CE Technical Files

Product：FLU A&B Antigen Test kit(Colloidal Gold Method)

File No.: CE/IVDD-YYM-01

Version: A/0

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Date	2022.04.02	**Date**	2022.04.02	**Date**	2022.04.02

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Yun Xu	2022.04.02

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General Description

1. Device description

1.1 Product name:

FLU A&B Antigen Test kit(Colloidal Gold Method)

Specification:

1 Test/Kit; 5 Tests/Kit; 10 Tests/Kit; 20 Tests/Kit; 25Tests/Kit;30Tests/kit; 50Tests/Kit

5 tests/kit;5 tests/kit;1 test/kit

The product picture is as below:

Figure 1. Picture of the product

1.2 Performance requirements

This clinical trial only conducts clinical verification for influenza A H1N1 and seasonal H3N2 subtypes, and simultaneously detects 1200 clinical specimens with PCR method. The test results show that the assessment reagents have high consistency with the marketed reagents. The results are as follows:

Cases		PCR results		Total
		Flu A Positive	Flu A Negative	
FLU A&B Antigen Test kit	Flu A Positive	161	16	177
	Flu A Negative	13	1010	1023
Total		174	1026	1200

Sensitivity: 92.5%(161/174) 95% CI: 87.64-95.58%
Specificity: 98.4%(1010/1026) 95% CI: 97.48-99.04%
Overall Accuracy:97.6%(1171/1200) 95% CI: 96.55-98.31%

2. Intended use

FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

3. Intended users

The product is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.

4. Principle of the assay method or the principles of operation

This product uses highly specific antigen-antibody reaction and immunochromatographic analysis technology, and qualitatively detects the FLU A&B antigens in the sample through the double-antibody sandwich detection principle. During the detection, if the sample to be tested contains Type A and (Or) Type B influenza virus antigen and the antigen concentration is higher than the minimum detection level. Type A and (or) Type B influenza virus antigens first form a reaction complex with the labeled antibody. Under the action of chromatography, the reaction complex moving forward along the nitrocellulose membrane, the influenza A nucleoprotein monoclonal antibody and/or influenza B nucleoprotein monoclonal antibody pre-coated by the detection area A and (or) B area on the nitrocellulose membrane are combined, in The detection area A and (or) B area finally forms a red band, and the result is positive at this time; on the contrary, if the sample does not contain A and B influenza virus antigens or the antigen concentration is lower than the detection amount, the detection area forms no red band, and the result is negative at this time. Regardless of whether there is type A or type B influenza virus antigen in the sample, a purple-red band will appear in the quality control area (C), and the purple-red band displayed in the quality control area (C) is to determine whether there is enough samples are the standard for whether the chromatographic process is normal, and it also serves as the internal control standard for reagents.

5. Applicable instrument and Consumable

The FLU A&B Antigen Test kit(Colloidal Gold Method) is a self-test kit, which is used alone to produce results without using instrument.

6. Device Classification

Classification: Others.

Rule: According to Annex II of In Vitro Diagnostic Medical Devices Directive (98/79/EC)

7. Conformity assessment procedures

We declare the conformity by issuing the EU declaration of conformity referred to Annex III of In Vitro Diagnostic Medical Devices Directive (98/79/EC).

8. Description of the components

No.	Components	Main ingredients
1	FLU A&B test cassette (Colloidal Gold Method)	The test card consists of a desiccant and a test strip. The test strip consists of a sample pad and a gold label pad (fixed with a colloidal gold-marked FLU A antibody Ⅰ and FLU B antibody Ⅰ), a nitrocellulose membrane (coated with FLU A antibody Ⅱ and FLU B antibody Ⅱ ,goat anti-mouse IgG polyclonal antibody as the quality control line (C line)), absorbent paper and PVC rubber plate composition. 1 piece for 1 test/kit
2	Extraction Reagent	1 tube for 1 test/kit
3	Sterile Swabs	1 piece for 1 test/kit
4	Extraction Tubes	1 piece for 1 test/kit

9. Sample Requirements

Nasal swab, and nasopharyngeal swab specimens

10. Precautions

1.Do not use the test kit if the pouch is damaged or the seal is broken.
2.Do not use this kit beyond the expiration date printed on the package label.
3.To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
4.Do not reuse any kit components.
5.Specific training or guidance is recommended if operators are inexperienced in specimen collection and handling. Wear protective clothing such as a lab coat, disposable gloves, and eye protection when specimen collection and analysis. Pathogenic microorganisms, including hepatitis virus and human immunodeficiency virus, may be present in clinical specimens.
6.If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and
culture specimens.

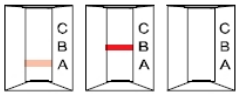
11. Test Procedure:

Read the instructions carefully before use and bring the test device, extraction reagent and samples back to room temperature. Open the package and take out the test cassette.
1.Insert a pipette tip firmly into the extraction tube, add two drops to the test device's sample well (s) and start the timer.
2.Read results at 15 minutes. Results should not be read after 20 minutes.

INTERPRETATION OF RESULTS
Negative result: Only a reddish purple Control line (C position), with no Test line at the A or B position, indicates that Influenza A or B antigen has not been detected.

Positive result: A reddish purple Control line (C position) and a reddish purple Test line (A or B position) indicate that Influenza A or B antigen has been detected.

Invalid Result: A reddish purple line should always appear at the Control line position (C). If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new test device.



12. Storage and expiration

The kit is sealed and stable in an aluminum foil bag at 4℃~30℃for 24 months. The test card should be used as soon as possible, within 1 hour of opening the foil.

Manufacturing and expiry date: See information on the label.

13. Clinical background, current knowledge, and state of art

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus.

An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing.Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral

therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment is of particular value in a clinical setting where accurate diagnosis can assist the healthcare professional with management of influenza patients who are at risk for complications. FLU A&B Antigen Test kit(Colloidal Gold Method) is a rapid immunoassay to be used as an aid for the differential diagnosis of influenza type A and type B.

14. Applicable Standard

No.	File No.	Version	File Title

1	IVDD 98/79/EC	1998	In vitro diagnostic medical devices
2	EN ISO 14971	2019	Medical Device -Application of Risk Management in Medical Device
3	EN ISO 18113-1	2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
4	EN ISO 18113-2	2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
5	EN 13612	2002	Performance evaluation of in vitro diagnostic medical devices
6	EN ISO 23640	2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
7	EN 13641	2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
8	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer

2 Information to be supplied by the manufacturer

2.1 Label and Language

2.1 Label and Language

2.1.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

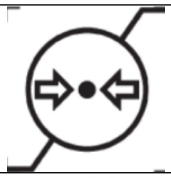
NOTE Symbols used with medical devices for use by other than healthcare professionals can require additional explanations.

2.1.2 Symbols used

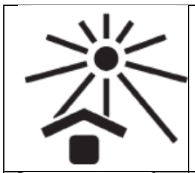
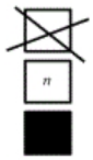
Symbol	Explain
CE	After passing CE certification, mark of CE needs to be printed on labels; a) Diameter of the pattern shall not be less than 5mm. b) CE marking shall be distinct, visible durable and in clear writing.
EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY" This symbol shall be accompanied by the name and the address of the authorized representative in the European Community, adjacent to the symbol (see A.8). NOTE The relative size of the symbol and the size of the name and address are not specified. b) Diameter of the pattern shall not be less than 5mm. c) CE marking shall be distinct, visible, durable and in clear writing.
	Symbol for "MANUFACTURER" This symbol shall be accompanied by the name and the address of the manufacturer (the person placing the device on the market), adjacent to the symbol.
	Symbol for "DATE OF MANUFACTURE" This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol. NOTE 1 The relative sizes of the symbol and the date are not specified.

	Symbol for “Use-by date”. Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown.
	Symbol for “BATCH CODE” This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol. NOTE 1 The relative size of the symbol and the size of the batch code are not specified. NOTE 2 Synonyms for "batch code" are "lot number", "batch number".
	Symbol for "CAUTION" NOTE 1 This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use”.
	Symbol for “Consult instructions for use” Indicates the need for the user to consult the instructions for use. NOTE 1 Synonym for “Consult instructions for use” is “Consult operating instructions”. NOTE 2 Consider the difference between the description of this symbol and that of symbol for “Caution”.
	Symbol for “In Vitro Diagnostic Medical Device”
	Symbol for “Non sterile product” Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
	Symbol for "Keep dry" Indicates a medical device that needs to be protected from moisture. NOTE This symbol can also mean “Keep away from rain” as referenced in ISO 7000.

	Symbol for “Keep away from Sunlight”. Indicates a medical device that needs protection from light sources.
	Symbol for “Do not use if package is damaged”. Indicates a medical device that should not be used if the package has been damaged or opened. NOTE This symbol may also mean “Do not use if the product sterile barrier system or its packaging is compromised”.
	Symbol for ”Importer” Indicates the entity importing the medical device into the locale
	Symbol for ”Distributor“ Indicates the entity distributing the medical device into the locale
	Symbol for “Model number” Indicates the model number or type number of a prod- uct
	Symbol for “Country of manufacture” To identify the country of manufacture of products
	Unique device identifier Indicates a carrier that contains unique device identifier information
	Symbol for “Contains or presence of natural rubber latex” Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Symbol for “Do not re-use” Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Symbol for “Upper limit of Humidity” Indicates the upper limit of humidity to which the medical device can be safely exposed.

	Symbol for “Humidity limitation” Indicates the range of humidity to which the medical device can be safely exposed.
	Symbol for “Atmospheric pressure limitation” Indicates the range of atmospheric pressure to which the medical device can be safely ex- posed
	Symbol for “Temperature limit” Indicates the temperature limits to which the medical device can be safely exposed.
	Symbol for “Lower limit of Temperature” Indicates the lower limit of temperature to which the medical device can be safely exposed.
	Symbol for “Upper limit of Temperature” Indicates the lower limit of temperature to which the medical device can be safely exposed.

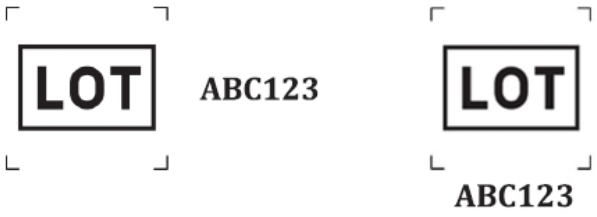
Other label identifications on cartons

	Away from the sunlight		Keep dry
	Storage temperature limit		Storage humidity limit
	Upwards		Stacking layer limit

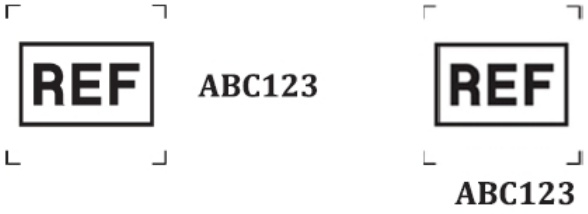
2.1.3 Examples of symbols application

A.1 Examples of use of symbol for "DATE OF MANUFACTURE"

A.2 Examples of use of symbol for "Batch Code"

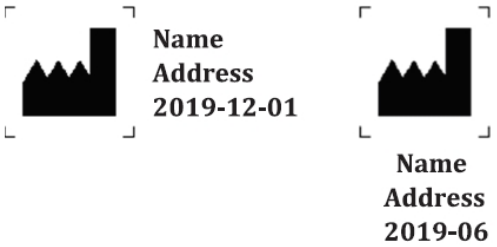


A.3 Example of use of symbol for “Catalogue number”



A.4 Example of use of symbol for "MANUFACTURER"

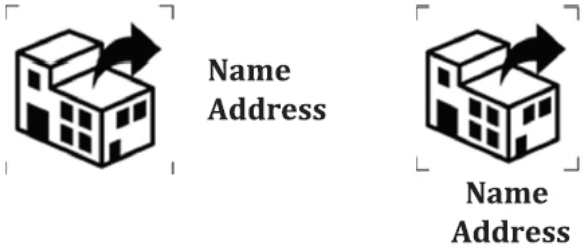
A.5 Example of use of symbol for “MANUFACTURER” combined with “DATE OFMANUFACTURE”



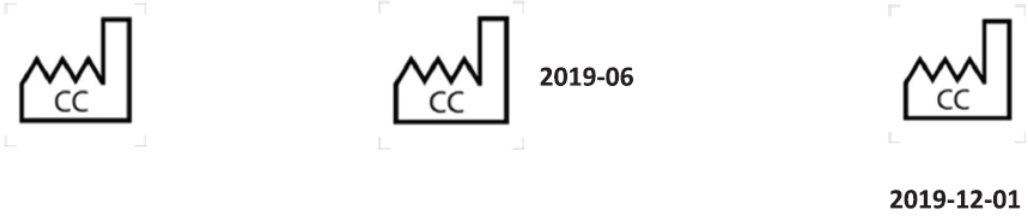
A.6 Example of use of symbol for "Authorized representative in the European Community/European Union"

A.7 Example of use of symbol for " IMPORTER "

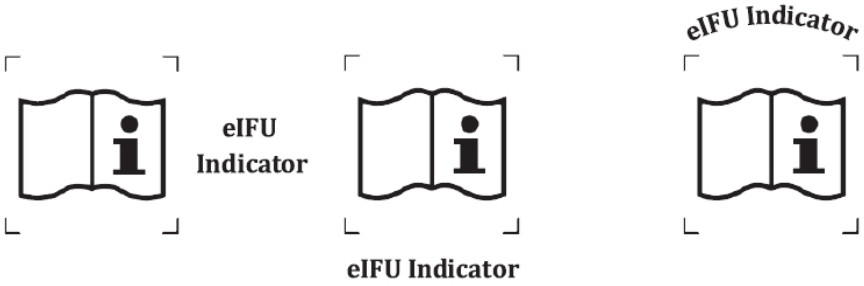
A.8 Example of use of symbol for " Distributor "



A.9 Example of use of symbol for " Country of manufacture "



A.10 Example of use of symbol for “Consult instructions for use or consult electronic instructions for use” for an electronic instruction for use (eIFU)



2.1.4 Language Requirements for Labeling in the EU Member States

Language / Country	Bulgarian	Croatian	English	Czech	Dutch	Danish	Estonian	Finnish	French	German	Greek	Hungarian	Irish	Italian	Latvian	Lithuanian	Maltese	Polish	Portuguese	Romanian	Slovak	Slovenian	Spanish	Swedish	Norwegian
Austria										★															
Belgium					★				★																
Bulgaria	★																								
Cyprus											★														
Croatia		★																							
Czechia				★																					
Denmark						★																			
Estonia							★																		
Finland								★																	
France									★																
Germany										★															
Greece											★														
Hungary												★													
Ireland			★										★												
Italy														★											
Latvia															★										
Lithuania																★									
Luxembourg									★	★															
Malta			★														★								
Netherlands					★																				

Poland																		★							
Portugal																			★						
Romania																				★					
Slovakia																					★				
Slovenia																						★			
Spain																							★		
Sweden																								★	
Norway																									★
Iceland			★																						

Label Sample

FLU A&B Antigen Test kit(Colloidal Gold Method)

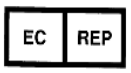
MODEL: XXXX

YYYY-MM-DD

YYYYMMDD

YYYYMMDD

Manufacturer: Yong Yue Medical Technology(Kunshan) Co.,Ltd
Address: No.6, kingdee road, kunshan city, jiangsu province, China 215300
Tel: 0086 0512-55256601



SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

CE

FLU A&B Antigen Test kit(Colloidal Gold Method)

Instructions For Use

INTENDED USE

FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

PACKING INFORMATION

1 Test/Kit; 5 Tests/Kit; 10 Tests/Kit; 20 Tests/Kit; 25Tests/Kit;30Tests/kit; 50Tests/Kit

SUMMARY

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus.

