WIZ BIOTECH

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Risk Management Report

Product name	SARS-CoV-2 Antigen Rapid Test (Saliva)
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Contents

Chapter 1 Summary

1. Purpose and scope of application

This reports is a report on risk management of the SARS-CoV-2 Antigen Rapid Test (Saliva), This reports on the risk management of SARS-CoV-2 Antigen Rapid Test (Saliva), Ensure that risk management plan has been completed successfully, and through to the product's risk analysis, risk evaluation and risk control, and the acceptability of an integrated residual risk evaluation, and to the production and production information gain method after review, confirm the product risk has carried on the effective management, and control in the acceptable range.

This report applies to SARS-CoV-2 Antigen Rapid Test (Saliva). The product is in the Design and development completed stage. It is mainly for home self-test occasions related risk management.

2. Product Description

2.1 Products Information

Product name: SARS-CoV-2 Antigen Rapid Test (Saliva)

2.2 Intended use

SARS-CoV-2 Antigen Rapid Test (Saliva) is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein) in Saliva sample from patients with suspected SARS-CoV-2 infection within the first 7 days after symptom onset in vitro.

The positive results indicate the existence of SARS-CoV-2 antigen. It should be further diagnosed by combining the patient's history and other diagnostic information. The positive results do not exclude bacterial infection or other viral infection. Pathogens detected are not necessarily the main cause of disease symptoms.

The negative results do not exclude SARS-CoV-2 infection, and should not be the only basis for treatment or patient management decisions (including infection control decisions). Pay attention to the patient's recent contact history, medical history and the same signs and symptoms of COVID-19, if necessary, it is recommended to confirm these samples by PCR test for patient management.

It is for laboratory personnel who have received professional guidance or training and have professional knowledge of in vitro diagnosis, also for relevant personnel who have received infection control or nursing training. At the same time, it is also applicable to the home self-test of non-professionals.

2.3 The principle of product

SARS-CoV-2 Antigen Rapid Test (Saliva) employs immuno-lateral chromatography technology for the qualitative detection of antigens. The colloidal gold particles labeled with the anti-SARS-CoV-2 antibody 1 and Rabbit IgG are fixed on the conjugation pad. The anti-SARS-CoV-2 antibody 2 is bound on the test line (T

line) of nitrocellulose membrane. The Goat Anti-Rabbit IgG is bound on the control line (C line) of nitrocellulose membrane. When the concentration of SARS-CoV-2 in the specimen is higher than the minimum detection limit, which can conjugate with the anti-SARS-CoV-2 antibody 1 labeled with colloidal gold particles to form a complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the anti-SARS-CoV-2 antibody 2 bound on the test line, forming "Au-Anti-SARS-CoV-2 antibody 1-(SARS-CoV-2) -Anti-SARS-CoV-2 antibody 2 complex. These complexes are deposited to display color as the determination of antigen positive, the Rabbit IgG labeled with colloidal gold particles conjugate with the Goat Anti-Rabbit IgG and deposit to display color as the determination of quality of the control line. When the concentration of SARS-CoV-2 in the specimen is lower than the minimum detection limit or the specimen have no SARS-CoV-2, the complexes only deposit and display color in the control line.

3. Brief description of the risk management plan and implementation

Our company has planned the risk management activities for this product, established the acceptable risk criteria, arranged the risk management activities during the product design development phase, the responsibilities and authority of the persons involved in the risk management activities, and the evaluation requirements for the acquisition of post-production information.

The company formed a risk management team to identify the project's head of risk management. To ensure that the project's risk management activities are carried out effectively in accordance with the risk management plan.

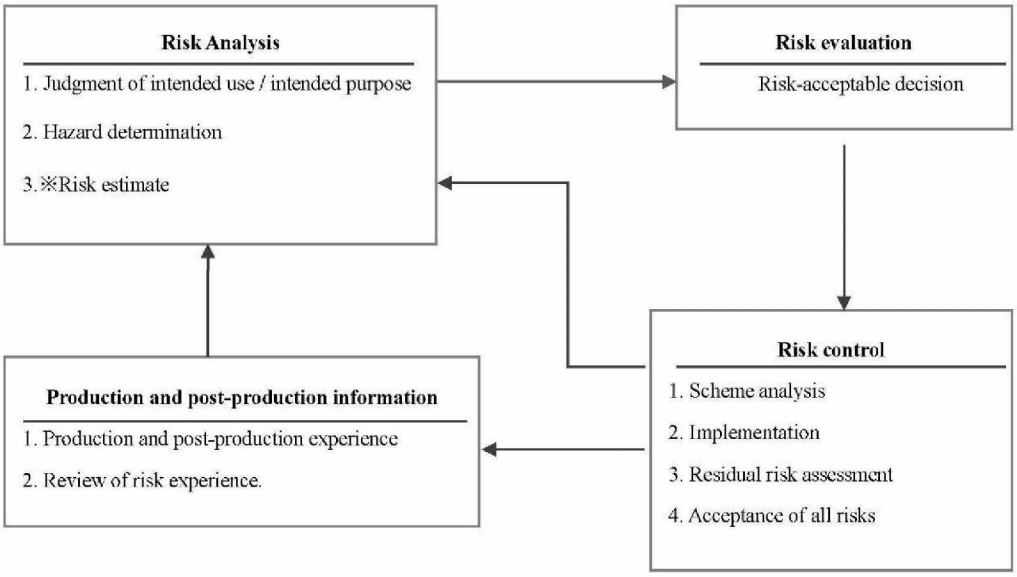
During the product design and project development phase, the risk management team conducted a risk management review and formed the relevant risk management documentation.

