional Use)
Şekiller/Figures:	Numune toplama gösterimi, Sonuçların Yorumlanması(Profesyonel Kullanım) Test Prosedürü, Sonuçların Yorumlanması (Amatör Kullanım) /Sample collection demonstration, Interpretation of Results (Professional Use) Test Procedure, Interpretation of Results (Amateur Use)
Üretici iletişim bilgileri/ Manufacturer contact information	CHİL TIBBİ MAL. SAN. TİC. LTD. ŞTİ. 10028 Sok. No.11 AOSB 35620 Çiğli-İzmir/Türkiye Tel:+90 232 2901688, Faks: +90 232 2901323 E-posta :info@chil.com.tr www.chil.com.tr
Kullanım amacına ve kullanan kitleye yönelik kit içeriği ve gerekli materyaller/Content of the kit and necessary materials for the intended use and the users:	TEMİN EDİLEN MALZEMELER: 1. Test kaseti 2. Swab 3. Tampon 4. Kullanım kılavuzu GEREKEN FAKAT SAĞLANMAYAN MALZEMELER: 1. Zamanlayıcı 2. Biyolojik tehlikeli malzemeler için atık 3. Kişisel koruyucu ekipman/ MATERIALS PROVIDED: 1. Test cassette 2. Swab 3. Buffer 4. Instructions For Use MATERIALS REQUIRED BUT NOT PROVIDED: 1. Timer 2. Waste for biohazardous materials 3. Personal protective equipment "

Uyarılarda göze çarpan eksiklik var mı?/Are there any noticeable deficiencies in the warnings?	**Yok/None**
Kit içeriğindeki tüm bileşenlerin kullanımı şekli açık ve net anlatılmış mı?/Is the use of all components in the kit clearly explained?	**Evet/Yes**
Düzeltilmesi Gerekeler/Corrective Actions:	x
Kaynakçanın gözden geçirilmesi/Review of the bibliography::	**Kaynakça gözden geçirildi/Bibliography reviewed**
Uyarı sembollerinin gözden geçirilmesi/Review of warning symbols::	**Uyarı sembolleri kontrol edildi/Warning symbols checked**

A.6.Paketleme Materyali/Packaging Material

Komponent Kodu/Component Code:	Komponent Adı/Component Name	Malzeme Özellikleri/Material Properties	Dikkat edilmesi gerekenler/Things to pay attention:
COM.RPO.02	Poşet/Pouch	7x12 cm, boyutlarında CHIL baskılı poşet./7x12 cm, CHIL printed pouch.	x
COM.RBOX.01	Kutu/Box	200x145x80 mm dış, 199 x 144 x 79mm iç, 400gr, Bristol baskılı , selefonlu/ 200x145x80 mm outer, 199 x 144 x 79mm inner, 400gr, Bristol printed, cellophane	x

B. KULLANILAN DONANIM/ USED EQUIPMENT

B.1. Tabaka İçin Kullanılan Donanım / Used Equipment for Sheet

NO	MAKİNE ADI/ MACHINE NAME	KALİBRASYON/CALIBRATION		
		Var/Done	Yok/Undone	GEREKLİ DEĞİL VEYA UYGULANAMAZ/NOT REQUIRED OR IMPLEMENTED
ME55	Dispanser/Dispanser	☐	☑	☐
ME35	Etüv/Oven	☐	☐	☑
ME26	Santrifüj/Centrifuge	☑	☐	☐
ME72,ME71,ME22, ME24	Mikropipet/Micropipette	☑	☐	☐

B.1. Tampon İçin Kullanılan Donanım / Equipment Used for Buffer Preparation

NO	MAKİNE ADI/ MACHINE NAME	KALİBRASYON/CALIBRATION		
		Var/Done	Yok/Undone	GEREKLİ DEĞİL VEYA UYGULANAMAZ/NOT REQUIRED OR IMPLEMENTED
x	Manyetik Karıştırıcı/Magnetic Stirrer	☐	☐	☑
x	Hassas Terazi/Precision Balance	☑	☐	☐
x	Değişik Hacimlerde Balon Joje ve Beher/Volumetric Flask and Beaker in Different Volume	☐	☐	☑
		☐	☐	☐
		☐	☐	☐
		☐	☐	☐

B.2. Tampon Dolum İçin Kullanılan Donanım/ Equipment Used for Buffer Filling

NO	MAKİNE ADI/ MACHINE NAME	KALİBRASYON/CALIBRATION		
		Var/Done	Yok/Undone	GEREKLİ DEĞİL VEYA UYGULANAMAZ/NOT REQUIRED OR IMPLEMENTED
	Peristaltik dolum cihazı/Peristaltic filling device	☑	☐	☐
		☐	☐	☐
		☐	☐	☐

B.3. Paketleme İçin Kullanılan Donanım/Equipment Used for Packaging

NO	MAKİNE ADI/ MACHINE NAME	KALİBRASYON/CALIBRATION		
		Var/Done	Yok/Undone	GEREKLİ DEĞİL VEYA UYGULANAMAZ/NOT REQUIRED OR IMPLEMENTED
	Poşet kapatma makinesi/Pouch sealing machine	☐	☐	☑
		☐	☐	☐
		☐	☐	☐
		☐	☐	☐

C. İŞLETME ORTAMI VE YERLEŞİM / ENVIRONMENT AND LOCATION

Adı/Name	Amacı/Purpose	Yeri/Location	İstenen Koşullar/Desired Condition
Üretim 1 /Production 1	Kaset doldurma kapatma /Cassette filling and closing	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Üretim 2 /Production 2	Paketleme/ Packaging	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Üretim 3 / Production 3	Tabaka kesim, tampon dolum/ Sheet cutting and buffer filling	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions

Üretim 4 / Production 4	Poşet baskısı / Pouch Printing	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Üretim 5 / Production 5	Kaset baskısı, etiket hazırlama ve basım/ Cassette printing, label preparation and printing	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Depo 1 / Warehouse 1	Tabaka Stok alanı/ Sheet Stock Area	Ana Bina/ Main Building	Nem oranı :%20-40 Sıcaklık: 2-30 °C /Humidity: 20-40% Temperature: 2-30°C
Depo 2 / Warehouse 2	Komponent Stok alanı/ Component Stock area	Ana Bina/ Main Building	Nem oranı :%20-40 Sıcaklık: 2-30 °C /Humidity: 20-40% Temperature: 2-30°C
Depo 3 / Warehouse 3	Komponent Stok alanı/ Component Stock area	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Depo 4 / Warehouse 4	Komponent Stok alanı/ Component Stock area	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Depo 5 / Warehouse 5	Komponent Stok alanı/ Component Stock area	Ana Bina/ Main Building	Normal oda koşulları /Normal room conditions
Depo 6 / Warehouse 6	Komponent Stok alanı/ Component Stock area	Prefabrik Ek Bina/Prefabricated Additional Building	Normal oda koşulları /Normal room conditions
Depo 7 / Warehouse 7	Komponent Stok alanı/ Component Stock area	Prefabrik Ek Bina/Prefabricated Additional Building	Normal oda koşulları /Normal room conditions
Depo 8 / Warehouse 8	Komponent Stok alanı/ Component Stock area	Prefabrik Ek Bina/Prefabricated Additional Building	Normal oda koşulları /Normal room conditions
Depo 9 / Warehouse 9	Komponent Stok alanı/ Component Stock area	Prefabrik Ek Bina/Prefabricated Additional Building	Normal oda koşulları /Normal room conditions

