COVID-19 nucleocapsid antigen Assay Kit
(Immunochromatography)

Risk Management Report

Content

Chapter 1 General

This article is a report on risk management of COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold), in which all possible hazards and the causes of each hazard are determined. The severity of each hazard and the probability of occurrence of the hazard are estimated. When a certain level of risk is unacceptable, control measures to reduce risk are taken, and the residual risk after control measures is evaluated. Finally, evaluate the acceptability of all residual risks and conduct risk benefit analysis.

1.1 Scope

This risk management is mainly based on the appendix in the requirements of ISO14971:2019 Medical Devices-Application of Risk Management to Medical Devices for COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) throughout its life cycle (1) product realization (including design and development, procurement, manufacturing, packaging, etc.), (2) delivery process (including transportation, etc.), (3) after delivery (including use, etc.) to plan for comprehensive risk management activities.

1.2 Basis of composing

1.2.1 Related standards

1) ISO14971：2019 Medical Devices-Application of Risk Management to Medical Devices

1.2.2 Product related documents

1) Instruction
2) Stability research materials
3) Technical specifications
4) Labeling and packaging
5) Design and development documents

1.3 Product introduction

1.3.1 Test Principle

This kit uses immunochromatography. The test card contains:1) colloidal gold-labeled N protein antibody N061; 2) one detection line (T line) and one quality Control line (C line) of nitrocellulose membrane. The T line is immobilized with N protein antibody N017 for detecting N antigen and the C line is immobilized with a quality control antibody. When an appropriate amount of the test sample is added to the sample loading hole of the test cassette, the sample will move forward along the test cassette under the action of the capillary. If the sample contains Covid-19 virus N protein antigen, the antigen will bind to the colloidal gold-labeled N protein antibody N061. The N protein antigen-gold-labeled N protein antibody N061 complex will then be captured by the N protein antibody N017 immobilized on the membrane to form a purple-red T line. The test cassette also contains a quality control line C. The purple-red quality control line C should appear regardless of whether a test line appears. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test cassette.1.3.2 Main Components

1 PC/box, each box contains
- 1×Test Kit pouch
- 1×Saliva swab
- 1×Instruction for use
- 1×Sample Diluent

5 PCS/box, each box contains
- 5×Test Kit pouch
- 5×Saliva swab
- 1×Instruction for use
- 5×Sample Diluent

25 PCS/box, each box contains
- 25×Test Kit pouch
- 25×Saliva swab
- 1×Instruction for use
- 25×Sample Diluent

1.3.3 Intended Use

COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) is a lateral flow immunoassay for the qualitative detection of Nucleocapsid Antigen of SARS-CoV-2 in human saliva as an aid for Diagnosis of Covid-19 induced pneumonia.

1.3.4 Environmental requirement

Restore the reagents and samples to room temperature before testing. Use it within 15 minutes after the aluminum foil bag is opened.

Chapter 2 Risk management Team and their Assignment of Responsibility

Table 1 Risk management Team Member and their Responsibility

Name	Department	Assignment of Responsibility	Note
Lin Li	R&D	Co-ordinator	
Jing Zhang	QC	Investigator (Operator)	
Yun Liu	QC	Investigator (Reviewer)	
Yong Yang	QC	Approver	

Chapter 3 Intended use/intended purpose and identification of characteristics related to the safety of the medical devices

