2019-nCoV IgM/IgG Antibody Coronavirus Rapid Test Cassette

User Manual

Cat.Nos.COV00212(25T/box)
Published 15 Feb 2020
Only for Research Use!

Add: Floor 2,Gate 6,289#,Minqiang Road,Songjiang District,Shanghai 201612
Tel: +86-21-54460832 Web: www.synthesisgene.com
Fax:+86-21-54460831 E-mail: master@shinegene.org.cn

【Product Name】

2019-nCoV IgM/IgG Antibody Coronavirus Rapid Test Cassette

【Packing Size】

25T/box

【Application】

The reagents used for the qualitative detection in vitro human whole blood, serum and plasma samples of 2019 new coronavirus IgG/IgM antibody, for 2019 new coronary viral pneumonia has auxiliary diagnosis effect, can be used for early diagnosis, a new type of coronavirus incubation period for 3 to 14 days, many patients the incubation period is long, only 10 minutes to quick interpretation results.

【Principles of testing】

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with 2019-nCoV antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to 2019-nCoV. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to 2019-nCoV, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result. Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【MATERIALS 】

Materials provided:

- Test cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided:

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Capillary tubes
- Centrifuge (for plasma only)
- Timer

- Pipette

【Test procedure】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

2. Place the cassette on a clean and level surface.

For Serum or Plasma specimen:

To use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 20uL), and transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 80 uL), and start the timer.

To use a pipette: To transfer 20 uL of specimen to the specimen well(S), then add 2 drops of buffer (approximately 80 uL), and start the timer

For Venipuncture Whole Blood specimen:

To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 20μL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 80 uL) and start the timer.

To use a pipette: To transfer 20 uL of whole blood to the specimen well(S), then add 2 drops of buffer (approximately 80 uL), and start the timer

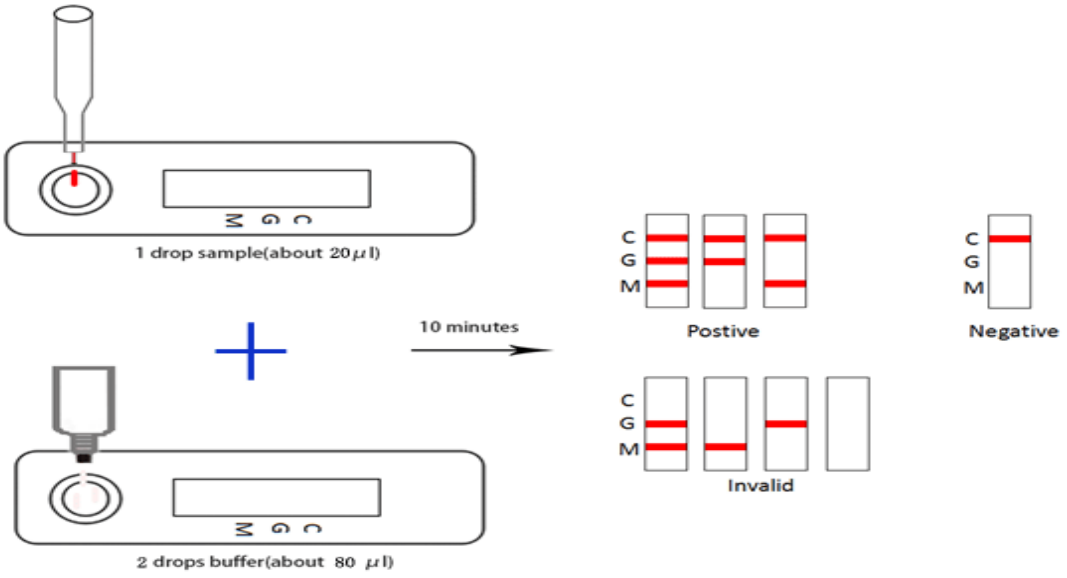
For Fingerstick Whole Blood specimen:

To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 20μL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 80 uL) and start the timer.

To use a capillary tube: Fill the capillary tube and transfer approximately 20uL of fingerstick whole blood specimen to the specimen well (S) of test cassette, then add 2 drops of buffer (approximately 80 uL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



Add: Floor 2,Gate 6,289#,Minqiang Road,Songjiang District,Shanghai 201612
Tel: +86-21-54460832 Web: www.synthesisgene.com
Fax:+86-21-54460831 E-mail: master@shinegene.org.cn

【INTERPRETATION OF RESULTS】

IgG 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.

IgM 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.

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

*NOTE: The intensity of the color in the test line regions may vary depending on the concentration of 2019-nCoV antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

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

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【References】

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china

2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2

3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003

4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9

5. World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus

6.Get the latest public health information from CDC: https://www.coronavirus.gov .

7.Get the latest research from NIH: https://www.nih.gov/coronavirus.

Add: Floor 2,Gate 6,289#,Minqiang Road,Songjiang District,Shanghai 201612
Tel: +86-21-54460832 Web: www.synthesisgene.com
Fax:+86-21-54460831 E-mail: master@shinegene.org.cn

Shanghai ShineGene Molecular Bio-tech Co.,Ltd.

Add：Floor 2,Gate 6,289#,Minqiang Road,Songjiang District,Shanghai 201612

Tel：+86-21-54460832

Fax: +86-21-54460831-18

E-mail:master@shinegene.org.cn

Website：www.synthesisgene.com