Clinical Trial Summary of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma)

COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) clinical trials were performed at two sites in China from February 2020 to March 2020. These clinical trials were aimed to evaluate the performance of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) by comparing with PCR.

1. Clinical Trial Location:

a. Zhejiang Provincial Center for Disease Control and Prevention
b. The First Hospital of Zhejiang Province

2. Clinical Specimens

79 specimens were collected from patients exhibiting pneumonia or respiratory symptoms. 83 specimens were also collected from convalescent patients. 227 negative specimens were collected in the study.

3. Methods

COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) was used to run the clinical specimens collected. The results were recorded and compared with the results obtained by PCR.

4. **Commercial kits used for Comparison**

PCR test kit

5. Test Results

Clinical specimens were used to test the performance of COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma).

Clinical Summary of COVID-19 IgG/IgM

For IgM detection:

Method		PCR+	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgM+	74	2	76
	IgM-	5	225	230
Total		79	227	306

Relative sensitivity: 93.7% (86.0%-97.3%)*
Relative specificity: 99.1% (96.8%-99.8%)*
Overall agreement: 97.7% (95.4%-98.9%)*
*95% Confidence Interval

For IgG detection:

Method		Convalescent samples	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgG+	82	3	85
	IgG-	1	224	225
Total		83	227	310

Relative sensitivity: 98.8% (93.5%-99.8%)*
Relative specificity: 98.7% (96.2%-99.5%)*
Overall agreement: 98.7% (96.7%-99.5%)*
*95% Confidence Interval

6. Conclusion

By the data obtained from these clinical investigations, we conclude that COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) has relatively high sensitivity, specificity and accuracy. It is a fast and convenient, which requires only room temperature storage conditions. It does not need any instrument to read the result. The background of the test is clean and the interpretation of test result is clear-cut. The test has been determined to be effective and safe.

Scientist: Echo Ge R & D Manager:

Date: 03-11-2020 Date: 03-11-2020

COVID-19 IgG/IgM

Rapid Test Device

COV-W23M **(Whole Blood/Serum/Plasma)**

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Device is an *in vitro* immunoassay for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human whole blood, serum, or plasma as an aid in the diagnosis of COVID-19.The test is for professional use only.

INTRODUCTION

Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats.
The two highly pathogenic viruses, SARS-CoV and MERS-CoV, cause severe respiratory syndrome in humans, and the other four human coronaviruses (HCoV-NL63, HCoV-229E, HCoV-OC43 and HKU1) induce only mild upper respiratory diseases in immunocompetent hosts, although some of them can cause severe infections in infants, young children and elderly individuals[1,2,3].
COVID-19 is the disease associated with SARS-CoV-2, which was identified in China at the end of 2019. Coronaviruses cause respiratory and intestinal infections in animals and humans[1].
The virus is transmitted mainly via respiratory droplets that people sneeze, cough, or exhale. The incubation period for COVID-19 is currently estimated at between two and 14 days. Common symptoms of COVID-19 infection include fever, cough and respiratory symptoms such as shortness of breath and breathing difficulties. More serious cases develop severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock that can lead to the death of the patient. People with existing chronic conditions seem to be more vulnerable to severe illness.
Detection of IgM indicates recent infection and can be used for early diagnosis of infection. IgG antibodies gradually appear and increase in the late stage of infection, and the COVID-19 IgG/IgM Rapid Test Device is a simple lateral flow immunoassay for the direct detection of anti-SARS-CoV-2 IgG/IgM antibody. It will provide a presumptive diagnosis of COVID-19.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Device detects anti-SARS-CoV-2 IgG/IgM antibody through visual interpretation of color development.
Anti-human IgG and anti-human IgM are used to detect specific antibodies in the human whole blood, serum, or plasma specimen. When specimen is added to the sample well, specific IgM and/or IgG antibodies, if present, will bind to the SARS-CoV-2 antigens conjugated to colored particles on the conjugate pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-human IgM and/or anti-human IgG antibodies immobilized on the test region(s). Excess colored particle are captured at the internal control region.
The presence of a red band(s) on the test region(s) indicates a positive result for the particular IgG and/or IgM antibodies, while its absence indicates a negative result. A red band at the control region (C) serves as a procedural control, indicating that membrane wicking is working.

