

COVID-19 / Influenza A&B Antigen Test was evaluated with the currently available strains.

Analytical Reactivity Study Results			
Influenza Virus (Type/Subtype)	Virus Strain Name	Minimum Detectable Concentration	Positive/Replicates
SARS-CoV-2(XBB.1.5)	hCoV-19/USA/MD-HP40900/2022	7.8x10 ¹ TCID ₅₀ /mL	10/10
SARS-CoV-2 (JN.1)	JN.1 variant derived from clinical sample	9.18 x 10 ⁴ GE/mL	5/5
A(H1N1)pdm09	A/California/04/2009	2.80 x10 ² TCID ₅₀ /mL	3/3
	A/Brisbane/02/18	1.51 x10 ² TCID ₅₀ /mL	3/3
	A/Michigan/45/15	1.86 x10 ¹ TCID ₅₀ /mL	3/3
	A/Guangdong- Maonan/SWL1536/19	2.09 x10 ² TCID ₅₀ /mL	3/3
	A/NY/03/09	2.29 x10 ² TCID ₅₀ /mL	3/3
	A/Indiana/02/2020	9.70x10 ² CEID ₅₀ /mL	3/3
	A/Wisconsin/588/2019	7.00x10 ³ FFU/mL	3/3
	A/Sydney/5/2021	4.80 x10 ¹ TCID ₅₀ /mL	3/3
	A/Hawaii/66/2019	1.85 x10 ³ CEID ₅₀ /mL	3/3
	A/Wisconsin/67/22	4.21 x10 ² TCID ₅₀ /mL	3/3
A(H3N2)	A/Tasmania/503/2020	1.30 x10 ³ FFU/mL	3/3
	A/New York/21/2020	2.60 x10 ² CFU/mL	3/3
	A/Alaska/01/2021	3.75 x10 ³ FFU/mL	3/3
	A/Hong Kong/445/2019	1.50 x10 ³ FFU/mL	3/3
	A/Hong Kong/2671/19	1.05 x10 ³ TCID ₅₀ /mL	3/3
	A/Indiana/08/2011	8.10 x10 ² TCID ₅₀ /mL	3/3
A(H1N1)	A/Ohio/09/2015	7.00x10 ³ CEID ₅₀ /mL	3/3
A(H1N2)	A/Minnesota/19/2011	4.00 x10 ³ CEID ₅₀ /mL	3/3
A(H5N1)	A/mallard/Wisconsin/2576/2009	4.00 x10 ³ CEID ₅₀ /mL	3/3
A(H5N6)	A/duck/Guangxi/S11002/2024	3.38 x10 ² EID ₅₀ /mL	3/3
A(H5N8)	A/duck/Guangxi/S10888/2024	6.76 x10 ² EID ₅₀ /mL	3/3
A(H5N8)	A/goose/Liaoning/S1266/2021	6.76 x10 ² EID ₅₀ /mL	3/3
A(H7N3)	A/northern pintail/Illinois/100S3959/2010	7.00x10 ² CEID ₅₀ /mL	3/3
B(Non Victoria and Non Yamagata)	B/Maryland/1/59	3.38 x10 ³ CEID ₅₀ /mL	3/3
B(Victoria lineage)	B/Brisbane/60/2008	1.29 TCID ₅₀ /mL	3/3
	B/Colorado/06/17	5.85 x10 ¹ TCID ₅₀ /mL	3/3
	B/Texas/02/2013	2.45 x10 ¹ TCID ₅₀ /mL	3/3
	B/Michigan/01/2021	1.43 x10 ⁴ TCID ₅₀ /mL	3/3
B(Yamagata lineage)	Yamagata – B/Texas/06/2011	7.55x10 ² TCID ₅₀ /mL	3/3
	Yamagata – B/Utah/09/2014	1.26 x10 ³ TCID ₅₀ /mL	3/3
	B/Wisconsin/01/2010	1.78 x10 ² TCID ₅₀ /mL	3/3

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity of the WELLife™ COVID-19 / Influenza A&B Antigen Test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the WELLife™ COVID-19 / Influenza A&B Antigen Test including twenty (20) bacteria, twenty (20) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of co-spiked UV-inactivated SARS-CoV-2, influenza A, and B at 3 x LoD. No cross-reactivity was observed with the listed microorganisms when tested at the concentration presented in the table below. No interference was observed with the listed microorganisms when tested at the concentration presented in the table below in the presence of the target analytes.

