SARS-CoV-19 Assure (Ecotest) 15-Minute Rapid ANTIBODY Test Cassette

Frequently Asked Questions (FAQ)

- *What are IgG and IgM?*

Immunoglobulins are antibodies themselves and are part of our immune system. When we get an infection, such as COVID-19, immunoglobulins are produced, which attach to the virus and activate the rest of the immune system to attack and clear the virus. IgM is the first immunoglobulin to be produced and is a general antibody that can bind to many different types of pathogen. The presence of IgM is an indicator of early infection. IgG is a more specialized antibody that specifically binds to the SARS-CoV-2 virus. The presence of IgG is an indicator of later stage infection (usually 5-7 days or longer after infection).

- *Is the test specific for COVID-19?*

The IgG that the test detects is specific to COVID-19 antibodies, so a positive result with a positive IgM is a presumptive diagnosis of Covid-19 infection and definitive testing is required. IgM is a more generalized antibody, but there is some specificity for Sars-Cov-2, but not as strong as IgG.

- *What samples can I use?*

The test cassette will work with whole blood, plasma, or serum. Capillary blood is the easiest to obtain via a finger pinprick, however, venous blood obtained via venipuncture is also suitable.

- *What do the results mean?*

The test strip has 3 different lines; one for IgG, one for IgM and one control line. There are four different valid results:

IgM + Control - The sample is positive for IgM. This means the patient is in the early stages of an infection and combined with the common symptoms, is suspect to be impending positivity for COVID-19

IgG + IgM + Control - The sample is positive for both IgG and IgM and therefore has a presumptive diagnosis for COVID-19

*Control only - The sample is negative. Must turn from **BLUE** to **RED**.*

If the control line does not change to a FULL red line, the test is void and should be repeated, irrespective of how many test lines are visible.

- *I did not read the results after 20 minutes. What should I do?*

For the result, the window of accuracy is 15-20 minutes, after you add the buffer solution to the blood sample. If you forget to read the results after this time, the test results are erroneous, and you should repeat it.

- *How should I store the tests?*

The recommended storage temperature is 2-30°C, however, we do not recommend you store them in the fridge, unless there is a risk of them overheating. ***Do not freeze the test cassettes or buffer solution****. Tests should be performed at room temperature (2 - 30°C), so if you have stored tests in the fridge, you should allow them to reach room temperature before performing a test.*

- *How accurate is the test?* ***FDA data listed below from the authorization.***

Assure Tech. Assure COVID-19 IgG/IgM Rapid Test Device

Developer: Assure Tech. (Hangzhou Co., Ltd)
Test: Assure COVID-19 IgG/IgM Rapid Test Device
Technology: Lateral Flow
Target: Spike and Nucleocapsid

Antibody	Performance Measure	Estimate of Performance	95% 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 at prevalence = 5%	81.4%	(40.9%; 96.0%)
Combined	NPV at prevalence = 5%	100%	(99.4%; 100%)

- *Can babies and young children be tested?*

Yes, there are no issues with testing babies and young children.

- *Is there anyone that should not be tested?*

No, the more people that are tested, the better it will be to understand the spread of the virus, which will result in better measures being taken to prevent its spread

However, as the test requires a blood sample, anyone who is immunocompromised, has a blood condition, or any abnormal health condition should be evaluated by a healthcare professional before performing a test.

- *What should I do if I test positive?*

If you test positive, you should follow your local health departments guidance on COVID-19 infection. This means PCR or antigen testing, along with at least quarantine for 7 days or more, avoiding contact with others and remaining hydrated; all at the instruction of your healthcare provider.

- *What if I test negative?*

A negative result means the biomarkers are not present in your blood, but you should still exercise caution, as you may still be in the early stages of infection (before IgM and/or IgG levels rise to a detectable level). If symptoms develop, follow the protocols as above and retest, as guided by your healthcare provider. If symptoms do not develop, it is potentially unlikely you have COVID-19 but should still follow strict hygiene procedures and your health providers guidance. Ensure you wash your hands regularly, avoid social gatherings and work from home if possible.

- *What if I test positive but do not display any symptoms?*

In this case, there are two options. Either you are infected and may begin to display symptoms in the next few days, or you are infected but are asymptomatic (you will not display symptoms). In both cases, you should treat it as though you are positive for the virus and should follow the appropriate healthcare guidelines. Speak to your healthcare practitioner for further advice.

- *So, can the test detect asymptomatic patients?*

Yes, as the test will be able to detect IgM / IgG in asymptomatic people, as they will have or have had an immune response even though they do not display symptoms. The timeline of infection will be the same as someone displaying symptoms.