4. The group of risk assessment and their responsibilities

Assessor	Department	Duties and responsibilities
5.1.2e	General Manager	The team leader presides over the review work. Ensure the continued suitability and effectiveness of risk management activities.
	Management Representative	The team member is responsible for the implementation of the alert system, and the discovery of safety or quality accident to take effective action quickly, when issuing advice notice, mentioned safety of patients, users and others.
	Technology Department	The team member is responsible for the formulation of risk management plans, organizing risk analysis and risk evaluation activities to ensure that risk is reduced to acceptable levels during the design phase of the product.
	Producing Department	The team member is responsible for the implementation and verification of risk control measures and put forward the review opinions on the production verification process.

5.1.2e	Quality Department	The team member supervises the implementation and validation of risk control measures and the collection of risk management documents, and makes reviews on quality control.
	Sales Department	The team member provides review opinions on marketing sales and customer feedback, is responsible for the implementation of after-sales supervision procedures, and reviews product information obtained post-production.

5. Risk management flow char



Chapter 2 Risk Management Review Input

1. Acceptability Criteria of Risk

The Risk Management Team evaluated the risk assessment/risk acceptability guidelines established in the Company's Risk Management Control Procedures and concluded that the risk acceptable guidelines based on the SARS-CoV-2 Antigen Rapid Test (Saliva) in their risk management activities remained at their original level.

1.1 The level of severity

Level	Code	System risk definition
Catastrophic	S1	Results in patient death
Serious	S2	Results in permanent impairment or life-threatening injury
Medium	S3	Results in temporary injury or impairment requiring professional medical intervention
Minor	S4	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	S5	Inconvenience or temporary discomfort

1.2 Probability of damage

Level	Code	Probability range (per year)
Frequent	P1	>1
Probable	P2	$1–10^{-2}$
Occasional	P3	$10^{-2}–10^{-4}$
Remote	P4	$10^{-4}–10^{-6}$
Improbable	P5	$<10^{-6}$

1.3 Risk assessment criteria

Probability		Severity Categories				
		S5	S4	S3	S2	S1
		Negligible	Minor	Medium	Serious	Catastrophic
Frequent	P1	R	U	U	U	U
Probable	P2	R	R	R	U	U

Occasional	P3	A	R	R	R	U
Remote	P4	A	A	R	R	R
Improbable	P5	A	A	A	A	R

Note:

A: Acceptable risk;

R: Reasonably feasible to reduce risk;

U: An unacceptable risk which without through risk/benefit analysis.

2. Basis

2.1 Standard:

ISO 14971-2019 Medical devices — Application of risk management to medical devices

ISO / TR 24971:2020 Medical devices — Guidance on the application of ISO 14971

2.2 Internal reagent risk analysis management system

2.3 Instruction for use.

Chapter 3 Risk Management Review

1. Completion of risk management plan

The person in charge of project risk management manages the obtained production and post-production information. When necessary, the risk management team carries out activities to implement dynamic risk management. Based on the requires of standard, the enterprise judged the expected use and safety-related characteristics of the SARS-CoV-2 Antigen Rapid Test (Saliva), and passed the manufacturing and expected use of the SARS-CoV-2 Antigen Rapid Test (Saliva), intended use, reasonably foreseeable misuse and final disposal, etc. to raise a series of questions, gradually understand the safety characteristics of the product, and lay the foundation for further risk analysis. For a detailed list of product safety features, please refer to "Appendix 1: Expected Uses of Medical Devices, Expected Purposes, and Records of Safety-Related Features".

In the hazard analysis, reasonable and foreseeable conditions are considered, which include normal conditions and fault conditions; the consequences or damage to the hazards include: harm to patients, harm to the environment, etc. For the initial hazard analysis table of the product, see "Appendix 2: Initial Correlation Analysis of the SARS-CoV-2 Antigen Rapid Test (Saliva)", including the sequence of foreseeable events, the hazardous situation and the possible damage and initial risk control case analysis.

