Risk Management Report

Product: Rapid SARS-CoV-2 Antigen Test Card

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1. Overview

1.1 Product Description

1.1.1 Intended Use

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

1.1.2 Principle

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

1.1.3 Product Components

Product components include:

- Test line: SARS-CoV-2 antibody coated on nitrocellulose membrane;
- Control line: goat anti-mouse IgG polyclonal antibody coated on nitrocellulose membrane;
- Conjugate pad: colloidal gold conjugated SARS-CoV-2 antibody; and
- Sample extraction buffer.

1.2 Risk Management Scope

This risk management is applicable to all risk management activities during the life cycle of the product, including:

1) Design and development;
2) Product realization (purchasing, production and packing);
3) Delivery processes (shipping and installation);
4) Post-delivery (in use);
5) End-of-life (failure) disposal.

1.3 Risk Management Personnel and Responsibility

Department	Position
General Manager	Review Team Leader
Management Representative	Team Member
R&D (Project Leader)	Team Member
R&D (Head of R&D 1)	Team Member
Production	Team Member
Quality	Team Member
Sales	Team Member
Market Service	Team Member
International	Team Member
Purchasing	Team Member
Biomaterials	Team Member

2. Risk Evaluation Standards

2.1 Severity Level of Harm

Level	Code	Systematic Definition
Low	S1	No to minor injury
Medium	S2	Medium harm
Fatal	S3	Death or serious injury of 1 person
Catastrophic	S4	Multiple deaths or serious injuries

2.2 Probability Level of Harm Occurrence

Level	Code	Frequency*
Improbable	P1	$<10^{-6}$
Remote	P2	$<10^{-5} \geq 10^{-6}$
Rare	P3	$<10^{-4} \geq 10^{-5}$
Occasional	P4	$<10^{-3} \geq 10^{-4}$
Probable	P5	$<10^{-2} \geq 10^{-3}$
Frequent	P6	$\leq 10^{-1} \geq 10^{-2}$

*Note: For IVD reagents, the frequency refers to the probability of harm occurrence per test.

2.3 Risk Evaluation Criteria

Probability of Occurrence		Severity			
		Low (S1)	Medium (S2)	Fatal (S3)	Catastrophic (S4)
Frequent	P6	*	N/ACC	N/ACC	N/ACC
Probable	P5	*	*	N/ACC	N/ACC
Occasional	P4	*	*	*	N/ACC
Rare	P3	ACC	*	*	*
Remote	P2	ACC	ACC	*	*
Improbable	P1	ACC	ACC	ACC	ACC

Note: N/ACC – not acceptable; ACC – acceptable; * - practically as low as possible.

3. Identification of Characteristics Related to Safety

3.1 Determination of the Intended Use of Medical Device and Characteristics Related to Safety

With reference to YY/T 0316 / ISO14971 Annex C - Questions that can be used to identify medical device characteristics that could impact on safety

Question	Identification of Characteristic
C.2.1 What is the intended use and how is the medical device to be used? Factors that should be considered include: - what is the medical device's role relative to • diagnosis, prevention, monitoring, treatment or alleviation of disease, • compensation for injury or handicap or • replacement or modification of anatomy, or control of conception? - what are the indications for use (e.g. patient population)? - does the medical device sustain or support life? - is special intervention necessary in the case of failure of the medical device?	For the rapid qualitative determination of SARS-CoV-2 virus antigen in nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. The product is for non-professional personal use.
C.2.2 Is the medical device intended to be implanted? Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation.	No. The product is an in vitro diagnostic device.

C.2.3 Is the medical device intended to be in contact with the patient or other persons? Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact.	The test specimen is nasal swab. Contact between the user and product occurs mainly through: swab contact with patient during sample collection; taking out the test card from the package; using the test card to test nasal samples; disposal of used test kit as medical waste after test completion. The test process may involve direct contact with reagent components. The entire testing process takes about 15-20 min.
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device? Factors that should be considered include: - compatibility with relevant substances; - compatibility with tissues or body fluids; - whether characteristics relevant to safety are known; - is the device manufactured utilizing materials of animal origin? See YY/T 0316 (ISO14971) Annex I and ISO22442 series of standards	The test card consists of a molded plastic cassette lid and base and one test strip. The test strip consists of a backing card, nitrocellulose membrane, conjugate pad, and an absorbent pad. The nitrocellulose membrane contains SARS-CoV-2 antibody and goat anti-mouse IgG antibody, and the conjugate pad contains colloidal gold-conjugated SARS-CoV-2 antibody.
C.2.5 Is energy delivered to or extracted from the patient? Factors that should be considered include: - the type of energy transferred; - its control, quality, quantity, intensity and duration; - whether energy levels are higher than those currently used for similar devices.	No, the product uses nasal swab specimens.
C.2.6 Are substances delivered to or extracted from the patient? Factors that should be considered include whether the substance is delivered or extracted; whether it is a single substance or range of substances; the maximum and minimum transfer rates and control thereof.	Yes, the product uses human nasal swab specimens.

C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation? Factors that should be considered include the type of process and substance(s) processed (e.g. autotransfusion, dialysis, blood component or cell therapy processing).	No. The product is for single-use, and no biological materials are processed.
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable? Factors that should be considered include - whether the medical device is intended for single use or re-use packaging; - shelf-life issues; - limitation on the number of re-use cycles; - method of product sterilization; - the impact of other sterilization methods not intended by the manufacturer.	No, the test card is non-sterile. The product is designed for single-use only.
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user? Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the device.	No, the product does not need to be cleaned or disinfected.
C.2.10 Is the medical device intended to modify the patient environment? Factors that should be considered include: - temperature; - humidity; - atmospheric gas composition; - pressure; - light.	No, the product does not affect patient environment such as temperature, humidity, atmospheric gas composition, pressure or light.
C.2.11 Are measurements taken? Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	Yes, the qualitative result in the test window is determined visually by the operator.

C.2.12 Is the medical device interpretative? Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.	No, the product is a qualitative test and does not require data processing.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies? Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.	Yes, the product has to be used in conjunction with the supplied swab for testing.
C.2.14 Are there unwanted outputs of energy or substances? Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields. Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product. Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.	Yes, the used reagents should be disposed of as medical wastes.
C.2.15 Is the medical device susceptible to environmental influences? Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference.	Yes, the test card should be stored, shipped and used under 4-30°C. Every test card is sealed in an aluminum foil pouch with desiccant to prevent moisture. Users are required to place the test card on a horizontal and undisturbed lab surface during use.
C.2.16 Does the medical device influence the environment? Factors that should be considered include: - the effects on power and cooling supplies; - emission of toxic materials; - the generation of electromagnetic disturbance.	The test card itself does not influence the environment. After addition of human nasal swab specimens, the test card must be handled properly as a potentially infectious medical waste.

