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1. Objectives

The risk management plan which is written according to EN ISO14971:2012, provides guidance for the risk management activities throughout the entire life cycle of 2019-nCoV IgGIgM Rapid Test Device, including in the stages of R&D, product realization, post-market surveillance and etc.

2. Scope

It is intended for risk management during the whole process of production, storage, transportation and after-sale service of 2019-nCoV IgGIgM Rapid Test Device.

3. Reference

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

IEC 60812: 2006 Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)

4. Abbreviation

Abbreviation	Description
RE	Risk Evaluation
S	Severity
P	Probability of Occurrence
RPN	Risk Priority Number
NH	New hazard generated (no/yes-if the new hazard was not acceptable, the number of new hazard was remarked)
ALOR	Acceptable Level of Risk
A	Acceptable
AFAP	Risk is requried to be reduced As Far As Possible
UA	Unacceptable

5. Assignment of responsibilities and authorities

Name	Department / Title	Responsibilities and Authorities
	general manager and Management representative,Team	Organize, coordinate and supervise all stages of the risk management activities

	leader	
	R&D	Based on the design of product to identify the potential hazards of products, leading research design phase of the risk management activities. To collect all the records of risk management, comply risk management plan and report.
	Quality Dept.	Based on the regulatory and quality system, to identify possible hazards. Participate in all stags of risk management activities, and feedback quality problems to the team leader.
	Production Dept.	Participate in risk management activities to identify hazards in the stages of product development and production. Regularly feedback the problems in the production on to the leaders.
	Customer service/Manager	To collect information from users to identify the recognized and potential hazards after the products are put into the marker, and feedback to the leader.

6. Product Information

6.1 Intended Use

The 2019-nCoV IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV virus in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with 2019-nCoV viruses. Any reactive specimen with the 2019-nCoV IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

6.2 Test Principle

The 2019-nCoV IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of 2019-nCoV antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the Test region, anti-human IgM and IgG is coated. During testing, the specimen reacts with 2019-nCoV antigen-coated particles in the Test Device. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgM or IgG in test line region. If the specimen

contains IgM or IgG antibodies to 2019-nCoV, a colored line will appear in test line region.

Therefore, if the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in test line region M. If the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in test line region G. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

7.Risk Analysis

7.1 Identification of medical device characteristics that could impact on safety

Points to consider in estimating risk to the patient (Annex H2.5.4 of EN ISO 14971 standard) and questions that can be used to identify medical device characteristics that could impact on safety(Annex C of EN ISO 14971 standard) of the device are answered as follow:

Table 1.Points to consider in estimating risk to the patient

No.	Questions	Estimating risk
H.2.5.4.1	**What is the possibility that an incorrect result would be generated by the IVD medical device?** - In a likely fault mode?	Yes. E.g. the test is out of the expired date, storehouse environment unconformable with requirements, improper package; Incorrect operation;etc.
	- In normal use?	Yes. Other organisms may interfere the test resutls.
	- In reasonably foreseeable misuse?	Yes. E.g. Humidity and temperature can adversely affect results; insufficient blood sample; the environment temperature is beyond the standard rang; reuse the Test Device.
H.2.5.4.2	**What is the possibility that the incorrect IVD examination result would be detected by a user/laboratory?** - Are control materials provided with the IVD medical device?	Yes, To serve as a procedural control, a colored line will always appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
	- Are controls integrated into the device to detect the fault condition?	Yes. To serve as a procedural control, a colored line will always appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
	- How effective would the controls be in detecting the fault condition?	To serve as a procedural control, a colored line will always appeared in the control line