D. SİSTEM BİLEŞENLERİ ARASINDAKİ ARA YÜZLER/ INTERFACES BETWEEN SYSTEM COMPONENTS

Komponent Adı/Component Name	İstenen Koşullar/Desired Condition	Taşıma Koşulları/Transport Condition
Tabaka/Sheet	Nem oranı :%20-40 Sıcaklık: 2-30°C /Humidity: 20-40% Temperature: 2-30 °C	İçinde silika bulunan hava ve ışık almayan ağzı kapalı poşet içinde taşınmalıdır. /It should be transported in an air and light proof sealed bag containing silica.
Silika /Silica	Normal oda koşulları /Normal room conditions	Hava almayan kapalı poşetler içine taşınmalıdır. /It should be transported in airtight sealed pouchs
Tampon /Buffer	Sıcaklık: 2-30°C /Temperature 2-30°C	Kapağı kapalı şişelerde taşınmalıdır./It should be transported in sealed bottles.
Kutu /Box	Normal oda koşulları /Normal room conditions	Yırtılma riskine karşın kolide düzgün istiflenmiş şekilde taşınmalıdır./Despite the risk of tearing, it should be transported properly stacked in the box.
Poşet/Pouch	Normal oda koşulları /Normal room conditions	Buruşma ve yırtılma riskine karşın kolide taşınmalıdır./It should be transported in the box against the risk of wrinkling and tearing.

ANNEX IV

CHiL

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

HTEA No: 2
Date: 17.12.2020
Page: 1/1
Revision No: 0

PRODUCT NAME:	Covid-19 Antigen Rapid Test	PRODUCT CODE: CCOV-201, CCOV-202, CCOV-203,CCOV-206, CCOV-207	Process Responsible:	5.1.2e

RESPONSIBLE: 5.1.2e

S: Severity N: Neglible M: Modarete S_0: Significant P: Probability O: Importance T: Fixing

Process function Requirements	Potential failure mode	S	Failure's potential effects	O	Failure's potential causes	P	Present process controls	T	P.O.T	Corrective Actions	Responsible / date planned	Precautions	O	P	T	P.O.T
Production	Defected components	S_0	Danger without any warning	10	Low	2	High	3	60	Not necessery						
Production	Defected Products	S_1	Danger without any warning	10	Very Low	1	High	3	30	Not necessery						
Production	Packeging Damaged	M	Danger without any warning	10	Very Low	1	High	3	30	Not necessery						
Production	Quality Control Missed	N	Danger with warning	10	Low	2	Fairly High	4	80	Not necessery						
Final Control	Trouble in Quality Control	M	Danger with warning	9	Very Low	1	High	3	27	Not necessery						
Storage	Storage .conditions	M	Danger with warning	9	Very Low	1	High	3	27	Not necessery						
Storage	Humidity Effect	M	Danger with warning	9	Very Low	1	High	3	27	Not necessery						

CHIL

DOKÜMAN KODU / DOCUMENT CODE	SOP- 5.1
REVİZYON / REVISION	20.05.2020/3
SAYFA / PAGE	1 / 2
YAYIN TARİHİ / ISSUE DATE	01.03.2012
REFERANS STANDART / REFERENCE STANDARD	ISO 13485:2016 / 98/79/EC / MEDDEV 2.12-2 / MEDDEV 2.12./1 / WHO
REFERANS STANDART MADDE NO / REFERANCE STANDARD ARTICLE NO	8.5.1 / 8.2.1 / 8.2.2

SATIŞ SONRASI GÖZETİM PROSEDÜRÜ
POST MARKET SURVEILLANCE PROCEDURE

	POZİSYON ADI / POSITION	ADI SOYADI / NAME SURNAME	İMZA / SIGNATURE
HAZIRLAYAN / PREPARED BY	KALİTE GÜVENCE SORUMLUSU / QUALITY ASSURANCE RESPONSIBLE	5.1.2e	
KONTROL EDEN / CONTROLED BY	GENEL MÜDÜR YARDIMCISI / VICE GENERAL MANAGER		
ONAYLAYAN / APPROVED BY	GENEL MÜDÜR / GENERAL MANAGER		

REVİZYON NO REVISION NO	TANIM / DEFINITION	TARİH / DATE
0	İLK YAYIN / FIRST PUBLICATION	22.05.2012
1	Madde 6.1.1 Raporun EU, CA, NB..etc. sitelerden data içermesi şeklinde revize edildi. 2015 PCBC denetimine göre revize edildi. / Point 6.1.1 is revised for the report extension with NB, CA, EU..etc. web sites. Revised according to 2015 PCBC audit results.	12.08.2015
2	ISO 13485:2016 standardına göre revize edildi. / Revised according to ISO 13485:2016.	18.05.2016
3	Türkçe ve İngilizce versiyonları bir dökümanda bir araya getirildi ve yeni doküman numaraları verildi. / Turkish and English versions combined in a document and new document no is given	20.01.2020
4	Dünya Sağlık Örgütü'nün yayınladığı *in vitro* tanıları da içeren satış sonrası gözetim ve satış gözetim için rehberine göre güncelleme / Revision according to guidance for post-market surveillance and market surveillance of medical devices, including *in vitro* diagnostics of World Health Organization	15.04.2021
5		

CHiL	PROSEDÜR / PROCEDURE	Doküman Kodu / Document Code:	SOP – 5.1
		Revizyon Tarihi-No / Revision Date-No:	15.04.2021-4
		Sayfa No / Page No:	2 / 6

SATIŞ SONRASI GÖZETİM PROSEDÜRÜ
POST MARKET SURVEILLANCE PROCEDURE

1. AMAÇ / PURPOSE

Bu prosedürün amacı, firmamızın üretimini ve satışını gerçekleştirdiği ürünler konusunda, satış sonrası bilgilerden faydalanarak deneyim kazanma ve bu deneyimi gözden geçirmeye yönelik uygun bir sistem oluşturmaktır. / The objective of this procedure is to gain experience about the products that our firm produce and sell by benefiting from post market information and to constitute an appropriate system for reviewing this experience.