REAGENTS AND MATERIALS

Materials Provided

- Individually packed test devices
- 5uLdisposable pipettes
- 10uLdisposable pipettes
- Buffer
- Package insert

Materials Required but Not provided

- Clock, timer or stopwatch
- Transfer pipette

PRECAUTIONS

- For *in vitro* Diagnostic Use Only.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Care should be taken to store specimens as indicated in the document (refer to SPECIMEN COLLECTION AND STORAGE).
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin contact with all components containing sodium azide which is a skin irritant.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.

STORAGE AND STABILITY

- Store the COVID-19 IgG/IgM Rapid Test Device at 2~30℃when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 7 days. For long term storage, serum or plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 3 days after collection. Do not freeze whole blood specimens.
- Containers containing anticoagulants such as EDTA, citrate, heparin or oxalate should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen serum or plasma specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

TESTPROCEDURE

Specimen Collection:
Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30℃) prior to testing.

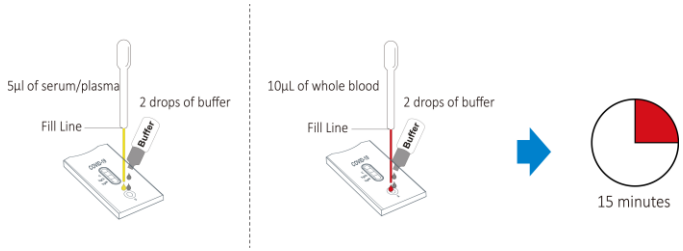
1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Label the test with patient or control identification.
   For Serum or Plasma Specimens:

a) Using the provided 5μL disposable pipette, draw the specimen up to the Fill Line, and transfer all the specimen (appr. 5 μL) into the specimen well of the test device, then add 2 drops of buffer and start the timer.

For Whole Blood Specimens:

a) Using the provided 10μL disposable pipette, draw the specimen up to the Fill Line, and transfer all the specimen (appr. 10 μL) into the specimen well of the test device, then add 2 drops of buffer and start the timer.

3. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Specimens can also be applied using a micropipette.



RESULT INTERPRETATION

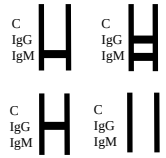
For COVID-19 IgG/IgM Test:

IgM Positive:*The colored line in the control region (C) changes from blue to red, and a colored line appears in the IgM test region. The result is positive for COVID-19 virus specific-IgM antibodies.

IgG Positive:*The colored line in the control region (C) changes from blue to red, and a colored line appears in the IgG test region. The result is positive for COVID-19 virus specific-IgG antibodies.

IgM and IgG Positive:*The colored line in the control region (C) changes from blue to red, and two colored lines should appear in IgG and IgM test regions. The color intensities of the lines do not have to match. The result is positive for IgM and IgG antibodies.

Negative: The colored line in the control region (C) changes from blue to red. No line appears in IgM or IgG test regions.



Invalid: Control line (C) is still completely or partially blue, and fails to completely change from blue to red. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Procedural Controls
The COVID-19 IgG/IgM Rapid Test Device has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the blue band should be always located at the "C" region before testing, and the red band should be always present before result interpretation.
External Positive and Negative Controls
Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

LIMITATIONS OF THE TEST

1. The COVID-19 IgG/IgM Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
4. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
5. A high dose "hook effect" may occur where the color intensity of test band decreases as the concentration of anti-SARS-CoV-2 IgG/IgM increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the test band.
6. Negative results do not preclude COVID-19 and should be confirmed via other methods such us molecular assay.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation:

79 specimens were collected from patients exhibiting pneumonia or respiratory symptoms. 83 specimens were also collected from convalescent patients. 227 negative specimens were collected in the study.

