Flowflex® PLUS

COVID-19 + Flu A/B Home Test Package Insert

REF L03A-R0645 REF L03A-R0845	REF L03A-R0745 REF L03A-R0945

English

A rapid test for the detection and differentiation of SARS-CoV-2, Influenza A, and/or Influenza B antigens in anterior nasal specimens. For *in vitro* diagnostic use only. For Over-the-Counter Use.

Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate results.

INTENDED USE

The Flow*flex* Plus COVID-19 + Flu A/B Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens 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 non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (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 therefore seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza (Flu) is an acute respiratory disease caused by Flu viruses (type A, type B and type C), which is highly infectious and has a short window period. Flu A and B viruses circulate and cause seasonal epidemics of disease. Flu A virus poses a greater risk as compared to Flu B virus. Based on the current epidemiological investigation, the incubation period is generally 1 to 7 days, most of which are 2 to 4 days. Flu patients usually have symptoms of high fever, headache, muscle pain and fatigue, accompanied by respiratory symptoms, such as sore throat, cough, and sputum. The disease is self-limiting, but infants, the elderly, and patients with underlying cardiopulmonary diseases are prone to severe complications such as pneumonia that can lead to death.

PRINCIPLE

The Flow*flex* Plus COVID-19 + Flu A/B Home Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, Influenza A, and/or Influenza B in human anterior nasal swab specimens from those suspected of COVID-19, Influenza A, and Influenza B. The Flow*flex* Plus COVID-19 + Flu A/B Home Test is validated for testing without transport media.

When specimens are processed and added to the test cassette, SARS-CoV-2 or Flu A/B antigens, if present in the specimen, will react with the colored anti-SARS-CoV-2 or Flu A/B antibody-coated particles, which have been pre-coated on the test strip. The antigen-antibody complex then migrates toward the membrane by capillary action. This complex is then captured by anti-SARS-CoV-2 or anti-Flu A/B monoclonal antibodies immobilized at the related test line region, and a colored line appears on the membrane.

Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines.

To serve as a procedure control, a red or pink line will always appear in the control line region after proper volume of specimen has been added, and membrane wicking has occurred.

REAGENTS AND MATERIALS

Materials Provided

Kit Component	Quantity	Description
Test Cassettes	1, 2, 5 or 25 individually wrapped for single use	Foil pouched test cassette containing one reactive strip pre-coated with monoclonal anti-SARS and anti-Flu A/B antibodies.
Extraction Buffer	1, 2, 5 or 25 single use buffer tubes, each with an integral dispensing tip	Detergent solution with 0.1% ProClin 300

Nasal Swabs	1, 2, 5 or 25 sterile swabs, single use specimen sampling swabs	For sample collection and transfer
Tube Holder	Only for 25 test quantity	Each holder has capacity for 10 extraction buffer tubes
Quick Reference Instructions	1 English QRI 1 Spanish QRI	

Materials Required But Not Provided

- Timer

REAGENT STORAGE

- The kit should be stored at temperatures between 36-86°F (2-30°C) out of direct sunlight.
- The test must remain in the sealed pouch until use and should be run at temperatures between 59-86°F (15-30°C).
- The test is stable until the expiration date printed on the sealed pouch.
- DO NOT FREEZE.
- Do not use after the expiration date.

QUALITY CONTROL

Internal procedural controls are included in the test. A red or pink line appearing in the control line region (Ctl) is an internal procedural control. The appearance of the procedural control line indicates that proper volume of specimen has been added and capillary flow occurred. If the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new cassette is recommended.

WARNINGS AND PRECAUTIONS

- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- This product is used only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens.
- Do not use the test after the expiration date shown on the test cassette pouch or if the test kit contents are damaged or opened.
- Do not use on anyone under 2 years of age.
- The swab specimen should be processed and tested immediately after collection.
- Do not use the test cassette if the pouch is damaged or open.
- Once opened, the test cassette should be used immediately.
- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**

- Test components are single-use. Do not re-use the test cassette, buffer, or swab.
- Testing should be done in an area with good lighting.
- Do not use this test if you have recently received a nasally administered influenza A or B vaccine.
- Please ensure that hands are dry after washing prior to performing the test.
- Remove any piercings from nose before starting the test.
- **Keep testing kit and components away from children and pets before and after use.**
- **Avoid contact with your skin, eyes, nose, and mouth. Do not ingest any kit components as the reagent solution contains harmful chemicals (see table below).**
- **If the reagent solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water.**

  If irritation persists, seek medical advice:

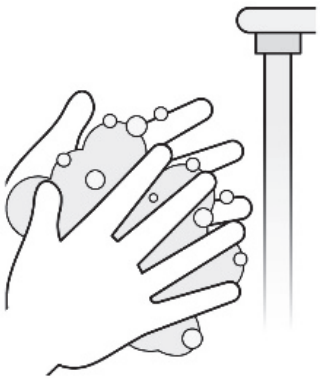
  https://www.poisonhelp.org or 1-800-222-1222

