COVID-19 IgM Antibody Rapid Test Kit

(Immunochromatography)

PRODUCT NAME

COVID-19 IgM Antibody Rapid Test Kit
(Immunochromatography)

INTENDED USE

The reagent is used to detect the Corona Virus-19 IgM Antibody in serum/plasma/whole blood qualitatively.

TEST PRINCIPLE

This kit is based on the principle of gold label immunochromatographic test and uses capture method to detect the COVID-19 IgM antibody in the sample.

When the sample contains the COVID-19 IgM antibody, it forms a complex with the gold label antigen (COVID-19 recombinant antigen). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgM monoclonal antibody) at the T line to form a complex and develop color (T line), which is a positive result. When the sample does not contain the COVID-19 IgM antibody, no complex can be formed at the T line, and no red band appears, which is a negative result.

Regardless of whether the COVID-19 IgM antibody is contained in the sample, the gold label quality control antibody (rabbit IgG antibody) will bind with the coated antibody (goat anti-rabbit IgG antibody) at the C line to form a complex and develop color (C line).

MAIN COMPONENTS

Cassette: T-line coated with mouse anti-human IgM monoclonal antibody, gold label pad solid phase COVID-19 recombinant antigen, rabbit IgG antibody, C-line coated with goat anti-rabbit IgG antibody

Sample dilution: composed of 20 mM phosphate buffer solution (PBS)

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30℃, avoid hot and sunshine, dry place, valid for 12 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity＞60%.

SAMPLE REQUIREMENT

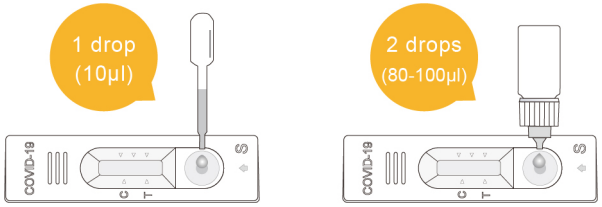
1. The reagent can be used for the serum, plasma and whole blood samples.
2. A serum / plasma / whole blood sample must be collected in a clean and dry container. EDTA, sodium citrate, heparin can be used as anticoagulants in plasma / whole blood samples. Detect immediately after collecting blood.
3.Serum and plasma samples may be stored at 2-8℃ for 3 days prior to assay. If testing is delayed more than 3 days, the sample should be frozen (-20℃ or colder). Repeat freeze and thaw for no more than 3 times. Whole blood samples with anticoagulant can be stored at 2-8℃ for 3 days, and should not be frozen; whole blood samples without anticoagulant should be used immediately (if the sample has agglutination, it can be detected by serum) .

TEST METHODS

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity≤60%, Temp: 20℃-30℃). Please use immediately when the humidity＞60%.

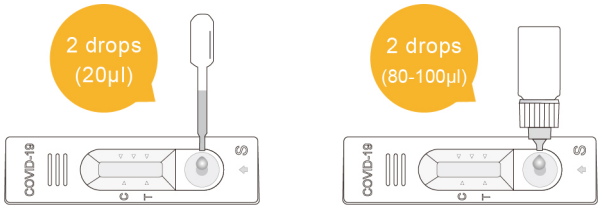
For Serum/Plasma

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of serum or plasma (10μl) vertically into the sample well.
3. Add two (2) drops (80-100μl) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add two (2) full drops of whole blood (20μl) vertically into the sample well.
3. Add two (2) drops (80-100μl) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

Positive **Negative** **Invalid**

LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of COVID-19 IgM antibody cannot be determined by this qualitative test. The depth of the T-line color is not necessarily related to the concentration of the antibody in the sample.
2. 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.

PERFORMANCE CHARACTERISTICS

COVID-19 IgM Ab Rapid Test	Nucleic Acid Test		Total
	Positive	Negative	
Positive	41	18	59
Negative	9	282	291
Total	50	300	350

Analysis of coincidence rate of COVID-19 IgM Ab rapid test and nucleic acid reagent in serum samples:

Positive coincidence rate=41 / (41+9) × 100% = 82%,

Negative coincidence rate=282 / (18+282) × 100% = 94%,

Total coincidence rate=(41+282) / (41+9+18+282) × 100% = 92.3%.

ATTENTIONS

1. For IN VITRO diagnostic use only.
2. Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.
3. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Don't use after the expiration date.
4.All specimens and reagents should be considered potentially hazardous and

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