For IgM detection:

Method		PCR+	PCR-	Total
COVID-19 IgG/IgM Rapid Test	IgM+	74	2	76
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Relative sensitivity: 93.7% (86.0%-97.3%)*

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Overall agreement: 97.7% (95.4%-98.9%)*

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For IgG detection:

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Relative specificity: 98.7% (96.2%-99.5%)*

Overall agreement: 98.7% (96.7%-99.5%)*

*95% Confidence Interval

Cross Reactivity

There was no cross-reactivity with any of the unrelated infections tested. No inhibition was observed with any of the specimens.

Anti-HAV IgM +	Chagas IgG+
Anti-HEV IgM +	Anti-Syphilis +
HBsAg +	Anti-Chlamydia +
Anti-HCV +	Anti-Tuberculosis +
Anti-HIV+	Typhoid IgM +
Anti-Rubella IgM +	Lyme disease+
Anti-CMV IgM +	P. falciparum +
Anti-HSV-I IgM +	P. vivax +
Anti-HSV-II IgM +	Toxoplasmosis +
EBV IgG +	HAMA +
Anti-Dengue virus +	RF +
Anti-Yellow fever +	ANA+
Anti-Zika virus +	
Anti-Chikungunya +	

Interfering Substances

The assay performance of COVID-19 IgG/IgM Rapid Test is not affected by substances at concentrations listed below.

Interfering substances	Concentration of analyate
Blood analytes	
Albumin	5 g/dL
Bilirubin	5 mg/dL
Hemoglobin	20 g/dL
Triglycerides	500 mg/dL
Anticoagulants	
EDTA	3.4 μmol/L
Heparin	3000 U/L
Sodium citrate	5 mg/mL
Potassium oxalate	2 mg/mL
Abnormal blood sample	
Visual hemolysis	NA
Icteric	NA
Lipemic	NA
Common medicines	
Acetylsalicylic acid	3.62 mmol/L
Ascorbic acid (Vitamin C)	342 μmol/L
Amoxicillin	206 μmol/L
Fluconazole	245 μmol/L
Ibuprofen	2425 μmol/L
Loratadine	0.78 μmol/L
Nadolol	3.88 μmol/L
Naproxen	2170 μmol/L
Paroxetine	3.04 μmol/L
Anti-malarial medicines	
Quinine	148 μmol/L
Anti-tuberculosis medicines	
Rifampicin	78.1 μmol/L
Isoniazid	292 μmol/L
Ethambutol	58.7 μmol/L
Common consumables	
Coffee (caffeine)	308 μmol/L
Alcohol (ethanol)	86.8 mmol/L

LITERATURE REFERENCES

1. Masters, P. S. & Perlman, S. in Fields Virology Vol. 2 (eds Knipe, D. M. & Howley, P. M.) 825–858 (Lippincott Williams & Wilkins, 2013).
2. Su, S. et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol. 24, 490–502 (2016).
3. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
4. Kan, B. et al. Molecular evolution analysis and geographic investigation of severe acute respiratory syndrome coronavirus-like virus in palm civets at an animal market and on farms. J. Virol. 79, 11892–11900 (2005).
5. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).
6. "Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)" https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

FaStep®

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
Zhejiang 310011, China

Lotus NL B.V.
Address: Koningin Julianaplein 10, le Verd, 2595AA,The Hague,Netherlands

ASSURE TECH. (HANGZHOU) CO., LTD.
2nd-5th Floor, Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China Tel: + 86 571 8102 2698 Fax: + 86 571 8886 5920 E-mail: contact@diareagent.com

