ADTech COVID-19 IgM / lgG KIT is a gold nanoparticle based immunochromatography test kit that qualitatively measures IgM and IgG antibodies COVID-19 in whole blood, serum or plasma. The kit is accurate, easy to use, and results can be checked the naked eye within 10 ~ 15 minutes.

PRODUCT DESCRIPTION

ADTech

COVID – 19 IgM / IgG RAPID KIT

Model No.: C 0430-1

Quantity: 20 Tests / KIT

Sample: Venous / Finger blood, Plasma and serum.

Test time: Reading in 10 ~ 15 minutes

Storage: 2℃ ~ 30℃(35.6℉ ~ 86℉)

Expiry: 2 year since manufactured

HOW TO USE

1. Collecting sample

For the test, 10 ㎕ of whole blood, plasma or serum is used. Collect the blood sample obtained by venipuncture into blood collection tubes or use fingertip blood.

2. Adding of sample

Add the collected sample into the sample inlet of the test cassette.

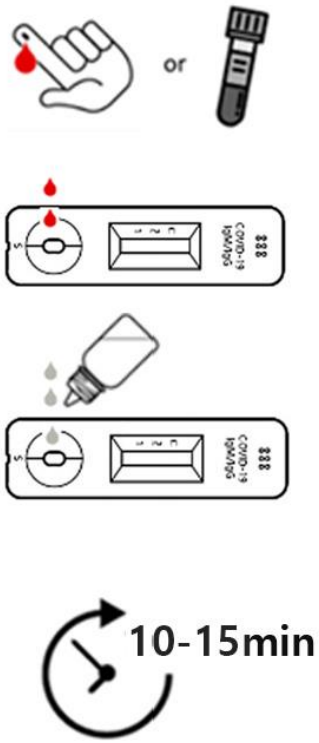
3. Dropping of sample buffer

Add 3 drops(90 ㎕) of sample into the inlet of the test cassette.

4. Reading the test results

Read the test result at 10 ~ 15 minutes.

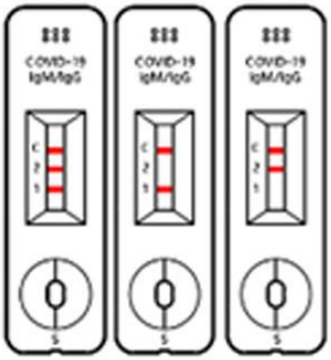
※ Do not read after 150minutes.



TEST RESULT

Positive

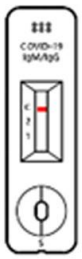
When all the 3 lines are shown at Test 1, Test 2 and control, then the test results is "POSITIVE". Even in case 2 lines are shown at 'control and Test 1' or 'Control and Test 2', the test result is "POSITIVE", too.



Negative

When the control line does show up without 2 Test lines, the test result is "NEGATIVE".

※ If the line us not shown up at the control line though test if fulfilled, then that test cassette and test result are invalid, at that time, you have to re-test with new test cassette.



Pre-Clinical Test Report

1. Pre-Clinical Test summary

1) Pre-clinical test is fulfilled by Domestic large clinical laboratory with ADTech COVID-19 IgM/IgG RAPID KIT

2) Tests are made by total 15 samples with 12 positive and 3 negative samples

3) Clinical Laboratory tested the sample with Immunofluorescence Analysis

2. Pre-clinical test result

1) Samples were tested by ADTech COVID-19 IgM/IgG RAPID KIT

2) Test result by ADTech's RAPID KIT

- 4 negatives and 11 positives results in 15 samples

3) Comparison between Immunofluorescence analysis and ADTech's RAPID KIT

- 14 test results are same(including negative and positive results)

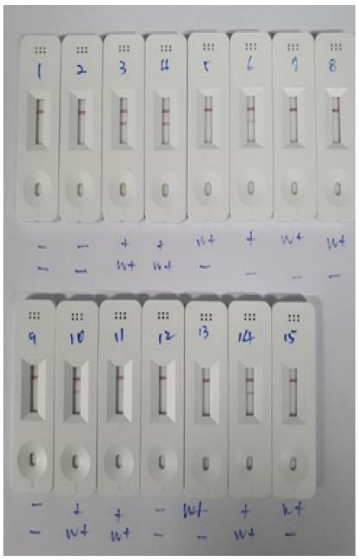
- 1 sample's test result are different(Positive Negative by ADTech)

4) Accuracy

- In total samples 93.3% (14/15)

