

Method		RT-PCR		Total
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	Results
	Negative	175	3	178
	Positive	1	120	121
Total Results		176	123	299

Relative Sensitivity: 97.6% (92.8% - 99.5%)* Relative Specificity: 99.4% (96.5% - 99.9%)*
Accuracy: 98.7% (96.5% - 99.6%)* *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 nasopharyngeal sample pool into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.6*10² TCID₅₀/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 ⁶ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Enterovirus	9.50 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus 229E	1.04 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus OC43	2.63 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus NL63	1.0 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Human Metapneumovirus	1.25 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	MERS-coronavirus	7.90 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Influenza A	1.04 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Influenza B	1.04 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 1	1.25 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 2	3.78 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 3	1.0 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 4	2.88 x 10 ⁶ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Respiratory syncytial virus	3.15 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Rhinovirus	3.15 x 10 ⁵ TCID ₅₀ /mL	No 3/3 negative	No 3/3 positive
	Human coronavirus-HKU1	1 x 10 ⁵ copies/mL	No 3/3 negative	No 3/3 positive
Bacteria	Bordetella pertussis	2.83 x 10 ⁹ CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia trachomatis	3.13 x 10 ⁸ CFU/mL	No 3/3 negative	No 3/3 positive
	Haemophilus influenza	1.36 x 10 ⁸ CFU/mL	No 3/3 negative	No 3/3 positive
	Legionella pneumophila	4.08 x 10 ⁹ CFU/mL	No 3/3 negative	No 3/3 positive
	Mycobacterium tuberculosis	1.72 x 10 ⁷ CFU/mL	No 3/3 negative	No 3/3 positive
	Mycoplasma pneumoniae	7.90 x 10 ⁷ CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus aureus	1.38 x 10 ⁷ CFU/mL	No 3/3 negative	No 3/3 positive

	Staphylococcus epidermidis	2.32 x 10 ⁹ CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pneumoniae	1.04 x 10 ⁸ CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pyogenes	4.10 x 10 ⁶ CFU/mL	No 3/3 negative	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10 ⁷ CFU/mL	No 3/3 negative	No 3/3 positive
	Pseudomonas aeruginosa	1.87 x 10 ⁸ CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia pneumoniae	1×10 ⁸ IFU/ml	No 3/3 negative	No 3/3 positive
Yeast	Candida albicans	1.57 x 10 ⁸ CFU/mL	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 control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 independent assays on the same specimen: 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

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

Index of Symbols

	Manufacturer		Contains sufficient for <n> tests		Temperature limit
	In vitro diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use		Batch code		Catalogue number
		Authorized representative in the European Community			 Date of manufacture

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Nasal Swabs	Nasal swabs
Nasopharyngeal Swabs	Nasopharyngeal Swabs
SARS-CoV-2 Antigen Rapid Test	SARS-CoV-2 Antigen Rapid Test



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