EN

NG-Test® SARS-CoV-2 Ag

Rapid test for the qualitative detection of SARS-CoV-2 virus in nasopharyngeal samples.
For professional in-vitro diagnostic use only.

Ref.: ENO202COV/Rev: 200910 / EN

Intended purpose

NG-Test® SARS-CoV-2 Ag is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 virus in nasopharyngeal samples.

Summary

Early in January 2020, a new coronavirus (named "SARS-CoV-2") was identified as being the infectious agent causing a viral pneumonia outbreak in Wuhan, China, where the first cases experienced symptoms in December 2019. The disease it causes was named "coronavirus disease 2019" (in short "COVID-19").
Coronaviruses are enveloped RNA viruses widely present among human beings, other mammals, and birds, and lead to respiratory, enteric, hepatic, and neurological diseases. Six coronavirus species are known to cause human diseases. Four viruses - 229E, OC43, NL63, and HKU1 - are common and typically cause common cold symptoms in immunocompetent people. Two other strains - severe acute respiratory syndrome coronavirus (SRAS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV) - are of zoonotic origin and have been associated with some potentially life-threatening diseases.
Common COVID-19 infection signs include respiratory symptoms, fever, cough, shortness of breath, and breathing difficulties. In more serious cases, the infection may cause pneumonia, severe acute respiratory syndrome, renal failure, and even death.
The standard recommendations to prevent infection spread include regular hand washing, cover of mouth and nose when coughing and sneezing, thorough cooking of meat and eggs. Avoid any close contact with any person experiencing respiratory disease symptoms such as cough and sneezing.

Principle

NG-Test® SARS-CoV-2 Ag is a qualitative immunochromatographic assay for the detection of SARS-CoV-2 virus in nasopharyngeal samples. During the test, the sample reacts with colloidal gold nanoparticles conjugated to monoclonal antibodies directed against SARS-CoV-2 in the test case. Then, the mix migrates through the membrane by capillary action, and reacts with another monoclonal antibody directed against SARS-CoV-2 that is printed at the test line (T) level. If the SARS-CoV-2 concentration present in the sample is higher than the detection limit, a coloured line appears on line T.
A colour line should always be present on the control line marked "C", indicating sufficient amount was applied and the test worked properly.

Reagents and materials supplied

Each kit contains:

- 20 cassettes individually packaged in aluminium pouches with desiccant
- 20 calibrated micropipettes to deliver up to 100 µL
- 20 Eppendorf tubes
- 1 buffer solution in a plastic dropper bottle
- 1 instruction leaflet

Materials required but not supplied

- Nasopharyngeal swab
- Transport medium
- Stop watch
- Vortex
- Personal protective equipment

Cautions

- For professional *in-vitro* diagnostic use only.
- It is recommended to use the test under a type-II microbiological safety cabinet to protect the person handling SARS-COV-2 virus.
- Do not use the test if the pouch is torn or damaged.
- If the pouch was stored between 4 and 8°C, wait at least 10 minutes so that the test reaches room temperature.
- The test cassette should remain in the sealed pouch until use.
- Once the aluminium pouch is open, carry out the test rapidly.
- The test should be placed on a flat surface while awaiting the result. The test should never be oriented upwards.
- Do no reuse the device.
- Handle all the samples as if they contained infectious agents. Follow the established precautions against microbiological risks throughout all the procedures, and follow the standard procedures to collect and dispose of the samples appropriately.
- Wear protective clothing such as lab coats, disposable gloves, and protective eyewear when analysing the samples.
- Make sure an appropriate amount of sample is used to carry out the tests. If the sample volume is too high or too low, the results may deviate.
- The used test should be disposed of in accordance with local regulations.
- Do not eat, drink, or smoke within the area where samples and kits are handled.

Storage and stability

Store the test in the sealed aluminium pouch between 4 and 30°C.The test is stable until the expiry date printed on the pouch. The test device should remain in the sealed pouch until use. Do not freeze. Do not use after the expiry date.

Specimen collection and procedure

The test was designed to be used under a type-II microbiological safety cabinet, as the air flow does not alter the migration.