- In positive samples 91.7% (11/12)

[ADTech's RAPID KIT Test result]



[Immunofluorescence Analysis]

No	Immunofluorescence		Remarks
	IgM	IgG	
1	negative	negative	Accurate
2	negative	negative	Accurate
3	**Positive**	**Positive**	Accurate
4	**Positive**	**Positive**	Accurate
5	negative	**Positive**	Accurate
6	negative	**Positive**	Accurate
7	**Positive**	negative	Accurate
8	**Positive**	**Positive**	Accurate
9	negative	negative	Accurate
10	**Positive**	**Positive**	Accurate
11	**Positive**	**Positive**	Accurate
12	negative	**Positive**	Inaccurate(ADTech: Negative)
13	negative	**Positive**	Accurate
14	**Positive**	**Positive**	Accurate
15	**Positive**	**Positive**	Accurate

ADTech COVID-19 IgM/IgG

REF C0430-1 (20Test/Kit)

[Intended Use]

Final Check COVID-19 IgM / IgG test kit is an in vitro diagnostic medical device that qualitative detection IgM and IgG for 2019 novel coronavirus (2019-nCoV) in whole blood, serum or plasma by immunochromatography.

[Summary]

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The origin of this virus is unknown, but it has been transmitted from person to person. It spreads mainly through drops that cough and sneeze. Common symptoms include fever, cough, and difficulty breathing. In most cases, minor symptoms develop, but some also progress to pneumonia and multi-organ failure.

Final Check COVID-19 IgM / IgG test kit can detect IgM and / or IgG antibodies from COVID-19 in the field.

The mouse anti-human IgM is immobilized on the IgM test line ("T1") of the nitrocellulose membrane inside this test device, and the mouse anti-human IgG is immobilized on the IgG test line ("T2"). Serum, plasma or whole blood is added to the sample inlet of the test device, and then the sample dilution solution is sequentially dropped into the sample inlet of the test cassette. The

novel coronavirus IgM and / or IgG in the specimen reacts with the gold particle conjugated recombinant novel coronavirus protein and reacts with coated mouse anti-human IgM and / or

mouse anti-human IgG of nitrocellulose membrane. If the specimen contains the novel coronavirus IgM, the color appears on the test line "T1". If the sample contains the novel coronavirus IgG, the color appears on the test line "T2". If there is no novel coronavirus antibody in the specimen, the test line does not develop and only the control line develops. If no color appears on the control line, the inspection is considered invalid.

[Warnings and Precautions]

1. This product is for in vitro diagnosis and professional use only.

2. Read the provided instruction before using the test kits.

3. Wear the protective gloves at all time while using the test kits and dispose the gloves immediately after testing.

4. The test kit can't be reused.

5. Do not use test kits if the package is damaged or seal is broken.

6. Do not use test kits if expiration date is past.

7. Do not swallow the sample buffer.

8. Dispose wastes in accordance with the local regulations.

[Component]

1. Test device (sealed in aluminium pouch with desiccant)

2. Sample buffer

3. Alcohol swab

4. Capillary tube

5. Lancet

[Additional Required Equipment]

1. Micropipet

2. Timer

3. Disposable gloves

[Specimen Collection and Preparation]

1. Serum, Plasma and Venous whole blood

● The whole blood is collected in a tube containing a coagulant or no anticoagulant, and centrifuged supernatant is used as a serum sample.

● Whole blood is collected in a tube with anticoagulant (Heparin, sodium citrate and EDTA) and centrifuged supernatant is used as a plasma sample.

● Whole blood is collected in tubes containing anticoagulants (Heparin, sodium citrate and EDTA) and shaken for use.

● It is recommended to immediately use the collected serum, plasma and venous whole blood. If it is difficult to use immediately, it can be stored in the refrigerator at 2 ~ 8 ℃ for 7 days, and frozen at -20 ℃ for 1 month.

● Do not repeat freezing and thawing.

2. Finger-Prick Blood

● Prick the tip of your finger with a lancet and use it as a finger-prick blood sample.

● Use finger-prick blood as soon as possible.

[Preparation Before Test]

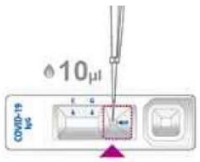
For refrigerated test kits, sample buffer, and samples, leave them at room temperature before starting the test, set the temperature to the same temperature, and use it.

[Test Procedure]

1. Serum, Plasma and Venous whole blood

(1) Remove the test device from the sealed pouch, and place it on a clean and flat surface.