C.2.17 Are there essential consumables or accessories associated with the medical device? Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.	Yes, every test kit provides the sample extraction buffer and sterilized swab.
C.2.18 Is maintenance or calibration necessary? Factors that should be considered include: - whether maintenance or calibration are to be carried out by the operator or user or by a specialist; - are special substances or equipment necessary for proper maintenance or calibration?	No. The product is an in vitro diagnostic device and does not need maintenance or calibration.
C.2.19 Does the medical device contain software? Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.	No. The product is an in vitro diagnostic device and does not contain software.
C.2.20 Does the medical device have a restricted shelf-life? Factors that should be considered include labelling or indicators and the disposal of such medical devices when the expiration date is reached.	Yes. The product has a restricted shelf-life that's indicated on the aluminum foil pouch and packing box.
C.2.21 Are there any delayed or long-term use effects? Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.	No, the product is for single-use only.
C.2.22 To what mechanical forces will the medical device be subjected? Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.	The product is subjected to mechanical forces from the shipping environment and possible accidental drop from table top to the floor.
C.2.23 What determines the lifetime of the medical device? Factors that should be considered include ageing and battery depletion.	The shelf-life stability study helps to determine the product lifetime (shelf-life).
C.2.24 Is the medical device intended for single use? Factors that should be considered include: does the medical device self-destruct after use? Is it obvious that the device has been used?	Yes, the test card is designed for single use. Used products are obvious.
C.2.25 Is safe decommissioning or disposal of the medical device necessary? Factors that should be considered include the waste products	Yes, the test card is handled and properly disposed of as a potentially infectious

that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous material, or is the material recyclable?	medical waste.
C.2.26 Does installation or use of the medical device require special training or special skills? Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.	Test card operation is described in the provided instructions for use (IFU). No special training is required.
C.2.27 How will information for safe use be provided? Factors that should be considered include: - whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training; - commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills; - based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.	Information for safe use is provided in the IFU.
C.2.28 Will new manufacturing processes need to be established or introduced? Factors that should be considered include new technology or a new scale of production.	No, the company has established production processes for similar products.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error? Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of color coding. See IEC 60601-1-6 for additional guidance on usability and IEC 60601-1-8 for guidance on alarms.	The product can be used by directly adding sample to the sample well and the results in the test window can be observed visually by naked eyes. All procedures can be well described.

C.2.29.2 Is the medical device used in an environment where distractions can cause use error? Factors that should be considered include: - the consequence of use error; - whether the distractions are commonplace; - whether the user can be disturbed by an infrequent distraction.	The test card is used by non-professionals, and needs to take into account outside distractions and disturbances.
C.2.29.3 Does the medical device have connecting parts or accessories? Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.	No, the product does not have connecting parts.
C.2.29.4 Does the medical device have a control interface? Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.	No. The product is an in vitro diagnostic device and does not have a control interface.
C.2.29.5 Does the medical device display information? Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information.	Yes, the test result is displayed in the test window. The interpretation of results might be affected by the user's visual acuity.
C.2.29.6 Is the medical device controlled by a menu? Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	No. The product is a diagnostic device and is not controlled by a menu.
C.2.29.7 Will the medical device be used by persons with special needs? Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?	The product is for non-professional use. Children need to be tested by adults.

C.2.29.8 Can the user interface be used to initiate user actions? Factors that should be considered include the possibility of initiating a deliberate action for the user to enter a controlled operation	No. The product is an in vitro diagnostic device and does not have a user interface.
C.2.30 Does the medical device use an alarm system? Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8.	No. The product is an in vitro diagnostic device and does not have an alarm system.
C.2.31 In what way(s) might the medical device be deliberately misused? Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.	The provided IFU should limit misuse, such as inability of the operators to provide proper sample types, inappropriate amount of sample addition to the test card, or incorrect timing for the interpretation of results.
C.2.32 Does the medical device hold data critical to patient care? Factors that should be considered include the consequence of the data being modified or corrupted.	No, the product does not have a data storage function.
C.2.33 Is the medical device intended to be mobile or portable? Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.	The product is intended to be portable and should be placed on a smooth horizontal lab surface during use.
C.2.34 Does the use of the medical device depend on essential performance? Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems.	Yes. Correct sample collection, sample volume, and interpreting results within the correct time frames are critical.

3.2 Determination of the Intended Use of In vitro Diagnostic Device and Characteristics Related to Safety

With reference to YY/T 0316/ ISO14971 Annex H - Guidance on risk management for in vitro diagnostic medical devices

Questions	Identification of Characteristics
H.2.1 Identification of intended uses H.2.1.1 General IVD medical devices for laboratory or point of care examinations have two users: (1) an operator who performs the examination, and (2) a healthcare provider who receives, interprets and acts on the results. In the case of IVD medical devices for self-testing, the patient could be the only user. Identification of intended uses should consider the objective intent of the manufacturer with respect to both elements of use: (1) use of the IVD medical device to produce an examination result, and (2) use of the examination result to reach a decision on the diagnosis, treatment or monitoring of a patient.	The users of the products are non-professionals. The intended use of the product is to provide test results.
H.2.1.2 Intended use The intended use of an IVD medical device can include the measurement system, analyte, kind-of-property, sample matrix, examination procedure (qualitative, semi-quantitative or quantitative), type of operator and site of use.	For the rapid qualitative determination of SARS-CoV-2 virus antigen in nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. The product is for non-professional personal use. Operators are non-professionals. The site of use is personal living environment.
H.2.1.3 Indications for use The indications for use include the medical applications and patient populations for which the IVD medical device is intended.	For the rapid qualitative determination of SARS-CoV-2 virus antigen in nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. The product is for non-professional personal use.
H.2.2 Identification of possible use errors H.2.2.1 Use errors Use errors include actions not intended by the manufacturer, such as procedure shortcuts, optimization attempts and improvisation, as well as omissions of actions intended by the manufacturer, such as those prescribed in the	Potential use errors: - Errors in sample collection; - Use of expired or invalid test kits; - Incorrect time of result

instructions for use. H.2.2.2 Examples of possible use errors by laboratory personnel The following are examples of possible use errors in the laboratory. These examples are intended to illustrate the principles and are not an exhaustive checklist: - use of an IVD medical device with an inappropriate calibrator, reagent, instrument or sample matrix; - attempt to optimize an examination procedure in order to improve its performance characteristics; - abbreviation of an examination procedure (taking "shortcuts"); - neglect of instrument maintenance; - disabling or failing to enable safety features; - operation in adverse environmental conditions.	interpretation (too early or too late); - Incorrect sample type; - Incorrect sample dilution ratio; - Incorrect volume of sample addition; - Reuse of test device.
H.2.2.3 Examples of possible use errors by healthcare providers The following are examples of possible use errors by a healthcare provider. These examples are intended to illustrate the principles and are not an exhaustive checklist: - use of IVD examination results in order to screen a population for a disease when the examination procedure is intended for diagnosing the disease (the performance characteristics might not be appropriate for population screening); - use of IVD examination results in order to diagnose a disease when the examination procedure is intended for monitoring a condition (the performance characteristics might not be appropriate for diagnosis); - use of IVD examination results for a new clinical application that is not claimed by the manufacturer (the performance characteristics might not be appropriate for the new application).	Potential use errors: - Diagnosis of COVID-19 based solely on the test results; - Incorrect intended use.
H.2.2.4 Examples of possible use errors by patients in self-testing The following are examples of possible use errors by a patient during self-testing. These examples are intended to illustrate the principles and are not an exhaustive checklist: - using insufficient volume of sample; - failure to insert a reagent module properly; - dividing reagent strips (e.g. to reduce cost);	The product is for self-testing. The following errors may occur: - using insufficient volume of sample; - failure to insert a reagent module properly; - dividing reagent strips

