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NADAL® COVID-19 IgG/IgM Test (test cassette)

REF 243001N-10

IVD CE

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NADAL® COVID-19 IgG/IgM Test (Ref. 243001N-10)

1. 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) 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.

2. Introduction and Clinical Significance

COVID-19 (Corona Virus Disease) is the infectious disease caused by the recently discovered coronavirus SARS-CoV-2. This new virus was unknown before the disease outbreak in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, dry cough, fatigue, sputum production, shortness of breath, sore throat and headache. Some patients may have myalgia, chills, nausea, nasal congestion and diarrhoea. These symptoms begin gradually and are mild in most of the cases. Some people become infected but do not develop any symptoms and do not feel unwell. Most people (about 80%) recover from the disease without special treatment. Approximately one in six people who get infected with COVID-19 becomes seriously ill and develops difficulty breathing. Elderly people, and those with pre-existing conditions, such as high blood pressure, heart problems or diabetes, are more likely to develop serious illness. So far, about 2% of infected people have died.

COVID-19 is transmitted via respiratory droplets that are exhaled by infected people via coughing, sneezing or talking. These droplets can be inhaled or ingested directly by other people or can contaminate surfaces, which can then be infectious for several days. Most estimates of the incubation period for COVID-19 range from 1 to 14 days, during which people might already be infectious without showing disease symptoms.

3. Test Principle

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.

Anti-human IgM are pre-coated onto the test line region 'IgM' and anti-human IgG are pre-coated onto the test line region 'IgG' of the membrane. During testing, the specimen reacts with SARS-CoV-2 antigens which are conjugated to coloured particles. The mixture then migrates along the membrane chromatographically by capillary action and reacts with the anti-human IgM and anti-human IgG in the test line region 'IgM' and 'IgG' of the membrane. The presence of a coloured line in the test line region 'IgM' and/or 'IgG' indicates a positive result. The absence of a coloured line in the test line region 'IgM' and/or 'IgG'indicates a negative result.

The formation of a coloured line in the control line region 'C' serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Reagents and Materials Supplied

- 10 NADAL® COVID-19 IgG/IgM Test cassettes*
- 10 disposable pipettes
- 1 buffer (3 mL)**
- 1 package insert

*containing the preservative sodium azide: <0.02% (7.5 ng/test)
**Phosphate buffer containing the following preservatives: sodium azide: 0.2 mg/mL and kanamycin sulfate: 0.25 g/L

No hazard labelling is required according to Regulation (EC) Nº 1272/2008 CLP. Concentrations are below exemption threshold.

5. Additional Materials Required

- Specimen collection containers (appropriate for specimen material to be tested)
- Centrifuge (for serum or plasma specimens only)
- Alcohol pads
- Lancets (for fingerstick whole blood specimens only)
- Timer

6. Storage & Stability

Test kits should be stored at 2-30°C until the indicated expiry date. Test cassettes are stable until the expiry date printed on the foil pouches. Test cassettes must remain in the sealed foil pouches until use. Do not freeze the test kit. Do not use tests beyond the expiry date indicated on the packaging. Care should be taken to protect test kit components from contamination. Do not use test kit components if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to inaccurate results.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- Carefully read through the test procedure prior to testing.
- Do not use the test beyond the expiration date indicated on the packaging.
- Do not use test kit components if the primary packaging is damaged.
- Tests are for single use only.
- Do not add specimens to the reaction area (result area).
- In order to avoid contamination, do not touch the reaction area (result area).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not substitute or mix components from different test kits.
- Do not eat, drink or smoke in the area where specimens and test kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
- Handle all specimens as if they contain infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
- The test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals

does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled in accordance with usual safety precautions (e.g., do not ingest or inhale).

- Temperature can adversely affect test results.
- Used testing materials should be disposed of according to local regulations.

8. Specimen Collection and Preparation

The NADAL® COVID-19 IgG/IgM Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

To collect fingerstick whole blood specimens:

- Wash the patient's hand with soap and warm water or clean it with an alcohol pad. Allow it to dry.
- Massage the hand, without touching the puncture site, by rubbing along the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first drop of blood.
- Gently rub the hand from the wrist to the palm, and then to the finger to form a rounded drop of blood over the puncture site.

