PART A - CONFORMITY ASSESSMENT DOCUMENTATION

1.1 Manufacturer and Authorized Representative:

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1.2 Design Facilities: Shanghai Outdo Biotech Co., Ltd.
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Phone: +86 021-51320288

1.3 Notified body
Not applicable

1.4 Product Identification and Classification:
Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test
Product Classification: others
EDMA Code: 15 70 03 90

1.5 Conformity Assessment Procedure:
98/79/EC In vitro diagnostic medical devices, Annex III

1.6 Relevant Regulations:

Shanghai Outdo Biotech Co., Ltd. products in this file are manufactured and distributed under the following regulations/standards:
98/79/EC In Vitro Diagnostic Medical Devices Directive
EN ISO 13485:2016;

1.7 Licenses and Registrations
The product has registered in EU market via EU REP.

1.8 Essential Requirements and List of Applicable Standards:

The applicable sections of the essential requirements of the Directive(s) have been identified and are documented in the Essential Requirements Checklist. Rationale is provided for any requirement(s) that are deemed not applicable. Please refer to Appendix D for the Essential Requirements Checklist for Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test.

A list of the standards applicable to the design, production and distribution of Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test have been met and the standards are documented. Please refer to Appendix E for the List of Applicable Standards for Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

1.9 Quality Systems Manual:

A Quality Manual encompassing all aspects of the Quality System requirements per ISO 13485 is maintained and is referenced in Part B of this file. The Quality Manual and Quality System Record are controlled documents and are reviewed and updated on a regular basis.

1.10 EC Declaration of Conformity:

Refer to Appendix B for the Declarations of Conformity for the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test listed in this file.

Product Information:

2.1 General Description

The Novel Coronavirus (SARS-CoV-2) antibody (IgM/IgG) test is a device that utilizes immunochromatography for the qualitative detection of Novel Coronavirus IgM/IgG antibody in a serum, plasma or whole blood specimen. The test is in cassette format and intended for professional use only. The device is for in vitro diagnostic use.

The Novel Coronavirus (SARS-CoV-2) antibody (IgM/IgG) test incorporates non-viable materials of animal origin. The only materials of animal origin are the antibody used to capture the Novel Coronavirus antibody in specimen. Sucrose and BSA are used as processing reagent. The reagent and BSA are non-infectious and therefore, pose no risk to the end user. Each raw material supplier has been evaluated and qualified as a part of Shanghai Outdo Biotech's supplier control process. As part of the approval process, suppliers are asked to indicate whether or not animals and /or animal products are used to manufacture raw materials.

Each cassette is packaged individually in the pouch and then in the kit box.

2.2 Product Format and Configurations:

Package: 1 test / kit

- Test cassette, 1 case
- Sample diluent, 1 ml/vial*1 vail
- Instruction for use

Package: 20 tests / kit

- Test cassette, 20 cases
- Sample diluent, 3.6 ml/vial*1 vail
- Instruction for use

Package: 50 tests / kit

- Test cassette, 50 cases
- Sample diluent, 3.6 ml/vial*1 vail
- Instruction for use

2.3 Intended use

The Novel Coronavirus (SARS-CoV-2) antibody (IgM/IgG) test is a device that utilizes immunochromatography for the qualitative detection of Novel Coronavirus IgM/IgG antibody in a serum, plasma or whole blood specimen. The test is in cassette format and intended for professional use only. The device is for in vitro diagnostic use.

2.4 Clinical Data Summary

The clinical specimens are tested by the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG). The test results are compared to the clinical diagnosis. A total of 600 clinical specimens were run and analyzed.

		Compared Clinical Diagnostic results		total
		Positive	Negative	
Novel Coronavirus Antibody test results	Positive	246	5	251
	Negative	35	314	349
total		281	319	600

Sensitivity = 87.54%; specificity = 98.43%; Kappa=0.87＞0.75,95% conference range (0.82, 0.91). The results show that the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) test has good correlation compared to the clinical diagnosis result.

Clinical reports for the product are included in the Design History Files referenced in Part B and included in Appendix H of this file.

