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

REF: 243001N-10 (10 Cassettes)

243001N-10CAN (10 Cassettes)

243001N-20CAN (20 Cassettes)

243001N-50CAN (50 Cassettes)

243001N-100CAN (100 Cassettes)

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Ver 7.0c, 2021-03-01
CANADA

NADAL® COVID-19 IgG/IgM Test

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 antibodies in human serum or plasma specimens (see section 12 'Limitations') in response to recent or prior infection and may also detect a response to vaccination. The test procedure is not automated and requires no special training or qualification. **The NADAL COVID-19 IgG/IgM test is for laboratory use only, not for point-of-care use.**

This assay is not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 infection.

This assay is not intended for home testing (or self-testing).

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

Negative results must be combined with clinical observations, patient history, and epidemiological information.

False negative results can occur in elderly and immunocompromised patients.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The performance of the device has not been assessed on specimens from individuals who have been infected with emerging new variants of SARS-CoV-2, including the UK SARS-CoV-2 variant, SARS-CoV-2 VOC 202012/01 (B.1.1.7) or the new South Africa SARS-CoV-2 variant, 501Y.V2.

2. Introduction and Clinical Significance

COVID-19 (Corona Virus Disease) is the infectious disease caused by the recently discovered coronavirus SARS-CoV-2. 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 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 '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

243001N-10/243001N-10CAN

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

243001N-20CAN

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

243001N-50CAN

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

243001N-100CAN

- 100 NADAL® COVID-19 IgG/IgM Test cassettes*
- 100 disposable pipettes
- 10 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.

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5. Additional Materials Required

- Specimen collection containers (appropriate for specimen material to be tested)
- Centrifuge (for serum or plasma specimens)
- Alcohol pads
- 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 serum or plasma.

Serum and plasma specimens

Containers containing anticoagulants, such as K_2EDTA, sodium citrate, or sodium heparin, should be used for the preparation of plasma specimens.

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

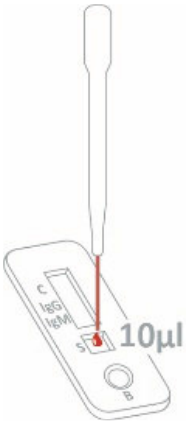
Icteric, lipemic, haemolyzed, heat-treated and contaminated specimens may lead to inaccurate test results.

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. **For serum/ plasma samples:** Holding the pipette vertically, draw the specimen up to the mark (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.



****Ensure NOT to add more sample than the required <u>10 µL</u>. Excess sample volume increases the risk of false positive results****

4. Holding the buffer bottle vertically, add 2 drops (approximately 80 µL) of buffer to the buffer well (B). **Avoid air bubbles forming.**

****Ensure to add ONLY the required <u>2 drops</u> of buffer. More buffer volume increases the risk of false positive results caused by non-specific binding.****

5. Start the timer.

NADAL® COVID-19 IgG/IgM Test

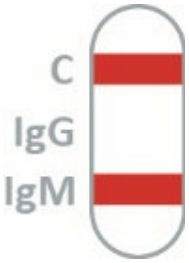
6. Wait for the coloured line(s) to appear.

   Read the test result after 10 minutes.

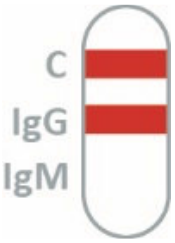
   Do not interpret the result after more than 20 minutes.

10. Results Interpretation

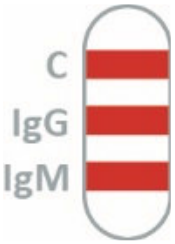
Positive for IgM
A coloured line develops in the control line region 'C' and another coloured line develops in the test line region 'IgM'. The result is indicative of the presence of antibodies against SARS-CoV-2.



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 the presence of antibodies against SARS-CoV-2.



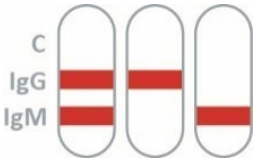
Positive for IgG and IgM
In addition to the control line 'C', a coloured line develops in the test line region 'IgM' and another in the test line region 'IgG'. The result is indicative of the presence of antibodies against SARS-CoV-2.