- disabling or failing to enable safety features; - storing reagent in inappropriate conditions.	(e.g. to reduce cost); - failure to dispose of reagents after use as required; - incorrect time of result interpretation (too early or too late); - incorrect sample type; - incorrect sample dilution ratio; - incorrect volume of sample addition; - reuse of test device; - storing reagent in inappropriate conditions.
H.2.3 Identification of characteristics related to safety H.2.3.1 General In addition to chemical, mechanical, electrical and biological characteristics in common with other medical devices, IVD medical devices have performance characteristics that determine the accuracy of the examination results. Failure to meet the performance characteristics required for a specific medical use could result in a hazardous situation that should be evaluated for risk to patients.	Performance characteristics that do not meet specific requirements for medical use could result in hazardous situations.
H.2.3.2 Performance characteristics of quantitative examination procedures Quantitative examination procedures are intended to determine the amount or concentration of an analyte. Results are reported on an interval scale. The main analytical performance characteristics of quantitative examination procedures are precision (imprecision), trueness (bias), analytical specificity and quantitation limit. Performance requirements depend on the medical application. A falsely high or falsely low result can lead to an incorrect diagnosis or delayed treatment, and the consequent harm to the patient could depend on the concentration of analyte and magnitude of bias.	Not applicable. The product is a qualitative test device.
H.2.3.3 Performance characteristics of qualitative examination procedures Qualitative examination procedures are only intended to detect the presence or absence of an analyte. Results are reported as positive, negative or inconclusive. Performance of qualitative examination procedures is generally expressed	The main performance characteristics of the product are sensitivity and specificity. False positives or false negatives can lead to incorrect diagnosis or delayed treatment and harm

in terms of diagnostic sensitivity and specificity. A positive result when the analyte is absent or a negative result when the analyte is present can lead to incorrect diagnosis or delayed treatment and to harm to the patient.	to the patient.
H.2.3.4 Dependability characteristics When physicians depend on IVD examination results to help make urgent medical decisions, such as in an intensive critical care setting, timely results can be as important as accurate results. Failure to produce a result when it is needed could result in a hazardous situation.	Not applicable. The product test results cannot help make urgent medical decisions.
H.2.3.5 Ancillary patient information In some cases, examination results can require demographic information about the patient, as well as pertinent information about the sample or its examination for proper interpretation. Patient identification, sample identification, sample type, sample description, measurement units, reference intervals, age, gender, and genetic factors are examples of such information, which might be entered manually by a laboratory analyst or automatically by a laboratory computer system. If an IVD medical device is designed to report ancillary information with the examination result, failure to associate the correct information with the examination result could affect the proper interpretation of the result and lead to a hazardous situation.	Not applicable. The product design does not ancillary information with the examination result.
H.2.4 Identification of known and foreseeable hazards H.2.4.1 Hazards to the patient From the standpoint of a patient, an IVD examination result is a hazard if it might lead to (1) inappropriate medical action that could result in injury or death, or (2) failure to take appropriate medical action that could prevent injury or death. An incorrect or delayed IVD examination result can be caused by an IVD medical device malfunction, which is the initiating hazard in a foreseeable sequence of events leading to a hazardous situation. The identification of hazards and sequences of events are intended to help the manufacturer compile a comprehensive list of hazardous situations. The manufacturer determines what is considered a hazard during the risk analysis. A hazardous situation can occur if a healthcare provider receives an incorrect result and acts upon it. A hazardous situation can also occur if a result is not available when it is needed. In the case of devices for self-testing, a hazardous situation can occur when an incorrect result is obtained by a patient, or a result is not available when it is needed. For quantitative examination procedures, a result can be	Incorrect results may cause or contribute to misdiagnosis due to the potential for harmful medical intervention or delay.

considered incorrect if the difference from a correct value exceeds a limit based on clinical utility. The clinical significance of an incorrect result can depend on the magnitude of the difference between the measured value and a correct value, as well as the physiological status of the patient (e.g., hypoglycaemic or hyperglycaemic). For qualitative examination procedures, in which only a positive or negative result is provided, (e.g., HIV and pregnancy examinations), results are either correct or incorrect. The following hazards could cause or contribute to misdiagnosis with the potential for harmful medical intervention or delays: - incorrect results (see H.2.3.2 and H.2.3.3); - delayed results (see H.2.3.4); - incorrect information accompanying the result (see H.2.3.5).	
H.2.4.2 Relationship to performance characteristics Failure to meet specifications for any of the performance characteristics related to safety (see H.2.3) should be evaluated in order to determine if a hazardous situation could result.	Failure to meet specifications for any of the performance characteristics related to safety should be evaluated in order to determine if a hazardous situation could result.
H.2.4.3 Identifying hazards in fault conditions Failure modes that can result in not meeting the performance characteristics required for medical use (e.g., trueness, precision, specificity, etc.) should be considered when identifying IVD hazards in fault conditions; e.g., - within-batch inhomogeneity; - batch-to-batch inconsistency; - non-traceable calibrator value; - non-commutable calibrator; - non-specificity (e.g., interfering factors); - sample or reagent carryover; - measurement imprecision (instrument-related); - stability failures (storage, transportation, in-use). Failure modes that can result in delayed results in urgent care situations should be considered when identifying IVD hazards in fault conditions; e.g., - unstable reagent;	Failure modes that can result in not meeting the performance characteristics required for medical use include: - within-batch inhomogeneity; - batch-to-batch inconsistency; - sensitivity decrease; - non-specificity (e.g., interfering factors); - stability failures (storage, transportation, in-use); - package failures.

