Elabscience®

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（FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSTICS !）

COVID-19 IgG/IgM Rapid Test Development Kit

Cat. No: E-ELC-RTD001

Specifications: 100000/500000/1000000 Tests

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help (info in the header of each page).

Phone: 240-252-7368(USA) 240-252-7376(USA)

Email: techsupport@elabscience.com

Website: www.elabscience.com

Please refer to specific expiry date from label on the side of box.

Please kindly provide us with the lot number (on the outside of the box) of the kit for more efficient service.

Intended Use

This kit contains essential reagents for the development of COVID-19 IgG/IgM Lateral Flow (Rapid Test) assay to help with the qualitative detection of IgG and IgM antibodies specific to SARS-CoV-2 in human biological fluids.

Kit Components & Storage

The components listed can be purchased separately.
Keep the components according to the specific storage conditions once you receive the kit.

Cat NO.	Description	Storage conditions
E-ELC-002	Recombinant SARS-CoV-2 N Protein (with colloidal gold conjugated)	2-8℃ for 2 months
E-ELC-003	Mouse anti-human IgG monoclonal	-20℃ for 12 months. Avoid repeated freeze-thaw cycles
E-ELC-004	Mouse anti-human IgM monoclonal	-20℃ for 12 months. Avoid repeated freeze-thaw cycles
E-ELC-005	Goat anti-chicken IgY polyclonal	-20℃ for 12 months. Avoid repeated freeze-thaw cycles
E-ELC-006	Chicken IgY (with colloidal gold conjugated)	2-8℃ for 2 months
E-ELC-008	Buffer for Rapid Test development(02)	2-8 ℃ for 3 months

Other consumables required for development

1.Sample pad
2.Conjugated pad (for colloidal gold conjugated antigen and control)
3.Nitrocellulose filter (NC filter) (for coating with IgG test line, IgM test line and control line)
4.Absorbent pad
5.PVC board
6.Plastic cards

Test principle

We are providing materials for development of COVID-19 IgG/IgM Rapid Test. It applies the GICA (Gold Immunochromatography) method for the detection of IgG and IgM specific to SARS-CoV-2 (2019-nCoV) in human bilogical fluids. It consists of two test lines, an IgG line and an IgM line, and a control line. The mouse anti-human IgG monoclonal is pre-coated in IgG test line region while the mouse anti-human IgM monoclonal is pre-coated in IgM test line region. And the goat anti-chicken IgY polyclonal is pre-coated in the control line region. During testing, the sample reacts with SARS-CoV-2 (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 sample contains IgG antibodies to SARS-CoV-2 (2019-nCoV), a colored line will appear in IgG test line region. In the same way, if the sample contains IgM antibodies to SARS-CoV-2 (2019-nCoV), a colored line will appear in IgM test line region. And if the tested sample does not contain antibodies specific to SARS-CoV-2 (2019-nCoV), no colored line will appear in either of the two test line regions, which indicates 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 sample has been added and membrane wicking has occurred.

Protocols for use

1. Blocking for sample pad and conjugated pad

a) Prepare the reagents for treatment of conjugated pad, the treatment buffer can be purchased from our company if you need.

b) Prepare the reagents for treatment of sample pad, the treatment buffer can be purchased from our company if you need.

c) Treat the sample pad and conjugated pad with the prepared reagents respectively, then dry them for subsequent use.

2. Spray for conjugated pad with colloidal gold conjugated antigen and control

a) Spray the conjugated antigen and control to the dried conjugated pad at 2μL/cm.

b) Dry the pad for subsequent use.

3. Coating on test lines and control line

Note: Prepare the required nitrocellulose filters before this process.

a) C line (Control line): Dilute the **Goat anti-chicken IgY polyclonal** to 0.2-0.5mg/mL with **Buffer**, then use it for the control line coating (0.8-1.0μL/cm).

b) T1 line (IgG test line): Dilute the **Mouse anti-human IgG monoclonal** to 1.0-1.5mg/mL with **Buffer**, then use it for the IgG test line coating (0.8-1.0μL/cm).

c) T2 line (IgM test line): Dilute the **Mouse anti-human IgM monoclonal** to 0.4-0.8mg/mL with

Buffer, then use it for the IgM test line coating (0.8-1.0μL/cm).

d) Dry them for subsequent use.

4. Pasting for PVC board

a) Paste the absorbent pad (be cut) to the PVC board, overlap the bottom of it with NC filter for 2mm.

b) Paste the conjugated chicken IgY pad to the bottom of PVC board, overlap it with conjugated N protein pad for 4mm.

c) Paste the conjugated N protein pad to the bottom of conjugated chicken IgY pad, overlap it with the NC filter for 2mm.

d) Overlap the sample pad and conjugated N protein pad for 2mm, make sure the sample pad is aligned with the bottom of PVC board.

e) Keep the prepared board to a foil bag with desiccant for subsequent use.

5. Method for the finished test card

Cut the board prepared according to above process to strips by a cutter at appropriate condition, put the strips to plastic cards, and keep the cards to foil bags with desiccant for use.

Declaration

1. The reagents provided in this kit have been validated for application of lateral flow (Rapid Test) in house. The operators should be well trained and professional on the operations of the assays.
2. The final experimental results will be closely related to the validity of reagents, applicability of consumables, operational skills of the operators and the experimental environments etc.
3. To get the best results, it is recommended to use the matched reagents supplied by the manufacturer. If any reagents from other suppliers are used, please ensure the validity and good performances.
4. In order to get reproducible results, the operation of every step in the assay should be controlled.
5. Every kit has strictly passed QC test. However, results from end users might be inconsistent with our data due to some variables such as transportation conditions, different lab equipments, and so on.