SARS-CoV-2 Antigen Test Kit (Colloidal Gold) Risk management report

Genrui Biotech Inc.

Content

1 Overview

1.1 Product introduction

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is an immunochromatographic analysis method for rapid and qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen in nasal swabs. The test kit consists of test card, diluent solution and nasal swabs.

1.2 Purpose of risk management review

The risk management activities of SARS-CoV-2 Antigen Test Kit (Colloidal Gold) at each stage before marketing were comprehensively evaluated to ensure that reasonable control measures were taken for the risks of the product and the risks were within the acceptable range.

1.3 Standard

EN ISO 14971:2012 Medical devices-Application of risk management to medical devices.

1.4 Risk management team members and responsibilities

Reviewer	Department	Position	Responsibility
[redacted]			Responsible for the whole process of risk management management, control and allocation of related resources.
			Responsible for the supervision and implementation of the whole process of risk management, ensuring that the risk management activities are carried out in accordance with the system documents, evaluating from the perspective of regulations, and analyzing the rationality of relevant control measures. Approve the 《risk management plan》 and 《management report》

5.1.2e

5.1.2e

5.1.2e	Carry out risk assessment from the perspective of technical feasibility and implement relevant risk control measures.
	Carry out risk assessment from product inspection and quality control, and implement relevant risk control measures.
	Evaluate the selection and control of raw material suppliers, review the suppliers, and participate in the risk management review.
	Collect customer needs, timely feedback market information, participate in analysis and review from the market perspective.
	Participate in the risk (source) identification, risk assessment, residual risk assessment and the formulation and implementation of risk control measures in the clinical confirmation process.

1.5 Risk management plan

According to the product life cycle stages covered by the plan, make corresponding arrangements for risk management activities in each stage, including verification and review activities.

1.5.1 Risk management schedule

The risk management activity plan for the product lifecycle phase is shown in the table below:

The life cycle phase	Risk management activities	Responsible
Proposal stage	Develop the risk management plan	Risk Management team

Planning Stage		Risk analysis, evaluation and control program analysis: 1. List of product safety characteristics (appendix C) A. Hazard (source) identification and label B. Risk analysis, evaluation and control program analysis 2. Risk analysis of in vitro diagnostic medical devices (appendix H) A. Hazard (source) identification and label B. Risk analysis, evaluation and control program analysis	Risk Management team
Design and development phase	Input	Input the results of previous risk management.	Project group
	Development	1. Implement various risk control measures; 2. Verify the necessary control measures; 3. Residual risk assessment; 4. Evaluate whether the risk control measures generate new risks.	Project group; Risk Management team
	Output	All risk control measures are implemented in the output design document.	Project group
	Review	1. Evaluate the implementation of various risk controls; 2. Evaluate the integrity of risk control measures; 3. Review whether the risk control measures generate new risks.	Risk Management team
Design transition phase	Input	Implement various risk control measures.	Project group; Reagent production department
	Verification	1. Verify the implementation of risk control measures; 2. Verify the effect of risk control measures.	Project group; Reagent quality department
	Validation	1. Further evaluate the effectiveness of risk control measures through clinical/trial/identification; 2. Assess the acceptability of the comprehensive residual risk; 3. Conduct a risk/benefit analysis of the risks that are deemed unacceptable and that are not feasible for further risk control.	Project group; Risk Management team

	Risk management review	1. Review the risk management activities in the design and development phase to ensure A) the risk management plan for medical devices has been fully implemented; B) comprehensive residual risk is acceptable; C) appropriate methods are available to obtain relevant production and post-production information. 2. Prepare the risk management report for the design and development stages according to the review results.	Risk Management team
	Organize design and process documents	Organize risk management documents.	Project group; Risk Management team
	product registration	Submit a risk management report	Project group;
Transfer and post-production	Transferring phase	Implement the risk management in the production process according to the 《control procedure for nonconforming products》, 《data analysis control procedure》 and 《corrective and preventive measures control procedure》.	Production department, quality department
	Post-production stage	1. Collect information during use and maintenance according to 《quality control procedures》 and 《after-sales service control procedures of medical devices》; 2. Evaluate information that may involve security; 3. In the event of "the occurrence of a previously unknown hazard or hazard situation" or "the occurrence of one or more estimated risks arising from the hazard situation is no longer acceptable", the previous risk management process and risk management documents shall be evaluated and appropriate measures shall be taken; 4. The evaluation results and appropriate measures	Sales department; after-sales Department; quality department

		shall be documented in the risk management documents.	

1.5.2 Risk management plan and implementation status brief

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) was proposed in January 2020. The company has planned the design and development of the products, and set up a risk management team to carry out risk analysis for each stage of design and development.

The risk management team reviewed the risk management plan, determined the acceptable risk criteria, and planned the risk management activities at each stage of product design and development, as well as the methods for obtaining production and post-production information.

The risk management team carried out risk management at each stage of design and development in strict accordance with the plan of the risk management plan, and established and maintained relevant risk management documents.

1.6 Risk acceptance criteria

According to the characteristics of the product category, the risk management team developed the risk acceptability criteria.

