SARS-CoV-2 Ab IgG/IgM Rapid Test Cassette Procedure*

SPECIMEN COLLECTION AND PREPARATION

- The ACON SARS-CoV-2 IgG/IgM Rapid Test can be performed using serum, or plasma or whole blood specimen collected using K2-EDTA, sodium heparin or sodium citrate anticoagulants.
- Testing should be performed immediately after specimen collection. Store specimens right after collection, if not tested immediately. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if not tested immediately. The specimens must be tested within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed more than once.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- Anticoagulants sodium heparin, K2-EDTA and sodium citrate do not affect the test result.

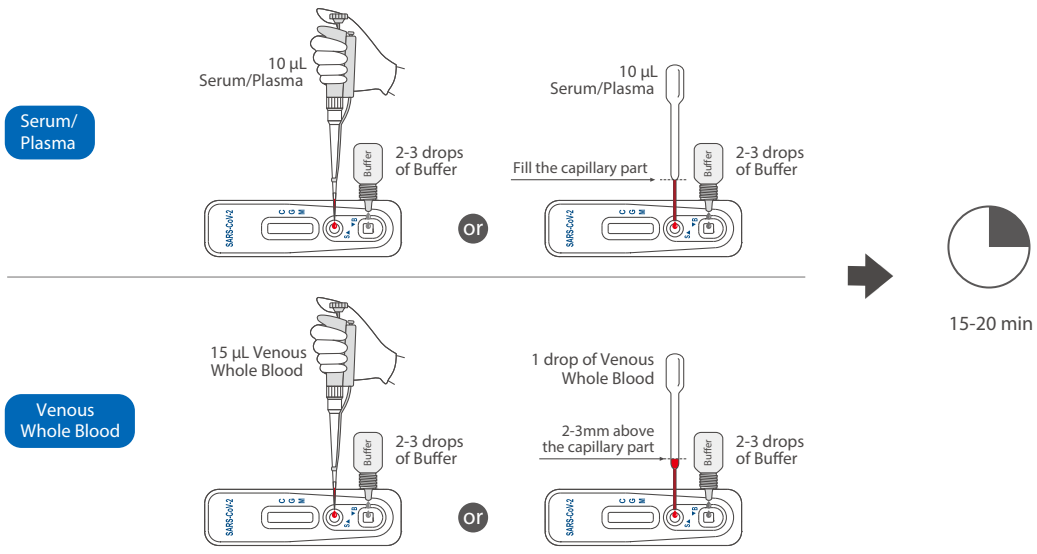
HOW TO PERFORM A TEST

Allow the test, specimen and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test on a flat and clean surface. Transfer the specimen by a Pipette or a Dropper:
   - To use a **Pipette** for Serum, Plasma (sodium heparin, K2-EDTA and sodium citrate) or venous whole blood (sodium heparin, K2-EDTA and sodium citrate): Transfer 10 µL of Serum, Plasma, or 15 µL of venous Whole blood specimen into the Sample Well (S), then add 2~3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for Serum or Plasma (sodium heparin, K2-EDTA and sodium citrate): Hold the dropper vertically and fill the capillary part of the dropper (not to exceed the capillary part) with Serum or Plasma (approximately 10 µL), then carefully dispense the specimen into the Sample Well (S), immediately add 2-3 drops of buffer into the Buffer Well (B), and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for venous whole blood (sodium heparin, K2-EDTA and sodium citrate): Hold the dropper vertically, draw the specimen about 2-3 mm above the capillary part and then transfer 1 full drop (approximately 15 µL) of specimen into the Sample Well (S). Immediately add 2-3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.

Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

TEST PROCEDURE



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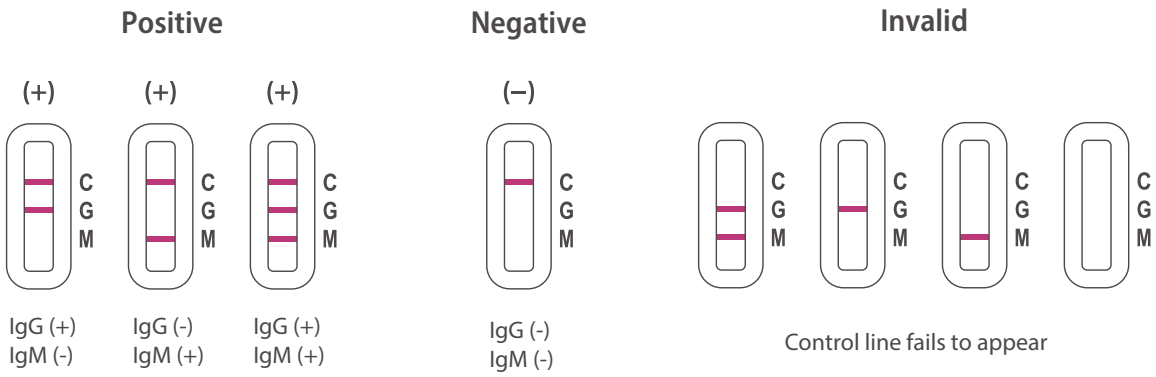
INTERPRETING THE RESULTS



Results	Interpretation of results (Please refer to the illustration above)
IgG (+) IgM (-)	Colored control line appears in the control region and one colored line appears in the IgG line region (G). The result is positive for IgG antibodies and negative for IgM antibodies to SARS-CoV-2.
IgG (-) IgM (+)	Colored control line appears in the control region and one colored line appears in the IgM line region (M). The result is negative for IgG antibodies and positive for IgM antibodies to SARS-CoV-2.
IgG (+) IgM (+)	Colored control line appears in the control region, one colored line appears in the IgG line region (G), and one colored line appears in the IgM line region (M). The color intensities of the lines do not have to match. The result is positive for IgG and IgM antibodies to SARS-CoV-2.
IgM (-) IgG (-)	Only one colored control line appears in the control region. The result is negative for SARS-CoV-2 virus specific IgM and IgG antibodies.
INVALID	Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat testing with a new test cassette. If the problem persists, do not use the test kit and contact ACON Laboratories Inc.

* Emergency use of this test is limited to 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.
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.

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