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Xiamen Boson Biotech Co., Ltd.

Technical documentation

Rapid SARS-CoV-2 Antigen Test Card

Version: 1.0
March 11, 2021

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1 General Application Information

This application is submitted on behalf of Xiamen Boson Biotech Co., Ltd., and is intended as an exemption for placing the Rapid SARS-CoV-2 Antigen Test Card on the Dutch market as a self-test. Current regulatory approvals and processes are listed below:

1. The Rapid SARS-CoV-2 Antigen Test Card manufactured by Xiamen Boson Biotech Co., Ltd. has received the CE mark for professional use as an antigen rapid test (See Section 7.2 and 7.3 for the CE certificate and Declaration of Conformity).
2. We have already started the conformity assessment procedure to obtain a CE certificate for the use of this antigen rapid test as a self-test via TÜV SÜD. See Section 7.7 for the confirmation email for the CE submission).
3. The professional test is included in the most recent version of the op 17 February 2021 adopted list of the Health Security Committee "A common list of COVID-19 rapid antigen tests". See Section 7.5 for the screenshot of the document with the listed product, and check the following website for the official document:

   https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf
4. The home test is special approved by BfArM in Germany as a test for personal use by laypeople. See Section 7.6 for the screen shot from the official website of BfArM and check the following website for the original contents:

   https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html

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2 PRODUCT DESCRIPTION

2.1 General Description

Product / Device name:	Rapid SARS-CoV-2 Antigen Test Card
Catalog Number:	1N40C5-2 (1 Test/Box) 1N40C5-4 (5 Tests/Box)
Mode of Action	RDT (Rapid diagnostic test)

2.2 Intended Use & Operation

2.2.1 Diagnostic Principle

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatographic lateral flow device that employs the principle of double antibody sandwich method. Colloidal gold conjugated anti-SARS-CoV-2 antibodies are dry-immobilized on the test device. When the specimen is added, it migrates by capillary diffusion through the strip to re-hydrate the gold conjugate complexes. If present at or above the limit of detection, SARS-CoV-2 viral antigens will react with the gold conjugate complexes to form particles, which will continue to migrate along the strip until the Test Zone (T) where they are captured by the immobilized anti-SARS-CoV-2 antibodies to form a visible red line. If there are no SARS-CoV-2 viral antigens in the specimen, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until being captured by immobilized antibody in the Control Zone (C) to form a red line, which indicates the validity of the test.

2.2.2 Intended Use

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. Rapid SARS-CoV-2 Antigen Test Card cannot be used as the basis to diagnose or exclude SARS-CoV-2 infection.

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3 PHOTOGRAPHS OF COMPONENTS

3.1 Comprehensive Description of the Product

The Rapid SARS-CoV-2 Antigen Test Card is a cassette device for detecting the presence or absence of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. The plastic housing of device is designed to affix the test strip inside the device. There is no functional design that may affect the test strip's performance in the test card.

Each test strip contains an absorbent pad, coated membrane, gold conjugate pad, and sample pad with adhesive sticker. The test strip is used to assemble the test card device.

Components	For 1 Test/Box	For 5 Tests/Box
Rapid SARS-CoV-2 Antigen Test Card (sealed foil pouch)	1	5
Sterilized swab	1	5
Extraction tube	1	5
Sample extraction buffer	1	5
Instructions for use	1	1
Tube stand	1 (In Box)	1

For 1 Test/Box: All components of the test kit are the same to the original professional use kit.

For 5 Tests/Box: All components of the test kit are the same to the original professional use kit, except for the different sample extraction buffer specifications. For the professional use kit, the sample extraction buffer is 1 bottle for 2mL. For the self-test kit, the sample extraction buffer is 5 single packs.

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3.2 Photographs of Components

Picture of all components for 1 test/kit

Picture of all components for 5 tests/kit

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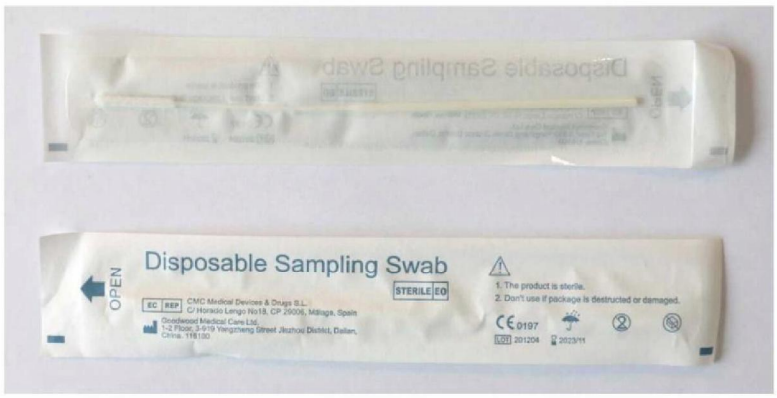
Picture of swab



Picture of sample extraction buffer

Picture of extraction tube

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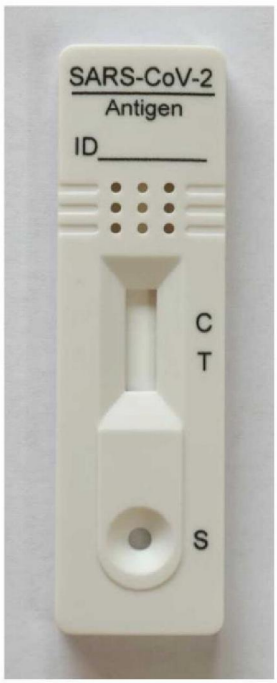
Picture of test card



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4 VALIDATION STUDIES

4.1 Analytical Performance Studies of the Test in Professional Use

No.	Study	Reference
1	Analytical Sensitivity	See Appendix 3-1 - Analytical Sensitivity Studies See Appendix 3-2 - Analytical Sensitivity Studies- Nasal Sample Validation Report
2	Analytical Specificity-Cross Reactivity	See Appendix 4 – Analytical Specificity – Cross Reactivity Studies
3	Analytical Specificity-Interference	See Appendix 5 – Analytical Specificity – Interference Studies
4	Precision Studies	See Appendix 6 – Precision Studies
5	High Dose Hook Effect	See Appendix 7 – Hook Effect Studies

4.2 Stability Studies

No.	Study	Reference
1	Storage Stability	See Appendix 8 – Storage Stability Studies
2	Freeze-Thaw Stability	See Appendix 9 – Freeze-Thaw Stability Studies
3	Transport Stability	See Appendix 10 – Transport Stability Studies
4	Heat Stability	See Appendix 11 – Heat Stability Studies
5	Open-Pack Stability	See Appendix 12 – Open Pack Studies

4.3 Clinical Evidence

See Appendix 13 – Clinical Evaluation Report.

4.4 Analytical Performance Studies of the Test in Self-Use

Because the components for the professional and self-use tests are identical, the analytical performance studies of the test in self-use are the same as for the professional test.

4.5 User-Friendliness Study for Self-Test

See Appendix 14 – Private-Use Usability Study.

The private use usability study was completed in Austria. Considering that the majority of

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population in both the Netherlands and Austria are of the Caucasian origin, it is safe to extrapolate the test results in the report to the Dutch situation.

In the future, we also plan to carry out more layperson studies and validate the self-tests in the Netherlands. We will submit follow-up reports once they are available.

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5 LABELS & INSTRUCTIONS FOR USE

The requirements of Annex I, B, 8 ff in Directive 98/79/EC are fulfilled, as shown on the following pages. An easy-to-understand and easy-to-read instruction leaflet for safe and correct use is included with each kit.

