

HANGZHOU ALLTEST BIOTECH CO., LTD.

Usability Evaluation File

COVID-19 Antigen Rapid Test

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1 Introduction

1.1 Overview

This document provides a usability engineering evaluation report for COVID-19 Antigen Rapid Test.

1.2 Intended Use/Purpose

1.2.1 Medical Purpose:

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2 Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management.

Negative results should be

considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel.

1.2.2 Operator profile:

The intended users are trained clinical laboratory personnel.

1.3 Scope

This usability evaluation report addresses the usability engineering process and usability of COVID-19 Antigen Rapid Test.

1.4 Frequently used functions

1.4.1 Components of Kit:

Materials Provided

Description	Option 1	Option 2	Option 3

Test Cassettes		30	30	30
Sterile Swabs		30	30	30
Work Station		1	1	1
Package Insert		1	1	1
Extraction Buffer (NaCl 5g/L, Tris 3g/L, Proclin300, 0.02%, BSA 5g/L, TritonX-100 2g/L, pH 8.5)	in pre-filled integrated buffer tube	30	/	/
	in disposable buffer vial	/	/	30
	in 10mL buffer bottle	/	2	/
Extraction Tubes and Tips		/	30	30

Materials Required But Not Provided

- Timer

- Specimen Transport Tubes

1.4.2 Frequently used functions that involve USER interaction

No.	Items	Function	User interaction involved	Applicable regulation or standards
1	Test cassettes	rapid chromatographic immunoassay	The cassette design includes sample well, C line region and T line region	IVDD 98/79/EC
2	Foil pouch	Prevent rapid test from contamination and effect by environment	Pouch label or ink jetting	IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016
3	Sterile Swabs	Specimen collection	Label	MDD 93/42/EEC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016
4	Work Station	Fix the extraction tube to prevent it from moving or tilting	N/A	N/A
5	Integrated buffer tube with extraction buffer	Extract SARS-CoV-2 antigen and sample applying	Tube label if applicable, and operation procedure in PI	IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016
	10mL buffer bottle + Extraction Tubes and			IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011

	Tips			EN ISO 15223-1:2016
	disposable buffer vial + Extraction Tubes and Tips			IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016
6	PI	Guidance for user	PI	IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016
7	Kit box and box label	Container of all components and information for identification	Kit box and box label	IVDD 98/79/EC EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016

2 Usability engineering process

2.1 Inputs to the usability specification

2.1.1 Specification of the intended use

2.1.1.1 Medical purpose

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare providers.

2.1.1.2 Patient population

- Age: newborn to geriatric
- Weight: >2,5 kg
- Health: not relevant
- Nationality: multiple
- PATIENT state: PATIENT is not USER: not relevant, unless PATIENT is agitated

2.1.1.3 Part of the body or type of tissue applied to or interacted with

human nasopharynx: intact the surface of the posterior nasopharynx of patient.

2.1.1.4 Intended User

Trained laboratory professionals, can read and understand english Package Insert. Not restriction on patient's age group, weight range or health condition.

2.1.1.5 Application

Used in Clinical laboratory

Use temperature range: room temperature (15 °C to 30 °C). No limitation on humidity.

Storage temperature range: 2 °C to 30 °C.

2.1.2 Primary operating functions

2.1.2.1 Frequently used functions

Item	Task	Sub-task
1	Prepare rapid test kit	<ul style="list-style-type: none"> • <u>Check the packaging*</u> • <u>Check the content</u> • <u>Check the environment</u> • <u>make sure every component not excess expired date.</u>
2	Read package insert and label	<ul style="list-style-type: none"> • <u>Read the package insert before test</u>
3	Specimen collection, transport,	3.1 Swab specimen collection <ul style="list-style-type: none"> • Open the package of sterile swab. • Insert a sterile swab into the nostril of the patient, reaching the surface of the

storage and preparation		<p>posterior nasopharynx.</p> <ul style="list-style-type: none"> ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity.
	3.2 Specimen transport and storage	<ul style="list-style-type: none"> ● <u>Storage the swab in a dry, sterile, and tightly sealed plastic tube for no more than 8 hours at room temperature and 24 hours at 2-8 °C if swabs are not been processed immediately.</u> ● <u>If VTM is required, then the VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C.</u>
	3.3 Specimen extraction - Swab specimen extraction with pre-filled integrated buffer tube (Option 1)	<ul style="list-style-type: none"> ● Unscrew the cap of the extraction tube with extraction buffer inside. ● <u>Place the swab specimen into the extraction buffer and mix well.</u> ● Remove the swab. ● <u>Dispose of the used swab in biohazard waste.</u> ● Tighten the cap onto the sample extraction tube. ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u>
	3.4 Specimen extraction - Swab specimen extraction with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)	<ul style="list-style-type: none"> ● <u>Place the extraction tube in the workstation.</u> ● <u>Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial.</u> ● <u>Do not use ther extraction buffer in 10mL bottle beyond 3 months after opening the extraction buffer bottle.</u> ● <u>Place the swab specimen into the extraction buffer and mix well.</u> ● Remove the swab. ● <u>Dispose of the used swab in biohazard waste.</u> ● <u>Fit the tip onto the top of the extraction tube.</u> ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u>
	3.5 Specimen extraction - Viral Transport Media (VTM) specimen	<ul style="list-style-type: none"> ● <u>Balance the VTM containing the swab specimen to room temperature (15-</u>

		extraction	30°C). <ul style="list-style-type: none"> Using a pipette to transfer 350µL VTM specimen into the specimen extraction tube with approx.350µL extraction buffer inside, shake to mix it well for extraction. Use extracted sample solution as final sample for testing as soon as possible.
4	Directions for use	4.1 Run the test	<ul style="list-style-type: none"> Allow the test, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Remove the test cassette from the sealed foil pouch and use it within one hour. Shake the extracted sample solution to mix it well. Invert the sample extraction tube and add 3 drops of the Extracted Sample Solution to the specimen well(S) of the cassette. Start the timer. Wait for the colored line(s) to appear and read the result at 15 minutes. Do not interpret the result after 20 minutes.
5	Interpretation of results		<ul style="list-style-type: none"> Interpret test line(s) according to PI. Suggestion for invalid result. Suggestion for negative result. Suggestion for positive result.
6	Disposal		<ul style="list-style-type: none"> Disposal of residual specimen. Discard the used test.

*Note: the tasks underlined is functions related to safety.

2.1.3 Identification of hazards and hazardous situations related to usability

2.1.3.1 Identification of characteristics related to safety/task analysis table of usability

Item	Task	Sub-task	Hazard	Hazard-related use scenario description	Harm
1	Prepare rapid test kit	<ul style="list-style-type: none"> Check the packaging* Check the content Check the environment make sure every component not excess expired date. 	<ul style="list-style-type: none"> Incorrect result Contamination Hazard 	<p>Scenario 1. Missing component. Delayed examination result.</p> <p>Scenario 2. Foil pouch is contaminated or does not sufficiently protect the test. Delayed examination result.</p> <p>Scenario 3. The extraction buffer is contaminated.</p>	(Delayed result)Limited delay because the test can be quickly performed again (For false positive) Excessive

					Scenario 4. The sterile swab is contaminated Scenario 5. Incorrect storage and transportation conditions. Delayed examination result. Scenario 6. Use test, buffer and/or control after expired date.	mental stress to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed (Contamination Hazard) Patient's nostril get contact with non-sterile swab and get infected
2	Read package insert and label		<ul style="list-style-type: none"> ● <u>Read the package insert before test</u> 	<ul style="list-style-type: none"> ● Incorrect result ● Insufficient Training 	Scenario 7. Operator doesn't read PI completely before use. Scenario 8. Package's insert not reviewed for full compliance with IVD & EN ISO Scenario 9. The device is misused by people other than trained clinical laboratory professionals.	(For false positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed
3	Specimen collection, transport, storage and preparation	3.1 Swab specimen collection	<ul style="list-style-type: none"> ● Open the package of sterile swab. ● Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity. 	<ul style="list-style-type: none"> ● Incorrect result 	Scenario 10. The operator collect throat specimen instead of nasopharynx. Incorrect sample type. Scenario 11. The operator is not well trained for nasopharynx specimen collection and can not collect enough specimen while collection. Scenario 12. User distraction leads to sample leakage. laboratory personnel get infected.	(For false positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative&Invalid Result) Treatment delayed (Contamination Hazard)
		3.2 Specimen transport and storage	<ul style="list-style-type: none"> ● <u>Storage the swab in a dry, sterile, and tightly sealed plastic tube for no more than 8 hours at room temperature and 24 hours at 2-8 °C if swabs are not</u> 	<ul style="list-style-type: none"> ● Incorrect result 	Scenario 13. The specimen is stored beyond the expected storage condition and deteriorated. Scenario 14. VTM	(For false positive) Excessive mental stress to patient; Medical

		<p><u>been processed immediately.</u></p> <ul style="list-style-type: none"> ● If VTM is required, then the VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. <p><u>Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C.</u></p>		<p>containing guanidinium is used for specimen storage and antigen in swab gets deteriorated.</p> <p>Scenaria 15. Specimen is diluted by VTM which cause false negative result.</p> <p>Scenaria 16. The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.</p>	<p>interventions cause side effects in the body.</p> <p>(False Negative&Invalid Result) Treatment delayed</p>
	3.3 Specimen extraction - Swab specimen extraction with pre-filled integrated buffer tube (Option 1)	<ul style="list-style-type: none"> ● Unscrew the cap of the extraction tube with extraction buffer inside. ● Place the swab specimen into the extraction buffer and mix well. ● Remove the swab. ● Dispose of the used swab in biohazard waste. ● Tighten the cap onto the sample extraction tube. ● Use extracted sample solution as final sample for testing as soon as possible. 	<ul style="list-style-type: none"> ● Incorrect result 	<p>Scenario 17. The swab specimen and the extraction buffer are not well mixed and cause false negative result. (Option 1)</p> <p>Scenario 18. The swab is not disposed according to local regulation and cause other person infected. (Option 1)</p> <p>Scenario 19. The specimen after extraction were improperly stored and deteriorated. (Option 1)</p>	<p>(For false positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative&Invalid Result) Treatment delayed</p>
	3.4 Specimen extraction - Swab specimen extraction	<ul style="list-style-type: none"> ● Place the extraction tube in the workstation. ● Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial. ● Do not use ther extraction 	<ul style="list-style-type: none"> ● Incorrect result ● Contamination 	<p>Scenario 20. The non-intergrated extraction tube falls and the buffer/specimen pours. (Option 2&3)</p> <p>Scenario 21. The extraction buffer added into the extraction tube is</p>	<p>(Delayed result)Limited delay because the test can be quickly performed again (For false</p>