MATERIAL SAFETY DATA SHEET

According with Regulation (EC) No 1907/2006

QUALITY MANAGEMENT **Version 1.0, DATE: 03/16/2020**

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma)
Catalog number	COV-W23M
Chemical Family/Use of the substance preparation	In vitro diagnostic rapid test, it is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.
Formula	Proprietary mixture
Shipping name	Not applicable
Dot hazard classification	Not applicable
Manufacturer	Assure Tech. (Hangzhou) Co., Ltd No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China
Contact	contact@diareagent.com
Emergency telephone	Phone: #86-571-88868960 Fax: #86.571-88865920 Phone number is available during office hours as follows: Mon – Fri 8 :30 AM – 5:30 PM

SECTION 2: Hazards Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Label elements	**Labelling according to Regulation (EC) No 1272/2008** Void

SECTION 3: Composition/Information on Ingredients
This product is a mixture In vitro diagnostics medical device. Test strip impregnated with dries chemical / biochemical reagents. Swab and tube stand have no hazard ingredients.

SECTION 4: First-aid Measures	
The following first aid measures are only relevant in the event of serious misuse.	
After skin contact	Wash off immediately with plenty of water for at least 15 minutes.
After eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation persists, call a physician.
After ingestion	Consult a physician. Never give anything by mouth to an unconscious person.
After inhalation	Move to fresh air. If symptoms persist, call a physician.

SECTION 5: Firefighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Autoignition temperature	Not applicable
Extinguishing media	Suitable extinguishing media: Dry chemical, CO_2, water spray or alcohol-resistant foam. Extinguishing media which shall not be used for safety reasons: No information available.
Special fire combustion products	None
Protective equipment for firefighter	As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental Release Measures	
Personal safety precaution	Ensure adequate ventilation.

Spill and leak procedures	Absorb spill with inert material (e.g. dry sand or earth), then place in a chemical waste container.
Environmental precautions	Prevent further leakage or spillage if safe to do so.

SECTION 7: Handling and Storage	
Precaution to be taken in handling and storage	Ensure adequate ventilation.
Requirements to be met by storage conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Other precautions/special hazards	No information available.

SECTION 8: Exposure Controls/Personal Protection	
The product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.	
Exposure limits	No information available.
Derived no effect level (DNEL)	No information available.
Predicted no effect concentration (PNEC)	No information available.
Skin and body protection	Long sleeved clothing.
Eye protection	Safety glasses
Hand protection	Protective gloves.
Respiratory protection	No special protective equipment required.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and Chemical Properties	
Physical State	Solid
Color	White
Odor	Odorless
Flash point	No information available.
Self-igniting	No information available.
pH-value at 20°C	No information available.
Melting/freezing point	No information available.
Vapor pressure	No information available.
Vapor density	No information available.
Specific Gravity	No information available.
Water solubility	No information available.
Solubility in other solvents VALUE	No information available.

SECTION 10: Stability and Reactivity	
Chemical stability	Stable under normal conditions.
Conditions to avoid	Extreme of temperature and direct sunlight.
Incompatible materials	Acids.
Hazardous decomposition products	None under normal use conditions.

SECTION 11: Toxicological Information	
Product information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	No information available.
Eye contact	No information available.

Skin contact	No information available.
Ingestion	No information available.
Acute toxicity	No information available.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.

SECTION 12: Ecological Information	
Ecotoxicity effects	Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.
Persistence and degradability	No information available.
Bioaccumulative potential	No information available.
Mobility in soil	No information available.
Results of PBT and vPvB assessment	No information available.
Other adverse effects	No information available.

SECTION 13: Disposal Considerations	
Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport Information	
Identification	Not applicable.
Special provision for transport	Not applicable.

SECTION 15: Regulatory Information	
General information	This product is not classified as a dangerous preparation according to 1999/45/EC and 67/548/EEC and 2001/58/EC.