Table 2 List of characteristic questions that may affect safety

Questions Description	Identify
C.2.1 What is the intended use and how is the medical device to be used?	COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) is a lateral flow immunoassay for the qualitative detection of Nucleocapsid Antigen of SARS-CoV-2 in human saliva as an aid for Diagnosis of Covid-19 induced pneumonia.
C.2.2 Is the medical device intended to be implanted?	NO
C.2.3 Is the medical device intended to be in contact with the patient or ither persons?	NO
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?	1. Test cassette: binding pad (colloidal gold-labeled novel coronavirus N protein antibody N061), nitrocellulose membrane (C line coated with goat anti-mouse IgG polyclonal antibody, T line coated with N protein antibody N017), hemofiltration pad, sample pad, suction pad and PVC plate; 2. Desiccant; 3. Buffer.
C.2.5 Is energy delivered to or extracted from the patient?	NO
C.2.6 Are substances delivered to or extracted from the patient?	NO
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	NO
C.2.10 Is the medical device intended to modify the patient environment?	NO
C.2.11.Are measurements taken?	NO
C.2.12 Is the medical device interpretative?	NO User directly visualizes the results

	according to the instructions after testing
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO
C.2.14 Are there unwanted outputs of energy or substances?	YES Please refer to relevant laws and regulations for disposal of waste generated during use.
C.2.15 Is the medical device susceptible to environmental influences?	NO
C.2.16 Does the medical device affect the environment?	YES Improper waste disposal may affect the environment.
C.2.17Are there essential consumables or accessories associated with the medical device?	NO
C.2.18 Is maintenance or calibration necessary?	NO
C.2.19 Does the medical device contain software?	NO
C.2.20 Does the medical device have a restricted shelf-life?	The expiration date of the product will be indicated on the product label and instructions.
C.2.21 Are there any delayed or long-term use effects?	NO
C.2.22 To what mechanical forces will the medical device be subjected?	Does not bear mechanical force
C.2.23 What determines the lifetime of the medical device?	The standard, correct use, transportation and storage environment and validity period of this kit determine its service life.
C.2.24 Is the medical device intended for single use?	YES This product is a single-use in vitro diagnostic reagent, please do not reuse it, only for in vitro diagnostics.
C2.25 Is safe decommissioning or disposal of the medical device necessary?	YES After use, according to the relevant regulations of the hospital laboratory, uniform disinfection treatment according to the medical waste, see the instructions for details.

C2.26Does installation or use of the medical device require special training or special skills?	NO follow the operating steps in the manual for testing.
C2.27 How will information for safe use be provided?	Safety information is provided by the manual of the corresponding product.
C2.28 Will new manufacturing processes need to be established or introduced?	NO
C2.29Is successful application of the medical device critically dependent on human factors such as the user interface?	NO
C2.29.1 Can the user interface design features contribute to use error?	NO
C2.29.2Is the medical device used in an environment where distractions can cause use error?	NO
C2.29.3 Does the medical device have connecting parts or accessories?	NO
C2.29.4 Does the medical device have a control interface?	NO
C2.29.5 Does the medical device display information?	YES Color bands in the test line and quality control line show negative and positive results.
C2.29.6 Is the medical device controlled by a menu?	NO
C2.29.7 Will the medical device be used by persons with special needs?	NO
C2.29.8 Can the user interface be used to initiate user actions?	NO
C2.30 Does the medical device use an alarm system?	NO
C2.31 In what way(s) might the medical device be deliberately misused?	NO
C2.32 Does the medical device hold data critical to patient care?	NO
C2.33 Is the medical device intended to be mobile or portable?	YES It is a portable reagent.
C2.34 Does the use of the medical device depend on essential performance?	NO
H2.2 Possible usage error	Reagents that have lost their reactivity are used; incorrect reagent storage
H.2.3.2 Quantitative inspection program performance characteristics	NO

H.2.3.3 Performance characteristics of qualitative inspection procedures	YES The design and determination of the sensitivity and specificity of the test
H.2.3.4 Dependent characteristics	NO
H.2.3.5 Auxiliary information of patient	NO
H.2.4.1 Hazard(source) to the patient	Provide an incorrect result that may cause or contribute to a misdiagnosis
H.2.4.3 Identify the hazard (source) under fault conditions	May cause the performance characteristics (such as sensitivity, specificity, etc.) required for medical purposes to be in failure mode
H.2.4.4 Identify the hazards (source) during normal use	Under normal conditions of use, the test results may be incorrect due to the following factors (imperfect discrimination of positive and negative samples, measurement uncertainty, undesired effects of other components (interference factors) in the sample matrix, and analyte Inherent inhomogeneity)
H.2.4.5 Identify dangerous situations	Anti-interference ability of reagent

