NG-Test® IgG-IgM COVID-19

A rapid test for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 (virus of COVID-19) in human whole blood, serum or plasma. All-in-one format.

For professional in vitro diagnostic use only.

Ref: ENO102COV / Rev: 200506 / EN

Intended use

The NG-Test® IgG-IgM COVID-19 is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma.

Summary and Explanation

Early January 2020, a novel coronavirus (SARS-CoV-2) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Six coronavirus species are known to cause human disease. Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals. The two other strains — severe acute respiratory syndrome coronavirus (SARS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV) — are zoonotic in origin and have been linked to sometimes fatal illness.
Coronaviruses are zoonotic, meaning they are transmitted between animals and people.
Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.
Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

Test principle

The NG-Test® IgG-IgM COVID-19 is a qualitative immunochromatographic assay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, plasma and serum. During testing, the specimen reacts with SARS-CoV-2 antigen-coated gold nanoparticles in the test cassette. The mixture then migrates on the membrane chromatographically by capillary action and reacts with the anti-human IgG and/or IgM in their respective test line region. If the specimen contains IgG and/or IgM antibodies to SARS-CoV-2, a colored line will appear respectively in the IgG region between the letters “T” and “C” and/or in the IgM region next to the letter “T” (see paragraph Interpretation of results).
A colored line should always appear in the control line region (marked “C”), indicating that the proper volume of specimen has been added and that the test worked correctly.
The test contains anti-human IgM and anti-human IgG as the capture reagent, and SARS-CoV-2 antigen gold nanoparticles as the detection reagent.

Reagents and material provided

- 5 Test devices in pouch, each pouch containing 1 test device sealed in a foil pouch with a desiccant.
- 5 Alcool swabs
- 1 Buffer solution in a plastic dropper bottle
- 1 Package insert

Patented technology

Material required but not provided

- Timer
- Disposable gloves
- Micropipette (for use with venous whole blood, plasma or serum)
- Tissue or wipe

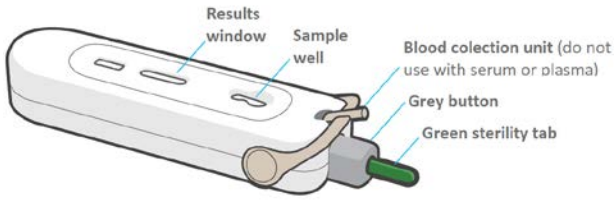
Precautions

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not use test if pouch is torn or damaged.
- In case the pouch has been stored at 4-8°C, allow at least 10 minutes for the device to come to room temperature.
- The test device should remain in the sealed pouch until use.
- Perform the test quickly after opening the aluminum pouch.
- The test must be placed on a flat surface while waiting for the results. The test should never be oriented upwards.
- The test device should not be reused.
- Handle all specimens as if they contain infectious agents and follow the standard procedures for proper collection and disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- **Make sure all collected blood is transferred on test strip**
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.

Storage and stability

Store as packaged in the sealed pouch between 4-30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

Specimen collection and procedure



Whole Blood – Capillary Collection:

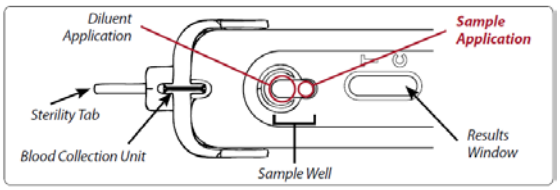
Refer to the procedure with diagrams on the last page.

Whole Blood– Venous Puncture:

1. Collect 10 µL of whole blood sample via a calibrated micropipette. Do not agitate the sample. Insert a pipette just below the surface of the sample for collection. Samples should be used immediately after collection and do not use hemolyzed blood samples.
2. Dispense sample into the sample well, at the sample application location indicated in the figure below. Then add 2 drops of buffer to the same well behind the sample **while holding the bottle vertically**. **If migration does not start, add an additional drop of buffer solution.**
3. Interpret the results at **15 minutes.**

Plasma & Serum (from a prepared sample in a laboratory):

1. Collect a 10 µL serum or plasma sample using a calibrated micropipette. Only samples that are clean, clear and with good fluidity can be used for the assay (do not use samples that are viscous or have high lipid levels).
2. Dispense sample into the sample well, at the sample application location indicated in the figure below. Then add 2 drops of buffer to the same well behind the sample **while holding the bottle vertically. If migration does not start, add an additional drop of buffer solution.**
3. Interpret the results at **15 minutes.**



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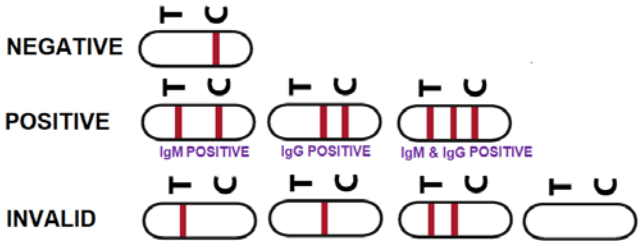
Interpretation of results



IgG POSITIVE: * **Two colored lines appear**. One colored line should always appear in the control line region (marked "**C**") and another line should be in the IgG line region (between the letters "T" and "C").