2. KAPSAM / SCOPE

- Tüm hızlı testler / All rapid tests

3. SORUMLULUKLAR / RESPONSIBILITIES

Bu prosedürün uygulanmasından ve koordinasyonundan Yönetim Temsilcisi sorumludur./ The Management Representative is responsible for the application and coordination of this procedure.

4. REFERANSLAR VE TANIMLAR / REFERENCES AND DEFINITIONS

4.1. Tanımlar / Definitions

- **Yetkili Kurum/ Authorized Body:** Ürünlere ilişkin mevzuat hazırlamaya ve yürütmeye yasal olarak yetkili kamu kurum ve kuruluşlarıdır./ Are the state institutions and organizations that are legally authorized to prepare and execute legislations related to the products.

- **Onaylanmış Kuruluş/ Notified Body (NB): :** Test, muayene ve/veya belgelendirme kuruluşları arasından bir veya birden fazla teknik düzenleme çerçevesinde uygunluk değerlendirme faaliyetlerinde bulunmak üzere Yetkili Kurum tarafından seçilen kuruluşlardır./ Are the organizations that are selected by the Authorized Body among the organizations of test, examination and/or certification to attend the suitability evaluation activities within the frame of one or more technical regulations.

- **Yetkili Temsilci/ Authorized Representative :** İmalatçı adına hareket etmek üzere, AB içinde ikamet eden, yetkilendirilmiş kişiye yetkili temsilci denir. Avrupa Birliği'nin Tıbbi cihazlar alanında Türkiye ile gümrük birliği sözleşmesinin yorumlandığı 11 şubat 2020 tarihli belgeye göre Türkiye'deki yerleşik üreticilerin Avrupa Birliği'nde satış yapmak için yetkili temsilci tayin etme zorunluluğun yoktur. / Is a representative that is authorized to act on behalf of the producer and that resides in the EU. According to interpretation of the customs union agreement with Turkey in the field of medical devices in 11 February 2020, there is no obligation to designate an authorised representative on the EU territory to sale in EU.

- **Olumsuz Olay/ Negative Case:** Hatalı üründen dolayı kullanıcının hayatını kaybetmesi, sakat kalması veya sağlığının ciddi boyutta tehdit altında bulunması. Hastanın vücut fonksiyonlarının sürekli bozulması veya vücut yapısında kalıcı bir hasar meydana gelmesi./ Due to the product with problem, that the user dies, becomes disabled, or his/her health is under threat, that the patient's body functions deteriorate or that a permanent damage occurs in his/her body.

- **Yetkili Kurum / Competent Authority:** Bu terim Avrupa Birliği'nde kullanılan terimdir. Amerikada bunun yerine "ulusal düzenleyici otorite (NRA)" terimi kullanılmaktadır. Kendi yetki alanı dahilinde tıbbi ürünlerin satışının yerel yasalarla uyuşmasını sağlamak için yaptırım uygulayarak tıbbi cihazların kullanımını veya satışını kontrol eden devlet kurumu veya başka bir kuruluşu ifade eder. / This term is used mainly in the EU. In Unites States of America " National Regulatory Authority (NRA)" is used. Refers to a government body or other organization that controls the use or sale of medical devices by taking enforcement action to ensure that the sale of medical products within its jurisdiction complies with local law.

4.2. Referanslar / References

- Geri Bildirim Alma Prosedürü / Feedback Procedure (SOP-5.1)
- Ürünün İzlenmesi ve Ölçümü Prosedürü /Monitoring and Measuring of Product Procedure (SOP-5.6)
- Düzeltici ve Önleyici Faaliyetler Prosedürü / Corrective and Preventive Action Procedures (SOP-5.9 / SOP-5.10)
- İhtiyat Sistemi Prosedürü / Vigilance System Procedure (SOP-5.3)
- Uygun Olmayan Ürünün Kontrolü Prosedürü / Procedure Control of Nonconforming Product (SOP-5.7)
- Risk Yönetim Prosedürü / Risk Management Procedure (SOP-4.1)
- ISO 14971:2019 Tıbbi Cihazlar – Tıbbi Cihazlara Risk Yönetiminin Uygulanması / Medical devices- Application of risk management to medical devices.
- ISO 13485'in 8.2.1, 8.2.2 ve 8.5.2 maddeleri / ISO 13485:2016 , articles 8.2.1, 8.2.2 and 8.5.2
- MEDDEV 2.12/2 rev2 (Satış sonrası klinik takip için tıbbi cihazlar rehberi)'de kapsam kısmında "Bu belge *in vitro* tanı cihazlarına uygulanmaz" ibaresi yer almaktadır. / "This document does not apply to *in vitro* diagnostic devices" is written on Scope of MEDDEV 2.12/2 rev2 (Guidelines on medical devices, Post market clinical follow-ıp studies).
- MEDDEV 2.12/1 rev8
- Dünya Sağlık Örgütü'nün *in vitro* tanıları da içeren satış sonrası gözetim ve satış gözetim için rehberi / World Health Organization's Guidance for post market surveillance and market surveillance of medical devices, including *in vitro* diagnostics.

5. KAYITLAR/ RECORDS

- Satış Sonrası Gözetim Planı / Post Market Surveillance Plan (CKS-174)
- Satış Sonrası Gözetim Raporu / Post Market Surveillance Report (CKS-103)
- Üretici Vaka Raporu / Manufacturer's Incident Report (CKS-043)
- Düzeltici Faaliyet Formu / Corrective Action Form (CKS-028)
- Önleyici faaliyet raporu/ Preventive action form (CKS-042)
- Müşteri Memnuniyeti Anketi / Customer Gratification Questionnaire (CKS-085)
- Satış Sonrası Gözetim Anketi/ Post Market Surveillance Survey
- Müşteri Sipariş Takip Formu / Customer Order Follow Form (CKS-144)
- Tıbbi Cihazlar Risk Yönetim Planı/ Medical Devices Risk Management Plan (CKS-091)

- Tıbbi Cihaz Risk Değerlendirme Tablosu / Risk Evaluation Table of Medical Devices (CKS-127)
- E-posta yazışmaları / E-mail correspondance
- Yetkili kuruluşlar listesi / List of Authorized Bodies (CKS-176)

6. UYGULAMA / APPLICATION

6.1. Satış Sonrası Gözetim Planı / Post-Market Surveillance Plan

Satış sonrası gözetim planı (CKS-174) kalite güvence bölümü tarafından yapılır ve ilgili sorumlulara dağıtılır. Bu sorumlular genellikle risk analiz ekibindeki kişilerdir. Planın kapsamında hangi tıbbi cihaz tipi veya ailesi olduğu belirtilir. Yapılacak satış sonrası gözetimin amacı planda belirtilir. Tüm aşamalarda sorumlular belirtilir. Veri toplama yöntemi belirtilir. Toplanan verilerin analiz yöntemi belirlenir. Analiz edilen verilerin risk analizi ve iyileştirme prosesleri gibi hangi proseslerde kullanılacağı belirlenir./ Post market surveillance plan (CKS-174) is prepared by quality assurance department and distributed to related responsibles. These responsibles are generaly from team of risk analysis. The type and family of medical device is indicated as scope of the plan.