An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing.Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment is of particular value in a clinical setting where accurate diagnosis can assist the healthcare professional with management of influenza patients who are at risk for complications. **FLU A&B Antigen Test kit(Colloidal Gold Method)** is a rapid immunoassay to be used as an aid for the differential diagnosis of influenza type A and type B.

PRINCIPLE

This product uses highly specific antigen-antibody reaction and immunochromatographic analysis technology, and qualitatively detects the FLU A&B antigens in the sample through the double-antibody sandwich detection principle. During the detection, if the sample to be tested contains Type A and (Or) Type B influenza virus antigen and the antigen concentration is higher than the minimum detection level. Type A and (or) Type B influenza virus antigens first form a reaction complex with the labeled antibody. Under the action of chromatography, the reaction complex moving forward along the nitrocellulose membrane, the influenza A nucleoprotein monoclonal antibody and/or influenza B nucleoprotein monoclonal antibody pre-coated by the detection area A and (or) B area on the nitrocellulose membrane are combined, in The detection area A and (or) B area finally forms a red band, and the result is positive at this time; on the contrary, if the sample does not contain A and B influenza virus antigens or the antigen concentration is lower than the detection amount, the detection area forms no red band, and the result is negative at this time. Regardless of whether there is type A or type B influenza virus antigen in the sample, a purple-red band will appear in the quality control area (C), and the purple-red band displayed in the quality control area (C) is to determine whether there is enough samples are the standard for whether the chromatographic process is normal, and it also serves as the internal control standard for reagents.

MAIN COMPONENTS

The test kit consists of a test cassette, Extraction Reagent, Sterile Swabs, and Sample Extraction Tubes.

No.	Components	Main ingredients
1	FLU A&B test cassette (Colloidal Gold Method)	The test card consists of a desiccant and a test strip. The test strip consists of a sample pad and a gold label pad (fixed with a colloidal gold-marked FLU A antibody Ⅰ and FLU B antibody Ⅰ), a nitrocellulose membrane (coated with FLU A antibody Ⅱ and FLU B antibody Ⅱ ,goat anti-mouse IgG polyclonal antibody as the quality control line (C line)), absorbent paper and PVC rubber plate composition. 1 piece for 1 test/kit
2	Extraction Reagent	1 tube for 1 test/kit
3	Sterile Swabs	1 piece for 1 test/kit
4	Extraction Tubes	1 piece for 1 test/kit

STABILITY AND STORAGE

The kit is sealed and stable in an aluminum foil bag at 4℃~30℃for 24 months. The test card should be used as soon as possible, within 1 hour of opening the foil.

Manufacturing and expiry date: See information on the label.

WARNINGS AND PRECAUTIONS

1.Do not use the test kit if the pouch is damaged or the seal is broken.

2.Do not use this kit beyond the expiration date printed on the package label.

3.To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.

4.Do not reuse any kit components.

5.Specific training or guidance is recommended if operators are inexperienced in specimen collection and handling. Wear protective clothing such as a lab coat, disposable gloves,and eye protection when specimen collection and analysis.Pathogenic microorganisms, including hepatitis virus and human immunodeficiency virus, may be present in clinical specimens.

6.If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing.Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

SPECIMEN COLLECTION AND PREPARATION

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results.Training in specimen collection is highly recommended because of the importance of specimen quality.

•To collect nasal Swab or nasopharyngeal swab specimens, only the swab provided in the test kit should be used.

• Use fresh samples for best performance. Freshly collected specimens should be tested immediately. If necessary,swab samples can be stored for up to 4 hours at room temperature or up to 8 hours at 2-8°C.

•Transport media should not be used. This test has not been validated or authorized using viral transport media.

Specimen Collection

Nasal Swab Sample:

It is important to obtain as much secretion as possible. Therefore, to collect a nasal swab sample, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

Nasopharyngeal Swab Sample:

It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the Swab into the posterior nasopharynx. Rotate the swab several times.

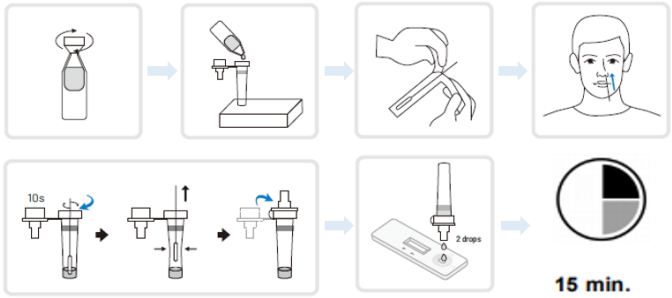
Specimen Handling

1.Twist the tip to open the extraction reagent, place the extraction reagent container downward to allow the solution to drip into the extraction tube without touching the edges of extraction tube. Add the entire contents to the extraction tube by squeezing the container.

2.Put the swab specimen into the extraction tube, rotate the swab in the liquid for about 10 seconds, and press the swab head against the tube wall to release the specimen in the swab.

3.Remove the swab while squeezing the sides of the tube to draw as much liquid as possible from the swab. Dispose of the swabs in accordance with biohazardous waste disposal regulations.

4.Firmly insert a pipette tip into the extraction tube.



TEST PROCEDURE

Read the instructions carefully before use and bring the test device, extraction reagent and samples back to room temperature. Open the package and take out the test cassette.

1.Insert a pipette tip firmly into the extraction tube, add two drops to the test device's sample well (s) and start the timer.

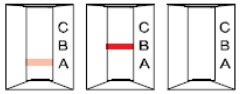
2.Read results at 15 minutes. Results should not be read after 20 minutes.

INTERPRETATION OF RESULTS

Negative result: Only a reddish purple Control line (C position), with no Test line at the A or B position, indicates that Influenza A or B antigen has not been detected.

Positive result: A reddish purple Control line (C position) and a reddish purple Test line (A or B position) indicate that Influenza A or B antigen has been detected.

Invalid Result: A reddish purple line should always appear at the Control line position (C). If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new test device.



LIMITATIONS

1.The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from nasal swab and nasopharyngeal swab specimens.

2.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

3.Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.

4.Test Results must be evaluated in conjunction with other clinical data available to the physician.

5.Negative test results do not rule-out possible other non-influenza viral infections.

6.Positive test results do not rule out co-infections with other pathogens.

7.Positive test results do not identify specific influenza A virus subtypes.

8.Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will often yield lower sensitivity than testing specimens from children.

9.Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

10.Individuals who received nasally administered influenza A vaccine may have positive test results for up to 3 days after vaccination.

11.Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.

12.If differentiation of specific influenza A subtypes and strains is needed, additional testing, in consultation with the State or Local public health department, is required.

PERFORMANCE CHARACTERISTICS

Clinical performance

This clinical trial only conducts clinical verification for influenza A H_1N_1 and seasonal H_3N_2 subtypes, and simultaneously detects 1200 clinical specimens with PCR method. The test results show that the assessment reagents have high consistency with the marketed reagents. The results are as follows:

Cases		PCR results		Total
		Flu A Positive	Flu A Negative	
FLU A&B Antigen Test kit	Flu A Positive	161	16	177
	Flu A Negative	13	1010	1023
Total		174	1026	1200

Sensitivity: 92.5%(161/174) 95% CI: 87.64-95.58%

Specificity: 98.4%(1010/1026) 95% CI: 97.48-99.04%

Overall Accuracy:97.6%(1171/1200) 95% CI: 96.55-98.31%

Cases		PCR results		Total
		Flu B Positive	Flu B Negative	
FLU A&B Antigen Test kit	Flu B Positive	148	20	168
	Flu B Negative	10	1022	1032
Total		158	1042	1200

Sensitivity: 93.7%(148/158) 95% CI: 88.74-96.53%

Specificity: 98.1%(1022/1042) 95% CI: 97.05-98.75%

Overall Accuracy:97.5%(1170/1200) 95% CI: 96.45-98.24%

Limit of Detection

Limit of detection (LOD) for SARS-CoV-2 and influenza A and B in the FLU A&B Antigen Test kit(Colloidal Gold Method) was determined by evaluating different concentrations of heat inactivated viruses. Natural nasopharyngeal swab specimens were obtained from healthy donors and confirmed negative for COVID-19 and Influenza A&B using the FLU A&B Antigen Test kit(Colloidal Gold Method) test.Negative natural nasopharyngeal swab specimens were eluted in PBS. Swab elutes were combined and mixed thoroughly to create a negative clinical matrix pool to be used as the diluent. The viruses were diluted in this natural nasopharyngeal swab matrix pool to generate virus dilutions for testing. Nasopharyngeal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert.

Virus Strains	Sources	LoD	#Positive/#Total	% Positive
InfluenzaA Victoria/361/11(H3N2)	Zeptometrix,Cat # 0810240CF	5 x 10^1 $TCID_{50}$/mL	20/20	100
Influenza A A/California/07/2009 (H1N1)	ATCC,Cat#VR-1894	2 x 10^5 $CEID_{50}$/mL	20/20	100
Influenza B Victoria/504/00	Zeptometrix, Cat#0810571CF	6 x 10^2 $TCID_{50}$/mL	20/20	100
Influenza B Yamagata/16/88	Zeptometrix, Cat#0810518CF	3 x 10^2 $TCID_{50}$/mL	20/20	100

Cross-Reactivity

Cross-reactivity for the FLU A&B Antigen Test kit was assessed by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the FLU A&B Antigen Test kit. Each organism and virus was tested in triplicate. The final concentration of the individual organisms is documented in the following table.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	2,8 x 10^5 U/mL	No
Human coronavirus OC43	1,0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1,0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1,0 x 10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1,0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1,0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1,0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5,2 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1,6 x 10^5 $TCID_{50}$/mL	No
SARS-CoV-2	2,8 x 10^5 $TCID_{50}$/mL	No
Enterovirus	4,0 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4,0 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1,1 x 10^5 PFU/mL	No
SARS-coronavirus	4,5 x 10^5 PFU/mL	No
MERS-coronavirus	1,5 x 10^5 $TCID_{50}$/mL	No
Haemophilus influenza	1,4 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1,0 x 10^6 CFU/mL	No
Streptococcus pyogenes	1,6 x 10^6 CFU/mL	No
Candida albicans	1,8 x 10^6 CFU/mL	No
Pooled human nasal wash	100%	No
Bordetella pertussis	1,4 x 10^6 CFU/mL	No
Mycoplasma pneumoniae	1,0 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1,0 x 10^6 IFU/mL	No
Legionella pneumophila	1,0 x 10^6 CFU/mL	No

INTERFERENCE

The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below with two strains each of influenza type A and type B to assess the potential interference of the substances on the performance of the FLU A&B Antigen Test kit.

Substances Tested	**Concentration Tested**
Mucin	1 mg/mL
Whole Blood	1%
Phenylephrine	10 mg/mL
Oxymetazoline	10 mg/mL
Sodium Chloride with preservative	20%
Beclomethasone	1 mg/mL
Dexamethasone	1 mg/mL
Flunisolide	1 mg/mL
Triamcinolone	1 mg/mL
Budesonide	1 mg/mL
Mometasone	1 mg/mL
Fluticasone	0.5 mg/mL

Luffa opperculata, sulfur	1%
Galphimia glauca	1%
Histaminumhydrochloricum	1%
Live intranasal influenza virus vaccine	1%
Benzocaine	1 mg/mL
Menthol	1 mg/mL
Zanamivir	1 mg/mL
Mupirocin	1 mg/mL
Tobramycin	1 mg/mL

Hook Effect

A high-dose hook effect was not detected in the FLU A&B Antigen Test kit, for the Influenza A and B viral strains at the concentration listed below.

Virus Type	Viral Strain	Concentration tested
Influenza A (H3N2)	A/California/2/2014	5.8 x 10^5 $TCID_{50}$/mL
Influenza A (H3N2)	A/Hong Kong/8/68	1.26 x 10^6 $TCID_{50}$/mL
Influenza A (H3N2)	Victoria/361/11	1.41 x 10^5 $TCID_{50}$/mL
Influenza A (H1N1)	A/California/07/2009	5.2 x 10^7 $CEID_{50}$/mL
Influenza B	B/Russia/69	1.5 x 10^6 $CEID_{50}$/mL
Influenza B	B/Florida/02/06	1.05 x 10^6 $TCID_{50}$/mL
Influenza B	B/Victoria/504/00	1.41 x $10^5$$TCID_{50}$/mL
Influenza B	B/Yamagata/16/88	1.70 x 10^5 $TCID_{50}$/mL

PRECISION STUDIES

The total, within-run, and between-run performance of the FLU A&B Antigen Test kit was evaluated for precision. A panel consisting of two different levels of influenza A antigen (Johannesburg/82/96; weak positive and strong positive) and two different levels of influenza B antigen (Harbin/7/94; weak positive and strong positive) were repeated five times with a single lot of FLU A&B Antigen Test kit on three different days. One hundred percent (100%) accuracy was obtained for all specimens tested.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		Do not reuse
	For in vitro diagnostic use only		Lot Number		Keep dry
	Store between 4-30°C		Manufacturer		Date of manufacture
	Contents sufficient for <n> tests		Authorized Representative		CE Mark
	Do not use if package is damaged				

Yong Yue Medical Technology(Kunshan) Co.,Ltd
Address: No.6, kingdee road, kunshan city, jiangsu province, China

SUNGO Europe B.V
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

3 Design and Manufacturing Information

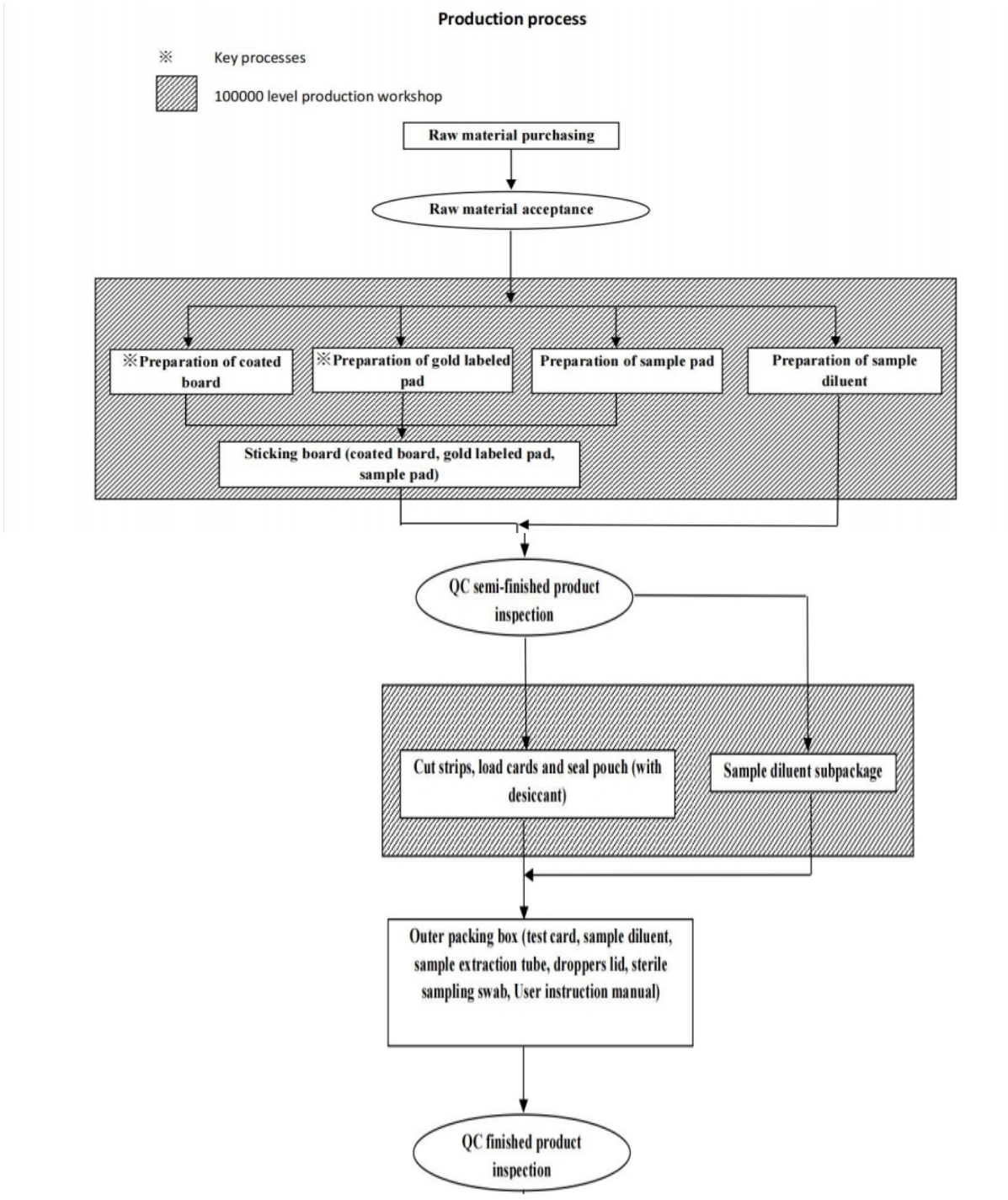
3.1 Company Introduction

Manufacturer: Yong Yue Medical Technology(Kunshan) Co.,Ltd

Address: No.6, kingdee road, kunshan city, jiangsu province, China 215300

Tel: 0086 0512-55256601

3.2 Manufacturing Information



3.3 Quality control system

3.3.1 Management Responsibility

3.3.1.1 Quality Policy

The quality policy shall be relevant to the Manufacturer's organizational goals and the expectations and needs of its customers. The Manufacturer shall ensure that this policy is understood, implement, and maintained at all levels of the organization.