IgM POSITIVE: * **Two colored lines appear**. One colored line should always appear in the control line region (marked "**C**") and another line should be in the IgM line region (in front of the letter "T").

IgG and IgM POSITIVE: * **Three colored lines appear**. One colored line should always appear in the control line region (marked "**C**") and two test lines should be in the IgG line region and IgM line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of SARS-CoV-2 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (**marked "**C**"**)**. No line appears in the IgG region and IgM region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (marked "C") is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The NG-Test® IgG-IgM COVID-19 is for research use only. This test should be used for detection of IgG and IgM antibodies to SARS-CoV-2 in finger prick whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to SARS-CoV-2 can be determined by this qualitative test.
2. The NG-Test® IgG-IgM COVID-19 will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, retesting after the window period or additional follow-up testing using other methods are suggested. A negative result at any time does not rule out the possibility of infection with SARS-CoV-2.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
6. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (early stage of infection, asymptomatic stage).

Performance characteristics

The NG-Test® IgG-IgM COVID-19 has been evaluated by Bicêtre hospital (bacteriology and hygiene service) and Paul Brousse hospital (virology service), AP-HP. Université Paris Saclay, France. The results of the test were compared to those of RT-PCR reference method.

	Number of days after symptoms			
	0 to 5 days	**6 to 10 days**	**11 to 15 days**	**> 15 days**
Sensitivity	9.3%	41.2%	70.6%	100%
	(2.4 - 26.2%)	(22.8 - 63.1%)	(44.0 – 88.6%)	(56.1% - 100%)
Specificity	100%	100%	100%	100%
	(85.0% - 100%)	(85.0% - 100%)	(85.0% - 100%)	(85.0% - 100%)
NPV	49.1%	66.7%	84.8%	100%
	(35.8% - 66.6%)	(50.3% - 80.0%)	(67.3% - 94.3%)	(85.0% - 100%)
PPV	100%	100%	100%	100%
	(31.0% - 100%)	(65.5% - 100%)	(69.9% - 100%)	(56.1% - 100%)
	TP = 3 FN = 29 TN = 28 FP = 0	TP = 10 FN = 14 TN = 28 FP = 0	TP = 12 FN = 5 TN = 28 FP = 0	TP = 7 FN = 0 TN = 28 FP = 0

	Number of days after diagnosis by RT-PCR		
	-1 to 0 days	**1 to 3 days**	**4 to 8 days**
Sensitivity	17.7%	75.0%	80.8%
	(8.9 – 31.4%)	(21.9 – 98.7%)	(60.0 – 92.7%)
Specificity	100%	100%	100%
	(85.0% - 100%)	(85.0% - 100%)	(85.0% - 100%)
NPV	40.0%	96.6%	84.8%
	(28.7 – 52.4%)	(80.3% - 99.8%)	(67.3% - 94.3%)
PPV	100%	100%	100%
	(62.9% - 100%)	(31.0% - 100%)	(80.8% - 100%)
	TP = 9 FN = 42 TN = 28 FP = 0	TP = 3 FN = 1 TN = 28 FP = 0	TP = 21 FN = 5 TN = 28 FP = 0

NPV: Negative Predictive Value; PPV: Positive Predictive Value; TP: True Positive; FN: False Negative; TN: True Negative; FP: False Positive

Bibliography:

1. *World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china*
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3. *Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003*
4. *Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9*
5. *World Health Organization (WHO). Coronavirus.* https://www.who.int/health-topics/coronavirus

Symbols

Σ	Content sufficient for		Use By
IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
LOT	Batch code	REF	Catalogue number
	Consult Instructions for Use-	+4°C +30°C	Temperature limitation
	Manufacturer		