		<p>n with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)</p>	<p>buffer in 10mL bottle <u>beyond 3 months after opening the extraction buffer bottle.</u></p> <ul style="list-style-type: none"> ● <u>Place the swab specimen into the extraction buffer and mix well.</u> ● <u>Remove the swab.</u> ● <u>Dispose of the used swab in biohazard waste.</u> ● <u>Fit the tip onto the top of the extraction tube.</u> ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u> 	<p>Hazard</p>	<p>too much or not enough. (Option 2&3) Scenario 22. The swab specimen and the extraction buffer are not well mixed and cause false negative result. (Option 2&3) Scenario 23. The swab is not disposed according to local regulation and cause other person infected. (Option 2&3) Scenario 24. The specimen after extraction were improperly stored and deteriorated. (Option 2&3) Scenario 25. The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle. (Option 2)</p>	<p>positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed (Contamination Hazard) Other people get infected</p>
		<p>3.5 Specimen extraction - Viral Transport Media (VTM) specimen extraction</p>	<ul style="list-style-type: none"> ● <u>Balance the VTM containing the swab specimen to room temperature (15-30°C).</u> ● <u>Using a pipette to transfer 350µL VTM specimen into the specimen extraction tube with approx.350µL extraction buffer inside, shake to mix it well for extraction.</u> ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u> ● <u>Allow the test, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing.</u> ● <u>Remove the test cassette from the sealed foil pouch</u> 	<ul style="list-style-type: none"> ● Incorrect result 	<p>Scenario 25. The VTM containing the swab specimen does not reach room temperature. Scenario 26. The VTM specimen added into the extraction tube is too much or not enough.</p>	<p>(Delayed result)Limited delay because the test can be quickly performed again (For false positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed</p>
4	Directions for use	<p>4.1 Run the test</p>	<p><u>and use it within one hour.</u></p> <ul style="list-style-type: none"> ● <u>Shake the extracted sample solution to mix it well.</u> ● <u>Invert the sample extraction tube and add 3 drops of the Extracted Sample Solution to the specimen well(S) of the cassette.</u> ● <u>Start the timer.</u> 	<ul style="list-style-type: none"> ● Incorrect result 	<p>Scenario 27. The test or extracted specimen is not equilibrate to room temperature. Scenario 28. The test cassette is removed from the pouch and left for too long. Scenario 29. The extracted specimen volume added is not</p>	<p>(Delayed result)Limited delay because the test can be quickly performed again (For false positive) Excessive mental stress</p>

		<ul style="list-style-type: none"> ● <u>Wait for the colored line(s) to appear and read the result at 15 minutes. Do not interpret the result after 20 minutes.</u> 		<p>enough or too much. Scenario 30. Operating instructions is too complex for the user to get the exact information from the PI. Scenario 31. User distraction leads to operation error.</p>	<p>to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed</p>
5	Interpretation of results	<ul style="list-style-type: none"> ● Interpret test line(s) according to PI. ● Suggestion for invalid result. ● Suggestion for negative result. ● Suggestion for positive result. 	<ul style="list-style-type: none"> ● Incorrect result 	<p>Scenario 32. User read the result beyond the recommended time frame. Scenario 33. The complex instructions lead to interpretation errors and false results.</p>	<p>(Delayed result)Limited delay because the test can be quickly performed again (For false positive) Excessive mental stress to patient; Medical interventions cause side effects in the body. (False Negative) Treatment delayed</p>
6	Disposal	<ul style="list-style-type: none"> ● <u>Disposal of residual specimen.</u> ● <u>Discard the used test.</u> 	<ul style="list-style-type: none"> ● Contamination hazard 	<p>Scenario 25. User does not follow the disposal of biohazard of the institution. Scenario 26. The test is used twice</p>	<p>(Contamination hazard) Hospital personnel might come in contact with contaminated test or accessories. Infection of hospital personnel</p>

*Note: the tasks underlined is functions related to safety.

2.2 Identification of known or foreseeable hazards and hazardous situation

2.2.1 Characteristics of medical device that associated with usability that could impact on safety

According to EN 62366:2008 Annex E

Annex. C	Qualitative product characteristics	Answer	A=applicable	Hazards identified	Hazards No.
			N/A= non-applicable		
E.2.1	Is the MEDICAL DEVICE supplied sterile or intended to be sterilized by the USER, or are other microbiological controls applicable?	The COVID-19 Antigen Rapid Test is Single use and not supplied or intended to be sterilized. The sample swab is supplied sterile.	A	Incorrect result	H1
				Contamination Hazard	H2
E.2.2	Are measurements taken?	No.	N/A	N/A	
E.2.3	Is the MEDICAL DEVICE intended for use in conjunction with medicines or other medical technologies?	No	N/A	N/A	
E.2.4	Are there unwanted outputs of energy or substances?	No	N/A	N/A	
E.2.5	Is the MEDICAL DEVICE susceptible to environmental influences?	Yes. Should keep the products into proper environment, and use it as soon as possible once open the original package.	A	Incorrect result	H3
E.2.6	Are there essential consumables or accessories associated with the MEDICAL DEVICE?	Yes. Sterile swabs, specimen collection tubes with extraction buffer and a package insert provided. Timer as additional accessory is required but not provided in kit.	A	Incorrect result	H4
				Contamination Hazard	H5

E.2.7	Is maintenance and/or calibration necessary?	No	N/A	N/A	
E.2.8	Does the MEDICAL DEVICE have a restricted shelf-life?	Yes. 24 months.	A	Incorrect result	H6
E.2.9	Are there any delayed and/or long-term use effects?	No	N/A	N/A	
E.2.10	To what mechanical forces will the MEDICAL DEVICE be subjected?	None if used according to instructions	N/A	N/A	
E.2.11	Is the MEDICAL DEVICE intended for single use?	Yes	A	Incorrect result	H7
E.2.12	Does installation or use of the MEDICAL DEVICE require special training or special skills?	Yes. Skills of preparation of nasopharyngeal specimen required, and bio-safety knowledge	A	Incorrect result	H8
				Insufficient Training	H9
E.2.13	How will information for safe use be provided?	Package insert provides information for safe use	A	Incorrect result	H10
E.2.14	Can the USER INTERFACE design features contribute to USE ERROR?	Yes. Insufficient packaging insert information contribute to use error.	A	Incorrect result	H11
E.2.15	Is the MEDICAL DEVICE used in an environment where distractions are commonplace?	Yes. The test is to be performed in laboratories, probably in an emergency situation where distractions can occur	A	Incorrect result	H12
				Contamination Hazard	H13
E.2.16	Does the MEDICAL DEVICE have connecting parts or accessories?	Yes. Accessories required during test.	A	Incorrect result	H14

E.2.17	Does the MEDICAL DEVICE have a control interface?	No	N/A	N/A	
E.2.18	How is information displayed by the MEDICAL DEVICE?	By checking C,T lines to interpret if the result is positive or negative. The detailed information is in PI.	A	Incorrect result	H15
E.2.19	Is the MEDICAL DEVICE controlled by a menu?	No	N/A	N/A	
E.2.20	Will the MEDICAL DEVICE be used by persons with special needs?	No	N/A	N/A	
E.2.21	In what way(s) might the MEDICAL DEVICE be deliberately misused?	Yes, if the test is used for 1) detection of specimen collected from other sampling point; 2) User neglects to test the patient with another technology in case of negative results	A	Incorrect result	H16
E.2.22	Is the MEDICAL DEVICE intended to be mobile or portable?	No, the COVID-19 Antigen Rapid Test is easy-portable but it is not intended by the manufacturer to be portable as it is for professional use only.	N/A	N/A	

2.2.2 Identification of HARM due to USABILITY related HAZARDS

Hazard #	Hazard identified	Hazard-related use scenario description	Hazardous situation	Harm	User Interface Risk Control Measure

H1	Incorrect result	The sterile swab is contaminated	Contamination Hazard	Patient's nostril get contact with non-sterile swab and get infected	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected. ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab. iii) Material specification of sterile swab iv) Training management procedure: pre-job training v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H2	Contamination Hazard	The sterile swab is contaminated	Contamination Hazard	Patient's nostril get contact with non-sterile swab and get infected	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected. ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab. iii) Material specification of sterile swab iv) Training management procedure: pre-job training v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H3	Incorrect result	Foil pouch is contaminated or does not sufficiently protect the cassette	False positive	Mental stress for patient (temporary discomfort)	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.

H3	Incorrect result	Foil pouch is contaminated or does not sufficiently protect the cassette	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H3	Incorrect result	Foil pouch is contaminated or does not sufficiently protect the cassette	Invalid result	Limited delay because the test can be quickly performed again	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H3	Incorrect result	Incorrect storage and transportation conditions	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.