3.3.1.2 Management Review

The Manufacturer's management with executive responsibility shall responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of these requirements.

3.3.2 Quality System

The Manufacturer shall establish, document and maintain a quality system as and maintain a quality system as a means of ensuring that product and maintain a quality system as a means of ensuring that product conforms the specified requirements.

3.3.3 Contract Review

Before submission of a tender, or the acceptance of a contract or order, the tender, contract, or order shall be reviewed by the Manufacturer.

3.3.4 Design Control

Not applicable.

3.3.5 Document and data control

The Manufacturer shall establish and maintain documented procedure to control all documents and data that relate to the requirements of this requirements including to the extent applicable, documents of external origin such as standard and customer drawing. The TCF for CE marking is one of the controlled documents.

The Manufacturer shall establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.

3.3.6 Control of Supplier

The Manufacturer shall establish and maintain documented procedures for the control of supplier provided raw and auxiliary material for the Manufacturer.

3.3.7 Product Identification and Tractability

Where appropriate, the Manufacturer shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.

3.3.8 Process Control

The Manufacturer shall identify and plan the production, installation and servicing

processes which directly affect quality and shall ensure that these processed are carried out under controlled condition.

3.3.9 Inspection and Testing

The Manufacturer shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met.

3.3.10 Control of Inspection,

Measuring, and Test Equipment shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring, and test equipment used by the Manufacturer to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test requirement shall be used in manners which ensure that the measurement uncertainty is known and is consistence with the required measurement capability.

3.3.11 Inspection and Test Status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed.

3.3.12 Control of Nonconforming Product

The Manufacturer shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation.

3.3.13 Corrective and Preventive Action

The Manufacturer shall establish and maintain documented procedure for implementing corrective and preventive action.

3.3.14 Handling, Storage, Packaging, Preservation and Delivery

The Manufacturer shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

3.3.15 Control of Quality Records

The Manufacturer shall establish and maintain documented procedures for identification, collection, indexing, access, fitting, storage, maintenance, and disposition of quality records.

3.3.16 Internal Quality Audits

The Manufacturer shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activity and related results comply with planned arrangements and to determine the effectiveness of the quality system.

3.3.17 Training

The Manufacturer shall establish and maintain documented Procedures for identifying training needs and provide for the training needs and provide for the training of all personnel performing activities affecting quality.

3.3.18 Servicing

Where servicing is specified requirements, the Manufacturer shall establish and maintain documented procedure for performing, verifying, and reporting that the servicing meets the specified requirements.

3.3.19 Statistical Techniques

The Manufacturer shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

3.3.20 Provisions for the change of design

Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer of the Manufacturer. If the change may effects the related electrical or mechanical characteristics.

4 Essential Requirement Checklist

File No.: CE/IVDD- YYM-01-04

Version: A/0

Product: FLU A&B Antigen Test kit(Colloidal Gold Method)

IVDD98/79/EC Essential Requirement Checklist	A/NA	Standard	Documentation	Conclusion (OK /not OK)
GENERAL REQUIREMENTS				
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN 13612:2002 EN ISO 23640:2015 EN 13641:2002	Risk analysis report User Manual Labeling Performance Evaluation report Stability Evaluation report	OK
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2) (b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical	A	EN 13612:2002 EN ISO 23640:2015 EN 13641:2002	Performance Evaluation report Stability Evaluation report	OK

specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer. The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.				
4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.	A	EN 13612:2002 EN ISO 23640:2015 EN 13641:2002	Performance Evaluation report Stability Evaluation report	OK
DESIGN AND MANUFACTURING REQUIREMENTS **1. Chemical and physical properties**				
1.1. The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in section A on the 'General requirements`. Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues,	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK

cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.				
1.2. The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
2. Infection and microbial contamination				
2.1. The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
2.2. Where a device incorporates biological stances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate stances and by using appropriate, validated inactivation, conservation, test and control procedures.	NA			
2.3. Devices labeled either as ‘STERILE’ or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.	NA			Non-sterile
2.4. Devices labeled either as 'STERILE` or as having a special microbiological state must have been processed by an appropriate, validated method.	NA			Non-sterile

2.5. Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
2.6. Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA			
2.7. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
3. Manufacturing and environmental properties				
3.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/or in the instructions for use.	NA			
3.2. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, stances and gases with which they may come into contact during normal conditions of use.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK

3.3. Devices must be designed and manufactured in such a way as to remove or reduce as far as possible: - the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features), - risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of stances into the device. Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.	A	EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011	Risk analysis report User Manual Labeling	OK
3.4. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable stances or stances which could cause combustion.	A	EN ISO 14971:2019	Risk analysis report	OK
3.5. Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	A	EN ISO 14971:2019	Risk analysis report	OK
3.6. The measuring, monitoring or display scale (including color change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	NA			
4. Devices which are instruments or apparatus with a measuring function				
4.1. Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability	NA			Qualitative device

and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.				
4.2. When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.	NA			
5. Protection against radiation				
5.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimized.	NA			This product does not produce radiation
5.2. When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: - designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted, - fitted with visual displays and/or audible warnings of such emissions.	NA			This product does not produce radiation
5.3. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	NA			This product does not produce radiation
6. Requirements for medical devices connected to or equipped with an energy source				
6.1. Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.	NA			
6.2. Devices must be designed and manufactured in such a way as to minimize the risks of	NA			

creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.				
6.3. Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.	NA			
6.4. Protection against mechanical and thermal risks 6.4.1. Devices must be designed and manufactured in such a way as to protect the user against mechanical risks. Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of stances, then appropriate protection means must be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	NA			
6.4.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	NA			
6.4.3. Devices must be designed and manufactured in such a way as to reduce as far as possible the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	NA			
6.4.4. Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimize	NA			The product cannot touch the

all possible risks.				connectors and connector
6.4.5. Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	NA			
7. Requirements for devices for self-testing				
Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.	NA			
7.1. Devices for self-testing must be designed and manufactured in such a way as to: - ensure that the device is easy to use by the intended lay user at all stages of the procedure, and - reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.	NA			
7.2. Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.	NA			
8. Information supplied by the manufacturer				

8.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labeling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
8.2. Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and color used must be described in the documentation supplied with the device.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
8.3. In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which, they are present, relevant danger symbols and labeling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use. The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	NA			This product does not contain dangerous goods
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	

(a) The name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer;				OK
(b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(c) where appropriate, the word 'STERILE` or a statement indicating any special microbiological state or state of cleanliness;	NA			
(d) the batch code, preceded by the word 'LOT`, or the serial number;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(e) if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;	NA			
(f) in case of devices for performance evaluation, the words 'for performance evaluation only;	NA			The product is not used in assessing the performance of devices
(g) where appropriate, a statement indicating the in vitro use of the device;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(h) any particular storage and/or handling conditions;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(i) where applicable, any particular operating instructions;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(j) appropriate warnings and/or precautions to take;	A	EN ISO 18113-1:2011	User Manual	OK

		EN ISO 18113-2:2011	Labeling	
(k) if the device is intended for self-testing, that fact must be clearly stated.	NA			the product is not intended for self-testing
8.5. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
8.6. Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	A	EN ISO 18113-1 2011 EN ISO 14971:2019	User Manual Risk analysis report	
8.7. Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in section 8.4 with the exception of points (d) and (e);	NA			The product is not sterile and performance evaluation instrument
(b) composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(c) the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(d) the performances referred to in section 3 of part A;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	NA			
(f) the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK

(g) a detailed description of the procedure to be followed in using the device;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(h) the measurement procedure to be followed with the device including as appropriate: - the principle of the method, - the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user, - the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.), - the indication whether any particular training is required;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(i) the mathematical approach upon which the calculation of the analytical result is made;	NA			
(j) measures to be taken in the event of changes in the analytical performance of the device;	NA			
(k) information appropriate to users on: - internal quality control including specific validation procedures, - the traceability of the calibration of the device;	NA			
(l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;	NA			The product need not repeated measurement reference
(m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK

(n) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;	NA			The product can be used without installation
(o) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	NA			The product is not installed, disinfection can be used
(p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(q) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and desterilization or decontamination, and any restriction on the number of reuses;	NA			The product is not reused
(r) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(s) precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes stances of human or animal origin, attention must be drawn to their potential infectious nature;	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK
(t) specifications for devices for self-testing: - the results need to be expressed and presented in a way that is readily understood by a lay person; information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result, - specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s)	NA			

produced by the device, - the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner, - the information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;				
(u) Date of issue or latest revision of the instructions for use.	A	EN ISO 18113-1:2011 EN ISO 18113-2:2011	User Manual Labeling	OK

5 Risk Management Report

(According to EN ISO 14971: 2019)

File No.: CE/IVDD- YYM-01-05

Version: A/0

Product: FLU A&B Antigen Test kit(Colloidal Gold Method)

Risk Management Plan For FLU A&B Antigen Test kit(Colloidal Gold Method)

1. Preface:

1.1 Introduction

The top management provided adequate resources and assigned qualified personnel for risk management process.

Top management defined and documented the policy for determining criteria for risk acceptability, this policy ensures that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns.

Also, top management reviewed the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process and document and decisions and actions taken, this review is part of the quality management system review. The following figure is provided to give and overview of the risk management process for the product manufactured by our company.

As indicated in Figure B.1, the process needs to be iterative, covering each risk in turn, and returning to earlier steps if risk control measures introduce new hazards or if new information becomes available.

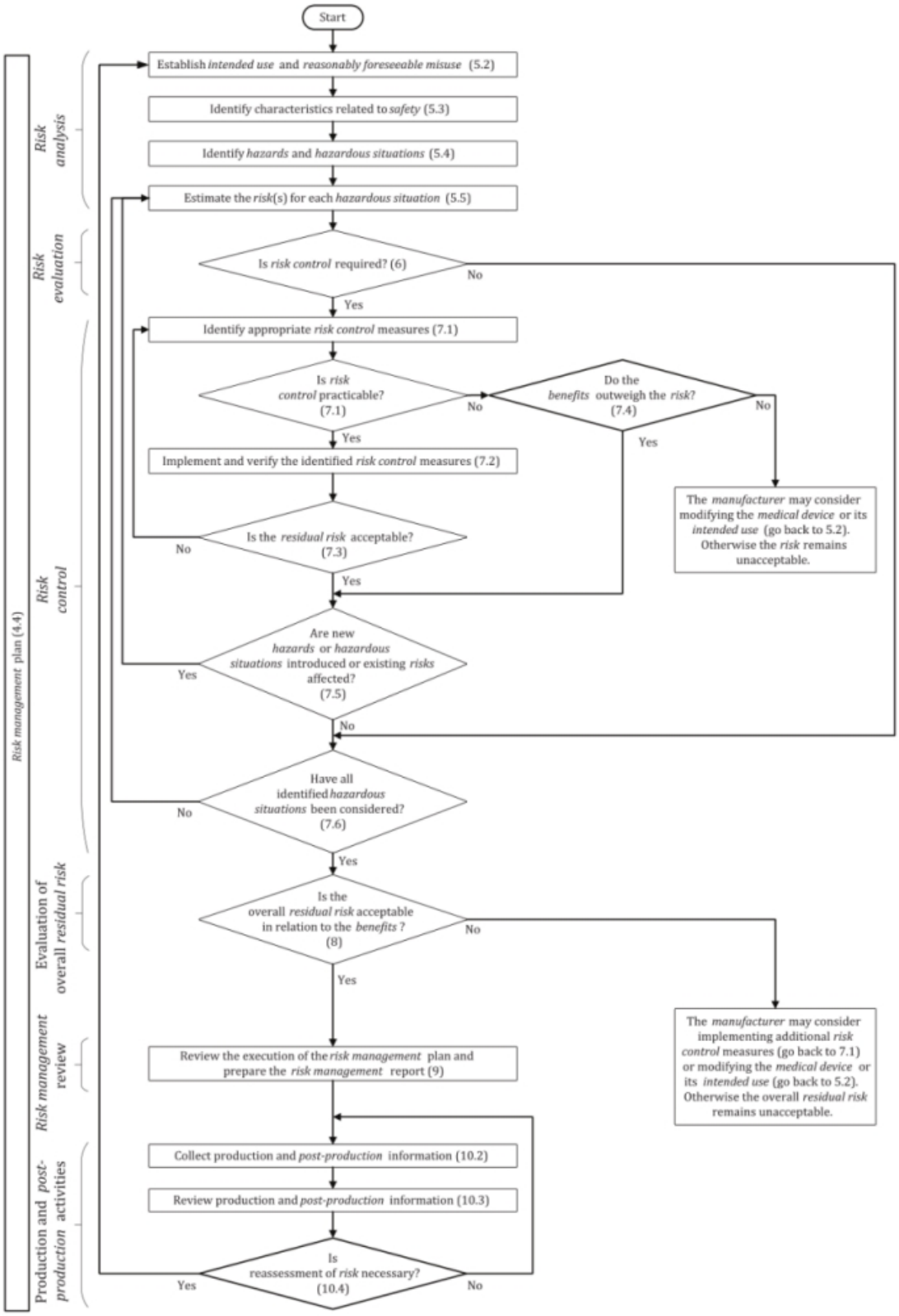


Figure B.1 — Overview of risk management activities as applied to medical devices of EN ISO14971:2019.

1.2 Purpose

This document is about the risk management to Human Metapneumo Virus Antigen Rapid Test Kit , overall potential harms and the potential reasons of each hazard are identified in the article. The likely degree caused by every hazard and the probability are evaluated. The necessary measures must be adopted according the risks which are not acceptable, and the residual risk level must be evaluated.

Result: The risks which because potential hazard are reduced to acceptable level by the proper measures. And the all risks accumulated from every kind of risks are reduced to the acceptable level.

