QuidelOrtho™

QuickVue™
Influenza+SARS Test

Instructions for Use

IVD

techdocs.quidelortho.com

For in vitro diagnostic use. For professional use. For use with anterior nasal swab specimens.
Please read instructions carefully before you perform the test. Failure to follow instructions may result in inaccurate test results.

Intended Use

The QuickVue Influenza+SARS Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out co-infection with other respiratory pathogens.

Test results should not be used as the sole basis for treatment or other patient management decisions.

Summary and Explanation

The QuickVue Influenza+SARS Test is an antigen test that can provide rapid detection of influenza A, influenza B, and/or SARS-CoV-2 viral proteins from symptomatic patients.

Influenza and SARS-CoV-2 (COVID-19) are highly contagious respiratory viruses causing acute upper respiratory infections with very similar symptoms such as headache, chills, dry cough, body aches, and fever. There are two main seasonal influenza viruses, influenza A and influenza B. Influenza A virus is typically more common. Influenza affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths. [1]. SARS-CoV2, often referred to as COVID-19, emerged in late 2019 and rapidly spread, causing a global pandemic with more than 777,000,000 infections worldwide and over 7 Million deaths. [2] Diagnosis of these viruses is difficult because all respiratory viruses cause similar initial symptoms. Accurate diagnosis may allow prompt treatment of patients and can have a positive effect on public health.

Principle of the Procedure

The QuickVue Influenza+SARS Test consists of a test cassette that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires an anterior nasal swab specimen to be inserted into the prefilled extraction buffer tube to elute the sample material for testing and disrupt the virus particles in the specimen. The eluted sample extract is then dropped into the sample well of the test cassette, and the swab is discarded.

If SARS-CoV-2, influenza A and/or influenza B antigens are present in the specimen, they will react with SARS-CoV-2 antibody and/or influenza A/B antibodies, all coupled to dye particles. They then migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody on the membrane's test line(s), and generate a colored pink to red line in the specific test line position. The rest of the sample and rabbit-antibody-dye-particle complexes continue to migrate to the Control line position (C), where immobilized goat anti-rabbit antibodies will capture the rabbit-antibody-dye-particle complexes and form the Control line. Formation of the pink to red Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

If the antigen level is equal to or above the detection limit, a visible colored band appears at the test region. Absence of this pink to red colored band in the test region of test strip and only a visible control line will appear, suggests a negative result.

The QuickVue Influenza+SARS Test has three Test lines, one for COVID-19, one for influenza A and one for influenza B. The three Test lines allow for the separate and differential identification of COVID-19, influenza A and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is positive for COVID-19 and/or influenza.

Results can be interpreted between 10 and 20 minutes after adding the extracted sample into the sample well.

Reagents and Materials Supplied

The QuickVue Influenza+SARS Test kit contains the items indicated below:

- Twenty Five (25) Sealed Test Cassettes
- Twenty Five (25) Buffer Tubes
- Twenty Five (25) Swabs
- One (1) Tube Holder
- One (1) Quick Reference Instructions (QRI)
- One (1) Instructions for Use

Materials Not Supplied

- Timer or watch
- Optional: QuickVue Influenza+SARS Test Control Kit (Catalog number 20519)

Warnings And Precautions

- **Do not use the test if individuals have had symptoms for more than 4 days or no symptoms at all.**
- Do not use if any of the test kit contents or packaging is damaged or open.
- When collecting a sample, only use the swab provided in the kit.
- All test components are single-use. Do not reuse the test cassette, processing solution, or swab.
- Testing should be performed in an area with good lighting.
- Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use this test if individuals have been vaccinated with the FluMist/FluMist quadrivalent live intranasal influenza virus vaccine within the last two weeks.
- Do not conduct this test if prone to nose bleeds or have a nose injury.
- Do not use this test if individuals are using nasal corticosteroids.
- Do not use this test if individuals are using zinc-based throat sprays.
- Remove any piercings from nose before starting the test.
- **Keep testing kit and kit components away from children and pets before and after use.**
- **Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.**

Chemical name	Harms (GHS Code) for each ingredient	Concentration
ProClin 300	Causes skin irritation (H315) Causes eye irritation (H320)	0.05%

For the most up-to-date information on COVID-19, please visit: *www.cdc.gov/COVID19*

Storage and Stability

- Store the test kit between 36-86°F (2-30°C) in a place out of direct sunlight.
- Reagents and devices must be used at room temperature (59-86°F/15-30°C).
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is on the package. Do not use beyond the expiration date.

