COVID-19
IgG/IgM Test Rapido

Technical Data Sheet

Brand Name: COVID-19 IgG/IgM Test Rapido

Reference: COVID-19

CE

IVD: For professional and in vitro diagnostic use only

Manufacturer: Assut Europe SpA – Via G. Gregoraci, 12 – 00173 Rome, Italy

Description: COVID-19 IgG/IgM Test Rapido is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma.
It provides an aid in the diagnosis of infection with Novel coronavirus.

Composition: The test contains a membrane strip coated with Mouse anti-Human IgM antibody and Mouse anti-Human IgG antibody on the test line, and a burgundy dyed pad which contains colloidal gold coupled with Novel coronavirus recombinant antigen.

Limitation: COVID-19 IgG/IgM Test Rapido is limited to provide a qualitative detection.
The intensity of the test line color does not necessarily correlate with the concentration of the antibody in the blood.
The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results together with patient's medical history, physical findings, and other diagnostic procedures.
A negative test result indicates that antibodies to Novel coronavirus are either not present or at levels undetectable by the test.

Kit components:
- 1 alcohol wipe to disinfect the surface of the skin
- 1 lancet
- 1 COVID 19 IgG/IgM Test Rapido
- 1 single-use pipette

Procedure:
The device and specimens should be stored between 15-30°C before use.

1. Remove the test cassette from the sealed pouch
2. Place the kit on a clean surface
   2a. Serum or plasma sample: put 10 uL of serum or plasma sample into well A, then add two drops (about 80 uL) of buffer in well B, and start the chronometer
   2b. Whole blood sample: put 20 uL of whole blood sample into well A, then add two drops (about 80 uL) of buffer into well B, and start the chronometer

3. Wait for the colored lines to appear

Interpret test results after 15 minutes. Do not read the results after 20 minutes since the test was done.

Validity: 12 months from the date of manufacture

Packaging: 1 / 2 / 20 / 25 units per box

Storage: Store the sealed pouch at a temperature (4-30°C). The kit remains intact within the expiry date indicated on the label.
Once the pouch is opened, the test should be used within an hour.
Prolonged exposure to a hot and humid environment causes deterioration of the product.

Reference list:

Reference	RDM	Classification
COVID-19	1945023	W0101060499

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