Medek
Health Systems

FDA Authorized Test Kit

COVID-19 Antibody

Rapid Diagnostic Test

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

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.

- **15 Minute COVID-19 Test**
- **Test Either Whole Blood, Plasm or Serum**
- **IgG & Igm Combined Test**

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.

For IgM Detection

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

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

For IgG Detection

Method		Convalescent Samples	PCR-
COVID-19 IgG/IgG	IgG	82	3
Rapid Test	IgM	1	224
Total		83	227

*Relative sensitivity: 98.8% (93.5%-99.8%)**
*Relative sensitivity: 98.7% (96.2%-99.5%)**
*Relative sensitivity: 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.

MEDEKTESTKITS.COM

131 Waterman Ave
Mount Dora - FL 32757
888-996-3335

The MEDEK supplied test kit is FDA authorized for use without a separate reading machine at the Point of Care.

Product Information and Limitations of Sale:

- Results in 15 minutes w/ rapid testing
- Each set (box) has 20 individual tests
- Have a shelf life of 9-months
- For use as an aid in identifying SARSCoV-2, nucleocapsid protein antigen
- Verification of use case prior to shipping is mandatory

Governance

A. Your product is a qualitative test intended for the detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, or plasma (sodium EDTA) specimens. The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

B. Policy for Diagnostic Tests for Coronavirus Disease 2019 during the Public Health Emergency issued on the web on March 16, 2020 by U.S. Food and Drug Administration (FDA") which may be found here:
https://www.fda.gov/media/135659/download

C. The Policy provides guidance on the emergency use of products for Covid-19 tests in this declared emergency, and provides authority to provide Covid-19 Rapid Cassette IgG/IgM tests ("Products") and submitted an Emergency Use Authorization to the FDA in compliance with the Policy;

Compliance

A. All sales of Products are subject to the purchaser's compliance with the Policy and that the Products shall only be used by health professionals as defined in subsection (g) at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.2

B. The Products shall not be made available, offered, distributed or marketed, directly or indirectly, to the general public, or made available, sold, distributed or marketed to anyone who the Representative or the Approved Account knows or has any reason to know will make available, offer, distribute or market, directly or indirectly, the Products to the general public.

C. The Products are only for preliminary screening purposes and shall only be used to determine if additional testing is required

Buyer Requirements

A. Qualified parties who agree to follow the guidance in the Policy including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization, clinical testing and distribution

B. Payment must be made prior to shipment

C. Payments accepted: Wire transfer or Credit Card (AMEX Preferred).

D. Order questions: Medek Health Systems, LLC- (352) 516-3072.

E. Wire transfer questions: (352) 383-2111.

F.

BANK:	First National Bank of Mount Dora 063104312
ABA:	063104312
BENEFICIARY:	Medek Health Systems, LLC
	131 Waterman Avenue
	Mount Dora, FL 32757
ACCOUNT NO:	30112085

Misc.

A. FDA guidelines for the product is attached bebw.

B. Safety Data sheet is attached below.

C. Fact sheet for healthcare providers is attached below.

D. Fact sheet for patients is attached below.

E. User guide is attached below.

F. FDA serology test evaluation is attached below.

G.

July 6, 2020

Frank Lou
Director
Azure Biotech Inc.
Representing: Assure Tech. (Hangzhou Co., Ltd)
5250 Gulfton St. #2C
Houston, TX 77081

Device:	Assure COVID-19 IgG/IgM Rapid Test Device
Company:	Assure Tech. (Hangzhou Co., Ltd)
Indication:	Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, or plasma (sodium EDTA). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

Dear Mr. Lou:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Assure Tech. (Hangzhou Co., Ltd).
[2] For ease of reference, this letter will use the term "your product" to refer to the Assure COVID-19 IgG/IgM Rapid Test Device for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test intended for the detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, or plasma (sodium EDTA) specimens. The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

To use your product, the device cassette, specimen, buffer, and/or controls should be equilibrated to room temperature. Using the provided disposable pipette, serum and plasma (approximately 5 µL) or venous whole blood (1 drop) is transferred to the specimen well. Two drops of buffer are then added to the specimen well. Wait for 15 minutes and read the test results. An IgM Positive Result occurs when a colored line appears at the IgM test region and the colored line in the

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

control region changes from blue to red, indicating that IgM against SARS-CoV-2 is present. An IgG Positive Result occurs when a colored line appears at the IgG test region and the colored line in the control region changes from blue to red, indicating that IgG against SARS-CoV-2 is present. A Positive Result for IgM and IgG occurs when colored lines occur at both IgM and IgG test regions as well as a blue to red color change in the line at the control region. A Negative Result occurs when the colored line in the control region changes from blue to red but no colored line appears in the IgM and IgG test regions, indicating that IgM and IgG antibodies against SARS-CoV-2 were not detected. An Invalid Result occurs when the colored line in the control region remains completely or partially blue and the test should be repeated.

Your product requires the following internal control, that is processed along with the sample on the device cassette. The internal control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control – The control line should change from blue to red on each strip for every test and checks that flow of reagents is satisfactory.

Your product also includes external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use:

- Positive Control: Lyophilized anti-SARS-CoV-2 IgG and anti-SARS-CoV-2 IgM, resuspended with one vial of negative serum as described in the Instructions for Use.
- Negative Control: Lyophilized negative human serum resuspended as described in Instructions for Use.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product is authorized to be accompanied with labeling entitled "Assure COVID-19 IgG/IgM Rapid Test Device" Instructions for Use (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and recipients:

- Fact Sheet for Healthcare Providers: Assure COVID-19 IgG/IgM Rapid Test Device
- Fact Sheet for Recipients: Assure COVID-19 IgG/IgM Rapid Test Device

The above described product, when accompanied by the Instructions for Use (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Assure Tech. (Hangzhou Co., Ltd) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized

[5] "Authorized Distributor(s)" are identified by you, Assure Tech. (Hangzhou Co., Ltd), in your EUA submission as an entity allowed to distribute your device.

labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.

D. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) will make available the control material or other authorized control materials for purchase at the same time as your product.

Assure Tech. (Hangzhou Co., Ltd) (You)

I. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. You may request to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product, but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. You will comply with the following requirements under FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other ancillary methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request substitution for or changes to the authorized materials used in the detection process of human antibodies against SARS-CoV-2. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You will evaluate the performance and assess traceability[6] of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

T. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must assure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

U. If requested by FDA, you must submit lot release procedures to FDA within 48 hours of such request, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S.

