

A circular logo consisting of a teal-colored ring with three teal-colored right-pointing triangles inside, arranged horizontally.

RAPID TEST

2019-nCoV IgG

REF V1401/20

Lateral Flow Test | **IVD**

for the detection of IgG Immunoglobulins against SARS-CoV-2 in whole blood, human serum or plasma specimens.

www.prognosis-biotech.com

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A. and complies with the specifications on the Standard EN ISO 13485:2016

Use only the current version of Product Data Sheet enclosed with the kit.

Rapid Test 2019-nCoV IgG V1401/V1420, is a qualitative Lateral Flow test for the detection of IgG against SARS-CoV-2 in human serum, plasma or whole blood specimens. The Lateral flow kit contains all reagents required for the immunoassay method.

Samples: Human serum, plasma or whole blood specimens.

- For *in vitro* diagnostic use only
 - For a medical diagnosis, the serological test result should always be interpreted together with the clinical symptoms of the patient and other result.
 - Test should only be conducted by a medical personnel.
 - This test has not been reviewed by the FDA.
 - Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
 - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
 - Not for the screening of donated blood
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- Test time (incubation time after specimens preparation): 15 min
 - Shelf life: 12 months
 - Storage: 4-30oC
- 3 This is an electronic version, please verify always the last one included in the kit.

1. Description

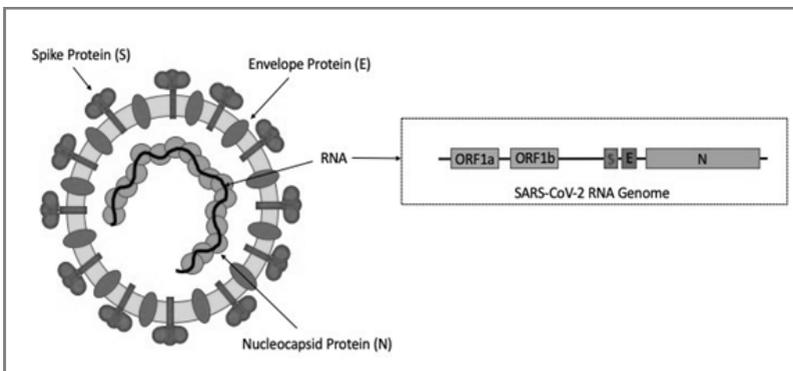
Rapid Test 2019-nCoV IgG is a qualitative Lateral flow test for the detection of IgG antibodies against the Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) in human serum, plasma or whole blood specimens.

2. Intended Use

- Rapid test 2019-nCoV IgG looks for COVID-19 spike protein antibodies in a blood sample. All currently available vaccines use the spike protein to produce an immune response. A positive antibody result indicates that you have produced antibodies in response to the vaccine or past COVID-19 infection.
- Rapid test 2019-nCoV IgG does not tell you if you have a current COVID-19 infection. This test can only tell you if you have had COVID-19 in the past or an immune response to a COVID-19 vaccine.
- Sample collection and testing at least two weeks after the vaccination or the onset of the symptoms in case of PCR confirmed COVID infection.
- False positive results for Rapid Test 2019-nCoV IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

3. General Information

Coronaviruses are enveloped, positive-sense, single-stranded RNA viruses with a nucleocapsid of helical symmetry and are composed of several proteins including the Spike (S), Envelope (E), Membrane (M) and Nucleocapsid (N) proteins. The S protein is very immunogenic with the Receptor Binding Domain (RBD) being the target of many neutralizing antibodies¹.



The 2019 Novel Coronavirus, formerly known as 2019-nCoV and now known as SARS-CoV-2, emerged in the Chinese province of Hubei (Wuhan) in December 2019 and has been declared a pandemic on 11 March 2020. This outbreak has spread rapidly, with millions of reported cases and thousands of deaths worldwide.

On December 2020 the first massive vaccination program started. A vaccine works by training the immune system to recognize and combat pathogens, either viruses or bacteria. To do this, certain molecules from the pathogen must be introduced into the body to trigger an immune response. Immunity after vaccination could reduce the danger of future severe infection and its complications although no vaccine is 100% protective.