Cross-Reactivity and Microbial Interference Study Results

Potential Cross-Reactant	Concentration Tested
SARS-CoV-1	1.25 x10 ³ PFU/mL
MERS-coronavirus	1.47 x10 ³ TCID ₅₀ /mL
Human coronavirus HKU1	1.74 x10 ¹ GE/mL [Ct 20.7]
Human coronavirus OC43	7.00x10 ² TCID ₅₀ /mL
Human coronavirus 229E	1.58 x10 ² TCID ₅₀ /mL
Human coronavirus NL63	7.05x10 ³ TCID ₅₀ /mL
Adenovirus Type 1	2.23 x10 ³ TCID ₅₀ /mL
Adenovirus Type 7	1.58 x10 ² TCID ₅₀ /mL
Cytomegalovirus	7.05x10 ³ TCID ₅₀ /mL
Epstein Barr Virus	1.83 x10 ² CP/mL
Human Metapneumovirus	3.50 x10 ² TCID ₅₀ /mL
Parainfluenza virus 1	2.00 x10 ² TCID ₅₀ /mL
Parainfluenza virus 2	1.75 x10 ³ TCID ₅₀ /mL
Parainfluenza virus 3	7.00x10 ³ TCID ₅₀ /mL
Parainfluenza virus 4	2.39 x10 ³ TCID ₅₀ /mL
Enterovirus Type 68	2.23 x10 ³ TCID ₅₀ /mL
Respiratory syncytial virus A	3.50 x10 ³ TCID ₅₀ /mL
Respiratory syncytial virus B	2.29 x10 ³ TCID ₅₀ /mL
Rhinovirus 1A	7.05x10 ⁴ TCID ₅₀ /mL
<i>Bordetella pertussis</i>	2.90 x10 ⁴ CFU/mL
<i>Candida albicans</i>	1.21 x10 ¹ CFU/mL
<i>Chlamydia pneumoniae</i>	4.33 x10 ⁴ IFU/mL
<i>Corynebacterium xerosis</i>	2.30 x10 ² CFU/mL
<i>Escherichia coli</i>	1.79 x10 ⁴ CFU/mL
<i>Hemophilus influenzae</i>	9.68x10 ⁴ CFU/mL
<i>Lactobacillus Acidophilus</i>	1.21 x10 ¹ CFU/mL
<i>Legionella spp pneumophila</i>	6.50 x10 ² CFU/mL
<i>Moraxella catarrhalis</i>	2.50 x10 ² CFU/mL
<i>Mycoplasma pneumoniae</i>	2.50 x10 ² CFU/mL
<i>Mycobacterium tuberculosis avirulent</i>	3.03 x10 ² CFU/mL
<i>Neisseria meningitidis</i>	3.43 x10 ² CFU/mL
<i>Neisseria sp. Elongata</i>	2.68 x10 ² CFU/mL
<i>Pneumocystis jirovecii</i>	1.30 x10 ² CFU/mL
<i>Pseudomonas aeruginosa</i>	3.45 x10 ² CFU/mL
<i>Staphylococcus aureus subsp. aureus</i>	2.60 x10 ² CFU/mL
<i>Staphylococcus epidermidis</i>	9.00x10 ¹ CFU/mL
<i>Streptococcus salivarius</i>	1.01x10 ² CFU/mL
<i>Streptococcus pneumoniae</i>	1.81 x10 ¹ CFU/mL
<i>Streptococcus pyogenes</i>	7.50x10 ¹ CFU/mL
Measles	8.48 x10 ² TCID ₅₀ /mL
Mumps	8.48 x10 ² TCID ₅₀ /mL
Poolled Negative Nasal Wash	NA

Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of SARS-CoV-2, influenza A and B was examined by testing nineteen (19) substances in a negative clinical matrix in triplicate, in the absence or presence of each virus at 3 x LoD concentrations for SARS-CoV-2, influenza A(H1N1), and influenza B(Yamagata). The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the WELLife™ COVID-19 / Influenza A&B Antigen Test. At 15% (v/v) and when diluted down to 0.75% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for Influenza A and Influenza B. At a dilution of 0.375% (v/v), the results were negative. Hand sanitizer containing 80% ethanol yielded false positive results for SARS-CoV-2 and Influenza B at a dilution of 15% (v/v) and when diluted down to 3.75% (v/v). At a dilution of 1.875% (v/v), the results were negative. At 15% (v/v) and when diluted down to 5% (v/v), the Zinc (TheraZinc Throat Spray) yielded false positive results for influenza A. At a dilution of 2.5% v/v, the results were negative. At 15% (v/v), the nasal corticosteroid (Fluticasone) yielded false negative results for SARS-CoV-2, Influenza A and Influenza B. At a dilution of 5%v/v, the results were positive. Two interferents produced false-negative results for Influenza B: hand sanitizer cream lotion (15% v/v) and hand soap liquid gel (10% w/v). All Influenza B results were positive when tested with 75% (v/v) hand sanitizer cream lotion and 0.05% (w/v) hand soap liquid gel.

No interference was observed with the other listed substances when tested at the concentration presented in the table below in the presence or absence of the target analytes.

Endogenous Interfering Substances Study Results

Potential Interferent	Concentration	Cross-reactivity (no analyte) (# pos reps / total reps)			Interference (3x LoD co-spiked analytes) (# pos reps / total reps)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Mucin	0.50%	0/3	0/3	0/3	3/3	3/3	3/3
Chloroseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic (Alkalol)	10% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tabramycin	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Osetamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist® FluMist Quadrivalent Live intranasal influenza vir us vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
Zanamivir	0.375% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	0/3
Hand Sanitizer, 80% ethanol, fast drying	7.5% v/v	-	-	-	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	3/3	0/3	2/3	3/3	3/3	3/3
Hand soap liquid gel	1.875% v/v	0/3	0/3	0/3	-	-	-
	10% w/v	0/3	0/3	0/3	3/3	3/3	0/3
	0.05% w/v	-	-	-	3/3	3/3	3/3
Throat lozenges (Menthol/Benzocaine)	3 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mucin from bovine submaxillary glands Type I-S	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Leukocytes	1x10 ⁴ cells/mL	0/3	0/3	0/3	3/3	3/3	3/3
	5x10 ² cells/mL	-	-	-	3/3	3/3	3/3
Zinc (TheraZinc Throat Spray)	15% v/v	0/3	3/3	0/3	3/3	3/3	3/3
	5% v/v	0/3	3/3	0/3	3/3	3/3	3/3
	2.5% v/v	0/3	0/3	0/3	-	-	-
	1.5% v/v	0/3	0/3	0/3	-	-	-
Nasal spray (Saline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Dexamethasone (Nasal corticosteroid)	1 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal corticosteroid (Fluticasone)	15% v/v	0/3	0/3	0/3	0/3	0/3	0/3
	5% v/v	-	-	-	3/3	3/3	3/3
Nasal gel (Galphimia glauca, Histaminium hydrochloricum, Luffa operculata, Sulfur)	0.01	0/3	0/3	0/3	3/3	3/3	3/3
Zicam nasal spray (Galphimia glauca, Luffa operculata)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminium hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Anti-viral drug (Remdesivir)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3

High Dose Hook Effect

A high-dose hook effect was not observed in WELLife™ COVID-19 / Influenza A&B Antigen Test for the SARS-CoV-2, influenza A and B viral strains at the concentration listed below.

High Dose Hook Effect Study Results

Virus Type	Virus Strain	Concentration Tested
SARS-CoV-2	UV inactivated, USA-WA1/2020	3.16x10 ² TCID ₅₀ /mL
Influenza A (H1N1)	A/Victoria/4897/2022	2.02x10 ² TCID ₅₀ /mL
Influenza A(H3N2)	A/Darwin/6/2021	4.17x10 ² TCID ₅₀ /mL
Influenza B (Victoria lineage)	B/Washington/02/2019	3.16x10 ² TCID ₅₀ /mL
Influenza B (Yamagata lineage)	B/Florida/4/2006	1.17x10 ² TCID ₅₀ /mL

Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and influenza A and influenza B at levels near LoD were tested in the presence of high levels of SARS-CoV-2. No competitive interference was seen between high levels of SARS-CoV-2 and low levels of Influenza A and B and between high levels of Influenza A and low levels of SARS-CoV-2 and influenza B in this testing at the concentration listed in the tables below. Competitive inhibition was observed between high levels of influenza B (Yamagata Lineage) and low levels of Influenza A in this testing at the concentration listed in the tables below.

