Risk Analysis Report

according to Directive 98/79/EC

Product: COVID-19 IgG/IgM Rapid Test Kit

Signature of Manufacturer

Weijun Ou

Signature of Test Agency

Lingling Su

Overview

This document provides a safety risk analysis for COVID-19 IgG/IgM Rapid Test Kit. The risk analysis followed Annex C and Annex H (H.2 Risk analysis) of EN ISO 14971:2012 to identify risk and Potential Hazard, and according to H.2 Risk analysis, H.3 Risk evaluation, H.4 Risk control, H.5 Production and post-production monitoring to carry out the COVID-19 IgG/IgM Rapid Test Kit risk analysis report.

Scope

This risk analysis addresses the safety risks that may affect the patient or the operator as associated with the operation of the COVID-19 IgG/IgM Rapid Test Kit.

Intended Use/Purpose

COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma.

Risk Management Committee Members

The risk analysis was done by representatives from R&D, Manufacturing, QC/QA and Regulatory.

Evaluation staff	Department	Responsibility
Weijun Ou	General Manager	Establish risk management policy； Supply with adequate resources and qualified personnel competence for risk management activities; Establish risk management responsibility and authority and authorize the quality department to determine the risk management team members; Hosting the annual quality system management review; Approval of the risk management report.
Lingling Su	Management representative	To supervise and audit risk management
Juan Zhang Fei Gu Hui Chu Hailiang Huang	R & D	Responsible for the development of risk management plan;To be responsible for the organization development risk management team to implement risk management activities;To be responsible for the organization to risk analysis, the design and development of products and finish the risk management report.
YanZi Lu	Quality control	Responsible for determining the risk management team members;Responsible for approval of risk management plan;Responsible for organization and coordination of risk management activities; Responsible for regular evaluation of product information (including production, inspection, customer complaints), determine the responsibility of unqualified products, when it comes to design, inform the r&d department related information.

Ling Li	Production	Responsible for the relevant risk control in the production process.
Jin Wang	Marketing	Be responsible for tracking of post-production and transfer relevant information within the company.

Risk acceptable criteria

No.	**Severity**	**Description**	Example
1	Negligible	Little harm or none	25%≥CV≥15%, affect clinical judgment
2	Marginal	Maybe little injury	Sensitivity: IgG>L2, IgM>L5
3	Serious	Severe injury	Infection, False positive, False negative.
4	Critical	Permanent injury or life-threatening injury	Virus spread widely, leading to large number of people infected.
5	Catastrophic	Death of user	Patient death

Definition of Probability of Occurrence（Unity：incident/year/each device）

improbable：$<10^{-6}$

remote：10^{-6}～10^{-5}

occasional： 10^{-5} ～10^{-4}

probable：10^{-4}～10^{-3}

frequent：$\geq 10^{-3}$

Risk assessment with harm severity and possibility

Possibility	Severity				
	1） Negligible	2） Marginal	3） Serious	4） Critical	5） Catastrophic
5）frequent	**U**	**U**	**U**	**U**	**U**
4）probable	**U**	**U**	**U**	**U**	**U**
3）occasional	**A**	**A**	**U**	**U**	**U**
2）remote	**A**	**A**	**A**	**U**	**U**
1）improbable	**A**	**A**	**A**	**A**	**A**

In table：

A：Acceptable risk

U：Unacceptable risk

Risk identification and Potential hazard evaluation

According to Annex C and Annex H(H.2 risk analysis) in ISO 14971，Risk identification and Potential hazard evaluation are addressed in following table. Hazard and risk management item was showed in risk management table.

