Covid-19 Ten Minute Rapid Test

DxAllergy through its national reach and established provider network of more than 200 clinics, has vetted and established distribution and supply chain aggreements with a select number of US based manufacturers that produce the Covid-19 IgG/ IgM 10 minute rapid test. Accordingly, we have preferred access to weekly/ monthly production allotments in order to meet demand. The identitiy of these manufacturers is protected under strict non disclosure and confidentiality agreements. Partner labs selected were required meet the following criteria:

The test has been FDA registered – carries a CE mark - passed review by FEMA and cleared for distribution under the FDA EUA – Made in the USA

HOW THE TEST WORKS

In response to the global pandemic caused by 2019n-CoV (COVID19), DxAllergy now offers the Covid 19 IgG/ IgM rapid Test. COVID19 IgG/IgM Test Cassette was developed as a 10-minute simple field test using a lateral flow immunoassay that will allow field personnel with minimal training to perform. The test detects the presence of IgG and IgM antibodies specific to 2019n-CoV (detected in China in 2019) generally available in whole blood/serum/plasma after infection by 2019n-CoV.

The COVID19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based, lateral flow immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component.

In the IgG component, anti-human IgG is coated in the IgG test line region on the membrane. During testing, when the specimen is added to the test cassette, it reacts with 2019-nCoV antigen-coated particles inside the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG coated in the IgG test line region. If the specimen contains IgG antibodies to 2019-nCoV, a complex will be formed resulting in a colored line that will appear in the IgG test line region. Similarly, anti-human IgM is coated in the IgM test line region and if the specimen contains IgM antibodies to 2019-nCoV, the conjugate-specimen complex reacts with anti-human IgM on the membrane. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred, and the test has been activated correctly.

IMPORTANT

- This test has not been reviewed by the public health FDA in the United States.
- This test is **not** for the screening of donated blood
- This test is for research and **emergency use authorization** only during the COVID-19 pandemic

INTENDED USE

COVID-19 IgG/IgM Rapid Test Cassette is intended to be used in conjunction with other test and/or clinical and epidemiological information:

- For the in vitro qualitative detection of IgM and IgG antibodies specific to 2019n-CoV (detected in China in 2019) in whole blood/serum/plasma collected directly from symptomatic patients. The test **may** cross-react with other viruses not tested for.
- For the presumptive identification of viral infections in patients who may be infected with 2019nCoV (detected in China in 2019) in conjunction with clinical and epidemiological risk factors. The test **may** cross-react with other viruses not tested for.
- To provide **epidemiologic information** for surveillance of 2019n-CoV (detected in China in 2019)
- For identification of individuals who may have developed immunity to the virus. IgM antibodies tends to indicate a recent exposure to SARS-CoV-2, whereas detection of COVID-19 IgG antibodies indicates virus exposure some time ago*.

NOTE: The USFDA updated their guidance, issued on March 16, 2020, to allow the distribution of this product for diagnostic use in laboratories or by public health care workers at point-of-care facilities. The updated policy can be viewed by clicking here.

All test results are presumptive and should be confirmed by an approved molecular assay. A presumptive negative test does not preclude 2019n-CoV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, a presumptive positive result does not rule out infections caused by other viruses.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PROCEDURE

SPECIMEN COLLECTION AND PREPARATION FOR TESTING

The COVID19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or finger prick), serum or plasma.

To collect Finger Prick Whole Blood Specimens (when ready to perform the test):

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Remove the cap of the lancet by twisting. Place the lancet over the finger and push down to puncture the skin. Wipe away the first sign of blood.
- Gently rub the hand from the wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the blood from the finger using the dropper provide or by using a capillary tube.
- Transfer the blood specimen to the sample well on the test device

To collect Whole Blood using Venipuncture and preparation of Serum and Plasma:

- Collect blood using the general guidelines for venipuncture.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing Preparation