6.1.1. Satış sonrası gözetim planının amaçları / Objectives of post market surveillance plan

Satış sonrası gözetim planı aşağıdaki sorulara yanıt toplayacak şekilde oluşturulur/ Post market surveillance plan is created to collect answers to the following questions :

1. Tıbbi cihaz için herhangi bir yeni tehlike veya tehlikeli durum tanımlanmış mı? veya benzeri tıbbi cihazlar veya risk kabul edilebilirliği değişti mi?/ Has any new hazard or hazardous situation been identified for the medical device or similar medical devices or has the risk acceptability changed?
2. Tıbbi cihazın yanlış kullanımı gerçekleşti mi?/ Has any misuse of the medical device occurred?
3. Tıbbi cihazların veya benzeri tıbbi cihazların öngörülemeyen yan etkileri var mı?/ Are there any unforeseen side-effects for the medical device or similar medical devices?
4. Fayda-risk analizini etkileyen bir tıbbi cihaz arızası var mı?/ Is there a medical device malfunction that impacts the benefit-risk analysis?
5. Kullanıcılar herhangi bir kullanılabilirlik sorunu yaşıyor mu?/ Do users experience any usability issues?
6. Servis / bakım eksikliklerinden kaynaklanan tekrarlayan arızalar mı?/ Are recurring malfunctions due to service/maintenance deficiencies?
7. Bu testlerin kullanımı hastanın yaşam kalitesini nasıl etkiler?/ How does using the tests affect the quality of life of the patient?
8. Kullanıcı / hasta eğitimi arıza olasılığını azaltabilir mi? / Can user/patient training reduce the likelihood of malfunction?
9. Tıbbi cihazda yapılabilecek iyileştirmeler var mı?/ Are there any improvements that can be made to the medical device?
10. Tıbbi cihazın tasarımı ve geliştirilmesinden bu yana son teknolojide bir değişiklik oldu mu? / Has state-of-the-art changed since design and development of the medical device?

11. Tıbbi cihazın kullanım amacı için güvenliği ve etkinliği sağlamak için endikasyonlar veya kontrendikasyonlar uygun mu?/ Are indications or contraindications appropriate to ensure safety and effectiveness for the intended use of the medical device?

6.2. Satış Sonrası Gözetim / Post Market Surveillance (PMS)

Firmamız PMS sisteminin etkinliğini değerlendirmek için, kullanım amacı ve ürünün kullanım riskine dayanan dereceli bir yaklaşım uygular. Cihazın risk analiz sonucu da dikkate alınır. PMS gereksinimleri, cihazın kullanım amacına bağlı risk ile doğru orantılıdır./ In order to evaluate the effectiveness of PMS, our firm uses a graded approach based on the intended purpose and the product's risk of the use. The result of the risk analysis of the product is also considered. The necessities of PMS are directly proportional with the risk that is connected with the use of the product

6.2.1. Chil, her yıl satış aktivitelerinin geri bildirim takibini yapmak için PMS raporu hazırlar. Bu rapor satılan ürünler, müşteri profili, pazar durumu, rekabet, uygunsuz ürün, her türlü şikayet..vs gibi bilgiler içerir. Ayrıca rapor, EU, CA, NB veya ilgili diğer web sitelerinden datalar içerebilir. Bunun için ilgili web siteleri gözden geçirilir./ Chil, prepares PMS report every year for the feedback following the sales activities. This PMS report involves sold products, customer profile, market situation, competition, nonconforming product, all type of complaints...etc. Furthermore, the report can involve the data from the EU, CA, NB or other web sites. These web sites are reviewed accordingly.

6.2.2. Firmamızda üretimi gerçekleştirilen bütün ürünler izlenebilirlik amacı ile "lot numaraları" ile Tanımlama ve İzlenebilirlik Prosedürü (SOP-4.6)'ne göre tanımlanır. Müşteride oluşan veya tespit edilen uygunsuzluklar ve şikâyetlerin koordinasyonu ve takibinden, Satış ve Pazarlama Müdürü ve Yönetim Temsilcisi sorumludur. / All products produced in our company are defined with "lot numbers" for traceability purposes according to the Definition and Traceability Procedure (SOP-4.6). The Sales and Marketing Manager and Management Representative are responsible for the coordination and follow-up of the nonconformities and complaints created or detected by the customer.

6.2.3. PMS prosesinin etkin bir şekilde uygulanabilmesi için müşteriye sevk edilen bütün ürünlerin çıkışları **Geribildirim Alma Prosedürü (SOP-5.1)** 'ne göre Müşteri Sipariş Takip Formu (CKS-144) ile takip edilir. Buradan hangi lot ürünlerin kimlere gittiği ve siparişten sevkiyata kadar tüm aşamaları takip edilebilir./ In order for the PMS process to be implemented effectively, the outputs of all products shipped to the customer are followed with the Customer Order Tracking Form (CKS-144) in accordance with the Feedback Procedure (SOP-5.1). From here, you can track which lot products go to whom and all stages from order to shipment.

6.2.4. Aşağıda sıralananlar PMS için kaynak olarak kabul edilebilir/ The following can be accepted as resource for PMS;

- Uzman Kullanıcı Grupları / Expert User Groups
- Satıcılardan Gelen tepkiler / Reactions from the sellers

- Müşteri şikayet, istek ve geri bildirimleri / Customer complaints, wishes and feedbacks
- Firma içi Kontroller / Interoffice controls
- Klinik inceleme ve değerlendirmeler / Clinical observations and evaluations
- Arıza Analizleri / Defect analyses
- Pazar trend ve yenilikleri / Market trends and improvements

6.2.5. Yukarıda belirtilen hususlar hakkında Yönetim Temsilcisi ve Genel Müdür tarafından derhal değerlendirilerek yapılacak çalışmalar **Düzeltici Faliyetler Prosedürü (SOP-5.9)** ve **Önleyici Faaliyetler Prosedürü (SOP-5.10)**'ne göre gerçekleştirilir./ The studies that will be made about the cases mentioned above by immediately evaluating by the Management Representative and General Director are implemented in accordance with the **Corrective Action Procedure (SOP-5.9)** and **Preventive Actions Procedure (SOP-510).**

6.2 İhtiyat Sistemi / Vigilance System

6.2.1 Tespit edilen uygunsuzluklar IVDD (In Vitro Diyagnostik Direktifi) ve ilgili ürün standartları doğrultusunda Yönetim Temsilcisi tarafından değerlendirilir. / The determined inappropriateness is evaluated by the Management Representative in accordance with IVDD (In-Vitro Diagnostic Directive) and with related product standards.