2. Introduction of Product

Refer to the 01-file of general description.

3. Controlling of the risk analysis process

The flow chart describes the levels of realization of the management process and designates single steps for the risk analysis, risk evaluation, action management and the risk controlling.

The flow chart is seen <Figure B.1 — Overview of risk management activities as applied to medical devices> of EN ISO14971:2019.

Risk management group

Risk management is carried out by special personnel from many departments. It includes the following departments:

Depart ment	Position	Educational background and work experience	Responsibility scope
QC Dept	Risk managemen t team leader	At least 10 years' experience in medical product quality assurance and control	To establish risk management team, risk management planning, directing and coordinating the risk management activity. To ensure that risk management activities conform to the requirements of the risk management, control, and guide the implementation of risk management activities in medical product design, manufacturing process and final product inspection .
Sales Dept	Risk managemen t team member	At least 10 years' experience in sales and marketing	Responsible for the post-marketing risk information collection and feedback.
R&D Dept	Risk managemen t team member	At least 10years experience in medical product development and design	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document.

V.P.	--	At least 15 years' experience in medical product quality control and 5 years' experience in medical product management	Review risk management of the document
G.M.	--	At least 20 years' experience in medical product development and design and management	Responsible for risk management of the document for approval.

a) the members of the review team shall be responsible for the correctness and effectiveness of the evaluation results.
b) all departments should cooperate with the board using "quality control procedures" and "Corrective and preventive action control procedures" related to the product safety review, provide the basis for comprehensive residual risk evaluation.
c) according to the following information related to safety, the product design and development, trial production and product production and after-sale stage shall be reviewed.
d) whether there are unknown hazards;
e) whether there is an estimated risk (one or more) of the risk caused by a particular hazard is no longer acceptable;
f) other aspects of the initial evaluation have been invalidated;
g) Whether the overall residual risk of the product has been reduced to acceptable level or judged by risk/benefit analysis is acceptable.
h) review the methods of obtaining information after production and production.
Maintain review records to verify that each element of the risk management plan has been properly implemented in the product specific life cycle phase.

Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device(According to ISO/TR 24971:2020 clause 5.2)

The intended use and each reasonably imaginable and foreseeable misuse will be described in the risk management plan together with the product performance properties, which may influence the safety of the medical device. Then, the performance properties will be taken over into the risk management worksheet and the risks will be evaluated which occur if these performance properties are not achieved. For describing the features of the medical device and its environment in which it is used, Annex C of the current standard ISO/TR 24971:2020 is applied.

Step 2: Identification of Hazards(According to ISO/TR 24971:2020 clause 5.4)

All known and foreseeable failures / dysfunctions / hazards, which infringe the function and safety of the medical device, will be identified. For this the medical device will be analyzed in its regular mode, failure mode, (also in case of reasonably foreseeable misuse). Moreover, already earlier discovered hazards, incidents or situations will be considered.

Step 3: Estimation of the Risk(s) for Each Hazardous Situation(According to ISO/TR 24971:2020 clause 5.4)

For each defined or assumed hazard of Step 2 the implied risk will be assessed. The expected physical damage or severity of harm, and probability of occurrence.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation will be considered and the resulting hazardous situation(s) will be recorded.

Step 4: Risk Evaluation(According to ISO/TR 24971:2020 clause 6)

After that each risk will be evaluated, whether it is acceptable or not and whether a risk reduction is required. The criteria to evaluate the acceptability are listed in the risk management plan.

Step 5 and 6: Adopt risk control measures(According to ISO/TR 24971:2020 clause 7.2)

For risks which are within the acceptable area no actions of risk control will be taken. Risks, which are outside this area, will be treated case by case.

The effectiveness of the risk control measures taken will be evaluated/verified and recorded in the risk management worksheet.

Step 7: Residual Risk Evaluation(According to ISO/TR 24971:2020 clause 7.2)

The residual risks will be evaluated and documented in the risk management worksheet. In case a residual risk is not acceptable, Step 5 and Step 6 will be repeated.

Step 8: Risk / Benefit Analysis(According to ISO/TR 24971:2020 clause 7.4)

Not acceptable risks can be accepted in exceptional cases, if a particularly high benefit is to be expected for the patient, and alternative products or treatment measures with minor risks are not available.

Step 9: Risks Arising from Risk Control Measures(According to ISO/TR 24971:2020 clause 7.5)

In this step whether the actions of risk control and/or risk reduction would introduce new hazards or hazardous situations will be evaluated. In this case Step 3 has to be repeated.

Step 10: Completeness of Risk Control(According to ISO/TR 24971:2020 clause 7)

In this step, whether all relevant risks have been considered and whether the risk evaluation process is complete will be checked. In case the risk evaluation is acknowledged as complete.

Step 11: Evaluation of Overall Residual Risk Acceptability(According to ISO/TR 24971:2020 clause 8)

After the completion of all risk control measures, the whole residual risks as well as the acceptability of the residual risks will be evaluated. The evaluation of the residual risks will be performed analogically to the evaluation of the basic risks.

Step 12: Result of risk management(According to ISO/TR 24971: 2020 clause 9)

There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy

4. Risk analysis

4.1Determination of intended use

4.1.1General provisions

This product is only allowed to be used in the corresponding diagnosis and inspection departments of medical institutions approved by the health administrative department.

4.1.2 Intended use

FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

4.1.3 Operating instruction

In order to ensure the normal and effective use of the product, the company has formulated the product instruction according to the relevant international and domestic

standards, regulations, industry specifications, enterprise standards and product related research data and literature. The instructions include the intended use, use method, precautions, etc.

4.2 Determine possible usage errors

4.2.1 Use error

The company's products are manufactured in strict accordance with the approved 《Product technical requirements》, and are fully equipped with relevant accessories, such as identification labels, product instructions and packaging materials that meet the requirements of the regulations. And a series of management and operation guidance documents that meet the standards and regulations such as 《The requirements of medical device quality management system used in laws》 and 《Regulations, detailed rules for the production and implementation of in vitro diagnostic reagents》, and product characteristics are formulated, reduce the risk of products in research and production and post production stage to an acceptable range.

4.2.2 Possible use error by laboratory personnel

In order to avoid the use of medical laboratory operator error (such as, the operator use irregular, operating environment, the operator does not have blatantly qualification, etc.), product of unintended use or cannot reach the intended use, the company strictly regulate the product technical documents, and after the sale, shall give necessary training to users, and to collect user feedback information.

4.2.3 Possible misuse by health care providers

Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

4.2.4 Patients may use errors in self-testing

This product is not offered to patients for self-testing, so this risk is within the acceptable range.

4.3 Security related feature determination

This product is subject to 《Production and quality inspection》 in accordance with the approved product technical requirements, and the product is delivered to the factory in strict accordance with the standard requirements and the relevant provisions of enterprise inspection.

4.3.1 Quantitatively check the performance characteristics of the program

In the technical requirements of the product, the relevant requirements have been clearly stipulated. Factory inspection is also clearly stipulated; this risk is acceptable.

4.3.2 Qualitatively check the performance characteristics of the program

The judgment principle of corresponding test items has been clearly defined in the product technical requirements and product operation instructions.

4.3.3 Dependency characteristics

This product does not involve the use of first aid, but is designed for a lateral flow chromatographic immunoassay. This risk is acceptable.

4.3.4 Auxiliary patient information

When the product is used alone, it is only inspected for independent samples and judged by visual observation. Therefore, when using this product in medical institutions, this risk is within the acceptable range on the premise of reading the instructions carefully.

4.4 Determine known and foreseeable hazards

4.4.1 Hazards to patients

The inspection result of this product does not directly affect the formulation of life-threatening medical measures for patients. The risk is within acceptable limits.

4.4.2 Relationship with performance characteristics

If the product fails to meet the performance characteristics specified in the <Product technical requirements>, false positive or false negative results will appear. Thus, influence the doctor to the patient's situation judgment.

4.4.3 Determine hazards under fault conditions

Inhomogeneity, in the product batch inconsistency between batch and batch, nonspecific (such as: interference factors), measurement precision (related to personnel), stability failure in the storage, transportation and use of and so on, all the possible causes of the detection result is not accurate, and the physician is unable to correctly determine the clinical situation, influence the diagnosis and treatment. In order to reduce the above risks to an acceptable range, the company has formulated procedures or measures for technical research of products, raw materials procurement, production, testing, sample retention and testing, storage and transportation, sales and after-sales service guidance, product information feedback, etc., and strictly implemented them to ensure that the products are qualified.

4.4.4 Determine hazards during normal use

When the product is used normally, it may also cause the diagnosis error of the patient's condition due to the biological difference of the sample, the difference of the operator's operation, and the difference of the judge's medical diagnosis level.

4.5 Estimation of patient risk

When invalid results appear in this product, it will cause inaccurate diagnosis by doctors, which will lead to inappropriate medical intervention.

4.5.1 Estimate the severity of the damage

This product only provides clinical reference, not as a basis for clinical judgment, but also needs clinical symptoms and further tests to make judgment.

4.5.2 Estimated probability of occurrence

Under normal use, the product appears invalid results and affects the doctor's diagnosis, resulting in the possibility of damage is almost impossible.

4.5.3 Estimate patient risk

4.5.3.1 What is the possibility of IVD medical devices producing incorrect results?

Incorrect storage leads to unexpected use after product failure, uncertainty of product inspection results and biological differences of samples under normal use.

4.5.3.2 What is the possibility for the user / laboratory to detect incorrect IVD results?

Unexpected use of the product.

4.5.3.3 What is the possibility of doctors detecting incorrect IVD results?

Based on the uncertainty of product inspection results under normal use.

Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results.

4.5.3.4 What is the possibility of the physician taking measures or failing to take measures for the results?

Incorrect medical intervention, such as medication. Does not exist the critical patient life medical intervention or causes the infection and so on the situation.

4.5.3.5 What is the possibility of the doctor taking measures / not taking measures that may cause or contribute to the damage to the patient?

The main impact on patients is inaccurate drug or non-drug treatment. However, it does not involve medical intervention or infection of life-threatening patients.

4.5.3.6 What is the severity of the damage caused?

The procedure of causing serious injury is temporary injury and temporary discomfort without medical intervention.

4.5.4 Risk information for IVD medical devices

No adverse events have been found for this product. In the process of product application, medical institutions and doctors who meet the requirements shall ensure that the product is safe and effective and can achieve the intended use under normal and expected use.

4.5.5 Risk assessment and risk acceptance criteria

4.5.5.1 Severity levels

SEVERITY	DESCRIPTION

CATASTROPHIC	RESULTS IN PATIENT DEATH
CRITICAL	RESULTS IN PERMANENT IMPAIRMENT OR LIFE-THREATENING INJURY
SERIOUS	RESULTS IN INJURY OR IMPAIRMENT REQUIRING PROFESSIONAL MEDICAL INTERVENTION
MINOR	LOW RISK FAILURE NOT EXPECTED TO CONTRIBUTE TO AN INJURY
NEGLIGIBLE	INSIGNIFICANT FAILURE NOT SERIOUS ENOUGH TO CONTRIBUTE TO AN INJURY

4.5.5.2 Criteria for risk acceptability

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5.Frequent	NAC	NAC	NAC	NAC	NAC
P4.Probable	AC	NAC	NAC	NAC	NAC
P3.Occasional	AC	AC	NAC	NAC	NAC
P2.Remote	AC	AC	AC	NAC	NAC
P1.Improbable	AC	AC	AC	AC	NAC

NAC=unacceptable AC= Acceptable

The estimated risk to each hazard/ reason is written list with the form of classification (NAC/AC), give clear indication if it has control measures.

4.5.5.3 Probability of occurrence

PROBABILITY OF OCCURRENCE	**PROBABILITY RANGE**	**DESCRIPTION**
FREQUENT	$\geq 10^{-3}$	OCCURRING OFTEN OR REPEATEDLY
PROBABLE	$< 10^{-3}$ and $\geq 10^{-4}$	REASONABLY LIKELY TO OCCUR
OCCASIONAL	$< 10^{-4}$ and $\geq 10^{-5}$	IRREGULAR OCCURRENCE,
REMOTE	$< 10^{-5}$ and $\geq 10^{-6}$	NOT LIKELY TO OCCUR
IMPROBABLE	$< 10^{-6}$	UNLIKELY TO EVER OCCUR

4.5.6 Judge the characteristics related to product safety(According to ISO/TR 24971: 2020 Annex A and ISO/TR24971:2020 Annex H, H2)

Table 1.Identification of Characteristics Related to the FLU A&B Antigen Test kit(Colloidal Gold Method)

(According to ISO/TR 24971:2020 Annex A, Annex H, H2)

Clause	Content	Decision feature	Potential hazards	Hazard number
A.2.1	What is the intended use and how is the medical device to be used?			
A.2.2	Is the medical device intended to be implanted?			
A.2.3	Is the medical device intended to be in contact with the patient or other persons?			
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?			
A.2.5	Is energy delivered to or extracted from the patient?			
A.2.6	Are substances delivered to or extracted from the patient?			
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?			
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?			
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?			
A.2.10	Does the medical device modify the patient environment?			
A.2.11	Are measurements taken?			

A.2.12	Is the medical device interpretative?			
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?			
A.2.14	Are there unwanted outputs of energy or substances?			
A.2.15	Is the medical device susceptible to environmental influences?			
A.2.16	Does the medical device influence the environment?			
A.2.17	Does the medical device require consumables or accessories?			
A.2.18	Is maintenance or calibration necessary?			
A.2.19	Does the medical device contain software?			
A.2.20	Does the medical device allow access to information?			
A.2.21	Does the medical device store data critical to patient care?			
A.2.22	Does the medical device have a restricted shelf-life?			
A.2.23	Are there any delayed or long-term use effects?			
A.2.24	To what mechanical forces will the medical device be subjected?			
A.2.25	What determines the lifetime of the medical device?			
A.2.26	Is the medical device intended for single use?			
A.2.27	Is safe decommissioning or disposal of the medical device necessary?			
A.2.28	Does installation or use of the medical device			

	require special training or special skills?			
A.2.29	How will information for safety be provided?			
A.2.30	Are new manufacturing processes established or introduced?			
A.2.31	Is successful application of the medical device critically dependent on the usability of the user interface?			
A.2.31.1	Can the user interface design features contribute to use error?			
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?			
A.2.31.3	Does the medical device have connecting parts or accessories?			
A.2.31.4	Does the medical device have a control interface?			
A.2.31.5	Does the medical device display information?			
A.2.31.6	Is the medical device controlled by a menu?			
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?			
A.2.31.8	Will the medical device be used by persons with special needs?			
A.2.31.9	Can the user interface be used to initiate unauthorized actions?			
A.2.32	Does the medical device include an alarm system?			
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?			
A.2.34	Is the medical device intended to be mobile or portable?			

