GENLISA™ Anti-SARS-Cov-2 (Covid-19) IgM (Coronavirus) Rapid Cassette

REF : KBR010

Ver 1.1

RUO

Rapid Immunochromatography for the Qualitative determination of IgM Antibodies to SARS-Cov-2 (Covid-19) in serum, plasma and whole blood

RUO	**For Research Use Only**	**REF**	**Catalog Number**
	**Store At**	**LOT**	**Batch Code**
	**Manufactured By**		**Biological Risk**
	**Expiry Date**		**Consult Operating Instructions**

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REF KBR010  25 tests

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Introduction:

The 2019 novel coronavirus disease (COVID-19; previously known as 2019-nCoV) outbreak that originated from Wuhan, Hubei province, China, at the end of 2019 was declared a public health emergency of international concern on Jan 30, 2020, by WHO.

Recent publications have focused on epidemiology, clinical features of COVID-19, and the structure or genetics of severe acute respiratory syndrome corona virus 2 (SARS-CoV-2).

Intended Use:

The GENLISA™ Anti-SARS-Cov-2 (Covid-19) IgM Rapid Test is used for qualitative detection of the Corona Virus-19 IgM Antibody in serum, plasma and whole blood.

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, indicates 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).

Materials Provided:

1. 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
2. Sample Diluent - 3 ml

Materials to be provided by the End-User:

1. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000 ul
2. Alcohol prep-pad
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

Handling / Storage:

1. All reagents should be stored at 2ºC to 8ºC for stability.
2. All the reagents and wash solutions should be used within 12 months from manufacturing date.
3. Before using, bring all components to room temperature (18-25ºC). Upon assay completion ensure all components of the kit are returned to appropriate storage conditions.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin.
2. For Research Use Only.

Sample Preparation and Storage:

Whole blood samples: Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with Alcohol Prep Pad. Place a Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against your fingertip. Wipe away the first drop of blood with sterile gauze or cotton. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3days.

Serum/Plasma samples: Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30 days at 2-8°C.

Store samples at 2-8°C. Samples not required for assay within 3 days should be stored frozen (-20°C or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

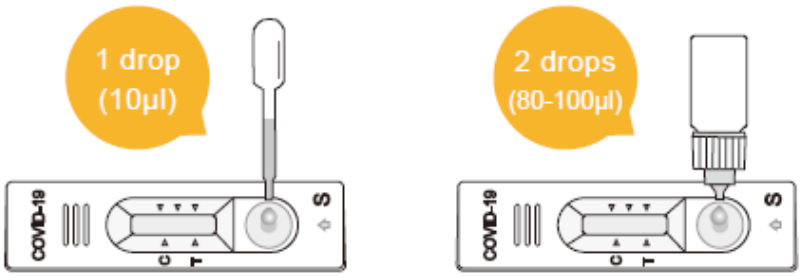
Preparation Before Use:

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%.

Assay Procedure:

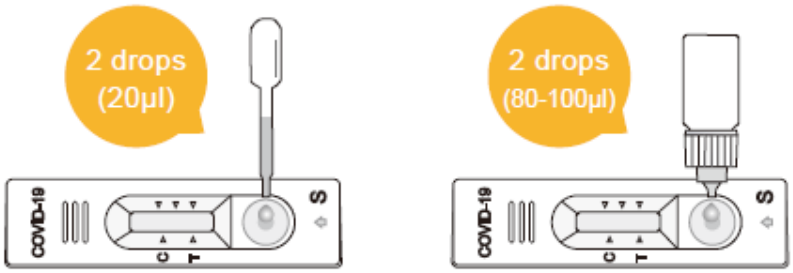
For Serum / Plasma

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 (10 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) 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 (20 ul) vertically into the sample well.
3. Add two (2) drops (80-100 ul) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

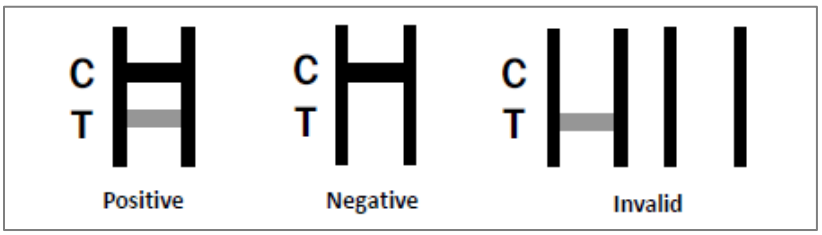


Interpretation of Results:

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.



Quality Control:

It is recommended that for each laboratory assay appropriate quality control samples in each run to be used to ensure that all reagents and procedures are correct.

Performance Characteristics of the Kit:

Sensitivity:
Negative coincident rate with Molecular testing: ≥ 97%, Positive coincident rate with Molecular testing: ≥ 75%.

Specificity:
The protein antigen employed in this immunochromatographic assay is recombinant Covid-19.

Limitations of Method

Healthy individuals should be tested negative by the Infliximab. Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are suggested to consider all clinical and laboratory findings possible to state a diagnosis.

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.

Safety Precautions:

- This kit is For Research Use only. Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Source materials maybe derived from human body fluids or organs used in the preparation of this kit were tested and found negative for HBsAg and HIV as well as for HCV antibodies. However, no known test guarantees the absence of such viral agents. Therefore, handle all components and all patient samples as if potentially hazardous.
- Since the kit contains potentially hazardous materials, the following precautions should be observed
  - Do not smoke, eat or drink while handling kit material
  - Always use protective gloves
  - Never pipette material by mouth
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

LIMITED WARRANTY

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