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 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.
- Use in conjunction with the testing strategy outlined by public health authorities in your area.
- 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.
- All results should be interpreted in conjunction with other clinical information available to the physician.
- At the beginning of the disease, the concentration of anti- SARS-CoV-2 IgM may be below the detection limit of the test.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the test early after infection is unknown.
- Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. **At this time, it is unknown how long IgM or IgG antibodies may persist following infection.**
- 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.
- Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection [or a successful immune response to a vaccine].
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- This test identifies antibodies to the spike protein of the SARS-CoV-2 virus and is therefore unable to distinguish between previously infected individuals and vaccinated individuals.
- 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.
- False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

- 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.
- Laboratories are required to report all positive results to the appropriate public health authorities.

13. Expected Values

A primary SARS-CoV-2 infection is characterised by the presence of detectable IgM antibodies at the beginning of the disease. The subsequent presence of IgG antibodies can indicate a previous SARS-CoV-2 infection for months – even when the pathogen is no longer detectable by PCR. These IgG antibodies can indicate immunity. However, in some cases antibodies can only be detected in sufficient quantities long after the infection. In case of a sufficient innate or a sufficient cellular immune response, the absence of detectable specific antibodies is also conceivable.

14. Performance Characteristics

Clinical performance

The NADAL® COVID-19 IgG/IgM Test was evaluated from clinical specimens in several studies. Each study has its own pool of reference samples obtained from patients clinically diagnosed for COVID-19. Those whose status was later confirmed by RT-PCR as positive make up the positive reference samples while those initially suspected of infection but had a negative RT-PCR result make up the negative reference samples.

As expected, clinical sensitivity (and specificity) for IgM and IgG individually as well as combined (IgM and/or IgG) increases after 14 days following exposure to the virus. Multiple studies have shown that the NADAL COVID-19 IgG/IgM test has a **clinical sensitivity of > 92%** and a **specificity of > 95%** when examining the combined IgG and IgM results.

Clinical sensitivity and specificity Study 1

All positive (85) reference samples in Study #1 were serum samples while the negative (371) reference samples were serum or plasma samples. The following table demonstrates the individual as well as the combined results for IgG and IgM test lines (negative: IgG and IgM; positive: IgM and/or IgG).

Parameter	Clinical Sensitivity (95% CI) N=85	Clinical Specificity (95% CI) N=371	Overall Agreement (95% CI) N=456
IgM+	91.8 % (83.8% - 96.6%)	99.2 % (97.7% - 99.8%)	97.8 % (96.0% - 98.9%)
IgG+	>99.9% (96.1% - 100.0%)[1]	99.5% (98.1% - 99.9%)[1]	99.6 % (98.4% - 99.9%)[1]
IgM+ &/or IgG+	94.1% (86.8% - 98.1%)	99.2% (97.7% - 99.8%)	98.2% (96.6% - 99.2%)

Clinical sensitivity and specificity Study 2

All reference samples in Study #2 were plasma samples from hospitalized, symptomatic patients. Samples were collected between 0- and 10-days post admission to the hospital.

Positive samples (70) were collected from patients who were either confirmed positive by chest imaging or by RT-PCR, while the 10 negative samples were collected from suspected, but SARS-CoV-2 negative patients as confirmed by RT-PCR or chest imaging.

The following table demonstrate the individual as well as the combined results for IgG and IgM for Study 2.

Parameter	Clinical Sensitivity (95% CI) N=70	Clinical Specificity (95% CI) N=10	Overall Agreement (95% CI) N=80
IgM+	90.0% (80.5% – 95.9%)	>99.9% (69.15% – 99.9%)	91.3% (82.8% – 96.4%)
IgG+	84.3% (73.6% – 91.9%)	>99.9% (69.15% – 99.9%)	86.3% (76.7% – 92.9%)
IgM+ &/or IgG+	91.4% (82.3% – 96.8%)	>99.9% (69.15% – 99.9%)	92.5% (84.4% – 97.2%)

Clinical sensitivity and specificity Study 3

All reference samples in Study #3 were serum samples from hospitalized, symptomatic patients. Samples were collected between 5 and 40 days after onset of disease symptoms.

Positive samples (100) were collected from RT-PCR confirmed SARS-CoV-2 infected patients while the 150 negative samples were collected from suspected, but SARS-CoV-2 negative patients as confirmed by RT-PCR.

The following tables demonstrate the individual as well as the combined results for IgG and IgM for Study #3.