H3	Incorrect result	Incorrect storage and transportation conditions	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.
H3	Incorrect result	Incorrect storage and transportation conditions	Invalid result	Limited delay because the test can be quickly performed again	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.
H3	Incorrect result	The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle.(Option 2)	False positive	Mental stress for patient (temporary discomfort)	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The open cap stability of buffer is studied.
H3	Incorrect result	The 10mL buffer is used for test beyond 3 months after opening	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The open cap stability of buffer is studied.

		the extraction buffer bottle.(Option 2)		patients	
H3	Incorrect result	The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle.(Option 2)	Invalid result	Limited delay because the test can be quickly performed again	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests</p> <p>ii) Prescribed storage conditions are provided on the product labels</p> <p>iii) The open cap stability of buffer is studied.</p>
H4	Incorrect result	Missing component.	Delayed result	Limited delay because the test can be quickly performed again	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Training management procedure: pre-job training</p> <p>ii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>
H4	Incorrect result	The extraction buffer is contaminated	False positive	Mental stress for patient (temporary discomfort)	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories.</p> <p>ii) Buffer's open cap stability study report</p> <p>iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control.</p> <p>iv) Buffer QC testing</p> <p>v) Training management procedure: pre-job training</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>

H4	Incorrect result	The extraction buffer is contaminated	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories. ii) Buffer's open cap stability study report iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control. iv) Buffer QC testing v) Training management procedure: pre-job training vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H4	Incorrect result	The extraction buffer is contaminated	Invalid result	Limited delay because the test can be quickly performed again	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories. ii) Buffer's open cap stability study report iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control. iv) Buffer QC testing v) Training management procedure: pre-job training vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.
H5	Contamination Hazard	The non-integrated extraction tube falls and the buffer/specimen pours. (Option 2&3)	Contamination Hazard	User get contact with poured buffer/specimen and get infected	Work station is provided to place the non-integrated extraction tube.

H5	Contamination Hazard	The sterile swab is contaminated	Contamination Hazard	Patient's nostril get contact with non-sterile swab and get infected	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected.</p> <p>ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab.</p> <p>iii) Material specification of sterile swab</p> <p>iv) Training management procedure: pre-job training</p> <p>v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production.</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>
H6	Incorrect result	Use test, buffer and/or control after expired date	False positive	Mental stress for patient (temporary discomfort)	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests</p> <p>ii) Prescribed storage conditions are provided on the product labels.</p> <p>iii) The shelf life is determined according to accelerated stability study result. The real time stability study and simulated shipping stability study is being studied.</p>
H6	Incorrect result	Use test, buffer and/or control after expired date	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests</p> <p>ii) Prescribed storage conditions are provided on the product labels.</p> <p>iii) The shelf life is determined according to accelerated stability study result. The real time stability study and simulated shipping stability study is being studied.</p>
H6	Incorrect result	Use test, buffer and/or control after expired date	Invalid result	Limited delay because the test can be quickly performed again	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests</p> <p>ii) Prescribed storage conditions are provided on the product labels.</p> <p>iii) The shelf life is determined according to accelerated stability study result. The real time stability study and simulated shipping stability study is being studied.</p>
H7	Incorrect result	The test is used twice	Delayed result	Limited delay because the test can be quickly performed again	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests.</p> <p>ii) The symbol for single use is provided on the labels.</p>
H8	Incorrect result	The operator collect throat specimen instead of nasopharynx.	False positive	Mental stress for patient (temporary discomfort)	<p>i) The correct sample type is indicated in product name and Package Insert.</p> <p>ii) The correct sampling method is described in Package Insert.</p>

		Incorrect sample type			
H8	Incorrect result	The operator collect throat speicmen instead of nasopharynx. Incorrect sample type	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.
H8	Incorrect result	The operator is not well trained for nasopharynx speicmen collection and can not collect enough specimen while collection.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.
H8	Incorrect result	VTM containing guanidinium is used for specimen storage and antigen in swab gets deteriorated.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	PI states do not use VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate)
H8	Incorrect result	Specimen is diluted by VTM which cause false negative result.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	PI states that minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen.
H8	Incorrect result	The storage condition of Swabs in VTM is beyond the expected storage	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was was studied and output into Package Insert.

		condition and deteriorated.			
H8	Incorrect result	The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was was studied and output into Package Insert.
H8	Incorrect result	The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was was studied and output into Package Insert.
H8	Incorrect result	The specimen is stored beyond the expected storage condition and deteriorated.	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.
H8	Incorrect result	The specimen is stored beyond the expected storage condition and deteriorated.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.
H8	Incorrect result	The specimen is stored beyond the expected storage condition and	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.

		deteriorated.			
H8	Incorrect result	The swab specimen and the extraction buffer are not well mixed and cause false negative result. (Option 1)	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	The corrected operate step to mix is detailed in PI with illustration.
H8	Incorrect result	The specimen after extraction were improperly stored and deteriorated. (Option 1&2&3)	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.
H8	Incorrect result	The specimen after extraction were improperly stored and deteriorated. (Option 1&2&3)	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.
H8	Incorrect result	The specimen after extraction were improperly stored and deteriorated. (Option 1&2&3)	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.
H8	Incorrect result	The VTM containing the swab specimen does not reach room temperature.	False positive	Mental stress for patient (temporary discomfort)	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.

H8	Incorrect result	The VTM containing the swab specimen does not reach room temperature.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.
H8	Incorrect result	The VTM containing the swab specimen does not reach room temperature.	Invalid result	Limited delay because the test can be quickly performed again	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.
H8	Incorrect result	The test or extracted specimen is not equilibrate to room temperature.	False positive	Mental stress for patient (temporary discomfort)	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.
H8	Incorrect result	The test or extracted specimen is not equilibrate to room temperature.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.
H8	Incorrect result	The test or extracted specimen is not equilibrate to room temperature.	Invalid result	Limited delay because the test can be quickly performed again	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.
H8	Incorrect result	The VTM specimen added into the extraction tube is too much or not enough.	False positive	Mental stress for patient (temporary discomfort)	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.

H8	Incorrect result	The VTM specimen added into the extraction tube is too much or not enough.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.
H8	Incorrect result	The extraction buffer added into the extraction tube is too much or not enough. (Option 2&3)	False positive	Mental stress for patient (temporary discomfort)	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.
H8	Incorrect result	The extraction buffer added into the extraction tube is too much or not enough. (Option 2&3)	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.
H9	Insufficient Training	Operator doesn't read completely before use	False positive	Mental stress for patient (temporary discomfort)	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.
H9	Insufficient Training	Operator doesn't read completely before use	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.
H9	Insufficient Training	Operator doesn't read completely before use	Invalid result	Limited delay because the test can be quickly performed again	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.
H9	Insufficient Training	The swab is not disposed	Contamination hazard	Hospital personnel might come in contact with contaminated test or	It is the responsibility of the hospital that the rules within the hospital are followed

	ng	according to legal regulation and cause other person infected. (Option 1&2&3)		accessories. Infection of hospital personnel	
H9	Insufficient Training	User does not follow the disposal of biohazard of the institution.	Contamination hazard	Hospital personnel might come in contact with contaminated test accessories. Infection of hospital personnel	It is the responsibility of the hospital that the rules within the hospital are followed
H10	Incorrect result	Package's insert not reviewed for full compliance with IVD & EN ISO	False positive	Mental stress for patient (temporary discomfort)	Package insert of the test was reviewed under the scope of risk management and usability evaluation.
H10	Incorrect result	Package's insert not reviewed for full compliance with IVD & EN ISO	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	Package insert of the test was reviewed under the scope of risk management and usability evaluation.
H10	Incorrect result	Package's insert not reviewed for full compliance with IVD & EN ISO	Invalid result	Limited delay because the test can be quickly performed again	Package insert of the test was reviewed under the scope of risk management and usability evaluation.
H11	Incorrect result	Operation instructions is too complex for the user to get the exact information from the PI.	False positive	Mental stress for patient (temporary discomfort)	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iv) The operation illustration is presented in Package Insert.
H11	Incorrect result	Operation instructions is too complex for the user to get the exact	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability

		information from the PI.		department, infecting other patients	evaluation. iv) The operation illustration is presented in Package Insert.
H11	Incorrect result	Operation instructions is too complex for the user to get the exact information from the PI.	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iv) The operation illustration is presented in Package Insert.
H12	Incorrect result	User distraction leads to operational errors.	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.
H12	Incorrect result	User distraction leads to operational errors.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.
H12	Incorrect result	User distraction leads to operational errors.	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.
H13	Contamination Hazard	User distraction leads to sample leakage. laboratory personnel get infected.	Contamination hazard	Hospital personnel might come in contact with contaminated test accessories. Infection of hospital personnel	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.
H14	Incorrect result	User doesn't use the accessories provided in kit	False positive	Mental stress for patient (temporary discomfort)	i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation. ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.

H14	Incorrect result	User doesn't use the accessories provided in kit	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation. ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.
H14	Incorrect result	User doesn't use the accessories provided in kit	Invalid result	Limited delay because the test can be quickly performed again	i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation. ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.
H15	Incorrect result	User read the result beyond the recommended time frame	False positive	Mental stress for patient (temporary discomfort)	i) The reading time flex is studied during design control process. ii) The proper reading time is put in Package Insert.
H15	Incorrect result	The complex instructions lead to interpretation errors and false results.	False positive	Mental stress for patient (temporary discomfort)	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iii) The illustration of results interpretation is presented in Package Insert.
H15	Incorrect result	The complex instructions lead to interpretation errors and false results.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iii) The illustration of results interpretation is presented in Package Insert.
H15	Incorrect result	The complex instructions lead to interpretation errors and false results.	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iii) The illustration of results interpretation is presented in Package Insert.
H16	Incorrect result	The operator collect throat specimen instead of nasopharynx. Incorrect	False positive	Mental stress for patient (temporary discomfort)	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.

		sample type			
H16	Incorrect result	The operator collect throat specimen instead of nasopharynx. Incorrect sample type	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.
H16	Incorrect result	The device is misused by people other than trained clinical laboratory professionals.	False positive	Mental stress for patient (temporary discomfort)	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient management decisions.
H16	Incorrect result	The device is misused by people other than trained clinical laboratory professionals.	False negative	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient management decisions.
H16	Incorrect result	The device is misused by people other than trained clinical laboratory professionals.	Invalid result	Limited delay because the test can be quickly performed again	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient management decisions.