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MATERIAL SAFETY DATA SHEET

According with Regulation (EC) No 1907/2006

QUALITY MANAGEMENT **Version 1.0, DATE: 03/16/2020**

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	Buffer
Catalog number	Not applicable
Chemical Family/Use of the substance preparation	Used with in vitro diagnostic rapid test to aid in the rapid differential diagnosis of COVID-19.
Formula	Proprietary mixture
Shipping name	Not applicable
Dot hazard classification	Not applicable
Manufacturer	Assure Tech. (Hangzhou) Co., Ltd No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China
Contact	contact@diareagent.com
Emergency telephone	Phone: #86-571-88868960 Fax: #86.571-88865920 Phone number is available during office hours as follows: Mon – Fri 8 :30 AM – 5:30 PM

SECTION 2: Hazards Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Label elements	**Labelling according to Regulation (EC) No 1272/2008** Void

SECTION 3: Composition/Information on Ingredients			
Chemical Name	**CAS No.**	**Weight %**	**Classification (Reg. 1272/2008)**
Sodium azide	26628-22-8	0.02	Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH032)
Sodium dihydrogen orthophosphate	7558-80-7	0.7	-
Kanamycin sulfate	25389-94-0	0.025	-
Sodium chloride	7647-14-5	0.8	-

SECTION 4: First-aid Measures	
The following first aid measures are only relevant in the event of serious misuse.	
After skin contact	Wash off immediately with plenty of water for at least 15 minutes.
After eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation persists, call a physician.
After ingestion	Consult a physician. Never give anything by mouth to an unconscious person.
After inhalation	Move to fresh air. If symptoms persist, call a physician.

SECTION 5: Firefighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable

Autoignition temperature	Not applicable
Extinguishing media	Suitable extinguishing media: Dry chemical, CO_2, water spray or alcohol-resistant foam. Extinguishing media which shall not be used for safety reasons: No information available.
Special fire combustion products	None
Protective equipment for firefighter	As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental Release Measures	
Personal safety precaution	Ensure adequate ventilation.
Spill and leak procedures	Absorb spill with inert material (e.g. dry sand or earth), then place in a chemical waste container.
Environmental precautions	Prevent further leakage or spillage if safe to do so.

SECTION 7: Handling and Storage	
Precaution to be taken in handling and storage	Ensure adequate ventilation.
Requirements to be met by storage conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Other precautions/special hazards	No information available.

SECTION 8: Exposure Controls/Personal Protection	
The product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.	
Exposure limits	No information available.
Derived no effect level (DNEL)	No information available.
Predicted no effect concentration (PNEC)	No information available.
Skin and body protection	Long sleeved clothing.
Eye protection	Safety glasses
Hand protection	Protective gloves.
Respiratory protection	No special protective equipment required.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No information available.

SECTION 9: Physical and Chemical Properties	
Physical State	Liquid
Color	Transparent
Odor	Odorless
Flash point	No information available.
Self-igniting	No information available.
pH-value at 20°C	No information available.
Melting/freezing point	No information available.
Vapor pressure	No information available.
Vapor density	No information available.
Specific Gravity	No information available.
Water solubility	No information available.
Solubility in other solvents VALUE	No information available.

SECTION 10: Stability and Reactivity

Chemical stability	Stable under normal conditions.
Conditions to avoid	Extreme of temperature and direct sunlight.
Incompatible materials	Acids.
Hazardous decomposition products	None under normal use conditions.

SECTION 11: Toxicological Information	
Product information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	No information available.
Eye contact	No information available.
Skin contact	No information available.
Ingestion	No information available.
Acute toxicity	No information available.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
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Reproductive toxicity	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
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SECTION 12: Ecological Information	
Ecotoxicity effects	Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.
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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Assure Tech. (Hangzhou) Co., Ltd.
2nd, 6th Floor. Building 1.
No. 10, Xiyuansan Rd.
Westlake Economic Zone
Hangzhou
310030 Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-07-13
Certificate Registration No.:	SX 60129700 0001
An audit was performed. Report No.:	15047225 011
This Certificate is valid until:	2020-02-24

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-07-13

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60129700 0001
Report No.: 15047225 011

Organization:
Assure Tech. (Hangzhou) Co., Ltd.
2nd, 6th Floor. Building 1.
No. 10, Xiyuansan Rd.
Westlake Economic Zone
Hangzhou
310030 Zhejiang
China

Scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse and Infectious Disease, In Vitro Diagnostic Test Kits and Related Instruments for the field of Immune Diagnosis

Site included:

2nd-5th Floor, Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China

Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse and Infectious Disease, In Vitro Diagnostic Test Kits and Related Instruments for the field of Immune Diagnosis

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-07-13

X. Ren

EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III

Manufacturer：Assure Tech (Hangzhou) Co., Ltd.
Address：Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China
Product/s：COVID-19 IgG/IgM Rapid Test Device
Category：Other Devices (All devices except Annex II and self-testing devices)
Conformity assessment route：Declaration of Conformity IVDD Annex III

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint

Lotus NL B.V.
Address: Koningin Julianaplein 10,
le Verd, 2595AA,The Hague, Netherlands

to act as our
European Authorised
Representative as defined in the
aforementioned Directive.

Signed on 2020/03/10
Place Hangzhou, China

Signature _____
Name of authorized signatory: Eric Ling, General Manager

Assure Tech

TÜVRheinland®
Certified manufacturer
according to ISO13485

Certificate

TÜVRheinland®

Certificate No.:	MD 465264 154320164-30
Manufacturer:	Assure Tech. (Hangzhou) Co., Ltd. 2nd-5th Floor, Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China
D-U-N-S No.:	53-075-7741
Certification criteria	ISO 13485:2016 Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Canada & USA: Design/development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Tests in the filed of Fertility, Drug of Abuse Testing Brazil: Design/development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Tests in the filed of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse, Infectious Disease Testing

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	154320164
Issue Date:	2018-07-09
Effective Date:	2018-07-09
Expiry Date:	2020-06-14

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: X. Ren
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

TÜVRheinland®
Precisely Right.

2020-02-21

To Whom It May Concern

This is to confirm that a 3rd Surveillance Audit for IVDD, Company Moving Audit, Re-certification Audit for ISO 13485 was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body (CE0197) as follows:

Applicant**:** **Assure Tech. (Hangzhou) Co., Ltd.**
Address: **Building4, No. 1418-50, Moganshan Road, Gongshu District, 310011 Hangzhou, China**

Scope: **Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse and Infectious Disease, In Vitro Diagnostic Test Kits and Related Instruments for the field of Immune Diagnosis, Blood Glucose Monitoring Systems (Blood Glucose Meter, Test Strip), Blood Cholesterol Monitoring Systems (Blood Cholesterol Meter, Test Strip), Digital Pregnancy Tests, Rotavirus Rapid Test Devices, H. pylori Antibody Rapid Test Devices**

Standards: **EN ISO 13485:2016, IVDD 98/79/EC Annex IV excl. (4) and (6)**

Date: 2019-11-18~21
Report No.: 15047225 016/017/018(TD)

The result of on-site audit is positive. It is recommended that the TÜV Rheinland LGA Products GmbH Notified Body (CE0197) approval should be remained valid.

The corrective action proposed by the company are acceptable, therefore the auditors will recommend that TÜV Rheinland LGA Products GmbH Notified Body (CE0197) Certificate for a Quality Assurance System should be issued in soon.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

TÜV Rheinland
(Shanghai) Co., Ltd.

TUV Building,
No. 177, Lane 777,
West Guangzhong Road,
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Tel. +86 21 6108 1188
Fax +86 21 6108 1099
+86 21 6108 1199
Hotline
800 999 3668/400 883 1300
service-gc@tuv.com

www.tuv.com

This is the box we used for shipment and its size is 200*130*81mm.
The size of the outboard carton is 630*370*300mm (outer diameter).
There are two cases of carton packing.
1. With blood collection needle and alcohol cotton, 20 products are packed in a box and 540 products in a carton, which is 27 boxes.
2. Without blood collection needle and alcohol cotton, 25 products are packed in a box and 675 products in a carton, which is 27 boxes.
The net weight of a carton is about 11kg and the volumetric weight is 14kg.