6.2.2 Olumsuz olayların Yetkili Makamlara bildirilmesi, **İhtiyat Sistemi Prosedürü (SOP-5.3)**'e göre Yönetim Temsilcisi tarafından **Vaka** ve **Düzeltici Faaliyet Raporları** hazırlanarak gerçekleşir. Yetkili Makamların iletişim bilgileri **Yetkili Kurumlar Listesi (CKS-176)**'nden temin edilir. Tüm vakalardan ayrıca kuruluşun ilgili belgelendirme kuruluşu bilgilendirilir./ Negative cases are notified to the Authorized Bodies by the Management Representative in accordance with the **Vigilance System Procedure (SOP-5.3)** by preparing **the Event Report** and **Corrective Actions Report.** The contact information of the Competent Authorities is provided from **the List of Authorized Bodies (CKS-176).** Besides, related NB is informed from the all cases.

6.3 Ürün Geri Çağırımı / Product Recall

6.3.1 Tespit edilen uygunsuzluklar doğrultusunda, ürünlerin pazardan geri toplatılması **Uygun Olmayan Ürünün Kontrolü Prosedürü'**ne göre gerçekleştirilir. Bu işlemden Yönetim Temsilcisi sorumludur./ According to the inappropriateness, recall of the products from the market is made in accordance with **the Control of Nonconforming Product Procedure.** The management repsesentative is responsible for this process.

7. EKLER/ ANNEX

CHiL	SATIŞ SONRASI GÖZETİM PLANI / POST MARKET SURVEILLANCE PLAN	Doküman No/ Document No: PMSP-21/01 İçerik Revizyon Tarihi -No/ Conten revision Date-No: 15.04.2021-0 Ürün Ailesi/ Product Family: COVID-19 antigen rapid test cassete Ref Codes: CCOV-201,CCOV-206 Hazırlayan/ Prepared by: 5.1.2e Onaylayan / Approved by: 5.1.2e

Aşamalar /Stages	Sorumlular/ Responsibles	Hedef /Objectives	Planlanan tarih/ Planned date	Gerçekleşen tarih/ Actual date	Veri Toplama Yöntemi/ Method of Data Collection	Veri Analiz Yöntemi/ Method of Data Analysis	Veri analiz edilince alınan aksiyon /Action when data is analysed
Müşterilere gönderilecek PMS anketinin hazırlanması veya gözden geçirilmesi/ Preparation or review of the PMS questionnaire to be sent to customers	Risk Ekibi/ Risk Team	Aşağıdaki hedeflere uygun soruları seçmek/ To chose questions that fit the following objectives.	May.21		Derleme/ Review	Yok/None	Anketin Müşterilere gönderilmesi / Sending the survey to customers
Müşterilerden geribildirim toplanması/ Collecting feedback from customers	Satış sorumlusu / Sale responsible	Eğer varsa yeni tehlikeli durumlar, yanlış kullanım, ön görülemeyen yan etki, fayda risk analizini etkileyen tıbbi cihaz arızası, kullanılabilirlik sorunu, servis-bakım eksikliklerinden kaynaklanan arıza, hastanın yaşam kalitesinin etkilenme şekli, kullanıcı-hasta eğitimi gerekliliği, iyileştirmeler, son teknoloji değişiklikleri, endikasyonlar ve			Anket / Survey	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research.

CHiL	SATIŞ SONRASI GÖZETİM PLANI / POST MARKET SURVEILLANCE PLAN				Doküman No/ Document No: PMSP-21/01 İçerik Revizyon Tarihi -No/ Conten revision Date-No: 15.04.2021-0 Ürün Ailesi/ Product Family: COVID-19 antigen rapid test cassete Ref Codes: CCOV-201 Hazırlayan/ Prepared by: 5.1.2e Onaylayan / Approved by: 5.1.2e		
Müşteriden toplanan yanıtlara göre ileri araştırma sorularının hazırlanması, cevaplarının toplanması ve kök-neden analizi / Preparation of advanced research questions, collection of answers and root-cause analysis based on the answers collected from the customer	Risk Ekibi/ Risk Team	değişiklikleri, endikasyonlar ve kontraendikasyonların saptanması./ To detect hazrdous situations, misuses, unforseen side-effects, medical device malfunction that impacts the benefit-risk analysis, useability issues, recurring malfunctions due to service/maintenance deficiencies, the way the patient's quality of life is affected, user-patient training requirement,state-of-art changes,indications and contraindications, if any.	Haziran 2021 ve Aralık 2021/ June 2021 and December 2021		Anket / Survey	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
İlgili yayınların internette taranması / Searching related publications on internet	Ar&Ge Sorumlusu/ R&D Responsible	Chil marka ürünlerin bilimsel çalışmalarda kullanılıp kullanılmadığının araştırılması. Chil marka ve benzer diğer ürünlerle yapılan çalışmalarda risk analizine katkıda bulunacak bilgiler toplamak. / Investigation of whether Chil branded products are used in scientific studies. To collect information that will contribute to risk analysis in studies conducted with Chil brand and other similar products.	Aralık 2021/ December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması / If necessary, updating the risk analysis and taking corrective and preventive actions

CHiL	SATIŞ SONRASI GÖZETİM PLANI / POST MARKET SURVEILLANCE PLAN				Doküman No/ Document No: PMSP-21/01 İçerik Revizyon Tarihi -No/ Conten revision Date-No: 15.04.2021-0 Ürün Ailesi/ Product Family: COVID-19 antigen rapid test cassete Ref Codes: CCOV-201 Hazırlayan/ Prepared by: 5.1.2e Onaylayan / Approved by: 5.1.2e		
Varsa şikayetlerin gözden geçirilmesi/ Reviewing of complaints, if any	Kalite Güvence Sorumlusu/ Quality Assurance Responsible	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Haziran 2021 ve Aralık 2021/ June 2021 and December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
Düzeltici faaliyetlerin gözden geçirilmesi/ Reviewing of corrective actions	Risk Ekibi/ Risk Team	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Haziran 2021 ve Aralık 2021/ June 2021 and December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
Önleyici faaliyetlerin gözden geçirilmesi/ Reviewing of preventive actions	Risk Ekibi/ Risk Team	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Haziran 2021 ve Aralık 2021/ June 2021 and December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. /If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
Risk analizinin gözden geçirilmesi/ Reviewing of risk analysis	Risk Ekibi/ Risk Team	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Haziran 2021 ve Aralık 2021/ June 2021 and December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. /If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.