2.3 USABILITY specification

After reading the PI, $\geq 90\%$ of users shall successfully test on their first try.
 $\geq 80\%$ of users shall rate the PI is easy to understand and the test is easy to operate.

All risks associated with usability should be reduced to acceptable levels.

3 Usability Validation Plan

3.1 Study Purpose

Validate the usability of COVID-19 Antigen Rapid Test

3.2 Study Method

10 laboratory professionals who have no responsibility of this product should be employed in this study. Each professionals should test 3 positive nasopharyngeal swab with recombinant antigen and 3 negative Nasopharyngeal Swab using 3 options of extraction tube separately and test 3 VTM specimen with recombinant antigen and 3 negative VTM specimen using 3 options of extraction tube separately.

Condition stype	Combination	Test
Condition 1	pre-filled integrated buffer tube + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 2	10mL buffer bottle + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 3	disposable buffer vial + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 4	pre-filled integrated buffer tube + VTM specimen	1 positive specimen and 1 negative specimen
Condition 5	10mL buffer bottle + VTM specimen	1 positive specimen and 1 negative specimen
Condition 6	disposable buffer vial + VTM specimen	1 positive specimen and 1 negative specimen

Questionnaire is prepared for all laboratory professionals.

3.3 Selection basis of operators

The operator should have good English reading.

The study will be arranged at afternoon after hours of work. 10 laboratory professionals will be kept alone in laboratory one by one to do the test.

3.4 Simulated environment

The light in laboratories should be low.

Test time for each professional is assumed 1 hour, twice call interrupt during test.

3.5 Acceptable criteria of usability validation

After reading the PI, $\geq 90\%$ of users shall successfully test on their first try.

$\geq 80\%$ of users shall rate the PI is easy to understand and the test is easy to operate.

3.6 Study Result

3.7 Questionare result statistics

3.8 Conclusion

4 User interface design and implementation

User interface refers to the labels and PI.

5 Usability Verification

5.1 General

Parameter	Description (design input)	Design verification*
Intended Use	the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens	Same
Intended Customer	Trained clinical laboratory Professional	Same
Test Format	Cassette	Same
Sample to be Tested	nasopharyngeal swab, including nasopharyngeal swab and nasopharyngeal swab stored in specified VTM	Same
Controls	Procedure control	procedure control
Sensitivity	≥80%	Same
Specificity (Randomized sample)	≥95%	Same
Buffer type	3 options: - pre-filled integrated buffer tube - 10mL buffer bottle - disposable buffer vial	1 extraction buffer
Operation Steps	1 Step	1 step
Time to Results	15 minutes	Same
Test Specimen Volume	3 drops of the extracted specimen	Same
Endpoint Desired	Two red lines	Same
Storage Conditions	2-30°C	2-30°C
Shelf Life from Date of Manufacture	24 months from mfg.	24 months from mfg.
Clinical Trial - Reference Method	PCR	Same

5.2 USE SCENARIOS

Worst case use scenarios:

- untrained clinical laboratory personnel;
- have been working for hours and tired;
- low ambient lighting;
- alone at the clinical laboratory;
- interrupted by telephone call (distracts attention).

5.3 USER actions related to PRIMARY OPERATING FUNCTIONS

Item	Task	Sub-task
1	Prepare rapid test kit	<ul style="list-style-type: none"> ● <u>Check the packaging*</u> ● <u>Check the content</u> ● <u>Check the environment</u> ● <u>make sure every component not excess expired date.</u>

2	Read package insert and label	<ul style="list-style-type: none"> ● <u>Read the package insert before test</u> 								
3	Specimen collection, transport, storage and preparation	<table border="1"> <tr> <td data-bbox="549 465 946 698">3.1 Swab specimen collection</td> <td data-bbox="946 465 1383 698"> <ul style="list-style-type: none"> ● Open the package of sterile swab. ● Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity. </td> </tr> <tr> <td data-bbox="549 698 946 1281">3.2 Specimen transport and storage</td> <td data-bbox="946 698 1383 1281"> <ul style="list-style-type: none"> ● <u>Storage the swab in a dry, sterile, and tightly sealed plastic tube for no more than 8 hours at room temperature and 24 hours at 2-8 °C if swabs are not been processed immediately.</u> ● <u>If VTM is required, then the VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.</u> ● <u>Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C.</u> </td> </tr> <tr> <td data-bbox="549 1281 946 1630">3.3 Specimen extraction - Swab specimen extraction with pre-filled integrated buffer tube (Option 1)</td> <td data-bbox="946 1281 1383 1630"> <ul style="list-style-type: none"> ● Unscrew the cap of the extraction tube with extraction buffer inside. ● <u>Place the swab specimen into the extraction buffer and mix well.</u> ● Remove the swab. ● <u>Dispose of the used swab in biohazard waste.</u> ● Tighten the cap onto the sample extraction tube. ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u> </td> </tr> <tr> <td data-bbox="549 1630 946 1848">3.4 Specimen extraction - Swab specimen extraction with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)</td> <td data-bbox="946 1630 1383 1848"> <ul style="list-style-type: none"> ● <u>Place the extraction tube in the workstation.</u> ● <u>Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial.</u> ● <u>Do not use ther extraction buffer in</u> </td> </tr> </table>	3.1 Swab specimen collection	<ul style="list-style-type: none"> ● Open the package of sterile swab. ● Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity. 	3.2 Specimen transport and storage	<ul style="list-style-type: none"> ● <u>Storage the swab in a dry, sterile, and tightly sealed plastic tube for no more than 8 hours at room temperature and 24 hours at 2-8 °C if swabs are not been processed immediately.</u> ● <u>If VTM is required, then the VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.</u> ● <u>Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C.</u> 	3.3 Specimen extraction - Swab specimen extraction with pre-filled integrated buffer tube (Option 1)	<ul style="list-style-type: none"> ● Unscrew the cap of the extraction tube with extraction buffer inside. ● <u>Place the swab specimen into the extraction buffer and mix well.</u> ● Remove the swab. ● <u>Dispose of the used swab in biohazard waste.</u> ● Tighten the cap onto the sample extraction tube. ● <u>Use extracted sample solution as final sample for testing as soon as possible.</u> 	3.4 Specimen extraction - Swab specimen extraction with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)	<ul style="list-style-type: none"> ● <u>Place the extraction tube in the workstation.</u> ● <u>Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial.</u> ● <u>Do not use ther extraction buffer in</u>
3.1 Swab specimen collection	<ul style="list-style-type: none"> ● Open the package of sterile swab. ● Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity. 									
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3.4 Specimen extraction - Swab specimen extraction with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)	<ul style="list-style-type: none"> ● <u>Place the extraction tube in the workstation.</u> ● <u>Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial.</u> ● <u>Do not use ther extraction buffer in</u> 									

			<p>10mL bottle beyond 3 months after opening the extraction buffer bottle.</p> <ul style="list-style-type: none"> ● Place the swab specimen into the extraction buffer and mix well. ● Remove the swab. ● Dispose of the used swab in biohazard waste. ● Fit the tip onto the top of the extraction tube. ● Use extracted sample solution as final sample for testing as soon as possible.
		3.5 Specimen extraction - Viral Transport Media (VTM) specimen extraction	<ul style="list-style-type: none"> ● Balance the VTM containing the swab specimen to room temperature (15-30°C). ● Using a pipette to transfer 350µL VTM specimen into the specimen extraction tube with approx. 350µL extraction buffer inside, shake to mix it well for extraction. ● Use extracted sample solution as final sample for testing as soon as possible. ● Allow the test, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
4	Directions for use	4.1 Run the test	<ul style="list-style-type: none"> ● Remove the test cassette from the sealed foil pouch and use it within one hour. ● Shake the extracted sample solution to mix it well. ● Invert the sample extraction tube and add 3 drops of the Extracted Sample Solution to the specimen well(S) of the cassette. ● Start the timer. ● Wait for the colored line(s) to appear and read the result at 15 minutes. Do not interpret the result after 20 minutes.
5	Interpretation of results		<ul style="list-style-type: none"> ● Interpret test line(s) according to PI. ● Suggestion for invalid result. ● Suggestion for negative result. ● Suggestion for positive result.
6	Disposal		<ul style="list-style-type: none"> ● Disposal of residual specimen. ● Discard the used test.