(2) Using a micropipet, add 10 μl of sample into the sample inlet.



(3) Hold the bottle containing the sample buffer vertically and drop 3 drops of the sample buffer into the sample inlet of the test device.

(4) Results are read after 10 to 15 minutes. Do not read test result after 15 minutes. It may give false results.

2. Finger-Prick Blood

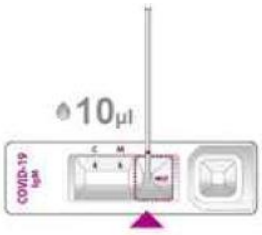
(1) Remove the test device from the sealed pouch, and place it on a clean and flat surface.

(2) Clean the finger tip with alcohol swap.

(3) Prick the tip of your finger with a lancet and use it as a finger-prick blood sample.

(4) Collect 10 ㎕ sample using an capillary tube.

(5) Add the collected sample to sample inlet of the test device.



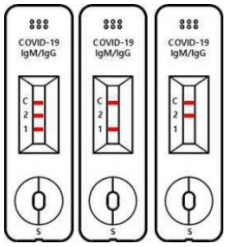
(6) Hold the bottle containing the sample buffer vertically and drop 3 drops of the sample buffer into the sample inlet of the test device.

(7) Results are read after 10 to 15 minutes. Do not read test result after 15 minutes. It may give false results.

[Interpretation of Test Result]

Positive

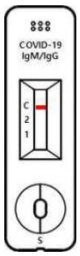
It is positive if the indicator appear on both "T1", "T2", and "Control line C". It is positive even if an indicator appears on "Control line C" and "T1" or "Control line C" and "T2".



Note : Regardless of the color saturation of the band on the test line, even a very weak band should be judged as a positive result.

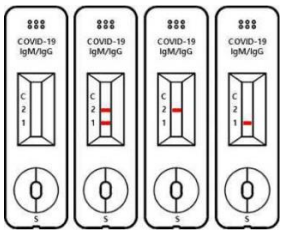
Negative

It is negative if the indicator appear only in “Control line C” and the indicator does not appear in “T1” and “T2”.



Invalid

This product must be marked in “Control line C”. If indicator does not appear in "Contrl line C", this test is invalid and must be retested with a new test kit.



[Performance Characteristics]

1. Limit of Detection

2. Sensitivity and Specificity

Out of ○○○ COVID-19 positive samples confirmed by real-time PCR, Final Check COVID-19 IgM/IgG detected ○○○ samples as a positive, showing the sensitivity of ○○○%.

Out of ○○○ COVID-19 negative samples confirmed by real-time PCR, Final Check COVID-19 IgM/IgG detected ○○○ samples as a negative, showing the specificity of ○○○%.

			Final Check COVID-19 IgM/IgG	
			Positive	Negative
real-time PCR	Positive	○○○	○○	○○
	Negative	○○○	○○	○○
	Total	○○○	○○	○○
Sensitivity : ○○○%, Specificity : ○○○%				

3. Interference

The following 13 substances is not interference of the Final Check COVID-19 IgM/IgG : Bovine submaxillary gland type I-S, Zanamivir, Oseltamivir, Artemether-lumefantrin, Dexycycline hyclate, Lamivudine, Rivabirine, Acetaminophen, Acetylsalicylic acid, Ibuprofen, Mupirocin, Erythromycin, Cirpfloxacin.

4. Cross Reactivity

Final Check COVID-19 IgM/IgG did not react the following matters : HIV positive plasma, Japanese Encephalitis positive plasma, Zika Virus positive plasma, Chikungunya positive plasma, Dengue IgM positive plasma, HBV antibody positive plasma, HCV antibody positive plasma, Salmonella typhi IgM positive plasma, Tick borne encephalitis IgM positive plasma, Brucella IgM positive plasma.

[Limitations]

1. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis when serum or plasma used.

2. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.

3. This test detects the presence of SARS-CoV-2 IgM/IgG in specimen and did not detect SARS-CoV-2 antigen.

4. A definitive clinical diagnosis should not be made based on the result of this test, but should only be made by a qualified physcian after all clinical and laboratory findings have been evaluated.

[Storage and Shelf-Life]

Final Check COVID-19 IgM/IgG should be stored at 2~30℃ (35.6~86℉) for 24 months.

[Reference]

1. Cormac Sheridan, "Fast, Portable Tests Come Online to Curb Coronavirus

Pandemic.", Nature Biotechnology 2020 Mar 23