Table 1 Risk identification and Potential hazard evaluation

Items	Characteristic Identification	Potential Hazard	Risk management Item
C.2.1, What is the intended use and how is the medical device to be used?	1. For the qualitative detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. 2. Just for professional users.	Usage error	H1
C.2.2, Is the medical device intended to be implanted?	No	None	
C.2.3, Is the medical device intended to be in contact with the patient or other persons?	Yes users may contact with the test device.	NaN_3 in strip may may causes Toxic reaction	H2
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?	No	None	
C.2.5, Is energy delivered to or extracted from the patient?	No	None	
C.2.6, Are substance delivered to or extracted from the patient?	Yes，whole blood, serum or plasma	1. Error sample be collected. 2. not collected in clean container 3. improper sample storage 4. sample is labeled wrong 5. Sample is contaminated. 6. Sample is not handled correctly.	H3

C.2.7, Are biological materials processed by the medical device for subsequent re-use, transplantation?	No	None	
C.2.8, Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No	None	
C.2.9, Is the medical device intended to be routinely cleaned and disinfected by the user?	No	None	
C.2.10, Is the medical device intended to modify the patient environment?	No	None	
C.2.11, Are measurements taken?	Yes, lower limit of IgG is L2, lower limit of IgM is L4	Inaccurate results	H4
C.2.12, Is the medical device interpretative?	Yes, interpret the results, positive or negative.	Inaccurate results	H4
C.2.13, Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No	None	
C.2.14, Are there unwanted outputs of energy or substances?	No	None	
C.2.15, Is the medical device susceptible to environmental influences?	It is used at room temperature (18-28) ℃ The storage Information is on the package and IFU, storage requirement is 2℃-30℃. Avoid direct sunlight; Keep away from high heat and damp conditions.	Inaccurate results. Improper temperature may lead to protein failure.	H5
C.2.16, Dose the medical device influences the environment?	No	None	
C.2.17, Are there essential consumables or accessories associated with the medical device?	Yes, there are Quantitative dropper in the Foil pouch.	Consumables are missing	H6
C.2.18, Is maintenance or calibration necessary?	No	None	
C.2.19, Dose the medical device contain software?	No	None	
C.2.20, Dose the medical	Yes, 12 months	Inaccurate results.	H7

device have a restricted shelf-life?		Using expired products may lead to inaccurate results.	
C.2.21, Are there any delayed or long-term use effects?	No	None	
C.2.22, To what mechanical forces will the medical device be subjected?	No	None	
C.2.23, What determines the lifetime of the medical decive?	Protein activity	Inaccurate results. Loss of protein activity leads to loss of product function.	H5
C.2.24, Is the medical device intended for single use?	Yes,	Inaccurate results. Reuse will cause inaccurate results.	H8
C.2.25, Is the decommissioning or disposal of the medical device necessary?	No	None	
C.2.26, Dose installation or use of the medical device require special or special skills?	No	None	
C.2.27, How will information for safe use be provided?	Instruction for use and labels will provide detailed information.	Inaccurate results. Information is incomplete, which may cause improper personal use.	H1
C.2.28, Will new manufacturing processes need to be established or introduced?	No	None	
C.2.29, Is successful application of the medical device critically dependent on human factor such as the user interface?	Yes, depends on if following IFU or not (speciously temperature, reading time, sample requirement)	Inaccurate results.	H1
C.2.29.1, Can the user interface design feature contribute to use error?	No	None	
C.2.29.2, Is the medical device used in environment where distractions can cause use error?	No	None	
C.2.29.3, Dose the medical device have connecting parts accessories?	Yes, there are Quantitative dropper in the Foil pouch.	Usage error. The sample-adding method is different for each type of	H6