No.	Questions	Estimating risk
		region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
	- Are there other quality assurance measures that might detect the incorrect result (e.g., critical value system, plausibility checks)?	Yes. There is QC testing and QA batch review of the product.
	- Would error messages allow a user to correct the problem and obtain a valid examination result upon reexamination? For example, the message "E-1" on an instrument for self-testing is intended prompt the user to repeat the examination.	This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
	- If the device is intended for laboratory use, do laboratories have effective systems for detecting such an incorrect result?	Yes. testing blood sample by using biochemistry analyzer.
H.2.5.4.3	**What is the possibility that the incorrect IVD examination result would be detected by the physician?** - Do current standards of medical practice require a confirmatory examination for this analyte?	Yes. testing blood sample by PCR method.
	- Is a confirmatory examination performed automatically by the laboratory following a positive screening examination result?	Yes. testing blood sample by using PCR method.
	- Is this type of incorrect result recognisable in the context of other results, signs, symptoms and the patient's medical history?	Yes. If user's test results is not consistent with user's symptoms, they should contact their healthcare professional and follow his or her advice.
	- Do physicians routinely corroborate the results for this analyte by other means and question those results that do not fit the clinical impression?	Yes. testing blood sample by using PCR method.
	- Are there other plausibility checks for this analyte that would alert the physician to an error?	Yes. testing blood sample by using PCR method.
	- Is the examination the sole basis for critical medical decisions? To what extent is the diagnosis based on the examination result (i.e., how does the examination contribute to the medical decision)?	No. The examination is not the sole basis for critical medical decisions, and a confirmed result for test should only be made by a physician after evaluating all clinical and laboratory findings.
	- Does the urgency of the situation require an immediate decision, without an opportunity to obtain confirmatory data or corroborating information? Does the examination result lead directly to a medical decision/treatment?	No. The examination result does not lead directly to a medical decision/treatment, and a confirmed disease should only be made by a physician after evaluating all clinical and laboratory findings.

No.	Questions	Estimating risk
	- Are alternative examinations available, such as in the central laboratory, if a point-of-care device were to fail?	Yes. testing blood sample by using PCR method.
H.2.5.4.4	**What is the possibility that a physician would act or fail to act on the result?** - Is the IVD medical device a major determinant of therapy for serious conditions, such as malignant tumours or life-threatening infections?	No, the device is applied to the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV virus in human whole blood, serum or plasma.
	- Is the IVD medical device intended for transfusion, transplant, or other medical use that could cause transmission of disease to recipients?	No, the device is applied to the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV virus in human whole blood, serum or plasma.
	- Is the IVD medical device intended to monitor a critical body function, so that error or delay could result in the death or permanent impairment of a patient?	No, the device is applied to the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV virus in human whole blood, serum or plasma.
H.2.5.4.5	**What is the possibility that a physician's action/inaction would cause or contribute to harm to the patient?** - Is the action irreversible, such as surgical resection or abortion?	Not applicable. All results must be interpreted by physicians along with clinical features and other laboratory test results.
	- To what extent is the action reversible?	Not applicable.
	- To what extent is the action likely to injure the patient?	Not applicable.
	- To what extent would failure to take action lead to death or injury?	Not applicable.
	- What physiological conditions would contribute to the possibility of harm?	Not applicable.
H.2.5.4.6	**What is the severity of the resulting harm?** - Death?	No.
	- Life-threatening injury?	No.
	- Reduction in life expectancy?	No.
	- Irreversible deterioration of the state of health?	No.
	- Permanent impairment?	No.
	- Permanent damage to a body function/structure?	No.
	- Injury requiring medical intervention to prevent serious harm?	No.
	- Reversible deterioration of the state of health?	No.
	- Minor physical injury?	Yes. Blood sampling will lead to a minor physical injury.

No.	Questions	Estimating risk
	- Temporary impairment not requiring medical intervention?	Yes. Blood sampling will lead to a minor physical injury.
	- Temporary discomfort?	Yes. Blood sampling will lead to a minor physical injury.

