**COVID-PRESTO®**

**TEST PROCEDURE**

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

Remove the test cassette from the sealed foil pouch and use it as soon as possible.

Best results will be obtained if the assay is performed within one hour.

1. Place the test device on a clean and level surface.

2. Perform the test as follow:

For **whole blood samples taken at the fingertip** (use of the 10μL micropipette):

o Using the lancet, prick the side of the fingertip. Form a large drop of suspended blood.

o Hold the micropipette horizontally and put the tip of the micropipette in contact with the blood.

DO NOT PRESS THE PEAR OF THE PIPETTE. The pipette automatically fills up to the black line.

o Place the micropipette vertically above the well (S) of the cassette and squeeze the bulb to deposit the blood.

o Immediately add 2 drops of buffer to the buffer well (B) of the cassette. Avoid air bubbles.

*Note: if blood is not expelled from the micropipette, plug the small hole in the middle of the black line with fingers of the other hand then squeeze the bulb.*

3. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window or if blood is still present in the specimen well (S), add 1 additional drop of the sample buffer to the buffer well (B).

The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.





**INTERPRETATION OF RESULTS**

**NEGATIVE:** The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G. The result is negative.

**IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region M. The result is anti-COVID-19 IgM positive.

**IgG POSITIVE:** The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region G. The result is anti-COVID-19 IgG positive.

**IgG and IgM POSITIVE:** The colored line in the control line region (C) changes from blue to red, and two colored lines appear in test line regions M and G. The result is anti-COVID-19 IgM and IgG positive.

**INVALID:** Control line is still completely or partially blue, and fails to completely change from blue to red. 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.

**QUALITY CONTROL**

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this 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.