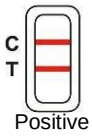
1. Wear protective gloves, protective eyewear, and a protective mask.
2. Collect the nasopharyngeal specimen using the laboratory method and an appropriate swab.
3. Place the swab in a virus transport medium (M4RT, UTM (Copan, ref. 346C), or Hardy Diagnostics (ref. R99).
4. Equilibrate the kit components to room temperature.
5. Dispense 4 drops (~100 µL) buffer in one of the Eppendorf tubes provided in the kit.
6. With the provided pipette, collect 100 µL sample in the transport medium, and dispense is in the Eppendorf tube.
7. Vortex, and then, with the same pipette, collect 100 µL of the mix and apply in the "S/R" sample well of the device.
8. Read the result after **15 minutes**. Do not read after 20 minutes.

Interpretation of the results

Negative

Negative result

Only one red line appears within the control area (C). The sample does not contain virus or the virus concentration cannot be detected by the test. This should be interpreted as a negative result.



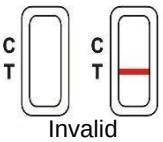
Positive

Positive result

Two red lines appear, one in the control area (C) and one in the test area (T). The sample contains SARS-CoV-2 virus and should be interpreted as a positive result.

NOTE: The intensity of the red test line (T) may vary depending on SARS-CoV-2 virus level in the sample. A low-intensity line should be considered as a positive result.

Invalid result



Invalid

If the control line (C) does not appear, the test result is invalid. Most often, the control line does not appear because of insufficient sample volume or an incorrect procedure. The kit may have been deteriorated. Repeat the procedure using a new test. If the problem persists, do not reuse the kit and contact your distributor.

Quality control

An internal control is included in the test. When the control line appears, it confirms the sample volume was sufficient and the procedure was correct. No control sample is provided with this kit. Nevertheless, as a good laboratory practice, it is recommended to test positive and negative controls to confirm the test procedure and ensure the test works well.

NG Biotech, Z.A. Courbouton, Secteur 1, 35480 Guipry, France
Tel.: +33 (0)2 23 30 17 83 Fax: +33 (0)9 71 70 53 10 Email: contact@ngbiotech.com
www.ngbiotech.com

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Limitations

1. NG-Test® SARS-CoV-2 Ag is for professional *in-vitro* diagnostic use only. With this test, you cannot determine the SARS-CoV-2 quantity in the sample.
2. With this test, you can confirm SARS-CoV-2 virus is present in a symptomatic patient. It should not be used as the only diagnostic criterion for SARS-Cov-2 infection.
3. As for any diagnostic test, the doctor should interpret the results taking into account other clinical data.
4. If the test result is negative, a confirmation test with PCR method should be performed.
5. The test will produce a negative result in the following conditions: the concentration of SARS-CoV-2 virus in the sample is lower than the minimum test detection limit.

Performance

NG-Test® SARS-CoV-2 Ag was assessed with 79 nasopharyngeal samples by Bicêtre Hospital (Bacteriology and Hygiene Department) and Paul Brousse Hospital (Virology Department), Public assistance/Paris hospitals. Paris University - Saclay, France. The test results were compared with the results obtained with the standard method (RT-PCR) and viral load for positive patients were also evaluated (based on clinical data, the viral load was considered as high for Ct value results between 14.0 and 24.0).

		RT-PCR		
		Positive		Negative
	Ct* value	[14.0-24.0]	[14.0-30.0]	/
NG-Test® SARS-CoV-2 Ag	Positive	23	26	0
	Negative	5	18	35
	Total	28	44	35

*Ct = Cycle threshold

	Ct = [14.0-24.0]	Ct = [14.0-30.0]
Diagnostic sensitivity	82% IC 95% [63 – 94%]	59% IC 95% [43 – 74%]
Diagnostic specificity	100% IC 95% [90 – 100%]	
Positive predictive value	100%	
Negative predictive value	82% IC 95% [67– 91%]	66% IC 95% [58 – 74%]

References

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Symbols

Σ	Sufficient content for		Expiry date
IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
LOT	Batch number	REF	Product reference
	Read the instructions before use	+4°C +30°C	Temperature limits
	Manufacturer		Do not use if package is damaged
	Keep dry		

NG Biotech
Z.A. Courbouton,
Secteur 1, 35480 Guipry,
France
Tel.: +33 (0)2 23 30 17 83
Fax: +33 (0)9 71 70 53 10
Email: contact@ngbiotech.com

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