Chapter4 Risk management

4.1 Hazard (source) identification

Guidelines for the determination of hazards (sources) are given in Appendix E of ISO14971：2019 as an auxiliary tool to determine potential hazards. Consider factors such as the hazard to the patient, the hazard to the operator, the hazard to the nearby personnel, the hazard to the environment, etc., under the conditions of normal use and abnormal use, as the basis for determining the hazard (source).

4.2 Risk estimation

4.2.1Severity levels：According to the severity of possible harm

Severity	Description
Negligible	No harm or slight harm to the user or operator, the environment

Moderate	Cause temporary injury or damage to the environment, users or operators that do not require professional medical intervention
Significant	Causes injury or damage to the environment, users or operators that require professional medical intervention, or loss of function or results

4.2.2 Probability levels

According to the probability of occurrence (times/box)

Probability range	Description
High	Likely to happen, often, frequent
Medium	Can happen, but not frequently
Low	Unlikely to happen, rare, remote

4.2.3 Risk Evaluation Criteria

Take probability as the "column" and injury severity as the "row" to form a 3X3 risk matrix.

	Negligible	Moderate	Significant
High	R3	R3	R3
Medium	R2	R2	R3
Low	R1	R2	R2
R3	Unacceptable risk level without risk/benefit analysis	R2	Reasonable and feasible reduction of risk level
R1		Acceptable risk level	

4.3 Risk evaluation

For each identified hazard, it is evaluated according to the risk acceptability standard, see 4.6 Risk Management Table for details.

4.4 Risk control

According to the risk estimation and risk evaluation results, when the risk needs to be reduced, risk control measures are adopted to reduce the risk to an acceptable level and determine whether to introduce new hazards or hazardous situations. See 4.6 Risk Management Table for details.

4.5 Residual risk evaluation

After taking risk control measures, see 4.6 Risk Management Table for details to evaluate the residual risks.

4.6 Risk Control Tables

Table 1 Common hazards of products

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
A1	Disposal of products and waste pollution after use	Incorrect waste disposal	Potential environmental pollution	Significant	Medium	**R3**	Unacceptable	YES	Instructions specifies the waste disposal methods	Instructions	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

A2	Reinfection	The operator is in contact with the sample during or after the sample is collected; the sample is mixed with microorganisms and bacteria; the incorrect use process; multiple people share it and cause	The user is infected with other diseases carried in the sample	Significant	Low	**R2**	Further risk reduction	YES	Operate strictly in accordance with the regulations in the instructions	Instructions	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
		cross-infection.																

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
A3	Failure to maintain hygiene and safety	Biological and/or chemical contamination during handling and operation	Potential environmental pollution	Moderate	Low	**R2**	Further risk reduction	YES	Operate in strict accordance with the standard operating procedures and instructions of each process	Production SOP, instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
A4	Sample contamination	Improper storage conditions of the collection device; incorrect sampling method	Wrong test result	Significant	Low	**R2**	Further risk reduction	YES	Instructions for sampling method	Instructions	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
A5	Biological contamination	The solution used in the production process is contaminated by microorganisms	Wrong test result	Significant	Low	**R2**	Unacceptable	YES	Operate in strict accordance with the standard operating procedures of each process	Production SOP	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
B1	Toxicity	Direct skin contacts with product for solution treatment	Production personnel poisoning	Significant	Low	**R2**	Unacceptable	YES	Operate in strict accordance with the standard operating procedures of each process	Production SOP	Compliance	No impact	Effective	NO	Moderate	Low	R2	Further risk reduction