5.4 USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS

Item	Task	Sub-task	USER INTERFACE requirements
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1	Prepare rapid test kit	<ul style="list-style-type: none"> ● Check the packaging ● Check the content ● Check the environment ● make sure every component not excess expired date. 	<p>Easy to identify the contents in kit box</p> <p>Easy to see the correct storage condition on box label</p> <p>Easy to see the expired date on box label</p> <p>Easy to open box with one hand</p>	
2	Read package insert and label	<ul style="list-style-type: none"> ● Read the package insert before test 	<p>Easy to identify the location of this sentence.</p>	
3	Specimen collection, transport, storage and preparation	3.1 Swab specimen collection	<ul style="list-style-type: none"> ● Open the package of sterile swab. ● Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. ● Swab over the surface of the posterior nasopharynx. ● Withdraw the sterile swab from the nasal cavity. 	<p>The sterile swab is easy to open.</p> <p>The sterile swab is small enough to insert into the nostril and long enough to reach the surface of the posterior nasopharynx.</p> <p>The sterile swab is easy to hand.</p> <p>The sterile swab is easy to withdraw and not break in the nostril.</p> <p>The sterile swab can take enough specimen while specimen collection.</p>
		3.2 Specimen transport and storage	<ul style="list-style-type: none"> ● Storage the swab in a dry, sterile, and tightly sealed plastic tube for no more than 8 hours at room temperature and 24 hours at 2-8 °C if swabs are not been processed immediately. ● If VTM is required, then the VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C. 	<p>The location of storage condition is easy to find.</p>
		3.3 Specimen extraction - Swab specimen extraction with pre-filled integrated buffer tube (Option 1)	<ul style="list-style-type: none"> ● Unscrew the cap of the extraction tube with extraction buffer inside. ● Place the swab specimen into the extraction buffer and mix well. ● Remove the swab. ● Dispose of the used swab in biohazard waste. ● Tighten the cap onto the sample extraction tube. ● Use extracted sample solution as final sample for testing as soon as possible. 	<p>The integrated buffer tube is easy to open and close.</p>

		<p>3.4 Specimen extraction - Swab specimen extraction with extraction buffer and tube separately (Option 2&3) (Extraction buffer in 10mL buffer bottle or disposable buffer vial)</p>	<ul style="list-style-type: none"> ● Place the extraction tube in the workstation. ● Add approx. 350µL Extraction Buffer into the extraction tube in 10mL bottle or extraction buffer in disposable buffer vial. ● Do not use the extraction buffer in 10mL bottle beyond 3 months after opening the extraction buffer bottle. ● Place the swab specimen into the extraction buffer and mix well. ● Remove the swab. ● Dispose of the used swab in biohazard waste. ● Fit the tip onto the top of the extraction tube. ● Use extracted sample solution as final sample for testing as soon as possible. 	<p>The work station can keep the tube up. The tube tip can fit the tube well. The disposable buffer vial is easy to open. The expired date of 10mL buffer before open is easy to find. The opening date of 10mL buffer can be recorded and hard to erase.</p>
		<p>3.5 Specimen extraction - Viral Transport Media (VTM) specimen extraction</p>	<ul style="list-style-type: none"> ● Balance the VTM containing the swab specimen to room temperature (15-30°C). ● Using a pipette to transfer 350µL VTM specimen into the specimen extraction tube with approx. 350µL extraction buffer inside, shake to mix it well for extraction. ● Use extracted sample solution as final sample for testing as soon as possible. 	<p>The location of VTM information is easy to find. The operation with VTM specimen is easy to understand and operate.</p>
4	Directions for use	<p>4.1 Run the test</p>	<ul style="list-style-type: none"> ● Allow the test, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing. ● Remove the test cassette from the sealed foil pouch and use it within one hour. ● Shake the extracted sample solution to mix it well. ● Invert the sample extraction tube and add 3 drops of the Extracted Sample Solution to the specimen well(S) of the cassette. ● Start the timer. ● Wait for the colored line(s) to appear and read the result at 15 minutes. Do not interpret the result after 20 minutes. 	<p>The foil pouch is easy to open. The expired date printed on foil pouch is easy to read and understand.</p>

5	Interpretation of results	<ul style="list-style-type: none"> ● Interpret test line(s) according to PI. ● Suggestion for invalid result. ● Suggestion for negative result. ● Suggestion for positive result. 	<p>The control line is strong enough to read.</p> <p>Though the test liner vary based on different antigen concentration, it should be red by visible to naked eyes.</p> <p>The control line region and test line region in easy to distiguish.</p>
6	Disposal	<ul style="list-style-type: none"> ● Disposal of residual specimen. ● Discard the used test. 	No additional requirement.

5.5 USER INTERFACE requirements for those USE SCENARIOS that are frequent or related to SAFETY

The whole test procedure shall be easy to understand and do after reading the labels and PI:
- components of PI complies with IVDD 98/79/EC, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016

- The test procedure includes: Read package insert and label, Specimen collection, transport, storage and preparation of 3 extraction options (extraction buffer in pre-filled integrated buffer tube or in 10mL buffer bottle or in disposable buffer vial) and 2 specimen type (Nasopharyngeal Swab stored or not stored in VTM specimen), directions for use, interpretation of results and disposal.

- Text version: English

- Font size: Arial 6.5 minimum

- Clearly understandable drawings for USERS illiterate in the language versions provided

- Only symbols proven to be intuitive for intended USERS

5.6 Requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER

See 5.4, no additional requirements.

6 Usability Validation Report

6.1 Study Purpose

Validate the usability of COVID-19 Antigen Rapid Test

6.2 Study Method

10 laboratory professionals who have no responsibility with this product should be employed in this study. Each professionals should test 3 positive nasopharyngeal swab with recombinant antigen and 3 negative Nasopharyngeal Swab using 3 options of extraction tube separately and test 3 VTM specimen with recombinant antigen and 3 negative VTM specimen using 3 options of extraction tube separately.

For each user:

Condition stype	Combination	Test
Condition 1	pre-filled integrated buffer tube + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 2	10mL buffer bottle + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 3	disposable buffer vial + Nasopharyngeal Swab specimen	1 positive specimen and 1 negative specimen
Condition 4	pre-filled integrated buffer tube + VTM specimen	1 positive specimen and 1 negative specimen
Condition 5	10mL buffer bottle + VTM specimen	1 positive specimen and 1 negative specimen
Condition 6	disposable buffer vial + VTM specimen	1 positive specimen and 1 negative specimen

6.3 Selection basis of operators

The operator should have good english reading.

The study will be arranged at afternoon after hours of work. 10 laboratory professionals will be kept alone in laboratory one by one to do the test.

6.4 Simulated environment

The light in laboratories should be low.

Test time for each professional is assumed 1 hour, twice call interrupt during test.

6.5 Acceptable criteria of usability validation

After reading the PI, $\geq 90\%$ of users shall successfully test on their first try.

$\geq 80\%$ of users shall rate the PI is easy to understand and the test is easy to operate.

6.6 Study Result

User No	Condition 1		Condition 2		Condition 3		Condition 4		Condition 5		Condition 6	
Test Result	Positive specimen	Negative specimen	Positive specimen	Negative specimen	Positive specimen	Negative specimen	Positive specimen	Negative specimen	Positive specimen	Negative specimen	Positive specimen	Negative specimen
User 1	+	-	+	-	+	-	+	-	+	-	+	-
User 2	+	-	+	-	+	-	+	-	+	-	+	-
User 3	+	-	+	-	+	-	+	-	+	-	+	-
User 4	+	-	+	-	+	-	+	-	+	-	+	-
User 5	+	-	+	-	+	-	+	-	+	-	+	-
User 6	+	-	+	-	+	-	+	-	+	-	+	-
User 7	+	-	+	-	+	-	+	-	+	-	+	-
User 8	+	-	+	-	+	-	+	-	+	-	+	-
User 9	+	-	+	-	+	-	+	-	+	-	+	-
User 10	+	-	+	-	+	-	+	-	+	-	+	-

6.7 Questionare result statistics

User No	Gender	Age	A - Very easy to understand PI B - Easy to understand PI C -Difficult to understand PI D - Very difficult to understand PI	A - Very easy to test B - Easy to test C -Difficult to test D - Very difficult to test	A - Very easy to interpret result B - Easy to interpret result C -Difficult to interpret result D - Very difficult to interpret result
User 1	Female	36	B	A	A
User 2	Female	27	B	B	A
User 3	Female	31	B	B	A
User 4	Female	25	B	B	A
User 5	Female	28	A	A	A
User 6	male	28	B	B	A
User 7	Female	26	B	B	A
User 8	Female	27	B	B	A
User 9	male	37	A	A	A
User 10	Female	30	B	A	A

6.8 Conclusion

100% users employed rate PI is easy to understand, the test is easy to operate and the result is easy to interpret. After reading the PI, 100% of users test successfully on their first try.

The interface design of the test meet the acceptance criteria.

7 Risk Analysis

7.1 Estimation of the risks for Each Hazardous Situation

7.1.1 Estimation of Severity of Harm

Severity Ranking	Severity Ranking (descriptive)	Description
1	Negligible	Mental stress for the patient (temporary discomfort) Limited delay because the test can be quickly performed again
2	Marginal	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms
3	Critical	Infection of hospital personnel
4	Catastrophic	Because the patient is not recognized as a Covid-19, he/she is treated in the wrong department, infecting other patients

7.1.2 Estimation of Detection of Incorrect Results

Severity Ranking	Detection Ranking (descriptive)	Description
1	Always possible	Use of another methodology to confirm results is required / Control line / cassette is unpacked
2	Maybe possible	Physician may detect discrepancies between results and clinical impression
3	Impossible	It cannot be detected by user (laboratory) nor by physician

7.1.3 Estimation of the Probability of Occurrence

Ranking	Likelihood	Description	Probability (in fractions)	Probability (in percentage)
1	Incredible	Almost impossible to occur	N/A	N/A
2	Improbable	Unlikely to occur	$N < 1/10,000$	$N < 0.01\%$
3	Remote	Unlikely but possible to occur	$1/10,000 < N < 1/1,000$	$0.01\% < N < 0.1\%$
4	Occasional	Likely to occur sometime	$1/1,000 < N < 1/100$	$0.1\% < N < 1\%$
5	Probable	Likely to occur several times	$1/1,00 < N < 1/10$	$1\% < N < 10\%$
6	Frequent	Likely to occur frequently	$1/1,0 < N$	$10\% < N$