- hardware/software failure; - packaging failure. Failure modes that can result in incorrect patient information should be considered when identifying IVD hazards in fault conditions; e.g., - incorrect patient name or identification number; - incorrect birth date or age; - incorrect gender.	
H.2.4.4 Identifying hazards in normal use Incorrect results can also occur in normal use, even when the IVD medical device meets the performance characteristics claimed by the manufacturer. This could be due to the uncertainty of examination results, the biological variability of patient samples, choice of a cut-off value or other factors. An incorrect result in normal use could lead to a hazardous situation for an individual patient; e.g., - imperfect discrimination between positive and negative samples: qualitative examination procedures typically exhibit inherent false negative and false positive rates, caused in part by uncertainties associated with determination of a suitable cut-off value; - uncertainty of measurement: state-of-the-art technology can limit the precision of quantitative IVD medical devices, such as glucose monitoring systems described in ISO 15197; if performance criteria only require 95 % of the results to meet a specified limit based on medical utility, then up to 5 % of the individual results are allowed to fall outside the limit; - unexpected influence of other constituents (interfering factors) in the sample matrix: new drugs, biochemical metabolites, heterophilic antibodies and sample preparation materials can affect the performance characteristics of an IVD examination procedure; - natural heterogeneity of the analyte: antibodies and other proteins in blood samples are mixtures of different isoforms; published performance characteristics of an IVD examination procedure might not apply to all components of the mixture.	An incorrect result in normal use could lead to a hazardous situation such as: - imperfect discrimination between positive and negative samples: qualitative examination procedures typically exhibit inherent false negative and false positive rates; - unexpected influence of other constituents (interfering factors) in the sample matrix: SARS or parainfluenza virus can affect the performance characteristics of an IVD examination procedure.

4. Risk Analysis and Evaluation

The R&D department has organized relevant personnel to conduct risk analysis using the failure mode and effects analysis (FMEA) on the following aspects:

1) Risk analysis on the users, patients, manufacturing risks, etc. during the input phase of

design development (see Table 3);

2) Risk analysis of the production processes (suppliers, material procurement, process control, process safety information) and other aspects during the trial production phase (see Table 4);
3) Risk analysis of the labels and IFU (See Table 5);
4) Risk analysis of transport, storage, and customer use before marketing (see Table 6).

5. Risk Control and Verification Results

Hazard #	Original No.	Potential Causes (Sequence of Events)	Before Control			Risk Control	After Control			
			Severity	Occurrence	Risk Index	Risk Mitigation Measures	Relevant Document or Record	Occurrence	Risk Index	Acceptability
1. Erroneous Test Results										
R1	A1	Sample is SARS-CoV-2 positive or contains other source(s) of infection leading to false positives.	S3	P4	M	1) Test kit design should avoid sample contact with the user; 2) All samples indicated in the IFU should be handled as potentially infectious.	IFU 07AG60SELF-003-03-12-DE	P1	L	ACC
R2	D3	Viral load below the LoD leading to false negatives.	S4	P2	M	Indicate the limitation in the IFU.	IFU 07AG60SELF-003-03-12-DE	P1	L	ACC
R3	D4	Amino acid mutation in some antigen sites leading to false negatives.	S4	P3	M	Indicate the limitation in the IFU.	IFU 07AG60SELF-003-03-12-DE	P1	L	ACC
R4	A11	Insufficient test sensitivity leading to false negatives.	S3	P3	M	Study and determine a reasonable sensitivity by looking up relevant literature, referring to IFUs of similar products on the market and combining with current technology level.	IFU 07AG60SELF-003-03-12-DE - Technical Requirements	P1	L	ACC
2. Labeling										
R5	A19	Unreasonable label design that fails to meet regulatory or standard requirements.	S4	P2	M	1) Collect relevant regulatory standards on labeling, and design the labels based on the standards and product specs; 2) Organize relevant personnel to conduct review on the labels; 3) Review and approve the labels in accordance with requirements.	- Label design drafts and review records; - D004 Design and Development Review Form	P1	L	ACC

R6	A20	IFU does not meet requirements and fails to meet regulatory or standard requirements, users unable to operate or operate incorrectly.	S4	P2	M	1) Collect relevant regulatory standards on IFU, and make the IFU based on the standards and product performance studies; 2) Organize relevant personnel to conduct review on the IFU; 3) Review and approve the IFU in accordance with requirements.	- Label design drafts and review records; - D004 Design and Development Review Form	P1	L	ACC
R7	A21	Poor readability of labels and IFU. User unable to comprehend, operate or operate incorrectly.	S4	P3	M	1) Adopt ISO 15223-1:2016 symbols; 2) Organize relevant personnel to conduct reviews on the labels and IFU.	- *Label design drafts and review records;* - *IFU07AG60SELF-003-03-12-DE and review records;* - *D004 Design and Development Review Form*	P1	L	ACC
R8	C1	Incomplete IFU, inappropriate or too complicated operation instructions	S3	P3	M	1) Organize relevant personnel to fully review of the IFU; 2) Carry out the QC test in accordance with the IFU.	- IFU07AG60SELF-003-03-12-DE and review records; - D004 Design and Development Review Form	P1	L	ACC
R9	C2	Inappropriate description of performance characteristics	S3	P3	M	Organize relevant personnel to fully review of the IFU based on the performance evaluation results.	- IFU07AG60SELF-003-03-12-DE and review records; - D004 Design and Development Review Form; - QS1N4003 Quality Standards	P1	L	ACC
R10	C3	Inappropriate description of intended use	S3	P3	M	Organize relevant personnel to fully review of the IFU based on the clinical evaluation results.	- IFU07AG60SELF-003-03-12-DE and review records; - D004 Design and Development Review Form; - Clinical Evaluation Report	P1	L	ACC
R11	C4	Inadequate disclosure of limitations	S3	P3	M	Organize relevant personnel to fully review of the IFU.	- IFU 07AG60SELF-003-0-12-DE and review records;	P1	L	ACC

							- D004 Design and Development Review Form			
R12	C5	Inadequate warnings about the hazards of single-use medical devices that are likely to be reused	S3	P3	M	1) Label in accordance with ISO 15223-1:2012; 2) Organize relevant personnel to fully review of the IFU.	- Label design drafts, IFU 07AG60SELF-003-03-12-DE and review records - D004 Design and Development Review Form	P1	L	ACC
R13	C6	Incorrect labeling, such as product name, lot number, and expiration date	S3	P3	M	1) Review of label design and label printing checks. 2) QC inspection.	- Q-001 Label and IFU Design and Review Form - PO1A0212-R01 Label Printing Records - QO1N4003 Packing Inspection	P1	L	ACC
3. Interfering Substances										
R14	A9, D9	Cross reactive or interfering substances present in sample (including endogenous and exogenous substances) leading to inaccurate results.	S3	P3	M	Conduct studies on common endogenous and exogenous interfering substances. List out the results of the interference and cross reactivity studies in the IFU.	- RR1N40018 Interference Studies - IFU07AG60SELF-0 3-03-12-DE	P1	L	ACC
4. Design										
R15	A12	Product performance characteristics fail to meet regulatory requirements and standards.	S3	P2	M	Determine reasonable performance indices by collecting relevant international/industry standards, laws and regulations and referring to IFUs of similar products on the market.	QS1N4003 Quality Standards	P1	L	ACC
R16	A14	Inappropriate selection of raw materials.	S3	P3	M	Carry out study on the raw materials and make the raw material list.	Raw Material Studies	P1	L	ACC
R17	A15	Unclear production process specs.	S4	P3	M	Carry out studies on the production processes and establish the production operation protocol.	RR1N400001 Process Studies	P1	L	ACC

