Datasheet

COVID-19 IgM/IgG Rapid Test

Product Name	COVID-19 IgM/IgG Rapid Test
Catalogue Number	ELA-UNCOV-40/ ELA-UNCOV-40-640
IVD or RUO	IVD
CE Marked	Yes
Size	40 tests/16 x 40 Tests

Description:

COVID-19(Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus. This highly contagious new virus and disease were unknown before the outbreak began in Wuhan, China which spread all over the world very quickly. COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.

According to the manufacturer, the EC Declaration of Conformity was issued in accordance with Directive 98/79/EC on 19th of March 2020.

Product Features:

Easier: No special equipment needed, intuitive visual interpretation

Rapid: Quick sampling by fingertip blood, result in 10-15min.

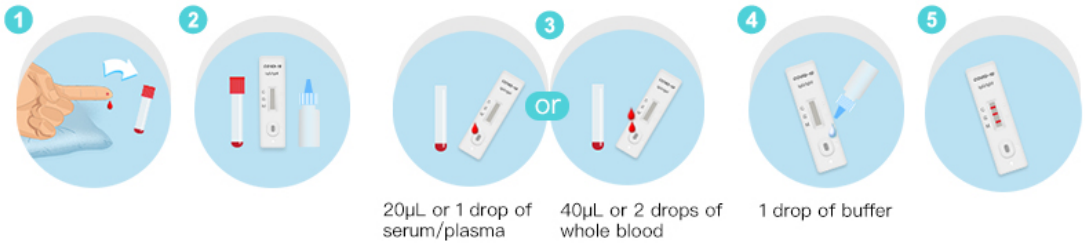
Application: For suspicious patients with symptoms, mild symptoms, or even without symptoms, also for testing people with close contact of infected patients and people under quarantine control.

Storage: The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable before the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

Materials Supplied

1. Test cassettes
2. Droppers
3. Package Inserts
4. Buffer bottle

Testing Procedure



1. Sample collection and preparation.
2. Keep the kit and sample at room temperature prior to testing
3. Add sample (20 ul serum/plasma or 40 ul whole blood) to the sample well using a micropipette.
4. Add 1 drop of buffer to the sample well.
5. Wait for the coloured line(s) to appear and read the results after 10 minutes.

Interpretation of results

IgM Positive: Primary COVID-19 infection.
IgG and IgM Positive: Secondary COVID-19 infection.
IgG Positive: Past COVID-19 infection.
Negative: No previous infection.
Invalid: Experiment failed.

FAQs

How is the COVID-19 Rapid Test Composed?
The test strip consists of a sample pad and a chromatographic membrane (the detection area is coated with a mouse anti-human IgM monoclonal antibody and a mouse anti-human IgG monoclonal antibody and goat anti-mouse IgG antibody), colloidal gold binding pad (coated with colloidal gold-labelled recombinant novel coronavirus (COVID-19) antigen and mouse lgG antibody), liner and absorbent pad.

What Influences the testing results?
Please make sure the kit is recovered into room temperature and perform the kit under the room temperature (15°C-30°C). The results will be affected by high or low temperature.

What are the sample requirements?
Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venepuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingertip should be tested immediately.

How accurate is the COVID-19 Rapid Test?
In order to test the detection sensitivity and specificity of the COVID-19 IgG-IgM combined antibody test, blood samples were collected from COVID-19 patients from multiple hospitals and Chinese CDC laboratories. A total of 1585 selected case specimens, of which 421 were clinically diagnosed patients with Coronavirus infection, 1164 were clinically excluded cases, no cases were found that did not conform to the program selected, and no cases of laboratory operation deviation were found.

The clinical sensitivity of the product was 98.81% (95% CI: 97.25%, 99.61%) and the specificity was 98.02% (95% CI : 97.05%, 98.74%) in 1585 clinical samples (4 21 positive and 1164 negative).

- 98.81% Sensitivity
- 98.02% Specificity

What are the alternatives?
The COVID-19 IgM/IgG Rapid Test can be used to screen patients suspected of having been affected by the novel coronavirus. However, results of test should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods such as nucleic acid PCR test.

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