- Testing should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/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 2 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by finger prick should be tested immediately.
- Bring specimens to room temperature prior to testings. Frozen specimens must be completely thawed and mixed well prior to testings. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations.
- EDTA K2, Heparin sodium, Citrate sodium, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

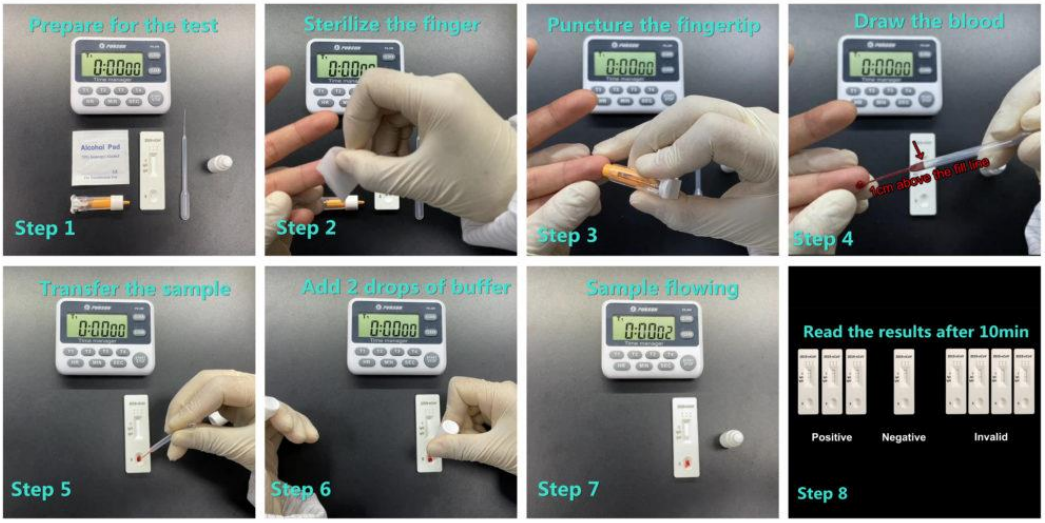
RUNNING THE TEST

For **Finger prick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically over the finger, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20µL) of a specimen to the sample well(**S**). Then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer **approximately 20µL of finger prick whole blood specimen** to the specimen well (**S**) of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See the illustration below.

Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of 2019-nCoV (COVID19) antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the IgG region and IgM region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to 2019-nCoV in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCoV can be determined by this qualitative test.
- The COVID-19 IgG/IgM Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to 2019-nCoV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCoV infections.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection.
- The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
- The test kits will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

PERFORMANCE CHARACTERISTICS

The clinical performance of the "*COVID19 IgG/IgM Test Cassette*" was evaluated in Shanghai, China with clinical samples derived from blood samples collected from 2019n-CoV infectious patients and 2019n-CoV non-infectious patients confirmed by PCR.

The study included testing of 64 known positive samples and 294 known negative samples.

The data are illustrated in the table below.

Method		**PCR + Clinical Diagnosis**	
COVID-19 IgG/IgM Rapid Test	Results	**Positive**	**Negative**
	Positive IgM	1	11
	Positive IgG+IgM	33	
	Positive IgG	28	
	Negative IgG + IgM	2	283
Total Result		64	294

- Relative Sensitivity: (1+33+28)/(1+33+28+2)X100% = 96.9% (95%CI*:88.7%-99.8%)
- Relative Specificity: 283/(283+11)X100% = 96.3% (95%CI*:93.4%-98.0%)
- Accuracy: (1+33+28+283)/(1+33+28+2+283+11)X100% = 96.4% (95%CI*:93.87%-97.9%)

*Confidence Interval

Cross-reactivity

The "*CO-VID19 IgG/IgM Rapid Test Cassette*" (Whole Blood/Serum/Plasma) has been tested against anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

- Triglyceride: 50 mg/dL - Ascorbic Acid: 20mg/dL - Hemoglobin 1000mg/dL - Bilirubin: 60mg/dL - Total cholesterol : 6mmol/L

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