- *What if I test negative but display symptoms?*

If you have the common symptoms of COVID-19, it is possible you have contracted the infection and should BOTH contact your health provider and self-isolate. It is likely your IgG/IgM levels have not risen to a detectable level yet. Speak to your healthcare practitioner for further advice.

- *What is the shelf-life of the test cassette? Is there a lot number on the package?*

The shelf-life is 24 months from the date of manufacture. The product expiry and the lot number are both printed onto the packaging for reference. Do not use after the expiry date. The lot number is used for traceability.

- *Do any medications, drugs or other proteins in the blood affect the test result?*

To date we have tested numerous common pharmaceuticals, none of which have interfered with the test. Also, Rheumatoid Factor and HIV does not interfere with the test, hence we currently see no cross-reactivity issues. We are looking at more drugs and will update customers accordingly.

- *Will IgG and IgM remain in the blood after I have recovered from COVID-19?*

There is evidence that IgG/IgM remains in the blood after recovery to potentially prevent reinfection. We have tested some patients and noticed that they still test positive for at over 33 days after first displaying symptoms. You may not be infectious after you recover, but even if you test positive, but you should still be cautious as long-term immunity has not yet been confirmed and reinfection may still occur.

- *Can pregnant or breast-feeding women be tested?*

Yes, there is no harm to the mother or baby when performing a test.

- *Is the test CE marked and FDA* Authorized via the EUA*?*

  Yes, the COVID-19 test is CE marked.

  Yes, the COVID-19 test is FDA authorized under the EUA.

- *What is CLIA?*

  The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program.

  The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

- *Is the test CLIA waived? If not, what are the requirements for the test?*

  No, the Assure COVID-19 test is NOT CLIA waived.

  The test is required to be facilitated by CLIA certified Personnel, trained to administer moderate to high complexity tests.

Important Documents to follow on further pages of this FAQ

1. *EUA Letter of authorization (**Issued 7/5/2020**)*
2. *Fact sheet for Healthcare Providers*
3. *Fact sheet for Recipients*
4. *Instructions for Use for the Assure Tech Test*

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,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

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

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of SARS-CoV-2 Antibody Tests During the COVID-19 Pandemic

April 28, 2020

Coronavirus Disease 2019 (COVID-19)

This General Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of certain SARS-CoV-2 Antibody Tests. For a list of the tests being referenced in this Fact Sheet, see https://www.fda.gov/media/137471/download

A number of SARS-CoV-2 Antibody Tests are authorized for the detection of antibodies to SARS-CoV-2 in human serum and/or plasma.

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 plasma or serum specimens.

All individuals whose specimens are tested with one of these tests will receive the Fact Sheet for Recipients: Emergency Use of SARS-CoV-2 Antibody Tests.

What are the symptoms of COVID-19?
Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, fever, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which poses risks to public health. Please check the CDC webpage for the most up-to-date information.

What do I need to know about COVID-19 antibody 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).

- SARS-CoV-2 Antibody Tests can be ordered by healthcare providers to test human plasma or serum to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- SARS-CoV-2 Antibody Tests 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.
- SARS-CoV-2 Antibody Tests are authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.
- Please refer to the test-specific instructions for use for additional information.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 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).

There are no approved available alternative tests. FDA has issued EUAs for other antibody tests that can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of SARS-CoV-2 Antibody Tests During the COVID-19 Pandemic

April 28, 2020

Coronavirus Disease 2019 (COVID-19)

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.***

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

The SARS-CoV-2 antibody test 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 a final diagnosis and patient management decisions.

All laboratories using this test must follow standard confirmatory 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, not all 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 the SARS-CoV-2 antibody test is unknown.

Risks to a patient of a false negative result include: restriction of activities 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 (U.S.) FDA has made these tests 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.

The EUA for the test you received 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).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
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 recipient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Manufacturer Contact Information:

Contact information for the manufacturer that developed the SARS-CoV-2 antibody test must be provided to the Authorized Laboratories performing the test and to healthcare providers receiving this fact sheet.

FACT SHEET FOR RECIPIENTS

Assure COVID-19 IgG/IgM Rapid Test Device - Assure Tech. (Hangzhou Co., Ltd)

July 6, 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.

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.

- **For the most up to date information on COVID19 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.
The virus, which can cause mild to severe respiratory illness has spread globally, including the United States.
The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

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 this test?
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 blood collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help you and 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 had recent or prior COVID-19 infection and that you have developed an antibody response to the virus. Your 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 the small possibility 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

- **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 RECIPIENTS

Assure COVID-19 IgG/IgM Rapid Test Device - Assure Tech. (Hangzhou Co., Ltd)

July 6, 2020

Coronavirus Disease 2019 (COVID-19)

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.