5.1 Labels

5.1.1 For 1 Test/Box

Foil Pouch Label:

Side 1:

Side 2:

Box Label:

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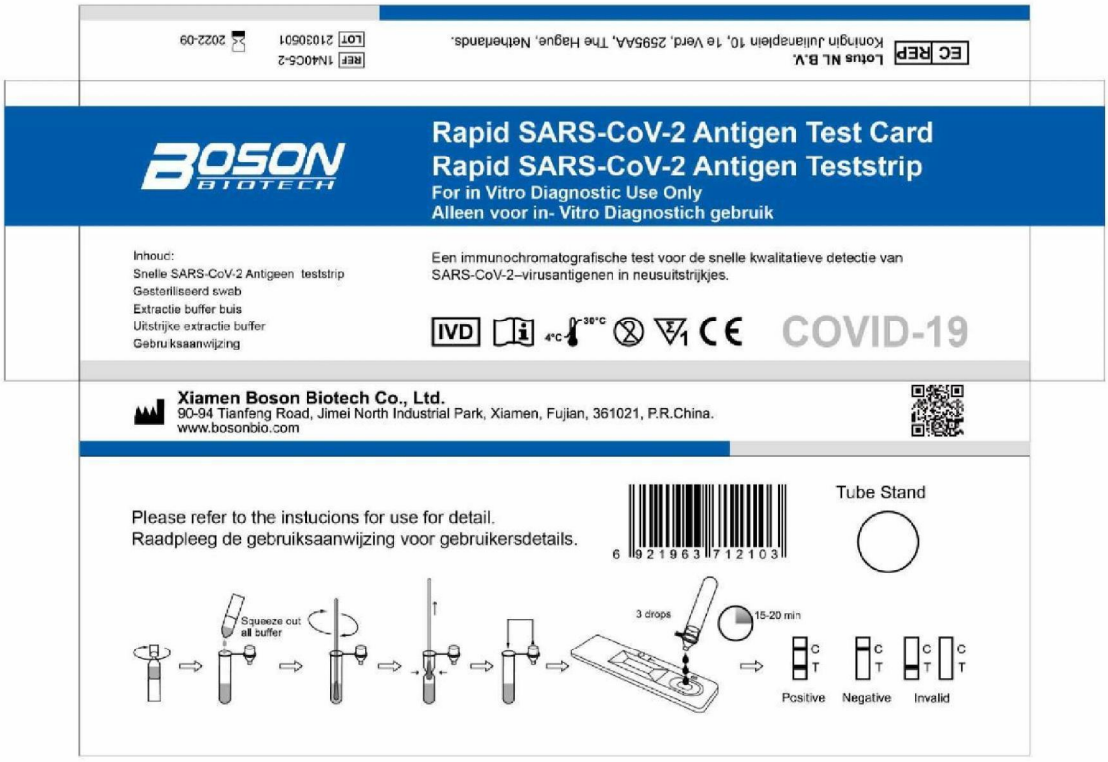

5.1.2 For 5 Tests/Box

Foil Pouch Label:

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Side 1:

Side 2:

Box Label:

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5.2 Instructions for Use (IFU)

5.2.1 Instructions for Use in English

RAPID SARS-COV-2 ANTIGEN TEST CARD

INSTRUCTION GUIDE FOR ANTERIOR NASAL SWAB SPECIMENS

For private use/home use/self-testing

REF	1N40C5-2	For 1 Test/Box
REF	1N40C5-4	For 5 Tests/Box

Please follow the instruction leaflet carefully.

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. Rapid SARS-CoV-2 Antigen Test Card shall not be used as sole basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

MATERIALS PROVIDED

Components	For 1 Test/Box	For 5 Tests/Box
Rapid SARS-CoV-2 Antigen Test Card (sealed foil pouch)	1	5
Sterilized swab	1	5
Extraction tube	1	5
Sample extraction buffer	1	5
Instructions for use (this leaflet)	1	1
Tube stand	1 (In box)	1

IMPORTANT INFORMATION BEFORE THE EXECUTION

1. Read this instruction guide carefully.
2. Do not use the product beyond the expiration date.
3. Do not use the product if the pouch is damaged or the seal is broken.
4. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
5. The product should be used at room temperature (15°C to 30°C). If the product has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using.
6. Handle all specimens as potentially infectious.
7. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
8. Use the swabs included in the test kit to ensure optimal performance of the test.
9. Correct specimen collection is the most important step in the procedure. Make sure to collect enough specimen material (nasal secretion) with the swab, especially for anterior nasal sampling.
10. Blow the nose several times before collecting specimen.
11. The specimens should be tested as soon as possible after collection.
12. Apply the drops of test specimen only to the specimen well (S).
13. Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
14. Children under 14 years of age should be assisted by an adult.

LIMITATIONS

1. The test is to be used exclusively for the qualitative detection of SARS-CoV-2 viral antigen in anterior nasal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined as part of this test.
2. Proper specimen collection is critical. Failure to follow the procedure may result in inaccurate test results. Improper collection, storage,

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or even freezing and thawing of the specimen can lead to inaccurate test results.
3. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be made by the physician after evaluation of all clinical and laboratory results.
5. A negative result does not exclude viral infection except for SARS-CoV-2 and should be confirmed by molecular diagnostic methods if COVID-19 is suspected.
6. A positive result does not exclude coinfection with other pathogens.
7. The SARS-CoV-2 rapid antigen test can detect both viable and non-viable SARS-CoV-2 material. The performance of the SARS-CoV-2 rapid test is dependent on viral load and may not correlate with other diagnostic methods performed on the same specimen.
8. Users should test specimens as soon as possible after specimen collection and within two hours of specimen collection.
9. Sensitivity for nasal or oroparyngeal swabs may be lower than nasopharyngeal swabs. It is recommended to use the nasopharyngeal swab specimens by healthcare professionals.
10. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
11. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.
12. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
13. The validity of Rapid SARS-CoV-2 Antigen Test Card has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.

PREPARATION

- Clear, clean and dry a flat surface.
- Check the test kit contents. Make sure that nothing is damaged or broken.
- Timer at hand.
- Blow your nose several times before collecting specimen.
- Wash hands.

DISPOSAL

The test kit may be disposed of with normal household waste in accordance with the applicable local regulations.

PROCEDURE

This test is suitable for people of all ages. The recommended operators are aging from 14 to 90. Children under 14 years of age should be tested by an adult. Do not continue the test if the child feels any pain.

1

Rotate the lid of sample extraction buffer bottle.

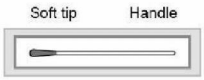
Caution: Open it away from your face and be careful not to spill any of the liquid.

2

Squeeze all extraction buffer out of the bottle into the extraction tube.

Caution: Avoid touching the bottle against the tube.

3



Find the swab in the sealed wrapper in front of you. Identify the soft, fabric tip of the swab.

4

Peel open the swab packaging and gently take out the swab.

Caution: Never touch the soft, fabric tip of the swab with your hands.

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5

Carefully insert swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab 3-4 times along the mucosa inside the nostril. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril. Withdraw swab from the nasal cavity.

Caution: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

6

Place swab into extraction tube. Roll swab three to five (3-5) times. **Leave swab in extraction buffer for 1 minute.**

7

Pinch extraction tube with fingers and remove the solution from swab as much as possible.

8

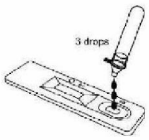
Install the nozzle cap onto the sample extraction tube tightly.