		product. Wrong way of sample-adding may lead to inaccurate results.	
C.2.29.4, Dose the medical device have a control interface?	No	None	
C.2.29.5, Dose the medical device display information?	Yes, display test results.	Unable to interpret the results.	H4
C.2.29.6, Is the medical device controlled by a menu?	No	None	
C.2.29.7, Will the medical device be used by persons with special needs?	No	None	
C.2.29.8, Can the user interface be used to initiate user actions?	No	None	
C.2.30, Does the medical device use an alarm system?	No	None	
C.2.31, In what way(s) might the medical device be deliberately misused?	No	None	
C.2.32, Does the medical device hold data critical to patient care?	No	None	
C.2.33, Is the medical device intended to be mobile or portable?	No	None	
C.2.34, Does the use of the medical device depend on essential performance?	Yes, it depends on the sensitivity, accuracy and specificity of the product.	Inaccurate results	H4
H.2.1 identification of intended uses	1. For the qualitative detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. 2. Just for professional users.	Usage error	H1
H.2.2 What are the clinical implications?	Clinical auxiliary diagnosis	Inaccurate results. Incorrect results can lead to inaccurate references.	H9
H.2.3 Does the kit need to be measured? Is it qualitative or quantitative?	Yes, lower limit of IgG is L2, lower limit of IgM is L4	Inaccurate results	H4
H.2.4 Whether the	Yes, read the results,	Inaccurate results	H4

measurement results need analysis and processing?	positive or negative		
H.2.5 How to determine the critical value or reference range?	Critical value of IgG is L2 and Critical value of IgM is L4.	Inaccurate results	H4
H.2.6 What are the requirements for sensitivity, specificity, coincidence rate, repeatability, recovery and other performance indicators?	It is expected to reach 95%.	Inaccurate results	H10
H.2.7 Is there a turnaround effect? How to control?	No	None	
H.2.8 What are the main causes of in-batch differences? How to control?	Reason: 1. Uncertainty of parameters 2. Operation of workers Control methods: 1. Determine the optimal parameters 2. Enhance personnel training	There are defective products in the same batch.	H11
H.2.9 What are the main causes of batch differences? How to control?	Reason: 1. Uncertainty of parameters 2. Operation of personnel Control methods: 1. Develop the optimal parameters 2. Enhance personnel training	There are defective products in different batches.	H11
H.2.10 What components or accessories are included in the kit?	Strip: test strip, desiccant, quantitative dropper and IFU Cassette: test cassette, desiccant, quantitative dropper, IFU	Usage error. The sample-adding method is different for each type of product. Wrong way of sample-adding may lead to inaccurate results.	H6
H.2.11 Does the kit contain toxic substances?	No	None	
H.2.12 Does the kit contain biological contamination?	No	None	
H.2.13 Are special production environment controls required?	Yes, temperature of 18℃ -28℃; humidity of 45%-65%; humidity of drying room, recombination and inner packing workshop lower than 40%; 100,000 level purification workshop.	Inaccurate results. Improper temperature will lead to protein failure.	H5
H.2.14 Can it be assembled in batches?	Yes, produce and assemble in batches	Inaccurate results. Assembling errors caused by unskilled workers.	H12

H.2.15 What is the shelf-life of the semi-finished products	Six months	Inaccurate results. Use the semi-finished product which is already invalid to make the finished product.	H13
H.2.16 Is there a storage life limit for the kit?	Yes, 12 months.	Inaccurate results. Using expired products can lead to inaccurate results.	H7
H.2.17 What determines the life of the kit?	The protein activity of antigens and antibodies.	Inaccurate results	H5
H.2.18 What is the packaging method of the kit? Big packing, small packing, medium packing?	Yes. Inner packing is aluminum foil pouch, medium packing is box, and large packing is packing-case.	Inaccurate results. Aluminum foil pouch swelling or incomplete sealing; IFU does not indicate that the test cannot be used if the pouch is broken; IFU does not indicate temperature, humidity, and to avoid light.	H14
H.2.19 How to transport? Will the transportation process affect the performance of the kit?	By ship, air or land. Yes, pay attention to temperature, humidity, and avoiding sunlight.	Inaccurate results. The IFU does not indicate temperature, humidity, and to avoid light.	H14
H.2.20 Is the kit environmentally sensitive? How to control?	Yes, dry storage at room temperature of 2-30℃; Avoid direct sunlight; Keep away from high heat and damp conditions	Inaccurate results. Improper temperature will lead to protein failure.	H5
H.2.21 What stability tests are needed?	Yes, real-time stability and accelerated stability experiments	Inaccurate results. Using unstable products results in inaccurate results.	H15
H.2.22 Does the kit have special requirements for test samples? How do I prepare?	No	None	
H.2.23 Does the addition of different anticoagulant plasma samples affect the results?	No	None	