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
B2	Degradation	Improper operation by production personnel	Degradation can cause changes in product detection sensitivity or specificity	Significant	Medium	**R3**	Unacceptable	YES	Operate in strict accordance with the standard operating procedures of each process	Production SOP	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
C1	Storage or operation deviates from the specified external environmental conditions	Improper storage or operation by users; warehouse environment does not meet requirements	Invalid product or test results	Significant	Medium	**R3**	Unacceptable	YES	Store or operate the warehouse in strict accordance with the conditions specified in the instruction manual	Instructions; warehouse environmental records	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
C2	Non-compliant production environment	Dust particles in clean area in excess of the standards, Non-compliant temperature and humidity, etc.	Affecting the product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Strictly implement work environment control procedures	Workshop environmental records	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
D1	Inappropriate operating instructions	Inaccurate description in the instruction	wrong detection	Significant	Medium	**R3**	Unacceptable	YES	Instruction review process	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
D2	Used by unskilled/ untrained personnel	User's improper operation	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Instruction guidance	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
D3	Reasonably foreseeable misuse	User's improper operation	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Instruction guidance	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
D4	Inadequate warnings about the hazards that single-use medical devices are likely to be reused	Inaccurate description	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	"Do not reuse" warning in the instruction	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
D5	Error or misjudgment	User's improper operation	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Accurate description in the instruction	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
D6	Sharp edges, sharp angles	Inappropriate packaging	scratches on the user's skin	Moderate	Low	**R2**	Further risk reduction	YES	Take packaging design into considerations	R&D documents	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
D7	Sample collection and processing errors	User's improper operation	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Instruction guidance	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
D8	Excessive or insufficient sample volume	User's improper operation	wrong detection t	Moderate	High	**R3**	Unacceptable	YES	Verification; Instruction guidance	R&D documents Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
D9	The issue of sample stability	Improper storage of samples	wrong detection	Moderate	High	**R3**	Unacceptable	YES	Sample stability verification instructions	R&D documents Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
E1	Unclear, unclear or inaccurate marking on the product	Unqualified marking	wrong detection	Significant	Medium	**R3**	Unacceptable	YES	Strict packaging design and review process	Packaging review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
E2	Unclearly marked protective measures on the packaging	Unqualified marking	Affecting users' safety	Moderate	Low	**R2**	Further risk reduction	YES	Strict packaging design and review process	Packaging review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
E3	The precautions and operation steps described in the manual are cumbersome or not clear and understandable or the information is incomplete	Inaccurate description in instruction	wrong detection	Moderate	Low	**R3**	Unacceptable	YES	Improve the instructions in the manual	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
E4	Biological changes of the sample	Inaccurate description in instruction	wrong detection	Significant	Medium	**R3**	Unacceptable	YES	Improve the instructions in the manual	R&D Verification Manual	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
E5	Negligence and error	User's improper operation	wrong detection	Moderate	Medium	**R2**	Unacceptable	YES	Operate in strict accordance with the instructions	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
F1	Air leakage of aluminum foil bag	Improper operation by production personnel; improper transportation; sealing problems; equipment issues	Cause the product to be damp, degraded, polluted, and reduce the product performance	Moderate	Medium	**R2**	unacceptable	YES	Production process confirmation; regular maintenance of equipment;;	Equipment management	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
F2	Improper use after opening	User's improper operation	wrong detection	Significant	Medium	**R3**	Unacceptable	YES	Operate in strict accordance with the instructions	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
F3	Reuse	Inaccurate description in the manual	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Operate in strict accordance with the instructions	Instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