A.2.35	Does the use of the medical device depend on essential performance?			
A.2.36	Does the medical device have a degree of autonomy?			
H.2.1	Intended use and reasonably foreseeable misuse			
H.2.1.1	Analytical and clinical use -a user who performs all or part of an examination (“analytical use”) and -a clinician who receives, interprets and acts on the examination results (“clinical use”）			
H.2.1.2	Is the device used alone to produce examination results or in combination with other devices?			
	-If the device is a standalone analytical system, is it automated (software, robotics)?			
	-If used in combination with other IVD medical devices to form a system, what is its role in producing the examination result (e.g. sample collection system, sample receptacle, measuring instrument, software, databases, reagents, calibrators, control materials, or accessory)?			
	- If part of a system, how does the IVD medical device interact with other components of the system?			
	- Are other reagents or accessories necessary but not provided?			
	- Does the device employ new or novel technology (e.g. for			

	measurement, communication)?			
	- Does the device employ digital information technology for documenting and/or transmitting examination results to clinicians or communicating with mobile applications?			
	- Do software applications provide diagnostic or treatment recommendations?			
	- Does the IVD medical device communicate with a medical device that immediately administers treatment based on the IVD result (e.g. an IVD medical device that measures blood glucose levels and communicates with an implanted insulin administration system)?			
H.2.1.3	Analytical use			
	What analyte is the device intended to measure or examine?			
	Will the examination results be qualitative, semi-quantitative or quantitative?			
	Will the device be used in the pre-examination, examination or post-examination phase?			
	What specimens can be analyzed (e.g. serum, plasma, blood, urine, other body fluids, tissues)?			
	Do other substances potentially found in these samples interfere with the analytical process?			
	In nucleic acid sequencing procedures, is the amplicon sensitive to			

	contamination from environmental sources of DNA/RNA?			
	Are there any additional limitations for use in specific use environments (e.g. medical laboratories, emergency room, operating room, ambulance, intensive care unit, neonatal care unit, nursing home, physician's office, screening clinics, or the patient's home)?			
	Does the IVD medical device interface, connect or communicate with other devices or networks?			
	Who will be using the IVD medical device to perform examinations, and what training and qualifications will be appropriate?			
H.2.1.4	Clinical use			
	- How the IVD examination results will be used in clinical decision making;			
	- The medical decision points and degree of accuracy required;			
	- Whether clinicians can recognize incorrect results (e.g. based on magnitude of error or consistency with other clinical information);			
	- What actions the clinician would take in the event of an abnormal or unexpected result;			
	- The clinical significance of delayed results, if any;			
	- Potential adverse consequences of			

	unnecessary medical intervention.			
	- Will the examination results be used for:			
	- Diagnosis in order to cure, treat or prevent a disease or other condition?			
	- Measuring body fluid constituents to determine a patient's state of health?			
	- Monitoring therapeutic drug levels to ensure an effective dose?			
	- Determining the safety of donated blood or organs?			
	- Screening a population for the presence or absence of a specific marker?			
	- Predicting the effectiveness of a therapeutic alternatives ("companion diagnostic")?			
	- Predicting the risk of developing a medical condition?			
	- Applications other than the intended use?			
	- What injury, illness or condition will the results be used to detect, diagnose, predict or monitor?			
	- Who will use the IVD examination results: medical specialists, general clinicians or patients?			
	Is the role of the examination results in medical decisions to be used? - As the basis for immediate medical decisions?			

	- With other relevant information to guide a medical decision? - Which patient populations will primarily experience the benefit from the IVD examinations? - Should any patient populations be explicitly contraindicated?			
H.2.2	Characteristics related to patient safety			
H.2.2.1	General considerations IVD medical devices have analytical performance and reliability characteristics that determine the suitability for their intended clinical use. Some IVD medical devices can perform multiple examinations simultaneously, and their clinical performance can rely on the interpretation of patterns of results (e.g. multiplex assays).			
H.2.2.2	Performance characteristics related to patient safety			
	Trueness of the measured values (bias, traceability to a reference standard);			
	Measurement precision (repeatability, intermediate precision, reproducibility);			
	Analytical specificity (influence of interfering or cross-reacting substances);			
	Analytical sensitivity (ability to discriminate between quantity limits or ranges);			
	Detection limit (lowest quantity that can be reliably detected);			
	Quantitation limit (lowest quantity that can be accurately measured);			

	Measuring interval (range of values over which the analytical performance was validated).			
H.2.2.3	Reliability characteristics related to patient safety			
	System reliability (mean time between failures, mean time to failure);			
	Component compatibility (including versions and critical tolerances);			
	Software reliability (error-free operation);			
	reagent or control stability;			
	system usability (avoidance of use errors).			
H.2.2.4	Digital information technology characteristics related to patient safety			
	The ancillary patient information required by the clinicians: - correct patient name and sample identification; - patient details (age, gender, population, genetic factors, medications, nutritional state); - sample details (sample type, description, acquisition time); - measurement details (measurement procedure, units of measure, measurement uncertainty); - application details (cut-off points, reference intervals).			
	Digital information technology characteristics that can affect patient safety: - connections between devices and/or networks (wireless or wired);			

	- internet data transmission; - interface with digital applications (networked or mobile); - applications that emulate results from an IVD medical device; - embedded software applications (e.g. interpretation or treatment recommendations); - unshielded data transfer (e.g. ESD susceptibility); - digital data storage (e.g. susceptibility to corruption, manipulation or deletion); - disruption of other connected devices (creating additional hazards).			

4.5.7 Risk analysis, hazard determination and risk control measures(According to ISO/TR 24971: 2020 Annex C)

According to the corrective and preventive measures for the problems in the production and manufacturing process, the safety related problems are evaluated, including the initial evaluation of the hazards and effectiveness that are not recognized in advance and cause the evaluated risks (one or more) no longer acceptable. See table below:

Table 2.Hazard's identification, Preliminary hazard estimation form
(According to ISO/TR 24971:2020 clause 5.5, and Annex C)

	Type of harmfulness	Foreseeable events and event sequence	Consequences or damages	Preliminary risk control scheme analysis

Evaluate the above item by item according to the number of hazard analysis, develop the source of control measures and verification data of measures, and evaluate the risk revaluation after risk control. In this table, only some hazard number items above are evaluated as examples(According to ISO/TR 24971:2020 Annex A, Annex C, ISO/TR 24971:2020 clause 7.4, 7.5,7.6).

Table 3.Risk Analysis, Control measurements and risk Evaluation after taking measures
(According to ISO/TR 24971:2020 Annex A,C, ISO/TR 24971:2020 clause 7.4,7.5,7.6)

Possible harm	ID reason	Before adopting measure			ID control measure	New risk	After adopting measure			Acceptable determinant
		S	P	R			S	P	R	

Table 4.Residual risk analysis

(According to ISO/TR 24971:2020 clause 8)

SN.	Hazard code	Whether there is no further reduction in technology (Economic factors are not taken into account)	Whether Risk reduction implements the regulation "as far as possible"	Whether adopting the latest technology	Whether it meets IVDD ER	Whether the clinical benefit is greater than the risk	Whether the residual risk is acceptable	Whether the measures of reducing risk create new risks

5. Comprehensive evaluation of hazards:

In the production process, the quality inspection department shall strictly check the quality of the products and carry out the production in strict accordance with the production operation instructions and conduct the necessary training for the production personnel on a regular basis. After hazard determination, the above hazards may exist at last, but after control measures are taken, the risk level is effectively reduced, and all remaining risks are within the acceptable range; meanwhile, no new risks are generated, and the overall risk level is acceptable.

6. Risk analysis, hazard judgment and risk control measures after production

Collect product information according to the content of 《Risk management implementation management system》 formulated by the company, such as investigation and review of customer return (customer complaint) information, design change review, corrective and preventive measures for problems in the manufacturing process, and evaluate safety related problems, including the occurrence of unrecognized risks, resulting in the evaluated risks (one or more) not the initial assessment of acceptable hazards and effectiveness, risk analysis, hazard determination and control measures.

7. Conclusion:

It has been concluded through the process of risk analysis that this is a low-risk device and any risks that existed were eliminated or reduced through safety testing, proper choice of materials, and thorough instructions for use.

Risk Management Report For FLU A&B Antigen Test kit(Colloidal Gold Method)

1. Preface:

1.1 Introduction

The top management provided adequate resources and assigned qualified personnel for risk management process.

Top management defined and documented the policy for determining criteria for risk acceptability, this policy ensures that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns.

Also, top management reviewed the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process and document and decisions and actions taken, this review is part of the quality management system review. The following figure is provided to give and overview of the risk management process for the product manufactured by our company.

As indicated in Figure B.1, the process needs to be iterative, covering each risk in turn, and returning to earlier steps if risk control measures introduce new hazards or if new information becomes available.

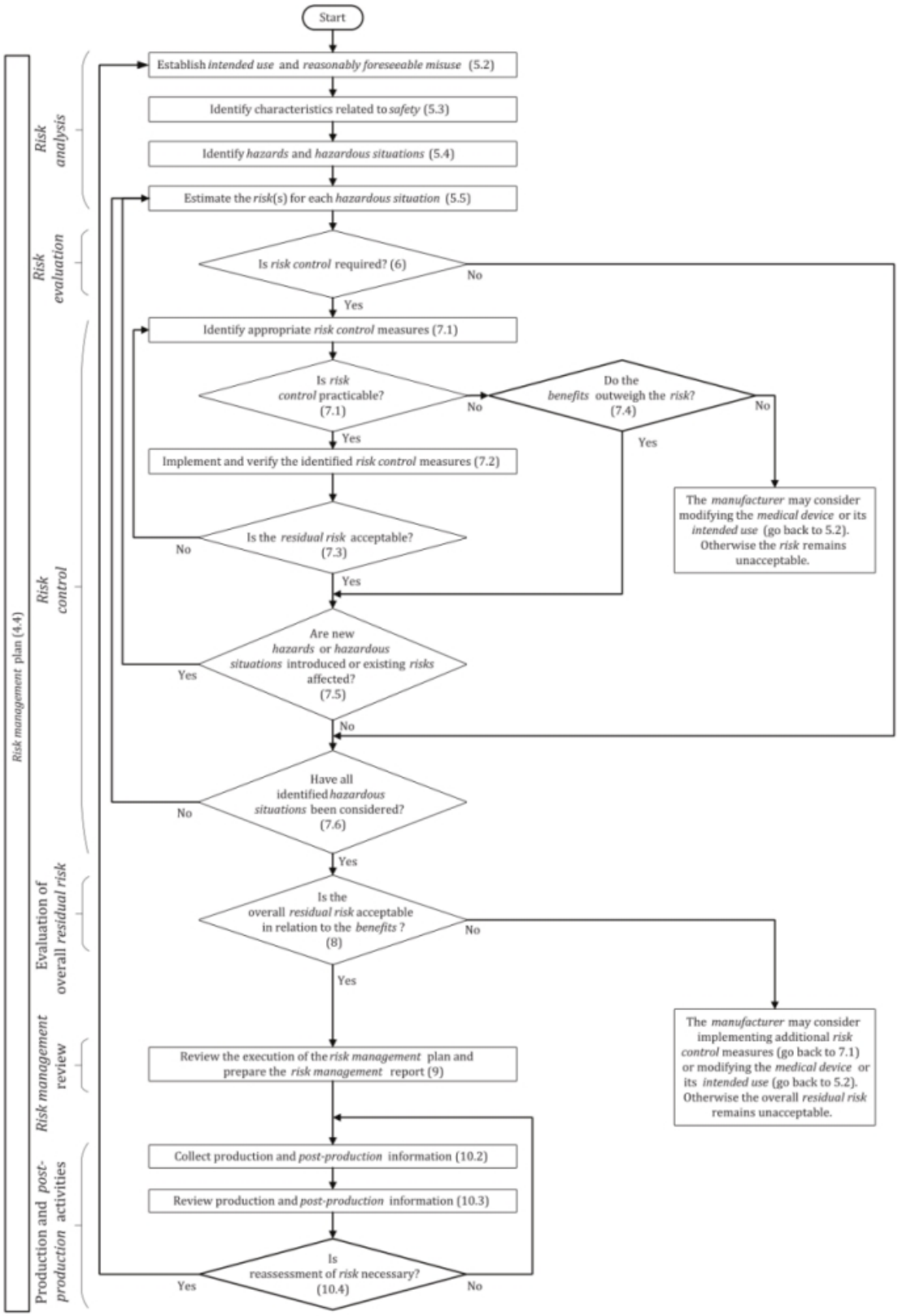


Figure B.1 — Overview of risk management activities as applied to medical devices of EN ISO14971:2019.

1.2 Purpose

This document is about the risk management to FLU A&B Antigen Test kit(Colloidal Gold Method) , overall potential harms and the potential reasons of each hazard are identified in the article. The likely degree caused by every hazard and the probability are evaluated. The necessary measures must be adopted according the risks which are not acceptable, and the residual risk level must be evaluated.

Result: The risks which cause potential hazard are reduced to acceptable level by the proper measures. And the all risks accumulated from every kind of risks are reduced to the acceptable level.

4. Introduction of Product

Refer to the 01-file of general description.

5. Controlling of the risk analysis process

The flow chart describes the levels of realization of the management process and designates single steps for the risk analysis, risk evaluation, action management and the risk controlling.

The flow chart is seen <Figure B.1 — Overview of risk management activities as applied to medical devices> of EN ISO14971:2019.

Risk management group

Risk management is carried out by special personnel from many departments. It includes the following departments:

Department	Position	Educational background and work experience	Responsibility scope
QC Dept	Risk management team leader	At least 10 years' experience in medical product quality assurance and control	To establish risk management team, risk management planning, directing and coordinating the risk management activity. To ensure that risk management activities conform to the requirements of the risk management, control, and guide the implementation of risk management activities in medical product design, manufacturing process and final product inspection .
Sales Dept	Risk management team member	At least 10 years' experience in sales and marketing	Responsible for the post-marketing risk information collection and feedback.
R&D Dept	Risk management team member	At least 10years experience in medical product	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document.

		development and design	
V.P.	--	At least 15 years' experience in medical product quality control and 5 years' experience in medical product management	Review risk management of the document
G.M.	--	At least 20 years' experience in medical product development and design and management	Responsible for risk management of the document for approval.

a) the members of the review team shall be responsible for the correctness and effectiveness of the evaluation results.
b) all departments should cooperate with the board using "quality control procedures" and "Corrective and preventive action control procedures" related to the product safety review, provide the basis for comprehensive residual risk evaluation.
c) according to the following information related to safety, the product design and development, trial production and product production and after-sale stage shall be reviewed.
d) whether there are unknown hazards;
e) whether there is an estimated risk (one or more) of the risk caused by a particular hazard is no longer acceptable;
f) other aspects of the initial evaluation have been invalidated;
g) Whether the overall residual risk of the product has been reduced to acceptable level or judged by risk/benefit analysis is acceptable.
h) review the methods of obtaining information after production and production.
Maintain review records to verify that each element of the risk management plan has been properly implemented in the product specific life cycle phase.

Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device(According to ISO/TR 24971:2020 clause 5.2)

The intended use and each reasonably imaginable and foreseeable misuse will be described in the risk management plan together with the product performance properties, which may influence the safety of the medical device. Then, the performance properties will be taken over into the risk management worksheet and the risks will be evaluated which occur if these performance properties are not achieved. For describing the features of the

medical device and its environment in which it is used, Annex C of the current standard ISO/TR 24971:2020 is applied.

Step 2: Identification of Hazards(According to ISO/TR 24971:2020 clause 5.4)

All known and foreseeable failures / dysfunctions / hazards, which infringe the function and safety of the medical device, will be identified. For this the medical device will be analyzed in its regular mode, failure mode, (also in case of reasonably foreseeable misuse). Moreover, already earlier discovered hazards, incidents or situations will be considered.

Step 3: Estimation of the Risk(s) for Each Hazardous Situation(According to ISO/TR 24971:2020 clause 5.4)

For each defined or assumed hazard of Step 2 the implied risk will be assessed. The expected physical damage or severity of harm, and probability of occurrence.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation will be considered and the resulting hazardous situation(s) will be recorded.

Step 4: Risk Evaluation(According to ISO/TR 24971:2020 clause 6)

After that each risk will be evaluated, whether it is acceptable or not and whether a risk reduction is required. The criteria to evaluate the acceptability are listed in the risk management plan.

Step 5 and 6: Adopt risk control measures(According to ISO/TR 24971:2020 clause 7.2)

For risks which are within the acceptable area no actions of risk control will be taken. Risks, which are outside this area, will be treated case by case.