9

Bring the kit components to room temperature before testing. Open the pouch and remove the card. Place the card on a flat and level surface.

Caution: Once opened, the test card must be used immediately.

10



Invert the extraction tube and add 3 drops of test specimen into the specimen well (S) by gently squeezing the extraction tube.

Caution: The formation of air bubbles in the specimen well (S) must be avoided.

11

Read the results at 15-20 minutes.

Caution: Results after 20 minutes may not be accurate.
Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

INTERPRETATION OF RESULTS

Positive

Positive:

If two colored bands appear with one colored band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive.

Caution: No matter how faint the colored band is in the Test Zone (T), the result

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should be considered as positive.

Negative

Negative:

If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative.

Invalid

Invalid:

If no color line appears in the control area (C) within 15-20 minutes, the test is invalid. Repeat the test with a new test card.

QUALITY CONTROL

The control line is an integrated reagent and is used to control the procedure. The control line appears when the test has been performed correctly and the reagents are reactive.

FREQUENTLY ASKED QUESTIONS (FAQ)

1. **How does the detection work?**
   The N protein of the SARS-CoV-2 virus reacts with the stripe-like coating of the test line and, if present, results in a color change, i.e. a red line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no red test line (T).

2. **When should/can I test myself?**
   You can test yourself whether you have symptoms or not. Studies show that earlier testing within the first 4 days of illness typically means a higher viral load, which is easier to detect. Since the test result is a snapshot valid for that point in time, testing should be repeated as recommended by local authorities.

3. **What can affect my test result? What should I pay attention to?**
   Be sure to blow your nose multiple times before collecting the specimen.
   Be sure to visibly collect sample material (nasal secretions).
   Perform the test immediately after taking the sample.
   Follow the instructions for use carefully.
   Apply the drops of extraction solution only to the sample well (S)
   Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.

4. **The test strip is clearly discolored or smudged? What is the reason for this?**
   Please note that the test card should not be used with more than 3 drops of sample, as the liquid absorption of the test strip is naturally limited. If the control line does not appear or the test strip is badly smudged or discolored, making it unreadable, please repeat the test according to the instructions.

5. **I have taken the test, but I don't see a control line (C). What should I do?**
   Your test result is invalid. Observe the answer to question 4 and repeat the test according to the instructions for use.

6. **I am unsure about reading the result. What should I do?**
   For the result to be positive, 2 straight horizontal lines must be clearly visible with the full width of the cassette. If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.

7. **My result is positive. What should I do?**
   If your result is positive and the test kit thus clearly indicates the control line as well as the test line, please contact your local GGD (municipal health service) for further instructions. Your test result may be double-checked and the GGD will explain the appropriate next steps.

8. **My result is negative. What should I do?**
   If the test kit only clearly shows the control line, this may mean that you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician, or the nearest health care facility as recommended by your local authorities.
   If the test results are consistently negative for 5 days after symptom onset, you can stop self-quarantining.
   If you are still unsure about the test results, make an appointment via **www.government.nl/coronavirus-test**, call **0800 1202**, or contact your local GGD for further instructions.

9. **How can I dispose of the product?**
   The test kit may be disposed of with normal household waste in accordance with the applicable local regulations.

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EXPLANATION FOR SYMBOLS

IVD	*In Vitro Diagnostics Use*		See Instructions for Use		Expiry Date
Σ	Tests per Kit		Keep dry	LOT	Batch Number
EC REP	Authorized Representative		Keep away from sunlight		Manufacturer
	Do not reuse		Do not use if package is damaged	4℃ 30℃	Store between 4- 30 °C
CE	CE Mark	REF	Catalogue Number		Warning, please refer to the instruction

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Authorized Representative: Lotus NL B.V.
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Version 1.0 Date: March 6th, 2021

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5.2.2 Instructions for Use in Dutch

RAPID SARS-COV-2 ANTIGEEN TESTSTRIP
HANDLEIDING VOOR VOORSTE NEUSSWAB UITSTRIJKJES

Voor privégebruik / thuisgebruik / zelftesten

REF	1N40C5-2	Voor 1 test/doos
REF	1N40C5-4	Voor 5 tests/doos

Volg de bijsluiter zorgvuldig op.

BEOOGD GEBRUIK

Rapid SARS-CoV-2 Antigeen Teststrip is een immunochromatografie gebaseerde éénstaps in-vitro test. Het is ontworpen voor de snelle kwalitatieve bepaling van SARS-CoV-2 virusantigeen in voorste neusswabs van personen die verdacht worden van COVID-19 binnen de eerste zeven dagen na het begin van het symptoom. De snelle SARS-CoV-2-antigeenteststrip mag niet als enige basis worden gebruikt om SARS-CoV-2-infectie te diagnosticeren of uit te sluiten.

SAMENVATTING

De nieuwe coronavirussen behoren tot het β geslacht. COVID-19 is een acute infectieziekte bij de luchtwegen. Mensen zijn over het algemeen vatbaar. Momenteel zijn de mensen die besmet zijn met het nieuwe coronavirus de belangrijkste bron van infectie, asymptomatische geïnfecteerde mensen kunnen ook een infectieuze bron zijn. Op basis van het huidige epidemiologische onderzoek is de incubatietijd 1 tot 14 dagen, meestal 3 tot 7 dagen. De belangrijkste manifestaties zijn koorts, vermoeidheid en droge hoest. Neusverstopping, loopneus, keelpijn, spierpijn en diarree worden in een paar gevallen gevonden.

GELEVERDE MATERIALEN

Onderdelen	Voor 1 test/doos	Voor 5 tests/doos
Rapid SARS-CoV-2 Antigeen Test Strip (verzegelde folie zak)	1	5
Gesteriliseerd swab	1	5
Monsterextractiebuis	1	5
Monsterextractiebufferfles	1	5
Gebruiksaanwijzing (deze bijsluiter)	1	1
Buisstandaard	1(Het doosje zelf)	1

BELANGRIJKE INFORMATIE VOOR DE UITVOERING

1. Lees deze gebruiksaanwijzing zorgvuldig door.
2. Gebruik het product niet langer dan de vervaldatum.
3. Gebruik het product niet als het zakje beschadigd is of als de afsluiting is verbroken.
4. Bewaar het testapparaat bij 4 tot 30°C in het originele afgesloten zakje. Niet bevriezen.
5. Het product moet worden gebruikt bij kamertemperatuur (15°C tot 30°C). Als het product in een koele ruimte (minder dan 15°C) is bewaard, laat het dan 30 minuten op normale kamertemperatuur staan voordat u het gebruikt.
6. Behandel alle uitstrijkjes als potentieel besmettelijk.
7. Ontoereikende of ongeschikte monsterverzameling, opslag en transport kunnen onnauwkeurige testresultaten opleveren.
8. Gebruik de swabs in de testkit om optimale prestaties van de test te garanderen.
9. Correcte monsterverzameling is de belangrijkste stap in de procedure. Zorg ervoor dat u voldoende monstermateriaal (neusafscheiding) verzamelt met de swab, vooral voor de voorste neus-uitstrijkje.
10. Snuit de neus meerdere keren voordat u de afscheiding verzamelt.
11. De afscheiding moeten zo spoedig mogelijk na het verzamelen worden getest.
12. Breng de druppels testmonster alleen aan op in de put van de strip (S).
13. Te veel of te weinig druppels extractieoplossing kunnen leiden tot een ongeldig of onjuist testresultaat.
14. Kinderen jonger dan 14 jaar moeten worden bijgestaan door een volwassene.