1.6.1 Severity level of risk

Rank name	Code	Definition
Negligible	S1	Inconvenience or temporary discomfort
Minor	S2	Results in temporary injury or impairment not requiring professional medical intervention
Serious	S3	Results in injury or impairment requiring professional medical intervention
Critical	S4	Cause permanent injury or life-threatening injury
Catastrophic	S5	Cause patient death

1.6.2 Probability levels of risk

Common term	Code	Probability
Improbable	P1	$<10^{-6}$
Remote	P2	$<10^{-5}$ and $\geqslant 10^{-6}$

Occasional	P3	$<10^{-4}$ and $\geqslant 10^{-5}$
Probable	P4	$<10^{-3}$ and $\geqslant 10^{-4}$
Frequent	P5	$\geqslant 10^{-3}$

1.6.3 Acceptable criteria for risk

Probability		Severity				
		S1	S2	S3	S4	S5
		Negligible	Minor	Serious	Critical	Catastrophic
Frequent	P5	U	U	U	U	U
Probable	P4	R	U	U	U	U
Occasional	P3	R	R	U	U	U
Remote	P2	A	R	R	U	U
Improbable	P1	A	A	R	R	R

Note:

A	Acceptable risk
R	Risk to be reduced further
U	Unacceptable risk

2 Risk analysis

2.1 Questions that can be used to identify medical device characteristics that could impact on safety (Annex C)

Identify product-specific safety issues and identify identified hazards (sources) according to Appendix C of EN ISO14971:2012.

C.2 Questions	Yes/No	Characteristics judgement	Possible hazard	Hazard identification
C.2.1 What is the intended use and how is the medical device to be used?	Yes	Intended Use: SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is an immunochromatographic analysis method for rapid and qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen in nasal swabs. Usage: strictly follow the instructions of the kit for correct operation and use.	Biological and chemical hazards (source) Operational hazard (source) Information hazard (source)	C1
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 other persons?	Yes	The kit has the opportunity to contact the operator and user.	Biological and chemical hazards (source)	C2
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical	Yes	The test kit consists of test card, sample diluent and nasal swabs. The nasal swab will come into contact with the human body during use.	Biological and chemical hazards (source)	C3

device?				
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?	Yes	Nasal swab should be from the patient as a test sample before testing.	Biological and chemical hazards (source)	C4
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?	Yes	It is intended for qualitatively detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen from the nasal swab specimen. Factors that may affect the measurement results include reagents, operator	Operational hazard (source)	C5

		proficiency, cross-contamination between reagents or samples, endogenous or exogenous interference of samples, etc.		
C.2.12 Is the medical device interpretative?	No	/	/	
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	Waste liquid and discarded samples after use.	Biological and chemical hazards (source)	C6
C.2.15 Is the medical device susceptible to environmental influences?	Yes	The kit shall be transported and stored at a temperature of 2-30℃ and operated at a humidity of less than 65%.	Operational hazard (source) Information hazard (source)	C7
C.2.16 Does the medical device influence the environment?	No	/	/	/
C.2.17 Are 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?	Yes	Shelf life of reagents.	Operational hazard (source) Information hazard (source)	C8
C.2.21 Are there any delayed or long-term use effects?	Yes	Using a kit beyond the expiration date may adversely affect the measurement results. No adverse effects after long-term use.	Operational hazard (source) Information hazard (source)	C9
C.2.22 To what mechanical forces will the medical device be subjected?	No	/	/	/
C.2.23 What determines the lifetime of the medical device?	Yes	Product formula, production process, transportation conditions, stability of reagent components, storage conditions of reagents, etc.	Operational hazard (source) Information hazard (source)	C10
C.2.24 Is the medical device intended for single use?	Yes	It is intended for single use.	Operational hazard (source) Information hazard (source)	C11
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	Yes	The waste liquid and used reagents are needed to be processed.	Biological and chemical hazards (source)	C12

			Operational hazard (source)	
C.2.26 Does installation or use of the medical device require special training or special skills?	No	/	/	/
C.2.27 How will information for safe use be provided?	Yes	Instruction manuals, labels, after-sales service engineers, etc.	Information hazard (source)	C13
C.2.28 Will new manufacturing processes need to be established or introduced?	No	/	/	/
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?	Yes	Misuse of reagents, incomplete instruction manuals, or inadequate label design will all lead to inaccurate results.	Information hazard (source)	C14
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	Yes	Incorrect use by users.	Operational hazard (source) Information hazard (source)	C15
C.2.29.3 Does the medical device have connecting parts or accessories?	No	/	/	/
C.2.29.4 Does the medical device have a control interface?	No	/	/	/
C.2.29.5 Does the medical device display	No	/	/	/

information?				
C.2.29.6 Is the medical device controlled by a menu?	No	/	/	/
C.2.29.7 Will the medical device be used by persons with special needs?	No	/	/	/
C.2.29.8 Can the user interface be used to initiate user actions?	No	/	/	/
C.2.30 Does the medical device use an alarm system?	No	/	/	/
C.2.31 In what way(s) might the medical device be deliberately misused?	Yes	Ignored the recommendations in the manual.	Operational hazard (source)	C16
C.2.32 Does the medical device hold data critical to patient care?	No	/	/	/
C.2.33 Is the medical device intended to be mobile or portable?	No	/	/	/
C.2.34 Does the use of the medical device depend on essential performance?	Yes	The reliability of the test results depends on the precision of the reagents, the minimum detection limit, and positive/negative percent agreement.	Information hazard (source)	C17

2.2 Guidance on risk management for in vitro diagnostic medical devices (Annex H)

The questions in accordance with EN ISO14971:2012 Appendix H contain important considerations for estimating the risk to the patient of IVD medical devices. Identify specific security issues for SARS-CoV-2 Antigen Test Kit (Colloidal Gold), and indicate

hazard identification.

