Risk Management Report

Product: SARS-CoV-2 Antigen Test Kit(GICA)

Model: 20 Tests/kit

Content

Chapter 1 Product Description

1.1 General

SARS-CoV-2 Antigen Test Kit (GICA) can qualitatively detect the content of SARS-CoV-2 Ag in human nasopharyngeal swabs and oropharyngeal swabs.

1.2 Intended Use

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab, and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The SARS-CoV-2 Antigen Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

1.3 Components

1. 20 Individual sealed pouches, each pouch contains:

- 1 x Test card.
- Desiccant pouch.

2. Sample Tube (1×20 PCS)
3. Sampling swab
4. Instruction for use

1.4 Accessories

None.

Chapter 2 Risk Management Participants and Responsibilities

2.1Participants and responsibilities of hazards identification and risk analysis

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2.2 Hazards risk analysis review team

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Chapter 3 Identification of Safety-Related Characteristics

3.1 Risk sources

3.1.1 Characterization of the device

SARS-CoV-2 Antigen Test Kit (GICA) is product of self-research-and-development.

3.1.2 Environmental and operating conditions

1. The test kit is sensitive to humidity and as well as to heat.
2. Store kit components at 2-30° C, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.
3. Perform the test immediately after removing the test device from a foil pouch.
4. After the aluminum foil bag is unsealed, the test card should be used as soon as possible within Two hours.
5. Do not freeze.
6. Valid Period: The individual kits and/or box correctly stored kits are valid for 12 months.

3.2 Identification of safety-related characteristics

Table 1 Questions that help to identify safety-related characteristics

No.	Questions that can be used to identify medical	Yes/No	Safety-related characteristics

	device characteristics that could impact on safety		
			□ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
1	What is the intended use/intended purpose and how is the medical device to be used?	/	Intended use: For in vitro qualitative determination of the content of SARS-CoV-2 Ag in human nasopharyngeal swabs and oropharyngeal swabs. User/Operator: Trained and qualified operators. Clinical environment: Clinical laboratory. **Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards ■ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances ■ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
2	Is the medical device intended to contact the	No	Classification by contact character: Non-contact device (Clinical product)

	patient or other persons?		
3	What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?	Yes	Material of biology resource is contained. **Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards ■ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
4	Is energy delivered to and/or extracted from the patient?	No	
5	Are substances delivered to and/or extracted from the patient?	Yes	The test speciments of this kit are human nasopharyngeal swabs and oropharyngeal swabs. **Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
6	Are biological materials	No	

	processed by the medical device for subsequent re-use?		
7	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No	
8	Is the medical device intended to be routinely cleaned or disinfected by the user?	No	
9	Is the medical device intended to modify the patient environment?	No	Patient environment is not intended to be modified. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices

10	Are measurements taken?	Yes	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
11	Is the medical device interpretative?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
12	Is the medical device intended for use in conjunction with medicines or other medical technologies?	Yes	Used in conjunction with immunofluorescence analyzer. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
13	Are there unwanted	Yes	

	outputs of energy or substances?		**Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards ■ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
14	Is the medical device susceptible to environmental influences?	Yes	The medical device must be stored at 2-30℃. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
15	Does the medical device influence the environment?	Yes	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards ■ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
16	Are there essential consumables or	No	The medical devices here are consumables. **Classification of hazards:**

	accessories associated with the medical device?		□ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
17	Is maintenance and/or calibration necessary?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
18	Does the medical device contain software?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
19	Does the medical device have a restricted shelf-life?	Yes	Storage expiration date and expiration date after removing the sealed pouch at 2~30°C. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting

			from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
20	Are there any delayed and/or long-term use effects? Man/Machine engineering and accumulation effects shall be considered.	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
21	To what mechanical forces will the medical device be subjected?	No	The medical devices will not subject to mechanical force. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
22	What determines the lifetime of the medical device?	/	Material contained in the medical devices will change. **Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances

			□ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
23	Is the medical device intended for single use?	Yes	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device ■ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) ■ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
24	Is safe decommissioning or disposal of the medical device necessary?	Yes	Used kits need to be disposed of as dangerous medical waste. **Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards ■ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
25	Does installation or use of the medical device require special training?	Yes	The medical devices need to be operated by trained and qualified personnel. **Classification of hazards:** □ 1. Energy hazards ■ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user

			interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
26	Will new manufacturing processes need to be established or introduced?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
27.1	Does the medical device have connecting parts or accessories?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
27.2	Does the medical device have a control interface?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices

27.3	Does the medical device display information?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
27.4	Is the medical device controlled by a menu?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices
28	Is the medical device intended to be mobile or portable?	No	**Classification of hazards:** □ 1. Energy hazards □ 2. Biological hazards □ 3. Environmental hazards □ 4.Hazards resulting from incorrect output of energy and substances □ 5.Hazards related to the use of the medical device □ 6.Inappropriate, inadequate or over-complicated user interface (man/machine communication) □ 7. Hazards arising from functional failure, maintenance and ageing □ 8. Hazards particularly related to In Vitro Diagnostic Devices

Chapter 4 Summary of Risk Management

Table 2 Summary of risk management

#	Potential hazards	Potential causes	Severity	Likelihood pre MoC/post MoC	Estimation of risk pre MoC/post MoC	Method of control (MoC)	Verification
1.	Energy hazards						
1.1.	Mechanical force	When the products are shipped, hazard may occur to operators or bystanders.	1	2/1	ACC/ACC	The size of product package shall be controlled and no sharp angles and edges shall be found on the package.	PASS The products of the largest package are less than 10Kg. Plastic boxes with no sharp edges or angles are used to avoid hazard to users.
2.	Biohazard						
2.1.	Infectivity	Product leakage or contact with products when running them will lead to infectivity.	2	3/1	ALARP/ACC	The raw material of products shall pass the biosafety test. Instructions for use shall specify that users should wear gloves when using the products.	PASS Inspection Regulations of Manufacturing Materials of antibody has stated the requirement of inspecting raw materials. Instructions for use of the product have required users to wear gloves when handling the products

3.	Environmental hazards						
3.1.	Environment contamination	Rest products or expired products are discarded directly without disposed of properly. Waste produced is discharged directly without disposed of properly	2	3/1	ALARP/ ACC	Instructions for use shall specify that users should dispose of the rest products, expired products and waste as dangerous medical waste in accordance with the requirements of the local government regulations.	PASS Instructions for use of the products have required users to dispose of the rest products, expired products and waste in accordance with the requirements of the Laboratory
4.	Hazards resulting from incorrect output of energy and substances						
4.1.	/						
5.	Hazards related to use of the medical device						
5.1.	Operation by untrained personnel	Operation by untrained personnel causes improper use or misoperation.	2	2/1	ALARP/ ACC	Instructions for use shall specify operation by doctors or trained personnel.	PASS Instructions for use of the product have required trained clinical personnel to use .
6.	Inappropriate, inadequate or over-complicated						

	user interface (man/machine communication)						
6.1.	Inappropriate or missing instructions for use	Operation description in instructions for use is not particular enough or users lose the instructions for use.	1	3/1	ALARP/ ACC	Instructions for use shall describe the operation clearly and particularly. Instructions for use shall be shipped with products. Users shall be able to obtain instructions for use from manufacturer if instructions for use is lost.	PASS The instructions for use have described clearly the operation methods and procedures. See instructions for use for details. Packing Process of the products has prescribed that instructions for use shall be shipped with products during the packing. Labels of products have listed how to contact the manufacturer.
6.2.	Insufficient warning of side effects	Insufficient warning of side effects lead to hazards due to users' ignorance of side effects.	2	3/1	ALARP/ ACC	Instructions for use or labels shall obviously warn operators of product potential hazards.	PASS Instructions for use the product have shown the potential hazards.
7.	Hazards arising from functional failure, maintenance and ageing						
7.1.	Functional failure	Use of functional failure products	2	2/1	ALARP/	Instructions for use shall prompt	PASS The instructions for use of

		lead to users' wrong judgment.			ACC	clearly that users can judge whether products are failed by checking the appearance before use or running them on analyzers and compare the difference between the results and target values.	controls have shown users how to judge whether product are failed.
8.	Hazards particularly related to In Vitro Diagnostic Devices						
8.1.	Shipping, storage and use conditions	Products need to be shipped, stored and used under prescribed conditions. Incorrect shipping, storage or use environment of products will lead to functional failure.	2	2/1	ALARP/ ACC	Instructions for use shall specify the shipping, storage and use conditions for products. Products shall be packed by heat preservation material and ice begs shall be put into the package to guarantee the shipping and storage conditions required.	PASS The instructions for use ha ve clearly specified the shi pping, storage and use cond itions. Transportation management of the products has require d that the Refrigerated truc k should meet the condition of the product temperature.