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. 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 available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other antibody tests that can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

- **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.

Assure COVID-19 IgG/IgM Rapid Test Device

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

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 or plasma (sodium EDTA). 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.
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

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

PRINCIPLE

The 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
- Sterile safety lancet
- Negative control
- Buffer
- Package insert
- Alcohol Prep pad
- Positive control

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°C.

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 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 false negative test results.
- 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.

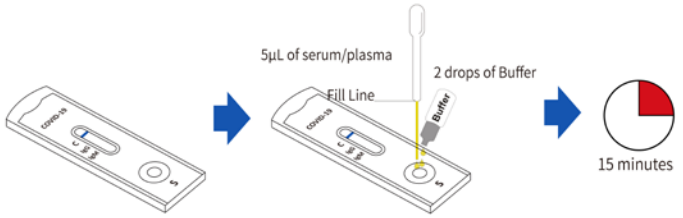
TEST PROCEDURE

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.

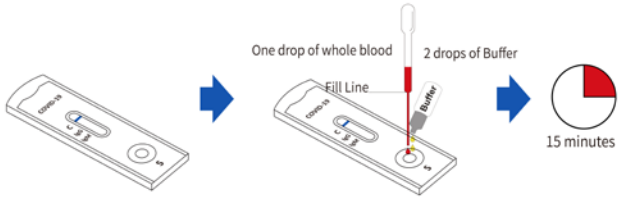
For Serum or Plasma Specimens

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



For Venous Whole Blood 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.



RESULT INTERPRETATION

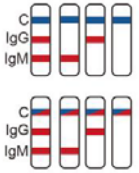
For Assure COVID-19 IgG/IgM Test:

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

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

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

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 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 Assure COVID-19 IgG/IgM Rapid Test Device is not validated for finger stick blood.
4. 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.
5. Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the results after 20 minutes.
6. 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 SARS-CoV-2.
7. In the early onset of symptom, anti-SARS-Cov-2 IgM and IgG antibody concentrations may be below detectable levels.
8. 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.
9. Results from immunosuppressed patients should be interpreted with caution.
10. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
11. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions, IgM 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. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings.
12. 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.
13. 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.
14. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
15. 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 the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required 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.

*The Letter of Authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests" as "authorized laboratories".

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 sensitivity and specificity results are summarized in following tables.

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

Site	Days post symptom onset	# PCR Positive at any time	Assure COVID-19 IgG/IgM Rapid Test Device		
			#Positive Results	PPA	95%CI
(Site 1+3+4) Serum	≤7	8	7	87.5%	52.9%-97.8%
	8-14	15	13	86.7%	62.1%-96.3%
	≥15	25	25	100%	86.7%-100%
(Site 2) Venous Whole Blood	≤7	1	1	100%	20.7%-100%
	8-14	3	3	100%	43.9%-100%
	≥15	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	-	61	58	95.1%	86.5%-98.3%

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

Site	# PCR Negative	Assure COVID-19 IgG/IgM Rapid Test Device		
		#Negative Results	NPA	95%CI
(Site 1+3+4) Serum	96	96	100%	96.2%-100%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	105	100%	96.5%-100%

Table 3. IgM PPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Site	Days post symptom onset	# PCR Positive at any time	Assure COVID-19 IgG/IgM Rapid Test Device		
			#Positive Results	PPA	95%CI
(Site 1+3+4) Serum	≤7	8	8	100%	67.6%-100%
	8-14	15	13	86.7%	62.1%-96.3%
	≥15	25	21	84%	65.3%-93.6%
(Site 2) Venous Whole Blood	≤7	1	1	100%	20.7%-100%
	8-14	3	3	100%	43.9%-100%
	≥15	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	-	61	55	90.2%	80.2%-95.4%

Table 4. IgM NPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Site	# PCR Negative	Assure COVID-19 IgG/IgM Rapid Test Device		
		#Negative Results	NPA	95%CI
(Site 1+3+4) Serum	96	94	97.9%	92.7%-99.4%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	103	98.1%	93.3%-99.5%

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 5 and 6 below.

Table 5. 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 6. 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	----------

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 7. Interference Study Data of Assure COVID-19 IgG/IgM Rapid Test Device@diareagent.com

Interfering substances	Concentration of analyate
Blood analytes	
Albumin	5 g/dL
Anticoagulants	
EDTA (sodium salt)	3.4 µmol/L
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

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GLOSSARY OF SYMBOLS

ρ	Catalog number	ϐ	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	*In vitro* diagnostic medical device	ε	Use by
μ	Manufacturer	σ	Do not reuse

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