Hazardous Ingredients for the Reagent Solution			
Hazard Category (mixture)	**GHS Hazard Statement for mixture**	**Labeling of Harm(s)**	**Hazardous Ingredients (%)**
2	Skin irritation	Causes skin irritation (H315)	• Proclin 300 / 0.1% • Tris / 1%
2	Eye irritation	Causes eye irritation (H320)	• Proclin 300 / 0.1% • Tris / 1%

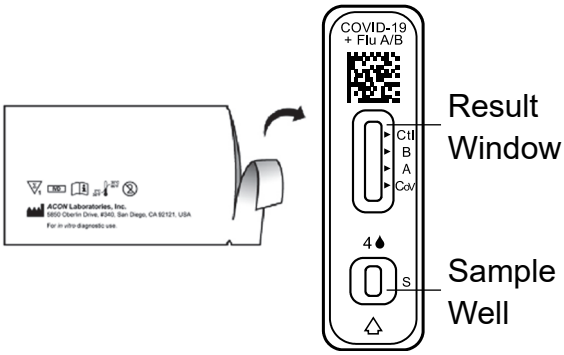
PREPARATION

Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate results.

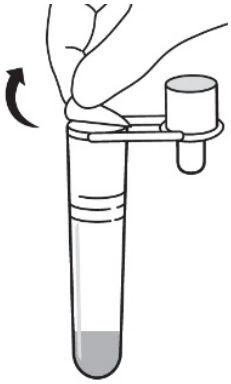
1. Wash or sanitize hands. Dry hands before testing.



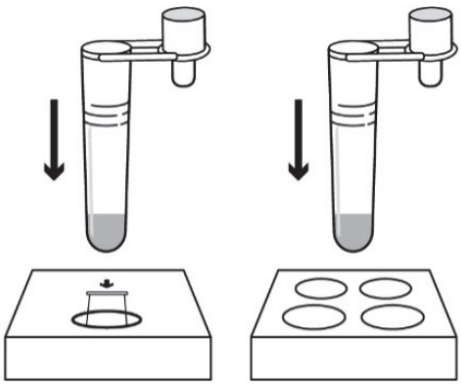
2. Remove the test cassette from pouch and lay on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.



3. Remove buffer tube from pouch. Remove the foil from tube.

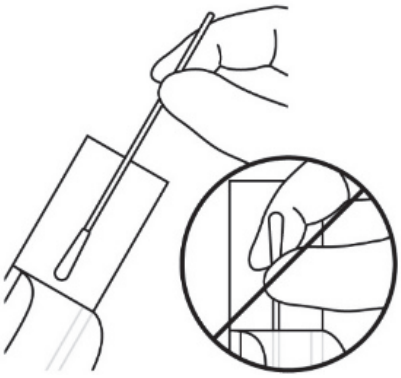


4. Punch through perforation on box to form a tube holder. Place tube in holder.

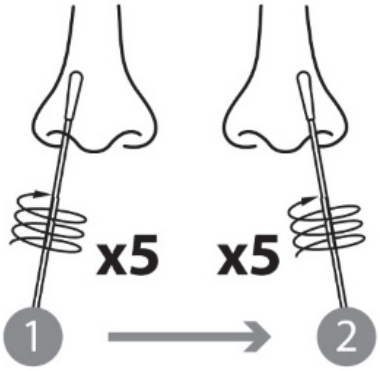


TEST PROCEDURE

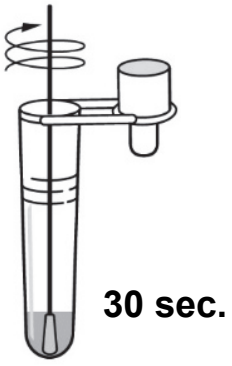
1. Open swab package at stick end. Take out swab. **Do not touch the swab tip.**



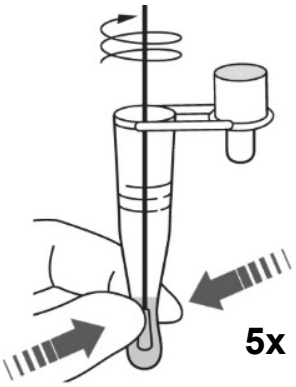
2. Gently insert tip of swab into 1 nostril (½ to ¾ of an inch). **With children, insert swab less than ¾ of an inch.** You may need to have a second person to hold the child's head while swabbing. **Firmly rub swab** in a circular motion against the inside wall of nostril **5 times** (15 sec.). Repeat this in the other nostril using the same swab. Please use a face mask when swabbing others.



