SARS-CoV-2 rapid antigen test

Leaflet

Flowflex™

REF L031-11815	

Rapid test for qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab samples.
For professional in vitro diagnostic use only

INTENDED USE

SARS-CoV-2 rapid antigen test Lateral flow chromatographic immunomethod for qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen in nasal swab specimens directly from persons suspected of having COVID-19 by their healthcare provider during the first seven days after the onset of symptoms. The SARS-CoV-2 rapid antigen test does not distinguish between SARS-CoV and SARS CoV-2.

The results represent the identification of the SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory tract samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but correlation with patient history and other diagnostic data is required to determine the infection status. Positive results do not rule out bacterial infections or co-infections with other viruses. The identified agent may not be the definitive cause of the disease.
Negative results in patients with symptoms after seven days should be considered as expected and should be verified by the molecular method if necessary for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of current patient exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The SARS-CoV-2 Rapid Antigen Test is intended for use only by trained clinical laboratory personnel and healthcare professionals.

SUMMARY

The new coronaviruses belong to the ÿ1 species . COVID-19 is an acute respiratory infectious disease. People they are generally prone to it. Currently, the main source of infection is patients infected with the new coronavirus; asymptomatic infected people can also be a source of infection. Based on current epidemiological research, the incubation period is 1 to 14 days, most often 3 to 7 days. Major manifestations include fever, fatigue, and dry cough. In several cases, there is a stuffy nose, blowing nose, sore throat, muscle aches and diarrhea.

PRINCIPLE

The SARS-CoV-2 Rapid Antigen Assay is a qualitative membrane chromatographic immunomethod for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen in human nasal swab specimens.
After processing the samples and applying them to the test cassette, there will be SARS-CoV-2 antigens, if present in the sample, react with particles coated with anti-SARS-CoV-2 antibodies that have been immobilized in the test strip. The mixture then travels through the membrane by capillary forces. The antigen-conjugate complexes travel through the test strip to the reaction region, where they are captured by a line of antibodies bound to the membrane. The results are interpreted visually after 15 minutes based on the presence or absence of visible colored lines. As an activity check, a colored line always appears in the control line area, confirming that the correct sample volume has been added and that the membrane has become wet.

REAGENTS

The test cassette contains particles coated with anti-SARS CoV-2 antibodies on the membrane. The positive control rod contains the loaded recombinant SARS-CoV-2 antigen.

WARNING

- For professional *in vitro* diagnostic use only. Do not use after the date consumption.
- Do not eat, drink or smoke in the area where samples and kits are handled.
- Do not use the tests if the packaging bag is damaged.
- Treat all specimens as if they contained infectious agents. During testing, follow established measures against microbiological hazards and follow standard procedures for proper sample disposal.
- Wear protective clothing such as a lab coat, disposable gloves, and goggles during sample testing.
- Used tests must be disposed of in accordance with local regulations. Used tests should be considered potentially infectious and should be disposed of in accordance with local regulations.

- Humidity and temperature may adversely affect the results.
- This package leaflet must be read in its entirety before performing the test. Non-compliance instructions in the leaflet may lead to inaccurate test results.

STABILITY AND STORAGE

- The kit can be stored at temperatures between 2-30 ° C.
- The test is stable until the expiration date printed on the sealed sachet.
- The test must remain in the sealed sachet until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

MATERIALS

Supplied materials

- Test cartridges
- Positive control bar
- Disposable swabs *
- Extraction buffer tubes
- Negative control rod
- Leaflet

* *Disposable swabs are manufactured by another manufacturer*

Necessary but not supplied materials

- Personal protective equipment • Stopwatch

SAMPLE COLLECTION AND PREPARATION

- The SARS-CoV-2 rapid antigen test can be performed using swab specimens from the nose.
- Testing should be performed immediately after sampling, or no more than one (1) hour after sampling.
- For nasal swab sampling:

1. Carefully insert the disposable stick that came with your kit into one nostril. Using a gentle rotation, push the stick 2.5 cm (1 inch) from the edge of the nostril.