Table 2.Questions that can be used to identify medical device characteristics that could impact on safety

No.	Questions	Identification of the characteristics
(1)	What is the intended use and how is the device to be used?	The 2019-nCoV IgG/IgM Rapid Test is a lateral fl immunoassay for the simultaneous detection a differentiation of IgG anti–2019-nCoV virus and Ig anti-2019-nCoV virus in human whole blood, ser or plasma. It is intended to be used by t professionals as a screening test and as an aid in t diagnosis of infection with 2019-nCoV viruses. A reactive specimen with the 2019-nCoV IgG/Ig Rapid Test must be confirmed with alternative testi method(s).
	a. What is the type of the device? • IVD kit, reagent, reagent product, calibration or control material; • IVD equipment, apparatus, instrument; • IVD software; • Specimen receptacle.	IVD kit, reagent, reagent product; IVD equipment, apparatus, instrument;
	b. What is the purpose of the device?	he 2019-nCoV IgG/IgM Rapid Test is a lateral fl immunoassay for the simultaneous detection a differentiation of IgG anti–2019-nCoV virus and IgM a 2019-nCoV virus in human whole blood, serum or plasm
	c. Who is the intended user? • Trained laboratory personnel • Other medical care personnel (nurse, doctor, …) • Untrained people • Patient (self-test) • Other	It is a professional use device.
	d. What is the intended site and environment for use? • Clinical laboratory and/or blood bank • Point-of-care (hospital room, …) • Doctor's office • Patient home environment • Special	• Clinical laboratory • Point-of-care • Doctor's office
(2)	Clinical reference value	Is a qualitative membrane-based immunoassay for the detection of 2019-nCoV antibodies in whole blood, serum, or plasma..

No.	Questions	Identification of the characteristics
(3)	How is the detection limit determined?	Is a qualitative methed.
(4)	Inappropriate characteristics of product?	Yes. The inappropriate design of product can be found in market feedback, confirmation and experiment.
(5)	Carryover effect?	No.
(6)	Is the medical device intended to be implanted?	No. The device is only for in vitro diagnostic use.
(7)	Is the device intended to come into contact with the patient or other persons?	Yes. The device may contact with the hand.
(8)	What materials and/or components are incorporated in the device or are used?	The test kit has following components: A. One Test devices B. Droppers C. Buffer D. Package insert E. Specimen collection containers(Optional) F. Timer(Optional)
(9)	Is energy delivered to and/or extracted from the patient?	No.
(10)	Are substances delivered to and/or extracted from the patient?	No.
(11)	Are biological materials processed by the device for subsequent re-use?	No.
(12)	Is the device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	Sterile lancets (Optional) from other manufacturer.
(13)	Is the medical device intended to be routinely cleaned and disinfected by the user?	Not applicable.
(14)	Is the device intended to modify the patient environment?	No.
(15)	Are measurements made?	Not applicable.
(16)	Is the device interpretative?	No.
(17)	Is the device intended to control or to interact with other medicines or other	No.

No.	Questions	Identification of the characteristics
	medical technologies?	
(18)	Are there unwanted outputs of energy or substances?	No.
	Noise	No.
	Vibration	No.
	Heat	No.
	Radiation ionising	No.
	Radiation non-ionizing	No.
	Radiation UV, visible, IR	No.
	Contact temperature	No.
	Leakage currents	No.
	Electrical fields	No.
	Magnetic fields	No.
	Toxic or hazardous waste	No.
	Hazardous body samples	No.
(19)	Is the device susceptible to environmental influences?	Yes.
	Operational condition:	Room temperature: 15℃- 35℃
	Storage condition	The Test Device should be stored at 2 ºC to 30ºC in the sealed vial to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.
(20)	Does the medical device influence the environment?	No.
(21)	Are there essential consumables or accessories associated with the device?	The test kit has following components: A. One Test devices B. Droppers C. Buffer D. Package insert E. Specimen collection containers(Optional) F. Timer(Optional)
(22)	Is maintenance and/or calibration necessary?	No.
(23)	Does the device contain software?	No.
(24)	Does the device have a restricted “shelf-life”?	NO, But the shelf life of Test Device is 24months. On the packaging box, there’s the expiry date.
(25)	Possible delayed and/or long-term use effects?	Not appliable.
(26)	To what mechanical forces will the device be subjected?	No mechanical forces that the device is subjected.

