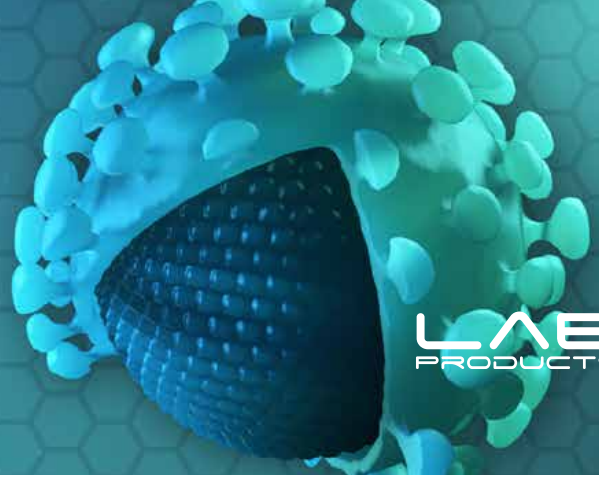
CORONAVIRUS
COVID-19
IgG And IgM Rapid Test



LAB X PRODUCTS

COVID-19 IgG/IgM Rapid Test Cassette – FDA Emergency Use Authorized

The U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) to the COVID-19 IgG and IgM rapid test manufactured by Hangzhou Biotest Biotech, Co., Ltd. used for the qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in whole blood, serum, or plasma. The product includes a complete testing kit that produces results in 10 minutes.

The FDA's decision to grant Biotest's product EUA is great news for communities across the U.S. by supporting an additional option for testing for past COVID-19 exposure. COVID-19 (Coronavirus Disease) is the infectious disease caused by the most recently discovered Coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December of 2019.

- Kit Contents include test cassette, buffer solution, disposable capillary, and package insert

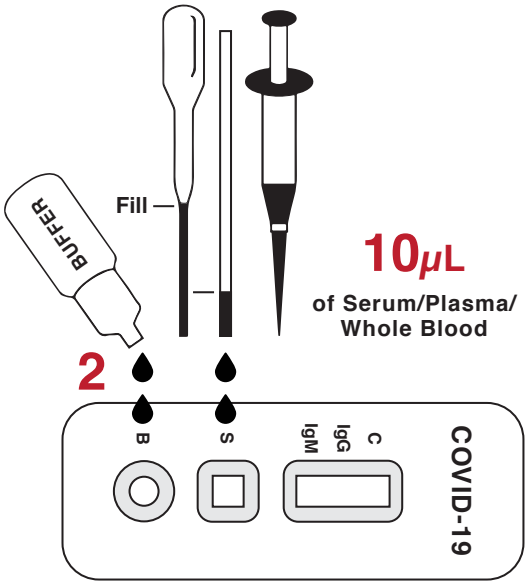
What is an EUA?

The United States 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 FDA-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.

Instructions For Use:
Allow the test cassette, 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 cassette from the sealed pouch and use it within one hour.

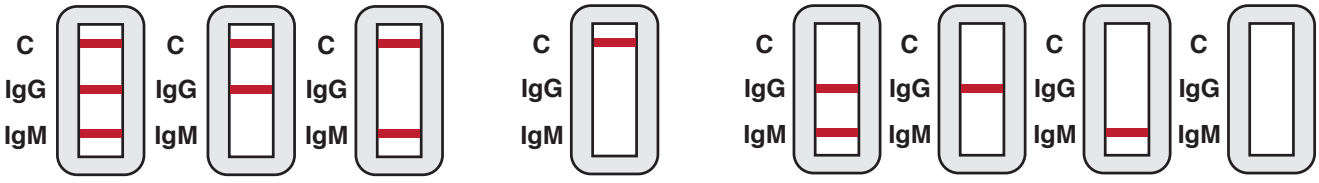
2. Place the test cassette on a clean and level surface. For Serum, Plasma, or Whole Blood Specimens:



Dropper Procedure: Hold the dropper vertically, draw the specimen up to the Fill Line **(approximately 10µl)**, and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer **(approximately 80µl)** to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.

Micropipette Procedure: Pipette and dispense **(10µl)** of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer **(approximately 80µl)** to the buffer well (B) and start the timer.

3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. **Do not** interpret the result after **20 minutes**.



Interpretation of Results:
(Please refer to the illustration above)
IgG and IgM Positive: Three lines appear. One colored line should be in the control line region (C), and two-colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.
IgG Positive: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.
IgM Positive: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.
***Note:** The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
Negative: One colored line should be in the control line region (C). No line appears in IgG and IgM test region(s).
Invalid: Control line fails to appear. Insufficient 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 cassette.

EUA Authorized Serology Test Performance

The COVID-19 IgG/IgM Rapid Test Cassette manufactured by Hangzhou Biotest Biotech is confirmed by the National Cancer Institute to have specificity and sensitivity exceeding FDA requirements (95% Confidence Interval).

Developer: Hangzhou Biotest Biotech
Test: RightSign COVID-19 IgG/IgM Rapid Test Cassette
Technology: Lateral Flow
Target: Spike

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgM	Sensitivity	100% (30/30)	(88.7%; 100%)
IgM	Specificity	100% (80/80)	(95.4%; 100%)
IgG	Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
IgG	Specificity	100% (80/80)	(95.4%; 100%)
Combined	Sensitivity	100% (30/30)	(88.7%; 100%)
Combined	Specificity	100% (80/80)	(95.4%; 100%)
Combined	PPV at prevalence = 5%	100%	(50.5%; 100%)
Combined	NPV at prevalence = 5%	100%	(99.4%; 100%)

Source: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance

John Hopkins University - Cross-Reactivity Evaluation

The robust performance of this immunoassay is supported by additional screening done at John Hopkins University. The study illustrates that 50 patient samples showed no false positives from other strains of coronavirus, specifically: Adenovirus, Coronavirus (229E, NL63, OC43, HKU1), Metapneumovirus, Influenza A H1N1, Rhinovirus, Enterovirus, Parainfluenza 4, and RSVB. The specificity was 100% (95% CI 97, 100) for both the IgG and IgM tests. Additionally, no challenge samples from individuals known to be infected by other coronaviruses was reactive by this assay. Through the study, no sample evaluated to date has generated a false positive result by the Hangzhou Biotest Biotech RightSign COVID-19 IgG/IgM Rapid Test Cassette.

Statements And Conditions:

- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has not been FDA cleared or approved;
- 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 diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(l) of the Act, 21 U.S.C. § 360bbb-3(b)(l), unless the authorization is terminated or revoked sooner.
- This product is not for home use (Emergency Use Authorization – In Vitro Diagnostic Use Only)
- Not for screening of donated blood

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