3. Remove the swab from nostril and immediately place into buffer tube. Swirl swab in buffer tube for 30 seconds.

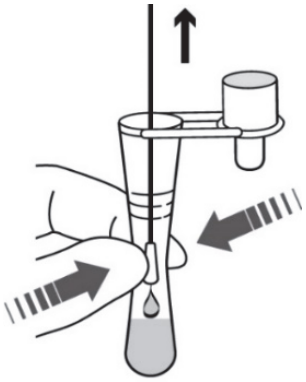


4. Rotate swab 5 times while **squeezing tube**. Incorrect results may be observed if the swab is not swirled for 30 seconds or rotated 5 times.



5. Remove swab **while squeezing tube**. Discard swab.

   Note: Swab with collected sample should be tested no more than 30 minutes after adding to the tube.

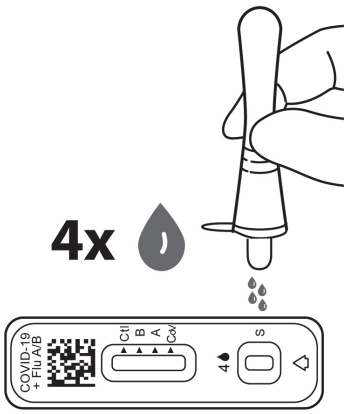


6. Attach dropper tip and mix by swirling or flicking bottom of tube.

   Note: A false negative result may occur if the swab is not swirled at least 30 seconds or rotated 5 times.

7. Invert the buffer tube and gently squeeze **4 drops** of sample into Sample Well. Discard tube.

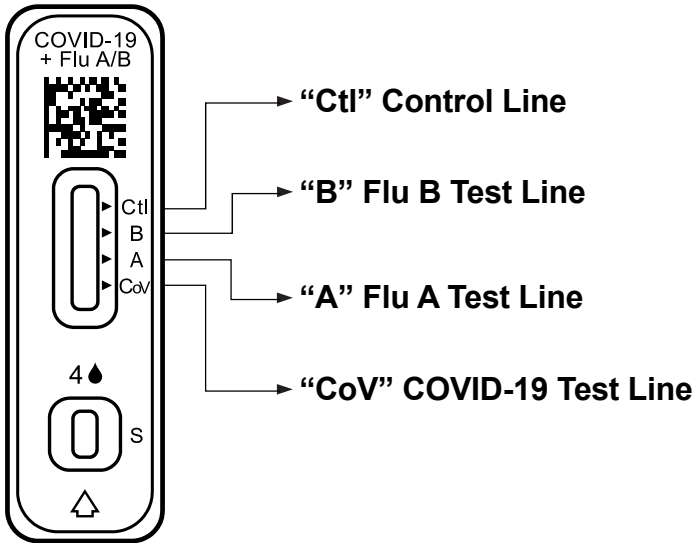
   Note: An invalid or false negative result may occur if less than 3 drops or more than 6 drops of fluid are added to the Sample Well.



8. Set timer and read result after 15 minutes. Do not read after 30 minutes. Discard test cassette.

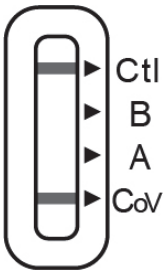
   Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

RESULT INTERPRETATION

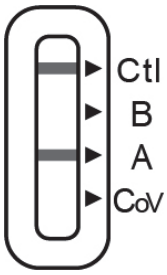


Note: Any visible faint red or pink line in the Test line region (CoV/A/B) should be read as positive. If there is no colored line in the Test line region (CoV, A, and/or B) and a colored line in the Control line (Ctl) region, then that test line (CoV, A, and/or B) should be read as negative.

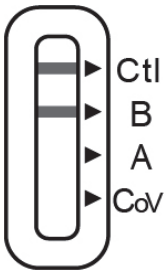
POSITIVE



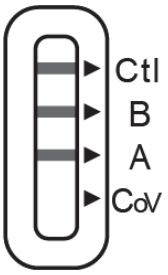
COVID-19 Positive



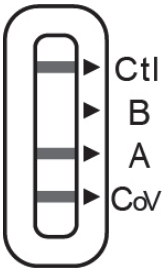
Flu A Positive



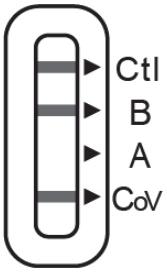
Flu B Positive



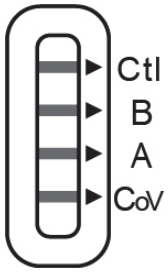
Flu A + Flu B Positive



COVID-19 + Flu A Positive



COVID-19 + Flu B Positive

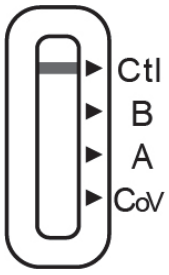


COVID-19, Flu A + Flu B Positive

If the Control (Ctl) line is visible and any other line or multiple lines, no matter how faint, at “CoV”, “A” and/or “B” appear, the test is positive for that virus.

Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation.