V. If requested by FDA, you will periodically submit new lots for testing at NCI, or by another government agency designated by FDA, to confirm continued performance characteristics across lots. In addition, FDA may request records regarding lot release data for tests to be distributed or already distributed. If such lot release data are requested by FDA, you must provide it within 48 hours of the request.

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

W. You will complete the agreed upon real-time stability study for your product. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Authorized Laboratories

X. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

Y. Authorized laboratories will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

Z. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

AA. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

BB. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: contact@direagent.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

CC. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

Assure Tech. (Hangzhou Co., Ltd) (You), Authorized Distributors and Authorized Laboratories

DD. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

EE. All descriptive printed matter, including advertising and promotional materials,

relating to the use of your product, shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

FF. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product, may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

GG. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product, shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S3

Digitally signed by Denise M. Hinton -S3
Date: 2020.07.06 14:56:12 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
Cc: Joe Shia, LSI International Inc., Consultant

SAFETY DATA SHEET

According with Regulation (EC) No 1907/2006

QUALITY MANAGEMENT **Version 2.0, DATE: 04/28/2020**

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 anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG 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** The product is not classified according to the CLP regulation
Other Hazards	No particular hazards if test is used according to the instructions. The product contains chemicals and materials of animal origin. Although the risk of infection is rated as extremely unlikely, a direct contact should be avoided.
SECTION 3: Composition/Information on Ingredients	

This product is a mixture In vitro diagnostics medical device.

Kit Components:

- Test devices: Strips inside the housing contain small amounts of chemicals (proteins, surfactants, biological buffers, salts, carbohydrates, polymers, gold particles and preservative (sodium azide)) and small amounts of antibodies or antigens as active ingredients of the detection reaction, conjugated to gold particles or immobilised on the test line regions.
  The backing plate of each test strip is made of polyethylene. The membrane is nitrocellulose. The strip further contains adsorbent pads (cellulose), polyester and glass fiber.
- Bottle with buffer solution
  Buffer components: Biological buffer, salts and surfactants. Preservatives: Sodium azide and ProClin 150 (<0.1%).
- Coated Aluminium Foil for single pouched test devices
- Disposable pipettes
- Desiccant (SiO_2)
- Package insert (paper)

● Lancet(if required) ● Alcohol cotton(if required)	
Hazardous Components: The product is no hazardous component according to the CLP regulation ((EC) No 1272/2008). Although the substance sodium azide (CAS 26628-22-8) and the Proclin 150 component 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (CAS 55965-84-9) are rated as hazardous, they do not need to be declared as hazardous components in this formulation because of the extremely low concentration on the test strip and in the buffer solution (CAS 26628-22-8: <0.1%; CAS 55965-84-9: <0.0015).	
Chemical Names and Synonyms	Not applicable
Chemical Family	Not applicable
Formula	Not applicable
Shipping Name	Not applicable
Hazard Classification	Not applicable
SECTION 4: First-aid Measures	
If used according to the instructions the described scenarios are extremely unlikely.	
After skin contact	The buffer solution and possibly other kit components may cause slight irritations upon contact. Remove contaminated clothing. Wash affected area with plenty of water. If irritation or signs of toxicity occur, seek medical attention.
After eye contact	The buffer solution and possibly other kit components may cause slight irritations upon contact. Remove from source of exposure. Wash with copious amounts of water (for appr. 15 min) with eyelid held open. If irritation or signs of irritation, pain or toxicity occur, seek medical attention.
After ingestion	If buffer solution, kit or test components have been ingested, rinse mouth with water provided the person is conscious. If irritation or signs of toxicity occur, seek medical attention.
After inhalation	Inhalation of any components of the kit is extremely unlikely. If a component is inhaled and causes discomfort, remove exposed person from source of exposure and take outside to fresh air. If breathing is difficult, irritation or signs of toxicity occur, seek medical attention.
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. Unsuitable extinguishing media: Not known. If possible, run-off water should be prevented from entering bodies of water or other environmentally sensitive areas.
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	Remove unprotected persons from source of exposure. Avoid contact with skin and eyes. Use universal precautions during clean-up

	procedures.
Spill and leak procedures	Large spills or leak of this kit are unlikely. Personnel who have received basic chemical safety trains can generally handle small-scale releases. Wear protective garment (safety glasses, gloves, lab coat). Take up spills with absorbent paper; if necessary clean with disinfectant afterwards and dispose of in accordance with the local regulations (see section 13). Clean affected area with water afterwards.
Environmental precautions	No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Generally a release to the environment should be avoided.
SECTION 7: Handling and Storage	
Precaution to be taken in handling and storage	Store at 2-30℃
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	Laboratory clothes
Eye protection	Protective Lab Glasses are recommended
Hand protection	Impervious Gloves (nitrile, rubber, latex or equivalent)
Respiratory protection	Mask
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No special environmental controls are required. Disposal of test according to section 13.
SECTION 9: Physical and Chemical Properties	
Physical State	Solid material Buffer solution: liquid
Color	White
Odor	Odorless
Flash point	Not determined
Flammability	Not determined
pH-value at 20°C	Not applicable for solid materials Buffer solution: ≈ 7
Melting/freezing point	Solid materials: Plastics decomposition at ~300°C Buffer solution: ≈ 0°C (do not freeze)
Vapor pressure (20°C)	Not applicable for solid components Buffer solution: ~23hPa (similar to water)
Vapor density	Not applicable.
Specific Gravity	No information available.

Water solubility	No information available.
Solubility in other solvents VALUE	No information available.
SECTION 10: Stability and Reactivity	
Reactivity	Not known
Chemical stability	The product is stable. Hazardous degradation products are not known, if the storage conditions are observed. Plastic components: Hazardous decomposition products during burning possible.
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.
Serious eye damage/irritation	No information available.
Skin corrosion/irritation	No information available.
Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information. Sodium azide (pure substance): Oral LD50 (rat): 27mg/kg; dermal LD50 (rabbit): 20mg/kg
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Summary of evaluation of the CMR properties	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	No information available. No adverse effects on the environment are expected. However, for sodium azide and the ProClin150 component 5-chloro-2-methyl-4- isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1), following applies: Harmful to aquatic life with long lasting effects. In the present amounts (<0.1% and <0.0015) hazardous influences on the environment are to be unlikely as the concentrations of hazardous components are below the threshold values that would require labeling.
Persistence and degradability	Generally plastic materials are not biodegradable and should not be dumped into the environment.
Bioaccumulative potential	The potential of kit components to accumulate in animal or plant systems is considered to be very limited.
Mobility in soil	No information available.
Results of PBT and vPvB assessment	No sufficient information available for assessment. To our knowledge this preparation contains no amounts of substances regarded as persistent, bioaccumulative and toxic (PBT) or substances that are