7.2 Result of the evaluation of usability risk

Hazard Identified	Hazardous situation	Hazard-related use scenario description	Hazard # (Trace)	Harm	Risk Assessment before Mitigation				Usability Interface Risk Control Measure	Risk Assessment before Mitigation					Item
					Risk Estimation			Risk Evaluation		Risk Estimation			Risk Evaluation	Any New Hazard Generated	
					Severity	Detection	Probability of Occurrence			Severity	Detection	Probability of Occurrence			
Incorrect result	Contamination Hazard	The sterile swab is contaminated	H1	Patient's nostril get contact with non-sterile swab and get infected	3	2	2	12	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected. ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab. iii) Material specification of sterile swab iv) Training management procedure: pre-job training v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.	3	2	1	6	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	1
Contamination Hazard	Contamination Hazard	The sterile swab is contaminated	H2	Patient's nostril get contact with non-sterile swab and get infected	3	2	2	12	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected. ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab. iii) Material specification of sterile swab iv) Training management procedure: pre-job training v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after	3	2	1	6	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	2

									double check.						
Incorrect result	False positive	Foil pouch is contaminated or does not sufficiently protect the cassette	H3	Mental stress for patient (temporary discomfort)	1	1	2	2	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <ul style="list-style-type: none"> i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check. 	1	1	1	1	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	3

Incorrect result	False negative	Foil pouch is contaminated or does not sufficiently protect the cassette	H3	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.	2	2	1	4	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	4
Incorrect result	Invalid result	Foil pouch is contaminated or does not sufficiently protect the cassette	H3	Limited delay because the test can be quickly performed again	1	1	2	2	Manufacturing process under EN ISO 13485:2016 certification: i) Purchase management procedure ii) Incoming material inspection procedure iii) Material specification of foil pouch iv) Manufacture verification control v) Training management procedure: pre-job training vi) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production. vii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.	1	1	1	1	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	5

Incorrect result	False positive	Incorrect storage and transportation conditions.	H3	Mental stress for patient (temporary discomfort)	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.	1	1	1	1	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	6
Incorrect result	False negative	Incorrect storage and transportation conditions.	H3	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.	2	2	1	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	7
Incorrect result	Invalid result	Incorrect storage and transportation conditions.	H3	Limited delay because the test can be quickly performed again	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The storage and transportation condition is being studied in real time stability study and simulated shipping studies.	1	1	1	1	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	8

Incorrect result	False positive	The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle.(Option 2)	H3	Mental stress for patient (temporary discomfort)	1	1	3	3	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The open cap stability of buffer is studied.	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	9
Incorrect result	False negative	The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle.(Option 2)	H3	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The open cap stability of buffer is studied.	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	10

Incorrect result	Invalid result	The 10mL buffer is used for test beyond 3 months after opening the extraction buffer bottle.(Option 2)	H3	Limited delay because the test can be quickly performed again	1	1	3	3	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests ii) Prescribed storage conditions are provided on the product labels iii) The open cap stability of buffer is studied.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>]	11
Incorrect result	Delayed result	Missing component.	H4	Limited delay because the test can be quickly performed again	1	1	2	2	Manufacturing process under EN ISO 13485:2016 certification: i) Training management procedure: pre-job training ii) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.	1	1	1	1	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>]	12

Incorrect result	False positive	The extraction buffer is contaminated	H4	Mental stress for patient (temporary discomfort)	1	1	3	3	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories.</p> <p>ii) Buffer's open cap stability study report</p> <p>iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control.</p> <p>iv) Buffer QC testing</p> <p>v) Training management procedure: pre-job training</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	13
Incorrect result	False negative	The extraction buffer is contaminated	H4	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories.</p> <p>ii) Buffer's open cap stability study report</p> <p>iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control.</p> <p>iv) Buffer QC testing</p> <p>v) Training management procedure: pre-job training</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	14

Incorrect result	Invalid result	The extraction buffer is contaminated	H4	Limited delay because the test can be quickly performed again	1	1	3	3	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories.</p> <p>ii) Buffer's open cap stability study report</p> <p>iii) Buffer preparation SOP: Preservative in the Buffer solution and the filled buffer was pasteurized. The buffer was filled in the clean room, and workshop environment control.</p> <p>iv) Buffer QC testing</p> <p>v) Training management procedure: pre-job training</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	15
Contamination Hazard	Contamination Hazard	The non-intergrated extraction tube falls and the buffer/specimen pours. (Option 2&3)	H5	User get contact with poured buffer/specimen and get infected	3	1	3	9	Work station is provided to place the non-intergrated extraction tube.	3	1	2	6	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	16

Contamination Hazard	Contamination Hazard	The sterile swab is contaminated	H5	Patient's nostril get contact with non-sterile swab and get infected	3	2	2	12	<p>Manufacturing process under EN ISO 13485:2016 certification:</p> <p>i) Purchase management procedure: the qualification of supplier and CE certificate of sterile swab was inspected.</p> <p>ii) Incoming material inspection procedure: Incoming QC inspect each lot of sterile swab.</p> <p>iii) Material specification of sterile swab</p> <p>iv) Training management procedure: pre-job training</p> <p>v) Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production.</p> <p>vi) Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.</p>	3	2	1	6	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	17
Incorrect result	False positive	Use test, buffer and/or control after expired date	H6	Mental stress for patient (temporary discomfort)	1	1	3	3	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests</p> <p>ii) Prescribed storage conditions are provided on the product labels.</p> <p>iii) The shelf life is determined according to accelerated stability study result. The real time stability study and simulated shipping stability study is being studied.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	18

Incorrect result	False negative	Use test, buffer and/or control after expired date	H6	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	19
Incorrect result	Invalid result	Use test, buffer and/or control after expired date	H6	Limited delay because the test can be quickly performed again	1	1	3	3	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	20
Incorrect result	Delayed result	The test is used twice	H7	Limited delay because the test can be quickly performed again	1	1	1	1	1	1	1	1	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	21

Incorrect result	False positive	The operator collect throat speicmen instead of nasopharynx. Incorrect sample type	H8	Mental stress for patient (temporary discomfort)	1	1	2	2	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	22
Incorrect result	False negative	The operator collect throat speicmen instead of nasopharynx. Incorrect sample type	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.	2	2	1	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	23

Incorrect result	False negative	The operator is not well trained for nasopharynx specimen collection and can not collect enough specimen while collection.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.	2	2	1	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	24
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Incorrect result	False negative	VTM containing guanidinium is used for specimen storage and antigen in swab gets deteriorated.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	PI states do not use VTM should not contain guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate)	2	1	2	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>]	25
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Incorrect result	False negative	Specimen is diluted by VTM which cause false negative result.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	PI states that minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen.	2	1	3	6	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	26
Incorrect result	False positive	The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.	H8	Mental stress for patient (temporary discomfort)	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	27

Incorrect result	False negative	The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was studied and output into Package Insert.	2	1	2	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	28
Incorrect result	Invalid result	The storage condition of Swabs in VTM is beyond the expected storage condition and deteriorated.	H8	Limited delay because the test can be quickly performed again	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The VTM specimen storage condition was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	29

Incorrect result	False positive	The specimen is stored beyond the expected storage condition and deteriorated.	H8	Mental stress for patient (temporary discomfort)	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	30
Incorrect result	False negative	The specimen is stored beyond the expected storage condition and deteriorated.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.	2	2	1	4	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	31

Incorrect result	Invalid result	The specimen is stored beyond the expected storage condition and deteriorated.	H8	Limited delay because the test can be quickly performed again	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	32
Incorrect result	False negative	The swab specimen and the extraction buffer are not well mixed and cause false negative result. (Option 1)	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	The corrected operate step to mix is detaled in PI with illustration.	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	33

Incorrect result	False positive	The specimen after extraction were improperly stored and deteriorated.(Option1&2&3)	H8	Mental stress for patient (temporary discomfort)	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	34
Incorrect result	False negative	The specimen after extraction were improperly stored and deteriorated.(Option1&2&3)	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.	2	2	1	4	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	35

Incorrect result	Invalid result	The specimen after extraction were improperly stored and deteriorated.(Option1&2&3)	H8	Limited delay because the test can be quickly performed again	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) The specimen stability after extraction was studied and output into Package Insert.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	36
Incorrect result	False positive	The VTM containing the swab specimen does not reach room temperature.	H8	Mental stress for patient (temporary discomfort)	1	1	3	3	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	37

Incorrect result	False negative	The VTM containing the swab specimen does not reach room temperature.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	2	1	3	6	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	38
Incorrect result	Invalid result	The VTM containing the swab specimen does not reach room temperature.	H8	Limited delay because the test can be quickly performed again	1	1	3	3	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	39

Incorrect result	False positive	The test or extracted specimen is not equilibrate to room temperature.	H8	Mental stress for patient (temporary discomfort)	1	1	3	3	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	40
Incorrect result	False negative	The test or extracted specimen is not equilibrate to room temperature.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	41

Incorrect result	Invalid result	The test or extracted specimen is not equilibrate to room temperature.	H8	Limited delay because the test can be quickly performed again	1	1	3	3	i) Describe and bold in Package Insert that allowing the test or extracted specimen to equilibrate to room temperature prior to testing. ii) Operation environment is verified during design control.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	42
Incorrect result	False positive	The VTM specimen added into the extraction tube is too much or not enough.	H8	Mental stress for patient (temporary discomfort)	1	1	3	3	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	43

Incorrect result	False negative	The VTM specimen added into the extraction tube is too much or not enough.	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.	2	1	2	4	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	44
Incorrect result	False positive	The extraction buffer added into the extraction tube is too much or not enough. (Option 2&3)	H8	Mental stress for patient (temporary discomfort)	1	1	3	3	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	45

Incorrect result	False negative	The extraction buffer added into the extraction tube is too much or not enough. (Option 2&3)	H8	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	i) The sample volume flex and operation method is verified and validated. ii) The specimen collection method is detailed in Package Insert.	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	46
Insufficient Training	False positive	Operator doesn't read PI completely before use	H9	Mental stress for patient (temporary discomfort)	1	1	3	3	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	47

Insufficient Training	False negative	Operator doesn't read PI completely before use	H9	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	48
Insufficient Training	Invalid result	Operator doesn't read PI completely before use	H9	Limited delay because the test can be quickly performed again	1	1	3	3	Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	49