H.2.24 Will the possible presence of interfering substances in the sample affect the results?	anti-Flu A antibody anti-Flu B antibody anti-RSV antibody anti-ADV antibody and anti-B group of Coxsackie virus antibody		H16
H.2.25 Will different sample containers affect the results?	No	None	
H.2.26 Are sample storage conditions required? Will the different storage conditions of samples affect the results?	Yes. At 2-8 ℃ store for up to 7 days. Long-term storage at -20 ℃. Repeated freezing and thawing no more than three times.	Inaccurate results. Improper storage of samples results in incorrect test results.	H17
H.2.27 Does the timing of sample collection affect the outcome for patients?	No	None	
H.2.28 How is the kit used?	The IFU specifies the operation method in detail.	Usage error.	H1
H.2.29 Can different batches of the same product be mixed?	Yes, can be mixed, but can only be used on one sample, such as a dropper.	Inaccurate results. Different samples were taken from the used dropper.	H18
H.2.30 Can the same component be used together in different packaging for the same batch of the same product?	Yes, can be mixed, but can only be used on one sample, such as a dropper.	Inaccurate results. Different samples were taken from the used dropper.	H18
H.2.31 Can the kit be reused? Is the life span of each component after the product is unsealed up to the expiry date specified by the product?	For single-use only. Humidity: ≤65% products can be used at 1 hours after opening. Humidity: >65% Products must be used as soon as possible after it opened	Inaccurate results. Using beyond the life span determined by the experiment may lead to result error.	H19
H.2.32 Can the kit be used again after being unsealed? What are the storage conditions and expiration dates after unpacking?	For single-use only. Humidity: ≤65% products can be used at 1 hours after opening. Humidity: >65% Products must be used as soon as possible after it opened	Inaccurate results. Using beyond the life span determined by the experiment may lead to result error.	H19
H.2.33 Is the kit in contact with patients or other persons?	Yes, users may contact with the test device.	NaN_3 in strip may cause bio safety risk.	H2

H.2.34 Does the kit need to be used with other medical devices?	No		
H.2.35 Are there substances available to or extracted from patients?	No		
H.2.36 Does the substance in the kit affect the environment?	No		
H.2.37 Does the use of the kit require calculating software?	No		
H.2.38 Are calibration and quality control products required?	Use internal Reference Substance	The result of using unqualified internal control product is inaccuracy.	H20
H.2.39 Does kit operation require special training?	No		
H.2.40 Will different washing methods affect the results?	No		
xH.2.41 Are there any exports of waste, polluting substances, etc.?	No		

Judgment of reasonably foreseeable hazards, hazard analysis and initial risk control plans

According to Appendix H, Risk Analysis (H.2), risk assessment (H.3), risk control (H.4), production and post-production monitoring (H.5) the HCG test kit (colloidal gold method) was conducted. Hazard analysis has been considered reasonably foreseeable conditions, which include under normal conditions, fault conditions; consequences or damage to the harm include: the hazards of the patient, the operator of harm, harm to nearby persons, for the environment. The initial hazard analysis of the HCG test kit (colloidal gold method) is shown in table 2, including predictable sequence of events, hazardous situation and damage and initial risk control program of analysis that can occur.