	considered to be very persistent and very bioaccumulative (vPvB) that need to be declared.
Other adverse effects	No information available.
SECTION 13: Disposal Considerations	
Waste from residues/unused products	No specifications required. In all cases disposal of tests should be in compliance with federal and local regulations. The potentially infectious character of the sample material should be taken into consideration before disposal. Observe regulations for proper disposal of such materials. Frequently tests can be disposed of with the regular garbage. If in doubt, we recommend to contact the relevant authorities and/or an approved waste-disposal company for information to ensure compliance.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for disposal. Non-contaminated packaging materials can be recycled.
SECTION 14: Transport Information	
Identification	Not applicable.
Transport(ICAO/IATA)	According to the 61st edition 2020 of IATA Dangerous Goods Regulation, the products are not dangerous, poisonous, harmful, corrosive flammable or explosive. They are not spiritual medicines, not anesthetic or narcotic, and cannot be used to make bio-chemical weapons. They are in sealed packages and conform to the export requirements by china customs and CAAC. The products is safe for transportation and not regulated by IATA DGR/IMDG.
SECTION 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	This safety datasheet complies with the requirements of Regulation (EC) No. 1907⁄2006.
Chemical safety assessment	For this product a chemical safety assessment has not been carried out.
SECTION 16: Other Information	
The given information is based on the current state of knowledge but does not guaranty product performances under cannot be used as basis for legal disputes For further information please contact Assure Tech.	

FACT SHEET FOR RECIPIENTS

Azure Biotech Inc.
Assure COVID-19 IgG/IgM Rapid Test Device

September 23, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the **Assure COVID-19 IgG/IgM Rapid Test Device.**

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

How are people tested for COVID-19?
Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

What is the Assure COVID-19 IgG/IgM Rapid Test Device?
This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

What does it mean if I have a positive test result?
If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is not known whether having antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection. Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

What does it mean if I have a negative test result?
A negative test result means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Additionally, a negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR HEALTHCARE PROVIDERS

Azure Biotech Inc. **September 23, 2020**

Assure COVID-19 IgG/IgM Rapid Test Device

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Assure COVID-19 IgG/IgM Rapid Test Device.

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

The Assure COVID-19 IgG/IgM Rapid Test Device is authorized for the detection of antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), fingerstick whole blood, serum, or plasma (sodium EDTA) specimens.

All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Azure Biotech Inc. – Assure COVID-19 IgG/IgM Rapid Test Device

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only human venous whole blood (sodium EDTA), fingerstick whole blood, serum, or plasma (sodium EDTA) specimens.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The Assure COVID-19 IgG/IgM Rapid Test Device can be ordered by healthcare providers to test human venous whole blood (sodium EDTA), fingerstick whole blood, serum, or plasma (sodium EDTA) specimens to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The Assure COVID-19 IgG/IgM Rapid Test Device should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The Assure COVID-19 IgG/IgM Rapid Test Device is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This test is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation to test fingerstick whole blood specimens.
- Please refer to the Assure COVID-19 IgG/IgM Rapid Test Device instructions for use for additional information.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "*Where can I go for updates and more information?*" section).

What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19?
A positive test result with the SARS-CoV-2 antibody test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and it is not known if they confer immunity to infection.

Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.

Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Assure COVID-19 IgG/IgM Rapid Test Device has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to the patient include the following: risk of infection by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected patients, limits in the ability to work, or other unintended adverse effects.

Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for antibodies against virus that causes COVID-19?
A negative test result with this test means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.***

The absolute sensitivity of the Assure COVID-19 IgG/IgM Rapid Test Device is unknown.

Risks to a patient of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibody response to SARS-CoV-2, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective at diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Contact Information:

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www.assurelabs.com

COVID-19 IgG/IgM Rapid Test Device

For Emergency Use Authorization Only
For prescription use only
For in vitro Diagnostic Use Only.

Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

INTENDED USE

The Assure COVID-19 IgG/IgM Rapid Test Device is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood. The Assure COVID-19 IgG/IgM Rapid Test Device is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Assure COVID-19 IgG/IgM Rapid Test Device should not be used to diagnose acute SARS-CoV-2 infection.
Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS-CoV-2 antibodies. The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.
Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
The sensitivity of Assure COVID-19 IgG/IgM Rapid Test Device early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
False positive results for Assure COVID-19 IgG/IgM Rapid Test Device may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.
The Assure COVID-19 IgG/IgM Rapid Test Device is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The Assure COVID-19 IgG/IgM Rapid Test Device is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma. This test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The conjugate pad contains recombinant SARS-CoV-2 antigen (antigen is recombinant Nucleocapsid Protein and Spike Protein (S1)) conjugated with colloid gold.
During testing, the specimen binds with SARS-CoV-2 antigen- conjugated gold colloid coated particles in the test cassette. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a red line which confirm a reactive test result. Absence of a red line in the test region indicates a non-reactive test result.
To serve as a procedural control, a red line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
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
- Disposable pipettes
- Buffer
- Package insert
- Sterile safety lancet
- Alcohol Prep pad

Optional Materials

- External Negative and Positive control (Available upon request)

External Negative and Positive Control
Negative controls are lyophilized human serum samples and positive controls are lyophilized IgG and IgM against SARS-CoV-2. Two negative control vials are supplied. Reconstitute each negative control vial with 30 µL purified water. Transfer one reconstituted 30 µL negative control to the positive control vial to make ready-to-use positive control. Controls can be used like a serum sample. Store reconstituted controls at 4℃.

Materials Required but Not Provided

- Clock, timer, or stopwatch
- Specimen collection container

WARNING AND PRECAUTIONS

- For use under an Emergency Use Authorization Only.
- For *in* vitro Diagnostic Use Only.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- 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.
- 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 erroneous test result.
- Avoid skin contact with buffer 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.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- Store the Assure 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. Serum and plasma specimens may be stored at 2-8°C for up to 7 days. For long term storage, serum or plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 3 days after collection. Do not freeze whole blood specimens.
- Containers containing anticoagulants such as sodium EDTA, 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.