H.2 Questions content			Yes/No	Characteristics judgement	Possible hazard	Hazard identification
H.2.1 Identification of intended uses	H.2.1.1 General	What users does the product include?	Yes	Operator and patient who have completed the examination.	/	/
	H.2.1.2 Intended use	What analytical substances are expected to be used in the product?	Yes	Novel Coronavirus （SARS-CoV-2）antigen		/
		Are measuring systems and procedures (instrumentation) required for their intended use?	No	Not required	/	/
		Can it be used to install inappropriate measurement systems and procedures (instrumentation)?	No	Used alone, no other system is involved	/	/
		Is the inspection procedure qualitative, semi-quantitative or quantitative?	Yes	Qualitative	/	/
		Is it possible to use a higher level measurement program incorrectly?	No	Impossible	/	/
		What types of samples can be used for the product?	Yes	Nasal swab	/	/
		Is there a possibility of improper sample type misuse?	Yes	It is possible that other body fluid may be misused	Operational or information hazard	H1

					source	
		What is the use place or environment of the product?	Yes	Self-testing places, such as a person's home, offices, etc	/	H2
		Is there an inappropriate place or environment for misuse?	Yes	Use in an unexpected environment	Operational or information hazard source	H3
	H.2.1.3 Instructions for use	What are the intended medical applications and patient populations? The results can be used to detect or assist in the diagnosis of diseases in which populations?	Yes	The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.	Operational or information hazard source	H4
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 improvization, as well as omissions of actions intended by the manufacturer, such as those prescribed in the instructions for use.	Yes	The user may not follow the instructions	Operational or information hazard source	H5
	H.2.2.2 Examples of possible use	Use of an IVO medical device with an inappropriate calibrator, reagent, instrument or sample matrix	Yes	The wrong sample type was used	Operational or information	H6

	errors by laboratory personnel				hazard (source)	
		Attempt to optimize an examination procedure in order to improve its performance characteristics	No	Not involved	/	/
		Abbreviation of an examination procedure (taking "shortcuts");	Yes	Possible	Operational or information hazard source	H7
		Neglect of instrument maintenance	No	Not involved	Operational or information hazard source	
		Disabling or failing to enable safety features	No	No safety device included	/	/
		Operation in adverse environmental conditions	Yes	Does not operate in the required temperature, humidity and clean environment	Operational or information hazard source	H8
	H.2.2.3	Checking program	No	/	/	/

	Examples of possible use errors by healthcare providers	Is this product used to diagnose a disease and not to screen a disease in a population?	Yes	Used as an adjuvant diagnosis of novel Coronavirus	Operational or information hazard source	H9
		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);	No	/	/	/
		Is this product used for status monitoring and not for disease diagnosis?	No	The kit should be used only for in vitro diagnosis and should not be used for other purposes	/	/
		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).	No	/	/	/
		Is it possible for users to extend the intended use of this product for the diagnosis of some other disease?	No	Novel Coronavirus antigen test only.	/	/

	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.: using insufficient volume of sample; failure to insert a reagent module properly; dividing reagent strips (e.g. to reduce cost); disabling or failing to enable safety features; storing reagent in inappropriate conditions.	Yes	Fail to follow the instructions.	Operational or information hazard source	H10
H.2.3 Identification of characteristics related to safety	H.2.3.1 General	Failure to meet the performance characteristics required for a specific medical use	Yes	Verify and validate in the design and development process.	Operational or information hazard source	H11
	H.2.3.2 Performance characteristics of quantitative examination procedures	Does the product have performance characteristics of quantitative examination procedures?	No	Qualitative reagent	/	/
		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.	No	Qualitative reagent	/	/
	H.2.3.3 Performance	Does the product have performance of qualitative examination procedures	Yes	Qualitative reagent	/	/

	characteristics of qualitative examination procedures					
	H.2.3.4 Dependability characteristics	Whether IVD test results can be used as the basis for physicians to make emergency medical decisions? 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.	No	It is used to detect novel coronavirus antigen	/	/
	H.2.3.5 Ancillary patient information	Whether 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 lead to a hazardous situation.	No	The patient's information was not designed to be reported along with the examination results	/	/
		Failure to associate the correct information with the examination result could affect the proper interpretation of the result?	Yes	There may be an incorrect interpretation	Information hazard source	H12
H.2.4	H.2.4.1	The hazards could cause or contribute to	No	/	/	/

Identification of known and foreseeable hazards	Hazards to the patient	misdiagnosis with the potential for harmful medical intervention or delays				
	H.2.4.2 Relationship to performance characteristics	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.	No	/	/	/
	H.2.4.3 Identifying hazards in fault conditions	within-batch inhomogeneity	Yes	Possible	Operational hazard source	H13
		batch-to-batch inconsistency	Yes	Possible	Operational hazard source	H14
		non-traceable calibrator value	No	With no calibration	/	/
		non-commutable calibrator	No	With no calibration	/	/
		non-specificity (e.g., interfering factors)	Yes	Possible	Operational hazard source	H15
		sample or reagent carryover	No	Single use	/	/
		measurement imprecision (instrument-related)	No	No supporting instrument	/	/
		stability failures (storage, transportation,	Yes	Possible	Operational	H16

		in-use)			hazard source	
		hardware/software failure	No	No supporting instrument	/	/
		packaging failure	Yes	Possible	Operational hazard source	H17
		incorrect patient name or identification number	No	/	/	/
		incorrect birth date or age	No	/	/	/
		incorrect gender	No	/	/	/
	H.2.4.4 Identifying hazards in normal use	This could be due to the uncertainty of examination results	Yes	Possible	Operational or information hazard source	H18
		This could be due to the biological variability of patient samples.	Yes	Possible	Operational or information hazard source	H19
		This could be due to choice of a cut-off value or other factors.	Yes	Possible	Operational or information	H20

					hazard source	

3 Risk evaluation and control

3.1 Evaluation and control of questions that can be used to identify medical device characteristics that could impact on safety (Annex C)

Based on the determination results of the safety characteristics of the SARS-CoV-2 Antigen Test Kit (Colloidal Gold), foreseeable sequences of events, hazardous situations, harm, risk assessments and risks control plan analysis are performed on the identified characteristics.