BEPERKINGEN

1. De test mag uitsluitend worden gebruikt voor de kwalitatieve detectie van SARS-CoV-2 viraal antigeen in voorste neusswabmonsters. De exacte concentratie van SARS-CoV-2 viraal antigeen kan niet worden bepaald als onderdeel van deze test.
2. Een goede monsterverzameling is van cruciaal belang. Het niet volgen van de procedure kan leiden tot onnauwkeurige testresultaten. Onjuiste verzameling, opslag of zelfs bevriezing en ontdooiing van het monster kan leiden tot onnauwkeurige testresultaten.
3. Als de virale belasting van het monster onder de detectiegrens van de test ligt, kan de test een negatief resultaat opleveren.
4. Zoals bij alle diagnostische tests, moet een definitieve klinische diagnose niet gebaseerd zijn op het resultaat van een enkele test, maar moet deze door de arts worden gesteld na evaluatie van alle klinische en laboratoriumresultaten.

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5. Een negatief resultaat sluit virale infectie niet uit, behalve SARS-CoV-2 en moet worden bevestigd door moleculaire diagnostische methoden als COVID-19 wordt vermoed.
6. Een positief resultaat sluit co-infectie met andere pathogenen niet uit.
7. De SARS-CoV-2 snelle antigeentest kan zowel levensvatbaar als niet-levensvatbaar SARS-CoV-2 materiaal detecteren. De prestaties van de SARS-CoV-2 snelle test zijn afhankelijk van de virale belasting en mogen niet correleren met andere diagnostische methoden die op hetzelfde monster worden uitgevoerd.
8. De gebruikers moeten de monsters zo spoedig mogelijk na het verzamelen van monsters en binnen twee uur na het verzamelen van monsters testen.
9. Gevoeligheid voor neus- of oroparyngeale swabs kan lager zijn dan nasopharyngeale swabs. Het wordt aanbevolen om de nasopharyngeal swab monsters te gebruiken door zorgverleners.
10. Monoklonale antilichamen kunnen sars-cov-2-virussen die kleine aminozuurveranderingen in het doel-epitoopgebied hebben ondergaan, niet detecteren of met minder gevoeligheid detecteren.
11. De hoeveelheid antigeen in een monster kan afnemen naarmate de ziekteduur toeneemt. Monsters verzameld na dag 5-7 van ziekte hebben meer kans om negatief te worden getest in vergelijking met een RTPCR-test.
12. De kit werd gevalideerd met de diverse swabs. Het gebruik van alternatieve swabs kan leiden tot valse negatieve resultaten.
13. De geldigheid van Rapid SARS-CoV-2 Antigeen Teststrip is niet bewezen voor dentificatie/bevestiging van weefselkweekisolaten en mag in deze hoedanigheid niet worden gebruikt.

VOORBEREIDING

- Maak een vlak oppervlak schoon, reinig en droog het.
- Controleer de inhoud van de testkit. Zorg ervoor dat er niets beschadigd of gebroken is.
- Timer bij de hand.
- Snuit uw neus meerdere keren voordat u een monster verzamelt.
- Handen wassen.

AFVALVERWERKING

De testkit mag met het normale huisvuil worden weggegooid in overeenstemming met de geldende plaatselijke voorschriften

PROCEDURE

Deze test is geschikt voor mensen van alle leeftijden. De aanbevolen leeftijd is van 14 tot 90 jaar. Kinderen jonger dan 14 jaar moeten worden getest door een volwassene. Ga niet door met de test als het kind pijn voelt.

1

Draai het deksel van de monsterextractiebufferfles.

Letop: Open het uit de buurt van uw gezicht en zorg ervoor dat u de vloeistof niet morst.

2

Knijp alle extractiebuffer uit de fles in deextractiebuis.

Let op: Breng de fles niet in contact met de extractiebuis.

3

Bekijk de swab in de verzegelde wikkel.

Let op: de zachte, stoffen punt van het swab. U moet de kant openen waar de stoffen punt zich niet bevindt.

4

Maak de verpakking van swab open en haal het swab voorzichtig eruit.

Let op: Raak de zachte, stoffen punt van het wattenstaafje nooit met uw handen aan.

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5

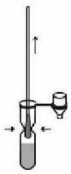
Steek voorzichtig de swab in één neusgat. De punt van het wattenstaafje moet op niet minder dan 2,5 cm (1 inch) van de rand van het neusgat worden geplaatst. Rol de swab 3-4 keer langs het slijmvlies in het neusgat. Laat de swab enkele seconden in het neusgat staan. Herhaal dit proces met dezelfde swab voor het andere neusgat. Trek de swab uit de neusholte.

Let op: Dit kan ongemakkelijk aanvoelen. Steek de swab niet dieper in als u een sterke weerstand of pijn voelt.

6

Plaats de swab in de extractie buis. Draai de swab drie tot vijf (3-5) keer. **Laat de swab 1 minuut in de extractiebuffervloeistof staan.**

7



Knijp de extractiebuis met de vingers en pers de oplossing zoveel mogelijk uit de swab.

8

Plaats de dop van het mondstuk stevig op de monsterextractiebuis.

9

Zorg dat de kitcomponenten op kamertemperatuur is. Open het zakje en en neem de teststrip uit. Plaats de teststrip op een vlakke en schone ondergrond.

Let op: Eenmaal geopend, moet de teststrip onmiddellijk worden gebruikt.

10

Keer de extractiebuis om en voeg 3 druppels toe (ongeveer 75 µL) van het testmonster in de put (S) van de teststrip, door voorzichtig in de extractiebuis te knijpen.

Let op: De vorming van luchtbellen in de monsterput (S) moet worden vermeden.

11

Lees de resultaten binnen 15 - 20 minuten af.

Let op: De resultaten na 20 minuten zijn mogelijk niet nauwkeurig.

Het gebruikte apparaat mag met het normale huisvuil worden weggegooid in overeenstemming met de geldende plaatselijke voorschriften.

INTERPRETATIE VAN DE RESULTATEN

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Positive

Positief:

Als er binnen 15-20 minuten twee gekleurde lijnen verschijnen met één gekleurde lijn in de controlezone (C) en één andere in de testzone (T), is het testresultaat positief.

Let op: Hoe zwak de gekleurde lijn ook is in de testzone (T), het resultaat moet als positief worden beschouwd.

Negative

Negatief:

Als één gekleurde lijn binnen 15-20 minuten in de controlezone (C) verschijnt en er binnen 15-20 minuten geen gekleurde lijn in de testzone (T) verschijnt, is het testresultaat negatief.

Invalid

Ongeldig:

Als er binnen 15-20 minuten geen kleurlijn in het besturingsgebied (C) wordt weergegeven, is de test ongeldig. Herhaal de test met een nieuwe teststrip.

KWALITEITSCONTROLE

De besturingslijn is een geïntegreerd reagens en wordt gebruikt om de procedure te regelen. De besturingslijn verschijnt wanneer de test correct is uitgevoerd en de reagentia reactief zijn.

VEELGESTELDE VRAGEN (FAQ)

1. **Hoe werkt de detectie?**
   Het N-eiwit van het SARS-CoV-2-virus reageert met de streepachtigecoating van de testlijn en resulteert, indien aanwezig, in een kleurverandering, d.w.z. er verschijnt een rode lijn. Daarom, als het monster geen virale eiwitten of antigenen bevat, zal er geen rode testlijn (T) zijn.