Insufficient Training	Contamination hazard	The swab is not disposed according to legal regulation and cause other person infected. (Option 1&2&3)	H9	Hospital personnel might come in contact with contaminated test or accessories. Infection of hospital personnel	3	1	3	9	It is the responsibility of the hospital that the rules within the hospital are followed	3	1	2	6	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	50
Insufficient Training	Contamination hazard	User does not follow the disposal of biohazard of the institution.	H9	Hospital personnel might come in contact with contaminated test or accessories. Infection of hospital personnel	3	2	2	12	It is the responsibility of the hospital that the rules within the hospital are followed	3	2	1	6	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	51

Incorrect result	False positive	Package's insert not reviewed for full compliance with IVD & EN ISO	H10	Mental stress for patient (temporary discomfort)	1	1	3	3	Package insert of the test was reviewed under the scope of risk management and usability evaluation.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	52
Incorrect result	False negative	Package's insert not reviewed for full compliance with IVD & EN ISO	H10	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	Package insert of the test was reviewed under the scope of risk management and usability evaluation.	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	53

Incorrect result	Invalid result	Package's insert not reviewed for full compliance with IVD & EN ISO	H10	Limited delay because the test can be quickly performed again	1	1	3	3	Package insert of the test was reviewed under the scope of risk management and usability evaluation.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	54
Incorrect result	False positive	Operation instructions is too complex for the user to get the exact information from the PI.	H11	Mental stress for patient (temporary discomfort)	1	1	2	2	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iv) The operation illustration is presented in Package Insert. 	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	55

Incorrect result	False negative	Operation instructions is too complex for the user to get the exact information from the PI.	H11	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iv) The operation illustration is presented in Package Insert. 	2	2	1	4	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	56
Incorrect result	Invalid result	Operation instructions is too complex for the user to get the exact information from the PI.	H11	Limited delay because the test can be quickly performed again	1	1	2	2	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Simplify and verify operation steps based on design control procedure. iii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iv) The operation illustration is presented in Package Insert. 	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	57

Incorrect result	False positive	User distraction leads to operational errors.	H12	Mental stress for patient (temporary discomfort)	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	58
Incorrect result	False negative	User distraction leads to operational errors.	H12	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	59
Incorrect result	Invalid result	User distraction leads to operational errors.	H12	Limited delay because the test can be quickly performed again	1	1	2	2	i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	60

Contamination Hazard	Contamination hazard	User distraction leads to sample leakage. laboratory personnel get infected.	H13	Hospital personnel might come in contact with contaminated test accessories. Infection of hospital personnel	3	2	2	12	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests.</p> <p>ii) It is the responsibility of the laboratory that the rules within the laboratory are followed.</p>	3	2	2	12	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	61
Incorrect result	False positive	User doesn't use the accessories provided in kit	H14	Mental stress for patient (temporary discomfort)	1	1	2	2	<p>i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation.</p> <p>ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	62

Incorrect result	False negative	User doesn't use the accessories provided in kit	H14	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation. ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	63
Incorrect result	Invalid result	User doesn't use the accessories provided in kit	H14	Limited delay because the test can be quickly performed again	1	1	2	2	i) Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation. ii) In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	64
Incorrect result	False positive	User read the result beyond the recommended time frame	H15	Mental stress for patient (temporary discomfort)	1	1	2	2	i) The reading time flex is studied during design control process. ii) The proper reading time is put in Package Insert.	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	65

Incorrect result	False positive	The complex instructions lead to interpretation errors and false results.	H15	Mental stress for patient (temporary discomfort)	1	1	2	2	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iii) The illustration of results interpretation is presented in Package Insert. 	1	1	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>]	66
Incorrect result	False negative	The complex instructions lead to interpretation errors and false results.	H15	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	<ul style="list-style-type: none"> i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests. ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation. iii) The illustration of results interpretation is presented in Package Insert. 	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>]	67

Incorrect result	Invalid result	The complex instructions lead to interpretation errors and false results.	H15	Limited delay because the test can be quickly performed again	1	1	2	2	<p>i) Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests.</p> <p>ii) Package insert of the test was reviewed under the scope of risk management and usability evaluation.</p> <p>iii) The illustration of results interpretation is presented in Package Insert.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	68
Incorrect result	False positive	The operator collect throat speicmen instead of nasopharynx. Incorrect sample type	H16	Mental stress for patient (temporary discomfort)	1	1	2	2	<p>i) The correct sample type is indicated in product name and Package Insert.</p> <p>ii) The correct sampling method is described in Package Insert.</p>	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	69

Incorrect result	False negative	The operator collect throat speicmen instead of nasopharynx. Incorrect sample type	H16	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	2	8	i) The correct sample type is indicated in product name and Package Insert. ii) The correct sampling method is described in Package Insert.	2	2	2	8	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	70
Incorrect result	False positive	The device is misused by people other than trained clinical laboratory professionals	H16	Mental stress for patient (temporary discomfort)	1	1	3	3	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for tratment or patient management decisions.	1	1	2	2	Yes [<input type="checkbox"/>] No [<input checked="" type="checkbox"/>	71

Incorrect result	False negative	The device is misused by people other than trained clinical laboratory professionals .	H16	Patient is not diagnosed as infected by Covid-19 but still treated for the severe symptoms + Because the patient is not recognized as a Covid-19 patient, he/she is treated in the wrong department, infecting other patients	2	2	3	12	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient management decisions.	2	2	2	8	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	72
Incorrect result	Invalid result	The device is misused by people other than trained clinical laboratory professionals .	H16	Limited delay because the test can be quickly performed again	1	1	3	3	i) Tests are exclusively sold to professional users. Lay-users do not have access to the test. ii) Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient management decisions.	1	2	2	2	Yes [<input type="checkbox"/> No [<input checked="" type="checkbox"/>	73

7.3 Usability Risk Evaluation

7.3.1 Risk Assessment Levels

Level	Safety Risk	Description
Red	Unacceptable	Risks in this region exceed the risk acceptability criterion and cannot be tolerated. Resolution Required – Risk reduction, re-design, do not release.
Yellow	AFAP As Far as possible	Risks are evaluated or reduced to As Far As Possible. According to Directive 98/79/EC and EN ISO 14971:2012, all risks have to be reduced as far as possible without there being room for economic considerations.
Green	Acceptable	Risk is considered to be negligible compared to the risk of other hazards.

7.3.2 Risk Acceptability

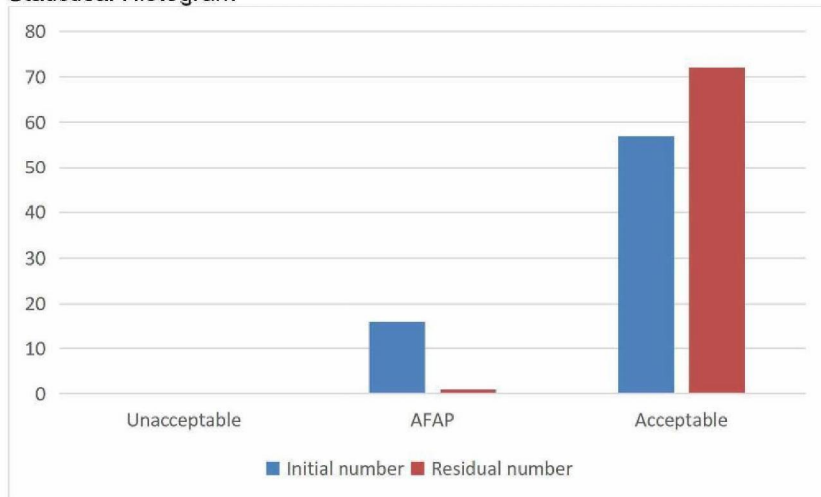
Detection & Probability	18	21	24	27
	15	18	21	24
	12	15	18	21
	9	12	15	18
	6	9	12	15
	3	6	9	12
	Negligible	Marginal	Critical	Catastrophic
	Severity			

7.3.3 Risk Evaluation

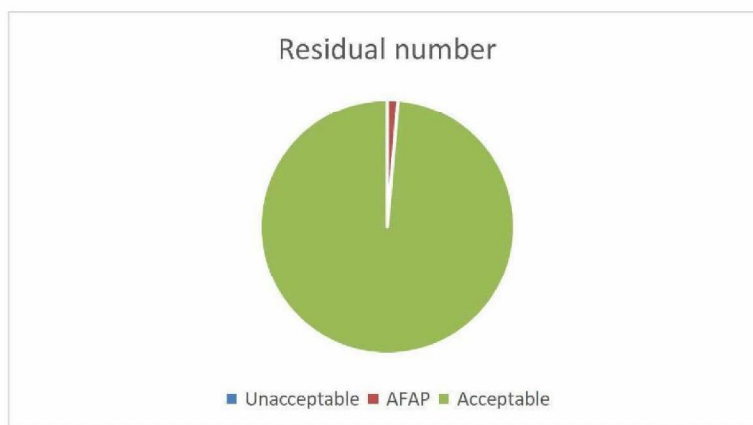
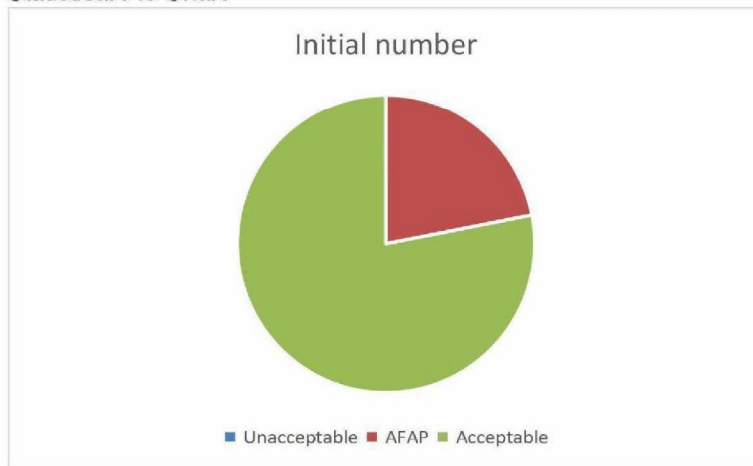
Total Risk Number:73

