EN

NG-Test® SARS-CoV-2 Ag

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

Ref: ENO221COV/ Rev: 201030/ EN

Intended purpose

The NG-Test® SARS-CoV-2 Ag is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens. The NG-Test® SARS-CoV-2 Ag is for professional use only and is intended for use as an aid in the diagnosis of SARS-CoV-2 infection. Note that the concentration of viral antigens may vary in the course of the disease and might fall below the detection threshold of the test, particularly when the duration of disease symptoms increases (specimens collected within 7 days of the first symptom are generally more likely to give a positive result). Infectivity cannot be excluded on the basis of negative test results alone.

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 (SARS-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. Then, the mix migrates through the membrane by capillary action, and reacts with another monoclonal antibody directed against SARS-CoV-2 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 migration occurred properly.

Reagents and materials supplied

Each kit contains :

- 20 cassettes individually packaged in aluminium pouches with desiccant.
- 20 extraction tubes and 20 dropper caps*.
- 2 extraction buffer vials with dropper
- 20 sterile swabs*.
- 2 tubes holders
- 1 package insert.

*Due to potential shortages of ancillary medical products related to COVID-19, the nasopharyngeal swabs and extraction tubes/dropper caps provided may be subject to change.

Materials required but not supplied

- Timer.
- Personal protective equipment (safety mask, goggles, gloves).
- Reagent holder.

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, nor the swab nor the extraction tube.
- 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.
- Do not add specimens to the reaction area (reading window).
- 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 aluminum pouch between 4 and 30°C in a clean, dark & dry place preservation. 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.

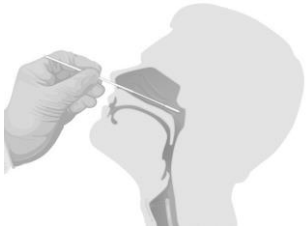
Specimen collection and procedure

1. Wear protective gloves, protective eyewear, and a protective mask.
2. Bring tests to room temperature prior testing.
3. Place clean extraction tube labeled with the patient ID into a reagent holder.
4. Holding the buffer bottle vertically and without touching the edge of the tube, add 10 drops into the extraction tube (~300µl).
   In case of foam (end of the first vial of buffer) switch to second full vial.
5. Collect the nasopharyngeal specimen using the standard laboratory method and the swab provided into the kit.

Use the swab provided on the kit, do not use any other swab.

Nasopharyngeal specimen :

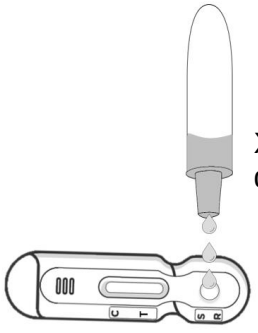
- Keep the patient's head slightly tilted backwards
- Insert the swab into the nostril and gently push it as far as possible along the floor of the nasal cavity, parallel to the palate, as described in the picture:



- Swab the epithelium of the nasal fossae with rotating movements for 15 seconds, scraping the walls of the nasopharynx to collect cells.
- Slowly remove the swab and place it in the extraction tube.

Remarks :
Swabbing can be performed in both nostrils of the same patient using the same swab, however this is not necessary if the swab is properly saturated with fluid from the first nostril sampled. Do not use samples that are contaminated with blood.

6. Unload the swab immediately after sampling by rotation in the extraction buffer 10-15 times and squizz it through the tube to extract as much volume of sample as possible.
7. Remove the swab and squizz it firmly against the tube walls to release as much liquid as possible.
8. Put the swab back into its original package and dispose it according to local regulations.
9. Remove the cassette from the aluminium pouch. Place the test on a clean and flat surface.
10. Immediately after extraction attached a dropper cap to the extraction tube and transfer 3 drops (~120µl) of the extracted sample to the « S/R » well of the test cassette and start the timer.
11. Read the result after exactly 15 minutes.
    Do not read after more than 20 minutes to avoid false positive results.



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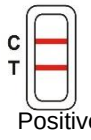
Results Interpretation

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.



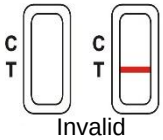
Positive

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 test migration occurred correctly. No control sample is provided with this kit. In case of doubt of test results or interpretation consult your attending doctor.

Performances

All performances have been evaluated on samples diluted in viral transport media, approximately at a dilution 1/20 compared to recommended direct procedure.

1. Evaluation of NG-Test® SARS-CoV-2 Ag

NG-Test® SARS-CoV-2 Ag was assessed with 79 nasopharyngeal samples placed in VTM, samples were diluted by a factor of 20 compared to the recommended procedure, 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%]

2. Limit of detection

The limit of detection was evaluated with inativated virus samples diluted in transport media and was found at 1.10^4 pfu/mL.

3. Repeatability and reproductibility

Repeatability and reproductibility of NG-Test SARS-CoV-2 Ag have been evaluated with viral transport media (spiked or not) as positive and negative samples. No significant difference was observed for between lot, between operators and between series results.

4. Interferences

The following potential interferences substances have not impact on the NG-Test SARS-CoV-2 Ag : viral transport media Hardy, UTM et M4RT, saliva and physiological solution NaCl 0.15 M.

5. Cross reactions

Cross reactions on NG-Test SARS-CoV-2 Ag were evaluated by testing the following batcteria and respiratory virus : Enterovirus, virus respiratoire syncytial, adenovirus, influenza B, parainfluenza, *mycoplasma pneumoniae*, *Bordetella pertussis*, metapneumovirus humain, influzenza A H1 et influenza A H3, influenza A H1 2009. Those virus have not impact on the results of the NG-Test SARS-CoV-2 Ag.

Limitations

1. NG-Test® SARS-CoV-2 Ag is for professional in-vitro diagnostic use only.
This test doesn't allow the quantitaitve SARS-CoV-2 determination in the sample.
2. This test permits to confirm the presence of SARS-CoV-2 virus in a symptomatic patient. **It shouldn't 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 the other clinical data.
4. If the test result is negative, a confirmation test by RT-PCR should be performed.
5. The test will produce a negative result if the concentration of SARS-CoV-2 virus in the sample is lower than the limit of detection or if the nasopharyngeal specimen collection was not performed adequately.

Bibliography

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4. 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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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		

CE

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