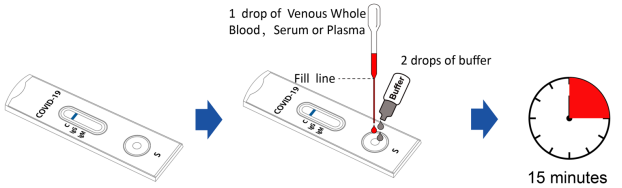
TESTPROCEDURE

Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30°C) 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. **Note:There should be a blue line in the control region (next to "C"), discard the device if there is no blue line.**
3. Label the test with patient or control identification.
4. Add the specimens.

For Venous Whole Blood Specimens, Serum or Plasma Specimens

a) Using the provided disposable pipette, draw the specimen above the fill line (avoid the specimen entering the bubble of disposable pipette) and transfer one drop of the specimen into the specimen well of the test device, then add 2 drops of buffer and start the timer. Adding more or less drops of specimen may lead to incorrect results. Adding 1 drop of buffer or more than 4 drops of buffer may lead to incorrect results.

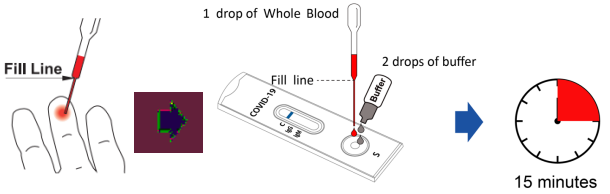


For Fingerstick Whole Blood

a) Clean the puncture site with the alcohol prep pad provided

b) Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.

c) Using the provided disposable pipette, draw the specimen above the fill line(avoid the specimenentering the bubble of disposable pipette) and transfer one drop (equivalent to 10µL) of the specimen into the specimen well of the test device, then add 2 drops of buffer and start the timer. Adding more or less drops of specimen may lead to incorrect results. Adding 1 drop of buffer or more than 4 drops of buffer may lead to incorrect results.



5. Wait for the blue line change to red line,read results at 15 minutes.
   Note: Do not read results earlier than 15 minutes or after 30 minutes
   Specimens can also be applied using a micropipette.

RESULT INTERPRETATION

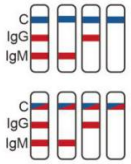
For Assure COVID-19 IgG/IgMTest:

IgM and IgG Positive:*The colored line in the control region (C) changesfrom 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.

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-19virus specific-IgG antibodies.

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

For use under an Emergency Use Authorization Only

1. Use of the Assure COVID-19 IgG/IgM Rapid Test Device is limited to laboratory personnel who have been trained. Not for home use.
2. The Assure COVID-19 IgG/IgM Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antibodies in venous whole blood, fingerstick whole blood, serum or plasma specimens only. Neither quantitative value nor the rate of increase in SARS-CoV-2 antibody concentration can be determined by this qualitative test.
3. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
4. Reading test results earlier than 15 minutes after the addition of Buffer may yield erroneous results. Do not interpret the results after 30 minutes.
5. Adding more or less than 1 drop of specimen may lead to erroneous results.
6. Adding 1 drop of buffer or more than 4 drops of buffer may lead to erroneous results.
7. The Assure COVID-19 IgG/IgM Rapid Test Device will only indicate the presence of SARS-CoV-2 antibodies in the specimen and should not be used for the diagnosis of acute SARS-CoV-2. A molecular assay should be used to evaluate symptomatic patients for acute COVID-19.
8. In the early onset of symptom, anti-SARS-Cov-2 IgM and IgG antibody concentrations may be below detectable levels.
9. *SARS-CoV-2 IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days.*
10. 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.
11. Results from immunosuppressed patients should be interpreted with caution.
12. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
13. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Antibodies may not be detected in the first few days of infection; the sensitivity of the Assure COVID-19 IgG/IgM Rapid Test Device early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
14. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
15. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
16. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
17. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
18. Not for the screening of donated blood.

The sensitivity of the test is impacted after being open for one hour-the intensity of the T line becomes weak. Testing must be performed within one hour after opening the pouch.

Conditions of Authorization for the Laboratory

The Assure COVID-19 IgG/IgM Rapid Test Device Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and other authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Authorized laboratories using the Assure COVID-19 IgG/IgM Rapid Test Device ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product will include the test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including theauthorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materialsrequired to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH（via email: CDRH-EUA-Reporting@fda.hhs.gov）and Assure Tech (Hangzhou Co., Ltd). (via email: contact@direagent.com) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Assure Tech. (Hangzhou Co., Ltd), authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Study I

Total of 61 positive and 105 negative serum or venous whole blood samples were collected at 4 different study sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Assure COVID-19 IgG/IgM Rapid Test device for antibodies. The obtained PPA/sensitivity and NPA/specificity results are summarized in following tables.

Table 1. IgG/IgM PPAfor the Assure COVID-19 IgG/IgM Rapid Test Device

Site	Days from symptom	# PCR Positive	IgG (Assure Device)			IgM (Assure Device)		
			Antibody Positive	PPA	95%CI	Antibody Positive	PPA	95%CI
(Site 1+3+4) Serum	0-7 days	8	7	87.5%	52.9%-97.8%	8	100%	67.6%-100%
	8-14 days	15	13	86.7%	62.1%-96.3%	13	86.7%	62.1%-96.3%
	≥15 days	25	25	100%	86.7%-100%	21	84%	65.3%-93.6%
(Site 2) Venous Whole Blood	0-7 days	1	1	100%	20.7%-100%	1	100%	20.7%-100%
	8-14 days	3	3	100%	43.9%-100%	3	100%	43.9%-100%
	≥15 days	9	9	100%	70.1%-100%	9	100%	70.1%-100%

Table 2. IgG/IgM NPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Site	# PCR Negative	IgG (Assure Device)			IgM (Assure Device)		
		Antibody Negative	NPA	95%CI	Antibody Negative	NPA	95%CI
(Site 1+3+4) Serum	96	96	100%	96.2%-100%	94	97.9%	92.7%-99.4%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	105	100%	96.5%-100%	103	98.1%	93.3%-99.5%

The NPA/specificity of the Assure COVID-19 IgG/IgM Rapid Test Device for IgG/IgM is 99.04%.

Study II: Independent Clinical Agreement Validation

The COVID-19 IgG/IgM Rapid Test Device from Assure Tech. (Hangzhou) Co., Ltd. was tested on 2020-06-15 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples was confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the Assure COVID-19 IgG/IgM Rapid Test Device. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using one lot of the Assure COVID-19 IgG/IgM Rapid Test Device. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the Tables 3 and 4 below.

