SARS-CoV-2 AB IgG/IgM Rapid Test Cassette S/P/W Frequently Asked Questions (FAQ)

Q: Is the test FDA approved ?

A: This test has not been FDA cleared or approved, but has been authorized for emergency use 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
The emergency use of 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Q: What type of blood sample can be used to perform this test ?

A: You may use the following type of samples, human serum, plasma (K2-EDTA, sodium heparin and sodium citrate) and venous whole blood (K2-EDTA, sodium heparin and sodium citrate), to perform this test.

Q: How does the test work ?

A: The ACON SARS-CoV-2 IgG/IgM Rapid Test is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma or whole blood collected using K2-EDTA, sodium heparin or sodium citrate anticoagulants.
The membrane is pre-coated with anti-human IgM antibody on the IgM Test Line region (M) and anti-human IgG antibody on the IgG Test Line region (G). During testing, SARS-CoV-2 antibodies, if present in the specimen, will react with the SARS-CoV-2 antigen-coated particles, which have been pre-coated on the test strip.

The test specimen, when applied, migrates upward on the membrane by capillary action, reacting with anti-human IgM antibody on the IgM Test Line region (M) and/or with anti-human IgG antibody on the IgG Test Line region (G), forming a colored line in IgM line region (M) and/or IgG line region (G). To serve as a procedure control, a colored line should appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.
The presence of the control line together with the absence of the colored lines in IgM line region (M) and IgG line region (G) indicates that the specimen does not have any SARS-CoV-2 antibodies.

Q: What do the test results mean?

A: Immunoglobulin tests for COVID-19 cannot confirm the presence of the virus in your system. It can only tell whether you have been exposed in the past or if you have never been exposed to SARS-CoV-2. Since the test will only indicate the presence of SARS-CoV-2 IgM and IgG antibodies in the blood specimen it should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.

aconlabs.com

ACON Laboratories, Inc.
5850 Oberlin Drive #340, San Diego, CA 92121
U.S.A. **Tel:** 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com

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Q: How do I know the test was performed properly ?

A: Internal procedural controls are included in the test. The control line is coated with anti-rabbit IgG antibody on membrane which will bind to the pre-coated gold-conjugated rabbit IgG when an adequate volume of test specimen is applied into the sample well and adequate buffer volume is applies to the corresponding well on the test cassette. In the control region of the membrane, a colored line appears regardless of the presence of SARS-CoV-2 IgG or IgM antibodies in the specimen. This confirms sufficient specimen and buffer volume, and correct procedural technique. Absence of this line indicates an invalid result.

Q: What are the known limitations of the test?

- This test is only to be used in CLIA certified laboratories that meet requirements to perform moderate or high complexity testing and not in point-of-care or at-home testing settings.
- The test should be used for the detection of SARS-CoV-2 antibodies in serum, or plasma, or whole blood specimens collected with anticoagulants K2-EDTA, sodium heparin and sodium citrate. Other specimens have not been evaluated and should not be used with this assay. Do not use with fingerstick (capillary) whole blood samples.
- The test is limited to the qualitative detection of IgM and IgG antibodies against the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
- It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection
- This test should only be used for testing samples collected 8 days after symptom onset. The performance of this test in samples collected less than 8 days after symptom onset has not been established
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. An assay that directly detects the virus should be used to evaluate symptomatic patients for acute COVID-19.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history, physical findings, local disease prevalence, and other diagnostic procedures in assessing the need for a second but different serology test to confirm an immune response.
- 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, OR if appropriate: Pedigreed specimens with direct evidence of antibodies to non-SARS-CoV-2 coronavirus (common cold) strains such as HKU1, NL63, OC43, or 229E have not been evaluated with this assay.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of this assay early after infection is unknown.
- 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.
- Results from immunosuppressed patients should be interpreted with caution.
- Reading test results earlier than 15 minutes or later than 20 minutes after the addition of Buffer may yield erroneous results.
- This test should not be used for screening of donated blood.

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