Table 2： Initial hazards analysis of HCG test kit

Hazard type	**Code**	**predictable sequence of events**	**Hazard situation**	**Consequence and harm**	**Initial risk contraol solution analysis**
Operation hazard	H1	User did not use it according to intended use on IFU	Potential biosecurity risks	User or other people infected	In strict accordance with IFU when used by the user.
Environmental Hazard	H2	contact with the product surface	the test containing a small amount of sodium azide, a Toxic	Users or other touch	Under supervision. the operator should

			reaction		wear gloves, according to IFU with " after Using the reagents and samples medical waste and other waste should be properly handled."
Operation hazard	H3-1	Sample is not Whole Blood, Serum or Plasma	Measurement is not correct	Failure and error of diagnostic harm patient	In strict accordance with the instructions in the "sample requirements" for collection
Operation hazard	H3-2	Inappropriate collection of samples, collected in the non-clean containers	Measurement is not correct	Failure and error of diagnostic harm patient	In strict accordance with the instructions in the "sample requirements" for collection
Operation hazard	H3-3	Samples were placed too long or failing to store at unreasonable temperature	Measurement is not correct	Failure and error of diagnostic harm patient	In strict accordance with the instructions in the "sample requirements" for collection
Operation hazard	H3-4	Sample ID error	Error for determining of prostate cancer	Diagnosis of errors, reducing reliability of screening test	Identification of samples using the determined (such as bar code), check after identification
Operation hazard	H3-5	Sample contamination	Error of measurement	Diagnosis errors, reducing reliability of screening results	With unpolluted and clean containers to collect, no contact with other test strips or detection reagents
environmental hazard	H3-6	mishandle sample after testing	Sample contamination	Harm other people	Strengthen accountability, read the Notice in the instructions
Operation hazard	H4	The IFU did not specify the minimum detectable quantity, interpretation method and	The product was used by the people who have not used it before.	Results were indecipherable.	In IFU, clearly describe the minimum detectable quantity, interpretation method and

		other performance characteristics			other performance characteristics.
Operation hazard	H5	Temperature or humidity too high for production and preservation; did not avoid direct sunlight; did not use in its useful life.	The product was used by the people who have not used it before.	Loss of protein activity, result error.	The storage conditions and useful life of the products are stated in detail in the IFU.
Operation hazard	H6-1	Disposable dropper is missed.	Cannot test	Measurement fails	Strictly control the production process
Operation hazard	H6-2	Do not know how to use dropper.	The product was used by the people who have not used it before.	False result	The IFU must indicate the way of adding sample.
Operation hazard	H7	Using expired product.	The product was used by ordinary people who have not used it before.	Result error	The expiry date must be marked on the IFU, packing box and foil pouch.
Operation hazard	H8	Ruse	The product was used by ordinary people who have not used it before.	Result error	Warning of not to reuse the disposable test kit must be clearly stated on the IFU and labeling.
Information hazard	H9	Incorrect reference information was provided	To provide reference for later diagnosis after the test with the kit.	Result error	The IFU must indicate that it is auxiliary diagnosis. Further testing needs to be done in a more reliable way.
Operation hazard	H10	Abnormal results	Users use the test kit.	Inaccurate results	Detailed information should be given during design and development validation.
Operation hazard	H11	The results are inconsistent.	Use the same batch/different batches of nonconforming products.	Inaccurate results	Product parameters should be determined during design and development, and workers

					should be trained and qualified to take up posts.
Operation hazard	H12	Wrong accessories were packed in.	Workers assemble the products.	False result	Train the workers and take up the post after they are qualified.
Operation hazard	H13	Stored for too long	Semi-finished products	False result	In the process of design and development, accelerated stability test and real-time stability test are used to determine the expiry date of semi-finished products. Inspect semi-finished products before making them into finished products.
Operation hazard	H14	False result	The small pouch that the user gets is broken but the test inside is used. Products that are exposed to direct sunlight during shipment or storage are still in use.	Product lose efficacy	During the design and development process, the product storage requirements should be determined, and the integrity of foil pouches should be inspected in batches. In the IFU, clearly indicate that the product with damaged foil pouch cannot be used.
Information hazard	H15	False result	Used for testing after a long-term storage	Inaccurate results	Real-time stability and accelerated stability are used to verify product validity.
Information hazard	H16	Interferents affect test results.	There were interferents in the sample during the test.	Inaccurate results	Operate test to verify that the substances do not affect the test