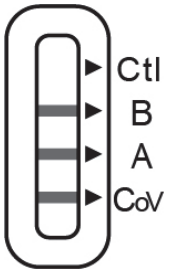
NEGATIVE



If the Control (Ctl) line is visible, but the Test (CoV/A/B) line is not visible, the test is negative. The COVID-19, Flu A, or Flu B virus have not been detected.

If respiratory symptoms persist, seek follow-up care with a healthcare provider.

INVALID



If the Control (Ctl) line is not visible, even if any other line is visible in the result window, the test is not valid. Re-test with a new test kit and sample.

If the problem persists, call (800) 838-9502 for assistance.

RESULTS REPORTING

Report your test result(s) at MakeMyTestCount.org-this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

LIMITATIONS

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2022 and March 2024. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of COVID-19 and influenza and their prevalence, which change over time. Additional testing with a laboratory-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

2. 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, handled or transported improperly.
3. 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.
4. False positive test results are more likely when the prevalence of SARS-CoV-2, Flu A/B is low in the community.
5. Positive results do not rule out co-infection with other respiratory pathogens.
6. 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.
7. This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
8. 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.
9. FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.
10. 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.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of Flow*flex* Plus COVID-19 + Flu A/B Home Test was established in a prospective all-comers clinical study conducted between December 2022 and March 2024, excluding summer months between the two respiratory seasons. Of the 741 anterior nasal swabs collected from symptomatic individuals, 720 samples derived from study subjects within 5 days of respiratory symptom onset (i.e., met the inclusion criteria for the analysis). These samples were either self-collected and tested by users > 14 years of age or collected and tested by an adult from users who were < 14 years of age. The study was conducted in a simulated home setting environment at ten study sites in the U.S. All adults and all minors ≥ 14 years of age performed the test unassisted and interpreted the result, using only the Quick Reference Instructions. The investigational sample was collected after the collection of the nasopharyngeal swab for comparator testing. The Flow*flex* Plus COVID-19 + Flu A/B Home Test results were compared to highly sensitive RT-PCR molecular assays to determine test performance in the tables below:

Table 1. Subject Demographics

Factor	Lay user collecting and testing (N=151)	Self-collecting and testing (N=569)	Overall (N=720)
Age			
Mean (SD)	7.3 (3.2)	44.4 (17.9)	36.6 (22.0)
Median [Min, Max]	7 [2, 13]	44 [14, 91]	35.5 [2, 91]
Age Group			
≥ 2 - <14 years of age	151 (100%)	0 (0%)	151 (21.0%)
14-24 years of age	0 (0%)	87 (15%)	87 (12.1%)
25-64 years of age	0 (0%)	394 (69%)	394 (54.7%)
≥ 65 years of age	0 (0%)	88 (15%)	88 (12.2%)
Sex at Birth			
Female	67 (44%)	319 (56%)	386 (53.6%)
Male	84 (56%)	250 (44%)	334 (46.4%)
Ethnicity			
Hispanic/Latino	52 (34%)	151(27%)	203 (28%)
Not Hispanic/Latino	99 (66%)	418 (73%)	517 (72%)
Race			
Black or African American	4 (2.6%)	65 (11.4%)	69 (9.6%)
Asian	89 (59%)	189 (33%)	278 (38.6%)
White	3 (2%)	151 (26.5%)	154 (21.4%)
Other	3 (2.0%)	13 (2.3%)	16 (2.2%)

Table 2. COVID-19 result of the Flow*flex* Plus COVID-19 + Flu A/B Home Test compared to reference RT-PCR Assay

COVID-19 Result of Flow*flex* Plus COVID-19 + Flu A/B Home Test	RT-PCR for COVID-19		
	Positive	Negative	Total
COVID-19 Positive	160	4	164
COVID-19 Negative	17	535	552
Total	177	538	716*
Positive Percent Agreement (PPA)	90.4% (160/177) (95%CI: 85.1% - 94.3%)		
Negative Percent Agreement (NPA)	99.4% (535/538) (95%CI: 98.4% - 99.9%)		

* 4 samples excluded due to invalid/inconclusive results with comparator methods.

Table 3. COVID-19 Clinical Performance stratified by Days Post Symptom Onset of the Study Subject

Days Post Symptom Onset	Number of Subject samples tested	Flow*flex* Plus COVID-19 + Flu A/B Home Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95%CI)
Day 0	26	4	6	23.08%	66.7% (22.3%, 95.7%)
Day 1	198	39	42	21.21%	92.9% (80.5%, 98.5%)
Day 2	214	47	52	24.30%	90.4% (79.0%, 96.8%)
Day 3	157	50	53	33.76%	94.3% (84.3%, 98.8%)
Day 4	75	16	19	25.33%	84.2% (60.4%, 96.6%)
Day 5	46	4	5	10.87%	80.0% (28.4%, 99.5%)
Total	716	160	177	24.7%	90.4% (85.1%, 94.3%)