Hazard (source) No.	Hazard (source)	Foreseeable sequences of events	Hazardous situations	Harm	Risk estimation			Analysis of initial risk control plan
					Severity	Probability	Risk level	
C1	Biological and chemical hazards (source) Operational hazard (source) Information hazard (source)	1.Non-professional use 2.The intended use of the reagent is not fully described	1. Nasal swab, specimen are not processed as a potential source of infection 2. Reagent is used incorrectly or improperly	1. Infected contacts 2. Incorrect detection results	S2	P4	U	1. Strictly follow the instructions, take protective measures when collecting samples and testing. 2. According to the regulations and guidance for the preparation of In vitro Diagnostic Reagent Instructions.

C2	Biological and chemical hazards (source)	Operators operate without gloves	Relevant personnel directly or indirectly contact kit components	Skin irritation or infection	S1	P3	R	1.Production process regulations require corresponding protection throughout the production process; 2.Production or inspection personnel need systematic training; 3. The instruction manual reminds the operator to take necessary protection during operation and maintenance.
C3	Biological and chemical hazards (source)	Reagent contamination	Waste samples after testing cause contamination.	Polluted environment	S2	P4	U	After the test, waste samples should be put into biosafety bags, according to the requirements of local laws and regulations, strictly according to the provisions of the disposal..
C4	Biological and chemical hazards (source)	Sample contamination	Nasal swab, nasopharyngeal swab or opharyngeal swab specimen should be taken from the patient before the test.	Infected contacts	S2	P3	R	It is clear in the manual that the waste after the test should be put into the biosafety bag and disposed of in strict accordance with the local regulations.
C5	Operational hazard (source)	Incorrect measurement results	Mixing different batches of reagents, using	Test result error	S2	P4	U	1. Mark the lot number and expiration date of the product at the obvious position of the product label;

			samples other than those specified by the kit, the samples have interference effects.					2. In the instructions, clearly indicate the sample collection.
C6	Biological and chemical hazards (source)	Waste liquid, waste, etc. are not treated as required.	Waste liquids, wastes, etc. that are not handled as required are exposed to the environment	Polluted environment	S2	P3	R	1. It is clear in the manual that the waste after the test should be put into the biosafety bag and disposed of in strict accordance with the local regulations.
C7	Operational hazard (source) Information hazard (source)	1.Storage and transportation or operation do not under the required storage and transportation conditions or working conditions 2.Incomplete or	The product is stored, transported or operated under incorrect storage or transportation conditions or working conditions	1.Product deterioration, causing economic losses 2.Incorrect detection results	S2	P4	U	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with relevant regulations. 3. Request for the transportation company.

		incorrect temperature identification						
C8	Operational hazard (source) Information hazard (source)	1.Use products that exceed the storage validity period; 2. No obvious validity period is given.	Testing with reagents that exceed the actual expiration date	Product failure, resulting in false test results.	S2	P5	U	1. Use strictly before the expiration date specified in the instructions. 2. Give the obvious expiry date and the stability expiry date in the instructions and / or labels.
C9	Operational hazard (source) Information hazard (source)	1.Use products that exceed the storage validity period; 2. No obvious validity period is given.	Testing with reagents that exceed the actual expiration date	Product failure, resulting in false test results.	S2	P5	U	1. Use strictly before the expiration date specified in the instructions. 2. Give the obvious expiry date and the stability expiry date in the instructions and / or labels.
C10	Operational hazard (source) Information hazard (source)	Product performance failed	Imperfect formulas and processes, poor storage conditions, caused unstable	Measurement results are incorrect, leading to misjudgment	S2	P5	U	1. Perform reagent stability research, improve reagent stability performance, perform reagent stability testing and long-term stability tracking, and improve the process. 2. Indicate the transportation, storage and use conditions of the reagents in the instruction

			performance					manual and / or label.
C11	Operational hazard (source) Information hazard (source)	Reuse of reagents, cross contamination	The instructions are unclear	Measurement results are incorrect and cause cross-contamination. Misjudgment result	S2	P2	R	It is clearly stated in the reagent instruction manual that the reagent is single use.
C12	Biological and chemical hazards(source) Operational hazard (source)	Waste liquid, waste bottles or waste samples are not processed as required, causing environmental pollution.	Pollution due to failure to dispose of waste as required.	Impact of the work environment.	S2	P4	U	1. It is clear in the manual that the waste after the test should be put into the biosafety bag and disposed of in strict accordance with the local regulations. 2. The reagent instructions and labels should be clear.
C13	Information hazard (source)	No safety use information provided	Relevant protective measures were not taken when using the kit	Skin irritation or infection	S1	P3	R	Provide safety use information through instruction manuals, labels, and after-sales service engineers.
C14	Information hazard (source)	Incomplete instruction manual or label	May lead to incorrect use	Incorrect detection results	S2	P5	U	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with the requirements of relevant regulations.

C15	Operational hazard (source) Information hazard (source)	1. Storage and transportation or operation do not under the required storage and transportation conditions or working conditions. 2. Incomplete or incorrect temperature identification.	The product is stored, transported or operated under incorrect storage or transportation conditions or working conditions.	1. Product deterioration, causing economic losses. 2. Incorrect detection results.	S2	P5	U	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with relevant regulations. 3. Request for the transportation company.
C16	Operational hazard (source)	1. Ignored the sample requirements, testing methods or precautions on the manual	Use of wrong sample type.	Incorrect detection results	S2	P3	R	1. Follow the instructions strictly. 2. The reagent instructions and labels should be clear.
C17	Information hazard (source)	The minimum detection limit, precision and other performance of the	Testing using reagents that do not meet the requirements	Incorrect or inaccurate test results	S2	P5	U	1. In the development process, evaluate the analytical performance and stability of the reagents, improve the process, and improve the relevant analytical performance and stability

		labeling or advertising reagent do not meet the technical requirements of the product.						performance of the reagents. 2. During the production process, commissioning and inspection are strictly performed in accordance with the production process regulations.

