COVID-19 Serology POC Testing Kits

Warnings and Precautions Only for human in vitro clinical diagnostics only.The product should only be used by trained clinical professionals.After opening the sealed cassette pouch the test should be used within one hour.Do not immerse test cassette in water.Do not freeze test cassette or buffer solution.Handle specimens in accordance to the OSHA Standard on Bloodborne PathogensWear protective gloves, clothing, and eyewearWash hands thoroughly after handling specimens.Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.Dispose of all used or damaged test cassettes, capillary samplers, or other kit component as biohazardous materials.Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.Do not use samples containing lipids, hemolysis, or turbidity which can affect results.

COVID-19 Serology POC Testing Kits

Storage Instructions The reagent should be stored in the dark at room temperature (2° to 45°C) and has a shelf-life of 12 months. The container should be protected from light after being opened. Do not freeze.

COVID-19 Serology POC Testing Kits

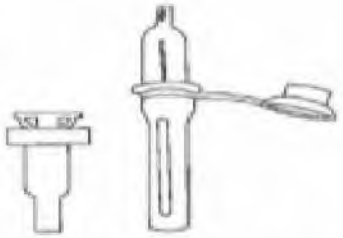
Sample Requirements Suitable for human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly used anticoagulants (EDTA, heparin, sodium citrate).Fresh samples should be collected and tested immediately.Serum and plasma samples can be stored at 2-8°C for 5 days.If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature (15-30° C) and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.

COVID-19 Serology POC Testing Kits

Test Procedure Do not open pouch until ready to use. Prep necessaryMaterials: test cassette, buffer solution, capillary sampler label test cassette with patient IDObtain a specimen using standard laboratory protocols.The finger is usually the preferred site for capillary testing in an adult patient. Apply alcohol to the entry site and allow to air dry Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris (sloughing skin).Avoid squeezing the finger or heel too tightly because this dilutes the specimen with tissue fluid (plasma) and increases the probability of hemolysis. Using capillary sampler, obtain 20µL of fingerstick or venous whole blood specimen or 10µL of serum or plasma.For intravenous sampling follow standard laboratory protocols.When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding.Dispense the specimen into the Test Cassette sample well.Ensure that the entire sample is dispensed into the sample well.Remove cap of the Buffer Solution bottle and dispense 2-3 drops into the Test Cassette sample well.Remove any air bubbles in the dropper.Test on a level surface at room temperature.Allow test to run for 10 minutes. Read the results by viewing the detection window.Test results that have run over 15 minutes are invalid.

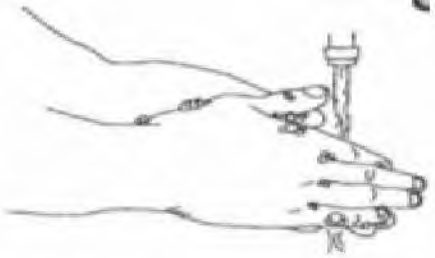
COVID-19 Serology POC Testing Kits

Potential Complications Complications that can arise in capillary sampling include:Collapse of veins if the tibial artery is lacerated from puncturing the medial aspect of the heelOsteomyelitis of the heel bone if utilizing the heel Hematoma and loss of access to the venous branch used if utilizing a vein ScarringLocalized or generalized necrosis (a long-term effect)Skin breakdown from repeated use of adhesive strips (particularly in very young or very elderly patients) – this can be avoided if sufficient pressure is applied and the puncture site is observed after the procedure. DO NOT puncture the skin more than once with the same lancet, or use a single puncture site more than once, because this can lead to bacterial contamination and infection.



1. Lancet and collection tube.

2. Assemble equipment and supplies.



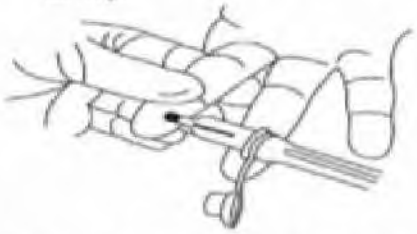
3. Perform hand hygiene (if using soap and water, dry hands with single-use towels).