R18	A16	Unclear quality inspection methods or standards for raw materials, process products or finished products.	S 3	P3	M	Carry out product performance studies, establish the inspection instructions and quality standards.	RR1N40028 Analytical Performance Studies	P1	L	ACC
R19	A17	Control materials cannot be prepared, purchased or traced.	S3	P3	M	Carry out study on the internal controls.	RR1N40029 Studies of Control Materials	P1	L	ACC
5. Production Process										
R20	B1	Raw materials not up to standard, affecting product performance leading to nonconforming reagents.	S4	P2	M	1) Sign quality agreement with the raw material supplier to specify responsibilities of both parties; 2) Establish inspection documents and acceptance criteria; 3) Inspect every batch of raw materials.	- Quality Agreement - QO1N4001 and QO1N4002 Raw Material Inspection and Quality Standards	P1	L	ACC
R21	B2	Supplier material change / lot-to-lot variance, affecting product performance leading to nonconforming reagents.	S4	P2	M	1) Sign quality agreement with the raw material supplier to specify changes; 2) Establish inspection documents and acceptance criteria; 3) Inspect every batch of raw materials.	- Quality Agreement - QO1N4001 and QO1N4002 Raw Material Inspection and Quality Standards	P1	L	ACC
R22	B3	Facility environment / equipment does not meet processing requirements; unable to produce.	S4	P2	M	1) Specify production environment; 2) Make an equipment list; 3) Verify the environment and equipment.	- QO-61-001 and QO-61-002 Environment Monitoring - Equipment List - V1516 Cleaning Verification of Membrane Coating Machine	P1	L	ACC
R23	B4	Incorrect preparation or confusion of coating solutions, leading to nonconforming products.	S4	P2	M	1) Establish the corresponding operation protocol; 2) Inspect every batch of coating solution.	PO1N4001 Preparation of Coating Solution and Inspection Records	P1	L	ACC

R24	B5	Incorrect preparation or confusion of coating membranes leading to nonconforming products.	S4	P2	M	1) Establish the corresponding operation protocol; 2) Standardize labeling; 3) Check materials before production; 4) Inspect every batch of coating solution.	PO1N4002 Preparation of Coating Membrane and Inspection Records	P1	L	ACC
R25	B6	Errors in the labeling process leading to nonconforming products.	S4	P2	M	1) Establish the corresponding operation protocol; 2) Inspect every batch of labeling materials.	PO1N4003 Preparation of Labeling Materials and Inspection Records	P1	L	ACC
R26	B7	Incomplete drying of conjugate pad leading to nonconforming products.	S4	P2	M	1) Establish the corresponding operation protocol; 2) Inspect every batch of conjugate pad.	- PO1N4004 Preparation of Conjugate Pad and Inspection Records - V1107 Verification of Conjugate Pad Drying Process	P1	L	ACC
R27	B8	Non-firm component attachment leading to nonconforming products and abnormal sample propagation.	S4	P2	M	1) Establish the corresponding operation protocol; 2) Inspect every batch of uncut sheet.	PO1N4005 Preparation of Uncut Sheets and Inspection Records	P1	L	ACC
R28	B9	Assembly of incorrect components into the uncut sheet leading to nonconforming product.	S4	P2	M	1) Standardize labeling; 2) Check materials before production; 3) Inspect every batch of uncut sheet.	- PO1N4005 Preparation of Uncut Sheets and Inspection Records - BS-QA-011 Production and Service Control Procedures	P1	L	ACC
R29	B10	Within-lot or lot-to-lot variance leading to inconsistent test results.	S3	P2	M	1) Verify and specify the maximum batch quantity; 2) Perform inspection for every batch of uncut sheet.	- V2029 Verification of Maximum Batch Quantity for Colloidal Gold Reagents - PO1N4005 Preparation of Uncut Sheets and Inspection Records	P1	L	ACC

R30	B11	Desiccant missing in aluminum foil pouch, and unable to distinguish whether test kit is usable.	S3	P2	M	1) Establish packing operation protocol; 2) Strengthen personnel training; 3) Process monitoring and inspection.	- PO1N4006 Packing Operation Protocol - A-003 Training Records	P1	L	ACC
R31	B12	Use of invalid desiccant leading to invalidation of test kit.	S3	P2	M	1) The warehouse should perform material shelf-life management strictly in accordance with requirements; 2) Check material information before production.	- BS-QA-021 Warehouse Management Protocol - BS-QA-011 Production and Service Control Procedures	P1	L	ACC
R32	B13	Poor heat sealing of aluminum foil pouch leading to invalidation of test kit.	S4	P2	M	Check the sealing specs before sealing.	E-045 Sealing Machine Operation Inspection Records	P1	L	ACC
R33	B14	Missing components such as swabs, sample extraction buffer or extraction tubes.	S3	P3	M	1) Establish the packing operation protocol; 2) Balance critical materials.	- PO1N4006 Packing Operation Protocol - PO1A0212-R01 Material Balance Records	P1	L	ACC
6. Testing Process										
R34	A2	Sample is SARS-CoV-2 positive or contains other source(s) of infection. Inappropriate handling may result in contamination risks.	S2	P4	M	Specify in the IFU that infectious materials should be handled and disposed following standard Lab procedure and biosafety guidelines.	IFU 07AG60SELF-003-03-12-DE	P1	L	ACC
R35	D1	Product transport or storage temperature not within the specified range leading to incorrect or invalid results.	S3	P4	M	Clearly mark the storage temperature on the label and in the IFU.	Label and IFU 07AG60SELF-003-03-12-DE	P1	L	ACC
R36	A6, D6	Improper sample handling (incorrect dilution ratio) leading to incorrect results.	S3	P3	M	Carry out sample dilution ratio studies.	RR1N40021 Sample Dilution Ratio Studies	P1	L	ACC
R37	A7, D7	Insufficient or excess sample addition leading to incorrect results.	S2	P3	M	Carry out sample addition volume studies.	RR1N40021 Sample Volume Studies	P1	L	ACC
R38	A8, D8	Inappropriate result interpretation time leading to incorrect results.	S3	P3	M	Carry out result interpretation time studies.	RR1N40021 Result Interpretation Time Studies	P1	L	ACC