Results of SARS-CoV-2 & Influenza A & Influenza B Virus (Yamagata Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus (H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Yamagata Lineage) B/Florida/4/2006	
Concentration (TCID ₅₀ /mL)	Percent Agreement	Concentration (TCID ₅₀ /mL)	Percent Agreement	Concentration (TCID ₅₀ /mL)	Percent Agreement
Negative	100%	6.73x10 ⁴	100%	1.76 x10 ²	100%
2.37x10 ¹	100%	6.73x10 ⁴	100%	Negative	100%
2.37x10 ²	100%	6.73x10 ⁴	100%	1.76 x10 ²	100%
Negative	100%	3.03x10 ²	0	3.90 x10 ²	100%
Negative	100%	3.03x10 ²	100%	7.80x10 ³	100%
Negative	100%	3.03x10 ²	0	1.95 x10 ⁴	100%
2.37x10 ¹	100%	Negative	100%	3.90 x10 ³	100%
2.37x10 ²	100%	Negative	100%	3.90 x10 ³	100%
2.37x10 ³	100%	Negative	100%	3.90 x10 ³	100%
2.37x10 ⁴	100%	Negative	100%	1.76 x10 ²	100%
1.05x10 ⁴	100%	Negative	100%	Negative	100%
1.05x10 ⁴	100%	Negative	100%	1.76 x10 ²	100%
1.05x10 ⁴	100%	3.03x10 ²	100%	1.76 x10 ²	100%

Results of SARS-CoV-2 & Influenza A & Influenza B Virus (Victoria Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus(H1N1pdm09) A/Victoria/4897/2022		Influenza B Virus (Victoria Lineage) B/Washington/02/19	
Concentration (TCID ₅₀ /mL)	Percent Agreement	Concentration (TCID ₅₀ /mL)	Percent Agreement	Concentration (TCID ₅₀ /mL)	Percent Agreement
Negative	100%	6.73 x10 ⁴	100%	3.51 x10 ²	100%
2.37 x10 ¹	100%	6.73 x10 ⁴	100%	Negative	100%
2.37 x10 ²	100%	6.73 x10 ⁴	100%	3.51 x10 ²	100%
Negative	100%	3.03 x10 ²	100%	1.05 x10 ²	100%
2.37 x10 ¹	100%	Negative	100%	1.05 x10 ²	100%
2.37 x10 ²	100%	3.03 x10 ²	100%	1.05 x10 ²	100%
1.05 x10 ²	100%	3.03 x10 ²	100%	Negative	100%
1.05 x10 ²	100%	Negative	100%	3.51 x10 ²	100%
1.05 x10 ²	100%	3.03 x10 ²	100%	3.51 x10 ²	100%

CLINICAL PERFORMANCE

A prospective study was performed in which seven hundred eighty-seven (787) study subjects were sequentially enrolled (between December 2023 and March 2024) and tested fresh. Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at nine (9) clinical sites. To be enrolled in the study, patients had to present at the participating study site within four (4) days of symptom onset with signs and symptoms of respiratory infection generally observed from SARS-CoV-2, influenza A and/or influenza B, during the study period. Two anterior nasal swab specimens were collected from each patient: one swab was collected by a healthcare professional and sent for testing using an FDA-cleared molecular comparator method, and the other swab was self-collected and tested immediately with the WELLife™ COVID-19 / Influenza A&B Antigen Test per the test procedure. The collection order for the investigational and the comparator tests' ANS swab was randomized. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2-13, in a simulated at-home environment. Out of 787 enrolled subjects, there were 705 evaluable subjects and 82 enrolled subjects were excluded.

SUBJECTS DEMOGRAPHICS

Characteristic	Lay-user/ Tester Collection N=160	Self-Collecting N=545	Overall N=705
Age			
Mean (SD)	8.7 (4.5)	45.8 (18.6)	37.4 (22.6)
Median[Min, Max]	8[2, 32]	43[14, 94]	35[2, 94]
Age Group			