According to the regulations, the risks involved in the SARS-CoV-2 Antigen Rapid Test (Saliva) were analyzed, and the risk (U) and reasonable and feasible reduction (R) that were determined to be unacceptable without risk / benefit analysis (R) the potential hazards require certain control measures to further reduce the risk. For details, please refer to "Appendix 3: the SARS-CoV-2 Antigen Rapid Test (Saliva) Product Risk Evaluation and Risk Control Measures Record Sheet".

The review team checks the status of the risk management plan and confirms that the product risk management plan has been completed.

2. Evaluation of overall residual risk acceptability

The review team analyzes all the residual risks and considers the impact of all the residual risks. The result is that the residual risks of the product are acceptable, as follows:

1) Are there conflicting requirements for risk control for individual risks?
Conclusion: the contradiction in existing risk control is Undiscovered.

2) Review of warnings (including whether there are too many warnings?)
The warning signs are clear and conform to standards.

3) Review of specifications (including whether there is any inconsistency, and whether it is difficult to comply with).
The Instruction for use conforms to the medical device manual and label management regulations, as well as

the product specific safety standard requirements. The relevant product safety description is clear and easy to understand, and easy for the user to read.

4) Professional conclusion

Conclusion: The residual risks of the product are acceptable.

3. Information about production and post-production

3.1 The production and post-production information acquisition methods are as follows:

Information about production and post-production	Acquisition method / timing	information
Changes in regulations (e.g. standards)	Collect regularly online.	
Adverse events (internal) Adverse events (external)	Adverse event report. Regular collection of adverse event reports online.	
Notice/Recall	According to the notice / recall process.	
Supervision and random inspection by regulatory authorities	Collect regularly online. Supervision spot check report.	
Customer feedback information (such as clinician evaluation, customer complaints, complaints, etc.)	Customer information summary. Investigation (analysis) and review results.	
Product changes	Product change review.	
Unqualified products	Quality analysis of purchased products. Supplier Evaluation Form. Corrective and preventive measures. Summarize quality information such as product inspection.	

3.2 Refer to the "production and post-production information acquisition method table" for information collection. The review panel assesses the suitability and effectiveness of the "production and post-production access to information table". The project risk management leader shall manage the obtained production and post-production information. If necessary, the risk management team shall carry out activities to implement dynamic risk management.

Chapter 4 Conclusions of risk management review

After reviewing the product of the SARS-CoV-2 Antigen Rapid Test (Saliva), the risk management review panel concludes that:

- Risk management has been properly implemented;
- Integrated residual risks are acceptable;
- Appropriate methods are available to collect relevant production and post-production information.

All residual risks of the SARS-CoV-2 Antigen Rapid Test (Saliva) is used in home self-testing are within the acceptable range of risk acceptance criteria, and the benefits exceed the risks.

Appendix 1: Expected Uses of Medical Devices, Expected Purposes, and Records of Safety-Related Features

Product Name	SARS-CoV-2 Antigen Rapid Test (Saliva)	
Questions	**Characteristics**	**Hazard**
1 What is the intended use and how is the medical device to be used?	The kit is intended for the qualitative detection of SARS-CoV-2 Antigen in Saliva specimens in vitro. The product can be used for home self-testing or professional testing occasions.	The test result is inaccurate.
2 Is the medical device intended to be implanted?	No	N/A
3 Is the medical device intended to be in contact with the patient or other persons?	No	N/A
4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Test device, ☐Extraction Solution tube (including treatment solution), Disposable sampling rod, and Disposable sample container.	The surface of the test card and the sample extraction tube is plastic, which will not cause other damage.
5 Is energy delivered to or extracted from the patient?	No	N/A
6 Are substances delivered to or extracted from the patient?	No	N/A
7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No	N/A
8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No, This product is a one-time use and does not require sterilization. Reagents can be used directly when they return to room temperature.	N/A
9 Is the medical device intended to be routinely cleaned and disinfected by the user?	No This product is for disposable use.	N/A
10 Is the medical device intended to modify the patient environment?	No	N/A
11 Are measurements taken?	No	N/A

12 Is the medical device interpretative?	No	N/A
13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No	N/A
14 Are there unwanted outputs of energy or substances?	Waste generation.	Waste pollutes the environment or people.
15 Is the medical device susceptible to environmental influences?	Yes, inappropriate storage conditions.	Use outside the environmental requirements set out in the instructions to produce incorrect test results.
16 Does the medical device influence the environment?	No	N/A
17 Are there essential consumables or accessories associated with the medical device?	Yes, basic consumables include sample dilutions, Disposable sampling rod and should meet the appropriate requirements.	Irregular operations result in incorrect detection results.
18 Is maintenance or calibration necessary?	No	N/A
19 Does the medical device contain software?	No	N/A
20 Does the medical device have a restricted shelf-life?	The kit is 24 months shelf-life from the date of manufacture.	Test with products that exceed the expiration date to produce the wrong results.
21 Are there any delayed or long-term use effects?	The kit can give a result within 20 minutes.	Test with products that exceed the expiration date to produce the wrong results.
22 To what mechanical forces will the medical device be subjected?	Yes, the aluminum foil bag needs to be torn along the tearing opening.	The wrong operation prevented the foil bag from being torn apart.
23 What determines the lifetime of the medical device?	The reaction of antibodies and adsorption materials. Conditions for device storage.	Unstable raw materials can lead to ineffective products. Failure to store the reagent in accordance with the instructions, resulting in failure