3.2 Evaluation and control of risk management for in vitro diagnostic medical devices (Annex H)

Based on the determination results of the safety characteristics of the SARS-CoV-2 Antigen Test Kit (Colloidal Gold), foreseeable sequences of events, hazardous situations, harm, risk assessments and risks control plan analysis are performed on the identified characteristics.

Hazard (source) No.	Hazard (source)	Foreseeable sequences of events	Hazardous situations	Harm	Risk estimation			Analysis of initial risk control plan
					Severity	Probability	Risk level	
H1	Operational hazard or information hazard source	There may be improper sample type misuse.	Use the error sample type	Error detection results	S2	P4	U	The applicable sample type of this product is specified in the instruction. Read this instruction carefully before using.
H2	Operational hazard or information	Maybe the sampling is wrong, the operation is wrong	Use the wrong sample type and the wrong action condition	False positive or false negative results may	S2	P4	U	The applicable sample type of this product is specified in the instruction. Read this instruction carefully before

	hazard source			occur				using.
H3	Operational hazard or information hazard source	Use in an unexpected environment.	Lack of strict control measures results in human exposure to the infected environment.	Human infection	S2	P4	U	Specify the intended operating environment in the manual.
H4	Operational hazard or information hazard source	It is possible that other diseases may also increase the test results, affecting the user's judgment of results.	The test results are adopted by the user.	Make incorrect judgments.	S2	P4	U	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do not rule out the possibility of infection. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.
H5	Operational hazard or information hazard source	The tester did not operate according to the instruction	Unable to obtain test results, or obtain error test results.	Failure to diagnose in a timely manner or misdiagnosis	S2	P3	R	Clearly stated in the IFU: Operate according to the instructions.
H6	Operational hazard or information	The wrong sample type was used	Other body fluid were detected.	Error detection results.	S2	P3	R	In the IFU, the type of test sample is specified.

	hazard source							
H7	Operational hazard or information hazard source	Simplify the reagent operation process	The unreliable test results were adopted.	Cause incorrect judgment.	S2	P3	R	The test procedure is clearly stated in the instruction, and the operation must be in strict accordance with the operation rules, careful operation can get the correct result, any modification to the operation procedure may affect the result.
H8	Operational hazard or information hazard source	Failed to operate under required test conditions.	The unreliable test results were adopted.	Cause incorrect judgment.	S2	P3	R	It is clearly stated in the instruction manual that when the kit is used for sample testing, it should be tested after the test conditions are met.
H9	Operational hazard or information hazard source	May be used by users to test ordinary patient samples.	High test results from other interfering substance.	The higher outcome was due to severe rheumatism in the patient	S2	P4	U	Clearly stated in the IFU: It is an aid in the diagnosis of patients with suspected novel coronavirus infection.
H10	Operational hazard or information hazard	Patients took insufficient samples, operated incorrectly, or stored reagents under	The obtained unreliable test results are used	It causes incorrect judgment	S2	P3	R	The test procedure is clearly stated in the manual, and the operation must be strictly in accordance with the operating procedures, careful operation

		inappropriate conditions.						to get the correct results, any changes to the operating procedures may affect the results.
H11	Operational hazard or information hazard source	The performance index cannot meet the requirement of medical use.	Products are used for testing without verification or confirmation.	Lead to incorrect results.	S1	P5	U	Verify and validate during design development and design transformation. Through strict control of the production process, strict implementation of the product technical requirements of the factory testing, Control the performance of the product in a reasonable range, qualified release.
H12	Operational hazard or information hazard source	Failure to report together may affect the proper interpretation of the results and lead to dangerous situations.	The user does not combine the patient's symptoms/signs, medical history or other information for diagnosis and treatment.	May lead to inaccurate judgments.	S2	P4	U	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do not rule out the possibility of infection. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.
H13	Operational hazard source	Within-batch inhomogeneity	Products are used for testing without verification or	Lead to incorrect results.	S2	P4	U	Verify and validate during design development and design transformation. Through strict control

			confirmation.					of the production process, strict implementation of the product technical requirements of the factory testing, Control the performance of the product in a reasonable range, qualified release.
H14	Operational hazard source	Batch-to-batch inconsistency	Products are used for testing without verification or confirmation.	Lead to incorrect results.	S2	P4	U	Verify and validate during design development and design transformation. Through strict control of the production process, strict implementation of the product technical requirements of the factory testing, Control the performance of the product in a reasonable range, qualified release.
H15	Operational hazard source	Nonspecific, such as the influence of interfering factors.	The influencing factors of interfering substances were not analyzed in the design and development process.	The test results are unreliable.	S3	P4	U	Test and evaluate possible cross substances and state in the instructions.
H16	Operational hazard source	Failure of stability (in storage, transportation and use)	Test with reagents that have exceeded their actual expiration date.	The test results are unreliable.	S2	P4	U	In the process of product development, the stability of the reagent (accelerated stability, long term stability, open vial

								stability, and transportation stability) should be studied. The storage and transportation conditions of the product and its validity period should be determined and indicated in the instructions..
H17	Operational hazard source	Poor sealing for plastic bottle will affect the product performance.	Misuse of reagents whose packages have been damaged or leaking.	The test results are unreliable.	S2	P3	R	Clearly stated in the IFU: The kit should not be used if the product packaging is damaged or the sample diluent is leaking.
H18	Operational hazard or information hazard source	The uncertainty of the examination results.	Test as per normal operation.	Results that do not correspond to reality appear.	S2	P3	R	Limited by the current technical level, the range of performance indicators of the qualitative test product is limited to the scope of the product.
H19	Operational hazard or information hazard source	Biological differences in samples.	Test as per normal operation.	The examination results do not agree with reality.	S2	P3	R	Clearly stated in the IFU: This kit is used for the determination of nasal swab samples.
H20	Operational hazard or information	Detect the results that appear at the cut-off point.	When the results are reported, judge according to the	The results may not be consistent with clinical	S2	P4	U	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do

	hazard source		interpretation of the test results in the instructions.	assessment.				not rule out the possibility of infection.

