

**Flowflex™**

	REF	L031-12525	English
	REF	L031-12535	

*For professional in vitro diagnostic use only.*

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.

Diagram illustrating the steps for using a microcentrifuge tube with a cap:

- Insert the cap.
- Tighten the cap by turning it clockwise.
- Hold the tube with the thumb and index finger, and shake it vigorously.
- Remove the cap by turning it counter-clockwise.
- The cap is shown separately, indicating it is removed.

เติมนําลายลงในหลอด  
จนกระทั่งนําลายถึงขีด  
ตรงกลางหลอด

ป็นข้างหลอด  
อย่างน้อย 5 ครั้ง

- แกว่งหรือสับบัด  
ก้นหลอด

15-30 นาที

สิ่งส่งตรวจ  
ที่เตรียมไว้แล้ว  
จำนวน 4 หยด

ผลลบ

ผลบวก

ไม่ถูกต้อง

1. The SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab and saliva specimens. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.  
***Please note that the viral load in saliva sample is relatively low, hence using nasal sample is recommended. Saliva sample can be used if nasal sampling is not possible.***
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
5. Test results should be correlated with other clinical data available to the physician.

6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.  
(If the differentiation of specific SARS viruses and strains is needed, additional testing is required.)

Performance Characteristics				
Clinical Sensitivity, Specificity and Accuracy				
Nasal swabs specimens				
The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:				
Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	
	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605

Relative Sensitivity: 97.1% (93.1%-98.9%)\*

Relative Specificity: 99.5% (98.2%-99.9%)\*

Accuracy: 98.8% (97.6%-99.5%)\*

\*95% Confidence Intervals

Stratification of the positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.8% (n=81) and 4-7 days has a PPA of 96.8% (n=62).

Positive samples with Ct value ≤33 has a higher positive percent agreement (PPA) of 98.7% (n=153) .

Saliva specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 341 saliva specimens collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test (Saliva)	Results	Negative	Positive	
	Negative	235	9	244
	Positive	1	96	97
Total Results		236	105	341

Relative Sensitivity: 91.4% (84.3%-95.6%)\*

Relative Specificity: 99.6% (97.4% - 99.9%)\*

Accuracy: 97.1% (94.6% - 98.5%)\*

\*95% Confidence Intervals

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of an inactivated viral sample. The viral sample was spiked with negative human nasal and saliva sample pool into a seral of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.6\*10<sup>2</sup> TCID<sub>50</sub>/mL.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Potential Cross-Reactant		Test Concentration	Cross-Reactivity (in the absence of SARS-CoV-2 virus)	Interference (in the presence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Enterovirus	9.50 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus 229E	1.04 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus OC43	2.63 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus NL63	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Human Metapneumovirus	1.25 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	MERS-coronavirus	7.90 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Influenza A	1.04 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Influenza B	1.04 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 1	1.25 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive

	Parainfluenza virus 2	3.78 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 3	1.0 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 4	2.88 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Respiratory syncytial virus	3.15 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Rhinovirus	3.15 x 10 <sup>5</sup> TCID <sub>50</sub> /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus-HKU1	1 x 10 <sup>5</sup> copies/mL	No 3/3 negative	No 3/3 positive
Bacteria	Bordetella pertussis	2.83 x 10 <sup>9</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia trachomatis	3.13 x 10 <sup>8</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Haemophilus influenza	1.36 x 10 <sup>8</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Legionella pneumophila	4.08 x 10 <sup>9</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Mycobacterium tuberculosis	1.72 x 10 <sup>7</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Mycoplasma pneumoniae	7.90 x 10 <sup>7</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus aureus	1.38 x 10 <sup>7</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus epidermidis	2.32 x 10 <sup>9</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pneumoniae	1.04 x 10 <sup>8</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pyogenes	4.10 x 10 <sup>6</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10 <sup>7</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Pseudomonas aeruginosa	1.87 x 10 <sup>8</sup> CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia pneumoniae	1×10 <sup>6</sup> IFU/ml	No 3/3 negative	No 3/3 positive
	Yeast	Candida albicans	No 3/3 negative	No 3/3 positive
Pooled human nasal wash			No 3/3 negative	No 3/3 positive

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The final concentration of the substances tested are listed below and were found not to affect test performance.

Interfering Substance	Active Ingredient	Concentration	Results (in the absence of SARS-CoV-2 virus)	Results (in the presence of SARS-CoV-2 virus)
Endogenous	Biotin	2.4 mg/mL	3/3 negative	3/3 positive
	Mucin	0.5% w/v	3/3 negative	3/3 positive
	Whole Blood	4% v/v	3/3 negative	3/3 positive
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	3/3 negative	3/3 positive
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	3/3 negative	3/3 positive
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	3/3 negative	3/3 positive
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	3/3 negative	3/3 positive
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	3/3 negative	3/3 positive
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	3/3 negative	3/3 positive

Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	3/3 negative	3/3 positive
NasalCrom Nasal Spray	Cromolyn	15% v/v	3/3 negative	3/3 positive
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	3/3 negative	3/3 positive
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	3/3 negative	3/3 positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negative	3/3 positive
Antibiotic	Mupirocin	10 mg/mL	3/3 negative	3/3 positive
Tamiflu	Oseltamivir Phosphate	5 mg/mL	3/3 negative	3/3 positive
Antibiotic	Tobramycin	4 µg/mL	3/3 negative	3/3 positive
Mometasone Furoate Nasal Spray	Mometasone Furoate	5%v/v	3/3 negative	3/3 positive
Physiological Seawater Nasal Cleaner	NaCl	15%v/v	3/3 negative	3/3 positive

Precision

Intra-Assay

Within-run precision was determined using 60 replicates of specimens: negative specimen and SARS-CoV-2 antigen positive specimen. The specimens were correctly identified >99% of the time.

Inter-Assay


Between-run precision was determined using 60 independent assays on the same specimens: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.


Bibliography


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


Index of Symbols


Manufacturer


In vitro diagnostic medical device


Consult instructions for use


Authorized representative in the European Community


Contains sufficient for <n> tests


Use-by date

Batch code

Temperature limit

Do not reuse

Catalogue number

Date of manufacture

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