

Datasheet

Nadal COVID-19 IgG/IgM Test

Product Name	Nadal COVID-19 IgG/IgM Test
Catalogue Number	BSV-243001N-10
IVD or RUO	IVD
CE Marked	Yes
Size	10

Description:

The NADAL COVID-19 IgG/IgM Test is a lateral flow chromatographic immunoassay for the qualitative detection of anti-SARS-CoV-2 IgG and IgM in human whole blood, serum or plasma specimens of symptomatic patients. Note that in the early stages of infection (3 to 7 days after the onset of symptoms) anti-SARS-CoV-2 IgG and IgM may be below the detection limit of the test. This test is intended for use as an aid in the diagnosis of primary and possible secondary SARS-CoV-2 infections. The test procedure is not automated and requires no special training or qualification. The NADAL COVID-19 IgG/IgM Test is designed for professional use only.

Product Details:

Sample type: Whole blood, serum or plasma

Intended use: The NADAL COVID-19 IgG/IgM Test is a lateral flow chromatographic immunoassay for the qualitative detection of anti-SARS-CoV-2 IgG and IgM in human whole blood, serum or plasma specimens of symptomatic patients (see section 12 'Limitations'). Note that in the early stages of infection (3 to 7 days after the onset of symptoms) anti-SARS-CoV-2 IgG and IgM may be below the detection limit of the test. This test is intended for use as an aid in the diagnosis of primary and possible secondary SARS-CoV-2 infections. The test procedure is not automated and requires no special training or qualification. The NADAL COVID-19 IgG/IgM Test is designed for professional use only.

Test procedure: Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it as soon as possible. The best results will be obtained if the test is performed immediately after opening the foil pouch. Label the test cassette with the patient or control identification.
2. Place the test cassette on a clean and level surface.

3. Holding the pipette vertically, draw the specimen (whole blood/serum/ plasma) up to the first widening (approximately 10 µL) and add it to the to the specimen well (S) of the test cassette. Alternatively, a micropipette (10 µl) may be used.
4. Holding the buffer bottle vertically, add 2 drops (approximately 80 µL) of buffer to the buffer well (B). Avoid air bubbles forming.
5. Start the timer.
6. Wait for the coloured line(s) to appear. Read the test result after 10 minutes. Do not interpret the result after more than 20 minutes.



Positive for IgM

A coloured line develops in the control line region 'C' and another coloured line develops in the test line region 'IgM'. The result is indicative of a primary SARS-CoV-2 infection.

Positive for IgG

A coloured line develops in the control line region 'C' and another coloured line develops in the test line region 'IgG'. The result is indicative of a possible secondary SARS-CoV-2 infection.

Positive for IgG and IgM

In addition to the control line 'C', a coloured line develops in the test line region 'IgM' and another in the test line region 'IgG'. The result is indicative of a possible secondary SARS-CoV-2 infection.



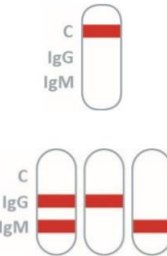
Negative

A coloured line develops in the control line region 'C'. No lines develop in the test line region 'IgM' and 'IgG'.

Invalid

The control line 'C' fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.

Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.



Storage: Store unopened product at 2-30°C and avoid direct exposure to sunlight. Do not open until ready to use. Do not freeze or store product outside the temperature range described above. Do not use this product after the expiration date

Regulatory/ Restrictions: For professional in-vitro diagnostic use only.