Quality Control

Internal Control

Each QuickVue Influenza+SARS Test has a built-in internal procedural control. The red line appearing at the "C" position verifies proper assembly and capillary flow of the test strip. A distinct red Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed using a new swab and new test kit.

External Quality Control

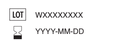
The QuickVue Influenza+SARS Test Control Kit (Catalog number 20519) can be separately sold for use with the QuickVue Influenza+SARS Test. The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify an operator's ability to properly perform the test and interpret the results. The external controls should be processed and tested in accordance with the nasal swab test procedure provided in the Instructions for Use or in the Quick Reference Instructions (QRI). Use of Kit Control reagents manufactured by any other source may not produce the expected results, and therefore, will not meet the requirements for an adequate quality assurance program for the QuickVue Influenza+SARS Test. If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact QuidelOrtho Technical Support.

It is recommended that the positive and negative controls are run once for each untrained operator, once for each new shipment of kits –provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

Preparing for the Test

Note: Do not open the test materials until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

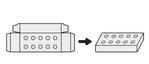
1. Check the expiration date of the test printed on the outer box.



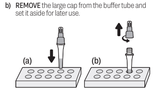
2. Ensure all test components are at room temperature (59-86°F/15-30°C) before use.

3. **WASH** your hands with soap and water for 20 seconds or use hand sanitizer and dry them thoroughly.

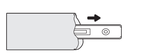
4. **ASSEMBLE** the tube holder in the kit.



5.
a) **INSERT** the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.
b) **REMOVE** the large cap from the buffer tube and set it aside for later use.



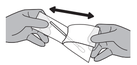
6. **REMOVE** test cassette from sealed pouch and lay it on a flat surface.



Sample Collection

7. **REMOVE** the swab from the pouch.

⚠ Do not touch the swab tip (soft end) with hand.



8.
a) **CAREFULLY INSERT** the swab no more than 3/4 inch (1.5 cm) into the nostril. Slowly rotate the swab at least 5 times against the nostril wall.

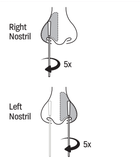
⚠ Do not insert the swab any further if you feel any resistance.

b) **REMOVE** the swab and repeat in the other nostril using the same swab.

Check: Did you swab BOTH nostrils?

Note: With children, the maximum depth of insertion into the nostril may be less than 1/2 to 3/4 of an inch, and you may require another adult to hold the child's head while swabbing.

Note: Failure to swab properly may cause false negative results.



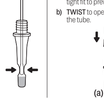
Running the Test

9. **IMMERSE** the swab into the buffer tube, and ensure it is touching the bottom of the TUBE and **SWIRL** the swab in the buffer. Ensure the sample is mixed thoroughly by making **at least 10 circles**.

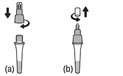
⚠ Sample must be adequately mixed into the buffer, otherwise incorrect results may occur.

10. **LEAVE** the swab in the buffer tube for 1 minute. A timer is recommended for this step.

11. After 1 minute, **PINCH** the tip of the swab from the outside of the tube to remove any excess liquid from the swab. **REMOVE** and **DISCARD** the swab.



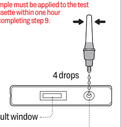
12.
a) **HOLD** the buffer tube upright and **SCREW** the large cap back onto the tube. Ensure a tight fit to prevent leaking.
b) **TWIST** to open the small cap at the top of the tube.



13. **INVERT** the buffer tube and **SQUEEZE 4 drops** of test sample into the sample well on the test cassette. Then **DISCARD** the buffer tube.

Note: Incorrect results may be observed if less than 4 drops of sample are added.

⚠ Sample must be applied to the test cassette within one hour of completing step 9.



14. **START** the timer. Read results at 10 minutes.

⚠ Do not interpret results before 10 minutes or after 20 minutes. Inaccurate test interpretations may occur.

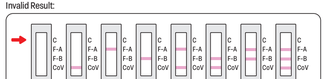
Interpretation of Results

Look for lines next to **C** (Control), **F-A**, **F-B** and **CoV**.

