



Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

Certificate of Analysis

Product Name:	nCOV IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma)
Catalog Number:	176552-1-44
Lot Number:	NCP20030150
Exp. Date:	2022-Mar
Date of Sampling:	2020-Mar-14
Date of Analysis:	2020-Mar-14
Buffer Lot:	20030623
Buffer EXP:	2022-Mar

QC Item		Standard & Criteria	Test Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance:	Positive Sample	Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Conclusion: This Batch of product meet the QC standards.

Pass/Reject: Pass

QC Signature:

Himanshu Singh

Date: 2020-Mar-14



2019-nCoV IgG/IgM RapidCard™
Insta Test
(Whole Blood/Serum/Plasma)
REF 176552-1-44

*A rapid test for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimens
 For professional in vitro diagnostic use only*

INTENDED USE

The Cortez Diagnostic, Inc. 2019-nCoV IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimen

SUMMARY AND EXPLANATION

Early January 2020, a novel coronavirus (2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.¹ Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.² Six coronaviruses are known to cause human disease.³ Four typically cause common cold symptoms in immunocompetent individuals.⁴ The two other strains — severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) — are zoonotic in origin and have been linked to sometimes fatal illness.⁴ Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.⁵ Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing

and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.⁵

TEST PRINCIPLE

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.

REAGENTS

The test contains anti-human IgM and anti-human IgG as the capture reagent, 2019-nCoV antigen as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

MATERIALS AND COMPONENTS

- Materials provided with the test kit**
- Test cassettes
 - Buffers
 - Droppers
 - Package inserts

Materials required but not provided

Specimen collection containers

- 1. Lancets (for fingerstick whole blood only)
- Capillary tubes
- Centrifuge (for plasma only)
- Timer
- Pipette

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Please ensure that an appropriate number of samples are used for testing. Too much or too little sample size may lead to deviation of results.
7. The used test should be discarded according to local regulations.
8. Humidity and temperature can adversely affect results.

STORAGE

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.

SPECIMEN COLLECTION AND PREPARATION

- The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood Specimens:**
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingertick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 20µL. Avoid air bubbles.
- **Separate serum or plasma from blood** as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the Serum and plasma specimens for prolonged periods. For up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C. If the test is to be run within 2 days of collection, do not freeze whole blood specimens. Whole blood collected by fingertick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA, K₂ Heparin, sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

ASSAY 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 10µL), and transfer the specimen to the specimen well (S), then add **2 drops of buffer** (approximately 80 µL), and start the timer.
 - To use a pipette: To transfer 10µL of specimen to the specimen well(S), then add **2 drops of buffer** (approximately 80 µL), and start the timer.

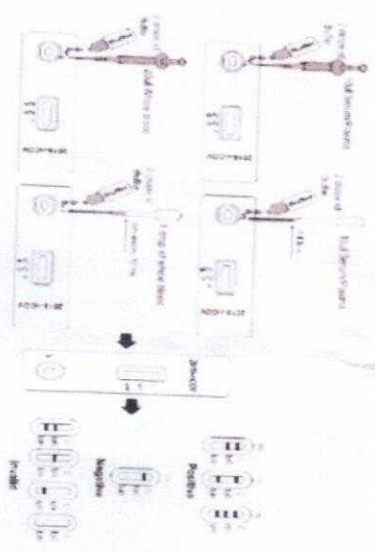
For Venipuncture Whole Blood specimen:

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

For Fingertick 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 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer **approximately 20µL of fingertick whole blood specimen** to the specimen well (S) of test cassette, then add **2 drops of buffer** (approximately 80 µL) 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.



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).

(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.

DETECTION PERIOD

IgM antibody and IgG antibody are very low or none in the period 0-14 days after infectious which is called incubation time. The IgM antibody can be found in the blood 2-7 days after symptom appears (fever/tired), so the IgG antibody or/and IgM antibody will be negative in the period as follows:

1. Incubation time.
2. Early symptom time. IgG false negative or both because low titer of antibody.
3. IgM false negative > 28 days after confirmed by PCR/CT.

PERFORMANCE CHARACTERISTICS

Sensitivity & 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.



IgG Result

Method	Results	Positive	Negative	Total Results
2019-nCoV IgG/IgM Rapid Test	Positive	20	0	20
	Negative	0	49	49
Total		20	49	70

Relative Sensitivity: 100% (95%CI* 86.0%-100%)*
 Confidence Interval Relative Specificity: 98.0% (95%CI* 89.4%-99.9%)
 Accuracy: 98.6% (95%CI* 92.3%-99.96%)

IgM Result

Method	Results	Positive	Negative	Total Results
2019-nCoV IgG/IgM Rapid Test	Positive	17	2	19
	Negative	3	48	51
Total		20	50	70

Relative Sensitivity: 85.0% (95%CI* 62.1%-96.8%)*
 Confidence Interval Relative Specificity: 96.0% (95%CI* 86.3%-99.5%)
 Accuracy: 92.9% (95%CI* 84.1%-97.6%)

Cross-reactivity

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-KSV, anti-Adenovirus, HBSAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood) and no interference was observed.

- Triglyceride: 50 mg/dl
- Ascorbic Acid 20mg/dl
- Hemoglobin 1000mg/dl
- Bilirubin 60mg/dl
- Total cholesterol 6mmol/L

QUALITY CONTROL

COR CODE #44

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.

LIMITATIONS OF PROCEDURE

- 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 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.
- 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 as the sole criteria for the diagnosis of 2019-nCoV infections.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- 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.
- The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

REFERENCES

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Coronavirus



Diagnostic Automation/
 Cortez Diagnostics, Inc.
 21250 Califa St, Suite 102 and 116,
 Woodland Hills, California 91367 USA
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2019-nCoV IgG/IgM Rapid Test™
 Insta Test (Whole Blood/Serum/Plasma)

CEpartnr@du, Esdoornlaan 13,
 3961DB Maarn, The Netherlands.
www.cepartnr@du.eu

EC REP

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