SG Diagnostics
Committed to Quality of Health

Rapid Test Risk Management Report

Introduction

This report addressed the risk management activities of the Non-critical disease lateral flow rapid test developed and distributed by SG Diagnostics.

Properties and functions of the Rapid Test could have hazards associated with them. These hazards coupled with the likelihood of their occurrence give rise to a risk to the patient or operator. It was the purpose of this risk management activity to quantify these risks and thereby highlight those most likely to cause harm. The results allowed for judgments to be made about the suitability of the routes chosen to minimize those risks and to determine what risks were acceptable.

We have conducted the following risk management activities:

- Hazard Identification
- Risk Analysis and Evaluation
- Risk Evaluation
- Risk Control and Effectiveness Assessment
- Residue Risk Evaluation
- Production Process Risk Analysis, Evaluation, and Control
- Collection and evaluation of Production and Post-production Information

There is no requirement for the elimination of risk, in fact, risk is acknowledged as a part of all medical procedures, however, we intended to show that: where a significant risk existed, we had addressed its reduction by use of known/existing techniques and technology; or where a reduction was not feasible, we had given adequate information and warnings; and ultimately that even with a risk, the device had a net beneficial effect for the patient compared to other existing treatments.

The content of this report includes:

- 1. Scope
- 2. Reference and related documents
- 3. Product description
- 4. Risk management process and result
- 5. Conclusion
- 6. Attachment

1 Scope

This report applies to COVID-19 Antigen lateral flow rapid tests marketed by SG Diagnostics.

Each product is composed of individually sealed test device in either strip format or in cassette format with a desiccant to keep the device from moisture. Collection tube with cap and sterilized nasal swab may be included with the device or packed separately. Sample extraction buffer and other components are provided as components of the product, if applicable.

2 Reference and Related Documents

2.1 Reference

ISO14971:2019 Medical devices- Application of risk management to medical devices.
WI-71-01-6: Risk Management Plan
Operational Procedure SOP-71-01 Production Planning and Risk Analysis

2.2 Product related Documents

Instruction of Use
MSDS
Certificate of Analysis

3 Product Information

3.1 Product Name

SG Diagnostics COVID-19 Antigen Rapid Test Kit

3.2 Intended use and benefit

The COVID-19 Antigen test is a lateral flow chromatographic immunoassay for the qualitative detection of antigen of SARS-Cov-2. Non-critical diseases refer here the diseases do not cause immediate death or contagious to public. It is intended to be used as a screening test by professionals and as an aid in the diagnosis of infections or determination of the disease status after infection. Any reactive specimen with the Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

The traditional disease diagnosis requires equipment and skilled lab technicians or specialized pathologist. It is in generally time consuming. In contrast, these rapid tests are a self-contained test device. It does not require equipment. Little training is required and the test result is visually readable within 15 to 20 minutes. They become more and more popular. It is particularly suited for urgent care, remote areas, and small clinics.

3.3 Test Procedure

Use procedure is quite simple. Applying few drops of the specimens which is extracted by sample buffer if required to the device and read result within designated time frame. It requires minimal training to perform the test. However, user is instructed to read the Instruction of Use prior to perform the test as each product has different test procedures and different data interpretation method.

3.4 Product characteristics

These products are self-contained, single use device. It consists of a test device in a plastic cassette, accessories such as sample application pipette and buffer, or others as product specific. A description of each particular test device is included on the specific product label.

These products are used by laboratory technician and physicians for purposes of obtaining instant reference information in aid of disease diagnosis and therefore to facilitate treatment on time. It can be stored at room condition with temperature ranging from 2-30°C.