Table 3. Summary Results

Assure COVID-19 IgG/IgM Rapid Test Device		Comparator Method			Total
		Positive (IgM/IgG) +	Negative (IgM/IgG) -	Negative, HIV+	
Positive	IgM+/IgG+	27	0	0	27
	IgM+, IgG-	3	1	0	4
	IgM-, IgG+	0	0	0	0
Negative	IgM-/IgG-	0	69	10	79
Total (n=110)		30	70	10	110

Table 4. Summary Statistics

Measure	Estimate	Confidence Interval
IgM+ Sensitivity (PPA)	(30/30) 100%	(88.7%; 100%)
IgM- Specificity (NPA)	(79/80) 98.8%	(93.3%; 98.8%)
IgG+ Sensitivity (PPA)	(27/30) 90.0%	(74.4%; 96.5%)
IgG- Specificity (NPA)	(80/80)100%	(95.4%; 100%)
Combined Sensitivity	(30/30) 100%	(88.7%; 100%)
Combined Specificity	(79/80) 98.8%	(93.3%; 98.8%)
Combined PPV for prevalence = 5%	80.8%	(40.9%; 96%)
Combined NPV for prevalence = 5%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	(0/10) 0% not detected	----------

Study III

Total of 42 positive and 113 negative fingerstick whole blood samples were collected and tested at 3 different POC sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Assure COVID-19 IgG/IgM Rapid Test device for antibodies. The PPA/sensitivity and NPA/specificity results are summarized in following tables.

Table 5. IgG/IgM PPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Site	Days from symptom	# PCR Positive	IgG (Assure Device)			IgM (Assure Device)		
			Antibody Positive	PPA	95%CI	Antibody Positive	PPA	95%CI

(Site 1+2+3)	0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%
	8-14 days	12	10	83.3%	55.2%-95.3%	10	83.3%	55.2%-95.3%
	⩾15 days	28	28	100%	91.2%-100%	25	89.3%	72.8%-96.3%

Site 1		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	0	0	NA	NA	0	NA	NA	0	NA	NA
8-14 days	0	0	NA	NA	0	NA	NA	0	NA	NA
≥15 days	11	11	100%	80.3%-100%	10	90.9%	62.3%-98.4%	11	100%	80.3%-100%
Site 2		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%	2	100%	42.5%-100%
8-14 days	7	6	85.7%	48.7%-97.4%	7	100%	72.1%-100%	7	100%	72.1%-100%
≥15 days	9	9	100%	76.9%-100%	9	100%	76.9%-100%	9	100%	76.9%-100%
Site 3		IgG			IgM			IgG/IgM		
Days from symptom	# PCR positive	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI	Antibody positive	PPA	95% CI
0-7 days	0	0	NA	NA	0	NA	NA	0	NA	NA
8-14 days	5	4	80%	37.6%-96.4%	3	60%	23.1%-88.2%	5	100%	64.9%-100%
≥15 days	8	8	100%	74.7%-100%	6	75%	40.9%-92.9%	8	100%	74.7%-100%

Table 6. IgG/IgM NPA for the Assure COVID-19 IgG/IgM Rapid Test Device

(Site 1+2+3)	# PCR Negative	IgG (Assure Device)			IgM (Assure Device)		
		Antibody Negative	NPA	95%CI	Antibody Negative	NPA	95%CI
Combined Sites	113	113	100%	97.7% -100%	113	100%	97.7%-100%

Site 1	**IgG**			**IgM**			**IgG/IgM**		
# PCR negative	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**
20	20	100%	88.1%-100%	20	100%	88.1%-100%	20	100%	88.1%-100%
Site 2	**IgG**			**IgM**			**IgG/IgM**		
# PCR negative	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**
53	53	100%	95.1%-100%	53	100%	95.1%-100%	53	100%	95.1%-100%
Site 3	IgG			IgM			IgG/IgM		
# PCR negative	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**	**Antibody negative**	**NPA**	**95% CI**
40	40	100%	93.7%-100%	40	100%	93.7%-100%	40	100%	93.7%-100%

The NPA/specificity of the Assure COVID-19 IgG/IgM Rapid Test Device for IgG/IgM in fingerstick whole blood samples is 100%.

Cross Reactivity

There was no cross-reactivity with plasma specimens meeting the disease state shown below. No IgM or IgG false positive results were observed with the following potential cross-reactants:

Table 7. Cross-reactivity Study Data of Assure COVID-19 IgG/IgM Rapid Test Device

Conditions	Number of samples	Conditions	Number of samples
Anti-HAV IgM +	5	Lyme disease+	5
Anti-HEV IgG +	2	P. falciparum +	5
HBsAg +	5	P. vivax +	5
Anti-HCV +	5	Toxoplasma IgM +	5
Anti-HIV +	5	HAMA +	1
Anti-Rubella IgM +	5	RF +	5
Anti-CMV IgM +	5	ANA+	5
Anti-HSV-I IgM +	5	Anti-Influenza A IgM +	3
Anti-HSV-II IgM +	5	Anti-Influenza B IgM +	1
EBV IgM +	4	Anti-RSV IgM +	3
Anti-Dengue IgM +	5	Legionella pneumophila IgM+	2
Anti-Yellow fever +	5	Anti-Adenovirus IgM +	1
Anti-Zika IgG +	5	Anti-Mycoplasma pneumonia IgM +	3
Chagas Ab+	5	Anti-Chlamydia pneumonia IgM +	3
Anti-Syphilis IgG +	4	Anti-Chlamydia pneumonia IgG +	2
Anti-Tuberculosis +	5	Measles IgG +	1
Typhoid IgM +	5	Mumps IgG +	1

Interfering Substances

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

Table 8. Interference Study Data of Assure COVID-19 IgG/IgM Rapid Test Device

Interfering substances	Concentration of analyate
Blood analytes	
Albumin	5 g/dL
Anticoagulants	
EDTA (sodium salt)	3.4 µmol/L
Heparin	3000 U/L
Sodium citrate	5 mg/mL
Potassium oxalate	2 mg/mL
Abnormal blood sample	
Visual hemolysis (Hemoglobin)	20 g/dL
Icteric (Bilirubin)	5 mg/dL
Lipemic (Triglycerides)	500 mg/dL
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. Forni, D., Cagliani, R., Clerici, M. &Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2. 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).

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	②	Do not reuse

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

Serology Test Evaluation Report for “FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test” from Assure Tech. (Hangzhou) Co., Ltd.