4. Put on well-fitting, non-sterile gloves.

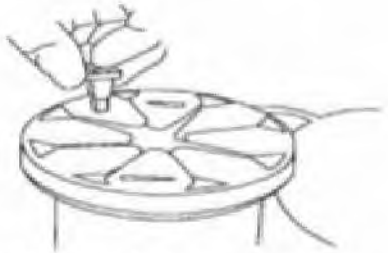
5. Select the site. Apply 70% isopropyl alcohol and allow to air dry.

6. Puncture the skin.

7. Wipe away the first drop of blood.

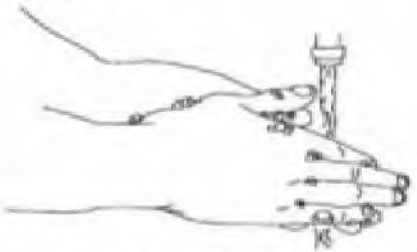


8. Avoid squeezing the finger too tightly.



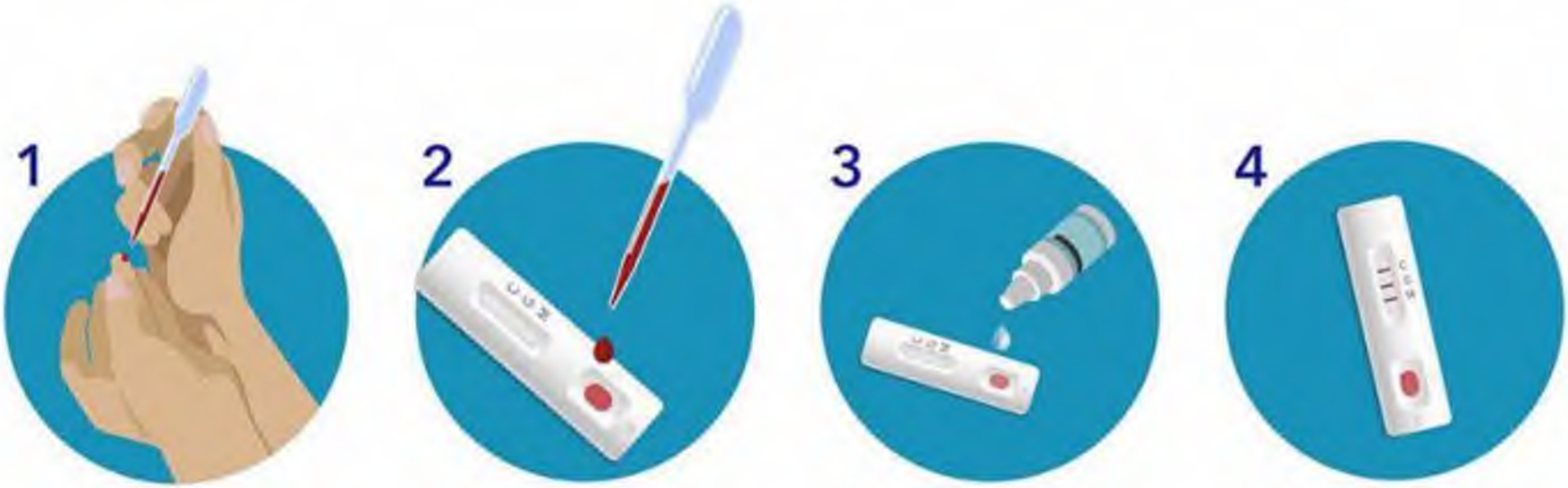
9. Dispose of all sharps appropriately.

10. Dispose of waste materials appropriately.



11. Remove gloves and place in general waste. Perform hand hygiene (if using soap and water, dry hands with single-use towels).