		of the reagent or incorrect test results.
24 Is the medical device intended for single use?	Single use, unused products have sealed packaging, easy to distinguish.	Repeated use of reagents can lead to the wrong result.
25 Is safe decommissioning or disposal of the medical device necessary?	Used products should be sterilized to prevent biological contamination.	Improper storage and transportation results in invalid products.
26 Does installation or use of the medical device require special training or special skills?	No special training required. Operate according to the instruction.	Wrong operation led to wrong inspection results.
27 How will information for safe use be provided?	Provide instructions to users directly. Instruction of Use, label.	Undetailed instructions lead to incorrect operation.
28 Will new manufacturing processes need to be established or introduced?	No	N/A
29 Is successful application of the medical device critically dependent on human factors such as the user interface?	Yes, failure to follow the instructions may result in errors.	The wrong result.
29.1 Can the user interface design features contribute to use error?	No	N/A
29.2 Is the medical device used in an environment where distractions can cause use error?	Yes, the operator may ignore the amount of sample, the judgment time of the result, etc.	The wrong result.
29.3 Does the medical device have connecting parts or accessories?	No	N/A
29.4 Does the medical device have a control interface?	No	N/A
29.5 Does the medical device display information?	The positive results indicate the existence of SARS-CoV-2 antigen. It should be further diagnosed by combining the patient's history and other diagnostic information. The positive results do not exclude bacterial infection or other viral infection. Pathogens detected are not necessarily the main cause of disease symptoms.	Misunderstanding the meaning of the test results.

	The negative results do not exclude SARS-CoV-2 infection, and should not be the only basis for treatment or patient management decisions (including infection control decisions). Pay attention to the patient's recent contact history, medical history and the same signs and symptoms of COVID-19, if necessary, it is recommended to confirm these samples by PCR test for patient management. The invalid result indicates that the procedure is not correct or that the test device is out of date or invalid. In this case, the Instruction of Use should be read carefully and repeat the test with a new test device.	
29.6 Is the medical device controlled by a menu?	No	N/A
29.7 Will the medical device be used by persons with special needs?	No	N/A
29.8 Can the user interface be used to initiate user actions?	No	N/A
30 Does the medical device use an alarm system?	Quality control line can be used as an alarm prompt.	Failure of quality control line leads to failure of warning.
31 In what way(s) might the medical device be deliberately misused?	To the speed, not looking at the instruction of use leads to the wrong operation.	Cause the wrong result.
32 Does the medical device hold data critical to patient care?	No	N/A
33 Is the medical device intended to be mobile or portable?	No	N/A
34 Does the use of the medical device depend on essential performance?	No	N/A
35 Is there a degree of autonomy in the use of medical devices?	No	N/A
36 Do medical devices produce outputs as inputs to determine clinical operations?	No, the test results of the kit are for clinicians' reference only, and should not be used as the only basis for clinical	N/A

	diagnosis. The clinical diagnosis of the patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory test results and treatment responses, etc.	
37 Possible risk analysis in expected use:	The product can be used for home self-testing or professional testing occasions.	The user did not understand the instruction of use or did not follow the instruction of use, resulting in incorrect detection results
38 What is the clinical reference value?	To Auxiliary diagnose whether the subject is infected with SARS-CoV-2.	Results in temporary injury or impairment not requiring professional medical intervention.
39 Does the measurement result need to be analyzed?	The positive results indicate the existence of SARS-CoV-2 antigen. It should be further diagnosed by combining the patient's history and other diagnostic information. The positive results do not exclude bacterial infection or other viral infection. Pathogens detected are not necessarily the main cause of disease symptoms. The negative results do not exclude SARS-CoV-2 infection, and should not be the only basis for treatment or patient management decisions (including infection control decisions). Pay attention to the patient's recent contact history, medical history and the same signs and symptoms of COVID-19, if necessary, it is recommended to confirm these samples by PCR test for patient management.	The wrong perception leads to the wrong processing.
40 Indications for use	Follow the reagent instruction for use for proper operation and use.	Misuse, resulting in incorrect detection results.
41 How is the threshold or reference range determined?	According to the ability of the kit to detect the virus.	Results in temporary injury or impairment not requiring professional