June 17, 2020

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1 Introduction

The FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test from Assure Tech. (Hangzhou) Co., Ltd. was tested on 2020-06-10 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). Tests were from lot number I2003183. The FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test is intended to qualitatively detect IgM and IgG separately.

1.1 Panel composition

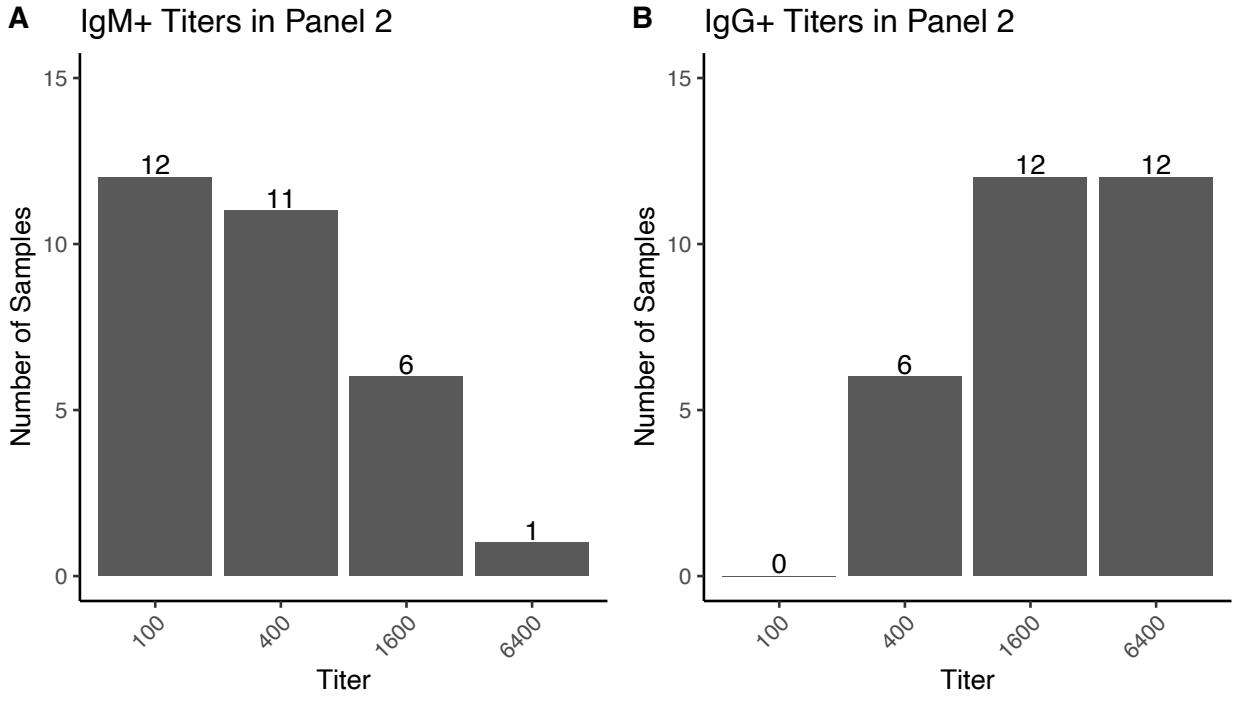

Figure 1: Titer levels for (A) IgM+ and (B) IgG+ samples according to the CDC SARS-CoV-2 Spike antigen assay

The test was evaluated against “Panel 2,” which includes frozen SARS-CoV-2 antibody-positive serum samples ($n = 30$) and frozen antibody-negative serum and plasma samples ($n = 80$). The panel size and composition were chosen to enable a laboratory-based evaluation and to provide reasonable estimates and confidence intervals for test performance in the context of limited sample availability. The sample size is comparable to that of a typical sample size used to support Emergency Use Authorization (EUA) by FDA for tests of this type.

1.1.1 Positive samples

Positive samples used in Panel 2 were from patients previously confirmed to have SARS-CoV-2 infection with a nucleic acid amplification test (NAAT). Time between symptom onset, NAAT testing, and sample collection is not known for all samples. Both SARS-CoV-2 IgM and IgG antibodies are present in all Panel 2 positive samples. The Centers for Disease Control and Prevention (CDC) detected the presence of IgG and IgM antibodies at their laboratory using their SARS-CoV-2 spike enzyme-linked immunosorbent assay (ELISA) tests.[1] The presence of antibodies was confirmed at FNLCR using CDC's developed ELISAs (Pan-Ig, IgG, and IgM) as well as an IgG Receptor Binding Domain (RBD) ELISA developed by the Krammer Laboratory at the Icahn School of Medicine at Mount Sinai.[2] The positive samples selected may not reflect the distribution of antibody levels in patient populations that would be evaluated by such a test. Because all samples are positive for both IgM and IgG, this evaluation cannot verify that tests intended to detect IgM and IgG antibodies separately detect these antibodies independently.

Positive samples were assessed at dilutions of 1:100, 1:400, 1:1600, and 1:6400 by CDC on their Pan-Ig assay, their IgM assay, and their IgG assay. Some samples were run at additional dilutions. Any samples that were positive at a dilution greater than 1:6400 were assigned a titer of 6400 because 1:6400 was the highest dilution at which all Panel 2 positive samples were assessed.

1.1.2 Negative samples

All Panel 2 negative samples were collected prior to 2020, before the SARS-CoV-2 virus is known to have circulated in the United States. Panel 2 groups include:

- "Negatives" ($n = 70$): selected without regard for clinical status. This group includes a sample, C0063, that showed reactivity in the Pan-Ig CDC spike ELISA at FNLCR.
- "HIV+" ($n = 10$): selected from banked serum from HIV+ patients.[3] This group includes 3 samples, C0018, C0155, and C0182, that showed reactivity in the IgG RBD ELISA at FNLCR.

All Panel 2 negative samples were assessed at dilutions of 1:100 and 1:400 by CDC on their Pan-Ig assay. A subset of samples was assessed in parallel at additional dilutions and on the CDC IgM and IgG assays. All Panel 2 negative samples were negative at a dilution of 1:100 on the CDC Pan-Ig assay. These samples were assigned an undetectable titer (represented as zero (0) in the line data) for the Pan-Ig assay, the IgM assay, and the IgG assay.

[1] See `https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html`, which notes "CDC's serologic test is designed and validated for broad-based surveillance and research that will give us information needed to guide the response to the pandemic and protect the public's health. The test is not currently designed to test individuals who want to know if they have been previously infected with COVID-19."