2. **Wanneer moet/kan ik mezelf testen?**
   U kunt zelf testen of u symptomen heeft of niet. Studies tonen aan dat eerdere tests binnen de eerste 4 dagen van ziekte meestal een hogere virale belasting betekenen, wat gemakkelijker te detecteren is. Aangezien het testresultaat een momentopname is die op dat moment geldig is, moet de test worden herhaald zoals aanbevolen door de lokale autoriteiten.

3. **Wat kan mijn testresultaat beïnvloeden? Waar moet ik op letten?**
   Zorg ervoor dat u uw neus meerdere keren snuit voordat u het monster verzamelt.

   Zorg ervoor dat u zichtbaar monstermateriaal (neusafscheidingen) verzamelt.

   Voer de test onmiddellijk na het nemen van het monster uit.

   Volg de gebruiksaanwijzing zorgvuldig op.

   Breng de druppels extractieoplossing alleen aan op de monsterput (S)

   Te veel of te weinig druppels extractieoplossing kunnen leiden tot een ongeldig of onjuist testresultaat.

4. **De teststrip is duidelijk verkleurd of besmeurd? Wat is de reden hiervoor?**
   Houd er rekening mee dat de teststrip niet met meer dan 3 druppels monster mag worden gebruikt, omdat de vloeistofabsorptie van de teststrip van nature beperkt is. Als de controlelijn niet verschijnt of de teststrip slecht besmeurd of verkleurd is, waardoor deze onleesbaar is, herhaalt u de test volgens de instructies.

5. **Ik heb de test gedaan, maar ik zie geen controlelijn (C). Wat moet ik doen?**
   Uw testresultaat is ongeldig. Neem het antwoord op vraag 4 in acht en herhaal de test volgens de gebruiksaanwijzing.

6. **Ik ben niet zeker over het lezen van het resultaat. Wat moet ik doen?**
   Om het resultaat positief te laten zijn, moeten 2 rechte horizontale lijnen duidelijk zichtbaar zijn met de volledige breedte van de cassette. Als u nog steeds niet zeker bent over de resultaten, neem dan contact op met de dichtstbijzijnde gezondheidsinstelling volgens de aanbevelingen van uw lokale autoriteiten.

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7. **Mijn uitslag is positief. Wat moet ik doen?**
   Als uw uitslag positief is, en de testkit het zowel aangeeft via de controlelijn als de testlijn, neem dan contact op met uw lokale GGD(gemeentelijke gezondheidsdienst) voor verdere instructies. Uw test uitslag zal opnieuw gecontroleerd worden en de GGD raadt u verdere benodigde instructies aan.

8. **Mijn uitslag is negatief. Wat moet ik doen?**
   Als de test kit duidelijk één controlelijn laat zien, kan dit betekenen dat u negatief bent of dat de virale hoeveelheid te laag is om te worden gedetecteerd. Als u symptomen ervaart (hoofdpijn, koorts, migraine, verlies van reuk- of smaakzin,enz) neem dan contact op met uw huisarts, of de dichtstbijzijnde zorginstelling, zoals aanbevolen door uw lokale autoriteiten.

   Als de testuitslagen consistent negatief zijn gedurende 5 dagen na het begin van de symptomen, dan kunt u stoppen met thuisquarantaine.

   Als u nog steeds onzeker bent over uw testresultaten, maak dan een afspraak via www.coronatest.nl, bel 0800-1202, of neem contact op met uw locale GGD voor verdere advies.

9. **Hoe kan ik dit product in afval verwerken?**
   De testkit mag met het normale huisvuil worden weggegooid in overeenstemming met de geldende plaatselijke voorschriften.

VERKLARING VOOR SYMBOLEN

IVD	*In Vitro Gebruik* van diagnostiek		Zie Gebruiksaanwijzing		Vervaldatum
Σ	Tests per Kit		Droog houden	LOT	Batchnummer
EC REP	Gemachtigde verlegenwoordiger		Blijf uit de buurt van zonlicht		Fabrikant
	Niet opnieuw gebruiken		Niet gebruiken als de verpakking beschadigd is	30°C 4°C	Bewaren tussen 4-30°C
CE	CE-markering	REF	Catalogusnummer		Waarschuwing, raadpleeg de instructie

Fabrikant:

Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian, 361021, P.R.China.

Gemachtigde vertegenwoordiger:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, Den Haag, Nederland.

Versie 1.0

Datum: 6 maart 2021

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6 SPECIFICATION OF MATERIALS

6.1 Compositions of the Test Kit

Component	Amount	Specification	Function	Supplier
Conjugate Pad	0.2 μg/test unit	Au-Mouse anti-SARS-CoV-2 antibodies Conjugate	Conjugating antibody	Hangzhou Clongene Biotech Co., Ltd.
Test membrane, test line	0.6 μg/test unit	Mouse anti-SARS-CoV-2 antibodies	Coating antibody	Hangzhou Clongene Biotech Co., Ltd.
Test membrane, control line	0.6 μg/test unit	Goat anti mouse IgG antibody	Quality control	Boson
Nitrocellulose Membrane	1.83 cm × 0.4 cm	Nitrocellulose	Coating control line and test line	Shenzhen Bai Sui Kang Industrial Co., Ltd.
Glass Fiber Paper	1.7 cm × 0.4 cm	Glass Fiber	Sample addition	Hangzhou Huarun Paper Co., Ltd.
Absorbent Paper	2.27 cm × 0.4 cm	Wood Fiber	Keeping capillary attraction	Hangzhou Special Paper Industry Co., Ltd. (Newstar)
Swab	1 pc or 5 pcs	Flocking and PP	Collecting nasal samples	Goodwood Medical Care Ltd.
Sample Extraction Buffer	0.27 mL/Bottle, 1 bottle or 5 bottles	$Na_2HPO_4 \cdot 12H_2O$, $NaH_2PO_4 \cdot 2H_2O$, NaCl, TERGITOL 15-S-9 and Proclin300	Lysis virus	Boson

All the specifications, functions and suppliers of the components for the self-test are the same as for the professional use test.

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7 CERTIFICATIONS

7.1 ISO13485 Certificate

Xiamen Boson Biotech Co., Ltd. is certified to EN ISO 13485:2016 by notified body TÜV SÜD. Certificate No. Q5 061317 0005 Rev. 00.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 061317 0005 Rev. 00

Holder of Certificate: **Xiamen Boson Biotech Co., Ltd.**
90-94 Tianfeng Road
Jimei North Industrial Park
361021 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park, 361021
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic kits for detection of Infection Diseases, Tumour Markers, Drug Abuse, Hormones, Cardiac Markers and Related Biomaterial**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1807513