The effectiveness of the risk control measures taken will be evaluated/verified and recorded in the risk management worksheet.

Step 7: Residual Risk Evaluation(According to ISO/TR 24971:2020 clause 7.2)

The residual risks will be evaluated and documented in the risk management worksheet. In case a residual risk is not acceptable, Step 5 and Step 6 will be repeated.

Step 8: Risk / Benefit Analysis(According to ISO/TR 24971:2020 clause 7.4)

Not acceptable risks can be accepted in exceptional cases, if a particularly high benefit is to be expected for the patient, and alternative products or treatment measures with minor risks are not available.

Step 9: Risks Arising from Risk Control Measures(According to ISO/TR 24971:2020 clause 7.5)

In this step whether the actions of risk control and/or risk reduction would introduce new hazards or hazardous situations will be evaluated. In this case Step 3 has to be repeated.

Step 10: Completeness of Risk Control(According to ISO/TR 24971:2020 clause 7)

In this step, whether all relevant risks have been considered and whether the risk evaluation process is complete will be checked. In case the risk evaluation is acknowledged as complete.

Step 11: Evaluation of Overall Residual Risk Acceptability(According to ISO/TR 24971:2020 clause 8)

After the completion of all risk control measures, the whole residual risks as well as the acceptability of the residual risks will be evaluated. The evaluation of the residual risks will be performed analogically to the evaluation of the basic risks.

Step 12: Result of risk management (According to ISO/TR 24971: 2020 clause 9)

There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy

6. Risk analysis

4.1Determination of intended use

4.1.1General provisions

This product is only allowed to be used in the corresponding diagnosis and inspection departments of medical institutions approved by the health administrative department.

4.1.2 Intended use

FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of

respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

. **4.1.3 Operating instruction**

In order to ensure the normal and effective use of the product, the company has formulated the product instruction according to the relevant international and domestic standards, regulations, industry specifications, enterprise standards and product related research data and literature. The instructions include the intended use, use method, precautions, etc.

4.2 Determine possible usage errors

4.2.1 Use error

The company's products are manufactured in strict accordance with the approved 《Product technical requirements》, and are fully equipped with relevant accessories, such as identification labels, product instructions and packaging materials that meet the requirements of the regulations. And a series of management and operation guidance documents that meet the standards and regulations such as 《The requirements of medical device quality management system used in laws》 and 《Regulations, detailed rules for the production and implementation of in vitro diagnostic reagents》, and product characteristics are formulated, reduce the risk of products in research and production and post production stage to an acceptable range.

4.2.2 Possible use error by laboratory personnel

In order to avoid the use of medical laboratory operator error (such as, the operator use irregular, operating environment, the operator does not have blatantly qualification, etc.), product of unintended use or cannot reach the intended use, the company strictly regulate the product technical documents, and after the sale, shall give necessary training to users, and to collect user feedback information.

4.2.3 Possible misuse by health care providers

Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

4.2.4 Patients may use errors in self-testing

This product is not offered to patients for self-testing, so this risk is within the acceptable range.

4.3 Security related feature determination

This product is subject to 《Production and quality inspection》 in accordance with the approved product technical requirements, and the product is delivered to the factory in

strict accordance with the standard requirements and the relevant provisions of enterprise inspection.

4.3.1 Quantitatively check the performance characteristics of the program

In the technical requirements of the product, the relevant requirements have been clearly stipulated. Factory inspection is also clearly stipulated, this risk is acceptable.

4.3.2 Qualitatively check the performance characteristics of the program

The judgment principle of corresponding test items has been clearly defined in the product technical requirements and product operation instructions.

4.3.3 Dependency characteristics

This product does not involve the use of first aid, but is designed for a lateral flow chromatographic immunoassay. This risk is acceptable.

4.3.4 Auxiliary patient information

When the product is used alone, it is only inspected for independent samples and judged by visual observation. Therefore, when using this product in medical institutions, this risk is within the acceptable range on the premise of reading the instructions carefully.

4.4 Determine known and foreseeable hazards

4.4.1 Hazards to patients

The inspection result of this product does not directly affect the formulation of life-threatening medical measures for patients. The risk is within acceptable limits.

4.4.2 Relationship with performance characteristics

If the product fails to meet the performance characteristics specified in the <Product technical requirements>, false positive or false negative results will appear. Thus, influence the doctor to the patient's situation judgment.

4.4.3 Determine hazards under fault conditions

Inhomogeneity, in the product batch inconsistency between batch and batch, nonspecific (such as: interference factors), measurement precision (related to personnel), stability failure in the storage, transportation and use of and so on, all the possible causes of the detection result is not accurate, and the physician is unable to correctly determine the clinical situation, influence the diagnosis and treatment. In order to reduce the above risks to an acceptable range, the company has formulated procedures or measures for technical research of products, raw materials procurement, production, testing, sample retention and testing, storage and transportation, sales and after-sales service guidance, product information feedback, etc., and strictly implemented them to ensure that the products are qualified.

4.4.4 Determine hazards during normal use

When the product is used normally, it may also cause the diagnosis error of the patient's condition due to the biological difference of the sample, the difference of the operator's operation, and the difference of the judge's medical diagnosis level.

4.5 Estimation of patient risk

When invalid results appear in this product, it will cause inaccurate diagnosis by doctors, which will lead to inappropriate medical intervention.

4.5.1 Estimate the severity of the damage

This product only provides clinical reference, not as a basis for clinical judgment, but also needs clinical symptoms and further tests to make judgment.

4.5.2 Estimated probability of occurrence

Under normal use, the product appears invalid results and affects the doctor's diagnosis, resulting in the possibility of damage is almost impossible.

4.5.3 Estimate patient risk

4.5.3.1 What is the possibility of IVD medical devices producing incorrect results?

Incorrect storage leads to unexpected use after product failure, uncertainty of product inspection results and biological differences of samples under normal use.

4.5.3.2 What is the possibility for the user / laboratory to detect incorrect IVD results?

Unexpected use of the product.

4.5.3.3 What is the possibility of doctors detecting incorrect IVD results?

Based on the uncertainty of product inspection results under normal use.

Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results.

4.5.3.4 What is the possibility of the physician taking measures or failing to take measures for the results?

Incorrect medical intervention, such as medication. Does not exist the critical patient life medical intervention or causes the infection and so on the situation.

4.5.3.5What is the possibility of the doctor taking measures / not taking measures that may cause or contribute to the damage to the patient?

The main impact on patients is inaccurate drug or non-drug treatment. However, it does not involve medical intervention or infection of life-threatening patients.

4.5.3.6 What is the severity of the damage caused?

The procedure of causing serious injury is temporary injury and temporary discomfort without medical intervention.

4.5.4 Risk information for IVD medical devices

No adverse events have been found for this product. In the process of product application, medical institutions and doctors who meet the requirements shall ensure that

the product is safe and effective and can achieve the intended use under normal and expected use.

4.5.5 Risk assessment and risk acceptance criteria

4.5.5.1 Severity levels

SEVERITY	DESCRIPTION
CATASTROPHIC	RESULTS IN PATIENT DEATH
CRITICAL	RESULTS IN PERMANENT IMPAIRMENT OR LIFE-THREATENING INJURY
SERIOUS	RESULTS IN INJURY OR IMPAIRMENT REQUIRING PROFESSIONAL MEDICAL INTERVENTION
MINOR	LOW RISK FAILURE NOT EXPECTED TO CONTRIBUTE TO AN INJURY
NEGLIGIBLE	INSIGNIFICANT FAILURE NOT SERIOUS ENOUGH TO CONTRIBUTE TO AN INJURY

4.5.5.2 Criteria for risk acceptability

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5.Frequent	NAC	NAC	NAC	NAC	NAC
P4.Probable	AC	NAC	NAC	NAC	NAC
P3.Occasional	AC	AC	NAC	NAC	NAC
P2.Remote	AC	AC	AC	NAC	NAC
P1.Improbable	AC	AC	AC	AC	NAC

4.5.5.3 Probability of occurrence

PROBABILITY OF OCCURRENCE	PROBABILITY RANGE	DESCRIPTION
FREQUENT	≥ 10^{-3}	OCCURRING OFTEN OR REPEATEDLY
PROBABLE	< 10^{-3} and ≥ 10^{-4}	REASONABLY LIKELY TO OCCUR
OCCASIONAL	< 10^{-4} and ≥ 10^{-5}	IRREGULAR OCCURRENCE,
REMOTE	< 10^{-5} and ≥ 10^{-6}	NOT LIKELY TO OCCUR
IMPROBABLE	< 10^{-6}	UNLIKELY TO EVER OCCUR

4.5.6 Judge the characteristics related to product safety(According to ISO/TR 24971: 2020 Annex A and ISO/TR24971:2020 Annex H, H2)

Table 1.Identification of Characteristics Related to the FLU A&B Antigen Test kit(Colloidal Gold Method)

(According to ISO/TR 24971:2020 Annex A, Annex H, H2)

Clause	Content	Decision feature	Potential hazards	Hazard number
A.2.1	What is the intended use and how is the medical device to be used?	Please refer to the Instruction for User	Information hazards (hazards of inappropriate intended use),use error	H1
A.2.2	Is the medical device intended to be implanted?	NO		
A.2.3	Is the medical device intended to be in contact with the patient or other persons?	NO		
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Nasal swab, and nasopharyngeal swab specimens.	Chemical hazards	H2
A.2.5	Is energy delivered to or extracted from the patient?	NO		
A.2.6	Are substances delivered to or extracted from the patient?	Nasal swab, and nasopharyngeal swab specimens.	Information hazards (hazards of inappropriate intended use),use error	H3
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO		
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO		
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	NO		
A.2.10	Does the medical device modify the patient environment?	NO		

A.2.11	Are measurements taken?	NO		
A.2.12	Is the medical device interpretative?	NO		
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO		
A.2.14	Are there unwanted outputs of energy or substances?	Waste liquid etc.	Biological and chemical hazards	H4
A.2.15	Is the medical device susceptible to environmental influences?	NO		
A.2.16	Does the medical device influence the environment?	NO		
A.2.17	Does the medical device require consumables or accessories?	NO		
A.2.18	Is maintenance or calibration necessary?	NO		
A.2.19	Does the medical device contain software?	NO		
A.2.20	Does the medical device allow access to information?	NO		
A.2.21	Does the medical device store data critical to patient care?	NO		
A.2.22	Does the medical device have a restricted shelf-life?	The kit should be stored at 2~30°C, valid for 12months.	Operational hazards, Hazards of overdue use	H5
A.2.23	Are there any delayed or long-term use effects?	NO		
A.2.24	To what mechanical forces will the medical device be subjected?	NO		
A.2.25	What determines the lifetime of the medical device?	Storage life	Operational hazards, Hazards of overdue use	H6
A.2.26	Is the medical device intended for single use?	Yes, there is no possibility of reuse		
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	NO		

A.2.28	Does installation or use of the medical device require special training or special skills?	Yes, the operators need special training to use it.	Information hazards, use error	H7
A.2.29	How will information for safety be provided?	Safety information is indicated on the product label and product manual	Information hazards	H8
A.2.30	Are new manufacturing processes established or introduced?	NO		
A.2.31	Is successful application of the medical device critically dependent on the usability of the user interface?	Yes, the user must be professionally trained	Information hazards, use error	H9
A.2.31.1	Can the user interface design features contribute to use error?	NO		
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	NO		
A.2.31.3	Does the medical device have connecting parts or accessories?	NO		
A.2.31.4	Does the medical device have a control interface?	NO		
A.2.31.5	Does the medical device display information?	NO		
A.2.31.6	Is the medical device controlled by a menu?	NO		
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?	Yes, the operators need special training to use it.	Information hazards, use error	H7
A.2.31.8	Will the medical device be used by persons with special needs?	Yes, operators need special training before using.	Information hazards, use error	H10
A.2.31.9	Can the user interface be used to initiate unauthorized actions?	NO		
A.2.32	Does the medical device include an alarm system?	NO		
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?	NO		

A.2.34	Is the medical device intended to be mobile or portable?	NO		
A.2.35	Does the use of the medical device depend on essential performance?	NO		
A.2.36	Does the medical device have a degree of autonomy?	NO		
H.2.1	Intended use and reasonably foreseeable misuse			
H.2.1.1	Analytical and clinical use -a user who performs all or part of an examination (“analytical use”) and -a clinician who receives, interprets and acts on the examination results (“clinical use”）	YES Intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.	Information hazards, use error	H11
H.2.1.2	Is the device used alone to produce examination results or in combination with other devices?	This kit is used alone to produce results.	Information hazards, use error	H12
	-If the device is a standalone analytical system, is it automated (software, robotics)?	NO		
	-If used in combination with other IVD medical devices to form a system, what is its role in producing the examination result (e.g. sample collection system, sample receptacle, measuring instrument, software, databases, reagents, calibrators, control materials, or accessory)?	NO		
	- If part of a system, how does the IVD medical device interact with other components of the system?	NO		
	- Are other reagents or accessories necessary but not provided?	NO		

	- Does the device employ new or novel technology (e.g. for measurement, communication)?	NO		
	- Does the device employ digital information technology for documenting and/or transmitting examination results to clinicians or communicating with mobile applications?	NO		
	- Do software applications provide diagnostic or treatment recommendations?	NO		
	- Does the IVD medical device communicate with a medical device that immediately administers treatment based on the IVD result (e.g. an IVD medical device that measures blood glucose levels and communicates with an implanted insulin administration system)?	NO		
H.2.1.3	Analytical use			
	What analyte is the device intended to measure or examine?	Nasal swab, and nasopharyngeal swab specimens.	Information hazards	H12
	Will the examination results be qualitative, semi-quantitative or quantitative?	Qualitative		
	Will the device be used in the pre-examination, examination or post-examination phase?	NO		
	What specimens can be analyzed (e.g. serum, plasma, blood, urine, other body fluids, tissues)?	Nasal swab, and nasopharyngeal swab specimens.	Information hazards	H13
	Do other substances potentially found in these samples interfere with the analytical process?	YES	Misuse, use error	H14

	In nucleic acid sequencing procedures, is the amplicon sensitive to contamination from environmental sources of DNA/RNA?	YES	Misuse, use error	H14
	Are there any additional limitations for use in specific use environments (e.g. medical laboratories, emergency room, operating room, ambulance, intensive care unit, neonatal care unit, nursing home, physician's office, screening clinics, or the patient's home)?	YES The product is intended to use in medical environment.	Information hazards, use error	H15
	Does the IVD medical device interface, connect or communicate with other devices or networks?	NO		
	Who will be using the IVD medical device to perform examinations, and what training and qualifications will be appropriate?	YES Intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.	Information hazards, use error	H16
H.2.1.4	Clinical use			
	- How the IVD examination results will be used in clinical decision making;	The test results are for clinical reference only.	Use error	H17
	- The medical decision points and degree of accuracy required;	NO		
	- Whether clinicians can recognize incorrect results (e.g. based on magnitude of error or consistency with other clinical information);	Yes	Use error	H18
	- What actions the clinician would take in the event of an abnormal or unexpected result;	It is recommended to retest.	Use error	H19

