Risk Analysis

COMPANY NAME	Shenzhen Zhenrui Biotech Co.,Ltd
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PRODUCT	Covid-19 Antigen Rapid Test cassette(Nasal swab)
MODEL	
ACCESSORIES:	NA

Compiled by: 5.1.2e Date: 2021.3.30

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1.summary

a.Product introduction

b.Brief introduction of risk management plan and Implementation

The project was planned and approved in 2020. At the same time, we planned the risk management activities and formulated the risk management plan for the product.
The risk management plan determines the risk acceptance criteria, and arranges the risk management activities in the product design and development stage (including the trial production stage), the responsibilities and authorities of the relevant personnel in the risk management activities, and the review requirements for the methods of obtaining information after production and production.
The company has formed a risk management team and determined the risk management director of the project to ensure the effective implementation of the risk management activities of the project according to the risk management plan.
In the product design and project development stage, the risk management team conducted a total of risk management reviews and formed relevant risk management documents.

c.Purpose of the risk management review

The purpose of this risk management review is to ensure that the risk management plan has been successfully completed through the overall evaluation of risk management activities in various stages before the product is put on the market, and the product is confirmed to be qualified through the risk analysis, risk evaluation and risk control of the product, as well as the acceptability evaluation of the comprehensive residual risk, and the review of the method for obtaining the production and post production information The risk has been effectively managed and controlled in an acceptable range.

d.Risk management review team members and their responsibilities

Name	Department	Position
5.1.2e	5.1.2e	5.1.2e
5.1.2e	5.1.2e	5.1.2e
5.1.2e	Quality department	Team members
5.1.2e	Production department	Team members
5.1.2e	R & D department	Team members

2.Acceptance

RE	Risk Evaluation
S	Severity (9 – very serious, 0 –not serious)
O	Occurrence (9 – often, 0 – never)
D	Detection (9 –impossible to detect before risk occurs, 0 – will be certainly detected before risk occurs)

RL	Risk Level = Severity × Occurrence × Detection 1-9: neglectable risk, no further actions; 9-24:moderate: minimal risk, preventive action recommended; 25-48:moderate risk, preventive action required; >48:risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes)
ALOR	Acceptable Level of Risk

3.Risk management review

a.Completion of risk management plan

The review team inspected the completion of the discovery management plan one by one, and considered that the risk management plan had been basically implemented through the inspection of relevant risk management documents.

b.The comprehensive residual risk is acceptable for review

The review team conducted a comprehensive analysis of all residual risks and considered the role of all individual residual risks under the common influence. The review results showed that the comprehensive residual risk of the product was acceptable, and the specific evaluation aspects were as follows:

1) Are there conflicting requirements for risk control of single risk?

Conclusion: there is no contradiction in the existing risk control.

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

Conclusion: the warning tips are clear and conform to the standard.

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

Conclusion: the product instructions meet the requirements of "Regulations on the management of medical device instructions and labels", "guidelines for the preparation of in vitro diagnostic reagent instructions" and product specific safety standards. The description of related product safety is clear and easy to understand and easy to read by users.

4) Conclusion of review team

Conclusion: after analyzing the above aspects, the risk management review group unanimously evaluates that the comprehensive residual risk of the product is acceptable.

c.About production and post production information

For the method of obtaining production and post production information, please refer to the control procedure for user feedback and after-sales service. The review group evaluated the suitability and effectiveness of the method for obtaining production and post production information in the control procedure for user feedback and after-sales service, and concluded that the method is appropriate and effective, and the acquisition of production and post production information can be conducted in accordance with the user feedback and after-sales service control procedure If necessary, the risk management team will carry out activities to implement dynamic risk management. Since the product has not been formally produced, once the product is officially produced, all kinds of risks in the

production will be collected, analyzed, evaluated and controlled again, and the contents of risk management report will be updated.

4.Conclusion of risk management review

After reviewing the trial production products and reviewing the risk management process by checking the risk management documents, the risk management review team considers that:

- the risk management plan has been properly implemented
- the comprehensive residual risk is acceptable
- there are appropriate methods to obtain relevant production and post production information

Identification of qualitative and quantitative characteristics (acc. to ISO 14971:2019, cl. 4.2).