4. Principle of the Method

Rapid test 2019-nCoV IgG is an antibody capture immunochromatographic assay for the detection of IgG antibodies against Spike-S protein in human serum, plasma or whole blood specimens. Monoclonal antibodies against Human IgG are immobilized on the Test line of the nitrocellulose membrane. S protein is conjugated on colloidal gold and dispensed on the sample pad. During the test, after the dilution of the specimen, if there are antibodies present, they will interact with S protein. This mixture flows across the membrane and interacts with the Test line producing a pink color line indicating a positive result. If SARS-CoV-2 antibodies are absent in the sample, no pink line will appear in the test line, indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

5. Reagents Provided

	V1401	V1420
Test device	1	20
Dilution Buffer dropper bottle	1 mL	5 mL
Disposable microsafe tube (5µl)	1	20
Disposable safety Lancets (for fingerstick whole blood specimens)	1	20
Alcohol pads	1	20
Test tubes	1	20

6. Materials required but not provided

- Adjustable single channel micropipette of 10 µL with disposable tips (for other than fingerstick whole blood specimens)
- Gloves and container for biohazardous waste
- Clock or timer
- Centrifuge for serum or plasma specimens

7. Storage Instructions

Store kit components between 4 and 30°C (39.2 - 96°F). Do not freeze any components provided. Re-seal the unused strips in the storing tube together with the desiccant bag provided. Expiry of the kit and reagents is stated on their labels and no quality guarantee is accepted after the expiration date. The expiry of the kit components can only be guaranteed if the components are stored properly and the reagent is not contaminated prior handling.

8. Safety and Precautions for use

8.1 Health and safety precautions

- **Use gloves, protective clothing and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.** The product must only be used by qualified personnel, familiar with the potential hazards, in a clinical or research laboratory
- **WASTE MANAGEMENT:** Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.

5 This is an electronic version, please verify always the last one included in the kit.

8.2 Precautions related to the procedure

- In accordance with Article 1, Paragraph 2b of European Directive 98/79/EC, the use of in-vitro diagnostic medical devices is envisaged by the manufacturer to ensure the suitability, performance, and safety of these products. Consequently, the testing procedure, information, precautions, and warnings in the instructions for use must be followed rigorously. No changes to the test procedure are permitted, nor is any use in combination with other products not approved by the manufacturer. The user is solely responsible for any such changes. The manufacturer is not responsible for false results nor incidents arising as a result of these. The manufacturer is not responsible for any results obtained by visual analysis of patient samples.
- Do not use the kit if the packaging of components is damaged, if there is an expired reagent or if the desiccant bag is absent inside the vial containing the strips.
- All reagents should be warmed in room temperature before use. Use a clean disposable plastic pipette tip for each reagent, to avoid cross-contamination.
- Do not mix and interchange different specimens.
- Do not interchange individual reagents between kits of different lot numbers.

9. Specimens preparation

9.1 Whole blood specimen

- **Fingerstick:** Using the alcohol swab, clean the area of finger to be lanced and allow to dry. Twist the cap of the lancet, place the lancet against the area and press the trigger button. After you wipe away the first drop of blood collect the blood droplet using a capillary tube.

NOTE 1: Massage and/or rub the hand to stimulate blood flow towards the collection area.

NOTE 2: Place the capillary towards the collection area allowing the blood to flow till the indicated line. Press the bulb only to expel the drawn up blood into the test tube containing the dilution buffer and mix thoroughly by pipet 4-5 times.

- **Venipuncture:** Collect venous whole blood in a tube with anticoagulant. In general, whole blood samples should be tested immediately after sample collection. Whole blood specimens must be stored at 2-8°C if not tested immediately and tested within 24 hours of collection. **Do not freeze whole blood specimens.**

9.2 Serum and Plasma specimens Collection

Blood specimens should be collected aseptically using venipuncture techniques by qualified personnel. The correct performance of specimen collection and storage is crucial for the test result. Keep tubes sealed at all times. The use of sterile or aseptic techniques will preserve the integrity of the specimens.