CHiL	SATIŞ SONRASI GÖZETİM PLANI / POST MARKET SURVEILLANCE PLAN				Doküman No/ Document No: PMSP-21/01 İçerik Revizyon Tarihi -No/ Conten revision Date-No: 15.04.2021-0 Ürün Ailesi/ Product Family: COVID-19 antigen rapid test cassete Ref Codes: CCOV-201 Hazırlayan/ Prepared by: 5.1.2e Onaylayan / Approved by: 5.1.2e		
Klinik inceleme ve değerlendirmelerin derlenmesi/ Compilation of clinical reviews and evaluations	Regulasyon Sorumlusu/ Regulation Responsible	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Aralık 2021/ December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
Pazar trend ve yeniliklerin derlenmesi / Reviewing of market trends and improvements	Ar&Ge Sorumlusu ve varsa fuara katılanlar/ R&D Responsible and fair attendees, if any	Müşterilerin potansiyel eğilimlerini, hızlı test kasetleri kullanımına devam edip etmeyeceklerini tahmin etmek. / To predict customers' potential trends, whether they will continue to use rapid test cassettes.	Aralık 2021/ December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.
Müşteri profillerinin derlenmesi / Reviewing of customer profiles	Satış Sorumlusu/ Sale Responsible	Risk analizi ve satış sonrası gözetim için veri sağlamak/ Providing data for risk analysis and post-sales surveillance	Aralık 2021/ December 2021		Derleme/ Review	Uygun istatistiksel teknik / Appropriate statistical technique	Gerekiyorsa risk analizinin güncellenmesi, düzeltici ve önleyici faaliyetlerin alınması ve gerekiyorsa ileri araştırmaların yapılması. / If necessary, updating the risk analysis, taking corrective and preventive actions, and carrying out further research if necessary.

CHiL	SATIŞ SONRASI GÖZETİM PLANI / POST MARKET SURVEILLANCE PLAN				Doküman No/ Document No: PMSP-21/01 İçerik Revizyon Tarihi -No/ Conten revision Date-No: 15.04.2021-0 Ürün Ailesi/ Product Family: COVID-19 antigen rapid test cassette Ref Codes: CCOV-201 Hazırlayan/ Prepared by: 5.1.2e Onaylayan / Approved by: 5.1.2e		
Satış sonrası gözetim raporunun yazılması/ Writing of post market surveillance report	Kalite Güvence Sorumlusu/ Quality Assurance Responsible	Satış sonrası gözetim verilerinin derlenmesi / Reviewing of post market surveillance studies.	Ocak 2022/ January 2022		Derleme/ Review	Yok /None	Tüm kayıtlarda olduğu gibi, ilgili kalite güvence sistemi dosyasının güncellenmesi. / Updating the relevant quality assurance system file, as in all records.

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

No	Essential Requirements	Applicable (yes/no)	Standard - Requirement - Guideline / Complies with Standards (yes/no)	Reference to Documentation
A	GENERAL REQUIREMENTS			
1.	The devices must be designed and manufactured in such a way that, when used under the condition and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable constitute acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: *eliminate or reduce risks as far as possible (inherently safe design and construction), *where appropriate take adequate protection measures in relation to risks that cannot be eliminated, *inform users of the residual risks due to any shortcomings of the protection measures adopted.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
3.	The devices must be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (b), as specified by the manufacturer, taking into account of the generally acknowledged state of the art. The must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limit of detection, state by the intended by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.	yes	*CTS (Common Technical Specifications) *TS EN 13612:2009 Performance evaluation of in vitro diagnostic medical devices *TS EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes / (yes)	*CHIL Quality Manual (KEK) *Performance evaluations of the kits *Monitoring and measuring of product procedure (SOP.5.6)

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

No	Essential Requirements	Applicable (yes/no)	Standard - Requirement - Guideline / Complies with Standards (yes/no)	Reference to Documentation
4.	The characteristics and performances referred to in Sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patients or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime of stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents *TS EN ISO 23640:2015 Evaluation of Stability of IVD Reagents / (yes)	*Risk management reports of the kits *Stability evaluation reports of the kits. *Instruction for use of the kits
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport condition (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents *TS EN ISO 23640:2015 Evaluation of Stability of IVD Reagents / (yes)	*Stability evaluation reports of the kits *Risk management reports of the kits *Instruction for use of the kits
B	**DESIGN AND MANUFACTURING REQUIREMENTS**			
1.	**Chemical, and physical properties**			
1.1.	The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in Section A on the "General requirements". Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues, cells and body fluids and micro-organisms), intended to be used with the device, taking account of its intended purpose.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13612:2009 Performance evaluation of in vitro diagnostic medical devices *TS EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes *CTS (Common Technical Specifications) / (yes)	*Risk management reports of the kits *Performance evaluations of the kits *Monitoring and measuring of product procedure (SOP.5.6)
1.2.	The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents *TS EN ISO 23640:2015 Evaluation of Stability of IVD Reagents / (yes)	*Risk management reports of the kits *Packaging and labeling of the kits

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

No	Essential Requirements	Applicable (yes/no)	Standard - Requirement - Guideline / Complies with Standards (yes/no)	Reference to Documentation
2.	**Infection and microbial contamination**			
2.1.	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy hand ling and, when necessary, reduce as far as possible contamination of and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
2.2.	Where a device incorporates biological, the risk of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents *TS EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes / (yes)	*Risk management reports of the kits *Monitoring and measuring of product procedure (SOP.5.6)
2.3.	Devices labeled either as,STERILE, or as having a special microbiological state must be designed, manufactured and packed in appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.	no		
2.4.	Devices labeled either as "STERILE" or as having a special microbiological state must have been processed by an appropriate, validated method.	no		
2.5.	Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
2.6.	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	no		

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

No	Essential Requirements	Applicable (yes/no)	Standard - Requirement - Guideline / Complies with Standards (yes/no)	Reference to Documentation
2.7.	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
3.	**Manufacturing and environmental properties**			
3.1.	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/ or the instructions for use.	no		
3.2.	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits
3.3.	Devices must be designed and manufactured in such a way as to remove or reduce as far as possible: The risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features),risks linked to reasonably foreseeable external influences, such as magnetic fields, external electric effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device. Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices *TS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents / (yes)	*Risk management reports of the kits

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

3.4.	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	no		
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
3.5.	Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	yes	*TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	*Risk management reports of the kits *Instruction for use of the kits
3.6.	The measuring, monitoring or display scale (including color change and other visual indication) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	yes	*TS EN 13612:2009 Performance evaluation of in vitro diagnostic medical devices *TS EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes *TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices / (yes)	*Performance evaluations of the kits *Risk management reports of the kits
4.	**Devices which are instruments or apparatus with a measuring function**			
4.1.	Devices which are instruments or apparatus having a primary analytical measuring function be designed and manufactured in such a way as to provide an adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.	no		
4.2.	When values are expressed numerically, they must be given in legal units conforming to the provision of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of	no		
5.	**Protection against radiation**			
5.1.	Devices shall be designed; manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimized.	no		
5.2.	When device are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted, fitted with visual displays and/or audible warning of such emissions.	no		

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Essential Requirements of COVID-19 ANTIGEN RAPID TEST