1	Intended use and how to use	
2	Intended implantation	NA
3	Intended to contact patient or other person	The person should wear gloves to handle samples and reagents
4	Materials/components used	,
5	Energy to/from patient	NA
6	Substances to /from patient	Nasal swab
7	Biological materials processed	NA
8	Sterile/Intended to be sterilized	Non-sterile
9	routinely cleaned and disinfected by the user	NA
10	Modify patient environment	NA
11	Measurements	NA
12	Interpretative	NA
13	use in conjunction with medicines or other medical technologies	NA
14	Unwanted outputs of energy or substances	NA
15	Susceptible to environmental influences	2～30℃
16	influence the environment	The product shall be disposed in accordance with technical specifications for disinfection.
17	Consumables/accessories sociated	NA
18	Routine maintenance/calibration	NA
19	Software	NA
20	Restricted "shelf-life"	24 months
21	Delayed and/or long-term use effect	NA
22	Mechanical forces	NA
23	Lifetime of the device determined	Humidity, Temperature
24	Single use/re-use	Single use
25	Safe decommissioning or disposal	NA
26	Special training required to install or use	NA
27	How to provide secure access to information	Instruction For Use;Labels
28	New manufacturing processes need to be established or introducedintroduced?	NA
29	Successful application of the medical device critically dependent on human factors, such as user interface	
29.1	Interface design features lead to misuse	NA
29.2	Misuse in the inappropriate environment due to distraction	NA
29.3	connecting parts or accessories	NA
29.4	Control interface	NA
29.5	Display information	
29.6	Controlled by a menu	NA
29.7	Used by persons with special needs	NA
29.8	Initiate user actions	NA
30	Alarming system	Quality control line can be used as an alarm prompt
31	Intentional misuse	NA
32	With key data of the patients in nursing	NA
33	To be mobile or portable	NA
34	Rely on the basic function or not	NA
35	Inspection process is quantitative or qualitative	Qualitative
36	Results with dependent characteristics	NA
37	Requirement of other relevant information of the patients	YES
Letters in the first column refer to ISO 14971:2019		

Other important features

NO	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
D2. Energy Hazards Not Applicable										
1	Electricity	NA								
2	Heat	NA								
3	Mechanical force	NA								
4	Ionizing radiation	NA								
5	Non-ionizing radiation	NA								
6	Electromagnetic fields	NA								
7	Moving parts	NA								
8	Suspended masses	NA								
9	Patient support device failure	NA								
10	Pressure(vessel rupture)	NA								
11	Acoustic pressure	NA								
12	Vibration	NA								
13	Magnetic fields(e.g. MRI)	NA								
D3. Biological hazards										
1	Bio-contamination	NA								
2	Bio-incompatibility	NA								
3	Incorrect formulation (chemical composition)	Invalid test result	1	1	9	9	(1)Preparation of sample diluent standard operation procedure (2) Preparation of Coated solution preparation standard operation procedure (3) Technological Process Of Production	(1)QAQC Process Control File (2)Performance Test Report of Third Party Testing Institute (3)Technological Process Of Production	NH	YES
4	Toxicity	NA								
5	Allergenicity	NA								
6	Mutagenicity	NA								
7	Oncogenicity	NA								
8	Teratogenicity	NA								
9	Carcinogenicity	NA								
10	Re-and/or cross-infection	NA								
11	Pyrogenicity	NA								

12	Inability to maintain hygienic safety	Broken package or store in a bad environment	3	2	1	6	Strictly control shipping and storage process,	(1)Instruction For Use	NH	YES
13	Degradation	NA								
D4.Environmental hazards and contributory factors										
1	Electromagnetic fields	NA								
2	Inadequate supply of power or coolant	NA								
3	Susceptibility to electromagnetic interference	NA								
4	Emissions of electromagnetic interference	NA								
5	Inadequate supply of power	NA								
6	Inadequate supply of coolant	NA								
7	Storage or operation outside prescribed environmental conditions	Products may be invalid	4	2	1	8	Control storage condition	(1)Instruction For Use	NH	YES
8	Incompatibility with other devices	NA								
9	Accidental mechanical damage	NA								
10	Contamination due to waste products and /or device disposal		9	1	1	9	Labeled with identity to remind the operator to protect	(1)Instruction For Use (2)Labels	NH	YES
D5. Hazards resulting from incorrect output of energy and substances		**Not Aplicable**								
1	Electricity	NA								
2	Radiation	NA								
3	Volume	NA								
4	Pressure	NA								
5	Supply of medical gases	NA								
6	Supply of anaesthetic agents	NA								
D6.Hazards related to the use of the device and contributory factors										
1	Inadequate Labels	Wrong operation and false result	3	1	2	6	EN ISO 18113-1:2011	(1)Labels	NH	Yes
2	Inadequate operating Instruction For Use: ▪ inadequate specification of accessories ▪ inadequate specification	Wrong operation and false or invalid result	3	1	2	6	EN ISO 18113-1:2011	(1)Instruction For Use	NH	Yes