		medical intervention.
42 What are the main causes of intra-batch errors and how to control them?	Unstable production processes lead to the generation of in-batch deviations. Strengthen the control of the production process.	Unqualified products result in incorrect test results
43 What are the main causes of batch differences and how to control them?	The instability of the raw material leads to batch difference. Strengthen the quality control of raw materials.	Unqualified products result in incorrect test results
44 Whether special production environment control is required?	Strict control of temperature and humidity is required.	Products produced under an unsuitable production environment are not qualified.
45 What is the packaging method of the kit (small package, medium package, large package)?	The small package of aluminum foil bag is packed in the middle of the carton packaging; the outside is corrugated paper packaging.	Packing damage leads to product failure.
46 How to transport the kit? Whether the transportation process will affect the performance of the kit?	Normal transport.	High transport temperature results in shorter product life.
47 Does the kit have special requirements for testing samples? How do samples need to be prepared?	Prepare according to the sample collection method in the instructions. It should be noted that the sample may be infectious.	Inadequate protection leads to infection. The incorrect location of the sample collection leads to false negative results.
48 Whether the possible interfering substances in the sample will affect the determination results?	Cross reactions caused by other organisms.	The appearance of false positive results.
49 Identification of possible use errors	Improper use of reagents, instruments or sample substrates, and simplified testing procedures, neglect of instrument maintenance, and poor environmental conditions can lead to user/operator errors.	The wrong use resulted in the wrong detection results.
50 Incorrect sample storage conditions or too long lead to product failure.	If the samples cannot be tested in time, they should be kept in strict accordance with the instructions.	Incorrect sample storage conditions or too long lead to product failure.

51 Whether the different time of sample collection for patients will affect the determination results	Samples should be collected and processed in strict accordance with the instructions.	The wrong use resulted in the wrong detection results.
52 The same product, the same batch, different packaging of the same component can be mixed.	No	N/A
53 Performance characteristics of quantitative examination procedures	No, this product is a qualitative product and does not have quantitative characteristics.	N/A
54 Performance characteristics of qualitative examination procedures	There is an internal control line in the kit to prove the effectiveness of the product, but there will be false positive, false negative or uncertain results in the product testing process due to a variety of reasons.	The qualitative procedure only expects to detect the presence or absence of analysis, which can lead to incorrect diagnosis or delayed treatment and damage to the patient.
55 Dependability characteristics	The physician must make a comprehensive determination based on clinical characteristics, exposure history and clinical laboratory examination results, not as the sole or dependent basis.	The doctor simply based on the test results of the reagent, and did not base the false diagnosis on other evidence.
56 Ancillary patient information	Clinical touch history of the patient.	Incorrect or deliberately concealed touch history leads to incorrect diagnostic results.

Appendix 2: Initial Correlation Analysis of the SARS-CoV-2 Antigen Rapid Test (Saliva)

Hazard type	Predictable events and sequence of events	hazardous situation	The resulting consequence or damage	Initial risk control plan analysis
Energy hazards (Heat)	Product is stored or used at temperatures below 2℃ or above 30℃.	Product failure.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	The temperature requirements for the transportation and use of the product are indicated in the outer packing and the product operation manual.
Energy hazards (Mechanical energy)	Collisions and extrusions during transport or use.	Product failure due to damage.	The results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Design has taken into account product packaging protection and product external force resistance.
Biological hazards	After the product is used, the waste with biological hazard is not disposed of according to the regulations.	Users, laboratory personnel and others are exposed to waste	Causing human infection; The environment is destroyed.	Product specifications indicate that the product is potentially infectious.
Biological hazards	No corresponding protective measures were taken during the process of sample handling, transportation, and storage and testing.	The sample was contaminated by extraneous contamination	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Product instructions express sample requirements.
Chemical hazards	Direct discharge into sewers without treatment.	Pollution of the environment.	Cause pollution to the environment.	Develop a standard management system, strict acid or alkaline water discharge requirements.
Chemical hazards	Producing non-degradable plastic waste that may be biologically or chemically hazardous.	Together with household waste disposal.	Cause pollution to the environment.	Sign a solid waste disposal agreement with relevant professional institutions to regulate the disposal of plastic waste.
Operational hazards (function)	There are differences between batches of key raw materials	The sensitivity and specificity of products produced from different batches of raw materials vary greatly, and the products are unstable and cannot meet the standard requirements.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Strengthen the inspection and verification of key raw materials. Don't change the manufacturer
Operational hazards (function)	The production equipment is in abnormal working condition	The product is not up to standard.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	To strengthen the monitoring of production equipment; Strict ex-factory inspection
Operational hazards (function)	There is no specification of the process; Or not in accordance with the standard specifications to follow the process procedures	The product is not up to standard.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Formulate product process procedures and manufacture products in strict accordance with the procedures.
Operational hazards (function)	Production process changes.	Impact on product quality, not up to the standard requirements.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Strictly control the process change procedure