C = Control Line
F-A = Flu A Test Line
F-B = Flu B Test Line
CoV = COVID-19 Test Line

A red line should always appear at the **C** position; this is a control line and signals that the test is working properly.

Invalid Result:



Check to see if a pink to red line is visible at the control line **C** in the results window. If a line is not visible at **C**, even if any other line is visible in the results window, the result is considered invalid.

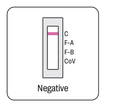
STOP: If you do not see a C line, DO NOT CONTINUE reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials.

Negative Result:

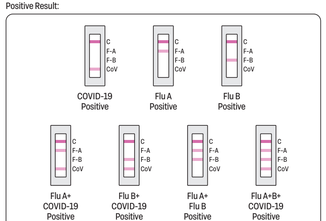
If a control **C** line is visible and you do not see a line at **F-A**, **F-B** or **CoV**, it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

If respiratory symptoms persist, individuals should seek follow-up care with their healthcare providers.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary. Negative results do not rule out SARS-CoV-2, Flu A, and/or Flu B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.



Positive Result:



If the control line at **C** is visible and any other line or multiple lines on **F-A**, **F-B** and/or **CoV** are visible, the test is positive for that virus.

Note: Any pink to red test line, no matter how faint, should be considered a positive result when the control line is also present.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2023 and March 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected or handled improperly.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 and influenza as compared to a molecular test, especially in samples with low viral load.
- False positive test results are more likely when the prevalence of SARS-CoV-2, influenza A, and/or influenza B is low in the community.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision — such as far-sightedness, glaucoma, or color blindness - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the sample.
- Hand soap and hand sanitizers may cause false negative results with this test.
- FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.
- Zinc-based throat sprays may cause false positive influenza A results with this test.
- Nasal corticosteroids may cause false negative results with this test.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.

Performance Characteristics

Analytical Performance

Lot-to-Lot Precision

A single-site lot-to-lot precision study was conducted to measure repeatability using three levels of contrived samples. A panel of three samples was tested: a negative sample (PBSM only), low positive sample (2x co-spike LoD of all analytes), moderate positive sample (5x co-spike LoD of all analytes). The strains used for testing were UV-inactivated SARS-CoV-2 USA-WA1/2020, live influenza A H1N1, and live influenza B Yamagata. One replicate per sample type was tested per run, per operator, and per lot across 10 days with two test runs per day for a total of 120 results per sample type (3 lots x 2 operators x 1 replicate x 10 days x 2 runs per day).

In addition, a supplemental precision study was conducted testing negative samples, a sample with spiked 0.9 x LoD SARS-CoV-2 and 0.8 x LoD Flu B and a sample spiked with 0.9 x LoD Flu A to demonstrate potential lot variability. These samples were tested with three lots by two operators for two replicates per run and two run per day over three days (3 lots x 2 operators x 2 replicates/sample x 2 runs/day/operator x 3 days).

Repeatability was determined by comparing test results to expected results across all lots, operators, and days. Results are shown in the following table.

Table 1
Lot-to-Lot Reproducibility Study Results

Sample	Analyte	% Agreement with Expected Result			
		Lot 1	Lot 2	Lot 3	Total
Negative	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
2x LoD	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
5x LoD	SARS-CoV-2	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu A	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
	Flu B	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)
Negative	SARS-CoV-2	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu A	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu B	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
<1X LoD SARS-CoV-2 and Flu B Co-Spiked	SARS-CoV-2	16/24 (67%)	22/24 (92%)	20/24 (83%)	58/72 (81%)
	Flu A	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu B	22/24 (92%)	23/24 (96%)	18/24 (75%)	63/72 (88%)
<1X LoD Flu A	SARS-CoV-2	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)
	Flu A	20/24 (83%)	24/24 (100%)	19/24 (79%)	63/72 (88%)
	Flu B	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%)

Limit of Detection (Analytical Sensitivity)

Limit of detection (LoD) for SARS-CoV-2 and influenza A and B in QuickVue Influenza+SARS Test was determined by evaluating different concentrations of UV-inactivated SARS-CoV-2 and live influenza A and B viruses. The viruses were diluted in pooled negative swab matrix (PNSM) to generate virus dilutions for testing. Anterior nasal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert. Range-finding testing was conducted with three replicates at various dilutions and confirmatory testing was conducted with 20 replicates. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration.