Risk Levels	Initial number	Residual number	Percentage of total risks
Unacceptable	0	0	0
AFAP	16	1	0
Acceptable	57	72	98.6%

Statistical Histogram



Statistical Pie Chart



7.4 Usability Risk Control

7.4.1 Risk Control Option Analysis

Control measure	Taken During Product Development	Taken During Manufacturing	Taken after Manufacturing	Protective Measures	Is it technically possible to decrease the risk further? Justify
Material specification of sterile swab	Yes	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Training management procedure: pre-job training	-	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Semi-product inspection procedure: the QC department inspects the functional performance of semi-product and only qualified semi-products would be used for final product production.	-	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Final product inspection procedure and COA: the QC department is responsible for the inspection of functional performance and physical appearance of final product and QA will release the qualified product for sale after double check.	-	-	Yes	-	No. Procedure complies with EN ISO 13485:2016 and EN 13975:2003
Instruction in PI says that the test should be discarded according to local regulations.	Yes	-	-	Yes	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011

Tests are intended to be used by clinical laboratory professionals who are trained to perform in vitro tests.	Yes	-	-	Yes	No. This measure prevents the test to be used by non clinical lab professional users.
The professionals should wear protective clothing such as lab coats, disposable gloves and eye protections when specimen are assayed.	-	-	-	Yes	No. The clinical lab professionals know how to protect themselves by wearing.
It is the responsibility of the laboratory that the rules within the laboratory are followed.	-	-	-	Yes	No. The clinical lab professionals know GLP rules.
The symbol for single use is provided on the labels.	Yes	-	-	-	No. Device development under the requirements of EN ISO 15223-1:2016
Purchase management procedure	-	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Incoming material inspection procedure	-	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Material specification of foil pouch	Yes	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Manufacture verification control	-	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Prescribed storage conditions are provided on the product labels	Yes	Yes	-	-	No. Device development under the requirements

					of EN ISO 15223-1:2016
The storage and transportation condition is being studied in real time stability study and simulated shipping studies.	Yes	-	-	-	No. Device development under the requirements of EN ISO 23640:2015
Buffer accelerated stability study report: the accelerated stability study of the test kit including buffer is conducted to study the shelf life of the test cassette and its accessories.	Yes	-	-	-	No. Device development under the requirements of EN ISO 23640:2015
Buffer's open cap stability study report	Yes	-	-	-	No. Device development under the requirements of EN ISO 23640:2015
Buffer preparation SOP: Preservative in the Buffer solution. The buffer was filled in the clean room, and workshop environment control.	Yes	Yes	-	-	No. Procedure complies with EN ISO 13485:2016
Buffer QC testing	-	Yes	Yes	-	No. Procedure complies with EN ISO 13485:2016
The shelf life is determined according to accelerated stability study result. The real time stability study and simulated shipping stability study is being studied."	Yes	-	-	-	No. Device development under the requirements of EN ISO 23640:2015

The correct sample type is indicated in product name and Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
The correct sampling method is described in Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of 18113-1:2011 and EN ISO 18113-2:2011
The sample volume flex and operation method is verified and validated.	Yes	-	-	-	No. Device development under the requirements of EN ISO 13485:2016
The specimen collection method is detailed in Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
The specimen stability was studied and output into Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
The specimen stability after extraction was studied and output into Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
Describe and bold in Package Insert that allowing the test or extracted	Yes	-	-	Yes	No. Device development under the requirements

specimen to equilibrate to room temperature prior to testing.					of EN ISO 13485:2016, EN ISO 18113-1:2011 and EN ISO 18113-2:2011
Operation environment is verified during design control.	Yes	-	-	-	No. Device development under the requirements of EN ISO 13485:2016
Describe in "Precaution" of Package Insert that Package Insert must be read completely before performing the test.		-	-	Yes	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
Package insert of the test was reviewed under the scope of risk management and usability evaluation.	Yes	-	-	-	No. Device development under the requirements of EN ISO 14971:2012 and IEC 62366-1:2015
Simplify and verify operation steps based on design control procedure.	Yes	-	-	-	No. Device development under the requirements of EN ISO 13485:2016
The operation illustration is presented in Package Insert.	Yes	-	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
Instruction in PI that only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation.	Yes	-	-	Yes	No. There is no other way to restrict the use of other buffers.

In "Precautions" and "Limitations" indicates not store specimens in VTM and not test with extracted specimens for PCR tests.		-	-	Yes	No. There is no other way to restrict the use of other buffers.
The reading time flex is studied during design control process.	Yes	-	-	-	No. Device development under the requirements of EN ISO 13485:2016
The proper reading time is put in Package Insert.	Yes	Yes	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
The interpretation of results is detailed in Package Insert.	Yes	-	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
The illustration of results interpretation is presented in Package Insert.		-	-	-	No. Device development under the requirements of EN ISO 18113-1:2011 and EN ISO 18113-2:2011
Tests are exclusively sold to professional users. Lay-users do not have access to the test.	Yes	-	Yes	-	No. There is no other way to prevent non-intended user from the tests.
Instruction in "Intended use" of PI that test result should not be used as the sole basis for treatment or patient		-	-	Yes	No. There is no other way to impose restriction on intended use.

management decisions.					
The open cap stability of buffer is studied.	Yes	-	-	Yes	No. There is no other way to verify the buffer stability.
Work station is provided to place the non-intergrated extraction tube.	Yes	-	-	Yes	No. The work station can prevent specimen or buffer pour
PI states do not use VTM containing guanidinium (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate)	Yes	-	-	Yes	No. There is no other way to restrict the use of VTM.
PI states that minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen.	Yes	-	-	Yes	No. The acceptable dilution in VTM sample has been verified.
The VTM specimen storage condition was studied and output into Package Insert.	Yes	-	-	Yes	No. There is no other way to study the VTM specimen storage condition and stability.
The corrected operate step to mix is detailed in PI with illustration.	Yes	-	-	Yes	No. There is no more way to make the instruction more clear.
Describe and bold in Package Insert that allowing the test or extracted	Yes	-	-	Yes	No. This step is clear to user.

specimen to equilibrate to room temperature prior to testing.					
Operation environment is verified during design control.	Yes	-	-	Yes	No. Device development under the requirements of EN ISO 13485:2016
The sample volume flex and operation method is verified and validated.	Yes	-	-	Yes	No. Device development under the requirements of EN ISO 13485:2016
The specimen collection method is detailed in Package Insert.	Yes	-	-	Yes	No. Device development under the requirements of EN ISO 13485:2016

7.5 Usability Residual Risk Evaluation

Residual Risks	Acceptable?	Justification
False positive	Yes	The severity of the risk is negligible
False negative	Yes	Though the severity of the risk can be very high, since the test is intended for professional use and the professionals in the field are aware of the diagnostic limitations of antigen tests, the probability that the user will use a different technology to confirm (not) the results is very high
Delayed results /Invalid result	Yes	The severity of the risk is negligible
Contamination hazard	Yes	Based on the current knowledge, it is assumed that hospitals are able to control the risk of bio-hazards as related incidents are not known

7.6 Usability Risk / Benefit Analysis

Residual Risks	Highest Risk Score	Benefits	Highest Benefit Value Score (Low, Medium, High)
False Positive	Acceptable	Quick access to results	High benefit value
		High diagnostic sensitivity for the target patients	High benefit value
		Easy to use	High benefit value
False Negative	Acceptable	Quick access to results	High benefit value
		High diagnostic specificity for the target patients	High benefit value
		Easy to use	High benefit value
Delayed Results /Invalid result	Acceptable	Quick access to results	High benefit value
		Easy to use	High benefit value
Contamination hazard	Acceptable	Easy to use	High benefit value
		Quick access to results	High benefit value
		High diagnostic sensitivity for the target patients	High benefit value
		High diagnostic specificity for the target patients	High benefit value
		Easy to use	High benefit value

7.6.1 Usability Conclusion

Risk for false positive, false negative, delayed results, contamination hazard are considered acceptable whereas the tests offers four (4) high value benefit.

7.7 Risks Arising from Risk Control Measures

No new risk is generated from the risk control measures.

7.8 Completeness of Usability Risk Control

We herewith state that to the best of our knowledge, all usability risks associated with the COVID-19 Antigen Rapid Test have been identified, evaluated and reduced to acceptable level.

7.9 Evaluation of Overall Residual Risk Acceptability of Usability Evaluation

Overall, the risks associated with the usability have been reduced to acceptable and the test provides four (4) high value benefits. Therefore, we consider that the test benefits outweigh the test risks when used as claimed by the manufacturer.

8 Accompanying document

The most important accompanying document for this product is Package Insert.

9 Training and materials for training

The clinical laboratory users should be trained to collect Nasopharyngeal Swab specimen and get familiar with the use of this product. This package insert must be read completely before performing the test.

10 Usability Evaluation Report

	Provided or not	Location
Usability engineering process	Provided	Section 2
- application specification	Provided	Section 2.1
- frequently used functions	Provided	Section 2.1.2.1
- identification of hazards and hazardous situations related to usability	Provided	Section 2.1.3
- primary operating functions	Provided	Section 2.1.2
- usability specification	Provided	Section 2.3
- usability validation plan	Provided	Section 3
- user interface design and implementation	Provided	Section 4
- usability verification	Provided	Section 5
- usability validation	Provided	Section 6
Residual risk	Provided	Section 7
Information for safety .	Provided	Section 2.2.1
Accompanying document	Provided	Section 8
Training and materials for training	Provided	Section 9

Change History Summary

Revision	Description	By	Effective Date
V01	Initial version	Nancy Sun	2020.08.04
V02	Update according to EN 62366:2008	Nancy Sun	2020.10.02