2.5 Stability Testing and Shelf Life:

Stability and shelf life are determined according to the procedures and requirements listed in EN ISO 23640:2015 Stability testing of in vitro diagnostic reagents. Refer to Appendix L for Stability Reports.

The projected shelf life of 12 months has been initially established for the Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test based on real time stability study. The real time stability study was evaluated between 4-30ºC. The tests were assayed using manufacturer's internal control panel.

Accelerate stability study was performed at 42ºC for 24 days, to simulate the real-time stability at 30ºC for 12 months. The results indicate that the acceptance criteria are met and that the shelf life of the test is projected for more than 12 months when stored properly.
Transportation stability study was performed and show the test is stable for 5 days at -20ºC or 45ºC.

2.6 Risk Analysis:

Risk analysis was conducted according to Shanghai Outdo Biotech Co., Ltd.'s Risk Management Procedure, and EN ISO 14971:2012. Risk analysis is performed using the Failure Mode and Effects Analysis (FMEA) model included with a Risk Management Report. Risk analysis for the product is included in the Design History Files referenced in Part B of this file. Refer to Appendix G for the Risk Management Report.

2.7 Indication of Performance

The documentation relating to the analytical performance of the tests (including LoD, Accuracy, hook effect, cross reactivity and etc.) is included in the Design History Files and is summarized on the Package Insert. These documents are referenced in Part B of this file. The Package Insert is also included in Appendix P of this file. Please also refer to Appendix Q performance characteristic.

Summary of technical specifications

Product name	Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test
Detection Technology	immunochromatography
Sample type	Whole Blood sample, serum, plasma
anticoagulant	EDTA, heparin, sodium citrate
Sample Volume	20ul
Sample diluent	70ul (2 drops)
Detection time	15 minutes
Limit of Detection	Tested the LoD samples. 20/21 replicates are positive.
Shelf life (accelerate)	12 months
Stability after first open	90 minutes at 20ºC~25ºC, RH 50%~60%
Storage ambient	4ºC ~ 30ºC
Negative control	the results are negative when testing patient serum, who were infected by Flu A, Flu B, adenovirus, respiratory syncytial virus, HCoV-HKU1
Cross reactivity I	No cross reaction with patient serum, who were infected by Flu A, Flu B, adenovirus, HSV, CMV, rubella, mycoplasma pneumoniae, HCoV-oc43, HcoV-nl63, HcoV-229e
Cross reactivity II	No influence when specimen contains 500mg/dl triglyceride or 50mg/dl total bilirubin.
HOOK effect	No influence when the detection concentration is 1000 times that of the limit of detection.
Repeatability	the results has no critical difference when tested 10 times the internal control (J)

2.8 Specification of Materials and Processes

Composition of the cassette:

Plastic housing	Backing pad	Label pad
anti-human IgG	Absorbent pad	nitrocellulose-membrane
anti-human IgM	Rabbit IgG	Goat anti rabbit IgG
novel coronavirus recombinant antigen	Sample pad	Gold particle

The specifications of the main animal origin materials are included in the Appendix N. The products do not contain any tissues of human origin or other substances derived from such tissues.

Composition of the Sample diluent:
the main component is phosphoric acid buffer.

Manufacturing Process:
A. Spray conjugate solution on the label pad.
B. Pre-coat anti-human IgG, anti-human IgM and control antibody to the membrane attached on the backing card.
C. Treat the sample pad with sample pad solution.
D. Laminate the label pad, absorbent pad, sample pad on the backing card with membrane.
E. Cut the laminated card into strips and assemble the strip into the plastic housing.
F. Pack the cassette and desiccant into the pouch and seal.
G. Test the cassette according to the QC procedure and release the finished product.

For more detailed information, refer to Appendix F for device master records and Appendix N for certificate of analysis and material safety data sheets.

2.9 Test Principle Description and Illustration

The Novel Coronavirus (SARS-CoV-2) antibody (IgM/IgG) test is a device that utilizes immunochromatography for the qualitative detection of Novel Coronavirus IgM/IgG antibody in a serum, plasma or whole blood specimen. The test is in cassette format only.