2. Rotate the rod 5 times against the mucosa inside the nostril to ensure adequate sampling.

3. Using the same stick, repeat this procedure in the second nostril to ensure that a sufficient amount of sample has been taken from both nostrils.

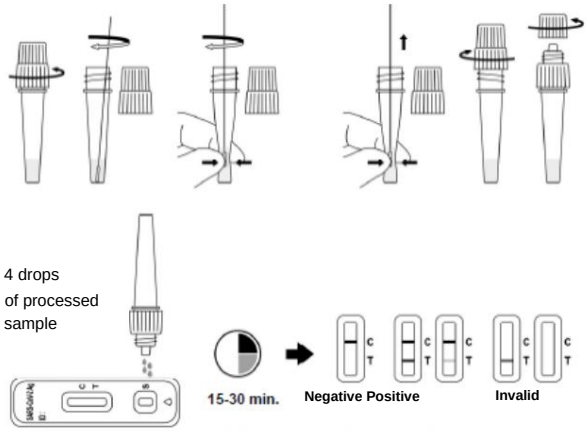
4. Remove the rod from the nasal cavity. The sample is now ready for preparation with extraction buffer tubes.

INSTRUCTIONS FOR USE

Allow the assay and extraction buffer to equilibrate to room temperature before testing (15-30 °C).

1. Use a separate extraction tube for each sample to be tested and use it appropriately mark.
2. Unscrew the dropper cap from the extraction tube without squeezing it.
3. Insert the rod into the tube and twist it for at least 30 seconds. Then twist the rod at least 5 times while squeezing the sides of the tube. Be careful not to spill the contents of the tube.

4. Remove the rod while squeezing the sides of the tube to expel the fluid.
5. Place the dropper cap firmly on the sample extraction tube. Mix thoroughly by swirling or vibrating the bottom of the tube.
6. Remove the test cartridge from the sealed bag and use it as soon as possible. The best results will be obtained if the analysis is performed as close as possible to the sampling time and **within a maximum of one hour** from the sampling time.
7. Place the test cartridge on a flat, clean surface.
8. Add the sample to the test cassette well
   a. Unscrew the small cap from the tip of the dropper.
   b. Invert the extraction tube with the dropper tip facing down and hold it vertically (approximately one inch above the sample well).
   c. Gently squeeze the tube and dispense 4 drops of the prepared sample into the sample well.
9. Wait for the colored line (s) to appear. The results need to be subtracted after 15-30 minutes. **Do not read the results after 30 minutes.**



INTERPRETATION OF RESULTS

(Please see the illustration above)

NEGATIVE: Only one colored line appears in the control area (C). No apparent line appears in the test line area (T). This means that no SARS-CoV-2 antigen was detected.

POSITIVE: * Two different lines appear. One line in the control line area and the other in the test line area. This indicates that the presence of SARS-CoV-2 antigen was detected.

* **NOTE:** The color intensity of the test line (T) may vary depending on the level of SARS-CoV-2 antigen present in the sample. Therefore, any shade of color in the test line area (T) should be considered positive.

INVALID: The control line does not appear. The most likely causes
Inadequate control lines are insufficient sample volume or incorrect procedure.
Review the procedure and repeat the test using a new test cartridge. If problems persist, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal control of the procedure is included in the test. Color line appearing in the control line area (C) is the internal control of the test. It confirms a sufficient sample volume and the correct technique.
Positive and negative control rods are included with each kit. These control rods should be used to ensure that the test cartridge is operating and that the test procedure is performed correctly.

Follow the "INSTRUCTIONS FOR USE" section to perform the control test.

LIMITATIONS

1. The SARS-CoV-2 rapid antigen test is for *in vitro* diagnostic use only. The test should only be used to detect SARS-CoV-2 antigens in nasal swab specimens. The intensity of the test line does not necessarily correlate with the viral titer of SARS CoV-2 in the sample.