Table 2
Limit of Detection (LoD) Study Results

Viral Strain	Stock Concentration ($TCID_{50}$/mL)	LoD ($TCID_{50}$/mL)	LoD ($TCID_{50}$/Swab)	#Positive/ #Total	Percent Detected (%)
SARS-CoV-2/UVinactivated USA-A1/2020	3.16×10^6	7.90×10^2	39.5	60/60	100%
Influenza A A/Victoria/4897/2022(H1N1)	2.02×10^6	1.01×10^2	5.05	60/60	100%
Influenza A A/Darwin/6/2021(H3N2)	4.17×10^6	2.09×10^2	10.45	60/60	100%
Influenza B B/Washington/02/2019(Victoria)	3.16×10^6	3.16×10^3	158	60/60	100%
Influenza B B/Florida/4/2006 (Yamagata)	1.17×10^5	5.85×10^1	2.93	60/60	100%

Analytical Reactivity

The analytical reactivity of the antibodies targeting Influenza A, influenza B, and SARS-CoV-2 in the QuickVue Influenza+SARS Test was evaluated with the currently available strains.

Table 3
Analytical Reactivity Study Results

Influenza Virus (Type/Subtype)	Virus Strain Name	Minimum Detectable Concentration	Positive/ Replicates
SARS-CoV-2(WBB1.5)	hCoV-19/USA/MD- HP40900/2022	7.9×10^{1} $TCID_{50}$/mL	10/10
SARS-CoV-2 (IN.1)	IN.1 variant derived from clinical sample	9.18×10^{4} GE/mL	5/5
A(H1N1)pdm09	A/California/04/2009	2.80×10^{3} $TCID_{50}$/mL	3/3
	A/Brisbane/02/18	1.51×10^{3} $TCID_{50}$/mL	3/3
	A/Michigan/45/15	1.86×10^{3} $TCID_{50}$/mL	3/3
	A/Guangdong- Maonan/SWL 1536/19	2.09×10^{3} $TCID_{50}$/mL	3/3
	A/NY/03/09	2.29×10^{4} $TCID_{50}$/mL	3/3
	A/Indiana/02/2020	9.70×10^{6} $CEID_{50}$/mL	3/3
	A/Wisconsin/588/2019	7.00×10^{3} FFU/mL	3/3
	A/Sydney/5/2021	4.80×10^{3} $TCID_{50}$/mL	3/3
	A/Hawaii/66/2019	1.85×10^{4} $CEID_{50}$/mL	3/3
	A/Wisconsin/67/2022	4.21×10^{4} $TCID_{50}$/mL	3/3
A (H3N2)	A/Tasmania/503/2020	1.30×10^{3} FFU/mL	3/3
	A/New York/21/2020	2.60×10^{3} FFU/mL	3/3
	A/Alaska/01/2021	3.75×10^{4} FFU/mL	3/3
	A/Hong Kong/45/2019	1.50×10^{4} FFU/mL	3/3
	A/Hong Kong/267/19	1.05×10^{6} $TCID_{50}$/mL	3/3
	A/Indiana/08/2011	8.10×10^{2} $TCID_{50}$/mL	3/3
A (H1N1)	A/Ohio/09/2015	4.00×10^{4} $CEID_{50}$/mL	3/3
A(H1N2)	A/Minnesota/19/2011	4.00×10^{4} $CEID_{50}$/mL	3/3
A(H5N1)	A/mallard/Wisconsin/2576/2009	4.00×10^{4} $CEID_{50}$/mL	3/3
	A/duck/Guangxi/S11002/2024	3.38×10^{3} EID_{50}/mL	3/3
A(H5N6)	A/duck/Guangxi/S10888/2024	6.76×10^{3} EID_{50}/mL	3/3
A(H5N8)	A/goose/Laoning/S1266/2021	6.76×10^{3} EID_{50}/mL	3/3
A(N7N3)	A/northern pintail/Illinois/100S3959/2010	7.00×10^{3} $CEID_{50}$/mL	3/3
B(Non Victoria and Non Yamagata)	B/Maryland/1/59	3.38×10^{3} $CEID_{50}$/mL	3/3
B(Victoria lineage)	B/Brisbane/60/2008	1.29 $TCID_{50}$/mL	3/3
	B/Colorado/06/17	5.85×10^{3} $TCID_{50}$/mL	3/3
	B/Texas/02/2013	2.45×10^{3} $TCID_{50}$/mL	3/3
	B/Michigan/01/2021	1.43×10^{4} $TCID_{50}$/mL	3/3
B(Yamagata lineage)	Yamagata – B/Utah/09/2014	7.55×10^{6} $TCID_{50}$/mL	3/3
	Yamagata – B/Utah/08/2014	1.26×10^{3} $TCID_{50}$/mL	3/3
	B/Wisconsin/01/2010	1.78×10^{3} $TCID_{50}$/mL	3/3