Parameter	Clinical Sensitivity (95% CI) N=100	Clinical Specificity (95% CI) N=150	Overall Agreement (95% CI) N=250
IgM+	93.0% (86.3% - 96.6%)	97.3% (93.3% - 99%)	95.6% (92.3% - 97.5%)
IgG+	86.0% (77.9% - 91.5%)	99.3% (96.3% - 99.9%)	94.0% (90.3% - 96.3%)
IgM+ &/or IgG+	95.0% (88.7% - 98.4%)	97.3% (93.3% - 99.3%)	96.4% (93.3% - 98.3%)

Clinical sensitivity and specificity Study 4

All reference samples in Study #4 were serum samples from hospitalized, symptomatic patients. Samples were collected between 0 and 68 days after onset of disease symptoms (0-14 days: n=65; >14 days: n=48).

Positive samples (113) were collected from patients who were confirmed positive by RT-PCR, while the 50 negative samples were collected from suspected, but SARS-CoV-2 negative patients as confirmed by RT-PCR.

The following table demonstrates the individual as well as the combined results for IgG and IgM for Study 4 for all subjects, regardless of when the samples were collected.

Parameter	Clinical Sensitivity (95% CI) N=113	Clinical Specificity (95% CI) N=50	Overall Agreement (95% CI) N=163
IgM+	64.6% (55.4% - 72.8%)	>99.9% (92.9% - 100%)	75.5% (68.3% - 81.4%)
IgG+	55.8% (46.6% - 64.6%)	>99.9% (92.9% - 100%)	69.3% (61.9% - 75.9%)
IgM+ &/or IgG+	67.3% (58.2% - 75.2%)	>99.9% (92.9% - 100)	77.3% (70.3% - 83.1%)

Evolution of Clinical Performance Over Time

A retrospective study examined the time course of the antibody development from samples collected in Studies 3 and 4 above. A total of 413 serum samples were examined of which 213 were confirmed positive by RT-PCR and 200 were confirmed as negative by RT-PCR.

From the RT-PCR positive patients, additional blood and swab samples were taken over the course of the disease (up to 68 days after onset of symptoms) to study the time course of the antibody test results.

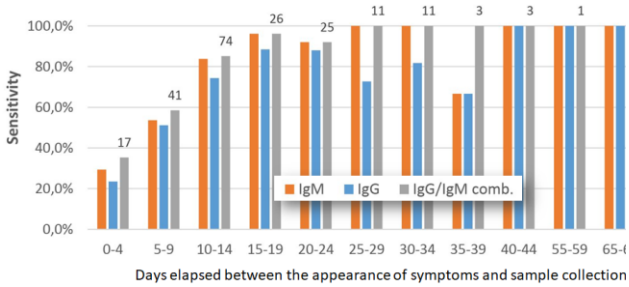
Calculated sensitivity and specificity values:

Parameter	Sensitivity (95% CI)		Specificity (95% CI)
	0-14 days	15-68 days	
IgM+	**67.4%** (59% –74.8%)	**95.1%** (88.0% –98.1%)	**98.0%** (95.0% – 99.2%)
IgG+	**60.6%** (52.1% –68.5%)	**85.2%** (75.9% –91.3%)	**99.5%** (97.2%– 99.9%)
IgM+ &/or IgG+	**70.5%** (62.2% –77.6%)	**96.3%** (89.7% –98.7%)	**98.0%** (95.0% – 99.2%)

For a more detailed analysis of the time course of IgM- and IgG detection performance, the following figure shows a sensitivity histogram for IgM and IgG individually as well as the combined IgM/IgG detection over the course of the study. On the X-axis, the sample taking time points after onset of the first disease symptoms are shown in classes of 5 days (complete range: 0-69 days). Numbers above bars shows the number of samples per group.

For each time window, the sensitivity for combined IgM/IgG detection was calculated from the results of the samples collected within these five days.

The results clearly show that sensitivity of the assay increases with larger time intervals between onset of symptoms and antibody testing. While the sensitivity is low in the first three sample taking windows, it rises above 96% for IgM detection in the 26 samples collected 15-19 days post symptom onset and stays above 92% for combined IgM/IgG for the remaining sample windows.



External Clinical Validation Studies

The NADAL® COVID-19 IgG/IgM Test was evaluated by several research groups external to nal von minden GmbH and are summarized below.