	- The clinical significance of delayed results, if any;	NO		
	- Potential adverse consequences of unnecessary medical intervention.	The test is invalid.	Misuse, use error	H20
	- Will the examination results be used for:	It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.	Misuse, use error	H21
	- Diagnosis in order to cure, treat or prevent a disease or other condition?	FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.	Misuse, use error	H21
	- Measuring body fluid constituents to determine a patient's state of health?	NO		
	- Monitoring therapeutic drug levels to ensure an effective dose?	NO		
	- Determining the safety of donated blood or organs?	NO		
	- Screening a population for the presence or absence of a specific marker?	FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.	Misuse, use error	H21
	- Predicting the effectiveness of a	NO		

	therapeutic alternatives ("companion diagnostic")?			
	- Predicting the risk of developing a medical condition?	NO		
	- Applications other than the intended use?	NO		
	- What injury, illness or condition will the results be used to detect, diagnose, predict or monitor?	FLU A&B Antigen Test kit(Colloidal Gold Method) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.	Misuse, use error	H21
	- Who will use the IVD examination results: medical specialists, general clinicians or patients?	Medical specialists	Misuse, use error	H22
	Is the role of the examination results in medical decisions to be used? - As the basis for immediate medical decisions? - With other relevant information to guide a medical decision? - Which patient populations will primarily experience the benefit from the IVD examinations? - Should any patient populations be explicitly contraindicated?	NO		
H.2.2	Characteristics related to patient safety			
H.2.2.1	General considerations IVD medical devices have analytical performance and reliability characteristics that determine the	NO		

	suitability for their intended clinical use. Some IVD medical devices can perform multiple examinations simultaneously, and their clinical performance can rely on the interpretation of patterns of results (e.g. multiplex assays).			
H.2.2.2	Performance characteristics related to patient safety			
	Trueness of the measured values (bias, traceability to a reference standard);	NO		
	Measurement precision (repeatability, intermediate precision, reproducibility);	NO		
	Analytical specificity (influence of interfering or cross-reacting substances);	NO		
	Analytical sensitivity (ability to discriminate between quantity limits or ranges);	NO		
	Detection limit (lowest quantity that can be reliably detected);	NO		
	Quantitation limit (lowest quantity that can be accurately measured);	NO		
	Measuring interval (range of values over which the analytical performance was validated).	NO		
H.2.2.3	Reliability characteristics related to patient safety			
	System reliability (mean time between failures, mean time to failure);	NO		
	Component compatibility (including versions and critical tolerances);	YES	Misuse, use error	H23
	Software reliability (error-free operation);	NO		
	reagent or control stability;	NO		

	system usability (avoidance of use errors).	YES	Misuse, use error	H23
H.2.2.4	Digital information technology characteristics related to patient safety			
	The ancillary patient information required by the clinicians: - correct patient name and sample identification; - patient details (age, gender, population, genetic factors, medications, nutritional state); - sample details (sample type, description, acquisition time); - measurement details (measurement procedure, units of measure, measurement uncertainty); - application details (cut-off points, reference intervals).	NO		
	Digital information technology characteristics that can affect patient safety: - connections between devices and/or networks (wireless or wired); - internet data transmission; - interface with digital applications (networked or mobile); - applications that emulate results from an IVD medical device; - embedded software applications (e.g. interpretation or treatment recommendations); - unshielded data transfer (e.g. ESD susceptibility); - digital data storage (e.g. susceptibility to	NO		

	corruption, manipulation or deletion); - disruption of other connected devices (creating additional hazards).			

4.5.7 Risk analysis, hazard determination and risk control measures(According to ISO/TR 24971: 2020 Annex C)

According to the corrective and preventive measures for the problems in the production and manufacturing process, the safety related problems are evaluated, including the initial evaluation of the hazards and effectiveness that are not recognized in advance and cause the evaluated risks (one or more) no longer acceptable. See table below:

Table 2.Hazard's identification, Preliminary hazard estimation form
(According to ISO/TR 24971:2020 clause 5.5, and Annex C)

	Type of harmfulness	Foreseeable events and event sequence	Consequences or damages	Preliminary risk control scheme analysis
H1	Information hazards	1. The specification does not indicate the sample requirements for testing; 2. Operator requirements are not indicated 3.Safety information is indicated on the product label and product manual.	Lead to incorrect test results, which may delay treatment;	This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
H2	Chemical hazards	The operator may touch the compatibility with tissues or body fluids.	Irritation or allergic symptoms	It is specified in the manual that it is only used by professionals

H3	Information hazards (hazards of inappropriate intended use),use error	1. Improper operation; 2. Residual pollution of samples or reagents;	Lead to incorrect test results, which may delay treatment	During the design, the accuracy and precision of the reagent test results and other performance indicators and test system shall be verified, and the operation specifications shall be specified
H4	Biological hazards	The used waste reagent is discarded at will and not treated as medical waste	Polluting the environment and even causing harm to people	The manual prompts the operator to dispose the waste liquid according to the environmental protection requirements
H5	Operational hazards, Hazards of overdue use	Use test paper beyond the validity period	Lead to incorrect test results, which may delay treatment	Storage requirements considered in design The product validity period shall be indicated on the instruction and package
H6	Operational hazards, Hazards of overdue use	Use test paper beyond the validity period	Cause use error	Instruction for use should be indicated in the IFU
H7	Information hazards, use error	Operators are not specially trained	Lead to incorrect test results, which may delay treatment;	The manual is clear that it is only for professional use.
H8	Information hazards	The operator ignores the information prompted by the manufacturer	Lead to incorrect test results, which may delay treatment;	Read the instruction manual before use. The manual is clear that it is only for professional use.
H9	Information hazards, use error	Untrained people use this product for testing	Lead to incorrect test results, which may delay treatment;	The design shall carry out professional training for operators before market promotion, and make it clear that it is only used by professionals.
H10	Information hazards, use error	Untrained people use this product for testing	Lead to incorrect test results, which may delay treatment;	The design shall carry out professional training for operators before market promotion, and make it clear that it is only used by professionals.

H11	Information hazards, use error	Untrained people use this product for testing	Lead to incorrect test results, which may delay treatment;	The design shall carry out professional training for operators before market promotion, and make it clear that it is only used by professionals.
H12	Information hazards, use error	Abnormal performance characteristics of test strip	Lead to incorrect test results, which may delay treatment;	In the design, the accuracy and precision of the reagent test results and the detection system are considered. Verify the product performance before delivery.
H13	Information hazards	The patient's test results are inconsistent with the patient's information	Inconsistencies in the outcome of treatment may cause harm to the patient.	The instrument matched with the reagent shall be used together. In this case, the software design shall consider the use of ID number to mark and test the patient information.
H14	Misuse, use error	Abnormal performance characteristics of test strip	Caused by abnormal performance characteristics	1.Indicate in the instruction for use that (i) Improper sample collection, transport and processing, and low viral titers in the sample may lead to false negative results. (ii) The optimal sample type and the optimal sampling time after infection (peak viral titer) have not been validated, therefore, multiple sampling at multiple sites in the same patient may avoid false negatives. 2.Indicate the use to use the fresh specimen.
H15	Information hazards, use error	Uncleared use environment	May use error	1.Indicate the use environment of the device in the instruction for use; 2.Verify the stability in the stated environment based on EN ISO 23640:2015
H16	Information hazards, use error	Incorrect operation method or untrained personnel use the device	May use error	Indicate in the instruction for use that the test kit is used by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.
H17	Use error	Uncleared explanation of result and recommended information and cautions.	Cause misunderstanding or misuse	1.Explain in the instruction for use each result situation, for example positive, negative, invalid. 2.Explain in the instruction for use that the test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. 3.Indicate in the instruction for use.

H18	Use error	Uncleared explanation of result and recommended information and cautions.	Cause misunderstanding or misuse	1.Indicate in the instruction for use that the test kit is only used by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures. 2.Indicate in the instruction for use.
H19	Use error	Uncleared instruction for use cause invalid result	The test result is invalid, use error	1.Indicate in the instruction for use that it is recommended to retest if there is an invalid result. 2.Indicate the repeatability in the instruction for use.
H20	Misuse, use error	In the process of storage and transportation will be affected by the impact and extrusion etc. Uncleared cross-reactivity and interfering substance, recommended information and cautions.	The instrument has the potential to withstand unexpected mechanical forces.	1.Indicate the test, store and transport environment of the test kit and indicate the user to follow the instruction for use. 2.Expain the cross-reactivity and interfering substance in the instruction for use. 3. Indicate in the instruction for use that the test result is for reference.
H21	Misuse, use error	Improper indication and intended use in the IFU	Might lead to misunderstanding or misuse of this device	Indicate in the instruction for use.
H22	Misuse, use error	Uncleared Clinical application, safety information Untrained personnel use the device	Cause misunderstanding or misuse	1.Explain in the instruction for use that the test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. 2.Indicate in the instruction for use that use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.
H23	Misuse, use error	Improper use method, pre-caution, limitation of the test	Cause misunderstanding or misuse	Indicate the use method, pre-caution, limitation of the test in the instruction for use.

Evaluate the above item by item according to the number of hazard analysis, develop the source of control measures and verification data of measures, and evaluate the risk revaluation after risk control. In this table, only some hazard number items above are

evaluated as examples(According to ISO/TR 24971:2020 Annex A, Annex C, ISO/TR 24971:2020 clause 7.4, 7.5,7.6).

Table 3.Risk Analysis, Control measurements and risk Evaluation after taking measures
(According to ISO/TR 24971:2020 Annex A,C, ISO/TR 24971:2020 clause 7.4,7.5,7.6)

Possible harm	ID reason	Before adopting measure			ID control measure	New risk	After adopting measure			Acceptable determinant
		S	P	R			S	P	R	
H1:Information hazards	1. The specification does not indicate the sample requirements for testing; 2. Operator requirements are not indicated 3.Safety information is indicated on the product label and product manual.	2	2	NAC	Indicated in the instruction	N	2	1	AC	Y
H2.Chemical hazards	The operator may touch the compatibility with tissues or body fluids.	1	3	AC	Indicated in the instruction	N	1	2	AC	Y
H3. Information hazards (hazards of inappropriate intended use),use error	1. Improper operation; 2. Residual pollution of samples or reagents;	1	3	AC	During the design, the accuracy and precision of the reagent test results and other performance indicators and test system shall be verified, and the operation specifications shall be specified	N	1	2	AC	Y
H4.Biological hazards	The used waste reagent is discarded at will and not treated as medical waste	1	3	AC	Indicated in the instruction	N	1	2	AC	Y
H5.Operational hazards	Use test paper beyond the validity period	2	2	AC	Indicated in the instruction	N	2	1	AC	Y

H6.Operational hazards, Hazards of overdue use	Use test paper beyond the validity period	2	2	AC	Indicated in the instruction	N	2	1	AC	Y
H7.Information hazards, use error	Operators are not specially trained	1	3	AC	Indicated in the instruction	N	1	2	AC	Y
H8.Information hazards	The operator ignores the information prompted by the manufacturer	1	3	AC	Indicated in the instruction	N	1	2	AC	Y
H9.Information hazards, use error	Untrained people use this product for testing	2	2	AC	Indicated in the instruction	N	2	1	AC	Y
H10.Information hazards, use error	Untrained people use this product for testing	2	2	AC	Indicated in the instruction	N	2	1	AC	Y
H11.Information hazards, use error	Untrained people use this product for testing	2	2	AC	Indicated in the instruction	N	2	1	AC	Y
H12.Information hazards, use error	Abnormal performance characteristics of test strip	2	3	NAC	In the process of design and development, all performance indexes shall be defined, verified and confirmed; the configuration of detection system shall be determined; the operation specification shall be determined	N	2	1	AC	Y
H13.Information hazards	The patient's test results are inconsistent with the patient's information	1	3	AC	The instrument matched with the reagent shall be used together. In this case, the software design shall consider the use of ID number to mark and test the patient information.	N	1	2	AC	Y

H14.Misuse,use error	Abnormal performance characteristics of test strip	2	2	AC	1.Indicate in the instruction for use that (i) Improper sample collection, transport and processing, and low viral titers in the sample may lead to false negative results. (ii) The optimal sample type and the optimal sampling time after infection (peak viral titer) have not been validated, therefore, multiple sampling at multiple sites in the same patient may avoid false negatives. 2.Indicate the use to use the fresh specimen.	N	2	1	AC	Y
H15.Information hazards, use error	Uncleared use environment	2	1	AC	1.Indicate the use environment of the device in the instruction for use; 2.Verify the stability in the stated environment based on EN ISO 23640:2015	N	2	1	AC	Y
H16.Information hazards, use error	Incorrect operation method or untrained personnel use the device	2	2	AC	Indicate in the instruction for use that the test kit is used by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.	N	2	1	AC	Y

H17. Use error	Uncleared explanation of result and recommended information and cautions.	2	2	AC	1.Explain in the instruction for use each result situation, for example positive, negative, invalid. 2.Explain in the instruction for use that the test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. 3.Indicate in the instruction for use.	N	2	1	AC	Y
H18.Use error	Uncleared explanation of result and recommended information and cautions.	2	2	AC	1.Indicate in the instruction for use that the test kit is only used by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures. 2.Indicate in the instruction for use.	N	2	1	AC	Y
H19.Use error	Uncleared instruction for use cause invalid result	2	2	AC	1.Indicate in the instruction for use that it is recommended to retest if there is an invalid result. 2.Indicate the repeatability in the instruction for use.	N	2	1	AC	Y

H20. Misuse, use error	In the process of storage and transportation will be affected by the impact and extrusion etc. Uncleared cross-reactivity and interfering substance, recommended information and cautions.	2	2	AC	1.Indicate the test, store and transport environment of the test kit and indicate the user to follow the instruction for use. 2.Expain the cross-reactivity and interfering substance in the instruction for use. 3. Indicate in the instruction for use that the test result is for reference.	N	2	1	AC	Y
H21.Misuse,use error	Improper indication and intended use in the IFU	2	2	AC	Indicate in the instruction for use.	N	2	1	AC	Y
H22.Misuse,use error	Uncleared Clinical application, safety information Untrained personnel use the device	2	4	AC	1.Explain in the instruction for use that the test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. 2.Indicate in the instruction for use that use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures.	N	2	1	AC	Y
H23.Misuse,use error	Improper use method, pre-caution, limitation of the test	2	2	AC	Indicate the use method, pre-caution, limitation of the test in the instruction for use.	N	2	1	AC	Y

Table 4.Residual risk analysis

(According to ISO/TR 24971:2020 clause 8)

SN.	Hazard code	Whether there is no further reduction in technology (Economic factors are not taken into account)	Whether Risk reduction implements the regulation "as far as possible"	Whether adopting the latest technology	Whether it meets IVDD ER	Whether the clinical benefit is greater than the risk	Whether the residual risk is acceptable	Whether the measures of reducing risk create new risks
1.	H1	yes	yes	yes	yes	yes	yes	N
2.	H2	yes	yes	yes	yes	yes	yes	N
3.	H3	yes	yes	yes	yes	yes	yes	N
4.	H4	yes	yes	yes	yes	yes	yes	N
5.	H5	yes	yes	yes	yes	yes	yes	N
6.	H6	yes	yes	yes	yes	yes	yes	N
7.	H7	yes	yes	yes	yes	yes	yes	N
8.	H8	yes	yes	yes	yes	yes	yes	N
9.	H9	yes	yes	yes	yes	yes	yes	N
10.	H10	yes	yes	yes	yes	yes	yes	N
11.	H11	yes	yes	yes	yes	yes	yes	N
12.	H12	yes	yes	yes	yes	yes	yes	N
13.	H13	yes	yes	yes	yes	yes	yes	N
14.	H14	yes	yes	yes	yes	yes	yes	N
15.	H15	yes	yes	yes	yes	yes	yes	N
16.	H16	yes	yes	yes	yes	yes	yes	N
17.	H17	yes	yes	yes	yes	yes	yes	N
18.	H18	yes	yes	yes	yes	yes	yes	N
19.	H19	yes	yes	yes	yes	yes	yes	N

20.	H20	yes	yes	yes	yes	yes	yes	N
21.	H21	yes	yes	yes	yes	yes	yes	N
22.	H22	yes	yes	yes	yes	yes	yes	N
23.	H23	yes	yes	yes	yes	yes	yes	N

5. Comprehensive evaluation of hazards:

In the production process, the quality inspection department shall strictly check the quality of the products and carry out the production in strict accordance with the production operation instructions and conduct the necessary training for the production personnel on a regular basis. After hazard determination, the above hazards may exist at last, but after control measures are taken, the risk level is effectively reduced, and all remaining risks are within the acceptable range; meanwhile, no new risks are generated, and the overall risk level is acceptable.