Table 4. Flu A results of Flow*flex* Plus COVID-19 + Flu A/B Home Test compared to reference RT-PCR Assay

Flu A Result of Flow*flex* Plus COVID-19 + Flu A/B Home Test	RT-PCR for Flu A		
	Positive	Negative	Total
Flu A Positive	76	1	77
Flu A Negative	7	636	643
Total	83	637	720
Positive Percent Agreement (PPA)	91.6% (76/83) (95%CI: 83.4% - 96.5%)		
Negative Percent Agreement (NPA)	99.8% (636/637) (95%CI: 99.1% - 100%)		

Table 5. Flu B results of Flow*flex* Plus COVID-19 + Flu A/B Home Test compared to reference RT-PCR Assay

Flu B Result of Flow*flex* Plus COVID-19 + Flu A/B Home Test	RT-PCR for Flu B		
	Positive	Negative	Total
Flu B Positive	44	2	46
Flu B Negative	3	671	674
Total	47	673	720
Positive Percent Agreement (PPA)	93.6% (44/47) (95%CI: 82.5% - 98.7%)		
Negative Percent Agreement (NPA)	99.7% (671/673) (95%CI: 98.9% - 100%)		

Usability Study

A total of 741 subjects were enrolled in the usability study for the Flow*flex* Plus COVID-19 + Flu A/B Home Test. The subjects were instructed to self-collect or collect a sample from a child, complete the required procedural steps, and interpret the test results unassisted in a simulated home-setting. The overall success of every task completed by all subjects enrolled was determined by the observation of unassisted professionals and the results were acceptable.

Readability Study

The readability study for the Flow*flex* Plus COVID-19 + Flu A/B Home Test was performed by 61 lay users with diverse ages, gender, educational background and including those with vision impairment (e.g., glasses, contacts).

A total of 244 test cassettes were read and recorded in this study. Lay users were able to perceive and interpret all negative results with 100% accuracy (475/475) and positive results at 5xLoD with 99.3% accuracy (133/134). As the Test Line intensity became fainter with low positive samples at 2xLoD, the agreement was 93.8% (115/123); 7 of 61 lay users (age 54 and above) with age related vision impairments found it difficult to determine the positive results for low positive samples at 2xLoD.

Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the Flow*flex* Plus COVID-19 + Flu A/B Home Test was determined using limiting dilutions of heat-inactivated SARS-CoV-2 virus and two strains each of live Flu A and Flu B viruses. LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time.

Nasal swabs from healthy donors were collected. Each collected swab was eluted with 350 µL of PBS. The swab eluates were combined and mixed thoroughly to create a negative pooled nasal swab matrix (PNSM). SARS-CoV-2 virus and Flu A/B virus were diluted in PNSM to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by applying 50 µL of each virus dilution onto the swab. The swab samples were processed and tested according to the package insert. Range-finding testing was conducted with five replicates at various dilutions and confirmatory testing was conducted with 20 replicates for each of three device lots.

Table 6. LoD of Flow*flex* Plus COVID-19 + Flu A/B Home Test

Virus	Subtype/ Lineage	LoD concentration ($TCID_{50}$/mL)	LoD concentration ($TCID_{50}$/swab)	# Positive /# Total	Percent Detected (%)
Flu A/Brisbane/02/18	H1N1	1.51×10^3	7.55×10^1	60/60	100%
Flu A/Perth/16/09	H3N2	1.87×10^3	9.35×10^1	60/60	100%
Flu B/Washington/02/19	Victoria	5.17×10^0	0.259	60/60	100%
Flu B/Phuket/3073/13	Yamagata	1.86×10^1	0.93	60/60	100%
SARS-CoV-2	USA-WA1/2020	1.27×10^3	6.35×10^1	60/60	100%

Based on confirmatory testing, the following LoDs were established for each analyte:

Based on this testing, the LoD of Flow*flex* Plus COVID-19 + Flu A/B Home Test was confirmed as 1.27×10^3 $TCID_{50}$/mL for COVID-19 (SARS-CoV-2 USA-WA1/2020), 1.51×10^3 $TCID_{50}$/mL for Flu A H1N1, 1.87×10^3 $TCID_{50}$/mL for Flu A H3N2, 5.17×10^0 $TCID_{50}$/mL for Flu B (Victoria), and 1.86×10^1 $TCID_{50}$/mL for Flu B (Yamagata) in PNSM.

The analytical sensitivity of the Flow*flex* Plus COVID-19 + Flu A/B Home Test was also determined using limiting dilutions of the 1st WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368) containing SARS-CoV-2 Omicron (B.1.1.529, sub-variant BA.1).

The WHO International Standard for SARS-CoV-2 antigen was diluted in PNSM to generate virus dilutions for testing. Contrived nasal swab samples were prepared by applying 50 µL of each virus dilution onto the swab. The swab samples were processed and tested according to the package insert. The analytical sensitivity was confirmed with 20 replicates for each of three device lots.