	of pre-use checks ▪ over-complicated operating Instruction For Use ▪ inadequate specification of service and maintenance									
3	Use by unskilled/untrained personnel	1. The user inputs the nasal swab in a too forceful way which leads to pain and discomfort or injuries 2. Sample contains blood which leads to inaccurate results 3. insufficient specimen is extracted due to e.g. wrong handling or not following the instructions precisely	2	1	2	4	Detailed operating procedures in the instruction manual, each step, there are icons	Instruction for Use To Risk 1: Under the Point „Warnings“ section 3 of the Instruction To Risk 2: Under „Warnings“ Section 5 of the Instruction for Use To Risk 3: Under „Warnings“ Section 4 of the User Instruction	NH	Yes
4	Reasonably foreseeable misuse	(1) Mixing with blood samples will affect the test results and is not recommended. (2)It should be balanced at room temperature before use. (3)Excessive sample addition may lead to sample backflow while resulting in false positive and other abnormal results. (4)Avoid microbial contamination of reagents.	2	1	3	6	Precautions in the Instruction For Use	(1)Instruction For Use (2)Labels	NH	Yes
5	Insufficient warning of side effects	NA								
6	Inadequate warning of hazards likely with re-use of single use devices	NA								
7	Incorrect measurement and other metrological aspects	NA								
8	Incompatibility with consumables/accessories/other devices	NA								
9	sharp edges or points	NA								

D7. Inappropriate, inadequate or over-complicated user interface (man/machine communication)										
1	Mistakes and judgement errors	Wrong operation of the instrument	2	1	3	6	Standard operating manual	(1)Instruction For Use	NH	Yes
2	Lapses and cognitive recall errors	NA								
3	Slips and blunders (mental or physical)	NA								
4	Violation or abbreviation of Instruction For Use, procedures, etc.,	NA								
5	Complex or confusing control system	NA								
6	Ambiguous or unclear device state	NA								
7	Ambiguous or unclear presentation of settings, measurements or other information	NA								
8	Mispresentation of results	NA								
9	Insufficient visibility, audibility or tactility	NA								
10	Poor mapping of controls to action, or of displayed information to actual state	NA								
11	Controversial modes or mappings as compared to existing equipment	NA								
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	NA								
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	NA								
3	Inadequate maintenance	NA								
4	Lack of adequate determination of end of device life	Package without expire date and users using it after the expire day	3	1	3	9	Precautions	(1)Instruction For Use	NH	Yes
5	Loss of electrical / mechanical integrity	NA								
6	Inadequate	Humidity,	4	2	1	8	Ensure desiccant and	(1)Performance	NH	Yes

	packaging(contamination and /or deterioration of the device)	Temperature and sealing problem make the product losing effect					packaging quality Raw material test regulation Packaging material handling procedure Storage conditions	Test Report of Third Party Testing Institute (2)Analyze Performance Evaluation Data		
7	re-use and / or Improper re-use	Get invalid result	3	1	1	3	Precautions	(1)Instruction For Use (2)Labels	NH	Yes
8	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	NA								
B2. Additional hazards to in vitro diagnostic medical devices										
1	Batch inhomogeneity, batch-to-batch inconsistency	The test results lead to instability so that users can not correctly judge	2	3	1	6	Pay attention to the time of sampling representative and stability study	(1)QAQC Process Control File (2)Analyze Performance Evaluation Data	NH	Yes
2	Common interfering factors	Humidity Temperature	4	2	1	8	(1)Storage under the conditions specified in the manual (2)The kit shouled be balanced to the room temperature before using.	(1)Instruction For Use	NH	Yes
3	Carry-over effects	Kit over the period of validity may lead to inaccurate results	5	1	1	5	The valid period of kit is written in the Instruction For Use and labels	(1)Instruction For Use (2)Labels	NH	Yes
4	Specimen identification errors	The test result is not correct	2	1	1	2	Prompting the user make the samples correctly labeled in the Instruction For Use	(1)Instruction For Use	NH	Yes
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	The expected results are not correct due to the failure of product stability study	3	1	2	6	Establish stability study requirements document	(1)Analyze Performance Evaluation Data	NH	Yes
6	Problems related to taking,	The prepared sample unqualified,	4	2	1	8	The sample type and	(1)Instruction For	NH	Yes

	preparation and stability of speciments	sample after treatment for a long time, may result in inaccurate test results					dilution method shall be specified in the Instruction For Use	Use		
7	Inadequate specification of prerequisites	The changes of raw material formula can cause the test value	3	2	1	6	Produce products according to product recipe	(1)Technological Process Of Production	NH	Yes
8	Inadequate test characteristics	NA								

Post-production information

	Post-production experience: Each department should collect required information; think possible existing risk or failure of first evaluation. If each department finds one, it should analysis, evaluate and control again in time.
	Review of risk management experience: All persons should been trained about risk management and have some theory base, who will identify and evaluate risks.