8.2.	Expiration date	Since products have expiration date, hazards exist due to misuse of products out of expiration date.	2	2/1	ALARP/ ACC	Product expiration date shall be indicated on the obvious position of product label.	PASS Packing Process of the products has specified the print format of expiration date, which guarantees the expiration date to be printed on the obvious position of product label.

Chapter 5 Completeness Evaluation of Risk Analysis

All known or foreseeable hazards have been analyzed.

Chapter 6 Residual Risk Evaluation

No residual risk evaluation.

Annex A Analysis Method

1. Identification of hazards

Reasonably foreseeable circumstance	Hazards to be included	Initiating causes to be included	Aspects to be included
Hazards shall be identified for all reasonably foreseeable circumstances including: ● normal use; ● incorrect use.	If appropriate, the initiating hazards to be considered shall included: ● hazards to patients; ● hazards to operators; ● hazards to service personnel; ● hazards to other persons nearby; ● hazards to environment.	If appropriate, the initiating causes to be considered shall include: ● human factors (including ergonomics limitations); ● hardware faults; ● software faults; ● integration errors; ● environmental conditions.	If appropriate, the aspects to be considered shall include: ● component compatibility, including both hardware and software; ● user interface, including instructions, warnings and error messages; ● translation of the user interface and instructions for use; ● data protection against intentional or unintentional actions; ● risk/benefit criteria; ● third-party software.

2. Estimation of risks

In estimating the risks of in vitro diagnostic devices, the following aspects shall be taken into account:

Risk evaluation of in vitro diagnostic medical devices

——Extent of reliance on the analytical result;

——plausibility checks;

——availability and use of controls;

——quality assurance measures/techniques applied in medical laboratories;

——detectability of deficiencies/errors;

——situations of use (e.g. emergency cases);

——professional use/non-professional use;

——method of presentation of information.

3. Risk evaluation

3.1 Severity classification and evaluation

Table 3 Severity classification and evaluation

Level	Severity	Hazard to human	Hazard to diagnostic or treatment information	Hazard to the equipment	Hazard to environment
4	Catastrophic	Death, severe physical functional disorder or mental derangement and all kinds of serious injury requiring cares.			Serious environmental contamination
3	Critical	Physical functional disorder or mental derangement, which leads to difficulty of normal life or requires hospitalization. Radiation exposure exceeding the limits stipulated by ICRP (1990).	Improper treatment or hospitalization caused by misdiagnosis.	Explosive breakdown. Energy emission or dropping with fatal power.	Building catches fire. Contamination of hazardous material
2	Marginal	Temporary damage to body structure as a result of accident, which does not endanger the life but requires medical treatment.		Equipment catches fire. Equipment is damaged and cannot be used again.	Part of the building or other equipment catches fire.
1	Negligible	Slight injury, burn or pain, which requires simple medical care. No mark will be left.	Incorrect measurement data. Misjudgment caused by abnormal image, incorrect labeling,	Equipment catches fire or is damaged partially. Equipment can be used	

			incorrect filing and lost data for diagnostic radiation exposure.	after repair. Unwanted movement of gantry, table, or detector.	
0	Uncomfortable	No injury or slight discomfort. Medical care is unnecessary. Bruise or burn does not need medical treatment. Radiation exposure below 1mGy.	Incorrect information that is easily recognized as erroneous.	No damage.	No damage.

3.2 Frequency classification and evaluation

Method 1: qualitative evaluation

Table 4 qualitative evaluation

Level	Frequency definition (one device per year)	
5	Frequent	＞1.E-02
4	Probable	1.E-02 to1.E-03
3	Occasional	1.E-03 to 1.E-04
2	Remote	1.E-04 to 1.E-05
1	Improbable	1.E-05 to 1.E-06
0	Incredible	＜1.E-06

Method 2: qualitative evaluation based on contributory factors

Table 5 qualitative evaluation

Level	Frequency definition	
5	Frequent	Immediate danger (s) caused by a single fault condition that frequently occurs.
4	Probable	Danger (s) caused by a single fault condition of reliable components or electrical circuits. Danger (s) caused by misoperation or malfunction (s).
3	Occasional	Danger (s) caused by two or three contributory factors, including user operation, occurring simultaneously.