4 Verification results of risk control measures

4.1 Risk assessment and verification of risk control measures (Annex C)

Hazard (source) No.	Hazard (source)	Risk estimation			Take control measures		Residual risk assessment			Whether new risks arise (if so, assess new risks)			Verification of risk control measures (effectiveness and implementation of measures)
		Severity	Probability	Risk level	Existing control measures	Implementation Verification	Severity	Probability	Risk level	Severity	Probability	Risk level	
C1	Biological and chemical hazards (source) Operational hazard (source) Information hazard (source)	S2	P4	U	1. Strictly follow the instructions, take protective measures when collecting samples and testing. 2. According to the regulations and guidance for the preparation of In vitro Diagnostic Reagent Instructions.	1. See the instruction chapter "Test Method". 2. See the specification chapter "Intended Use".	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐Measures not implemented

C2	Biological and chemical hazards (source)	S1	P3	R	1.Production process regulations require corresponding protection throughout the production process; 2.Production or inspection personnel need systematic training; 3. The instruction manual reminds the operator to take necessary protection during operation and maintenance.	Confirm the production procedure, see the production work instruction for details.	S1	P2	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
C3	Biological and chemical hazards (source)	S2	P4	U	After the test, waste samples should be put into biosafety bags, according to the requirements of local laws and regulations, strictly	Sample cleaning procedure in the manual.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not

					according to the provisions of the disposal.								implemented
C4	Biological and chemical hazards (source)	S2	P3	R	After the test, waste samples should be put into biosafety bags, according to the requirements of local laws and regulations, strictly according to the provisions of the disposal.	Follow the instructions strictly.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented
C5	Operational hazard (source)	S2	P4	U	1. Mark the lot number and expiration date of the product at the obvious position of the product label; 2. Identify sampling methods in the instruction manual.	1. See the batch number and validity of the label; 2. See the instructions for sample collection.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented

C6	Biological and chemical hazards (source)	S2	P3	R	1. It is clear in the manual that the waste after the test should be put into the biosafety bag and disposed of in strict accordance with the local regulations.	See the instructions for sample cleaning procedures.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented
C7	Operational hazard (source) Information hazard (source)	S2	P4	U	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with relevant regulations. 3. Request for the transportation company.	1. Refer to the Instructions chapter "Special storage &Transport conditions"; 2 Clear storage conditions on the label; 3. When necessary, a transport agreement shall be signed to guarantee the transport conditions.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented
C8	Operational hazard	S2	P5	U	1. Use strictly before the expiration date	1. See the Instructions chapter "Special storage	S2	P1	A	/	/	/	■Effective measures;

	(source) Information hazard (source)				specified in the instructions. 2. Give the obvious expiry date and the stability expiry date in the instructions and / or labels.	&Transport conditions".							☐Ineffective measures; ■Measures have been implemented; ☐Measures not implemented
C9	Operational hazard (source) Information hazard (source)	S2	P5	U	1. Use strictly before the expiration date specified in the instructions. 2. Give the obvious expiry date and the stability expiry date in the instructions and / or labels.	1. See the Instructions chapter "Special storage &Transport conditions".	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐Measures not implemented
C10	Operational hazard (source) Information hazard (source)	S2	P5	U	1. Perform reagent stability research, improve reagent stability performance, perform reagent stability testing and	1. Stability evaluation report; 2. Refer to the Instructions chapter "Special storage &Transport conditions" and label storage	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐Measures not

					long-term stability tracking, and improve the process. 2. Indicate the transportation, storage and use conditions of the reagents in the instruction manual and / or label.	conditions identification.							implemented
C11	Operational hazard (source) Information hazard (source)	S2	P2	R	It is clearly stated in the reagent instruction manual that the reagent is single use.	1. The instructions specify that it is for one-time use; 2. Product Label.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented
C12	Biological and chemical hazards(source)	S2	P4	U	1. It is clear in the manual that the waste after the test should be put into the biosafety bag	1. Read the product manual before use; 2. See the Instructions chapter "Test Method".	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have

	Operational hazard (source)				and disposed of in strict accordance with the local regulations. 2. The reagent instructions and labels should be clear.								been implemented; ☐Measures not implemented
C13	Information hazard (source)	S1	P3	R	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with the requirements of relevant regulations.	1. Instructions chapter "Precautions"; 2. Read the product manual before use.	S1	P2	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐Measures not implemented
C14	Information hazard (source)	S2	P5	U	1. Prepare product instructions in accordance with the requirements of relevant	1. Specify "Test method" in the instructions; 2. The label indicates the storage information	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have

					regulations. 2. Design labels in accordance with the requirements of relevant regulations.	of the product							been implemented; ☐Measures not implemented
C15	Operational hazard (source) Information hazard (source)	S2	P5	U	1. Prepare product instructions in accordance with the requirements of relevant regulations. 2. Design labels in accordance with relevant regulations. 3. Request for the transportation company.	1. Instructions confirmation; 2. Label confirmation; 3. If necessary, sign the cold chain transport agreement to ensure the transport environment	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐Measures not implemented
C16	Operational hazard (source)	S2	P3	R	1. Strengthen the training of clinical testing staff. 2. The reagent instructions and labels should be	1. Instructions chapter "Precautions"; 2. Read the product manual before use.	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented;

					clear.								☐Measures not implemented
C17	Information hazard (source)	S2	P5	U	1. In the development process, evaluate the analytical performance and stability of the reagents, improve the process, and improve the relevant analytical performance and stability performance of the reagents. 2. During the production process, commissioning and inspection are strictly performed in accordance with the production process	1. Analysis performance evaluation report; 2. Production records	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐ Measures not implemented

					regulations.								