Operational hazards (function)	The critical raw materials do not meet the requirements; There is no specification of the process; Or not in accordance with the standard specifications to follow the process procedures	Result in inaccurate test results	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Formulate product process procedures; Manufacture products in strict accordance with regulations; Strengthening inspection and verification of key raw materials; Strengthen outgoing inspection
Operational hazards (function)	Product aluminum foil bag leakage; Lack of desiccant.	Invalid product.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Double check.
Operational hazards (function)	The product is not stored in accordance with the prescribed conditions.	Invalid product.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	The product specification states the storage conditions of the product.
Operational hazards (function)	The product is stored beyond the specified period of time.	Invalid product.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	The product specification states the shelf life of the product.
Operational hazard (use error)	The experimenter simplified, tried to optimize, improve, and omit the test procedures described in the Instructions for Use of the product.	Result in incorrect test results	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Operate strictly in accordance with the Instructions for Use of the product.
Operational hazard (use error)	The samples and methods collected are incorrect.	Results of test results that do not correspond to the actual.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Instructions for Use clearly state the sample collection requirements.
Operational hazard (use error)	Missing reagent components, labels, instructions, etc.	Affecting the normal use of the product or resulting in incorrect substitution and use of the product.	Delays in treatment or test results are not consistent with the actual results, resulting in inappropriate medical behavior	Strengthen supervision and inspection of product packaging process
Operational hazard (use error)	The ingredients of different batches are mixed.	Cause the test result to be inconsistent with the actual result	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Instructions for Use clearly states that different batches of products cannot be mixed
Operational hazard (use error)	Ingredients were not allowed to return to room temperature before testing	Cause the test result to be inconsistent with the actual result	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Instructions for Use states that the product should be restored to room temperature before testing
Operational hazard (use error)	The amount of sample added does not meet the requirements of the specification	Cause the test result to be inconsistent with the actual result	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Operate strictly in accordance with the Instructions for Use of the product.
Operational hazard (use error)	The results were not interpreted in the time required by the instructions.	Cause the test result to be inconsistent with the actual result	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Operate strictly in accordance with the Instructions for Use of the product.
Operational hazard (use error)	The final diagnosis of the patient is only based on the test results, not in combination with the clinical, by the doctor to make a comprehensive judgment.	Cause the test result to be inconsistent with the actual result	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	The product specification states that the product is intended to assist in diagnosis only.

Operational hazard (use error)	Fail to operate according to the instructions for Use	operation mistake	Incorrect test results occurred.	Operate following the the instructions for Use strictly.
Operational hazard (use error)	Non-professional users eat the diluent by mistake.	Stomach pain, diarrhea, and even poisoning may occur.	It can lead to personal health problems and, in severe cases, life threatening.	The Instructions for Use clearly state that diluent is not to be edible.
Operational hazard (use error)	The sample required by the specification was not used for testing	Use the wrong sample	Incorrect test results occurred.	Use the correct sample strictly.
Information hazard	The operation instruction is not complete.	The inspectors adopted irregular testing procedures.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Improve the Instructions for Use of the product.
Information hazard	The matters needing attention in the process of use are not clearly or not adequately expressed.	Inspectors have adopted an irregular inspection process or procedure and made incorrect judgments.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Improve the Instructions for Use of the product.
Information hazard	The instructions are too complicated.	The inspectors misunderstood or did not fully understand the testing process, and adopted the non-standard testing process or steps, and made incorrect discrimination.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Simplify overly complex product specifications to make the presentation easy to understand.
Information hazard	The limitations of the test results are not adequately expressed.	Leads to incorrect judgment.	The test results are not consistent with the actual situation, resulting in inappropriate medical behavior.	Improve the Instructions for Use of the product.

Appendix 3: The SARS-CoV-2 Antigen Rapid Test (Saliva) Product Risk Evaluation and Risk Control Measures Record Sheet