Table 2 Risk analysis during product development

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G1	Incorrect design input	Incorrect marketing information	Product does not meet market demand	Significant	Medium	**R3**	Unacceptable	YES	Study on market input and technical feasibility;	Parameter design input; R&D personals make prototype samples	Compliance	No impact	Effective	NO	Negligible	Low	RI	Acceptable
G2	The quality of key raw materials (antibodies) did not produce the expected performance	Supplier issues	Affecting the product performance and stability	Moderate	Low	**R2**	Further risk reduction	YES	Design control requires QC incoming material inspection verification and confirmation;	Raw material inspection documents	Compliance	No impact	Effective	NO	Negligible	Low	RI	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G3	Large batch-to-batch difference of raw materials	Supplier issues	Affecting the product performance and stability	Moderate	Low	**R2**	Further risk reduction	YES	Validation of product transfer to production; supplier evaluation	Product development documents; verification reports	Compliance	No impact	Effective	NO	Negligible	Low	RI	Acceptable
G4	Incorrect raw material storage conditions	Supplier issues; insufficient research on R&D raw materials	Affecting the product performance and stability	Moderate	Low	**R2**	Further risk reduction	YES	Supplier's COA clarifies the shelf life of raw materials; regulates raw material storage conditions	Regulations of material storage and reinspection management	Compliance	No impact	Effective	NO	Negligible	Low	RI	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G5	Incorrect sample type	Inadequate consideration of R&D design/verification	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Different types of sample adaptability tests during the development process; the sample type is stated in the package;	Product development documents; instruction	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
G6	Lack of an appropriate decision on the end of life of medical devices;	Insufficient product verification	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	Validation and validation studies; Description in package;;	Product Development Document- Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G7	The intended use purpose was not fully demonstrated during design	Insufficient product verification	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	R&D batch verification; R&D verification and confirmation;	Product Development Document-Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
G8	Low sensitivity	Insufficient traceability of reference products during design	False positive or false negative	Significant	Medium	**R3**	Unacceptable	YES	Traceability and stability research of quality control product	Product Development Document-Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G9	Inappropriate packaging (contamination and/or deterioration of medical devices)	Insufficient product verification; incorrect design and packaging	wrong detection	Moderate	Low	**R2**	Further risk reduction	YES	R&D personnel should take packaging design, packaging and transportation, and stability verification after opening into consideration	Product Development Document-Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	Rl	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
G10	Inappropriate testing environment and temperature	Insufficient product verification	wrong detection	Moderate	High	**R3**	Unacceptable	YES	Environmental adaptability verification; Stated in the manual;	Product Development Document-Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
G11	Users don't know the use	Incorrect instructions	Wrong result	Moderate	Medium	**R2**	Moderate	YES	R&D verification and confirmation; instructional review process.	Product development documents-instruction output; QA approval	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

Table 3 Risk analysis in manufacturing process

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
Risk analysis in purchasing																		
H1	The key raw materials do not meet the specifications	The materials provided by the supplier do not meet the specification requirements	Affecting the product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	QC inspection of incoming materials	QC incoming inspection report and evaluation report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H2	The nitrocellulose membrane, glass fiber and polyester membrane do not meet the specification requirements	The materials provided by the supplier do not meet the specification requirements	Affecting the product performance and stability	Moderate	Medium	**R2**	Unacceptable	YES	QC inspection of incoming materials	QC incoming inspection report and evaluation report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H3	The test card does not meet the requirements of the specification	Mold defects	Affecting the product performance and appearance	Significant	Medium	**R3**	Unacceptable	YES	QC inspection of incoming materials	QC incoming inspection report and evaluation report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H4	The PVC board does not meet the specification requirements	The materials provided by the supplier do not meet the specification requirements	Affecting the product performance and appearance	Significant	Medium	**R3**	Unacceptable	YES	QC inspection of incoming materials	QC incoming inspection report and evaluation report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H5	Incorrect storage of raw materials	Failure to store in accordance with the requirements of raw materials;	Affecting the product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Specifications of warehouse management; Daily temperature and humidity monitoring	Daily records of temperature and humidity monitoring	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H6	Desiccant failure	Supplier issues; Storage issues	Affecting product stability	Significant	Medium	**R3**	Unacceptable	YES	Raw material inspection; storage environment temperature and humidity control	QC incoming inspection report; daily temperature and humidity monitoring record	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H7	Damaged or contaminated packaging	Supplier issues	Affecting the product performance and stability and appearance	Significant	Medium	**R3**	Unacceptable	YES	QC inspection of incoming materials	QC incoming inspection report;	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
Risk analysis of intermediate production links																		