2. Samples should be tested as soon as possible after collection and at most during one hour after collection.
3. Use of viral transport media may reduce the sensitivity of the test.
4. A false negative test may occur if the antigen level is in the sample below the test detection limit or if the sample was taken incorrectly.
5. Test results should be correlated with other clinicians available data.
6. A positive test result does not rule out co-infection with other pathogens.
7. A positive test result does not distinguish between SARS-CoV and SARS-CoV-2.
8. A negative test result does not rule out other viral or bacterial infections.
9. A negative test result in a patient with onset of symptoms after seven days should be considered as expected and should be verified by the molecular method if necessary for patient management.

(If different SARS virus and strain resolution is required, further testing is required).

PARAMETERS OF ACTIVITY

Clinical sensitivity, specificity and accuracy

The SARS-CoV-2 activity of the rapid antigen test was evaluated using 304 nasal swabs taken from individual symptomatic patients (within 7 days of onset) suspected of having COVID-19. The results show that the relative sensitivity and relative specificity are as follows:

Clinical efficacy of the SARS-CoV-2 rapid antigen test

Method		RT-PCR		Overall results
SARS-CoV-2 fast antigen test	The results	Negative	Positive	
	Negative	269 1 1 33 270 34		270
	Positive			34
Overall results				304

Relative sensitivity: 97.1% (83.8% -99.9%) Relative specificity: 99.6% (97.7% -99.9%) *
* Accuracy: 99.3% (97.5% -99.9%) * 95% confidence intervals

Detection limit (LoD)

The LoD SARS-CoV-2 rapid antigen test was determined using limiting dilutions of gamma-inactivated viral samples. The viral sample was enriched with a pooled human nasal swab in a series of concentrations. Each level was tested for 30 replicates. The results show that the LoD is 1.6 * 102 TCID50 / mL.

SARS-CoV-2 concentration in the sample	% Positive tests
1.28*103 TCID50/mL	100% (30/30)
6.4*102 TCID50/mL	100% (30/30)
3.2*102 TCID50/mL	100% (30/30)
1.6*102 TCID50/mL	96.7% (29/30)
8*10 TCID50/mL	0% (0/30)

Cross-reactivity and interference

No cross-reactivity was observed with samples from patients infected with coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU11.2, parainfluenza virus types (Type 1, Type 2, Type 3, Type 4), influenza A / B, human rhinovirus, human bocavir, human respiratory syncytial virus, human metapneumovirus, human adenovirus, enterovirus, Chlamydia pneumoniae, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, Pneumocystis jirovecii a MERS-koronavirem.

The SARS-CoV-2 rapid antigen test does not distinguish between SARS-CoV and SARS-CoV-2.
Interfering substances (whole blood, dafenlin, oxymetazoline hydrochloride spray, mometasone furoate nasal spray, fluticasone propionate, saline with seawater) of a certain concentration do not interfere with SARS-CoV-2 rapid antigen test

PRECISION

As part of the analysis

Precision in the analysis was determined using 10 replicate samples: negative controls and SARS-CoV-2 antigen positive controls. Samples were correctly identified in> 99% of cases.

Between analyzes

Inter-run precision was determined using 10 independent analyzes of the same sample: a negative sample and a SARS-CoV-2 antigen positive control. Using these samples, three different batches of SARS-CoV-2 rapid antigen assay were tested.
Samples were correctly identified in> 99% of cases.

LITERATURE

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502.

2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

List of symbols

	Producer		Contains enough for <n> tests		Temperature limit
IVD	In vitro diagnostick is medical equipment		Apply to date		Do not reuse
	See instructions for use	LOT	Batch code	REF	Catalog number
EC REP	Authorized representative in the European Community				Date of manufacture

Parts list

SARS-CoV-2 Antigen	SARS-CoV-2 antigen
Negative Control Swab	Negative control rod
Positive Control Swab	Positive control rod
Extraction Buffer Tubes	Extraction test tubes
Disposable Swabs	Disposable sticks
SARS-CoV-2 Antigen Rapid Test	SARS-CoV-2 rapid antigen test

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