					results and clearly state in the IFU.
Information hazard	H17	The storage time is too long at 2-8℃. Repeated freezing and thawing.	Sample preservation	Inaccurate results	In the process of design and development, the preservation of samples should be verified experimentally. The sample requirements should be indicated in the IFU.
Operation hazard	H18	The same dropper is used for two different samples.	User uses other accessories for testing.	False result	In the IFU, indicate the disposable accessories.
Operation hazard	H19	Continue to use the test after unpacking for some time.	Continue to use the test after unpacking for some time.	Inaccurate results	In the process of design and development, the validity period after unpacking should be determined experimentally. The IFU clearly indicate the period of validity after unpacking.
Operation hazard	H20	The quality cannot be guaranteed if unqualified standard substances are used for verification.	Using defective products	Inaccurate results	Purchase national standard products for verification.

Risk evaluation, risk control and risk control measure verification

The company evaluate the known hazards, according to the risk acceptance criteria to judge whether each hazard risks is an acceptable level, take risk control measure for reasonably risk reduction, without risk / benefit analysis and can be determined unacceptable risks, and verify the concrete measures, and implement the verification for risk after measures to estimate the level of risk is acceptable. The risk assessment, risk control measures recording for HCG test is shown in table 3:

Table 3：Risk evaluation, risk control and risk control measure recording

Hazard No.	Hazard type	Risk estimating and risk evaluation			Take control measure			Risk evaluation after take meausures			Does generate new risk（if yes, evaluate new risk）			Note	risk / benefit analysis
		Probability	Severity	Risk level	（Initial）Measure plan	Verification	Relevant document	Probability	Severity	Risk level	Probability	Severity	Risk level		
H1	Operation hazard	occasional	Serious	U	In strict accordance with IFU when used by the user.	The IFU clearly indicates the intended use and purpose of the product, and the description of operation is easy to understand.	IFU-COVID-19 IgG/IgM	improbable	Serious	A					
H2	Environmental Hazard	occasional	Slight	A	Under supervision. the operator should wear gloves, according to IFU with " after Using the reagents and samples	The IFU clearly indicates that the gloves must be wore before test.	IFU-COVID-19 IgG/IgM	improbable	Slight	A					

					medical waste and other waste should be properly handled."									
H3-1	Operation hazard	remote	Serious	A	In strict accordance with the instructions in the "sample requirements" for collection	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H3-2	Operation hazard	remote	Serious	A	In strict accordance with the instructions in the "sample requirements" for collection	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H3-3	Operation hazard	occasional	Serious	U	In strict accordance with the instructions in the "sample requirements" for collection	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H3-4	Operation hazard	occasional	Serious	U	Identification of samples using the determined (such as bar code), in particular to strengthen the sense of responsibility when self-testing, check	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				

					after identification									
H3-5	Operation hazard	occasional	Serious	U	With unpolluted and clean containers to collect, no contact with other test strips or detection reagents	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H3-6	Operation hazard	occasional	Serious	U	Strengthen accountability, read the Notice in the instructions	Sample collection requirements are stated in IFU	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H4	Operation hazard	occasional	Serious	U	In IFU, clearly describe the minimum detectable quantity and interpretation method.	The IFU states that the minimum detectable IgG is L2, IgM is L5. The result interpretation: colored lines C and G both appear means positive; colored lines C and M both appear means positive;	IFU-COVID-19 IgG/IgM	improbable	Serious	A				