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H8	Out of control of temperature and humidity in production environment	Malfunction of air conditioning, dehumidification instrumentation system	Affecting the product performance	Significant	Medium	**R3**	Unacceptable	YES	Regular maintenance of equipment; daily temperature and humidity monitoring	Equipment maintenance records; daily temperature and humidity monitoring records	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H9	Material error in solution preparation	Take the wrong material artificially	Affecting the product performance	Significant	Medium	**R3**	Unacceptable	YES	Double check, check the PH value in the SOP	Solution preparation SOP; double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H10	Wrong weighing of raw materials in solution preparation	Human negligence	Affecting the product performance	Significant	Medium	**R3**	Unacceptable	YES	Double check, check the PH value in the SOP	Solution preparation SOP; double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H11	Leakage of raw materials during solution preparation	Human negligence	Affecting the product performance	Significant	Medium	**R3**	Unacceptable	YES	Strictly operate and record in accordance with the production SOP, double-check, and check the PH value in the SOP	Solution preparation SOP; double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H12	Incorrect pH value of solution	Instrument problems, misoperation	Affecting the product performance	Significant	Medium	**R3**	Unacceptable	YES	Maintenance of PH instrument,Operating SOP of PH instrument	Equipment maintenance records	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H13	Intermediate solution contamination, bacteria growth	1) The intermediate solution is placed beyond the validity period 2) The workshop environment is out of control	Affecting the product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Check the solution label; Microbiological monitoring of workshop environment	QA check regularly; Regular environmental microbiological test report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H14	Scratch film, C/T line is not drawn	Instrument issues, pipe blockage	Product failure	Significant	Medium	**R3**	Unacceptable	YES	Add the light inspection link in the spot film SOP	Spot film SOP; Double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H15	Scratch film, the position of C/T line is reversed	Misoperation	Product failure; false positive test result	Significant	Medium	**R3**	Unacceptable	YES	Operate and record strictly in accordance with the production SOP, double review	Spot film SOP; Double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H16	Wrong antibody concentration	Misreading the concentration label artificially and calculating the sampling amount incorrectly	False positive or false negative test results	Significant	Medium	**R3**	Unacceptable	YES	Operate and record strictly in accordance with the production SOP, double review	Solution preparation SOP; double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H17	The setting parameters of membrane dispenser are wrong	Operation error; deviation or error of instrument parameters	False positive or false negative test results	Significant	Medium	**R3**	Unacceptable	YES	Scratch film SOP, double review; equipment verification and maintenance plan	Spot film SOP; Double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
	The gold-labeled pad or sample pad is not completely dry	H18	Sample moves slowly along the test strip when testing, or false negative test results	Significant	Medium	**R3**	Unacceptable	YES	Equipment verification and maintenance plan; temperature and humidity monitoring during use; strictly follow the production SOP operation and record, double review	Temperature and humidity records; double signature review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H19	Uniformity of gold-labeled pad or sample pad	Unverified drying room or oven drying process	Poor uniformity within or between batches	Significant	Medium	**R3**	Unacceptable	YES	Production process verification	Product Development Document-Verification Report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
Risk analysis of post-production link																		