No.	Questions	Identification of the characteristics
	a. Operation	No
	b. Transport	No
(27)	What determines the lifetime of the device?	For the Test Device, it is protected from direct sunlight by the strip and from moisture by the desiccant, but still need to be keep away from direct sunlight, moisture and heat.
(28)	Is the device intended for single use?	The Test Device is intended for single use.
(29)	Is safe decommissioning of disposal of the medical device necessary?	No.
(30)	Does installation or use of the medical device require special training?	No. The device can be used according to package insert.
(31)	How will information for safe use be provided? a. whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training;	The information of safe use is only provided by the manufacturer in the package insert.
	b. commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills;	Installation is not required for the device.
	c. based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.	This system is for professional use. Re-training or re-certification of operators or service personnel would not be required.
(32)	Will new manufacturing processes need to be established or introduced?	No.
(33)	Is successful application of the medical device critically dependent on human factors such as the user interface?	Not applicable.
	a. Can the user interface design features contribute to use error?	Not applicable.
	b. Is the medical device used in an environment where distractions can cause use error?	No.
	c. Does the medical device have connecting part or accessories?	No.
	d. Does the medical device have a control interface?	No.
	e. Does the medical device display information?	Yes. colored line will appear in test line region.
	f. Is the medical device controlled by a menu?	No.
	g. Will the medical device be used by	Yes. The user is patient with 2019-nCoV virus.

No.	Questions	Identification of the characteristics
	persons with special needs?	
	h. Can the user interface be used to initiate user actions?	Not applicable.
(34)	Does the medical device use an alarm system?	Yes. Control line (C) falls to appear indicate Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure.
(35)	In what way(s) might the medical device be deliberately misused?	No.
(36)	Does the medical device hold data critical to patient care?	No.
(37)	Is the medical device intended to be mobile or portable?	Yes. It is a small bulk, portable.
(38)	Does the use of the medical device depend on essential performance?	Yes.

7.2 Identification of hazards

Hazards are indentified in the following aspects:

A. Environment hazards

B. Hazards from production (manufacture hazards)

C. Operation Hazards (Hazards from user)

D. Specimen hazards

E. Ergonmic aspects hazards

Define primary hazards

Incorrect examination result – false high concentration

Incorrect examination result – false low concentration

No result – No result for the concentration.

Please see ***Annex I. Failure Mode and Effects Analysis*** for details of identification of hazards

8.Risk Evaluation and Risk Acceptability

8.1 Severity

The criteria for severity levels are shown as follows:

Table 1 Criteria for Severity Levels

Severity	Criteria	Scales
Critical	Death. Serious deterioration in state of health (permanent damage, etc). Significant decrease in life expectancy	5

Serious	Significant, but transient deterioration in state of health	4
Minor	Minor deterioration in state of health	3
Negligible	No medical consequences, but perception of bad quality	2
None	No effect	1

8.2 Probability of Occurrence

The criteria for probability of occurrence are shown as follows:

Table 2 Criteria for Probability of Occurrence

Probability	Criteria	Scales
Frequent	$\geq 10^{-3}$	5
Probable	$< 10^{-3}$ and $\geq 10^{-4}$	4
Occasional	$< 10^{-4}$ and $\geq 10^{-5}$	3
Remote	$< 10^{-5}$ and $\geq 10^{-6}$	2
Improbable	$< 10^{-6}$	1

NOTE: $10^{-n} = 1/10^{n}$, which means the harm may happen once in 10^{n} testing persons (times).