Fingerstick whole blood should be tested immediately.

Venipuncture whole blood specimens

Containers containing anticoagulants, such as K_2EDTA, sodium citrate, potassium citrate, sodium heparin, lithium heparin or sodium oxalate should be used for the preparation of venous whole blood or plasma specimens.

Testing should be performed immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods of time.

If the test is to be run within 2 days of specimen collection, whole blood collected by venipuncture should be stored at 2-8°C.

Do not freeze whole blood specimens.

Serum and plasma specimens

Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed specimens.

Testing should be performed immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods of time. Serum and plasma specimens can be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept at -20°C.

Bring specimens to room temperature prior to testing. Frozen specimens should be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

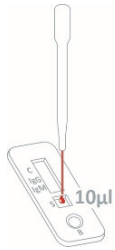
If specimens are to be shipped, they should be packed in compliance with all applicable regulations for the transportation of etiologic agents.

Icteric, lipemic, haemolysed, heat-treated and contaminated specimens may lead to inaccurate test results.

9. Test Procedure

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

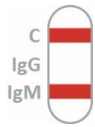
1. Remove the test cassette from the foil pouch and use it as soon as possible. The best results will be obtained if the test is performed immediately after opening the foil pouch. Label the test cassette with the patient or control identification.
2. Place the test cassette on a clean and level surface.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



10. Result Interpretation

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.

Note: The colour intensity in the test line region 'IgG' and 'IgM' may vary depending on the concentration of anti-SARS-CoV-2 antibodies in the specimen. Therefore, any shade of colour in the test line region 'IgG' or 'IgM' should be considered positive. Note that this is a qualitative test only and it cannot determine the analyte concentration in the specimen.

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.

11. Quality Control

An internal procedural control is included in the test cassette:

A coloured line appearing in the control line region 'C' is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice (GLP) recommends the use of external control materials to ensure proper test kit performance.

12. Limitations

- The NADAL® COVID-19 IgG/IgM Test is for professional *in-vitro* diagnostic use only. It should be used for the qualitative detection of anti-SARS-CoV-2 antibodies in human whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in the concentration of anti-SARS-CoV-2 antibodies can be determined with this qualitative test.
- The NADAL® COVID-19 IgG/IgM Test only detects the presence of anti-SARS-CoV-2 antibodies in specimens and should not be used as the sole criterion for a diagnosis of COVID-19.
- As with all diagnostic tests, all results should be interpreted in conjunction with other clinical information available to the physician.
- Shortly after the onset of fever, the concentration of anti-SARS-CoV-2 IgM may be below the detection limit of the test.
- The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
- Results from immunosuppressed patients should be interpreted with caution.
- A positive test result can also occur in case of negative PCR results because antibodies are still present in the blood after the illness and can be detected.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of a SARS-CoV-2 infection.

13. Expected Values

Primary SARS-COV-2 infection is characterised by the presence of detectable IgM 3-7 days after the onset of infection. Possible secondary SARS-COV-2 infection is characterised by elevated SARS-COV-2 IgG levels. In the majority of cases, IgM levels are also elevated. Persistent IgG levels in specimens after SARS-COV-2 infections may cause positive test results even after the concentration of the infectious agent in the blood has decreased below the detection limit of PCR.

14. Performance Characteristics

Clinical performance

Diagnostic sensitivity and specificity

The NADAL® COVID-19 IgG/IgM Test was evaluated using clinical specimens in comparison with a leading, commercially available PCR.

		PCR		
NADAL® COVID-19 IgG/IgM Test (IgG)		Positive	Negative	Total
	Positive	37	1	38
	Negative	1	142	143
	Total	38	143	181

Diagnostic sensitivity: 97.4% (86.2% - 99.9%)*

Diagnostic specificity: 99.3% (96.2% - 99.9%)*

Overall agreement: 98.9% (96.1% - 99.9%)*

*95% confidence interval

		PCR		
NADAL® COVID-19 IgG/IgM Test (IgM)		Positive	Negative	Total
	Positive	33	2	35
	Negative	5	141	146
	Total	38	143	181

Diagnostic sensitivity: 86.8% (71.9% - 95.6%)*

Diagnostic specificity: 98.6% (95% - 99.8%)*

Overall agreement: 96.1% (92.2% - 98.4%)*

*95% confidence interval

Interfering substances

SARS-CoV-2 negative specimens spiked with the following interfering substances showed no interference with the NADAL® COVID-19 IgG/IgM Test.