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity of the QuickVue Influenza+SARS 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 QuickVue Influenza+SARS 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.

Table 4
Cross-Reactivity and Microbial Interference Study Results

Potential Cross-Reactant	Concentration Tested	Potential Cross-Reactant	Concentration Tested
SARS-CoV-1	1.25×10^{5} PFU/ml	*Chlamydia pneumoniae*	4.33×10^{6} IFU/mL
MERS-coronavirus	1.47×10^{6} $TCID_{50}$/mL	*Corynebacterium xerosis*	2.30×10^{6} CFU/mL
Human coronavirus HKU1	1.74×10^{6} GE/mL (Ct 20.7)	*Escherichia coli*	1.79×10^{6} CFU/mL
Human coronavirus OC43	7.00×10^{5} $TCID_{50}$/mL	*Hemophilus influenzae*	9.68×10^{6} CFU/mL
Human coronavirus 229E	1.58×10^{5} $TCID_{50}$/mL	*Lactobacillus Acidophilus*	1.21×10^{7} CFU/mL
Human coronavirus NL63	7.05×10^{4} $TCID_{50}$/mL	*Legionella spp.pneumophila*	6.50×10^{6} CFU/mL
Adenovirus Type 1	2.23×10^{5} $TCID_{50}$/mL	*Moraxella catarrhalis*	2.50×10^{6} CFU/mL
Adenovirus Type 7	1.58×10^{5} $TCID_{50}$/mL	*Mycoplasma pneumoniae*	2.50×10^{6} CFU/mL
Cytomegalovirus	7.05×10^{4} $TCID_{50}$/mL	*Mycobacterium tuberculosis avirulent*	3.03×10^{6} CFU/mL
Epstein Barr Virus	1.83×10^{6} CP/mL	*Neisseria meningitidis*	3.43×10^{6} CFU/mL
Human Metapneumovirus	3.50×10^{5} $TCID_{50}$/mL	*Neisseria sp. Flavigata*	2.68×10^{6} CFU/mL
Parainfluenza virus 1	2.00×10^{5} $TCID_{50}$/mL	*Pneumocystis jirovecii*	1.30×10^{7} CFU/mL
Parainfluenza virus 2	1.75×10^{5} $TCID_{50}$/mL	*Pseudomonas aeruginosa*	3.45×10^{6} CFU/mL
Parainfluenza virus 3	7.00×10^{5} $TCID_{50}$/mL	*Staphylococcus aureus subsp. aureus*	2.60×10^{6} CFU/mL
Parainfluenza virus 4	2.39×10^{5} $TCID_{50}$/mL	*Staphylococcus epidermidis*	9.00×10^{6} CFU/mL
Enterovirus Type 68	2.23×10^{5} $TCID_{50}$/mL	*Streptococcus salivarius*	1.01×10^{6} CFU/mL
Respiratory syncytial virus A	3.50×10^{5} $TCID_{50}$/mL	*Streptococcus pneumoniae*	1.81×10^{7} CFU/mL
Respiratory syncytial virus B	2.29×10^{5} $TCID_{50}$/mL	*Streptococcus pyogenes*	7.50×10^{7} CFU/mL
Rhinovirus 1A	7.05×10^{4} $TCID_{50}$/mL	Measles	8.48×10^{6} $TCID_{50}$/mL
Bordetella pertussis	2.90×10^{6} CFU/mL	Mumps	8.48×10^{6} $TCID_{50}$/mL
Candida albicans	1.21×10^{6} CFU/mL	Pooled 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 QuickVue Influenza+SARS 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 7.5% (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.