R39	A10, D10	Inappropriate description of intended use leading to incorrect results.	S4	P3	M	Specify the intended use by looking up relevant literature, referring to IFUs of similar products on the market and combining with clinical trials.	Clinical Evaluation Report	P1	L	ACC
R40	D11	Reuse of disposable products (recycle) leading to incorrect results.	S3	P2	M	Use the "Do not re-use" symbol in ISO 15223-1:2016.	Label and IFU 07AG60SELF-003-02-12-EN	P1	L	ACC
R41	D12	Opening the test card and dividing reagent strips (e.g., to reduce cost), leading to Exposure to glass fibers resulting in skin redness or itchiness or incorrect or invalid results.	S3	P1	M	Clearly identify on the label that the product is for one person only, and specify the test procedures and precautions in the IFU.	Label and IFU 07AG60SELF-003-02-12-EN	P1	L	ACC
R42	D13	Insufficient depth of swab insertion into the nasal cavity during sampling and insufficient sampling volume leading to incorrect results.	S3	P2	M	Specify the depth of swab insertion into the nasal cavity in the IFU.	Label and IFU 07AG60SELF-003-02-12-EN	P1	L	ACC
R43	D14	Swab inserting too deep into the nasal cavity, causing user discomfort or pain.	S3	P2	M	Specify the depth of swab insertion into the nasal cavity in the IFU, and advise users to stop collecting samples when feeling discomfort or pain.	Label and IFU 07AG60SELF-003-02-12-EN	P1	L	ACC
R44	D15	Test results not reported in a timely manner. Patients tested positive may cause infection in other populations.	S4	P2	M	Specify the test result reporting methods in the IFU.	Label and IFU 07AG60SELF-003-02-12-EN	P1	L	ACC
7. Stability										
R45	A5, D5	Decrease of sample stability leading to incorrect results.	S3	P3	M	1) Carry out sample stability studies; 2) Specify the results of the sample stability study in the IFU.	RR1N40009 Sample Stability Studies	P1	L	ACC
R46	A13	Decrease of reagent storage, transport, and open-pack stability leading to incorrect results.	S3	P3	M	Carry out storage, transport and open-pack stability studies on the test kit based on relevant standard requirements.	RR1N40004- RR1N40007 Storage, Transport, and Open Pack Stability Studies	P1	L	ACC
R47	A18	Decrease of control material stability leading to incorrect test results and nonconforming product performance.	S3	P3	M	Carry out stability study on the internal controls.	RR1N40029 Control Material Stability Studies	P1	L	ACC

8. Specimen Type										
R48	A3, D2	Inappropriate sample type leading to incorrect results.	S3	P3	M	1) Carry out sample type studies; 2) Confirm with clinical study.	- RR1N40010 Sample Type Studies; - Clinical Evaluation Report	P1	L	ACC
R49	A4	Inappropriate sample collection method or container leading to incorrect results	S3	P3	M	Carry out study on the supplied sample collection swabs.	RR1N40028 Performance Evaluation Report	P1	L	ACC

Notes: ACC = acceptable, L = low, M = moderate.

6. Evaluation of Overall Residual Risk

After taking measures to mitigate risks, the risks of the hazards have been reduced to an acceptable level, and no new risk has been introduced. At the same time, a comprehensive analysis on the overall residual risks was conducted. Taking into consideration the effect of all residual risks, the review concluded that the overall residual risk is acceptable.

Specific evaluation aspects:

1) Are there conflicting requirements for the control of individual risks?

   Conclusion: No conflicts have been identified for existing risk controls.

2) Review of warnings (including whether there are too many warnings)

   Conclusion: The warnings are clearly indicated and comply with the specifications.

3) Review of IFU (including whether there are contradictions and whether it is difficult to comply)

   Conclusion: Product IFU comply with the "Label and IFU Management Protocol" and product-specific safety standard requirements. Descriptions on product safety are clear and understandable, and are easy to read.

4) Conclusion of the review team

   Conclusion: Based on the above analysis, the review team unanimously concluded that overall residual risk of this product is acceptable.

7. Production and Post-Production Information

7.1 Information Collection

Each department follows the "Post-Market Surveillance Control Procedures" (File No: BS-QA-037) to collect information from different sources including users, service providers, training personnel, incident reports and customer feedback, and monitor clinical use.

The company has established the "Deviation and Exceptional Circumstance Handling Protocol" (File No: PM-00-006) to collect internal information, and tests product performance through process verification, process control, quality inspection, and stability assessment.

7.2 Evaluation of Production and Post-Production Information Acquisition

The review team evaluated the appropriateness and effectiveness of methods of acquiring production and post-production information in "Customer Feedback Control Procedures", "Quality Control Procedures" and "Control Procedures for Adverse Event Monitoring and Re-Evaluation", and concluded that the methods are appropriate and effective. Production and post-production information can be obtained by following the requirements in "Post-Market Surveillance Control Procedures", "Customer Feedback Control Procedures", "Quality Control Procedures", "Control Procedures for Adverse Event Monitoring and Re-Evaluation", and "Deviation and Exceptional Circumstance Handling Protocol".

7.3 Information Review

The Quality Department is responsible for organizing relevant personnel, collecting information from each department and filling in the "Review of Production and Post-

marketing Information" in order to assess whether serious adverse events have occurred, clarify whether new risks have occurred and whether new risk control measures need to be taken. When necessary, the risk management team should carry out activities to implement dynamic risk management.

8. Conclusion

Based on the analysis and evaluation of the possible hazards in the design, production, storage and use of the product, and the control of the existing risks to an acceptable level, the product is concluded to be safe on a preliminary note. Potential risks and risk control measures should be verified during the production processes to ensure the safety of the product.