Ann. C	Qualitative product characteristics (see ISO 14971:2007 standard Annex. C)	Answer	Document
2.1	What is the intended use and how is the medical device to be used?	IVD	IFU
2.2	Is the medical device intended to be implanted?	No	
2.3	Is the medical device intended to contact the patient or other persons?	No	
2.4	What materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Plastic, antibodies, chemicals	MSDS, production doc.
2.5	Is energy delivered to or extracted from the patient?	No	
2.6	Are substances delivered to or extracted from the patient?	No	
2.7	Are biological materials processed by the medical devices for subsequent re-use, transfusion or transplantation?	No	
2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No	
2.9	Is the medical device intended to be routinely cleaned or disinfected by the user?	No	
2.10	Is the medical device intended to modify the patient's environment?	No	
2.11	Are measurements taken?	No	
2.12	Is the medical device interpretative?	No	
2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No	
2.14	Are there unwanted outputs of energy or substances?	No	
2.15	Is the medical device susceptible to environmental influences?	Yes	IFU and Label
2.16	Does the device influence the environment?	No	
2.17	Are there essential consumables or accessories with the medical device?	Yes, lancet, timer	IFU
2.18	Is maintenance and/or calibration necessary?	No	
2.19	Does the medical device contain software?	No	
2.20	Does the medical device have a restricted shelf-life?	Yes	IFU and label
2.21	Are there any delayed or long-term effects?	No	
2.22	To what mechanical forces will the medical device be subjected?	No	
2.23	What determines the lifetime of the medical device?	Aging	Label
2.24	Is the medical device intended for single use?	Yes, doesn't function if re-used	IFU and Label
2.25	Is safe decommissioning or disposal of the medical device necessary?	Yes	IFU and MSDS
2.26	Does installation or use of the medical device require special training or special skills?	Only minimal training required	IFU
2.27	How will information for safe use be provided?	Yes	IFU
2.28	Will new manufacturing processes need to be established or introduced?	Yes	N/A
2.29	Is successful application of the medical device critically dependent on human factors such as user interface?	Yes	
2.29.1	Can the user interface design features contribute to use error?	No	
2.29.2	Is the medical device used in an environment where distractions can cause use error?	Yes	IFU–procedure
2.29.3	Does the medical device have connecting parties or accessories?	No	
2.29.4	Does the medical device have a control interface?	No	
2.29.5	Does the medical device display information?	Yes	IFU-result
2.29.6	Does the medical device controlled by manual?	No	
2.29.7	Will the medical device be used by person with special needs	No	
2.29.8	Can the user interface be used to initiate user actions	No	
2.30	Does the medical device use an alarm system?	No	
2.31	In what way(s) might the medical device be deliberately misused?	To use as confirmatory test	IFU
2.32	Does the medical device hold data critical to patient care?	No	
2.33	Is the medical device intended to be mobile or portable?	No	
2.34	Does the use of the medical device depend on essential performance?	Yes	IFU

3.5 Environment

Requirement:

Working environment:

15-30°C

Storage environment:

2-30°C

4 Risk Management Procedure and Result.

We have established a Risk Management Plan for the Rapid Test product. The plan covers the responsibility and Risk Acceptance Criteria. We then conducted Risk Analysis; Risk Evaluation; Risk Control and Effectiveness Assessment; Residue Risk Analysis; Process Risk Analysis; Evaluation and Control; and Collecting and Analysis of Product and Post-production Information.

Abbreviations used

RE	Risk Evaluation
S	Severity (9 –very severe, 0 –not severe)
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 ×Detection1-9: 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 -if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

Ranking:

SEVERITY of Effect	Ranking
Injure a customer or employee	10
Be illegal	9
Render product or service unfit for use	8
Cause extreme customer dissatisfaction	7
Result in partial malfunction	6
Cause a loss of performance which is likely to result in a complaint	5
Cause minor performance loss	4
Cause a minor nuisance but can be overcome with no performance loss	3
Be unnoticed and have only minor effect on performance	2
Be unnoticed and not affect the performance	1

PROBABILITY of Failure	Failure Prob	Ranking
Very High: Failure is almost inevitable	>1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is unlikely	<1 in 1,500,000	1

Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Defect caused by failure is not detectable	**10**
Very Remote	Occasional units are checked for defect	**9**
Remote	Units are systematically sampled and inspected	**8**
Very Low	All units are manually inspected	**7**
Low	Manual inspection with mistake-proofing modifications	**6**
Moderate	Process is monitored (SPC) and manually inspected	**5**
Moderately High	SPC is used with an immediate reaction to out of control conditions	**4**
High	SPC as above with 100% inspection surrounding out of control conditions	**3**
Very High	All units are automatically inspected	**2**
Almost Certain	Defect is obvious and can be kept from affecting the customer	**1**

5. Conclusions:

We concluded that the risks associated with the use of the Non-critical disease Rapid Test are considered.

Risk Analysis

Company: **SG Diagnostics Pte Ltd** Product: **COVID-19 Antigen Rapid Test**

No.	Hazard General	Specific	Risk Evaluation				Risk Reduction	Evidence	NH	ALOR
			S	O	D	RL				
D2. Energy hazards Not Applicable										
1	Electricity									
2	Heat									
3	Mechanical force									
4	Ionizing radiation									
5	Non-ionizing radiation									
6	Electromagnetic fields									
7	Moving parts									
8	Suspended masses									
9	Patient support device failure									
10	Pressure (Vessel rupture)									
11	Acoustic pressure									
12	Vibration									
13	Magnetic fields									
D3. Biological hazards										
1	Bio-contamination	Yes, contamination of the reagents will influence measurements and judgments.	4	1	2	8	(1) Workshop and worker sanitary regulation (2) Raw material handling procedure	(1) Manufacturing Manage Standard (2) Quality control (3) Sanitary test record	No	Yes
2	Bio-incompatibility	No	0	0	0	0				
3	Incorrect formulation (chemical composition)	Yes. It will influence the accuracy of measurements.	4	1	1	4	Materials are purchased according to the requirements in quality system.Choose qualified suppliers and strengthen purchasing inspection. Preparation of the reagents is performed by appointed people.	(1) Workshop and worker sanitary regulation (2) Raw material handling procedure (3) Manufacturing Preparation (4) Manufacturing procedure (5) Quality control	No	Yes