Table 5
Endogenous Interfering Substances Study Results

Potential Interferent	Concentration	Cross-reactivity (no analytes) (# pos reps/total reps)			Interference (3xLoD 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
Chlorasseptic (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
Tobramycin	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 (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/ FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	0/3	3/3	3/3	3/3	3/3	3/3
	0.375% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Biotin	3,500 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% v/v	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	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
	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
	1.875% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand soap liquid gel	10% v/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	1×10^{6} cells/mL	0/3	0/3	0/3	3/3	3/3	3/3
	5×10^{5} 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	-	-	-
	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, Histaminum hydrochloricum, Luffa operculata, Sulfur)	1.25%	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 (Histaminum 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 the QuickVue Influenza+SARS Test for the SARS-CoV-2, influenza A and B viral strains at the concentration listed below.

Table 6
High Dose Hook Effect Study Results

Virus Type	Virus Strain	Concentration Tested
SARS-CoV-2	UV inactivated, USA-WA1/2020	3.16×10^{6} $TCID_{50}$/mL
Influenza A (H1N1)	A/Victoria/4897/2022	2.02×10^{6} $TCID_{50}$/mL
Influenza A(H3N2)	A/Darwin/6/2021	4.17×10^{6} $TCID_{50}$/mL
Influenza B (Victoria lineage)	B/Washington/02/2019	3.16×10^{6} $TCID_{50}$/mL
Influenza B (Yamagata lineage)	B/Florida/4/2006	1.17×10^{6} $TCID_{50}$/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.

Table 7
Results of SARS-CoV-2 and Influenza A and Influenza B Virus (Yamagata Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus (H1N1)pdm09) 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%	6.73×10^{4}	100%	1.76×10^{2}	100%
2.37×10^{3}	100%	6.73×10^{4}	100%	Negative	100%
2.37×10^{3}	100%	6.73×10^{4}	100%	1.76×10^{2}	100%
Negative	100%	3.03×10^{2}	0	3.90×10^{4}	100%
Negative	100%	3.03×10^{2}	0	1.95×10^{4}	100%
Negative	100%	3.03×10^{2}	100%	780×10^{3}	100%
Negative	100%	3.03×10^{2}	100%	3.90×10^{3}	100%
2.37×10^{3}	100%	Negative	100%	3.90×10^{4}	100%
2.37×10^{3}	100%	3.03×10^{2}	0	3.90×10^{4}	100%
2.37×10^{3}	100%	3.03×10^{2}	0	1.95×10^{4}	100%
2.37×10^{3}	100%	3.03×10^{2}	100%	780×10^{3}	100%
2.37×10^{3}	100%	3.03×10^{2}	100%	3.90×10^{3}	100%
1.05×10^{6}	100%	3.03×10^{2}	100%	1.76×10^{2}	100%
1.05×10^{6}	100%	Negative	100%	1.76×10^{2}	100%
1.05×10^{6}	100%	3.03×10^{2}	100%	1.76×10^{2}	100%

Table 8
Results of SARS-CoV-2 and Influenza A and Influenza B Virus (Victoria Lineage)

SARS-CoV-2 USA-WA1/2020		Influenza A Virus (H1N1)pdm09) 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%	6.73×10^{4}	100%	3.51×10^{2}	100%
2.37×10^{3}	100%	6.73×10^{4}	100%	Negative	100%
2.37×10^{3}	100%	6.73×10^{4}	100%	3.51×10^{2}	100%
Negative	100%	3.03×10^{2}	100%	1.05×10^{6}	100%
2.37×10^{3}	100%	Negative	100%	1.05×10^{6}	100%
2.37×10^{3}	100%	3.03×10^{2}	100%	1.05×10^{6}	100%
1.05×10^{6}	100%	3.03×10^{2}	100%	Negative	100%
1.05×10^{6}	100%	Negative	100%	3.51×10^{2}	100%
1.05×10^{6}	100%	3.03×10^{2}	100%	3.51×10^{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 QuickVue Influenza+SARS 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.

