



MATERIALS PROVIDED

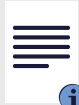
1. 50 TEST STRIPS IN SEALED CANISTER WITH DESICCANT



2. TEST CARDS



3. TEST BUFFER



4. INSTRUCTIONS FOR USE



5. 20 µL CAPILLARY TUBES



6. CANISTER

MATERIALS REQUIRED BUT NOT PROVIDED



1. TIMER

2. PERSONAL PROTECTIVE EQUIPMENT, SUCH AS GLOVES, MEDICAL MASK, GOGGLES AND LAB COAT OR GOWN



3. LANCETS

4. APPROPRIATE BIOHAZARD WASTE CONTAINER AND DISINFECTANTS



PREPARATION

Allow test device, sample, and test buffer to reach room temperature (15° - 30°C) for **30 minutes** prior to testing. Use test device within one hour after removing from closed canister.



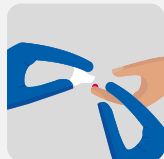
SAMPLE COLLECTION

Wash the patient's hands with soap and warm water or wipe the finger you intend to stick with an alcohol swab. Allow to dry.

1. Holding finger tight, squeeze the blood toward the tip of the finger.



2. Puncture skin using a sterile lancet. Wipe away first drop of blood. Gently squeeze hand from palm to finger, making sure to get a large hanging drop of blood.

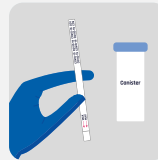


3. Touch the tip of the capillary tube to the drop of blood until filled (approximately **20 µL**). Avoid air bubbles.

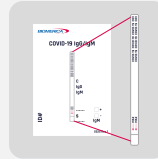


TEST PROCEDURE

1. Remove one test strip from canister and immediately reseal the canister.



2. Place one test strip on the test card on a level surface.



3. Transfer **20 µL** of sample to the sample area of the test strip (next to the "S" on the card).



4. Then add 1 drop of test buffer to the sample area "S" (approximately **40 µL**), and start the timer.



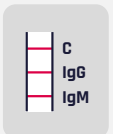
5. Pink/red-colored control and test line(s) should appear. Read results at **10 minutes**. Do not interpret results after 20 minutes.



INTERPRETATION

POSITIVE

If the sample contains IgM antibodies to SARS-CoV-2, a pink/red-colored band next to the "IgM" in the test area will appear. If the sample contains IgG antibodies to SARS-CoV-2, a pink/red-colored band will appear next to the "IgG" in the test area.



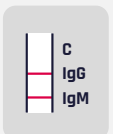
NEGATIVE

Only one pink/red-colored band appears next to the "C". No pink/red-colored band(s) appear next to the "IgM" or "IgG".



INVALID

An absence of a colored band next to the "C" regardless of the appearance of colored band(s) next to "IgM" and/or "IgG".



MATERIALS PROVIDED

1. 50 TEST STRIPS IN SEALED CANISTER WITH DESICCANT



2. TEST CARDS



3. TEST BUFFER



4. INSTRUCTIONS FOR USE



5. 20 µL CAPILLARY TUBES



6. CANISTER

MATERIALS REQUIRED BUT NOT PROVIDED



1. TIMER

2. PERSONAL PROTECTIVE EQUIPMENT, AS GLOVES, MASK...



3. PIPETTE AND PIPETTE TIPS



4. CENTRIFUGE



5. BIOHAZARD WASTE CONTAINER



6. SERUM/ PLASMA COLLECTION TUBE

PREPARATION

Allow test device, sample, and test buffer to reach room temperature (15° - 30°C) for **30 minutes** prior to testing. Use test device within one hour after removing from closed canister.

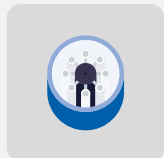


SAMPLE COLLECTION

1 Venous Whole Blood Collection: Using standard phlebotomy practices, collect desired sample(s) as follows: red top (serum), or lavender top (venous whole blood) tube.



2 Serum Processing and Storage: Allow whole blood collected without anticoagulant to clot at room temperature for **45-120 minutes** prior to centrifugation to collect serum. Once serum has been collected, store at 2-8°C within **30 minutes**.

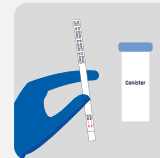


3 Plasma Specimen Processing and Storage: Separate plasma from blood as soon as possible to avoid hemolysis. Venous whole blood specimens should not be stored at room temperature for more than **30 minutes**.

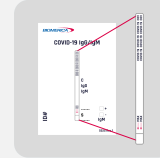


TEST PROCEDURE

1 Remove one test strip from canister and immediately reseal the canister.



2 Place one test strip on the test card on a level surface.



3 Transfer **10 µL** of sample to the sample area of the test strip (next to the "S" on the card).



4 Then add 1 drop of test buffer to the sample area "S" (approximately **40 µL**), and start the timer.



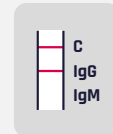
5 Pink/red-colored control and test line(s) should appear. Read results at **10 minutes**. Do not interpret results after 20 minutes.



INTERPRETATION

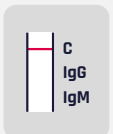
POSITIVE

If the sample contains IgM antibodies to SARS-CoV-2, a pink/red-colored band next to the "IgM" in the test area will appear. If the sample contains IgG antibodies to SARS-CoV-2, a pink/red-colored band will appear next to the "IgG" in the test area.



NEGATIVE

Only one pink/red-colored band appears next to the "C". No pink/red-colored band(s) appear next to the "IgM" or "IgG".



INVALID

An absence of a colored band next to the "C" regardless of the appearance of colored band(s) next to "IgM" and/or "IgG".