A comparative clinical study was performed by the **Laboratoire de santé publique du Québec (LSPQ)** and was published in the Journal of Clinical Microbiology (5). This study compared ten lab-based high throughput serological assays and 3 point-of-care serological assays, including the NADAL® COVID-19 IgG/IgM Test.

SARS CoV-2 samples (sensitivity panel: n= 176) were collected from patients with various clinical symptoms including 156 sera and 20 plasma. All 176 patients were confirmed positive for SARS CoV-2 infection by RT-PCR on nasopharyngeal specimens, 170 of these patients were symptomatic and six were asymptomatic.

Calculated sensitivity and specificity values:

	Sensitivity (95% CI)						Specificity (95% CI)
Days from symptom onset	0-7	8-14	**15-34**	**≥ 15**	**≥ 35**	All time points	
# of samples	46	36	60	94	34	176	148 to 166
IgM+ &/or IgG+	**35%** (21 –50)	75% (58-88)	92% (82-97)	95% (88-98)	100% (90-100)	75% (68-81)	98% (94-99)

In this sample population, the maximum sensitivities observed following the two-week acute window (≥15 days) was achieved by the NADAL® COVID-19 IgG/IgM Test with a sensitivity of 95% (CI, 88-98) and overall specificity of 98% (CI, 94-99).

A study conducted by **Dortet *et al*** (6) examined 10 commercially available SARS-CoV-2 rapid serological tests using the STARD methodology (Standards for Reporting of Diagnostic Accuracy Studies), including the NADAL COVID_19 IgG/IgM Test. A total of 250 sera from 159 PCR-confirmed SARS-CoV-2 patients (collected from 0 to 32 days after onset of symptoms) were tested. PCR Positive subjects were all symptomatic and over 95% of them were hospitalized. Control sera (N=254) were retrieved from pre-COVID periods. All samples were tested using rapid lateral flow immunoassays (LFIA) from ten manufacturers.

Calculated sensitivity and specificity values:

Sensitivity (95% CI) N=250				Specificity (95% CI) N=254
Days from symptom onset	0-9 Days	10-14 Days	≥ 14 Days	
IgM+	54.5 (44.3 - 64.3)	88.2 (79.0 - 93.9)	90.5 (79.8 - 96.1)	100.0 (98.1 - 100)
IgG+	18.8 (12.0 - 28.1)	54.1 (43.0 - 64.9)	90.5 (79.8 – 96.1)	99.2 (96.9-99.9)
IgM+ &/or IgG+	**55.4 (45.2 – 65.2)**	**90.6 (81.8 – 95.6)**	**92.1 (81.7 - 97.0)**	**99.2 (96.9-99.9)**

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	20,000 mg/L
Bilirubin	10,000 mg/L
Caffeine	200 mg/L
Creatine	2000 mg/L
Ethanol	1%
Gentisic acid	200 mg/L
Haemoglobin	10,000 mg/L
Oxalic acid	600 mg/L
Uric acid	20 mg/mL
Triglycerides	5,000 mg/L
	16,000 mg/L

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, anti-HCV, anti-SARS-CoV, HAMA and Rheumatoid Factor 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 for all substances tested except there were 2 out of 30 RF containing samples that showed a positive result for IgM and showed IgM/IgG positive results for SARS-CoV. It is not ruled out that, MERS-CoV positive specimens may show cross-reactivity with 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. Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK – ninth update, 23 April 2020. Stockholm: ECDC; 2020.
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, *et al*. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.
5. Therrien, C. *et al.* Multicenter Evaluation of the Clinical Performance and the Neutralizing Antibody Activity Prediction Properties of ten high throughput serological assays used in Clinical Laboratories. J Clin Microbiol 2020 Dec 10:JCM.02511-20. doi: 10.1128/JCM.02511-20. Epub ahead of print. PMID: 33303562
6. Dortet *et al* Evaluating ten commercially available SARS-CoV-2 rapid serological tests using the STARD (Standards for Reporting of Diagnostic Accuracy Studies) method. J Clin Microbiol. 2020 Nov 25:JCM.02342-20. doi: 10.1128/JCM.02342-20

Symbol	English
CE	CE marking of conformity
	Consult instructions for use
IVD	*in-vitro* diagnostic medical device
	Temperature limitation
LOT	Batch code
	Do not reuse
	Use by
REF	Catalogue Number
	Manufacturer
	Sufficient for <n> tests