[2] An implementation of this test, the COVID-19 ELISA IgG Antibody Test, has been granted an EUA authorization by FDA for use at the Mount Sinai Laboratory (MSL), Center for Clinical Laboratories, a division of the Department of Pathology, Molecular, and Cell-Based Medicine, New York, NY. See `https://www.fda.gov/media/137029/download`.

[3] HIV+ samples were deemed appropriate for inclusion in the panel: (1) to increase the sample size and reduce the confidence interval; and (2) to identify any possibility of cross-reactivity with HIV+ samples. It is anticipated that other types of samples, as they become available, may also be evaluated in any future analyses.

1.2 Analysis

Samples used in this evaluation were not randomly selected, and sensitivity (PPA) and specificity (NPA) estimates in this report may not be indicative of the real-world performance of the Assure Tech. (Hangzhou) Co., Ltd. FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test. Sensitivity and specificity were calculated for each antibody (e.g., IgM, IgG, IgA, and Pan-Ig, as applicable) separately. In addition, sensitivity and specificity were estimated in a combined manner, where a positive result for any antibody the Assure Tech. (Hangzhou) Co., Ltd. FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test is intended to detect was considered as a positive test result and a negative result meant that a sample tested negative for all antibodies the Assure Tech. (Hangzhou) Co., Ltd. FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test is intended to detect. Positive and negative predictive values were calculated for combined sensitivity and specificity assuming a prevalence of 5%. Cross-reactivity with HIV+ was evaluated, and results are presented separately. If cross-reactivity was detected, the samples with HIV+ were not included in calculations of specificity.

Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).[4] Confidence intervals for PPV and NPV were calculated using the values from the 95% confidence intervals for sensitivity and specificity. For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody negative samples with HIV was statistically higher than the false positive rate among antibody negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman.[5])

1.3 Important caveats

Sensitivity and specificity estimates in this report may not be indicative of the real world performance of the Assure Tech. (Hangzhou) Co., Ltd. FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test.

These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.

Information about anticoagulants used is not known.

The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

[4] CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008. See `https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31791`.

[5] Statistics with Confidence: Confidence Intervals and Statistical Guidelines. (2013). Wiley.

1.4 Notes about the evaluation procedure

- The Assure Tech. (Hangzhou) Co., Ltd. FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test was used per the manufacturer's package insert.
- Devices were tested within any expiration dates provided.
- Devices were not obviously defective / compromised.
- Devices were stored at FNLCR within their labeled conditions.
- A single operator conducted and read the test.
- The personnel who performed the testing were blinded to the identity / code of the sample and the expected results.
- The testing was performed in a non-clinical laboratory environment.
- Negative and positive samples were ordered randomly and then tested serially.
- The operator trained on the FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test with positive and negative controls prior to testing.

1.5 Additional notes, anomalies, and clarifications

FNLCR provided the following additional information:

A few buffer bottles had debris and were excluded from testing.

2 Results

Table 1: Summary Results

	Comparator Method			Collected pre-2020		
	Antibody Positive			Antibody Negative		
FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
IgM+, IgG+	27					27
IgM+, IgG-	3			1		4
IgM-, IgG+						
IgM-, IgG-				69	10	79
Total	30			70	10	110

Table 2: Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7%; 100%)
IgM Specificity	98.8% (79/80)	(93.3%; 99.8%)
IgG Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgG Specificity	100% (80/80)	(95.4%; 100%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined PPV for prevalence = 5.0%	80.8%	(40.9%; 96%)
Combined NPV for prevalence = 5.0%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

3 Line Data

In the table below, “Days” refers to “Days from symptom onset to blood collection.”

Table 3: Line Data

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
1	Negative	Negative				Pass	C0004	Plasma	0	0	0		Negative
2	Negative	Negative				Pass	C0005	Plasma	0	0	0		Negative
3	Negative	Negative				Pass	D0007	Plasma	0	0	0		Negative
4	Negative	Negative				Pass	D0011	Serum	0	0	0		Negative
5	Positive	Positive				Pass	D0012	Serum	6400	100	6400	28	Positive
6	Negative	Negative				Pass	C0155	Plasma	0	0	0		HIV+
7	Negative	Negative				Pass	D0015	Plasma	0	0	0		Negative
8	Positive	Positive				Pass	C0031	Serum	1600	400	6400	21	Positive
9	Negative	Negative				Pass	C0019	Plasma	0	0	0		Negative
10	Positive	Positive				Pass	D0020	Serum	1600	400	6400	42	Positive
11	Negative	Negative				Pass	C0089	Plasma	0	0	0		HIV+
12	Positive	Positive				Pass	D0022	Serum	400	100	1600	46	Positive
13	Positive	Negative				Pass	C0049	Serum	400	400	400	23	Positive
14	Negative	Negative				Pass	D0027	Serum	0	0	0		Negative
15	Positive	Positive				Pass	D0028	Serum	6400	400	6400	32	Positive
16	Negative	Negative				Pass	C0032	Plasma	0	0	0		Negative
17	Negative	Negative				Pass	D0034	Serum	0	0	0		Negative
18	Negative	Negative				Pass	C0099	Plasma	0	0	0		HIV+
19	Negative	Negative				Pass	C0041	Plasma	0	0	0		Negative
20	Negative	Negative				Pass	C0008	Plasma	0	0	0		Negative

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
21	Negative	Negative				Pass	C0051	Plasma	0	0	0		Negative
22	Negative	Negative				Pass	C0018	Plasma	0	0	0		HIV+
23	Negative	Negative				Pass	D0047	Serum	0	0	0		Negative
24	Negative	Negative				Pass	D0049	Plasma	0	0	0		Negative
25	Negative	Negative				Pass	C0185	Plasma	0	0	0		Negative
26	Positive	Positive				Pass	C0172	Serum	1600	400	1600	19	Positive
27	Negative	Negative				Pass	C0093	Plasma	0	0	0		HIV+
28	Positive	Positive				Pass	C0053	Serum	1600	1600	1600	28	Positive
29	Negative	Negative				Pass	D0056	Plasma	0	0	0		Negative
30	Negative	Negative				Pass	D0058	Serum	0	0	0		Negative
31	Negative	Negative				Pass	C0059	Plasma	0	0	0		Negative
32	Positive	Positive				Pass	C0145	Serum	6400	1600	6400	17	Positive
33	Negative	Negative				Pass	D0064	Plasma	0	0	0		Negative
34	Negative	Negative				Pass	C0065	Plasma	0	0	0		Negative
35	Negative	Negative				Pass	C0075	Plasma	0	0	0		Negative
36	Negative	Negative				Pass	D0073	Serum	0	0	0		Negative
37	Positive	Positive				Pass	C0153	Serum	400	100	400	31	Positive
38	Negative	Negative				Pass	C0197	Plasma	0	0	0		HIV+
39	Positive	Positive				Pass	C0144	Serum	6400	1600	6400	21	Positive
40	Negative	Negative				Pass	C0179	Plasma	0	0	0		Negative
41	Negative	Negative				Pass	D0083	Serum	0	0	0		Negative
42	Positive	Positive				Pass	D0084	Serum	1600	100	1600	41	Positive
43	Negative	Negative				Pass	D0086	Plasma	0	0	0		Negative
44	Positive	Positive				Pass	C0132	Serum	1600	1600	6400		Positive

