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CE

# *"See Now"* Coronavirus 2019 nCoV antibody Cassette Test

### Whole blood/Serum/Plasma

For in vitro Diagnosis Use
Product Code: SN 8.5

## INTENDED USE

The ***"See Now"*** **Coronavirus 2019 nCoV Ab**. test is used for the qualitative determination of the novel coronavirus (SARS-CoV-2) antibody **(IgG/IgM)** in human serum, plasma or whole blood.

## PRINCIPLE

The ***"See Now"*** **Coronavirus 2019 nCoV Ab.** test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of human novel coronavirus (SARS-CoV-2) **IgG/IgM** antibody in serum, plasma or whole blood. When the sample contains the SARS-CoV-2 antibody, it forms a complex with the gold label antigen SARS-CoV-2 (2019 nCoV antigen-coloidal gold conjugate). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human **IgG and IgM** monoclonal antibody) at the T lines (**G and M**) to form a complex and develop color ( lines **G and M**), which is a positive result. When the sample does not contain the SARS-CoV-2 antibody, no complex can be formed at the **G and M** lines and no red band appears, which is a negative result.
A build-in control line **(C**) always will appear in the test window when the test has performed properly regardless of the presence of absence of SARS-CoV-2 antibody in the specimen.

## MATERIALS SUPPLIED

- Test Device, capillary pipette, desiccant, Test Instruction, Sample buffer (PBS)

## MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

## STORAGE AND STABILITY

- The ***"See Now"*** **2019 nCoV IgG/IgM Ab** Test should be stored at room temperature (4-30ºC) in the sealed pouch or desiccated container.
- Do not use it after the expiration date.

## PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
- Decontaminate and dispose of specimens and all potentially contaminated materials if they contain infectious agent.
- As with all diagnostic tests, a definitive clinical 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 have been evaluated.

## SPECIMEN COLLECTIONAND STORAGE

- For serum samples collect blood in a tube without anticoagulant and allow it to clot.
- For whole blood or plasma samples collect blood in a tube containing anticoagulant (EDTA, citrate or heparin, respectively).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- **Finger puncture whole blood**

  Clean the finger with an alcohol pad and let dry

  Take a lancet and make a quick deep slab on the side of the finger.

  Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature

## TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- **For SERUM/PLASMA/ WHOLE BLOOD:** Holding the **capillary pipette** vertically, add **2µL** of specimen without air bubbles into the sample well, marked **S1**, then add **two (2) drops (80-100µl)** of sample buffer into the well marked **S.**
- Read the results in 15-20 minutes. Ensure that the background of the test area is white before interpreting the result. **Do not interpret result after 20 minutes.**

## INTERPRETATION OF RESULTS

**Positive**

Distinct pink colored bands (2 or 3) appear at the control and test lines regions (C, G, M lines).

**Negative**

Only one pink colored band appears at the control region (C).

**Invalid**

No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

## LIMITATION OF PROCEDURE

- The ***"See Now"*** **2019 nCoV Ab** test device is used for the detection of SARS-CoV-2, **IgG/IgM Ab**. in human serum, plasma, whole blood. Based on a single reactive test result, a sample should not be considered **2019 nCoV IgG/IgM** Ab. positive. Further testing, including confirmatory testing, should be performed before a specimen is considered positive for **2019 nCoV IgG/IgM** Ab. Specimens containing precipitate may give inconsistent test results.
- The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

## QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

## PERFORMANCE CHARACTERISTICS

- ***Relative Sensitivity - 90%***
- ***Relative Specificity - 99%***