Acetaminophen	**200 mg/L**
Acetylsalicylic acid	**200 mg/L**
Albumin	**20 g/L**
Ascorbic acid	**20000 mg/L**
Bilirubin	**10000 mg/L**
Caffeine	**200 mg/L**
Creatine	**2000 mg/L**
Ethanol	**1%**
Gentisic acid	**200 mg/L**
Haemoglobin	**10000 mg/L**
Oxalic acid	**600 mg/L**
Uric acid	**20 mg/mL**

Cross-reactivity

Anti-Influenza virus type A, anti-influenza virus type B, anti-RSV, anti-adenovirus, anti-HBsAg, anti-*T. pallidum*, anti-*H. pylori*, anti-HIV and anti-HCV positive specimens were tested using the NADAL® COVID-19 IgG/IgM Test. No cross-reactivity with the specimens was observed when tested using the NADAL® COVID-19 IgG/IgM Test.

Precision

Repeatability and reproducibility

Precision was established by testing 10 replicates of negative and anti-SARS-CoV-2 IgG/IgM positive specimens. Repeatability was established within the reproducibility study. Testing was performed using 3 independent NADAL® COVID-19 IgG/IgM test lots.

The NADAL® COVID-19 IgG/IgM Test demonstrated acceptable repeatability and reproducibility. The negative and positive values were correctly identified >99% of the time.

15. References

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
2. World Health Organization (WHO). Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). WHO; 28 Feb 2020
3. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
5. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Rev. 0, 2020-03-02 OM

Symbol	Deutsch	English	Français	Español	Italiano	Polski
CE	CE Konformitätszeichen	CE marking of conformity	Conforme aux normes européennes	Conformidad europea	Conformità europea	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Consultare le istruzioni per l'uso	Przestrzegać instrukcji obsługi
IVD	*in-vitro*-Diagnostika	*in-vitro* diagnostic medical device	Dispositif médical de diagnostic *in-vitro*	Producto sanitario para diagnóstico *in-vitro*	Dispositivo medico-diagnostico *in-vitro*	Tylko do diagnostyki *in-vitro*
	Temperaturbegrenzung	Temperature limitation	Limites de température	Límite de temperatura	Limiti di temperatura	Temperatura przechowywania
LOT	Chargenbezeichnung	Batch code	Numéro de lot	Código de lote	Codice lotto	Numer serii
	Nicht zur Wiederverwendung	Do not reuse	Ne pas réutiliser	No reutilizar	Non riutilizzare	Tylko do jednorazowego użytku
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Data ważności
REF	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
Σ	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Sufficiente per "n" saggi	Wystarczający na <n> Powtórzeń

Symbol	Português	Český	Suomi	Svenskt	Nederlands	Dansk	Norsk
CE	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-märkning	CE-markering	CE-mærkning	CE standardisert
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Se brugsanvisningen	Les bruksanvisning nøye
IVD	Dispositivo médico para diagnóstico *in-vitro*	Diagnostický zdravotnický prostředek *in-vitro*	*in-vitro* -diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för *in-vitro*-diagnostik	Medisch hulpmiddel voor in-vitrodiagnostiek	Medicinsk udstyr til *in-vitro*-diagnostik	*in-vitro* diagnostic medisinsk enhet
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperatur-begränsning	Temperatuurlimiet	Temperatur-begrænsning	Temperatur begrensning
LOT	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Code van de partij	Batchkode	Merking
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Niet opnieuw gebruiken	Må ikke genbruges	Må ikke brukes om igjen
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
REF	Número de catálogo	Katalogov éčíslo	Luettelonumero	Listnummer	Catalogus nummer	Best il l ingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
Σ	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrekkelig for<n> tester

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