5.3.	The operating instruction for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	no		
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
6.	**Requirements for medical devices connected to or equipped with an energy source**			
6.1.	Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent	no		
6.2.	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.	no		
6.3.	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.	no		
6.4.	*Protection against mechanical and thermal risks*			
6.4.1.	Devices must be designed and manufactured in such a way as to protect the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated. Any guards or other means included with the device tj provide protection, in particular against moving parts, must be secure and must not interfere with assess for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	no		

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Essential Requirements of COVID-19 ANTIGEN RAPID TEST

6.4.2.	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	no		
6.4.3.	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	no		
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
6.4.4.	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimize all possible risks.	no		
6.4.5.	Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	no		
7.	**Requirements for devices for self-testing** Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and influence resulting from variation that can reasonably be anticipated in users technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.			
7.1.	Devices for self-testing must be designed and manufactured in such a way as to: -ensure that the device is easy to use the intended lay user at all stages of the procedure, and -reduce as far as practicable the risk of user error in the handing of the device and in the interpretation of the results.	yes	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices, TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices , TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Risk Analysis, Instructions for Use, Packaging and labeling of the kits , Usability Study Report, Operation Video
7.2.	Devices for self-testing must, where reasonable possible, include user control, i.e. a procedure by which the user can verify that, at the time of the use, the product will perform as intended.	yes	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices, TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Instructions for Use, Packaging and labeling of the kits , Usability Study Report

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

8.	**Information supplied by the manufacturer**			
8.1.	Each device must be accompanied by the information needed to use it safely and property, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely and property must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labeling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used property and safely without them.	yes	*TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements *TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements	*Instruction for use of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
8.2.	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and color used must be described in the documentation supplied with the device.	yes	*TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits
8.3.	In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbol and labeling requirements of Directive 67/548/EEC() shall apply. Where there is insufficient space to put all the information on the devise itself or on its label, the relevant danger symbol shall be put on the label and the other information required by those Directives shall be given in the instruction for use. The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	no		
8.4.	*The label must bear the following particulars which may take the form of symbols as appropriate:*			

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

a)	The name or trade name and address of the manufacturer. For devices imported into the Community with a view of their distribution in the Community, the label, the outer packaging, or instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements/ (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
b)	The details strictly necessary for the user to identify the device and the contents of the packaging;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
c)	Where appropriate, the word "STERILE" or a statement indicating any special microbiological state of cleanliness;	no		
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
d)	The batch code, preceded by the word "LOT", or the serial number;	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
e)	If necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
f)	In case of devices for performance evaluation, the word "for performance evaluation only"	no		

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Essential Requirements of COVID-19 ANTIGEN RAPID TEST

g)	Where appropriate, a statement indication the in vitro use of the device;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
h)	Any particular storage and/or handling condition;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
i)	Where applicable, any particular operating instruction;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
j)	Appropriate warnings and/or precautions to take;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
k)	If the device is intended for self-testing, that fact must be clearly stated.	no		
8.5.	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instruction for use and, if appropriate, on the label.	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits

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Essential Requirements of COVID-19 ANTIGEN RAPID TEST

8.6.	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
8.7.	*Where appropriate, the instructions for use must contain the following particulars:*			
a)	The details referred to in Section 8.4 with the exception of point (d) and (e);	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
b)	Composition of the reagent product by nature and amount or concentration of the active ingredient(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
c)	The storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

d)	The performance referred to in Section 3 of part A;	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
e)	An indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
f)	The type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
g)	A detailed description of the procedure to be followed in using the device;	yes	TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
h)	The measurement procedure to be followed the device including as appropriate; * the principle of the method,		TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices - Symbols to	*Instruction for use of the kits *Packaging and

	*the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitation of the method and information about the use of available reference measurement procedures and materials by the user, *the details of any further procedure or handling needed before the device can be used (for example, reconstruction, incubation, dilution, instrument checks, etc.), *the indication whether any particular training is required;	yes	be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	labeling of the kits
i)	The mathematical approach upon which the calculation of the analytical result is made;	no		
j)	Measure to be taken in the event of changes in the analytical performance of the device;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
k)	Information appropriate to users on: *internal quality control including specific validation procedures, *the traceability of the calibration of the device;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits

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Essential Requirements of COVID-19 ANTIGEN RAPID TEST

l)	The reference intervals for the quantities being determined, including a description of the appropriate reference population;	yes	*TS EN 13612:2009 Performance evaluation of in vitro diagnostic medical devices	*Performance evaluations of the kits *Instruction for use of the kits
m)	If the device must be used combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;	no		
n)	All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operates properly and safely, information about safe waste disposal;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
o)	Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
No	**Essential Requirements**	**Applicable (yes/no)**	**Standard - Requirement - Guideline / Complies with Standards (yes/no)**	**Reference to Documentation**
p)	The necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

q)	If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination; and any restriction on the number of reuses;	no		
r)	Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc	no		
s)	Precaution to be taken against any special, unusual risks related to the use or disposal of the device including special protective measure; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits
t)	Specifications for device self-testing: *the results need to be expressed and presented in a way that is readily under stood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result,	yes	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices, TS EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	Risk Analysis Packaging and labeling of the kits, Instructions for use
	*specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device,	yes	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices, TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Packaging and labeling of the kits, Instructions
	*the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner,	yes	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices, TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Packaging and labeling of the kits, Instructions for use
	*the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;	no		

Essential Requirements of COVID-19 ANTIGEN RAPID TEST

No	Essential Requirements	Applicable (yes/no)	Standard - Requirement - Guideline / Complies with Standards (yes/no)	Reference to Documentation
u)	Date of issue or latest revision of the instructions for use.	yes	*TS EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements *TS EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements / (yes)	*Instruction for use of the kits *Packaging and labeling of the kits

Summary

The applicable Essential Requirements according to Annex I of the EC-Directive 98/79/EC are fulfilled.

5.03.2021

5.1.2e

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THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 118837

Date of Issue : 19 January 2021

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "CHİL TIBBİ MALZEME SAN. VE TİC. LTD. ŞTİ." (*Aosb Mh. 10028 Sk. No:11 ÇİĞLİ İZMİR*), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Turkey.

This certificate is issued to be given to the relevant competent authorities of other countries and is valid for 36 months from the date of issue.

The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele.

Yours sincerely,

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

Date of Issue : 19 January 2021

PRODUCT SCHEDULE

#	Barcode	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8680610133743	CHİL	COVID-19 IgG/IgM RAPID TEST	CCOV-205	64756
2	8680610133798	CHİL	COVID-19 IgG/IgM RAPID TEST	CCOV-204	64756
3	8680610133682	CHİL	COVID-19 IgG/IgM RAPID TEST	CCOV-200	64756
4	8680610133767	CHİL	COVID-19 ANTIGEN RAPID TEST	CCOV-201	64787

End of product schedule.