Table 7. Analytical Sensitivity of COVID-19 test with WHO International Standard SARS-CoV-2

WHO International Standard SARS-CoV-2 Concentration	# Positives/# Total	Percent Detected (%)
2.00×10^2 IU/mL	60/60	100%

The analytical sensitivity of the Flow*flex* Plus COVID-19 + Flu A/B Home Test with the WHO International Standard for SARS-CoV-2 antigen was confirmed as 200 IU/mL (10 IU/swab) in PNSM.

Multi-lot Precision Study

The multi-lot precision for the Flow*flex* Plus COVID-19 + Flu A/B Home Test was evaluated in two different studies to assess variability between reagent lots, days, runs and operators.

Study 1 was conducted testing 27 different samples comprised of analyte negative, single, double and triple analyte positive samples. Positive samples were generated by spiking various combinations of viruses each at its 1.5x LoD or 5x LoD, respectively. The 27 samples were prepared daily and divided into 3 panels of 9 samples that were tested twice a day. Each of three operators tested two different 9-sample panels once per day over a period of ten (10) non-consecutive using 3 independently manufactured test kit lots. Since virus and virus concentrations were randomized within the 27 samples and testing was further randomized and blinded across the 2 runs, 3 test kit lots, 3 operators and 10 days all study operators were efficiently blinded towards the test results in the sample panel. For each of the three (3) operators, this study generated 60 replicate test results for each analyte and concentration, i.e., a total of 180. While the study did not yield identical replicate numbers per lot of test kits, due to the randomization, it achieved 100% expected results across the entire study.

Table 8. Summary Results for Lot-to-Lot Precision Study 1

Sample level	Analyte	Results (obtained correct results per analyte* / Expected results per analyte)	Total percent lot-to-lot agreement	95% CI
Negative	SARS-CoV-2	Negative (180/180)	100%	98.0-100%
	Flu A	Negative (180/180)	100%	98.0-100%
	Flu B	Negative (180/180)	100%	98.0-100%
1.5xLoD	SARS-CoV-2	Positive (180/180)	100%	98.0-100%
	Flu A	Positive (180/180)	100%	98.0-100%
	Flu B	Positive (180/180)	100%	98.0-100%
5xLoD	SARS-CoV-2	Positive (180/180)	100%	98.0-100%
	Flu A	Positive (180/180)	100%	98.0-100%
	Flu B	Positive (180/180)	100%	98.0-100%

* Obtained correct results (same as the Expected result) per analyte

Study 2 was conducted testing 5 different samples, 1 sample negative for all three analytes, 1 sample positive for all three analytes, and 3 samples positive for the 2 viruses in different combinations. All viruses in the positive samples were spiked at their 0.75x LoD concentration. All sample panels were randomized and tested in a blinded manner by three (3) operators each of whom tested on two (2) days using three lots of test kits. Considering the distribution of analytes across the samples the study resulted in 36 negative and 72 positive test results for each analyte and concentration.

Table 9. Summary Results for Lot-to-Lot Precision Study 2

Analyte Concentration	Analyte	Lot 1		Lot 2		Lot 3		Lot-to-Lot Agreement		95% CI
		n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	n/N[1]	% Agmt[2]	
Negative	SARS-CoV-2	12/12	100%	12/12	100%	12/12	100%	36/36	100%	90.4-100%
	Flu A	12/12	100%	12/12	100%	12/12	100%	36/36	100%	90.4-100%
	Flu B	12/12	100%	12/12	100%	12/12	100%	36/36	100%	90.4-100%
0.75XLoD	SARS-CoV-2	18/24	75%	19/24	79%	14/24	58%	51/72	71%	58.9-81.0%
	Flu A	17/24	71%	18/24	75%	19/24	79%	54/72	75%	63.4-84.5%
	Flu B	17/24	71%	17/24	71%	18/24	75%	52/72	72%	60.4-82.1%

n/N[1]: number of obtained correct results per analyte / Number of expected results per analyte.

%Agmt[2] (% agreement) = (Obtained correct results per analyte / Expected results per analyte) X100%

The results of these two precision studies demonstrate a lot-to-lot precision that is consistent with the expectations for the analyte concentration in the samples at or above the LoD of the test.

Analytical Reactivity Study

Analytical reactivity study was conducted using contrived samples prepared by spiking various strains of SARS-CoV-2 virus, Flu A virus or Flu B viruses into pooled nasal swab matrix (PNSM) in a series of ten-fold dilution and three-fold dilutions tested in five replicates per the Quick Reference Instructions. Concentrations listed in the table below indicate the lowest detectable concentrations for which all 5 replicates were positive.