8.3 Criteria for risk acceptability

The risk level is calculated as follows:

		Probability of Occurrence (P)				
		5	**4**	**3**	**2**	**1**
Severity(S)	**5**	25	20	15	10	5
	4	20	16	12	8	4
	3	15	12	9	6	3
	2	10	8	6	4	2
	1	5	4	3	2	1

Risk Level= RPN (Risk Priority Number) = S × P

During the risk evaluation, in FMEA method, the RPN is calculated to evaluate the risk acceptability.

Criteria:

RPN ≥ 15: Risk is not acceptable.

4≤RPN < 15: Risk is required to be reduced as far as possible to the risk reduction end point (AFAP);

RPN<4: Risk is acceptable and insignificant.

8.4 Implementation of risk evaluation

Please see ***Annex I. Failure Mode and Effects Analysis*** for details of implementation of risk evaluation with criteria for risk acceptability.

9.Risk Control

9.1 Implementation of risk control measures

Risk control activities should be performed **to reduce the risk as low as possible to the risk reduction end point.**

One or more of the following risk control options shall be used:

a) Inherent safety by design;

b) Protective measures in the medical device itself or in the manufacturing process;

c) Information for safety.

Please see ***Annex I. Failure Mode and Effects Analysis*** for details of implementation of risk control measures.

10. Residual Risk Evaluation

After the risk control measures are applied, any residual risk shall be evaluated using the criteria for risk acceptability.

If the residual risk is not judged acceptable using these criteria, further risk control measures shall be applied.

Please see ***Annex I. Failure Mode and Effects Analysis*** for details of implementation of risk/benefit analysis.

11. Risk/benefit Analysis

The overall risk-benefit analysis was undertaken.

Please see ***Annex I. Failure Mode and Effects Analysis*** for details of implementation of residual risk evaluation

12. Risks Arising From Risk Control Measures

There are no new hazards (NH) arising from risk control measures.

13. Review and Verification Activities

The first verification is that make sure that the risk control measure has been implemented in the final design.

The second verification is that ensure that the measure as implemented actually reduces the risk.

Product life cycle	Review items	Review Time	Reviewed by	Review or verification items			
				The documentation consist with the requirement or not?	Risk control measures carried out or not?	Risk control measures reduced the risk or not?	Risk acceptable or not?
R &D	Risk evaluation, risk control measures	Before the design input	R&D engineer	Yes	Yes	Yes	Yes
Production	FMEA files	Put into production, Pre-market	Manufacturing engineer, Clinical engineer, Regulation engineer	Yes	Yes	Yes	Yes
Post-market	NO sales						

14. Production and Post-production Information

External data will be used to monitor some aspects of product performance as below:
-Adverse event reports;
-Customer complaints;
-Intra-laboratory quality control data;
-External Quality Assessment Schemes (EQAS): ISO13485 examination, ISO9001 examination etc.
Internal data that can be used to monitor certain performance characteristics in controlled. Conditions will be routinely generated. These sources include:
-Process monitoring;
-Stability monitoring;
-Calibrator value assignments;
-Acceptance testing;
-Equipment reliability testing;
-Validation activities.

15.Risk Management Conclusion

Through identification of Identification of medical device characteristics that could impact on safety and hazards; evaluation of severity, probability of occurrence; risk control measures of inherent safety by design, protective measures and information for safety; evaluation of residual risk; risk-benefit analysis, the hazards of the device can be controlled to be acceptable without arising new hazards.