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
Personal infection and environmental pollution	Users, experimenters and others are exposed to medical waste	After use, medical waste with biohazard has not been disposed according to the regulations.	S2	P3	R	The instruction warns that the waste may be contagious and the necessity of wearing glove. And the waste shall be discarded in special container.	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Sample is polluted	There hasn't protective measures during sample dealing, transportation, storage and testing.	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
Cause human injury	Acid or alkaline is sprinkled on the skin, Oral cavity and eyes, etc.	Use the Extraction solution unreasonably	S3	P3	R	Product Instructions for Use indicate safety information	See Instructions for Use	S3	P5	A	No.
Cause human injury	Non-professional users eat the diluent by mistake.	It can lead to personal health problems and, in severe cases, life threatening.	S3	P4	R	The Instructions for Use clearly state that diluent is not to be edible.	See Instructions for Use	S3	P5	A	No.
Cause environment polluted	It is discharged into the sewer without disposal	Acid or alkali is produced in the manufacture of the product.	S2	P2	U	Make standard management system to control the discharge of acid or alkali.	Follow Environment protection and unharmful Emission Principle	S2	P5	A	No.
Cause environment polluted	Mix with the household waste	The production of non-degradable plastic waste that may have biological or chemical hazards	S2	P2	U	Sign solid waste disposal agreement with relevant professional organizations to regulate the disposal of plastic waste.	Follow Environment Protection and Unharmful Emission Principle	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
The test result is inaccurate, which leads to improper medical behavior.	The product is not up to standard.	The production equipment is in abnormal working condition	S2	P3	R	Control production equipment and outgoing inspection	Put a label on the production equipment and use it only on right situation.	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	The product is not up to standard.	No standard specification, or not in accordance with the standard specification	S2	P3	R	Draft the product process procedures, and manufacture products in strict accordance with the procedures	Standard operating procedures for the entire process have been formulated, and corresponding reviewers are required.	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Cause false positive and false negative test results.	The process has changed	S2	P3	R	Take charge of the process change seriously	See Principle of Process Control	S2	P5	A	No.
Delayed treatment	Invalid product	The aluminum foil bag leaks air and lacks desiccant.	S2	P3	R	Reviewed by two person	Every process shall be reviewed by two people.	S2	P5	A	No.
Delayed treatment	Invalid product	The product is not stored at standard conditions.	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
Delayed treatment	Invalid product	The product is stored beyond its expiry date	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Cause incorrect result	The experimenter simplifies, optimizes, improves, and omits the test procedures described in instruction	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
The test result is inaccurate, which leads to improper medical behavior.	Cause incorrect result	Use different product Test device or invalid card	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Cause incorrect result	Incorrect samples and sampling way	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Cause incorrect result	The disposal, transportation and storage of the samples do not conform to the Instructions for Use	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Lead to incorrect test results	Mixing of product ingredients from different batches	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Lead to incorrect test results	The product is not restored to room temperature before testing.	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Cause incorrect test results	The sample volume does not meet the requirements of the Instructions for Use.	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Cause incorrect test results	Failure to Observed the results within the required time	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Cause incorrect test results	The test result cannot be obtained accurately.	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior	Cause incorrect test results	The final diagnosis of the patient depends only on the test results, and does not	S2	P2	U	Product Instructions for Use indicate safety information	See Instructions for Use	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
		combine with clinically relevant symptoms to make a comprehensive judgment by the doctor									
The test result does not match the actual situation, leading to inappropriate medical behavior	Inspectors used non-standard testing procedures, resulting in incorrect testing results	The content of the Instructions for Use is incomplete	S2	P2	U	Improve Instructions for Use	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Inspectors used non-standard testing procedures, Made an incorrect judgment	The precautions during use are not clearly expressed or not fully expressed	S2	P2	U	Improve Instructions for Use	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Cause incorrect test results	Inappropriate description of product performance characteristics (including labeling)	S2	P2	U	Correctly describe product performance characteristics (including identification)	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Inspectors used non-standard testing procedures, Made an incorrect judgment	Did not strictly follow the operation steps in the product manual	S2	P2	U	Operate strictly in accordance with the requirements of the Instructions for Use	See Instructions for Use	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
The test result does not match the actual situation, leading to inappropriate medical behavior	Inspectors used non-standard supporting products, resulting in judgment results that were inconsistent with the actual situation.	Other product requirements used in conjunction with the product are incorrectly stated.	S2	P2	U	Correctly indicate the specifications of other products used with this product in the product manual	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	The inspector misunderstands or does not fully understand the inspection process, adopts an irregular inspection process or procedure, and makes an incorrect judgment	Operating instructions are too complicated	S2	P2	U	Simplify overly complex Instructions for Use to make the expression easy to understand	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Cause incorrect result	The limitations of the test results are not fully expressed	S2	P2	U	Improve Instructions for Use	See Instructions for Use	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	The control region has no reaction.	The critical materials have not been controlled well.	S2	P2	U	The quality control line system of reagents has been optimized during product R&D. The Instruction for use has specified how to use the reagent, and the absence of a quality control line indicates that the result is	See product R&D report and Instruction for use.	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