- **Serum:** Use a serum separator tube (SST) and allow specimens to clot for 2 hours at room temperature or overnight at 4°C. Centrifuge the specimen for 10min at 4000xg at room temperature. Remove serum and assay immediately or aliquot and store specimens at -20°C or -80°C.
- **Plasma:** Collect plasma using Heparin, EDTA or Citrate as an anticoagulant. Centrifuge for 15 minutes at 4000xg within 30 minutes of collection. Assay immediately or aliquot and store specimens at -20°C or -80°C.

NOTE: Serum or plasma specimens can be subjected to a maximum of 1 freezing/ thawing cycle. **Do not heat the specimens.** Avoid highly lipemic, icteric or hemolytic specimens because they could affect the results of the assay. Specimens with visible microbial contamination should not be used. After centrifugation, serum or plasma can be stored at 2-8°C if the test is performed within 4 days.

10. Method Procedure

10.1 Add 5 drops of the Dilution Buffer to the test tube from the dropper bottle.

10.2 Introduce 5µL of the sample (or the indicated volume of the capillary tube) into the test tube using a micropipette of 10 µL. Mix by priming pipetting at least 5 times.

10.3 Close the extraction tube with the dropper cup. Add 3 drops in the circular window of the cassette.

10.4 After 15 minutes, the test strip can be visually read and interpreted according to the following table and corresponding figure.

Note: If the test is not read within 15 minutes, it is considered to be invalid and safe results cannot be obtained.

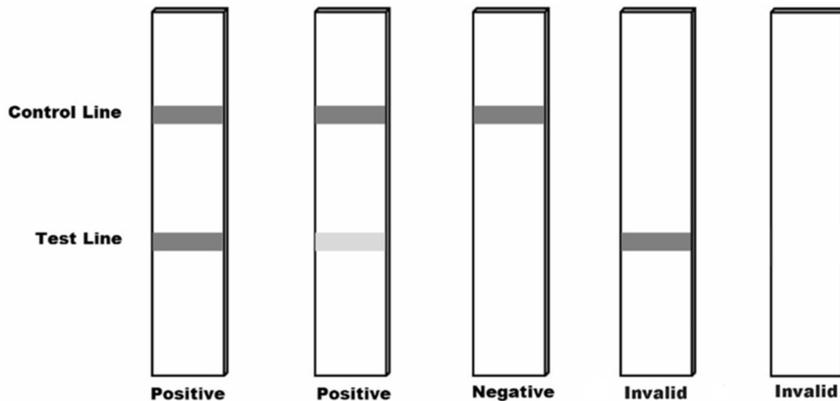
11. Interpretation of results

Positive: Two visible colored bands appear at both Test (T) and Control (C) line. It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.

Negative: One visible colored band appears at Control line. It indicates that the concentration of the SARS-CoV-2 antibodies is zero or below the detection limit of the test.

Note: In the case of whole blood specimens, a faded line may appear just above the pad of the strip. This line appears due to the blood composition and should not be taken under consideration.

Invalid: No colored band appears at Control line no matter whether it appears at Test line or not.



Interpretation of results

12. Limit of Detection

The lowest detectable concentration of an analyte in a method is known as LOD. In this case, serial dilutions of IgG chimeric antibodies were used to determine the LOD. The LOD is the level at which 95% of the replicates are characterized as positive. The results of 20 replicates of 10 dilutions with heat inactivate virus are shown at the table below.

LOD: 0,39 µg/mL

Concentration (µg/ml)	Positive Repli- cates	Visual Interpretation of results
25	20 / 20	Strong positive
12.5	20 / 20	Strong positive
6.25	20 / 20	Strong positive
3.125	20 / 20	Strong positive
1.56	20 / 20	Positive
0.78	20 / 20	Positive
0.39	19 / 20	Positive
0.195	2 / 20	Negative

13. Limitations of the immunoassay

- The detection of IgG antibodies against SARS-CoV-2 is dependent on the analyte concentration in the specimen. A negative or non-reactive result can occur if the quantity of anti-SARS-CoV-2 antibodies present in the specimen is below the LOD of the assay.
- This product is only used for testing of individual serum, plasma (Heparin, EDTA or Citrate) or whole blood. Other specimen types have not been evaluated and should not be used with this assay.
- A positive result does not mean that you are immune to the virus. It cannot tell you whether or not you can become ill with COVID-19 again. Nor can it tell you whether or not you can spread the virus to others. You should continue to follow all government guidance and restrictions.
- A negative result after vaccination or illness does not mean that you are not protected against severe infection in the future. Immunity does not depend only on the detectable IgG antibodies.