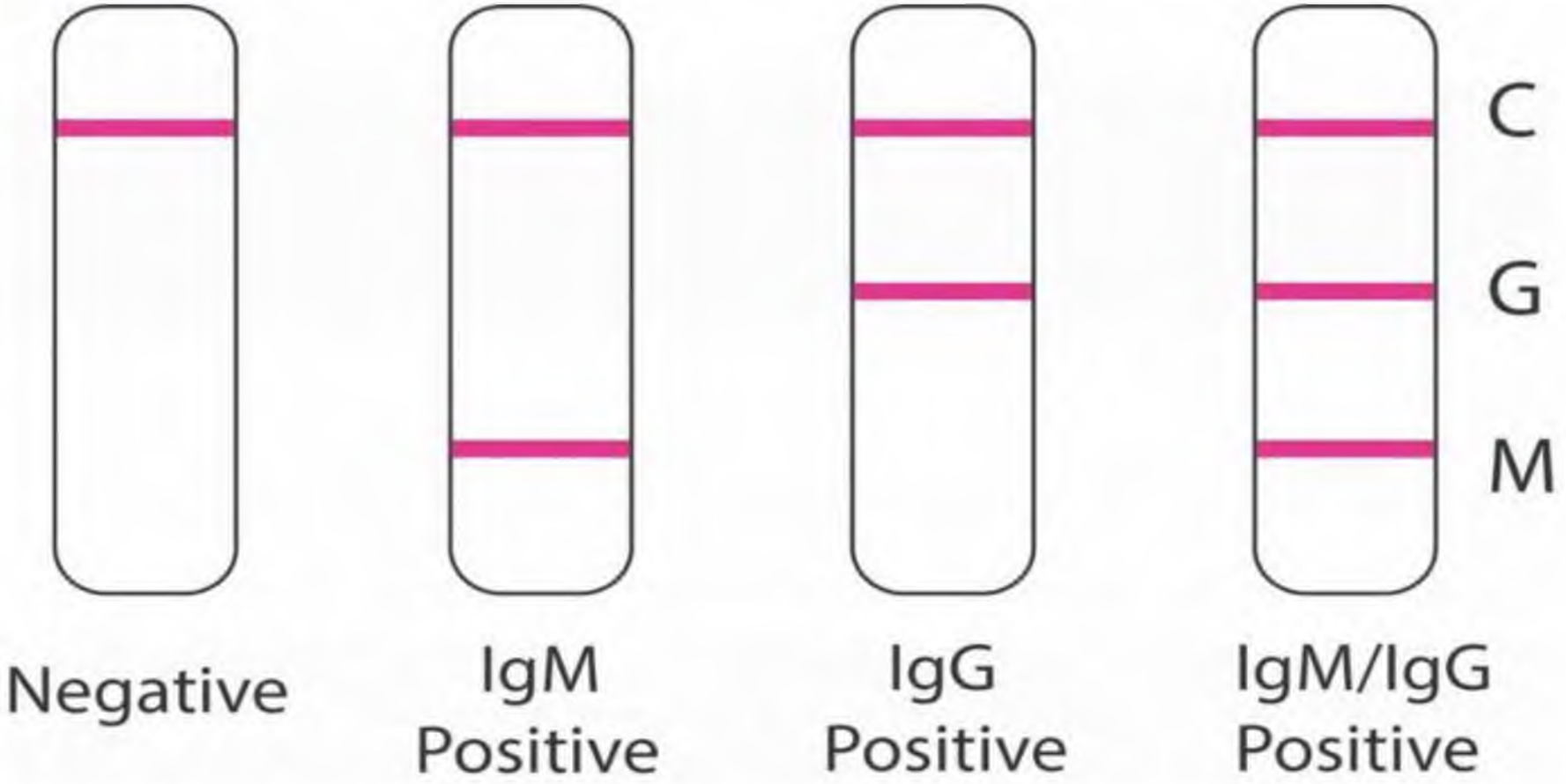
How It Works



Steps

1. Collect blood/serum/plasma sample.
2. Add blood/serum/plasma sample to sample well.
3. Place 2-3 drops of buffer in sample well.
4. Read results after 10 minutes and no more than 15 minutes.

Results



A total of three detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.

1 | Negative Result: If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

2 | Positive Result, M only: If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

3 | Positive Result, G only: If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

4 | Positive Result, G and M: If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.