Valid from: 2018-10-31
Valid until: 2021-10-30

5.1.2e

Date, 2018-09-27

A4 / 07.17

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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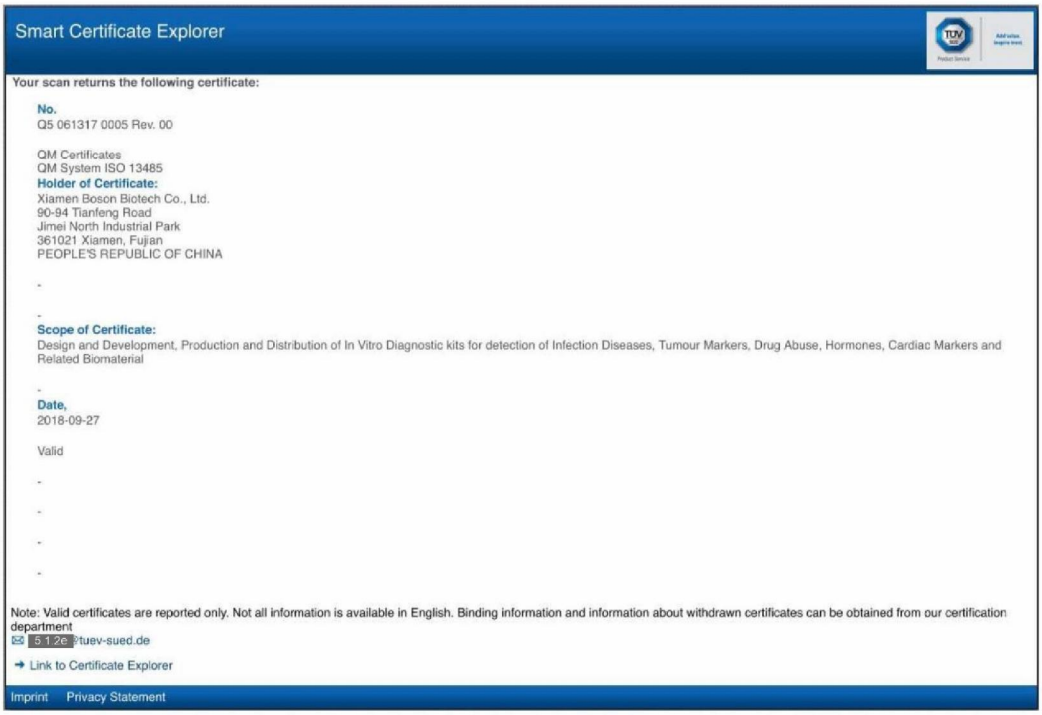

Smart Certificate Explorer

Your scan returns the following certificate:

No.
Q5 061317 0005 Rev. 00

QM Certificates
QM System ISO 13485
Holder of Certificate:
Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road
Jimei North Industrial Park
361021 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

-

-
Scope of Certificate:
Design and Development, Production and Distribution of In Vitro Diagnostic kits for detection of Infection Diseases, Tumour Markers, Drug Abuse, Hormones, Cardiac Markers and Related Biomaterial

-
Date,
2018-09-27

Valid

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-

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Note: Valid certificates are reported only. Not all information is available in English. Binding information and information about withdrawn certificates can be obtained from our certification department
5.1.2e @tuev-sued.de

→ Link to Certificate Explorer

Imprint Privacy Statement

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7.2 CE Certificate of Professional Use Test

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de 5.1.2e
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec
Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
5.1.2e
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203899

Bijlagen
-

Uw aanvraag
9 augustus 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 13 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Geachte 5.1.2e

Op 9 augustus 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Xiamen Boson Biotech Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

D-Dimer Test, H.Pylori Antigen Test, H.Pylori Antibody Test, Rotavirus Antigen Test, V.Cholerae O1/O139 Duo Test, Salmonella typhi Antigen Test, Salmonella typhi IgG/IgM Combo Test, Rickettsia IgG/IgM Combo Test, Tuberculosis Test,Cardiac Panel Test
(geen merknaam) (NL-CA002-2020-52870)
Rapid SARS-CoV-2 Antigen Test Card, Syphilis Antibody Test, Malaria Antigen Test, Dengue IgG/IgM Combo Test, Dengue NS1 Antigen and IgG/IgM Duo Panel Test, C-reactive Protein Test,HCG Pregnancy Test, LH Test,Troponin I Test,Myoglobin Test,CK-MB Test
(geen merknaam) (NL-CA002-2020-52869)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Pagina 1 van 2

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Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Xiamen Boson Biotech Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

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7.3 Declaration of Conformity of Professional Test

BOSON

Declaration of Conformity

Manufacturer Xiamen Boson Biotech CO,. Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park,
Xiamen, Fujian 361021, P. R. China.

European Representative Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Device/s Rapid SARS-CoV-2 Antigen Test Card

Classification Others

Confirmative Assessment Route 98/79/EC IVDD Annex III

We, Xiamen Boson Biotech Co., Ltd. declare that the above mentiond devices conforms to the relevant provisions of the EC Council Directive 98/79 and is in accordance with the Annex III, ISO 13485:2016 Quality Management System, as implemented by the European Union's Medical Devices Regulations and the Federal and Local Authorities.

Place, Date of Issue Xiamen, 2020-08-04

Signature 5.1.2e

(Signed By Boson Representative)

Name: 5.1.2e
Title: 5.1.2e

CE

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7.4 CE Certificate of Other Components (N/A)

Not applicable. The components of the self-test is the same as for the professional test.

7.5 EU Authorization

The professional test is included in the most recent version of the op 17 February 2021 adopted list of the Health Security Committee "A common list of COVID-19 rapid antigen tests". Below is the screenshot taken from page 4 of the original document. Refer to the following link for the full official document:

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

information in this platform and ensuring that the common list as agreed by Member States will be publicly available online.

The common list of rapid antigen tests will be regularly reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. Future updates to the list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

Future updates to the common list of rapid antigen tests will be published as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Methods.

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Deteciton os SARS-CoV-2
- Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTd, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc., STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

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7.6 BfArM Authorization for Self-Test

The home test is special approved by BfArM in Germany as a test for personal use by laypeople. Below is the screen shot from the official website of BfArM. Refer to the following link for the original contents:

https://www.bfarm.de/DE/Medizinprodukte/Antigentests/_node.html

Antigen-Tests auf SARS-CoV-2

STARTSEITE → MEDIZINPRODUKTE → ANTIGEN-TESTS AUF SARS-COV-2

Tests zur Eigenanwendung durch Laien

Das BfArM hat die ersten Sonderzulassungen nach §11 Absatz 1 Medizinproduktegesetz (MPG) von Antigen-Tests zur Eigenanwendung durch Laien (Selbsttests) zum Nachweis von SARS-CoV-2 erteilt. Weitere Informationen zur rechtlichen Grundlage und den dabei geprüften Anforderungen finden Sie weiter unten auf dieser Seite unter dem Menüpunkt „Hinweise zur Sonderzulassung von Antigen-Tests durch das BfArM".

Es handelt sich um folgende Tests, die Liste wird kontinuierlich aktualisiert:

Aktenzeichen der Sonderzulassung des BfArM	Hersteller	Antragsteller	Testname	BfArM-AT-Nummer*
5640-S-004/21	Healgen Scientific LLC	Siemens Healthcare Diagnostics Products GmbH	CLINITEST Rapid COVID-19 Self-Test	AT001/20
5640-S-007/21	Xiamen Boson Biotech Co., Ltd	Technomed Service GmbH	Rapid SARS-CoV-2 Antigen Test Card	AT116/20
5640-S-009/21	Hangzhou Laihe Biotech Ltd., Co.	Lissner Qi GmbH	LYHER® Covid-19 Antigen Schnelltest (Nasal)	AT011/20

7.7 Confirmation of CE Certificate Application for Use as Self-Test

See below for a confirmation email sent by TÜV SÜD on confirmation of CE certificate application for use as self-test.

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acceptance of the application for COVID-19 self testing

Weng, Chenchuan <5.1.2e @tuvsud.com>

发送时间: 2021/3/10 (周三) 15:27

收件人: 沈浩龙

Dear Mr. Haolong Shen,

Greeting from TUV SUD, notified body of IVDD 98/79/EC.