2	Remote	Danger (s) caused by two or three contributory factors, excluding user operation, occurring simultaneously.
1	Improbable	Danger (s) caused by more than three independent contributory factors occurring simultaneously.
0	Incredible	Danger (s) caused by more than four independent contributory factors occurring simultaneously.

3.3 Risk evaluation criteria

Table 6 Risk evaluation criteria

Frequency	severity				
	0	I	II	III	IV
5					
4					
3					
2					
1					
0					

Black area: (N/ACC)：Not acceptable region.

White area(ACC)：Broadly acceptable region.

Gray area (ALARP)：Risk as low as reasonable practicable region.

4. Analysis method of energy hazards

4.1 Energy hazards

Electricity; heat; mechanical force; ionizing radiation; non-ionizing radiation; moving parts; unintended motion; suspended masses; failure of patient-support device; pressure (e.g. vessel rupture); acoustic pressure; vibration; magnetic fields (e.g. MRI).

4.2 Biological hazards

Bio-contamination; bio-incompatibility; incorrect formulation (chemical composition); toxicity; allergenicity, mutagenicity; oncogenicity; teratogenicity; re-and/or cross-infection; pyrogenicity; inability to maintain hygienic safety; degradation.

4.3 Environmental hazards

Electromagnetic fields; susceptibility to electromagnetic interference; emissions of electromagnetic interference; inadequate supply of power; inadequate supply of coolant; storage or operation outside prescribed environmental conditions; incompatibility with other devices with which it is intended to be used; accidental mechanical damage; contamination due to waste products and/or medical device disposal.

4.4 Hazards resulting from incorrect output of energy and substances

Electricity; radiation; volume; pressure; supply of medical gases; supply of anaesthetic agents.

4.5 Hazards related to the use of the medical device and contributory factors

Inadequate labeling; inadequate operating instructions; use by unskilled/untrained personnel; reasonably foreseeable misuse; insufficient warning of side effects; inadequate warning of hazards likely with re-use of single-use medical devices; incorrect measurement and other metrological aspects; incompatibility with consumables/accessories/other medical devices; sharp edges or points.

4.6 Inappropriate, inadequate or over-complicated user interface (man/machine communication)

Mistakes and judgement errors; lapses and cognitive recall errors; slips and blunders (mental or physical); violation or abbreviation of instructions, procedures, etc; complex or confusing control system; ambiguous or unclear device state, settings, measurements or other information; misrepresentation of results; insufficient visibility, audibility or tactility; poor mapping of controls to action, or of displayed information to actual state; controversial modes or mappings as compared to existing equipment.

4.7 Hazards arising from functional failure, maintenance and ageing

Erroneous data transfer; lack of, or inadequate specification for maintenance including inadequate specification of post-maintenance; inadequate maintenance; lack of adequate determination of the end of life of the medical device; loss of

electrical/mechanical integrity; inadequate packaging (contamination and/or deterioration of the medical device); re-use and/or improper re-use; 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.

4.8 Particular hazards of in vitro diagnostic medical devices and contributory factors

Batch inhomogeneity, batch-to-batch inconsistency; common interfering factors; carry-over effect; specimen identification errors; stability problems (in storage, in shipping, in use, after first opening of the container); problems related to taking, preparation and stability of specimens; inadequate specification of prerequisites; inadequate test characteristics.

Potential hazards for the user can arise from radioactive, infectious, toxic or otherwise hazardous ingredients of reagents and from the packaging design. For instruments, the problem of potential contamination during handing, operation and maintenance should be considered in addition to the non-specific instrument-related hazards (e.g. energy hazards).

In estimating the risk for each hazard, the following aspects should be taken into account:

Extent of reliance on the analytical result (contribution to the medical decision); plausibility checks; availability and use of controls; quality assurance measures/techniques applied in medical laboratories; detectability of deficiencies/errors; situations of use (e.g. emergency cases); professional use/non-professional use; method of presentation of information.

If applicable, the following contributory factors should take the following into consideration: ergonomics limitations; hardware faults; software faults; integration error; environment conditions; component compatibility, including both hardware and software; user interface, including instructions, warnings and error messages; translation of the user interface and instructions for use; data protection against intentional or unintentional actions; risk/benefit criteria; third-party software.