4.2 Risk assessment and verification of risk control measures (Annex H)

Hazard (source) No.	Hazard (source)	Risk estimation			Take control measures		Residual risk assessment			Whether new risks arise (if so, assess new risks)			Verification of risk control measures (effectiveness and implementation of measures
		Severity	Probability	Risk level	Existing control measures	Implementation Verification	Severity	Probability	Risk level	Severity	Proba-bility	Risk level	
H1	Operational hazard or information hazard source	S2	P4	U	The applicable sample type of this product is specified in the instruction. Read this instruction carefully before using.	1. Read the product manual before use; 2. The Instructions chapter "intended use" indicates nasal swab as the sample types.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented

H2	Operational hazard or information hazard source	S2	P4	U	Specify the intended operating environment in the manual.	Instructions chapter "intended use"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H3	Operational hazard or information hazard source	S2	P4	U	Specify the intended operating environment in the manual.	Specify the intended operating environment in the manual.	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H4	Operational hazard or information hazard source	S2	P4	R	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do not rule out the possibility of	1. Instructions chapter "Limitations"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not

					infection. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.								implemented
H5	Operational hazard or information hazard source	S2	P3	R	Clearly stated in the IFU: Operate according to the instructions.	1. Instructions chapter "Test Method"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H6	Operational hazard or information hazard source	S2	P3	R	In the IFU, the type of test sample is specified.	1. The Instructions chapter "intended use"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented;

													☐ Measures not implemented
H7	Operational hazard or information hazard source	S2	P3	R	The test procedure is clearly stated in the instruction, and the operation must be in strict accordance with the operation rules, careful operation can get the correct result, any modification to the operation procedure may affect the result.	1. Instructions chapter "Test Method"	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐ Measures not implemented
H8	Operational hazard or information hazard source	S2	P3	R	It is clearly stated in the instruction manual that when the kit is used for sample testing, it should be tested after the test conditions are met.	1. Instructions chapter "Sample Requirements"	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐ Measures not

													implemented
H9	Operational hazard or information hazard source	S2	P4	U	Clearly stated in the IFU: It is an aid in the diagnosis of patients with suspected novel coronavirus infection.	1. The Instructions chapter "intended use"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H10	Operational hazard or information hazard source	S2	P3	R	The test procedure is clearly stated in the manual, and the operation must be strictly in accordance with the operating procedures, careful operation to get the correct results, any changes to the operating procedures	Instructions chapter "Test Method"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented

					may affect the results.								
H11	Operational hazard or information hazard source	S1	P5	U	Verify and validate during design development and design transformation. Through strict control of the production process, strict implementation of the product technical requirements of the factory testing, Control the performance of the product in a reasonable range, qualified release.	1. Production process regulations; 2. Provisions on release management	S1	P2	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented

H12	Operational hazard or information hazard source	S2	P4	U	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do not rule out the possibility of infection. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.	1. The Instructions chapter "intended use"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H13	Operational hazard source	S2	P4	U	Verify and validate during design development and design transformation. Through strict control of the	1. Production process regulations; 2. Provisions on release management	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not

					production process, strict implementation of the product technical requirements of the factory testing, Control the performance of the product in a reasonable range, qualified release.								implemented
H14	Operational hazard source	S2	P4	U	Verify and validate during design development and design transformation. Through strict control of the production process, strict implementation of the product technical requirements of the	1. Production process regulations; 2. Provisions on release management	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented

					factory testing, Control the performance of the product in a reasonable range, qualified release.								
H15	Operational hazard source	S2	P4	U	Test and evaluate possible cross substances and state in the instructions.	1. The Instructions chapter "Limitations"; 2. Confirmation of RESEARCH and development data	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H16	Operational hazard source	S2	P4	U	In the process of product development, the stability of the reagent (accelerated stability, long term stability, open vial stability, and transportation	1. Instructions chapter "Special storage &Transport conditions"; 2. DHF documents of R&D	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □Measures not implemented

					stability) should be studied. The storage and transportation conditions of the product and its validity period should be determined and indicated in the instructions..								
H17	Operational hazard source	S2	P3	R	Clearly stated in the IFU: The kit should not be used if the product packaging is damaged or the sample diluent is leaking.	1. Instructions chapter " Precautions"	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented; □ Measures not implemented
H18	Operational hazard or information hazard source	S2	P3	R	Limited by the current technical level, the range of performance indicators of the qualitative test	1. The Instructions chapter "Limitations";	S2	P1	A	/	/	/	■Effective measures; □Ineffective measures; ■Measures have been implemented;

					product is limited to the scope of the product.								☐ Measures not implemented
H19	Operational hazard or information hazard source	S2	P3	R	Clearly stated in the IFU: The optimal sample is nasal swab specimen.	1. The Instructions chapter "intended use"	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐ Measures not implemented
H20	Operational hazard or information hazard source	S2	P4	U	Clearly stated in the IFU: A positive test result requires further confirmation, and negative results do not rule out the possibility of infection.	1. The Instructions chapter "Limitations"	S2	P1	A	/	/	/	■Effective measures; ☐Ineffective measures; ■Measures have been implemented; ☐ Measures not implemented

5 Assess risk - secondary risk arising from risk control measures

According to 4.1 risk assessment and verification of risk control measures (Appendix C) and 4.2 Risk Assessment and verification of risk control measures (Appendix H), the risk assessment results generated by risk control measures and the implemented control measures did not generate new hazards, and all risks generated by risk control measures were considered and controlled.

