2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimens.

**PRECAUTIONS**

1. For professional in vitro diagnostic use only.

2. The IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for cross-reactivity with other coronaviruses such as 229E, OC43, NL63, and SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV), and has been shown to have sufficient sensitivity and specificity for the detection of the novel coronavirus.

3. For professional in vitro diagnostic use only.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection.

5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

6. The test will show negative results under the following conditions: the titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test; or the novel coronavirus antibody has not appeared at the time of sample collection (post-exposure stage).

**PERFORMANCE CHARACTERISTICS**

Sensitivity and Specificity

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR, the results show that 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

**INTERPRETATION OF RESULTS**

IgG Summary: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM Summary: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

**IgG Result**

NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG line region (L).

POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region (L).

**IgM Result**

NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgM line region (L).

POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region (L).

**QUALITY CONTROL**

Internal procedural controls are included in the test. A colored line appearing in the control line (C) is an internal procedural control. If not sufficient specimen volume and correct procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**REFERENCES**


**LIMITATIONS**

1. The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to 2019-nCoV in human whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCoV can be determined by this qualitative test.

2. The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to 2019-nCoV in the specimen and should not be used to determine the degree of infection.

3. As with all diagnostic tests, all results must be considered with other clinical information to determine the most appropriate course of action.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection.

5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

6. The test will show negative results under the following conditions: the titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test; or the novel coronavirus antibody has not appeared at the time of sample collection (post-exposure stage).