H20	Cutting issues of gold-labeled pad	Too many blanks or cuts when cutting the gold-labeled pad	Affecting the product performance; poor uniformity within or between batches	Significant	Medium	**R3**	Unacceptable	YES	Semi-finished product inspection Standard Operating Procedures for Cutting Colloidal Gold Bars	SOP for Gold-labeled pad Cutting	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H21	Wrong materials used in the board assembly process	Material picking error	Invalid product or affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Material picking control; standard operating procedures for board assembly and preparation	Double review; production order	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H22	Mixing during production	The production label does not meet the requirements of the specification; the site clearance issues	Invalid product or affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Identification management procedures; Site clearance management regulations	QA monitoring; site clearance record	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H23	Sheet, gold label, sample pad overlap error	Improper operation	Not move forward along the test strip; affects the release of gold label	Significant	Medium	**R3**	Unacceptable	YES	Operation specification for assembly	Sop for assembly	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H24	Damaged NC membrane of test strip	Cutting machine issues	affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Double review, pick out the damaged test strip and treat it as waste	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H25	Sample pad is missing	Cutting machine issues	Invalid product or affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Double review, pick out the damaged test strip and treat it as waste	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H26	Loss of accessories, including sampling rods, limit blocks, bases, etc.	Incorrect welding and assembly parts	affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Double review, pick out incomplete products and reassemble	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H27	No desiccant	Improper operation	affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Double review, pick out products without desiccant, and reassemble	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H28	Damaged or leaked aluminum foil bag because of the packaging and sealing process	Equipment issues, improper operation	affecting product performance	Significant	Medium	**R3**	Unacceptable	YES	Double review, pick out the defective aluminum foil bag, change the bag and seal; equipment verification and maintenance plan	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H29	Wrong or missing label	Wrong operation	Wrong information, mixing	Moderate	Medium	**R2**	Further risk reduction	YES	Double review, pick out products with wrong or missing labels, and relabel	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable
H30	No instructions	Wrong operation	Users don't know the use	Moderate	Medium	**R2**	Further risk reduction	YES	Double review, put the instructions in the box	Double review	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H31	Degradation of QC standard products	Insufficient stability verification of QC standard products; storage conditions issues	Out of control of product performance	Significant	Medium	R3	Unacceptable	YES	Stability verification of QC standard products; temperature and humidity monitoring	Stability verification report of standard product; daily temperature monitoring record	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H32	Non-compliant assembly workshop environment	The air conditioning and dehumidification instrument system in the workshop is not working properly; the temperature and humidity are not monitored	affecting product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Equipment verification and maintenance plan; temperature and humidity management regulations during production;	Temperature and humidity records; equipment maintenance report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H33	Non-compliant intermediate storage environment	The air conditioner, dehumidification instrument system or refrigerator in the workshop is not working properly	affecting product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Equipment verification maintenance plan, monitoring with medium temperature and humidity	Temperature and humidity records; equipment maintenance report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H34	Non-compliant finished product storage environment	Warehouse air conditioning and dehumidification instrument systems are not working properly	affecting product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Equipment verification maintenance plan, monitoring with medium temperature and humidity	Temperature and humidity records; equipment maintenance report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