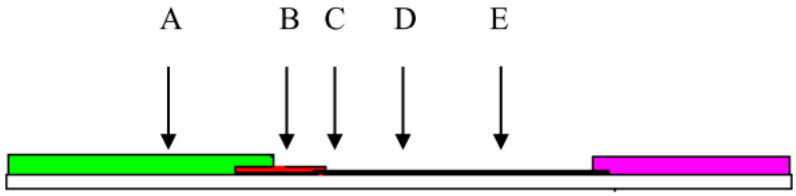
The test utilizes a combination of novel coronavirus recombinant antigen with gold particle and mixture of monoclonal anti-human IgM and monoclonal anti-human IgG coated on the nitrocellulose-membrane to qualitatively detect Novel Coronavirus antibody in specimen. Testing is done by applying sample and sample diluent, and visually observing the formation of colored lines.

After sample application and adding the sample diluent, specimen migrates via capillary action along the components of the test. During migration, novel coronavirus antibody molecules in the specimen react with the novel coronavirus recombinant antigen-gold particle conjugate, and also react with the mixture of anti-human IgM and anti-human IgG coated at the test region of the nitrocellulose membrane to form an anti-antibody-antibody-antigen-gold particle complex as a colored test line.

To serve as a procedural control, a red line will always appear in the control region, indicating adequate sample volume and proper wicking, regardless of the presence of Novel Coronavirus antibody in the specimen. Absence of the red control line in the control region indicates that the test result is “invalid”.

As shown below, the specimen applied to the sample pad (A) migrates though the label pad (B) via capillary action along the membrane. novel coronavirus antibody present in the specimen below limit of detection, will not react the binding sites of the gold-conjugated novel coronavirus recombinant antigen and not form a colored antibody-antigen complex (C). The gold-conjugated novel coronavirus recombinant antigen will not then be captured by mixture of anti-human IgM and anti-human IgG coated in the test region (D). No red line formed in the test region (D) indicates a negative result. A red line formed in the test region indicates a positive result and that the concentration of novel coronavirus antibody in specimen is above the limit of detection of the test.

In the control region of the membrane (E), it will produce a color line of goat anti rabbit IgG-rabbit IgG-gold particle complex, which regardless of the novel coronavirus antibody concentration of the specimen. This confirms the assay is functioning correctly. Absence of this line indicates an invalid result.

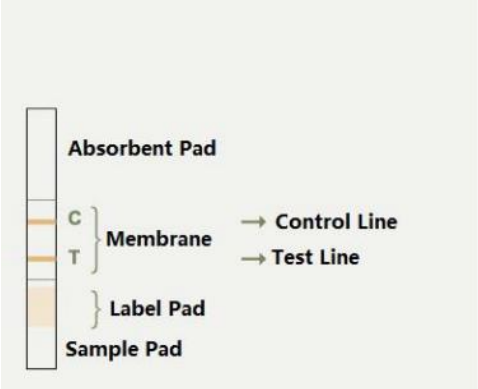


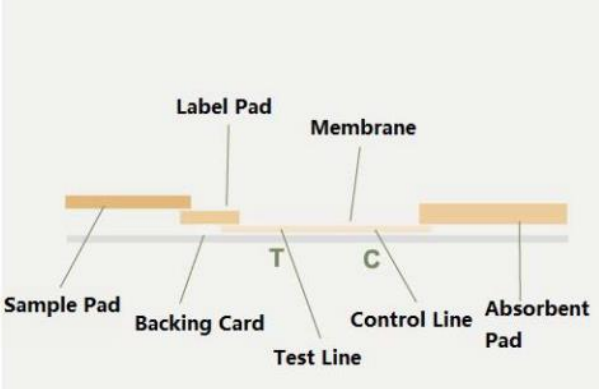
2.10 Flow of Manufacturing Process

Please refer to Appendix O for a Manufacturing Flow Chart of the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

2.11 Drawing and Diagrams

Please refer to Appendix R for Drawing and Diagrams of the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test. The below product drawing indicates the structure of embedded strip:





2.12 Labeling

Labeling for the Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test consists of the following items:

Package Insert
Label of sample diluent
Label of pouch package
Label of outer box

Labeling materials are referenced in Part B of this file and are located in Appendix P

2.13 Literature

Literature is on file at Document Center at Shanghai Outdo Biotech Co., Ltd.