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CE

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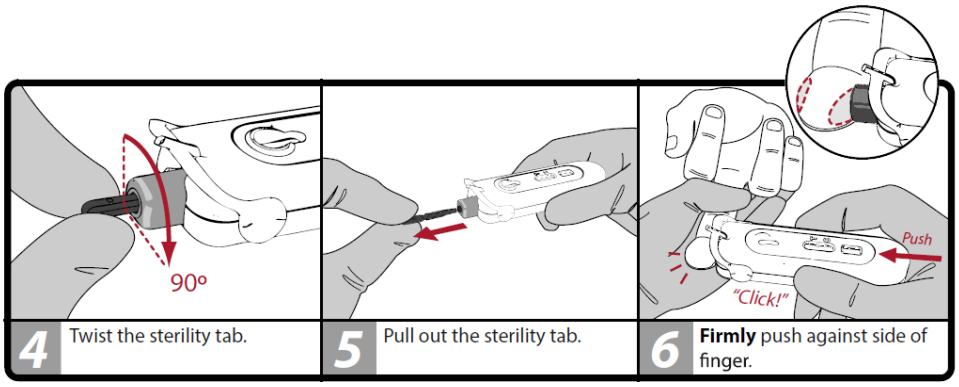
PREPARE FINGER

1 Select a finger and **firmly** massage for 5-10 seconds.

2 Clean fingertip with alcohol swab then **air dry**.

3 Tear open foil pouch and remove device.

PUNCTURE FINGER

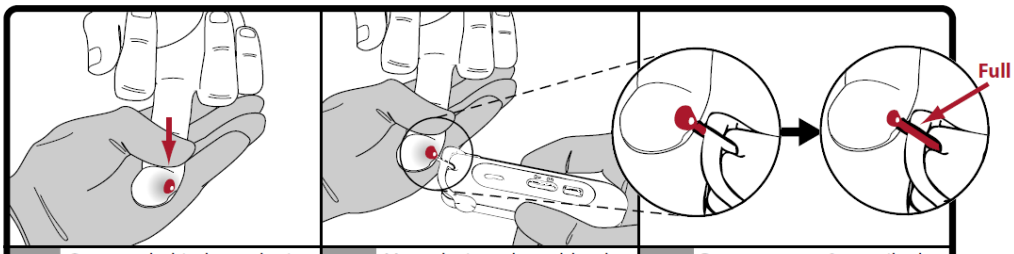


4 Twist the sterility tab.

5 Pull out the sterility tab.

6 **Firmly** push against side of finger.

COLLECT BLOOD

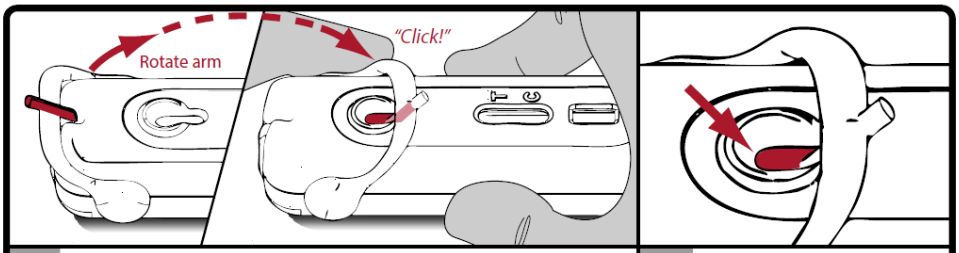


7 **Squeeze** behind sample site to form blood droplet.

8 Move device tube to blood droplet and fill.

9 Repeat steps 7 & 8 until tube is **full**.

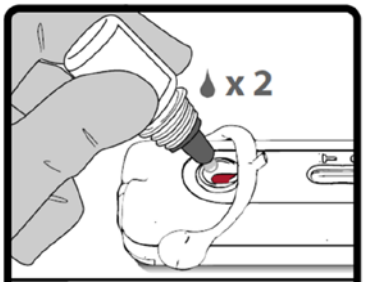
DELIVER BLOOD



10 Hold device on flat surface. Rotate arm until it clicks to release blood.

11 Make sure **all** collected blood is on the test strip.

ADD DILUIENT

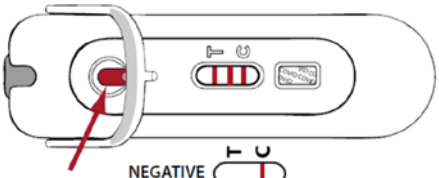


12 Add **2 drops** of diluent into the sample well. If migration does not start, add an addtional drop.

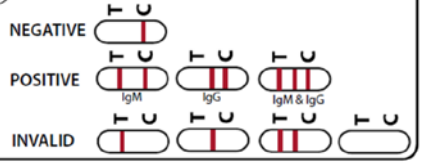
RESULT INTERPRETATION

Wait for 15 minutes for results.

15 min



NOTE: **blood must** be present on test strip.



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