Table 10. Summary of SARS-CoV-2 Analytical Reactivity with Flow*flex* Plus COVID-19 + Flu A/B Home Test

Type	Subtype/ Lineage	Virus Strain	Flow*flex* Plus COVID-19 + Flu A/B Home Test	
			Analytical reactivity ($TCID_{50}$/mL)	Positive rate (COVID-19)
SARS-CoV-2	B1.1.529, Omicron	SARS-CoV-2 (B.1.1.529 Omicron) *USA/MD-HP20874/2021*	5.01×10^2	100%
	B.1.17, Alpha	SARS-CoV-2 (B.1.1.7 Alpha)	4.20×10^2	100%
	B.1.351, South Africa	SARS-CoV-2 (B.1.351 South Africa)	1.05×10^3	100%
	B.1.617.2 Delta	SARS-CoV-2 (B.1.617.2 Delta)	1.05×10^3	100%
	BA. 2.3, Omicron	SARS-CoV-2 (BA.2.3 Omicron)	7.34×10^2	100%
	Brazil, P.1	SARS-CoV-2 (Brazil P.1)	1.26×10^3	100%
	B.1.1.529, Omicron	USA/CO-CDPHE-2102544747/2021	4.17×10^2	100%
	BA.2.12.1, Omicron	USA/NY-Wadsworth-22014351-01/2022	1.26×10^3	100%
	BA.2.75.5, Omicron	USA/NY-Wadsworth-22037154-01/2022	1.70×10^2	100%
	BA.4.6, Omicron	USA/MD-HP35538/2022	1.15×10^3	100%
	BA.5, Omicron	USA/COR-22-063113/2022	2.53×10^3	100%
	BA.5.5, Omicron	USA/NY-Wadsworth-22023478-01/2022	1.56×10^2	100%
	BF.5, Omicron	USA/MD-HP34985/2022	2.93×10^3	100%
	BF.7, Omicron	USA/NY-Wadsworth-22042128-01/2022	1.26×10^3	100%
	BQ.1, Omicron	USA/NY-Wadsworth-22050462-01/2022	1.43×10^3	100%
	BQ.1.1, Omicron	USA/MD-HP38861/2022	2.93×10^2	100%
	BQ.1.16, Omicron	USA/NY-Wadsworth-22050865-01/2022	2.19×10^3	100%
	BQ.1.3, Omicron	USA/NY-Wadsworth-22047869-01/2022	3.20×10^3	100%

	XBB, Omicron	USA/CA-Stanford-109_S21/2022	1.98×10^4	100%
	JN.1, Omicron	USA/New York/PV96109/2023	1.05×10^3	100%
	JN.1.4 (Omicron)	USA/NY-Wadsworth-23068107-01/2023	5.43×10^2	100%
	EG.5.1 (Omicron)	USA/MD-HP47946/2023	1.22×10^5	100%
	JG.3 (Omicron)	USA/NY-Wadsworth-23067147-01/2023	2.63×10^4	100%
	XBB.1.5 Omicron	USA/NY-Wadsworth-22061020-01/2022	1.15×10^4	100%
	HV.1 Omicron	USA/MD-HP49152/2023	8.73×10^3	100%

Table 11. Summary of Flu A Analytical Reactivity with Flow*flex* Plus COVID-19 + Flu A/B Home Test

Type	Subtype/ Lineage	Virus Strain	Flow*flex* Plus COVID-19 + Flu A/B Home Test	
			Analytical Reactivity ($TCID_{50}$/mL)	Positive rate (Flu A)
Influenza A	H1N1	A/California/07/09	1.38×10^4	100%
		A/Guangdong Maonan/SWL/1536/19	1.39×10^4	100%
		A/Kumamoto/102/02	1.05×10^4	100%
		A/Mexico/4108/09 (pdm)	2.41×10^3	100%
		A/Michigan/45/15	6.20×10^2	100%
		A/New Caledonia/20/99	1.67×10^3	100%
		A/New York/18/09 (pdm)	1.41×10^2	100%
		A/Puerto Rico/8/34	1.67×10^3	100%
		A/Solomon Islands/03/06	5.62×10^1	100%
		A/Taiwan/42/06	4.57×10^3	100%
		A/Victoria/4897/22	3.24×10^2	100%
		A/Baltimore/JH-22400/2022	8.9×10^4	100%
		A/Connecticut/11/2023	9.3×10^2	100%
		A/Wisconsin/67/22	1.16×10	100%
	H3N2	A/Brisbane/10/07	4.17×10^2	100%
		A/Hong Kong/2671/19	5.67×10^2	100%
		A/Kansas/14/17	3.80×10^3	100%
		A/Norway/466/14	1.23×10^4	100%

		A/Singapore/INFIMH-16-0019/16	1.67 x 10^3	100%
		A/Texas/50/12	1.18 x 10^3	100%
		A/Victoria/361/11	1.80 x 10^3	100%
		A/Wisconsin/67/05	4.70 x 10^2	100%
		A/Michigan/173/20	5.20 x 10^4	100%
		A/Cambodia/E0826360/20	1.17 x 10^3	100%
		A/Tasmania/503/20	1.41 x 10^4	100%
	H5N1	A/Chicken/Liaoning/SD007/2017	1.3 x 10^4	100%
		A/Vietnam/1194/2004	1.1 x 10^4	100%
	H5N8	A/H5N8	1.1 × 10^3	100%
	H7N3	A/waterfowl/Chenhu/367-1/2021	5.0 x 10^3	100%