Table 3. Design Input FMEA Analysis

Design Input FMEA Analysis

Hazard	Known or suspected problem	Potential effects	Severity	Occurrence	Risk index	Recommended Action	Responsible Department
A1	Sample is SARS-CoV-2 positive or contains other source(s) of infection	Health risks to users	S3	P4	Moderate	1) Test kit design should avoid sample contact with the user; 2) All samples indicated in the IFU should be handled as potentially infectious.	R&D 1
A2	Sample is SARS-CoV-2 positive or contains other source(s) of infection	Contamination risks due to inappropriate disposal	S2	P4	Moderate	Specify in the IFU that infectious materials should be handled and disposed following standard Lab procedure and biosafety guidelines.	R&D 1
A3	Inappropriate sample type	Incorrect results	S3	P3	Moderate	1) Carry out sample type studies; 2) Confirm with clinical study.	R&D 1
A4	Inappropriate sample collection method or container	Incorrect results	S3	P3	Moderate	Carry out study on the supplied sample collection swabs.	R&D 1
A5	Decrease of sample stability	Incorrect results	S3	P3	Moderate	Carry out sample stability studies.	R&D 1
A6	Improper sample handling (incorrect dilution ratio)	Incorrect results	S3	P3	Moderate	Carry out sample dilution ratio studies.	R&D 1
A7	Insufficient or excess sample addition	Abnormal sample propagation and invalid results	S2	P3	Moderate	Carry out sample addition volume studies.	R&D 1
A8	Inappropriate result interpretation time	Incorrect results	S3	P3	Moderate	Carry out result interpretation time studies.	R&D 1
A9	Cross reactive or interfering	Incorrect results	S3	P3	Moderate	Carry out studies on common	R&D 1

	substances present in sample (including endogenous and exogenous substances)					endogenous and exogenous interfering substances.	
A10	Inappropriate description of intended use	Incorrect results	S4	P3	Moderate	Specify the intended use by looking up relevant literature, referring to IFUs of similar products on the market and combining with clinical trials.	R&D 1
A11	Insufficient test sensitivity	False negatives	S3	P3	Moderate	Study and determine a reasonable sensitivity by looking up relevant literature, referring to IFUs of similar products on the market and combining with current technology level.	International
A12	Product performance characteristics fail to meet regulatory requirements and standards	Unable to pass registration inspection	S3	P2	Moderate	Determine reasonable performance indices by collecting relevant international/industry standards, laws and regulations and referring to IFUs of similar products on the market.	R&D 1
A13	Decrease of reagent storage, transport, and open-pack stability	Incorrect results	S3	P3	Moderate	Carry out storage, transport and open-pack stability studies on the test kit.	R&D 1
A14	Inappropriate selection of raw materials	Reagent performance does not meet requirements or incorrect results	S3	P3	Moderate	Carry out study on the raw materials and make the raw material list.	R&D 1
A15	Unclear production process specs	Unable to produce, nonconforming reagent performance	S4	P3	Moderate	Carry out studies on the production processes and establish the production operation protocol.	R&D 1
A16	Unclear quality inspection	Unable to correctly	S3	P3	Moderate	Carry out product performance	R&D 1

	methods or standards for raw materials, process products or finished products	evaluate reagent performance; nonconforming reagent performance				studies, establish the inspection instructions and quality standards.	
A17	Control materials cannot be prepared, purchased or traced	Cannot carry out quality control; nonconforming reagent performance	S3	P3	Moderate	Carry out study on the internal controls.	R&D 1
A18	Decrease of control material stability	Incorrect test results; nonconforming reagent performance	S3	P3	Moderate	Carry out stability study on the internal controls.	R&D 1
A19	Unreasonable label design	Unable to meet regulatory or standard requirements	S4	P2	Moderate	1) Collect relevant regulatory standards on labeling, and design the labels based on the standards and product specs; 2) Organize relevant personnel to conduct review on the labels; 3) Review and approve the labels in accordance with requirements.	R&D 1, Quality
A20	IFU does not meet requirements	Unable to meet regulatory or standard requirements; users unable to operate or operate incorrectly	S4	P2	Moderate	1) Collect relevant regulatory standards on IFU, and make the IFU based on the standards and product performance studies; 2) Organize relevant personnel to conduct review on the IFU; 3) Review and approve the IFU in accordance with requirements.	R&D 1, Quality
A21	Poor readability of labels and IFU	User unable to comprehend, operate or operate incorrectly	S4	P3	Moderate	1) Adopt ISO 15223-1:2016 symbols; 2) Organize relevant personnel to conduct reviews on the labels and IFU.	R&D 1, International

Table 4. Risk Analysis for Procedural Control

Risk Analysis for Procedural Control

Hazard	Activity	Function	Potential Failure Modes	Potential Effects of Failure Mode	Severity	Potential Causes of Failure	Current Controls	Occurrence	Risk Index	Recommended Action	Action Owner
B1	Raw material purchasing	Required production material	Raw materials not up to standard	Effect on product performance leading to nonconforming products	S4	Unqualified supplier supply; no inspection on incoming materials	Established the "Purchasing Control Procedures" to manage suppliers by category.	P2	Moderate	1) Sign quality agreement with the raw material supplier to specify responsibilities of both parties; 2) Establish inspection documents and acceptance criteria; 3) Inspect every batch of raw materials.	Purchasing, Quality
B2	Supplier material change / lot-to-lot variance	Required production material	Raw materials not up to standard	Effect on product performance leading to nonconforming products	S4	Unqualified supplier supply	Established the "Purchasing Control Procedures" to manage suppliers by category.	P2	Moderate	1) Sign quality agreement with the raw material supplier to specify changes; 2) Establish inspection documents and acceptance criteria; 3) Inspect every batch of raw materials.	Purchasing, Quality
B3	Current manufacturing facilities and equipment	Required production facilities / equipment	Facility environment / equipment does not meet	Unable to produce	S4	No inspection on production environment / equipment	Established the "Production Environment and Service Control Procedures" and the	P2	Moderate	1) Specify production environment; 2) Make an equipment list;	R&D 1, Quality

			processing requirements				"Equipment Control Procedures"			3) Verify the environment and equipment.	
B4	Preparation of coating solution	Critical process	Incorrect preparation or confusion of coating solutions	Nonconforming products	S4	No operation protocol or inspection	Established the "Job Operation Protocol"	P2	Moderate	1) Establish the corresponding operation protocol; 2) Inspect every batch of coating solution.	R&D 1, Quality
B5	Preparation of coating membrane	Preparation of in-process products	Incorrect preparation or confusion	Nonconforming products	S4	No operation protocol or non-standardized labeling	Established the "Job Operation Protocol"	P2	Moderate	1) Establish the corresponding operation protocol; 2) Standardize labeling; 3) Check materials before production; 4) Inspect every batch of coating solution.	R&D 1, Quality, Production
B6	Labeling	Critical process	Errors in the labeling process	Nonconforming products	S4	No operation protocol or inspection	Established the "Job Operation Protocol".	P2	Moderate	1) Establish the corresponding operation protocol; 2) Inspect every batch of labeling materials.	R&D 1, Quality, Production
B7	Incomplete drying of conjugate pad	Drying process of in-process products	Incomplete drying of conjugate pad	Nonconforming products	S4	No operation protocol or verification of processes	Established the "Job Operation Protocol"; verified the conjugate pad processes.	P2	Moderate	1) Establish the corresponding operation protocol; 2) Inspect every batch of conjugate pad.	R&D 1, Quality
B8	Uncut sheet assembly	Production of semi-finished products	Non-firm component attachment	Sample unable to propagate	S4	No operation protocol	Established the "Job Operation Protocol".	P2	Moderate	1) Establish the corresponding operation protocol; 2) Inspect every batch of uncut sheet.	R&D 1, Quality
B9	Uncut sheet assembly	Production of semi-finished products	Assembly of incorrect components	Nonconforming products	S4	Non-standardized material labeling	Established the "Label and Traceability Control Procedures".	P2	Moderate	1) Standardize labeling; 2) Check materials before production; 3) Inspect every batch of uncut sheet.	Production, Quality