Table 9
Subject 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			
<14	139 (86.9%)	0	139 (19.7%)
14-24	20 (12.5%)	79 (14.5%)	99 (14.0%)
25-64	1 (0.6%)	351 (64.4%)	352 (49.9%)
>64	0	115 (21.1%)	115 (16.3%)
Sex at Birth			
Female	90 (56.3%)	343 (62.9%)	433 (61.4%)
Male	70 (43.8%)	202 (37.1%)	272 (38.6%)
Ethnicity			
Hispanic/Latino	87 (54.4%)	226 (41.5%)	313 (44.4%)
Not Hispanic/Latino	73 (45.6%)	304 (55.8%)	377 (53.5%)
Unknown/Prefer not to answer	0	15 (2.8%)	15 (2.1%)
Race			
American Indian or Alaskan Native	0	2 (0.4%)	2 (0.3%)
Asian	19 (11.9%)	150 (27.5%)	169 (24.0%)
Black or African American	36 (22.5%)	85 (15.6%)	121 (17.2%)
White	101 (63.1%)	267 (49.0%)	368 (52.2%)
Native Hawaiian or Other Pacific Islander	0	0	0
More than one race	1 (0.6%)	5 (0.9%)	6 (0.9%)
Unknown/Prefer not to answer	2 (1.3%)	30 (5.5%)	32 (4.5%)
Other	1 (0.6%)	6 (1.1%)	7 (1.0%)

SARS-CoV-2 Performance

Table 10
Clinical Performance Compared to Reference PCR: SARS-CoV-2

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
Candidate Positives	101	1	102
Candidate Negatives	14	589	603
Total	**115**	**590**	**705**
Positive Percent Agreement (PPA) = 87.8% (101/115)	95% CI: 80.6% - 92.6%		
Negative Percent Agreement (NPA) = 99.8% (589/590)	95% CI: 99.1% - 100%		

Table 11
SARS-CoV-2 Clinical Performance Stratified by Days Post Symptoms Onset

Days Post COVID-19 Symptoms	Number of Subjects Samples Tested	QuickVue Influenza+SARS Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95%CI)
Day 0	39	3	5	12.80%	60.0% (23.1%, 88.2%)
Day 1	168	26	28	16.70%	92.9% (77.4%, 98.0%)
Day 2	236	30	36	15.25%	83.3% (68.1%, 92.1%)
Day 3	156	27	27	17.30%	96.3% (81.7%, 99.3%)
Day 4	106	16	19	17.90%	84.2% (62.4%, 94.5%)
Total	705	101	115	16.31%	87.8% (80.6%, 92.6%)

Influenza A Performance

Table 12
Clinical Performance Compared to Reference PCR: Influenza A

Influenza A	Comparator Positives	Comparator Negatives	Total
Candidate Positives	75	2	77
Candidate Negatives	11	617	628
Total	86	619	705
Positive Percent Agreement (PPA) = 87.2% (75/86)	95% CI: 78.5% - 92.7%		
Negative Percent Agreement (NPA) = 99.7% (617/619)	95% CI: 98.8% - 99.9%		

Influenza B Performance

Table 13
Clinical Performance Compared to Reference PCR: Influenza B

Influenza B	Comparator Positives	Comparator Negatives	Total
Candidate Positives	20	2	31
Candidate Negatives	4	670	674
Total	33	672	705
Positive Percent Agreement (PPA) = 87.9% (29/33)	95% CI: 72.7% - 95.2%		
Negative Percent Agreement (NPA) = 99.7% (670/672)	95% CI: 98.9% - 99.9%		

Support

For questions regarding the use of this product or to report a problem, visit quidelortho.com/techsupportcontact for contact information for your region. Otherwise, call 1.800.874.1517 (8:00 a.m. to 8:00 p.m. EST M-F in the U.S.), email technicalsupport@quidelortho.com or contact your local distributor.

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References

1. US Department of Health and Human Services. National Institutes of Health. Influenza (Fact Sheet). January 2011.
2. World Health Organization (WHO). Coronavirus disease (COVID-19) at https://www.who.int/emergencies/diseases/novel-coronavirus-2019. January 2025.

Glossary

REF — Catalogue Number

IVD — *in Vitro* Diagnostic Medical Device

Keep away from sunlight

Keep Dry

Batch Code

Temperature Limit

Use-by date

Manufacturer

Do Not Reuse

Consult Instructions for Use

Do not use if package is damaged

Contains sufficient for <n> tests

A symbols glossary can be found at *quidelortho.com/global/en/resources/symbol-glossary*.

Revision History

Revision	Date	Description of Changes
1593900EN00	09/2025	Initial Release

REF 20518 — QuickVue Influenza+SARS Test

IVD

Manufactured by:
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Made in China

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