6. Risk analysis, hazard judgment and risk control measures after production

Collect product information according to the content of 《Risk management implementation management system》 formulated by the company, such as investigation and review of customer return (customer complaint) information, design change review, corrective and preventive measures for problems in the manufacturing process, and evaluate safety related problems, including the occurrence of unrecognized risks, resulting in the evaluated risks (one or more) not the initial assessment of acceptable hazards and effectiveness, risk analysis, hazard determination and control measures.

7. Conclusion:

It has been concluded through the process of risk analysis that this is a low-risk device and any risks that existed were eliminated or reduced through safety testing, proper choice of materials, and thorough instructions for use.

6 Analytical Performance Test

File No.: CE/IVDD- YYM-01-06

Version: A/0

Product: FLU A&B Antigen Test kit(Colloidal Gold Method)

6.1 Product Performance Evaluation Test

The product should meet the quality requirements that performance test and stability test should be conducted, please refer to **Annex2_Analytical Performance Test** about the and test reports.

7 Clinical Performance Test

File No.: CE/IVDD- YYM-01-07

Version: A/0

Product: FLU A&B Antigen Test kit(Colloidal Gold Method)

7.1 Product Clinical Test

The product should meet the quality requirements that clinical study should be conducted, please refer to **Annex3_Clinical Performance Test** about the and test reports.

8 PMS & Vigilance System

File No.: CE/IVDD- YYM-01-08

Version: A/0

Product: FLU A&B Antigen Test kit(Colloidal Gold Method)

Table of Contents

PMS & Vigilance System

1. Scope and Purpose

This Quality Procedure covers the actions to be taken once our company receives information concerning an Incident involving a Medical Device according to Medical Device Directives.
The purpose of this procedure is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeating in different places at different times and to provide for a system and instructions, and to assign responsibilities for gathering and analyzing post-production feedback and for meeting customer requirements. This is to be achieved by the evaluation of reported incidents and dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

2. Term and Definition

2.1 Vigilance System, VS

Europe Community system about CE mark

2.2 Advisory notice

Notice having information about the use, revision, destroy and recall of medical device

2.3 Recall

In case of serious incident of health or risk of death, relating action about recall, revision, change or destroy according to instructions in Advisory notice

2.4 Notified Body (NB)

European institution approved CE

2.5 Competent Authority (CA)

European institution having a right of CE approval for Medical Device

2.6 Authorized Representative (AR)

Any natural or legal person established in the Europe who, explicitly designated by our company, acts and may be addressed by Europe instead of our company with regard to the latter’s obligations under the directive.

2.7 Near Incidents

Any event type which results in imminent risk of death, serious deterioration instate of health, or serious illness that requires prompt remedial action

2.8 Feedback System

Receiving information related to product to notice about quality problem and operate corrective action

3. Responsibility and Authority

3.1 President

(1) Approve Advisory Notice

(2) Approve the contract with Europe Authorized representative

(3) Approve the declaration of conformity

3.2 QMR

(1) Review Advisory Notice, contract and the declaration of conformity

(2) Approve the result post-market information

3.3 Quality control Manager

(1) Information correction and analysis after producing

(2) Solve the problem described in advisory notice

(3) Preparation and review of Post-market information

4. Procedure

4.1 Vigilance System

4.1.1 Definition of Vigilance System's correspondence

4.1.1.1 The Vigilance System is intended to allow data to be correlated between Competent Authorities and manufacturers and so facilitate corrective action earlier than would be case if data were collected and action taken on a States by State basis.

4.1.1.2 Whilst we have the responsibility for taking any action necessary, Competent Authorities should also monitor the effectiveness of the manufacturer's follow-up on reported incidents. The Competent Authority should take any further action that may be necessary to supplement the actions of the manufacturer.

4.1.1.3 Once corrective action is identified, hospital administrators, medical practitioners and other health-care professionals and user representatives responsible for the maintenance and the safety of medical devices, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the manufacturer.

4.1.1.4 Competent Authorities may also monitor experience with devices of the same kind made by different manufacturers.

4.1.2 General Principles

4.1.2.1 Information held by Competent Authorities in connection with the Vigilance System is to be held in confidence, as defined by the relevant Articles of Directives. In order to achieve the purpose of the Vigilance System, any incident report should be available on request, and in confidence, to the other Competent Authorities.

4.1.2.2 The act of reporting an incident to a Competent Authority is not to be construed as an admission of liability for the incident and its consequences. Written reports may carry a disclaimer to

this effect.

4.1.2.3 The initial report on an incident under the Vigilance System is made by manufacturer to the Competent Authority for recording and evaluation. Each initial report should lead to a final report, but not every initial report will lead to a corrective action.

4.1.2.4 We ensure that their authorized representative within the EEA, persons responsible for placing devices on the market.

4.1.2.5 We inform our Notified Body of those incidents affecting the certification. However, it remains the role of the Competent Authority of monitor the investigation being carried out by us.

4.1.3 Vigilance System Procedure

4.1.3.1 Guidelines on types of indents to be reported in case of occurring following incidents, QMR review and determine the report considering following things and then approve to President.

(1) Incidents which need to be reported are defined in the Directives as follows:

1) Those which led to a death

2) Those which led to a serious deterioration in the state of health of a patient, user or other person

- Life-threatening illness or injury
- Permanent impairment of a body function or permanent damage to a body structure
- condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

3) Those which might have led to death or serious deterioration in health

- An incident associated with a device happened
- The incident was such that, if it occurred again, it might lead to death or serious deterioration in health
- testing or examination of the device or the information supplied with the device, or any scientific literature indicated some factor (eg a deterioration in characteristics or performance, or a shortcoming in the information) which could lead to an incident involving death or serious deterioration in health

4) The Incident or near incident and the device or the information supplied with the device

- A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions. This excludes just the state of trouble not injury on body and aging of device.
- This includes problems caused by unpredicted biological effects relating to the device.
- Inaccuracy in the labeling, instructions for use

(2) Determine whether the incident is related with medical device or caused by the defection of medical device. (Refer to MEDDEV 2.12-1 rev8 Annex 1)

4.1.3.2 Initial report

To protect near incident, the incident having the possibility of defection with product and information

must be found out. Manufacturer must report to the National Competent authority as fast as possible. So the all incident reports must be reported immediately

(1) QMR must submit an initial incident report to the National Competent Authority for recording and evaluation. Reports on incidents concerning devices in Class II or Class III and IVDs listed in Annex II or for self-testing and occurring in countries outside the EEA and which result in corrective action, should be made to the Competent Authority in the State where the Notified Body is situated and which made the attestations which led to the CE marking being attached to the device.

(2) If applicable, notify European Sales agent or European Agent.

(3) The initial report includes following provisions

1) Name, Authorized Representative's Name, address, contact number including fax number.

2) The date when the incident came to the knowledge of the manufacturer

3) Medical device kind, commercial name, catalogue number/model, serial/batch/lot number, software version

4) Identification number of the Notified Body involved in the conformity assessment procedure

5) Associated devices and/or accessories involved in the incident

6) Date, Patient, Detail information including users

7) Current position of product related to incident

8) User's contact number occurring incident

9) Preliminary comments of manufacturer

10) Next planning or corrective action schedule

11) Statements whether know about similar incident affecting current incident

12) If so, any other Competent Authorities to which these incidents have been reported, and the reference/date of the report

13) Any other EEA state in which the device is known to be on sale

(4) Reported incident or Product information

Consider following cases.

1) Medical practitioner's opinion basis of available evidence

2) Preliminary reported conclusion of incident

3) Previous or similar incident evidence

4) Any other evidence having manufacturer

5) Malfunction or Quality deterioration from the function and characters of products. But quality deterioration excludes aging of products.

6) Inaccuracy in the labeling, instructions for use

7) Report the above things otherwise keep the file.

4.1.3.3 Investigation

(1) After initial report, QMR start to investigate generally and report to the competent authority how

process. The Competent authority monitors and if necessary, investigates for itself. At that time, manufacturer should support the competent authority. The monitoring includes following provisions.

1) Investigation's action or method

2) Process or schedule

3) Result

(2) Investigation may include

1) Quantity of products

2) Post-market period

3) Detail information of design change

(3) Need contact point about Notified body, users, the competent authority, testing institution.

(4) If the manufacturer is not able to perform the investigation of an incident then he should inform the Competent Authority without delay.

4.1.3.4 Actions

(1) Outcomes may include, for example

1) No action

2) Additional surveillance or follow-up of devices in use

3) Dissemination of information to users, eg by advisory notice

4) Corrective action on future production

5) Corrective action on devices in use

6) Recall

(2) Systematic Recalls

The manufacturer should issue advisory notices when implementing recalls. Copies of advisory notices should be sent to the Competent Authorities of the countries to which they are applicable, and for devices in Class II or Class III, the Competent Authority in the State where the Notified Body is situated and which made the attestation which led to the CE marking being attached to the device, the Competent Authority in the State where the manufacturer's registered place of business under Article 14 is situated. Manufacturers should consider sending copies of advisory notices to Competent Authorities under cover of a report which takes the same structure as the Final Report.

4.1.3.5 Completion of investigation and file

Once takes action and complete the incident, QMR must report to The Competent Authority. The Competent Authority should place the manufacturer's final report on file and make any other observations necessary. The file may then be endorsed as "closed". The Competent Authority should inform the manufacturer when a file is "closed"

4.1.3.6 Timescale for the initial reporting of an INCIDENT

Upon becoming aware that an event has occurred and that one of its devices may have caused or contributed to that event, the medical device manufacturer must determine whether it is an

INCIDENT.

The following time lines apply in a case of:

- Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the manufacturer of this threat.
- Death or UNANTICIPATED serious deterioration in state if health: IMMEDIATELY (without any that could not be justified) after the manufacturer established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness if the event.
- Others: IMMEDIATELY (without any delay that could not be justified) after the manufacturer established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness if the event. If after becoming aware of a potentially reportable ICIDENT there is still uncertainty about whether the event is reportable, the manufacturer must submit a report within the timeframe required for that type of ICIDENT. All report refer to when the National Competent Authority must first be notified. The relevant contact points are available from the Commission's website.

4.2 Post-market Surveillance

4.2.1 Customer feedback system

4.2.1.1 The customer feedback system is for collecting and analyzing information about post-production performance of our products. The purpose is to provide early warning of quality problems and for input into the corrective and preventive action processes

4.2.1.2 Feedback information is collected from the following sources;

• **Customer, user and patient complaints:** Complaints are collected, classified and analyzed by Customer Service in accordance with Quality Procedure, Customer Complaints. Complaints related to product quality are forwarded to Quality Assurance for evaluation and investigation of root causes.

• **Defective or otherwise nonconforming product returned by customers:**

Returned products alleged to be defective or nonconforming are inspected and evaluated to determine the problem, in accordance with Quality Procedure, Control of Nonconforming Product. These inspection reports are evaluated by Quality Assurance to determine whether a corrective or preventive action should be initiated.

4.2.2 Self-monitored feedback

• **Monitoring orders for spare parts**: Sales monitors' orders for spare parts to identify trends that might be indicative of unusual failure rates. Any such trends are reported to Quality Assurance for further investigation and, where appropriate, follow-up with corrective or preventive actions.

• **Clinical evaluations:** Results of any clinical evaluations or studies, whether undertook by our company or by other organizations are closely reviewed to determine whether any corrective or preventive actions might be warranted to improve the product or address its weaknesses. These reviews are conducted by Design Engineering and Quality Assurance.

• **Reviews and articles in trade and professional publications:** Marketing is responsible for monitoring trade and professional publications, trade shows, and other such media and venues to identify opinions and reviews concerning our products. Any such feedback that could relate to product design or quality is communicated to Design Engineering and Quality Assurance for further evaluation and, where appropriate, follow-up with corrective or preventive actions.

4.3 Device Recall and Advisory Notices

4.3.1 General

The recall of a device is the removal from the field of a marketed device that is in violation of the related regulations. Recall does not include market withdrawal or stock recovery. A recall is necessary when it has been determined that there is a risk of serious deterioration of the state of health or death. A recall includes the return of a medical device to the supplier; its modification by the supplier at the site of installation; its exchange; or its destruction. An advisory notice is issued to provide information and/or advice on what action should be taken in the use, modification, disposal or return of a medical device. Market withdrawal and stock recovery activities are not governed by this procedure. These activities pertain to the removal of distributed devices that are not in violation of current regulations, but are the result of normal stock rotation or the replacement of an old style with an improved device; and to the recovery of devices that have not been marketed or have not left the direct control of the company's premises.

4.3.2 Recall responsibilities

• The recall committee is responsible for initiating the recall and coordinating related activities. The committee includes the President, Quality Assurance Manager and Production Manager. In an emergency, and when there is no time to assemble the full committee, the President or the Quality Assurance Manager alone is authorized to initiate a recall.

• Possible recall situations are reported immediately to the Quality Assurance Manager. Quality Assurance analyzes the product for compliance with the specifications and/or regulatory requirements, determines the extent of the problem and reports the results to the President. When the situation warrants it, the President convenes a meeting of the recall committee.

• Production and Sales are responsible for organizing and conducting all recall activities. This includes the determination of the location of all suspect lots, internally and externally.

4.3.3 Recall

1) The recall committee decides whether a recall is necessary and, if so, determines the following:

• The extent and nature of health hazard and recall classification;

• Proposed depth of recall;

• Type of notice to consignees, i.e., letter, fax or telephone;

• Content of notice to consignees;

• Method for verifying effectiveness of recall.

2) When the above data is available, the proper authorities are contacted with the proposed recall plan.

4.3.4 Receipt of recalled devices

1) Quality Assurance designates and prepares a quarantine area for the receipt and holding of recalled devices.

2) Devices are logged to include the quantity returned, lot number and source of the return. This log is used to verify that all suspected devices have been located and returned. The log is reviewed regularly and the data is utilized to prepare the necessary reports.

3) At the conclusion of the recall a decision is made regarding the disposition of the recalled devices.

4.3.5 Issue of advisory notices

1) The recall committee determines the need for issuing advisory notices. The process for making this determination is similar to that which applies to recalls. All advisory notices are sent via certified mail or other traceable method.

5. Record and Storage

No.	Document and Record Names	Preservation Period	Management Team
1	Advisory notices	10 Years	Quality dept.
2	Customer Complaint Handling Management Ledger	10 Years	Quality dept.
3	Customer Dissatisfaction Handling Work Process	-	Quality dept.
4	Manufacturer’s Incident Report	10 Years	Quality dept.
5	Field Safety Corrective action	10 Years	Quality dept.

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	**Yong Yue Medical Technology(Kunshan) Co.,Ltd.**
Address:	No.6, Kingdee Road, Kunshan City, Jiangsu Province, China.
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	FLU A&B Antigen Test kit(Colloidal Gold Method)
Specification:	1 Test/Kit; 5 Tests/Kit; 10 Tests/Kit; 20 Tests/Kit; 25Tests/Kit;30Tests/kit; 50Tests/Kit
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011

EN 13612:2002+AC:2002 EN ISO 23640:2015 EN 13641:2002

EN ISO 20417: 2021

Signature: _____

Position: GM

Date: 2022.4.5

Place: Jiangsu / China

永生医疗科技(昆山)有限公司 3205830381349