6 Integrity assessment of risk control

By checking 4.1 risk assessment and verification of risk control measures (Appendix C) and 4.2 Risk assessment and verification of risk control measures (Appendix H), all control measures have been verified and all risks have been considered and controlled.

7 Comprehensive residual risk assessment

All residual risk has carried on the comprehensive analysis by the risk management group, with taking into account the results of all residual risk under the common effect condition. The conclusion of evaluations as follows: the product overall residual risk is acceptable. The Specific evaluations as following:

1) Whether there are conflicting requirements for the risk control of individual risks?

Conclusion: Conflicting risk controls have not yet been identified.

2) Warning review (including whether there are too many warnings?)

Conclusion: The warning is clear and in accordance with the specification.

3) Review of manual (including whether there is contradiction condition, or difficult to follow)

Conclusion: the product manual meets regulation and special safety standards related to the description of product safety aspects and it is clear and easy to understand, to facilitate the user to read.

4) Review team conclusions

Conclusion: After analyzing the above aspects, the risk management review team unanimously evaluated that the comprehensive residual risk of this product is acceptable.

8 Risk/benefit analysis

According to 4.1 risk evaluation, risk control measures verification (appendix C) and 4.2 risk evaluation, risk control measures verification (appendix H) and the result of risk control, it can be seen that the current to be expected and known risk after risk control measures, there is no unacceptable (U) level of risk. Conduct risk/benefit analysis:

I. Benefit analysis

a. What are the clinical benefits of testing to users or to society (public health) in screening, diagnosing or monitoring specific diseases, conditions or risk factors?

Conclusion: The kit can assist in the diagnosis of novel coronavirus antigen, which can reduce the spread of the epidemic and the pressure of the medical system.

b. What would be the benefit to users or society if the tests could be used at home rather than only by professionals?

Conclusion: The reagent provides a convenient solution for the general user to assist in the diagnosis of Novel Coronavirus antigen, which can reduce the pressure on the medical system by conducting preliminary screening.

II. Risk analysis

a. What is the impact of false positive or false negative test results on the user or society (e.g., failure to follow up the user's follow-up actions or poor medication use)?

Conclusion: The test is an adjuvant to diagnosis and should not be used as the sole basis for treatment or other management decisions. It is necessary to go to the relevant departments for diagnosis according to local regulations.

b. What is the risk to users or society in delaying access to professional examinations if a home IVD intended for symptomatic subjects gives false or undetermined results?

Conclusion: Reagents are an adjuvant to diagnosis and should not be used as the sole basis for treatment or other management decisions. It is necessary to go to the relevant departments for diagnosis according to local regulations.

c. What is the risk of accidental use of household IVD in an inappropriate environment?

Conclusion: It is necessary to read the instructions carefully. Inaccurate results may occur if the test is performed in an inappropriate environment.

1) If the control line does not appear in the test, the test results will be considered invalid under such circumstances. Please re-test with the new kit. If the result of the test cannot be definitively determined, please contact the nearest medical institution according to local government regulations.

2) The result is positive. The control area (C) and test area (T) can be seen and the patient should contact the nearest medical institution immediately in accordance with the regulations of the local government.

3) The result is negative. If only horizontal color lines are visible in the control area (C), it may indicate that result is negative or the patient has a low viral load that cannot be recognized by the test. When the patient experiences similar symptoms such as headache, migraine, fever, loss of taste and the sense of taste, please go to the nearest medical institution for diagnosis according to the requirements of the local government.

d. What are the risks faced by users or the society for improper disposal after the occurrence of operational errors?

1) If the control line does not appear in the test, in this case, the test results will be considered invalid. Please re-test with the new kit. If the result of the test cannot be definitively determined, please contact the nearest medical institution according to local government regulations.

2) The result is positive. The control area (C) and test area (T) can be seen and the patient should contact the nearest medical institution immediately in accordance with the regulations of the local government.

3) The result is positive. If only horizontal color lines are visible in the control area (C), it may indicate that the result is negative or the patient has a low viral load that cannot be recognized by the test. When the patient experiences similar symptoms such as headache, migraine, fever, loss of taste and the sense of taste, please go to the nearest medical institution for diagnosis according to the requirements of the local government.

To sum up, this kit, as an auxiliary diagnosis of novel coronavirus, cannot be used as the sole basis for treatment or other management decisions. It can make it more convenient for users to use, effectively assist in controlling the spread of the epidemic, and will not cause greater risk, and the benefits are far greater than the risks after evaluation.

9 Production and post-production information

Production and post-production information acquisition methods are mainly collected from the following aspects:

No.	Information Source	Responsible department	Collecting and sorting frequency	Remark
1	Changes in regulations and standards	Regulation Department	1time/year	/
2	Adverse event report	System Management Department	1 time/year	/
3	Advisory Notice (Product recall)	System Management Department	1 time/year	/
4	The results of spot check by the department responsible for supervision	System Management Department	1 time/year	/
5	Customer complaints	Marketing/Sales Department	1 time/year	/
6	Quality of goods purchased	Supply chain	2 times/year	Use of nonconforming
7	Product manufacturing	Product department	2 times/year	Process change and validation
8	Product inspection results (Trend analysis)	Quality Department	2 times/year	/
10	Product design changes	R&D Department	1 time/year	/

10 Enforcement Measures for Collection of Information

The regulations department collects information about the changes of external regulations, organizes training and promotion, and then converts them into internal requirements. According to the customer feedback collected by the Marketing Department and the supervision of the supervision department, the system management department shall respond in time and issue recall or advisory notices. The supply chain tracks the quality of the purchased products, and the raw materials that do not meet the requirements shall be executed according to the requirements of our company. The production department and the quality department shall strictly execute according to the relevant operation instructions, and correct the non-conformities in time. According to the market demand, the R&D department shall complete the design changes in response. For the changes, it shall carry out verification and risk assessment before making the changes.