Annex I. Failure Mode and Effects Analysis

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
A. Hazards from environment															
A1	Environment	Disposal of hazardous materials, risk to environment	Biological or chemical contamination after the removal of the used disposables	3	3	9	AF AP	The user is a trained professional / The potentially contaminated material should be disposed in special containers Absence of critical chemical component Biological components in very low concentration: no chance of environment contamination	1.SOP; 2. IQC testing report.	3	1	3	A	Benefit > Risk	No
	Environment	Disposal of hazardous materials, risk to environment	Removal of strips that contains (BSA, antigens, antibodies)	3	3	9	AF AP	The package insert warns the user about the removal conditions The raw material is controlled to insure the absence of infectious Ag and Ab. The antibody, antigen and BSA are in very low concentrations and under a dry form on the membrane. In case of removal of non used material (expired) the cassette should still be in the blister	1.SOP; 2. IQC testing report.	3	1	3	A	Benefit > Risk	No
	Environment	Disposal of hazardous materials, risk to environment	Non recycling plastic (strips / bottle)	2	3	6	AF AP	Strip and vials recyclable	1.SOP; 2. IQC testing report.	2	1	2	A	Benefit > Risk	No
	Environment	Disposal of hazardous materials, risk to environment	Non recycling packaging	1	3	3	A	Packaging recyclable	1.SOP; 2. IQC testing report.	1	1	1	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
	Environment	False result	Physical Alteration during the shipment	2	2	4	AF AP	The composition of the kit does not contain hazardous chemical products	1.SOP; 2. IQC testing report.	2	1	2	A	Benefit > Risk	No
B. Hazards from manufacture															
B1	False result	Absence of control line	No color display pads	2	2	4	AF AP	Production process control procedures, standard operating procedures.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	lost of sensitivity and/or specificity of the test	Critical raw materials, recognition problem with some samples	2	2	4	AF AP	The product is designed to obtain the required performances. Every lot of antigens and antibody is controlled by QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Lost of sensitivity and/or specificity of the test	Wrong or concentration deviation on the color display pad using the raw material	2	3	6	AF AP	Production process control procedures, standard operating procedures.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Lost of sensitivity and/or specificity of the test	Color rendering pad treatmentwhether the net is clean and dry	2	3	6	AF AP	Production process control procedures, standard operating procedures.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Absence of control line	Critical raw material, manufacturing not well controlled, Interference because of biotin in the	2	2	4	AF AP	The design will optimise the test to have a control line. The package insert indicates how to perform the test, that the result is invalid in the absence of C line. It also indicates not to	1.SOP; 2. QC testing report. 3.Test Device	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
			samples					re-use the cassette but use a new one to repeat the test.	Package Insert						
	False result	Lost of sensitivity and/or specificity of the test	Critical raw materials	2	2	4	AF AP	The product is designed to obtain the required performances. Every lot of antigens and antibody is controlled by QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Absence of control line	Critical raw materials, batch to batch heterogeneity	2	2	4	AF AP	The design will optimise the test to have a control line. The package insert indicates how to perform the test, that the result is invalid in the absence of C line. It also indicates not to re-use the cassette but use a new one to repeat the test. Every lot of raw material is controlled by QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Lost of sensitivity and/or specificity of the test	Modification of performances (sensitivity and specificity) critical raw material, stability	2	4	8	AF AP	Qualification of several suppliers if possible, implementation of technical requirements, qualification of each batch with antigens and antibodies	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Lost of sensitivity and/or specificity of the test	Modification of performances (sensitivity and specificity) critical raw material	2	4	8	AF AP	Qualification of each batch, Material and manufacturing procedures will be validated during development and validation phases.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	Lost of sensitivity and/or specificity of the test	Correct position with T-line and C-line	2	3	6	AF AP	Production process control procedures, standard operating procedures.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	False result	Modification of performances (sensitivity and	2	3	6	AF AP	Qualification of each batch after coating. The requirements are defined during development and verification to finalize the control	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
			specificity) critical raw material, stability					procedures. A stability procedure will be studied	3.Test Device Package Insert						
	False result	False result	Modification of performances (sensitivity and specificity) critical raw material	2	3	6	AF AP	Qualification of each batch, treated sample pad unique are well controlled, The use of this sample pad will be optimized with every possible usage.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	False result	Modification of performances (sensitivity and specificity) because of the buffer: the buffer interferes or the quantity of buffer to add is not well controlled	2	3	6	AF AP	The different possible interfering substances will be tested during development and validation studies. The results obtained with the different interfering substances should be identical. The quantity of buffer to add will be tested during development and validated during validation studies. The explanations will be in the package insert	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	False result	The pad does not conform to specifications difference	2	3	6	AF AP	Manufacturing and QC procedures, and optimal procedure	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Quality of the antigens and antibodies do not guaranty the expected performance	2	3	6	AF AP	Spec. and In coming QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Storage conditions not correct	2	3	6	AF AP	The shelf life of the raw material will be defined in COA from vender and validate by R&D and Manufacture technology	1. Stability test verification report. 2. QC testing report. 3.Test Device	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
