



Celltrion DiaTrust™

COVID-19 IgG/IgM Rapid Test



USING WHOLE BLOOD,
PLASMA OR SERUM



FOR IN VITRO DIAGNOSTIC
USE ONLY



READ THE RESULT
IN 15 MINS

Please read the instructions carefully before use!

For Emergency Use Authorization only
For prescription use only
For in vitro diagnostic use only

INTENDED USE

Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test is an *in vitro* diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of Immunoglobulin G and Immunoglobulin M antibodies of the novel Coronavirus (COVID-19) in human whole blood, plasma or serum.

Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test is intended as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test should not be used to diagnose acute SARS-CoV-2 infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform moderate or high complexity tests.

Results are for the detection of IgG/IgM SARS-CoV-2 antibodies. The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. The virus may be detectable in individuals for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second but different IgG/IgM assay.

Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test is only for use under the Food and Drug Administration Emergency Use Authorization (EUA).

SUMMARY AND EXPLANATION

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illnesses associated with COVID-19, but it likely spreads to others when individuals show signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

The test is designed to detect antibodies to SARS-CoV-2, the virus that causes COVID-19 in blood specimens. Testing of sample(s) will help assess if an individual has antibodies to the virus that causes COVID-19.

PRINCIPLE OF THE TEST

"Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test" is an immunochromatographic assay test which detects IgG and IgM antibodies to COVID-19 in human blood. A nitrocellulose membrane strip in the device contains two test lines (G and M lines) and a control line (C). The G line is pre-coated with mouse anti-human IgG for detection of IgG anti-COVID-19, and the M line is pre-coated with mouse anti-human IgM for detection of IgM anti-COVID-19. The C line is coated with goat anti-mouse IgG.

When the sample is added to the sample pad, it moves through the conjugate pad, where the recombinant antigen-colloidal gold particle will react with the IgG and IgM antibodies specific to COVID-19 in the sample, forming an immunocomplex. The complex moves along the membrane by capillary action and makes contact with the immobilized antibody coated in the test region. A colored line in the test region indicates a positive result for the coronavirus. The absence of a colored line in the test region suggests a negative result. The complex continues to move to the control region and will react with immobilized reagents that capture the colored conjugate regardless of test specimen composition. The resulting visible colored line in the control region confirms that the assay is functioning correctly and its result is valid.

CONTENTS

- Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test device (25 ea/box)
- Assay diluent buffer (5 mL, 1 ea/box)
- Instruction for use leaflet (1 ea/box)
- Capillary tube (10 µL, 25 ea/box)

MATERIAL COMPOSITION

1 test device contains:

- Mouse anti-human IgM monoclonal antibody.....0.44±0.11 µg
- Mouse anti-human IgG monoclonal antibody0.44±0.11 µg
- 2019-nCoV n recombinant protein0.08±0.02 µg
- Goat anti-mouse IgG0.8±0.02 µg

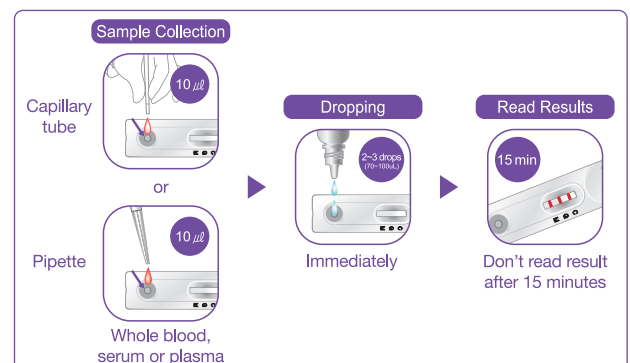
SPECIMEN COLLECTION AND PREPARATION

The device can be performed using anticoagulated whole blood, anticoagulated plasma, or serum.

- Whole blood: Collect specimen in collection tube with an anticoagulant such as EDTA, heparin or sodium citrate. Perform test immediately after collection. The whole blood sample can be stored at 2-8°C (36-46°F) for up to 24 hours before the test.
- Plasma: Collect specimen in collection tube with an anticoagulant such as EDTA, heparin or sodium citrate, and centrifuge the sample. The plasma sample can be stored at 2-8°C (36-46°F) for up to 3 days. Freeze the sample for longer storage.
- Serum: Collect specimen in collection tube without an anticoagulant, place it in room temperature for 30 minutes, and then centrifuge the sample. The serum sample can be stored at 2-8°C (36-46°F) for up to 3 days. Freeze the sample for longer storage.

TEST PROCEDURE

1. If the collected specimens were stored in refrigerated condition, leave the samples in room temperature for 15 to 30 minutes before the test. Avoid unsealing the device if the device temperature is lower than room temperature.
2. Open the sealed pouch and place the device on a clean, dry and level surface.
3. Release 10 µL of whole blood, plasma, or serum into the sample well. Then add 2 drops of sample diluent immediately.
4. Read the result in 15 minutes. Do not read result after 15 minutes.



INTERPRETATION OF RESULT

Negative

If no colored line appears in the test region (G and M) and a colored line is present in the control region (C), then the result is negative.



Positive

In addition to the presence of a colored line in the control region (C):



IgG and IgM positive: if there are colored lines in both test regions (G and M), then the result is positive.



IgG positive: if there is a colored line in region G but no line in region M, then the result is IgG positive.



IgM positive: if there is no colored line in region G, but there is a visible colored line in region M, then the result is IgM positive.

Invalid

If there is no colored line in the control region (C), the result is invalid.