								standard.		
4	Toxicity	No	0	0	0	0				
5	Allergenicity	No	0	0	0	0				
6	Mutagenicity	No	0	0	0	0				
7	Oncogenicity	No	0	0	0	0				
8	Teratogenicity	No	0	0	0	0				
9	Carcinogenicity	No	0	0	0	0				
10	Re-and/or cross-infection	No	0	0	0	0				
11	Pyrogenicity	No	0	0	0	0				
12	Inability to maintain hygienic safety	No	0	0	0	0				
13	Degradation	No	0	0	0	0				
	D4. Environmental hazards and contributory factors									
1	Electromagnetic fields	No	0	0	0	0				
2	Inadequate supply of power or coolant	No	0	0	0	0				
3	Susceptibility to electromagnetic interference	No	0	0	0	0				
4	Emissions of electromagnetic interference	No	0	0	0	0				
5	Inadequate supply of power	No	0	0	0	0				
6	inadequate supply of coolant	No	0	0	0	0				
7	Storage or operation outside prescribed environmental conditions	Yes. Test cassette that exceed stability limit should not be used any longer. Test cassette that do not follow the storage condition should not be used, otherwise it may lead to incorrect measurements, mislead injury.	5	1	1	5	Outer environmental condition for storage is indicated on the container. EN ISO 18113-2:2011	Instruction for use; Management of Quality control samples and corresponding records	No	Yes
8	Incompatibility with other devices	No	0	0	0	0				
9	Accidental mechanical damage	No	0	0	0	0				
10	Contamination due to waste products and /or device disposal	Product after-use must be treated according to local laws as the biohazard waste with potential HBV contamination. Reuse the kit or inappropriate treatment is prohibited otherwise there is a risk of HBV infection.	2	1	1	2	Instruction for use and label of product declare that the product can't be thrown randomly but be treated in time and reliably. EN ISO 18113-2:2011	See instruction for use.	No	Yes

D5. Hazards resulting from incorrect output of energy and substances										
1	Electricity	No	0	0	0	0				
2	Radiation	No	0	0	0	0				
3	volume	No	0	0	0	0				
4	Pressure	No	0	0	0	0				
5	Supply of medical gases	No	0	0	0	0				
6	supply of anaesthetic agents	No	0	0	0	0				
D6. Hazards related to the use of device and contributory factor										
1	Inadequate labeling	Yes. Inadequate labeling will lead to incorrect usage.	2	1	1	2	The label is designed according to the requirements EN ISO 18113-2:2011	Product Label	No	Yes
2	Inadequate operating instructions: ▪ inadequate specification of accessories ▪ inadequate specification of pre-use checks ▪ over-complicated operating instructions ▪ inadequate specification of service and maintenance	Yes, inadequate or incorrect usage of the instruction will lead to misusage	1	1	1	1	Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use.	No	Yes
		and thereby influence normal usage. Misusage of the instruction will lead to wrong measurements, mislead doctor's diagnosis and produce serious injury.	5	2	1	10				
		No	0	0	0	0				
3	Use by unskilled/untrained personnel	Yes. Abnormal measurements.	5	1	1	5	Professional use only usage is indicated on the IFU. EN ISO 18113-2:2011	See instruction for use. Package label	No	Yes
4	Reasonably foreseeable misuse	Lead to wrong operation and false results.	5	1	1	5	Shown in detail in packaging insert	Packaging insert	No	Yes
5	Insufficient warning of side effects	No	0	0	0	0				
6	Inadequate warning of hazards likely with re- use of single use devices	Yes. The product is for single use only. Repeated usage will lead to contamination and inaccurate measurements.	6	2	1	12	Forbidden of double usage is indicated on the label. EN ISO 18113-2:2011	Package label Instruction for use	No	Yes
7	Incorrect measurement and other metrological aspects	False positive and false negative result	5	1	1	5	EN ISO 18113-2:2011	Package label	No	Yes
8	Incompatibility with consumables	No	0	0	0	0				