									Package Insert						
		False result	Non respect of manufacturing procedures	2	3	6	AFAP	Manufacturing Procedures, QC at the threshold.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Non respect of manufacturing procedures	2	3	6	AFAP	Manufacturing Procedures, QC at the threshold.	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Non respect of manufacturing procedures, inconsistency in the dispense of solution on the membrane, mistake three kinds of solution	2	3	6	AFAP	Manufacturing Procedures, Validation of the equipment, In process and final QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Color rendering pad treatmentis uniform	2	3	6	AFAP	Manufacturing procedure, Validation of the equipment, In process and final QC	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Bad clipping of the cassette (deviation from specifications)	2	3	6	AFAP	Manufacturing in process control	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		Optimal inconsistency	Operator mistake	2	3	6	AFAP	Optimal test	Test Device Package Insert	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
		False result	Wrong QC Samples used, QC procedure does not fit with the needs.	2	3	6	AFAP	QC samples and QC procedure	1.SOP; 2. QC testing report. 3.Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Mix of components (from different tests)	2	3	6	AFAP	Manufacturing Process lot numbers will be on the box labeling	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No
		False result	Storage conditions are not correct (2℃ to 30℃)	2	3	6	AFAP	The package insert mentions the storage conditions	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No
		False result	The labeling is altered or lost	2	3	6	AFAP	The final QC verifies the presence of the labeling	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No
		False result	Storage conditions are not correct (2 ℃ to 30 ℃): freezing, humidity, higher temperature	2	3	6	AFAP	Stability protocol, the package insert mentions the storage condition	1. Stability test verification report. 2. QC testing report.	2	1	2	A	Benefit > Risk	No
		Product unusable	Dropper, desiccant or some other things missing	2	2	4	AFAP	Double check	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No
		False result	Insert missing	2	2	4	AFAP	Final release check	1.SOP; 2. QC testing report.	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
		Product damage	Transmission damage	1	2	2	A	Transmission control		1	1	1	A	Benefit > Risk	No
		False result	Time to Recovery to Ambient temperature is not respected	1	3	3	A	The package insert mentions the use conditions	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	Incorrect buffer is used (confused with Reagent, or use incorrect volume of reagent)	1	2	2	A	The buffer is included in the kit. The quantity to be used will be in the package insert.	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
			Cross reaction with other virus	3	2	6	AFAP	Interferences with other virus were tested during development and field trials		3	1	3	A	Benefit > Risk	No
		False result	Shipment condition of the sample is not respected	2	2	4	AFAP	The package insert mentions the condition of Shipment condition	Test Device Package Insert	2	1	2	A	Benefit > Risk	No
		False result	Temperature storage not respected	1	2	2	A	The storage conditions of the test device are established during development and validation. The package insert mentions the condition of device storage	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	The assay step is not correct	1	2	2	A	The package insert mentions the condition of dilution	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	The nature/characteristic of the sample gives interference	2	3	6	AFAP	Different kind of samples are tested, whole blood and some other medicines that may be used	Test Device Package Insert	2	1	2	A	Benefit > Risk	No
	False result	False result	Too little sample (insufficient migration)	1	2	2	A	The conditions are tested during development and validated during the validation studies. The package insert mentions condition of migration	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	Too much sample (flooding)	1	2	2	A	The conditions are tested during development and validated during the validation studies. The package insert mentions condition of migration	Test Device Package Insert	1	1	1	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
		False result	Finger contact leads to contamination of the test	3	2	6	AF AP	The user is a trained professional / The package insert warns the user not to touch the membrane	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
		False result	Reading Time not respected	1	3	3	A	Reading times are established during development and validated during the validation studies. The package insert gives the reading times to fulfill	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	Confusion between Control line and test line band results	1	3	3	A	The letter are printed on the cassette and information is provided in the package insert	Test Device Package Insert	1	1	1	A	Benefit > Risk	No
		False result	Absence of positive control in the kit	3	2	6	AF AP	Manufacturing procedures from Raw material to final product are optimised during development and validation In process QC procedures Final QC procedures with specific sample library	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
Hazards from user															
	User	Hazard to the user	Risk of contamination with the sample and buffers	3	3	9	AF AP	The user is harmed. The package insert mentions the use of gloves	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
	User	False result	Risk of contamination with the sample and buffers	3	3	9	AF AP	The bystander should not be in contact with the samples or buffers, only the user should be in contact with the sample or buffers during the test	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
	User		The user is contaminated with the biological material (raw material of animal origin) and /or chemicals contained in the test	2	2	4	AF AP	The user is a trained professional / The package insert informs the user about the biological material present in the test. The raw material is controlled to insure the absence of infectious Ag and Ab. the recombinant antigen and BSA are in very low concentrations and under a dry form on the membrane. There is barely no chance of contamination	Test Device Package Insert	2	1	2	A	Benefit > Risk	No