						colored lines C, M and G all appear means positive; only colored C line appears means negative; no lines appear anywhere on the control zone means invalid.								
H5	Operation hazard	Remote	Serious	U	The storage conditions of the products should be stated in detail in the IFU.	Products are stored at room temperature of 2-30 ℃ and are valid for 1 years. In the production process, the temperature is 18-28 ℃ and the humidity is 45%-65%. Humidity in drying room, recombination room and inner packing room is less than 40%.	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H6-1	Operation hazard	Remote	Serious	U	Only droppers supplied can be used	For Serum or Plasma Specimens:Add 2uL of sample to the sample pad, then add 2 drops of	IFU-COVID-19 IgG/IgM	improbable	Serious	A				

						sample buffer to the buffer pad. For Whole Blood Specimen: Add 4uL of sample to the sample pad, then add 2 drops of sample buffer to the buffer pad.								
H6-2	Operation hazard	Remote	Serious	U	The instructions state how to add samples	For Serum or Plasma Specimens:Add 2uL of sample to the sample pad, then add 2 drops of sample buffer to the buffer pad. For Whole Blood Specimen: Add 4uL of sample to the sample pad, then add 2 drops of sample buffer to the buffer pad.	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H7	Operation hazard	Remote	Serious	U	The expiry date must be marked on the IFU, packing box and foil pouch.	Mark on the IFU, packing box and foil pouch that the product is valid for 12 months.	IFU-COVID-19 IgG/IgM	improbable	Serious	A				
H8	Operation hazard	Remote	Serious	U	Warning of not to reuse the	There is disposable mark. State in the	IFU-COVID-19 IgG/IgM	improbab	Serious	A				

					disposable test kit must be clearly stated in the IFU and labeling.	IFU that reuse may lead to inaccurate results.	Label-COVID-19 IgG/IgM	le							
H9	Information hazard	Remote	Serious	U	The IFU must indicate that it is auxiliary diagnosis.	The IFU must indicate that it is auxiliary diagnostic reagent	IFU-COVID-19 IgG/IgM	improbable	Serious	A					
H10	Operation hazard	Remote	Serious	U	Detailed information should be given during design and development validation.	State this information in the IFU.	IFU-COVID-19 IgG/IgM	improbable	Serious	A					
H11	Operation hazard	Remote	Serious	U	1. Determine the optimal parameters 2. Train the workers and take up the post after they are qualified.	1.Determine the parameters. 2. Worker training, fillout training record and test paper.	1.QES-SC-ZJ-067 COVID-19 IgG/IgM technological parameter 2.RC6.2.2-004 Training record	improbable	Serious	A					
H12	Operation hazard	Remote	Serious	U	Train the workers and take up the post after they are qualified.	Worker training, fillout training record and test paper.	RC6.2.2-004 Training record	improbable	Serious	A					
H13	Operation	occasional	Serious	U	In the process of	After experiment,	Design and	impr	Serio	A					

	hazard				design and development, accelerated stability test and real-time stability test are used to determine the expiry date of semi-finished products. Inspect semi-finished products before making them into finished products.	the period of validity of semi-finished products is determined to be half a year. In order to control the quality of products, matching tests are required before each finished products are made.	development: Validation test of semi-finished products inspection record Matching test report	obable	us					
H14	Operation hazard	Remote	Serious	U	During the design and development process, the product storage requirements should be determined, and the integrity of aluminum foil pouches should be inspected in batches. In the IFU, clearly indicate that the product with damaged	Product storage temperature condition is 2-30℃. Avoid high temperature and humidity, keep away from light. In the IFU, clearly indicate that the product with damaged aluminum foil pouch cannot be used. Check aluminum foil bag integrity by batch sampling.	IFU-COVID-19 IgG/IgM	improbable	Serious	A					