B10	Uncut sheet assembly	Production of semi-finished products	Within-lot or lot-to-lot variance	Inconsistent test results	S3	Did not perform inspection for every batch, did not specify maximum batch quantity	Established inspection documents for performance of process products	P2	Moderate	1) Verify and specify the maximum batch quantity; 2) Perform inspection for every batch of uncut sheet.	R&D, Quality
B11	Pouch packing	Inner packing	Desiccant missing in aluminum foil pouch	Unable to distinguish whether test kit is usable	S3	Non-standardized operation	Established the "Packing Job Operation Protocol"	P2	Moderate	1) Establish packing operation protocol; 2) Strengthen personnel training; 3) Process monitoring and inspection.	R&D 1, Production
B12	Pouch packing	Inner packing	Use of invalid desiccant	Invalidation of test kit	S3	No management on material expiration	Established the "Material Shelf-Life Management Protocol"	P2	Moderate	1) The warehouse should perform material shelf-life management strictly in accordance with requirements; 2) Check material information before production.	Production
B13	Aluminum foil pouch sealing	To keep the reagent dry	Poor heat sealing of aluminum foil pouch	Invalidation of test kit	S4	No verification of heat-sealing process; failure to heat seal as required	Verified the heat-sealing process of aluminum foil pouches.	P2	Moderate	Check the sealing specs before sealing.	Production
B14	Box packing	Outer packing	Missing components such as swabs, sample extraction buffer or extraction tubes	Unusable test kit	S3	No operation protocol or material balance	Established the "Packing Job Operation Protocol"	P3	Moderate	1) Establish the packing operation protocol; 2) Balance critical materials.	Production
B15	Label printing	Labeling	Incorrect labeling of product name, lot number, or expiration date	Unusable test kit	S3	No operation protocol or double-check of labels	Established the "Label Printing Job Operation Protocol".	P2	Moderate	Double check each batch of labels.	Production

Table 5. Risk Analysis of Labels and IFU

Risk Analysis of Labels and IFU

Hazard	Known or suspected problem	Potential effects	Severity	Occurrence	Risk index	Recommended Action	Responsible Department
C1	Incomplete IFU, inappropriate or too complicated operation instructions	User errors leading to incorrect results	S3	P3	Moderate	1) Organize relevant personnel to fully review of the IFU; 2) Carry out the QC test in accordance with the IFU.	R&D 1; Quality
C2	Inappropriate description of performance characteristics	Improper user awareness of reagents leading to incorrect interpretation of results	S3	P3	Moderate	Organize relevant personnel to fully review of the IFU based on the performance evaluation results.	R&D 1
C3	Inappropriate description of intended use	Use for other purposes leading to incorrect results	S3	P3	Moderate	Organize relevant personnel to fully review of the IFU based on the clinical evaluation results.	R&D 1
C4	Inadequate disclosure of limitations	Incorrect interpretation of results	S3	P3	Moderate	Organize relevant personnel to fully review of the IFU.	R&D 1
C5	Inadequate warnings about the hazards of single-use medical devices that are likely to be reused	Repeated use leading to incorrect results	S3	P3	Moderate	1) Label in accordance with ISO 15223-1:2012; 2) Organize relevant personnel to fully review of the IFU.	R&D 1; Quality
C6	Incorrect labeling, such as product name, lot number, and expiration date	Inappropriate use of reagents leading to incorrect results	S3	P3	Moderate	1) Review of label design and label printing checks. 2) QC inspection.	Quality; Production

Table 6. Risk Analysis for Storage, Transport, and Usage

Risk Analysis for Storage, Transport, and Usage

Hazard	Known or suspected problem	Potential effects	Severity	Occurrence	Risk index	Recommended Action	Responsible Department
D1	Product transport or storage temperature not within the specified range	Incorrect or invalid test results	S3	P4	Moderate	Clearly mark the storage temperature on the label and in the IFU.	R&D 1
D2	Inappropriate sample type	Incorrect results	S3	P3	Moderate	Define the sample type in the IFU based on results of the sample type study.	R&D 1
D3	Viral load below the LoD	False negative	S4	P2	Moderate	Indicate the limitation in the IFU.	R&D 1
D4	Amino acid mutation in some antigen sites	False negative	S4	P3	Moderate	Indicate the limitation in the IFU.	R&D 1
D5	Decrease of sample stability	Incorrect results	S3	P3	Moderate	Specify the results of the sample stability study in the IFU.	R&D 1
D6	Improper sample handling (incorrect dilution ratio)	Incorrect results	S3	P3	Moderate	Specify the sample handling procedures in the IFU based on results of the sample handling study.	R&D 1
D7	Insufficient or excess sample addition	Abnormal sample propagation and invalid results	S2	P3	Moderate	Specify the sample addition volume both with texts and pictures based on results of the sample addition volume study.	R&D 1
D8	Inappropriate result interpretation time	Incorrect results	S3	P3	Moderate	Specify the result interpretation time both with texts and pictures based on results of the result interpretation time study.	R&D 1
D9	Cross reactive or interfering	Incorrect results	S3	P3	Moderate	List out the results of the	R&D 1

	substances present in sample					interference and cross reactivity studies in the IFU.	
D10	Inappropriate description of intended use	Incorrect results	S4	P3	Moderate	Specify the intended use based on the sample handling study.	R&D 1
D11	Reuse of disposable products	Incorrect results	S3	P2	Moderate	Use the "Do not re-use" symbol in ISO 15223-1:2016.	R&D 1
D12	Opening the test card and dividing reagent strips (e.g., to reduce cost).	Exposure to glass fibers resulting in skin redness or itchiness; incorrect or invalid results	S3	P1	Moderate	Clearly identify on the label that the product is for one person only, and specify the test procedures and precautions in the IFU.	R&D 1
D13	Insufficient depth of swab insertion into the nasal cavity during sampling and insufficient sampling volume.	Incorrect results	S3	P2	Moderate	Specify the depth of swab insertion into the nasal cavity in the IFU.	R&D 1
D14	Swab inserting too deep into the nasal cavity	User discomfort or pain	S3	P2	Moderate	Specify the depth of swab insertion into the nasal cavity in the IFU, and advise users to stop collecting samples when feeling discomfort or pain.	R&D 1
D15	Test results not reported in a timely manner	Patients tested positive may cause infection in other populations	S4	P2	Moderate	Specify the test result reporting methods in the IFU.	R&D 1