PERFORMANCE CHARACTERISTICS

Precision

The reproducibility study of Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test was conducted by multiple operators at multiple sites, using blind coded specimens that were negative, low positive (1:50 dilution), medium positive (1:25 dilution) and high positive (1:1 dilution), SARS-CoV-2 viral samples. The test was conducted over 5 to 20 different days. There were no differences in the test results observed within run, between run, between sites or between operators; all negative samples showed negative results and all positive samples showed positive results.

Cross-reactivity

Cross-reactivity of the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test was evaluated using serum or plasma samples containing antibodies to pathogens shown in the table below. The test samples were prepared by spiking standard solution into negative serum or plasma samples. The tests were run in three replicates using the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test and following its instructions. None of the tested cross-reactivity substances had any effect on the test performance of the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test, and they all showed negative results.

IgG Cross-reactants	IgM Cross-reactants
Anti-influenza A IgG	Anti-influenza A IgM
Anti-influenza B IgG	Anti-influenza B IgM
Anti-HCV IgG	Anti-HCV IgM
Anti-HBV IgG	Anti-HBV IgM
Anti-Haemophilus influenzae IgG	Anti-Haemophilus influenzae IgM
Anti-229E (alpha coronavirus) IgG	Anti-229E (alpha coronavirus) IgM
Anti-NL63 (alpha coronavirus) IgG	Anti-NL63 (alpha coronavirus) IgM
Anti-OC43 (beta coronavirus) IgG	Anti-OC43 (beta coronavirus) IgM
Anti-HKU1 (beta coronavirus) IgG	Anti-HKU1 (beta coronavirus) IgM
ANA IgG	ANA IgM
Anti-RSV IgG	Anti-RSV IgM
Anti-HIV IgG	Anti-HIV IgM
Anti-CMV IgG	Anti-CMV IgM
Anti-Mycoplasma IgG	Anti-Mycoplasma IgM
Anti-Dengue IgG	Anti-Dengue IgM

Class Specificity

The study was performed to demonstrate that the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test correctly detects each IgG and IgM antibody class 10 serum samples were collected from individual patients confirmed positive for SARS-CoV-2 by RT-PCR, and which showed positive results for both IgM and IgG using the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test in duplicate.

The Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test showed 100% agreement with the expected result, indicating that it can accurately detect and specify each IgG and IgM antibody class.

Clinical evaluation

The clinical performance of the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test was evaluated by testing a total of 125 clinical samples from individual patients:

50 positive and 75 negative samples.

The statistical analysis was carried out as indicated in the CLSI EP12 A2 "User Protocol for Evaluation of Qualitative Test Performance." The positive and negative performance agreement between the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test and the RT-PCR assay was calculated as seen below, with 95% confidence interval:

a. Positive percent agreement (PPA)

= True positives / (True positives + False negatives) x 100 (%)

b. Negative percent agreement (NPA)

= True negatives / (True negatives + False positives) x 100 (%)

The result of the clinical evaluation of the Celltrion DiaTrust™ COVID-19 IgG/IgM Rapid Test was as follows:

IgM Result		RT-PCR		Total
		Positive	Negative	
Celltrion DiaTrust™ COVID -19 IgG/IgM Rapid Test	Positive	48	1	49
	Negative	2	74	76
Total		50	75	125

Positive percent agreement (PPA) for IgM = 96.0% (48/50), (95% CI: 86.6% - 98.9%)

Negative percent agreement (NPA) for IgM = 98.7% (74/75), (95% CI: 92.8% - 99.8%)

IgG Result		RT-PCR		Total
		Positive	Negative	
Celltrion DiaTrust™ COVID -19 IgG/IgM Rapid Test	Positive	46	0	46
	Negative	4	75	79
Total		50	75	125

Positive percent agreement (PPA) for IgG = 92.0% (46/50), (95% CI: 81.2% - 96.8%)

Negative percent agreement (NPA) for IgG = 100.0% (75/75), (95% CI: 95.1% - 100.0%)

PRECAUTIONS

- For *in vitro* diagnostic use only
- Store the test device packaged in a sealed foil pouch at 2 to 30°C (36 to 86°F).
- Do not use the test device beyond the expiration date.
- Keep sealed until usage, and use immediately once opened.
- Do not use the test device if the pouch is damaged or the device is seriously broken.
- Do not re-use the device.
- Handle all specimens safely as it may be potentially infectious.

LIMITATIONS

- Failure to follow the procedures may give inaccurate results.
- The test should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- Results are not intended to be used as the sole basis for treatment or patient management decisions. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- False positive results due to cross-reactivity with antibodies to other coronaviruses can occur. Positive results may be due to past or present infection of non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- The recommended sample collection period is dating from 7 to 21 days after the onset of symptoms.
- This test is not for at home testing.
- This test is not for screening of donated blood.
- This test has not been reviewed by the FDA.

REFERENCES

- Korean Centers for Disease Control <http://ncov.mohw.go.kr/>
- FIND <https://www.finddx.org/covid-19/>
- CDC <https://www.cdc.gov/>
- Development and Clinical Application of a Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. Z Li, Journal of Medical Virology

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IVD : For <i>in vitro</i> diagnostic use	LOT : Lot number
i : Consult instruction for use	REF : Catalogue number
2°C - 30°C : Store at 2 to 30°C (36 to 86°F)	EXP : Use by / Expiry date
: Manufactured by	: Do not reuse
: Contains sufficient for <n> tests	
CE : This product fulfills the requirements for Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.	