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CRT 2019-NCOV IGG/IGM 2019-NCOV IGG/IGM RAPID SINGLE USE TEST (FINGERSTICK WHOLE BLOOD)

FAST

EASY

PRECISE

ABOUT THE IMPORTER

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Advent Life is part of Advent Group - an established leader in health and education with a global presence on five continents through legal entities in Paris, Sofia, Montreal, as well as representatives based in London, Munich, Kuala Lumpur, Vienna and Budapest. Advent Group is a registered distributor of medical devices.

CRT 2019-NCOV IGG/IGM 2019-NCOV IGG/IGM RAPID SINGLE USE TEST (FINGERSTICK WHOLE BLOOD)

The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV. The test provides preliminary test results. Negative results do not preclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision. Negative results do not preclude COVID-19 infection. Positive results may arise due to past or present infection with non-SARS-CoV-2 coronavirus strains (such as coronavirus HKU1, NL63, OC43, or 229E.). For in vitro diagnostic use only.

CHARACTERISTICS

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HIGH ACCURACY, SPECIFICITY AND SENSITIVITY:

SPECIFICITY:	**99.0%**
ACCURACY:	**96.8%**
SENSITIVITY:	**87,8%**

Early detection of infection.
Discard after first use. The test cannot be used more than once. Do not touch the reaction area of test strip.
Do not use test kit beyond the expiration date.
Do not use the kit if the pouch is punctured or not well sealed.
Results in 15 minutes.

WHAT'S IN THE PACKAGE

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1 Test cassette

1 Desiccant pouch

1 Disposable droppers

1 Detection buffer

1 Instructions for use

WHAT'S IN THE PACKAGE

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1 box contains 10 indivudual test kits

STEP-BY-STEP INSTRUCTIONS

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1. Allow the device, buffer and specimen to equilibrate to room temperature (10ºC ~30ºC) prior to testing.

2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.

3. Transfer 10 µL serum or 10 µL plasma or 20 µL of whole blood specimen to the sample well “S” and then add 1~2 drops (50 µL) of buffer solution to the sample well “S”.

4. As the test begins to work, you will see purple color move across the result window in the center of the test device.

5. Wait for 15 minutes and read the results. Do not read results after 20 minutes.

For Serum and Plasma

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma, use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect results.

2. Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.

3. Test should be performed within 8 hours after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2ºC～8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC for up to 9 days.

* Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat inactivated specimens are not recommended.

RESULTS

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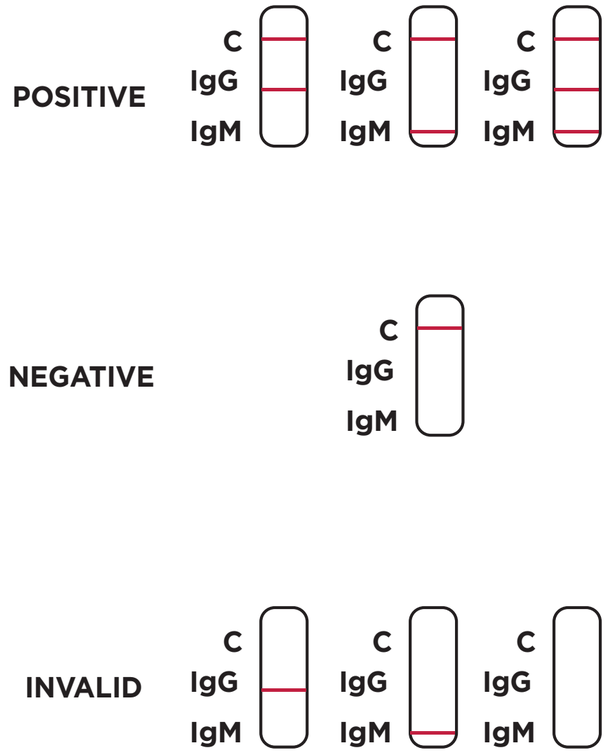
POSITIVE: Colored bands appear at both test line (IgG/IgM) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen. Both IgG/IgM Positive: Control line and both test lines appear. IgM Positive/IgG Negative: Both control lines and the second test line (the lower test line which is closer to the sample well) appears. It indicates the possibility of primary infection. IgM Negative/IgG Positive: Both control line and the second test line (the higher test line) appear. It indicates the possibility of secondary infection or past infection.

NEGATIVE: Colored band appears at control line (C) only. It indicates that the concentration of the SARS CoV-2 antibodies is zero or below the detection limit of the test.

INVALID: No visible colored band appears at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



IMPORTANT INFORMATION

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This test has not been reviewed by the FDA.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Not for the screening of donated blood.

This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.

This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.

The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test results.

The test results of this test are for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.

Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.

In the early stage of infection, if IgM and IgG antibodies are not produced or the titer is very low, false negative results will occur.