P4DETECTCOVID-19 IgM/IgG

※ Please read the instruction for use carefully

▶INTENDED PURPOSE

P4DETECT COVID-19 IgM/IgG is a rapid chromatographic immunoassay for the qualitative detection of Coronaviurs (SARS-CoV-2) IgM and IgG antibody in serum, plasma, whole blood specimens.

▶EXPLANATION OF THE TEST

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by 2019-nCoV, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread between people via respiratory droplets from infected individuals when they cough or sneeze. Time from exposure to onset of symptoms is generally between 2 and 14 days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness. Further development may include pneumonia and acute respiratory distress syndrome.

P4DETECT COVID-19 IgM/IgG is a chromatographic immunoassay kit for rapid qualitative determination for coronavirus infection.

▶PRINCIPLE OF THE METHOD

P4DETECT COVID-19 IgM/IgG is a qualitative, lateral flow immunoassay for the detection of Coronavirus IgM and IgG nucleoproteins in serum, plasma, whole blood specimens.

▶COMPOSITION

P4DETECT COVID-19 IgM/IgG contains the following items to perform the test.

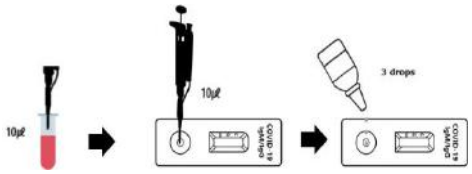
1) Test devices sealed in a foil pouch with desiccant
2) Sample diluent
3) Instruction for use

▶SPECIMEN COLLECTION AND PREPARATION

1. Whole blood specimen collection
   1) Whole blood is collected in syringe or evacuated tube containing the anticoagulant
   2) Whole blood specimens should be tested immediately after collection.
      In the case of storing at 2~8℃, it should be tested within 24 hours.
2. Plasma / Serum specimen collection
   1) Plasma or serum specimens should be tested immediately after collection.
   2) Do not leave the specimens at room temperature for prolonged period.
      Specimens may be stored at 2~8℃ for up to 3days. For long term storage, specimens should be kept below -20℃

▶TEST PROCEDURE

1. This test should be carried out at the room temperature, hence the test reagent which is stored in the cold storage, should be removed and kept outside 15~30 minutes before the test, so that it is at room temperature.
2. Remove the test device from sealed pouch immediately before use
3. Put the test device on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver sample 10μL into the sample port on the test device. Then add 3 drops of sample diluent immediately



5. Interpret the result between 10~15 minutes.

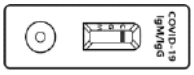
※ Please do not interpret after 15 minutes.

▶READING AND INTERPRETATION OF RESULT

1. Control (C) band means that the test is working properly.
2. Test ('M' and 'G') band indicates the test result.

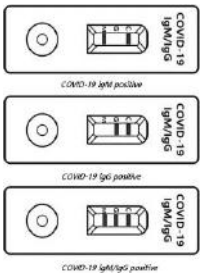
NEGATIVE:

The presence of only 'C' band indicates a negative result



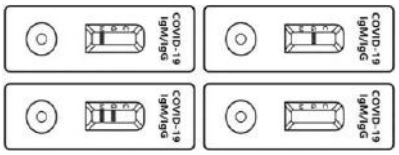
POSITIVE:

The Presence of Test band ('M' and/or 'G') with control ('C') band indicates a positive result.



INVALID:

If Control (C) band is not appeared in the result window after performing test, the result is considered invalid.



※ The directions may not have been followed correctly or the test device may have been deteriorated. It is recommended that the specimens be re-tested with the new device.

▶FOLLOW-UP ACTION

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

▶LIMITATIONS OF THE METHOD

1. The test is for in vitro diagnostic use only.
2. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti-SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

▶WARNING AND PRECAUTIONS

1. For professional in vitro diagnostic use only
2. Do not re-use the test device
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5. Do not use test kit if the packing is damaged or the seal is broken.
6. Do not use the kit beyond the expiration date.
7. Avoid splashing or aerosol formation while handling specimens.
8. Clean up spilled specimens thoroughly using an appropriate disinfectant.
9. The test device is sensitive to humidity. Pull out the test device from the foil pouch right before use.
10. This test kit contains a little of sodium azide. Avoid contact with skin, eyes.
    If you get the solution on your body, immediately wash thoroughly with flushing water. And contact a doctor if you need to.
11. Decontaminate and dispose of all specimens, tested kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
12. Since the test may give you the false positive or false negative result, final diagnosis should not be made only by this product's test result.

▶STORAGE AND SHELF LIFE

P4DETECT COVID-19 IgM/IgG should be stored at 2~30℃ (36~86℉). The test device is sensitive to humidity as well as to heat. Do not use it beyond the expiration date, 24 months from manufacturing date.

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