This is to confirm that the manufacturer

Xiamen Boson Biotech Co., Ltd., 90-94 Tianfeng Road, Jimei North Industrial Park, 361021 Xiamen, Fujian, People's Republic of China

have initiated the application process for a SARS-CoV-2 Rapid Antigen Test intended for self-testing acc. to IVDD (98/79/EC), Annex III.6. TÜV SÜD has already given the first feedback to Xiamen Boson.

Please note: the acceptance of the application does not guarantee a successful certification of the product.

Kind regards,

5.1.2e

5.1.2e In Vitro Diagnostic Medical Device

PS:MHS
Phone: +86 5.1.2e
Fax: +86 5.1.2e
Email address: 5.1.2e @tuvsud.com
http://www.tuv-sud.cn

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8 ESSENTIAL REQUIREMENTS CHECKLIST

Device: Rapid SARS-CoV-2 Antigen Test Card

Applicable REF:

1N40C5 Rapid SARS-CoV-2 Antigen Test Card

Manufacturer: Xiamen Boson Biotech Co., Ltd. **Date: 2021.02.06**

A. GENERAL REQUIREMENTS

No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
1.	The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of patients, or the safety and 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 when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	Yes	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.	Product Dossier Section 4.1, Analytical Performance Studies of the Test in Professional Use. Product Dossier Section 4.3, Clinical Evidence. Section 4.4, Analytical Performance Studies of the Test in Self-Use. Product Dossier Section 9, RISK MANAGEMENT	Design and Development Control Procedures BS-QA-008 DM-00-001 Clinical Trial Management Protocol BS-QA-007 Risk Management Control Procedures
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)	Yes	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.	Product Dossier Section 9, RISK MANAGEMENT. Product Dossier Section 5.2, Instructions for Use (IFU). Precautions and Limitations section.	BS-QA-007 Risk Management Control Procedures

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	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated. - inform users of the residual risks due to shortcomings of the protection measures adopted.				
3.	The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated 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	ISO 13485:2016: Medical devices - Quality management systems. EN ISO 13612:2002: Performance evaluation of in vitro diagnostic medical devices. EN ISO14971:2012: Medical devices - Application of risk management to medical devices.	Product Dossier Section 4.1, Analytical Performance Studies of the Test in Professional Use. Product Dossier Section 4.3, Clinical Evidence. Section 4.4, Analytical Performance Studies of the Test in Self-Use. Product Dossier Section 9, RISK MANAGEMENT.	BS-QA-008 Design and Development Control Procedures DM-00-001 Clinical Trial Management Protocol BS-QA-007 Risk Management Control Procedures
4.	The characteristics and performance 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 is 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	EN ISO 13640:2002: Stability testing of in vitro diagnostic medical devices.	Product Dossier Section 4.2, Stability Studies.	Stability Inspection Management Protocol QM-00-032
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 during transport and storage (temperature, humidity, etc.) taking into account the instructions and information provided by the manufacturer.	Yes	ISO 13485:2016 EN ISO 13640:2002: Stability testing of in vitro diagnostic medical devices.	Product Dossier Section 4.2, Stability Studies.	Stability Inspection Management Protocol QM-00-032

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B. DESIGN AND MANUFACTURING REQUIREMENTS

No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
1. 1.1	**Chemical and physical properties** 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 and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	Yes	ISO 13485:2016 EN ISO 13612:2002: Performance evaluation of in vitro diagnostic medical devices.	Product Dossier Section 6, SPECIFICATION OF MATERIALS.	BS-QA-008 Design and Development Control Procedures
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 product.	Yes	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.	Product Dossier Section 9, RISK MANAGEMENT.	BS-QA-007 Risk Management Control Procedures
2. 2.1	**Infection and microbial contamination** 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 handling and, where 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	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.	Product Dossier Section 5.2, Instructions for Use (IFU). Clinical sample volume and application defined in Procedure section, specimen handling and proper disposal defined in Important Information before the Execution section.	BS-QA-008 Design and Development Control Procedures BS-QA-007 Risk Management Control Procedures

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
2.2	Where a device incorporates biological substances, the risks 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.	N/A			
2.3	Devices labelled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an 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.	N/A			
2.4	Devices labelled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.	N/A			
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 sterilised 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	ISO 13485:2016	Each test device is packaged in a moisture barrier pouch with 0.5g desiccant. Raw material must meet material specification requirements before release. Production environment for each process specified in the manufacturing process flow chart. Except for box packaging, all production processes are carried in Level 100,000 clean area.	Production Environment Control Procedures BS-QA-010 SARS-CoV-2 Antigen Process Protocol PS-11-038 Inspection documents and standards for various raw materials QO-

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
2.6	Devices intended to be sterilized, must be manufactured in appropriately controlled (e.g. environmental) conditions.	N/A			
2.7	Packaging systems for non-sterile devices must keep the product without deterioration in 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	ISO 13485:2016 EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.	Production environment for each process specified in the manufacturing process flow chart. Except for box packaging, all production processes are carried in Level 100,000 clean area.	Production Environment Control Procedures BS-QA-010
3 3.1	**Manufacturing and environmental properties** 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 the use must be indicated on the label or in the instructions for use.	N/A			
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.	N/A			
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 electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device.	 N/A Yes	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.	Humidity and temperature reference Product Dossier Section 5.2, Instructions for Use (IFU).	Stability Management Protocol QM-00-032

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	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.	N/A	EN ISO 13640: 2002: Stability testing of in vitro diagnostic medical devices.		
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.	Yes	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.	Product Dossier Section 9, RISK MANAGEMENT.	BS-QA-007 Risk Management Control Procedures
3.5	Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	Yes	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.	Product Dossier Section 5.2, Instructions for Use (IFU). Important Information before the Execution section.	BS-QA-008 Design and Development Control Procedures
3.6	The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	Yes	EN ISO 13612:2002: Performance evaluation of in vitro diagnostic medical devices.	Device is intended for visual qualitative interpretation.	BS-QA-008 Design and Development Control Procedures BS-QA-007 Risk Management Control Procedures
4 4.1	**Devices which are instruments or apparatus with measuring function** Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide 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.	N/A			

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
4.2	When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.	N/A			
5 5.1	**Protection against radiation** Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.	N/A			
5.2	When devices 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 warnings of such emissions.	N/A			
5.3	The operating instructions 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.	N/A			
6 6.1	**Requirements for medical devices connected to or equipped with an energy source** 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.	N/A			
6.2	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.	N/A			

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
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.	N/A			
6.4 6.4.1	**Protection against mechanical and thermal risks** 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 to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	N/A			
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.	N/A			
6.4.3	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from	N/A			

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	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.				
6.4.4	Terminals and connectors to 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 minimise all possible risks.	N/A			
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.	N/A			
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.	N/A			
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.	N/A			
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.	N/A			

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
8 8.1	**Information supplied by the manufacturer** Each device must be accompanied by the information needed to use it safely and properly, 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 properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling 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 must 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 properly and safely without them.	Yes Yes Yes N/A	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. EN ISO 18113-4:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 4: In vitro diagnostic reagents for self-testing	Product Dossier Section 5.2, Instructions for Use (IFU). Product Dossier Section 5.1, Labels. The "SARS-CoV-2 Antigen Packaging Operation Protocol" specified one IFU per test kit.	Management Protocol for Labels and IFU QM-00-001 SARS-CoV-2 Antigen Packaging Operation Protocol PO1N4006
8.2	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.	Yes	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.	Product Dossier Section 5.1, Labels.	Management Protocol for Labels and IFU QM-00-001
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 symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. Where there is	N/A N/A			