	/accessories/ other devices									
9	Sharp edges and points	No	0	0	0	0				
D7. Inappropriate, inadequate or over-complicated user interface (man/machine communication)										
1	Mistakes and judgement errors	Yes. Misread or misuse of information will lead to wrongjudgments.	4	2	2	16	Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use. Use word and picture to shown the how to read the test results.	No	Yes
2	Lapses and cognitive recall errors	No	0	0	0	0				
3	Slips and blunders (mental or physical)	No	0	0	0	0				
4	Violation or abbreviation of instructions, procedures, etc.,	Yes. Abnormal measurements	7	1	1	7	Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use. Shown it clearly in the packaging insert.	No	Yes
5	Complex or confusing control system	No	0	0	0	0				
6	Ambiguous or unclear device state	No	0	0	0	0				
7	Ambiguous or unclear presentation of settings, measurements or other information	Results at incorrect times will lead to wrong measurements, mislead doctor's diagnosis and may produce injury.	5	2	1	10	Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use. Shown it clearly in the packaging insert.	No	Yes
8	Mispresentation of results	Mis-operationof the diagnostic reagentwill lead to wrong measurements of the reagents.	4	2	1	8	EN ISO 18113-2:2011 Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use.	No	Yes
9	Insufficient visibility, audibility or tactility	No	0	0	0	0				
10	Poor mapping of controls to action, or of displayed information to actual state	No	0	0	0	0				
11	Controversial modes or mappings as compared to existing equipment	No	0	0	0	0				
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	No	0	0	0	0				
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance	No	0	0	0	0				

	functional checks									
3	Inadequate maintenance	No	0	0	0	0				
4	Lack of adequate determination of end of device life	Yes. The kit should be stored and transported at 2-30°C for the duration of shelf life, otherwise it may lead to inaccurate measurements. so storage condition should be followed strictly during transportation.	5	3	1	15	It is informed in the instruction. See "storage and self-life" of the instruction.	Instruction for use.		
5	Loss of electrical / mechanical integrity	No	0	0	0	0				
6	Inadequate packaging(contamination and /or deterioration of the device)	Yes. Contamination or damage.	6	1	1	6	Packaging is performed according to the procedure guidance.	Document for inner packaging procedure	No	Yes
7	re-use and / or Improper re-use	An invalid test result, HBV contamination	7	1	1	7	Design the instruction for use according to EN ISO 18113-2:2011	See instruction for use.	No	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.	No	0	0	0	0				
B2. Additional hazards to in vitro diagnostic medical devices										
1	Batch in homogeneity, batch-to-batch inconsistency	Yes. It will lead to inaccurate measurements.	5	2	3	30	Compile testing protocols for preparation and final products to control the production process and thereby ensure intra-and inter-batch consistency. Product quality should be controlled before it comes out from the factory.	Testing report for final products To performance control during the manufacture process.	No	Yes
2	Common interfering factors	No	0	0	0	0				
3	Carry-over effects	No	0	0	0	0				
4	Specimen identification errors	Yes. It will lead to wrong measurements.	6	2	3	36	It should be used by professional staff as required in the instruction.	Quality control records	No	Yes
5	Stability problems (in storage, in shipping, in use, after first opening of	Yes. Contaminated test cassette or test cassette that exceed	5	2	2	20	EN13612:2002 EN 23640:2015	Performance evaluation studied report	No	Yes

	the container)	expiry date should not be used. Once opened, the assay kit should be used ASAP					EN 13641: 2002 EN 13975:2003	Stability and aging studied		
6	Problems related to taking, preparation and stability of specimens	would lead a false result and invalid result	6	2	2	24	Requirements for the sample and storage condition are specified in the instruction.	Instruction for use.	No	Yes
7	Inadequate specification of prerequisites	No	0	0	0	0				
8	Inadequate test characteristics	would lead a false result and invalidity result	5	1	1	5	EN13612:2002 EN 23640:2015 EN 13641: 2002 EN 13975:2003	Performance evaluation studied report Stability and aging studied	No	Yes
Post-production information										
	Post-production experience: Our company has the mature platform for the development of colloidal gold –conjugate rapid assay and accumulated rich experience in this area. The proposed COVID 19 Antigen assay kit uses the monoclonal antibodies to SARS-Cov-2 coated on the nitrocellulose membrane to detect the SARS-Cov-2 Nucleoprotein in Nasal and Nasopharyngeal Swab. The performance of this assay is satisfactory, the raw material, semi-product, final products have been accepted and marketed in different countries under other companies' names. It has reached the step for SG Diagnostics to register with CE under its own name.									
	Review of risk management experience: From the design input to the final product output, major target is to obtain the best performance (sensitivity and specificity et al), we have finished the process. Based on the requirements of Risk Management, each risk which had been identified was evaluated, the plan and method of reduce the risks have been established, according to the plan, the risks was reduced and controlled. During the process, we evaluate the remnants risk again, to ensure the integrality of risk evaluate. Finally, we prepare the risk management report for whole process.									

Reported Date: 18 March 2021
Revision: 01