						invalid. At the same time, it was pointed out that in this case, a new card was needed for testing.					
The test result does not match the actual situation, leading to inappropriate medical behavior	The sensibility and specificity cannot meet the requirements	The storage conditions of raw materials are wrong.	S2	P3	R	The validity period and storage conditions of raw materials are verified by the technical department and the production department.	See material storage management system.	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	The sensibility and specificity cannot meet the requirements	The labeling cannot get the desired result.	S2	P2	U	Strictly follow the production and quality inspection procedures	See standard operation procedure of label	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	The sensibility and specificity cannot meet the requirements	Mark particles is up to the standard	S2	P3	R	Strengthen material inspection.	See standard operating procedures for the evaluation of Mark particles.	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Incorrect result	There is not conformity with the instruction and package.	S2	P3	R	Product according to the procedure	See product production process chart	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	The results of debugging are inconsistent	The experimenters make mistakes.	S2	P3	R	Follow the procedure strictly	Follow standard operation procedure of experiment	S2	P5	A	No.
The test result does not match the actual situation, leading to inappropriate medical behavior	Incorrect result	Wrong QC sample used; QC process is not suitable	S2	P4	R	Use correct QC specimens and QC procedures	Follow standard operating procedures for product quality inspection.	S2	P5	A	No.
The test result is inaccurate, which	Incorrect result	The labels are changed or missed.	S2	P3	R	The QC shall confirm the labels accurate	Follow standard operation	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
leads to improper medical behavior.						finally	procedure of product quality control				
The test result is inaccurate, which leads to improper medical behavior.	Invalid product	Improper storage conditions during	S2	P2	U	Experiment the product stability. There has stated the storage requirements in Instruction for use.	See product stability report and product Instruction for use.	S2	P5	A	No.
Delayed treatment	Product cannot be used or Invalid	Loss of reagent components	S2	P1	U	Reviewed by two persons	Follow standard operation procedure of production	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Use the product wrongly	The Instructions for use have been lost	S2	P2	U	Reviewed by two persons	Follow standard operation procedure of production	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	The sensibility and specificity cannot meet the requirements	The products are not restored to room temperature.	S2	P2	U	The condition of use is specified in instruction.	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Incorrect result	Sample collection and transport at irregular situation	S2	P2	U	How to Sample collection and transport the samples to be inspected are detailed in Instruction for use	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Incorrect result	Samples to be inspected are not stored as required.	S2	P2	U	There has stated the storage conditions in Instruction for use	See Instructions for Use	S2	P4	A	No.
User hazard	Incorrect result	The user is contaminated by biological materials	S3	P5	A	The instructions have informed the user that the reagent contains	/	S5	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
		(raw materials derived from animals) and/or chemical reagents in the reagents.				biological material. Moreover, these biological materials are controllable and guaranteed to contain no infectious antibodies.					
The test result is inaccurate, which leads to improper medical behavior.	Incorrect result	Too little sample volume (cannot complete chromatography)	S2	P2	U	There has confirmed the sample volume during the R&D and validation. And clearly inform in the Instructions for use.	See Instructions for Use	S2	P5	A	No.
Delay in treatment	False negative result	Too much sample volume (overflow)	S2	P2	U	There has confirmed the sample volume during the R&D and validation. And clearly inform in the Instructions for use.	See Instructions for Use	S2	P5	A	No.
User hazard	User Infection	The user comes into contact with the tested sample during or after the sample loading process	S2	P2	U	The Instructions for Use have warned users of the fact that the test sample is potentially infectious. The Instructions for Use recommends that users wear gloves to operate.	See Instructions for Use	S2	P5	A	No.
The test result is inaccurate, which leads to improper medical behavior.	Incorrect result	The membrane is contaminated by users.	S2	P3	U	There have warned users not to touch the membrane	See Instructions for Use	S2	P5	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
The test result is inaccurate, which leads to improper medical behavior.	Incorrect result	Cannot distinguish between quality control line and test line	S2	P2	U	The position of the quality control line and the test line are printed on the reagent card. Related information is also reflected in the instructions for use	see instructions for use	S2	P5	A	No.
Bystander pollution	Bystander infected with disease	Biological and/or chemical contamination occurs after discarding used reagents.	S2	P4	R	Personnel entering the laboratory must be restricted or authorized. The instructions warn about possible pollutants and explain the necessity of wearing gloves. Contaminated substances should be discarded in special containers.	see instructions for use	S2	P5	A	No.
Environmental hazard	It is harmful to the environment to discard harmful raw materials.	There exists the biological or chemical hazards after disposing the used Reagent	S2	P1	U	Potentially infectious substances are discarded in special containers. Raw materials do not have serious biological and/or chemical pollution and will not pollute the environment.	See Instructions for Use	S2	P5	A	No.
Environmental hazard	It is harmful to the environment to discard harmful raw	Dispose the test strips coated antibody	S4	P4	A	The raw material is controlled to ensure that there are no infectious antibodies,	See Instructions for Use	S5	P4	A	No.

Result or damage (failure effect)	Hazard situation (failure model)	Foreseeable event and sequence (failure reason)	Pre-processing risk assessment			Risk control measures		Post-processing risk assessment			Is there any new risk (yes, assess it/they)
			Definition		Risk assessment			Definition		Risk assessment	
			assessment	Validation		Initial plan	Validation	severity	probability		
	materials.					and the concentration of antibodies on the NC membrane is very low and dry.					
Environmental hazard	It is harmful to the environment to discard harmful raw materials.	Unrecoverable plastic	S4	P3	R	Use the recoverable plastic	See Instructions for Use	S5	P4	A	No.