	Risk Analysis			Risk Evaluation				Risk Control	Verified in	Residual Risk Evaluation				Risk-benefit analysis	NH?
ID	Item/ Function	Adverse Effect	Cause	S	P	RPN	ALOR	Protective measures		S	P	RPN	ALOR		
	User	False result	The User is in contact with the sample during or after the migration	3	3	9	AFAP	The user is a trained professional / The package insert warns the user about the fact that the sample is potentially infectious. The package insert mentions the use of gloves	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
	User	Operator can contract disease	Biological and/or chemical contamination after the removal of the used disposables	3	3	9	AFAP	The user is a trained professional / The package insert warns the user about the potentially contaminated material and the necessity to wear gloves. The potentially contaminated material should be disposed in special containers	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
	User	Operator can contract disease	Biological and/ or chemical contamination after the removal of the used disposables	2	3	6	AFAP	The user is a trained professional. The access to the laboratory should be restricted to authorized persons only The potentially contaminated material should be disposed in special containers The package insert warns the user about the potentially contaminated material and the necessity to wear gloves	Test Device Package Insert	3	1	3	A	Benefit > Risk	No
	User	Operator can contract disease	The bystander is contaminated with the biological material (raw material of animal origin) contained in the test during the removal of non used material (expired)	3	2	6	AFAP	The user is a trained professional. The access to the laboratory should be restricted to authorized persons only The package insert informs the user about the biological material present in the test. The raw material is controlled to insure the absence of infectious Ag and Ab. The antibodies, and BSA are in very low concentrations and under a dry form on the membrane. In case of removal of non used material (expired) the cassette should still be in the blister There is barely no chance of contamination	Test Device Package Insert	3	1	3	A	Benefit > Risk	No

NOTE:

Abbreviation	Description
RE	Risk Evaluation
S	Severity
P	Probability of Occurrence
RPN	Risk Priority Number
NH	New hazard generated (no/yes-if the new hazard was not acceptable, the number of new hazard was remarked)
ALOR	Acceptable Level of Risk
A	Acceptable and insiginificant
AFAP	Risk is requried to be reduced As Far As Possible
UA	Unacceptable