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

1373692

Date : 02 JUL 2018
Ref.No : 50151223 – 742
Dept. :
Subject :

AEGEAN REGION
CHAMBER OF INDUSTRY

COPY OF REGISTRATION FILE

Name of the company	CHİL TIBBİ MALZEME SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Address	AOSB MAHALLESİ 10028 SOKAK NO:11 ÇİĞLİ-İZMİR
Trade registration no	159143
Date of member ship our chamber	27.04.2017
Chamber registration no	23741
Registered capital	50.000,00
Degree	3.Degree
Business Activity	C32.50.10 Medical, surgical or laboratory sterilization instrument production

The authority that will receive this copy To whom it may concern

We hereby certify that the company whose name address and registration number appear above is our chamber's active member

This document is issiued upon member's request

[redacted]
5.1.2e

EC UYGUNLUK BEYANI

EC DECLARATION OF CONFORMITY

General In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

98/79/EC Direktifi uyarınca Genel *In vitro* Tıbbi Tanı Cihazları

Doküman Numarası / Document Number: DoC-EC/20-002

Üretici/ Manufacturer : Chil Tıbbi Mal. San. Tic. Ltd. Şti.

Adres/ Address : 10028 Sok. No:11 AOSB 35620 Çiğli/İzmir-Turkey

Ürün adı/ Product name : COVID-19 Antijen Hızlı Test / COVID-19 Antigen Rapid Test

Marka/ Brand : CHIL®

Sınıf/ Classification : Profesyonel kullanım IVD/ Professional usage IVD
Kişisel Test Kullanımı IVD / Self Test IVD

Rota/ Route : Profesyonel Kullanım IVD Ek III/ Professional Usage IVD Annex III
Kişisel Test Kullanımı IVD Ek III.6 / Self Test IVD Annex III.6

We, here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Burada, yukarıda belirtilen ürünlerin vücut dışı kullanılan (*In-Vitro*) Tıbbi Tanı Cihazları için 98/79/EC konsey direktifinin hükümlerini karşıladığını beyan ederiz. Tüm destekleyici belgeler üreticinin bünyesinde saklanır.

Uygulanan Standartlar ve Düzenlemeler /Applied Standards & Regulations : List is available in QAS / Liste KGS'de mevcuttur.

Start of CE Marking Date / CE Başlangıç Tarihi : 09.10.2020

İmza/Signature: İsim/Name: Senay ÇİL

Görevi/Position : MANAGEMENT RESPONSIBLE/ YÖNETİM TEMSİLCİSİ

CE

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EC UYGUNLUK BEYANI

EC DECLARATION OF CONFORMITY

General In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

98/79/EC Direktifi uyarınca Genel *In vitro* Tıbbi Tanı Cihazları

Doküman Numarası / Document Number: DoC-EC/20-002

Üretici/ Manufacturer : Chil Tıbbi Mal. San. Tic. Ltd. Şti.

Adres/ Address : 10028 Sok. No:11 AOSB 35620 Çiğli/İzmir-Turkey

Ürün adı/ Product name : COVID-19 Antijen Hızlı Test / COVID-19 Antigen Rapid Test

Marka/ Brand : CHIL®

Sınıf/ Classification : Profesyonel kullanım IVD/ Professional usage IVD

Rota/ Route : Ek III/ Annex III

We, here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Burada, yukarıda belirtilen ürünlerin vücut dışı kullanılan (*In-Vitro*) Tıbbi Tanı Cihazları için 98/79/EC konsey direktifinin hükümlerini karşıladığını beyan ederiz. Tüm destekleyici belgeler üreticinin bünyesinde saklanır.

Uygulanan Standartlar ve Düzenlemeler /Applied Standards & Regulations : List is available in QAS / Liste KGS'de mevcuttur.

Start of CE Marking Date / CE Başlangıç Tarihi : 09.10.2020

Revizyon Tarihi – No/ Revision Date – No: 09.10.2020-0

İmza/Signature: **İsim/Name:** Senay ÇİL

Görevi/Position : MANAGEMENT RESPONSIBLE/ YÖNETİM TEMSİLCİSİ

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98/79/EC European In Vitro Medical Devices Directive Annex I.7 Requirements

7. Requirements for devices for self-testing

Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.

7.1. Devices for self-testing must be designed and manufactured in such a way as to:

— ensure that the device is easy to use by the intended lay user at all stages of the procedure, and

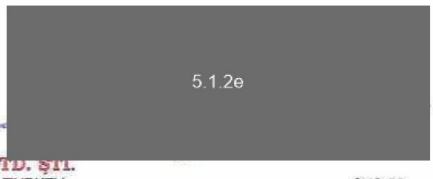
— reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.

7.2. Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.

Prove For 7.1;

As can be seen in the documents we have sent, the instructions for use have been specially prepared for amateur users. Step by step the whole test procedure is explained in plain language using visual support materials. Possible questions for the user were added to the user manual, making it easier for the user to fully understand the test and interpret the results. (Refer to instructions for use) Quick reference instructions and important warnings have also been added on the box labeling (Refer to box design). The validity of these measures was verified by conducting a usability study. (Refer to usability study). Foreseeable misuse parameters(Refer to Risk Analysis Annex II) were evaluated in risk analysis and necessary measures were placed on the product. It was seen in the usability study that user errors were prevented thanks to these measures.

The video given in the Operation Video QR code section on the box is given to users to see the application of the test and to make it easier for them to apply it to themselves.



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Prove For 7.2;

When using the test, the interpretation of the results on the box and in the instructions for use is given in detail so that the user can check that the product is working as intended. In this way, the user is provided with full support on how to interpret the result and what to do after the result is obtained. (Refer to Intended Use Section).

Intended Use in Instructions For Use Paragraph 2

Persons who test positive with the CHIL COVID-19 Antigen Rapid Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Hilda ÇİL KAYA
General Manager

09.04.2021

Manufacturer: Chil Tıbbi Mal. San ve Tic. Ltd. Şti.

Address : 10028 Sok. No:11 AOSB 35620 Çiğli/İzmir-Turkey

Product Name: CHIL COVID-19 Antigen Rapid Test (Home Test- Nasal Swab-Cassette)

File number of the special approval of the BfArM: 5640-S-078/21

We, herewith declare that the above mentioned product CHIL COVID-19 Antigen Rapid Test(Home Test-Nasal Swab-Cassette) is analytically same as our product CHIL COVID-19 Antigen Rapid Test(Nasopharyngeal/Oropharyngeal Swab-Cassette).

CHIL COVID-19 Antigen Rapid Test(Nasopharyngeal/Oropharyngeal Swab-Cassette) is listed in the BfArM list with the AT337/20 AT number; and its performance is evaluated by Paul-Ehrlich-Institut (PEI) with the product name **COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette**).

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