					aluminum foil pouch cannot be used.									
H15	Operation hazard	Remote	Serious	U	Real-time stability and accelerated stability are used to verify product validity.	In the validation phase, prove the effectiveness of the product via experiments.	1.Design and development: Real-time stability experiment 2.Design and development: Accelerated stability experiment	impr obab le	Serio us	A				
H16	Information hazard	occasional	Serious	U	Operate test to verify that the substances do not affect the test results and clearly state in the IFU.	There's no cross-reactivity observed with Flu A, Flu B,RSV(respiratory syncytial virus), EV71, CA16, ADV.	1. Interferen ce experiment 2.IFU-COVID -19 IgG/IgM	impr obab le	Serio us	A				
H17	Operation hazard	Remote	Serious	U	In the process of design and development, the preservation of samples should be verified experimentally. The sample requirements	In the IFU, state that the samples should be tested in time after collection, if not, place the sample in the refrigerator at 2-8℃ for at most 7 days,	1. Experime nt on sample storage conditions 2. IFU-COVI D-19 IgG/IgM	impr obab le	Serio us	A				

					should be indicated in the IFU.	long-term storage should be at -20℃. No more than 3 times of repeated freezing and thawing.									
H18	Operation hazard	Remote	Serious	U	In the IFU, indicate the disposable accessories.	In the IFU, clearly state that the product is disposable.	IFU-COVID-19 IgG/IgM	improbable	Serious	A					
H19	Operation hazard	Remote	Serious	U	In the process of design and development, the validity period after unpacking should be determined experimentally. The IFU clearly indicate the period of validity after unpacking.	the product is stable at Humidity: ≤65%, we suggest it used at one hour. When the humidity is >65%, the product must be used as soon as possible after it opened	1. Experiment of validation after unpacking 2. IFU-COVID-19 IgG/IgM	improbable	Serious	A					
H20	Operation hazard	Remote	Serious	U	Use internal Reference Substance	Identification of internal control products	1. IFU -internal Reference Substance. 2. Report for internal reference substance maked-up	improbable	Serious	A					

The evaluation of synthetic residual risk

After our company taking measures to reduce risk, H1 ~ H20hazards have dropped to an acceptable level of risk.

Detail evaluation:

1）Is there with individual risk after risk control?

Conclusion: conflicting requirements exist now.

2）Review of warning

Conclusion: No warning

3）Review of IFU

Conclusion: IFU meet the provision of EN ISO 15223-1, and description of product safety is clear and understandable, easy to read.

4) Compared with similar products

Need clinical validation.

5) Expert conclusion

Conclusion: after analyzing the above aspects, the risk management review panel made comprehensive communication with clinical application specialists; finally they agreed on that this product's overall residual risk is acceptable.

Production and post-production monitoring

Medical equipment COVID-19 IgG/IgM Rapid Test Kit is planned to put into production after applying for examination and registration. Our company needs the collection and review of production and after production information, also needs filling the tables accordingly (table 4) to decide whether to improve product (especially security) and service or not.

The person in charge of risk management should mange production and post-production information he received. If it is necessary, the risk management panel should imply the dynamic risk management activities.

After acquiring the post-market safety information, our company will take the following measures according to the evaluation results:

1). Strengthening monitoring or follow-up of listed products to collect more security information;

2) .Report the latest security information to the client, users or the public;

(3) Take timely corrective action, including making improvement in product design, production, sales, installation process;

(4) Supply or modify packaging, labels, manuals etc.

(5) Take corrective measures on medical devices in the field;

(6) Stop selling the same batch products with adverse reaction immediately and recall the listed products from the market.

Table 4: COVID-19 IgG/IgM Rapid Test Kit production and post-production information collection table

Type	**Serial number**	**Information content**	**source**
Internal information	1		
	2		
	3		
	4		
	5		
External information	1		
	2		
	3		
	4		
	5		

The conclusion of risk management review

After reviewing the COVID-19 IgG/IgM Rapid Test Kit， the panel of risk management review made such conclusions:

1. Risk management plan has been properly implemented.
2. Overall residual risk is acceptable.
3. Having had appropriate methods for related production and after production information, and had started the dynamic risk management procedures when it is appropriate.

All residual risks of COVID-19 IgG/IgM Rapid Test Kit are in an acceptable range, and its benefits outweigh the risks.