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
45	Positive	Positive				Pass	C0064	Serum	1600	1600	6400	20	Positive
46	Negative	Negative				Pass	D0094	Serum	0	0	0		Negative
47	Positive	Negative				Pass	C0095	Plasma	0	0	0		Negative
48	Negative	Negative				Pass	D0097	Plasma	0	0	0		Negative
49	Negative	Negative				Pass	C0098	Plasma	0	0	0		Negative
50	Negative	Negative				Pass	C0063	Plasma	0	0	0		Negative
51	Negative	Negative				Pass	C0101	Plasma	0	0	0		Negative
52	Negative	Negative				Pass	C0103	Plasma	0	0	0		Negative
53	Positive	Positive				Pass	D0104	Serum	400	100	400	17	Positive
54	Negative	Negative				Pass	C0105	Plasma	0	0	0		Negative
55	Negative	Negative				Pass	C0109	Plasma	0	0	0		Negative
56	Negative	Negative				Pass	C0198	Plasma	0	0	0		Negative
57	Negative	Negative				Pass	D0115	Serum	0	0	0		Negative
58	Negative	Negative				Pass	C0117	Plasma	0	0	0		Negative
59	Negative	Negative				Pass	D0120	Serum	0	0	0		Negative
60	Negative	Negative				Pass	C0121	Plasma	0	0	0		Negative
61	Negative	Negative				Pass	D0123	Plasma	0	0	0		Negative
62	Negative	Negative				Pass	D0126	Serum	0	0	0		Negative
63	Negative	Negative				Pass	D0128	Serum	0	0	0		Negative
64	Negative	Negative				Pass	D0130	Serum	0	0	0		Negative
65	Negative	Negative				Pass	D0131	Serum	0	0	0		Negative
66	Negative	Negative				Pass	D0132	Plasma	0	0	0		Negative
67	Negative	Negative				Pass	C0133	Plasma	0	0	0		Negative
68	Negative	Negative				Pass	C0134	Plasma	0	0	0		Negative

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
69	Negative	Negative				Pass	D0135	Plasma	0	0	0		Negative
70	Negative	Negative				Pass	C0137	Plasma	0	0	0		Negative
71	Positive	Positive				Pass	C0127	Serum	400	400	1600	23	Positive
72	Negative	Negative				Pass	C0199	Plasma	0	0	0		Negative
73	Negative	Negative				Pass	C0140	Plasma	0	0	0		Negative
74	Negative	Negative				Pass	D0141	Plasma	0	0	0		Negative
75	Negative	Negative				Pass	D0142	Plasma	0	0	0		Negative
76	Negative	Negative				Pass	D0145	Plasma	0	0	0		Negative
77	Negative	Negative				Pass	C0054	Plasma	0	0	0		HIV+
78	Negative	Negative				Pass	D0148	Plasma	0	0	0		Negative
79	Positive	Negative				Pass	D0149	Serum	400	100	400	43	Positive
80	Positive	Positive				Pass	C0152	Serum	400	400	6400	24	Positive
81	Negative	Negative				Pass	D0153	Plasma	0	0	0		Negative
82	Negative	Negative				Pass	D0154	Plasma	0	0	0		Negative
83	Negative	Negative				Pass	C0156	Plasma	0	0	0		Negative
84	Negative	Negative				Pass	D0158	Serum	0	0	0		Negative
85	Positive	Negative				Pass	D0159	Serum	100	100	400	24	Positive
86	Positive	Positive				Pass	D0161	Serum	1600	100	1600	44	Positive
87	Negative	Negative				Pass	C0162	Plasma	0	0	0		Negative
88	Negative	Negative				Pass	C0026	Plasma	0	0	0		Negative
89	Negative	Negative				Pass	D0166	Plasma	0	0	0		Negative
90	Negative	Negative				Pass	C0138	Plasma	0	0	0		HIV+
91	Negative	Negative				Pass	D0169	Serum	0	0	0		Negative
92	Negative	Negative				Pass	D0170	Plasma	0	0	0		Negative

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
93	Negative	Negative				Pass	D0173	Serum	0	0	0		Negative
94	Positive	Positive				Pass	D0180	Serum	6400	400	6400	39	Positive
95	Negative	Negative				Pass	C0079	Plasma	0	0	0		Negative
96	Negative	Negative				Pass	D0184	Plasma	0	0	0		Negative
97	Positive	Positive				Pass	C0071	Serum	6400	1600	6400	20	Positive
98	Negative	Negative				Pass	D0187	Plasma	0	0	0		Negative
99	Positive	Positive				Pass	D0188	Serum	400	400	1600	24	Positive
100	Negative	Negative				Pass	C0193	Plasma	0	0	0		Negative
101	Negative	Negative				Pass	C0150	Plasma	0	0	0		HIV+
102	Negative	Negative				Pass	C0182	Plasma	0	0	0		HIV+
103	Negative	Negative				Pass	C0196	Plasma	0	0	0		Negative
104	Positive	Positive				Pass	C0187	Serum	6400	6400	6400	29	Positive
105	Positive	Positive				Pass	C0080	Serum	1600	400	1600	29	Positive
106	Positive	Positive				Pass	D0201	Serum	100	100	400	33	Positive
107	Positive	Positive				Pass	D0205	Serum	400	400	1600	26	Positive
108	Positive	Positive				Pass	D0206	Serum	1600	100	1600	25	Positive
109	Positive	Positive				Pass	D0208	Serum	400	100	1600	22	Positive
110	Positive	Positive				Pass	D0210	Serum	1600	100	1600	26	Positive