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions 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.				
8.4	The label must bear the following particulars which may take the form of symbols as appropriate:				
	a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;	a) Yes	EN ISO 18113-4:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 4: In vitro diagnostic reagents for self-testing	Product Dossier Section 5.2, Instructions for Use (IFU).	Management Protocol for Labels and IFU QM-00-001
	b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;	b) Yes	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.	Product Dossier Section 5.1, Labels. SARS-CoV-2 Antigen Packaging Operation Protocol	SARS-CoV-2 Antigen Packaging Operation Protocol PO1N4006
	c) where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;	c) N/A			BS-QA-007 Risk Management Control Procedures
	d) the batch code, preceded by the word 'LOT', or the serial number;	d) N/A		Product Dossier Section 5.1, Labels (lot number specified).	
	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;	e) Yes		Product Dossier Section 5.1, Labels (shelf-life specified).	BS-QA-008 Design and Development Control Procedures
	f) in case of devices for performance evaluation, the words 'for performance evaluation only';	f) Yes		Management Protocol for Labels and IFU	

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	g) where appropriate, a statement indicating the *in vitro* use of the device; h) any particular storage and/or handling conditions; i) where applicable, any particular operating instructions;[1] j) appropriate warnings and/or precautions to take; k) if the device is intended for self-testing, that fact must be clearly stated.	g) Yes h) Yes i) Yes j) Yes k) Yes		Intended use specified in IFU. Storage conditions specified in IFU and labels. Test procedures and relevant precautions specified in IFU. Relevant precautions and protective measures specified in IFU based on risk analysis. IFU specifies that the test is for self-testing.	
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 instructions for use and, if appropriate, on the label.	Yes	EN ISO 18113-4:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 4: In vitro diagnostic reagents for self-testing	Product Dossier Section 5.2, Instructions for Use (IFU). Product Dossier Section 5.1, Labels.	Management Protocol for Labels and IFU QM-00-001 BS-QA-008 Design and Development Control Procedures
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	EN ISO 18113-4:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing	Product Dossier Section 5.1, Labels.	Lot Number Management Protocol PM-00-002

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
8.7	Where appropriate, the instructions for use must contain the following particulars:		EN ISO 18113-4:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling). Part 4: In vitro diagnostic reagents for self-testing		
	a) the details referred to in section 8.4 with the exception of points d) and e);	a) Yes		Product Dossier Section 5.2, Instructions for Use (IFU).	Management Protocol for Labels and IFU QM-00-001
	b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	b) Yes		Above contents included in IFU. Major raw materials and composition specified in IFU	BS-QA-008 Design and Development Control Procedures
	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;	c) Yes	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.	IFU specifies that the test card should be used immediately after opening.	
	d) the performances referred to in section 3 of part A;	d) Yes		Relevant information specified in IFU.	
	e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	e) N/A			
	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;	f) Yes		Sample type, collection, and handling specified in IFU.	
	g) a detailed description of the procedure to be followed in using the device;	g) Yes		Detailed test procedures specified in IFU.	
	h) the measurement procedure to be followed with the device including as appropriate: — the principle of the method, — the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability,	h) Yes		Test principle, product performance characteristics and sample handling methods specified in IFU. Testing does not require specific training if carried in accordance with the IFU.	

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations 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, reconstitution, incubation, dilution, instrument checks, etc.), — the indication whether any particular training is required; i) the mathematical approach upon which the calculation of the analytical result is made; j) measures to be taken in the event of changes in the analytical performance of the device; k) information appropriate to users on: — internal quality control including specific validation procedures, — the traceability of the calibration of the device; l) the reference intervals for the quantities being determined, including a description of the appropriate reference population; m) if the device must be used in 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	i) N/A j) N/A k) N/A —N/A —N/A l) N/A m) N/A		Product Dossier Section 5.1, Labels.	

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	order to obtain a safe and proper combination;				
	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 device operates properly and safely; information about safe waste disposal;	n) Yes		The reagent is the test, and does not require installing, maintenance and calibration. Waste disposal specified in IFU.	
	o) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.);	o) N/A			
	p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	p) N/A			
	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;	q) N/A			
	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.;	r) N/A			
	s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;	s) N/A			
	t) specifications for devices for self-testing:	t) Yes		Above contents included in IFU.	

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No.	Essential Requirement	Applicable ? (yes/no/na)	Method of Conformity	Evidence of Compliance and Location; Other remarks	SOP
	— the results need to be expressed and presented in a way that is readily understood 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, — 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, — 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, — 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; date of issue or latest revision of the instructions for use.				

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9 RISK MANAGEMENT

Risk Analysis and Control Summary

In accordance with the standard requirements of EN ISO 14971:2012, the R&D department has organized relevant personnel to conduct risk analysis using the failure mode and effects analysis (FMEA) on the following aspects:

1) Risk analysis on the users, patients, manufacturing risks, etc. during the input phase of design development;
2) Risk analysis of the production processes (suppliers, material procurement, process control, process safety information) and other aspects during the trial production phase;
3) Risk analysis of the labels and IFU;
4) Risk analysis of transport, storage, and customer use before market launch.

Through risk analysis and assessment, a series of risk control measures were established and validated by the R&D department, including:

1) study on common interfering substances to SARS-CoV-2 virus to avoid potential effects on the test results;
2) study on the storage, transport and in-use stabilities within the product shelf-life to avoid effect of stability on the test results;
3) verification of the reagent processes to ensure that the production processes are reasonable and feasible.
4) Inspection of every batch of reagents, verification of maximum batch quantity, and specification of maximum batch quantity in BS-QA-011 "Production and Service Control Procedures" to avoid within-lot and lot-to-lot variance;
5) Tight sealing in product design and specification in the IFU on how to handle reagents after use to avoid the impact of testing on user safety and the environment;
6) Illustrations and accompanying texts in the IFU to specify the operation procedures and precautions to avoid testing errors in private use that could lead to erroneous test results.

Measures have been taken to minimize the risks that may arise in each process. See "Appendix 1 – Risk Management Report" for more comprehensive risk analysis and control measures. Based on analysis of the residual risks and the risk guidelines, the medical benefits of the intended use were evaluated to outweigh the residual risks.

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Finally, the "Post-Marketing Surveillance Control Procedures" was established to specify the responsibilities of each department to collect information on production and post-production activities as required, and to provide continuous follow-up on the post-marketing status of the SARS-CoV-2 antigen test kits. See "Appendix 2 - Post-Marketing Surveillance Control Procedures" for the complete document.

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10 List of Appendices

In numerous places in this Technical File, references are made to the following appendices which are to be regarded as binding parts of this document.

Appendix 1 - Risk Management Report.pdf

Appendix 2 - Post-Market Surveillance Control Procedures

Appendix 3-1 - Analytical Sensitivity Studies.pdf

Appendix 3-2 - Analytical Sensitivity Studies - Nasal Sample Validation Report.pdf

Appendix 4 - Analytical Specificity - Cross Reactivity Studies.pdf

Appendix 5 - Analytical Specificity - Interference Studies.pdf

Appendix 6 - Precision Studies.pdf

Appendix 7 - Hook Effect Studies.pdf

Appendix 8 - Storage Stability Studies.pdf

Appendix 9 - Freeze-Thaw Stability Studies.pdf

Appendix 10 - Transport Stability Studies.pdf

Appendix 11 - Heat Stability Studies.pdf

Appendix 12 - Open Pack Stability Studies.pdf

Appendix 13 - Clinical Evaluation Report.pdf

Appendix 14 - Private-Use Usability Study.pdf