14. Immunoassay Performance

14.1 Cross-reactivity

Cross-reactivity has been evaluated by testing SARS-CoV-2 seronegative specimens from patients with antibodies to other coronaviruses or other pathogens. A total of 68 specimens from 11 different categories were tested. The number of samples tested for each category is listed below.

Pathogen	Tested sample number	False positive sample
Influenza A virus	6	0
Influenza B virus	5	0
Hepatitis C virus	6	0
Hepatitis B virus	7	0
Hemophilus influenzae	6	0
Alpha coronavirus 229E	7	0
Alpha coronavirus NL63	7	0
Beta coronavirus OC43	6	0
Beta coronavirus HKU1	5	0
Antinuclear antibodies	6	0
Respiratory syncytial virus	7	0

14.2 Internal validation characteristics

The internal validation of the Rapid Test 2019-nCoV IgG was assessed during a multi evaluation on specimens obtained from a general asymptomatic population of pre-epidemic individuals (blood donors, hospitalized patients), on individuals after vaccination against SARS-CoV-2 and on patients with clinical symptoms of coronavirus COVID-19 tested positive with RT-PCR assay.

14.2.1 Diagnostic Specificity

A total of 468 specimens (blood donors or hospitalized asymptomatic patients), collected prior to the outbreak of the COVID-19 pandemic, were tested. The specificity was 99.15%, 464/468 (95% CI: 97.83% to 99.77%).

14.2.2 Diagnostic Sensitivity

Internal study was performed with 124 specimens after vaccination and PCR confirmed SARS-CoV-2 infection. Samples were collected at least 2 weeks after the vaccination or the onset of the clinical symptoms. The sensitivity was 97.58%, 121/124 (95% CI: 93.09% to 99.50%).

	Mean Value	95% confidence interval
Sensitivity	97.58%	93.09% to 99.50%
Specificity	99.15%	97.83% to 99.77%
Positive Predictive Value (PPV)	96.80%	91.93% to 98.77%
Negative Predictive Value (NPV)	99.36%	98.06% to 99.79%

Diagnostic Specificity: 99.15%

Diagnostic Sensitivity: 97.58%

15. Method Summary

Total procedure time (after specimens preparation): 15 min.

Add 5 drops of the Dilution Buffer into the test tube



In the case of the capillary tube, pierce the finger with the lancet



Add 5 µL of sample into the test tube and mix thoroughly



Close the test tube with the dropper cup. Add 3 drops in the circular window of the device.



(Wait 15mins)

Formation of 2 lines indicates presence of SARS-CoV-2 IgG antibodies in the sample

16. References

1. Long, Q., Liu, B., Deng, H. et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. *Nat Med* (2020). <https://doi.org/10.1038/s41591-020-0897-1>.
2. Berry, J .D., e t al. Neutralizing epitopes of the SARS-CoV S-protein cluster independent of 446 repertoire, antigen structure or mAb technology. *MAbs* 2, 53-66 (2010).
3. Tai, W., He, L., Zhang, X. et al. Characterization of the receptor-binding domain (RBD) of 2019 novel coronavirus: implication for development of RBD protein as a viral attachment inhibitor and vaccine. *Cell Mol Immunol* (2020). <https://doi.org/10.1038/s41423-020-0400-4>.
4. [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-(covid-19)-vaccines)



In Vitro Diagnostics Medical Device



Content sufficient for <n> tests



Catalog number



Manufacturer



Storage Conditions



Instructions for use



Expiration Date



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