No.	Hazard (source) identification			Risk estimation and risk evaluation				Risk control							Residual risk evaluation			
	Classification of hazard (source)	Risk (source) formation factors	Potentially harmful consequences	Severity (S)	Probability (O)	Risk level	Risk acceptability	Whether control measures are needed	Control measures (plan)	Evidence of measure implementation (verification)	Measure compliance evaluation	Evaluation of the impact of measures on product performance	Measures effectiveness review	Whether to produce new hazards (NH)	Severity (S)	Probability (O)	Risk level	Risk acceptability
H35	Damage during transportation	Damaged product or package	affecting product performance and stability	Significant	Medium	**R3**	Unacceptable	YES	Stability verification of destructive transportation; taking packaging design into considerations	Packaging verification report; destructive transport report	Compliance	No impact	Effective	NO	Negligible	Low	R1	Acceptable

4.7 Acceptability evaluation of comprehensive residual risk
Evaluation Team of Risk Management agree with that comprehensive residual risk is acceptable after considering influence of all residual risk.
Specific Evaluations:
Is any risk control inconsistency?
Conclusion: None.
Warning Evaluation (including if there are too many warnings?)
Conclusion: Clear and Meet Specification.
IFU Evaluation (including if any inconsistency or difficulty to comply with)
Conclusion: It meets《Guidelines for writing instructions for in vitro diagnostic reagents》. It clearly describes product safety and it is user friendly.
Conclusion of Evaluation Team
Conclusion: All agree with that comprehensive residual risk is acceptable.
Evaluation Team Member: Lin Li, Jing Zhang, Yun Liu
Team Leader: Yong Yang

5 Post-production information
5.1 Effectively control risk of products in the trial production stage by Risk Management. Will continue collection of further post-production information to analyze and control residual risk in real-time.

5.2 Methods to collect post-production information:
1）Regularly collect variation of new version regulations and standards;
2）Regularly collect interior or exterior adverse event;
3）Advisory Notice and Product Recall;
4）Regularly collect reports on the results of supervision and random inspection by the supervision department;
5）Customers' complaints and returns, Diagnosis and Evaluation Result;
6）Evaluation & verification of variation of design or technical flow;
7）Summary analysis of the quality of purchased products;
8）Problems in the manufacturing process and corrective and preventive measures（Production process control status, unqualified status, and ability to produce qualified products in key processes（Whether to verify, the monitoring situation after verification）, monitoring results during product storage（Environment, packaging integrity, storage life））;
9）Product inspection results (trend analysis) and corrective and preventive measures.

The above information can be obtained from system records. In addition, the latest technological level factors and the feasibility of its application should also be taken into consideration. Not only should the relevant information of the company's similar products be collected, but also the public information of other similar products on the market.

5.3 The above-mentioned information received should be reviewed and analyzed, and the analysis results may involve safety information should be evaluated whether the following conditions exist:
1）Is there a previously unrecognized hazard (source)?

2）Whether there is one or more unpredictable risks arising from the occurrence of hazards (sources), which are no longer acceptable.
If any of the above happens, on the one hand, the impact of previously implemented risk management activities should be evaluated, fed back into the risk management process as an input, and review the product risk management documents. If the results of the review may have one or more residual risks or their acceptability has changed, the impact of the previously implemented risk control measures shall be evaluated, and further measures shall be taken if necessary, to make the risks acceptable.

5.4 According to results of the previous analysis and review, find the direction of product improvement, repeat and improve appropriate risk management process, and modify the corresponding risk management documents and risk management reports.

5.5 Review Risk Analysis
Over time, when new technology/data/data applications may eliminate or reduce the risk of a hazard (source), R&D department will conduct a new risk analysis and review. Any changes in risk management can be linked to the management review process. We do not produce this product at present. Once it is officially produced, it will be re-analyzed, evaluated and controlled according to the above scheme.

According to the above requirements, this product has undergone sample trial production and small batch trial production, from which preliminary production and post-production information has been obtained, including raw material verification, packaging material verification, performance verification, process verification, stability test, equipment verification, and personnel training. In general, this product meets the intended use, and its safety and effectiveness meet its technical requirements. There were no abnormalities nor adverse events in the product and production process during product trial production, small batch trial production and the entire design verification process. According to the currently collected production and post-production information, compared with the identified hazards (sources) and risks, new hazards (sources) and risks do not appear, unacceptable conditions for the identified risks do not appear, and inconsistency of existing risk control does not appear. Warnings clear and meet specifications. It clearly describes product safety, and it is user friendly.

6 Conclusion
The risk management evaluation team has reviewed the trial-produced products and the risk management process by checking the risk management documents. They agree:
－Risk management plan has been properly implemented;
－Comprehensive residual risk is acceptable;
－Appropriate methods are in place to obtain relevant production and post-production information;
－All remaining risks are within the acceptable range of risk acceptance criteria, and the benefits exceed the risks.

Agree to approve the registration.

Signature：

Date：