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

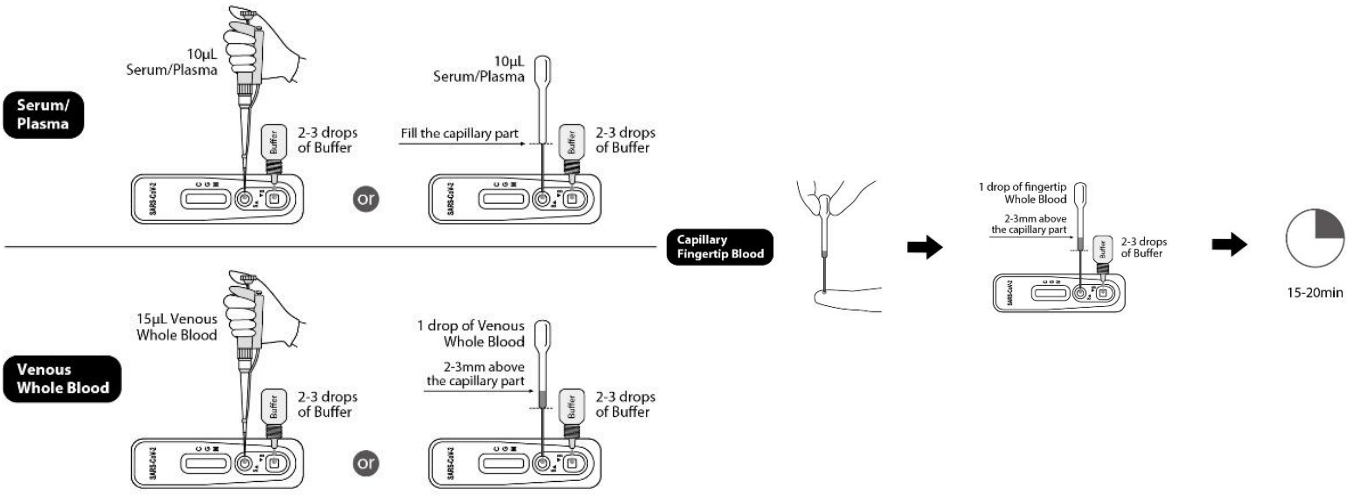
SPECIMEN COLLECTION AND PREPARATION

1. The SARS-CoV-2 IgG/IgM Rapid Test can be performed using serum, plasma, or whole blood specimen from venous or fingerstick collection.
2. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for long-term storage. 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.
3. Whole blood collected by fingerstick should be tested immediately. Fingerstick blood collection method:
   Step 1: Wash both hands with soap and warm water and disinfect the puncture site with a topical skin antiseptic such as an alcohol swab.
   Step 2: Puncture the skin with a single use auto-disabling safety lancet.
   Step 3: Gently massage from the surrounding area toward the puncture site to get a drop a blood.
   Step 4: Collect the required blood volume using the Dropper.
4. 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 repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
6. Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test result.

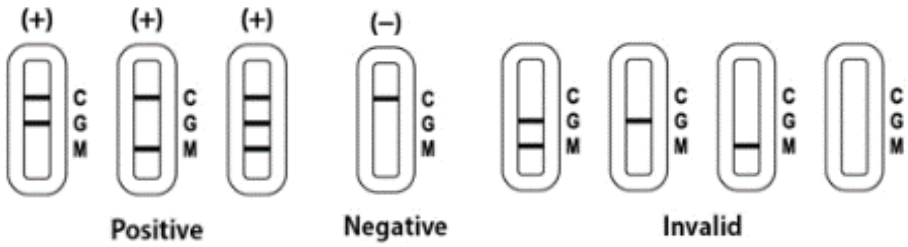
HOW TO PERFORM A TEST

Allow the test, specimen, and buffer to come 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, or venous Whole blood:
     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:
     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 or fingertip Capillary blood:
     Hold the dropper vertically, draw the specimen about 2-3mm 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
3. Wait for the colored line(s) to appear. The **result should be read at 15 minutes**. Do not interpret the result after 20 minutes.



4. Interpreting Results:



- **POSITIVE*: Colored control line appears in the control region and colored test line(s) appears in the test line region.**
- **IgG positive**: Colored control line appears in the control region and one colored line appears in the IgG line region (G).
- **IgM positive:** Colored control line appears in the control region and one colored line appears in the IgM line region (M).
- **IgG and IgM positive:** 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).

  ***NOTE**: The color intensity of the IgM and IgG test line(s) may vary depending on the concentration of the SARS-CoV-2 IgM antibodies and SARS-CoV-2 IgG antibodies present in the specimen.
- **NEGATIVE:** Only colored control line appears in the control 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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