Table 12. Summary of Flu B Analytical Reactivity with Flow*flex* Plus COVID-19 + Flu A/B Home Test

Type	Subtype/ Lineage	Virus Strain	Flow*flex* Plus COVID-19 + Flu A/B Home Test	
			Analytical Reactivity ($TCID_{50}$/mL)	Positive rate (Flu B)
Influenza B	Victoria	B/Alabama/2/17	1.39 x 10^2	100%
		B/Lee/40	1.26 x 10^3	100%
		B/Malaysia/2506/04	1.27 x 10^3	100%
		B/Michigan/01/21	3.87 x 10^4	100%
		Austria/1359417/21	9.40 × 10^2	100%
	Yamagata	B/Panama/45/90	3.80 x 10^3	100%
		B/Florida/02/06	4.70 x 10^1	100%
		B/Florida/04/06	3.55 x 10^1	100%
		B/Massachusetts/2/12	4.20 x 10^2	100%
		B/Texas/6/11	2.41 x 10^2	100%
		B/Utah/9/14	1.27 x 10^3	100%
		B/Victoria/504/00	4.20 x 10^2	100%
		B/Wisconsin/1/10	1.87 x 10^1	100%
		B/Yamagata/16/88	4.70 x 10^1	100%
		B/Brisbane/9/14	4.20 x 10^2	100%

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity and Microbial interference were evaluated by testing a panel of related viruses, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in nasal swab specimens. Each microorganism was tested in the absence or presence of SARS-CoV-2 virus (USA-WA1/2020), Influenza A H1N1 virus (Strain: Brisbane/02/18) and Influenza B virus (Washington/02/19) at a low concentration (3 x LoD) in triplicate.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below.

Table 13. Summary of analytical specificity of Flow*flex* Plus COVID-19 + Flu A/B Home Test

Microorganism	Concentration of microorganism applied to dry swab	Cross-reactivity Results	Interference Results
Adenovirus Type 1	2.82 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
Adenovirus Type 7	1.15 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
Bordetella pertussis	1.16 x 10^9 CFU/mL	No cross-reactivity	No Interference
Candida albicans	1.31 x 10^7 CFU/mL	No cross-reactivity	No Interference
Chlamydia pneumonia	1.4 x 10^7 IFU/mL	No cross-reactivity	No Interference
Chlamydia trachomatis	3.52 x 10^8 IFU/mL	No cross-reactivity	No Interference
Corynebacterium jeikeium	5.18 x 10^7 CFU/mL	No cross-reactivity	No Interference
Cytomegalovirus	1.00 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Enterovirus	1.95 x 10^4 $TCID_{50}$/mL	No cross-reactivity	No Interference
Epstein-Barr Virus	2.94 x 10^6 cp/mL	No cross-reactivity	No Interference
Escherichia coli	7.17 x 10^8 CFU/mL	No cross-reactivity	No Interference
Haemophilus influenzae	3.87 x 10^7 CFU/mL	No cross-reactivity	No Interference
Human coronavirus 229E	2.09 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Human coronavirus HKU1 specimen	Ct 13.7 - Ct 19.8	No cross-reactivity	No Interference
Human coronavirus NL63	1.78 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Human coronavirus OC43	2.09 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Human Metapneumovirus	3.80 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Lactobacillus salivarius	5.15 x 10^8 CFU/mL	No cross-reactivity	No Interference
Legionella pneumophila	3.27 x 10^9 CFU/mL	No cross-reactivity	No Interference
Measles Virus	1.23 x 10^7 $TCID_{50}$/mL	No cross-reactivity	No Interference
MERS-coronavirus	1.05 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Moraxella catarrhalis	5.92 x 10^7 CFU/mL	No cross-reactivity	No Interference

Mumps Virus	4.78 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
Mycobacterium tuberculosis	1.21 x 10^7 CFU/mL	No cross-reactivity	No Interference
Mycoplasma pneumoniae	2.70 x 10^7 CCU/mL	No cross-reactivity	No Interference
Neisseria meningitidis	2.04 x 10^7 CFU/mL	No cross-reactivity	No Interference
Neisseria mucosa	1.49 x 10^8 CFU/mL	No cross-reactivity	No Interference
Neisseria sicca	9.55 x 10^8 CFU/mL	No cross-reactivity	No Interference
Parainfluenza virus 1	3.80 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Parainfluenza virus 2	3.39 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
Parainfluenza virus 3	1.15 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
Parainfluenza virus 4	9.55 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Pooled human nasal cavity wash	n/a	No cross-reactivity	No Interference
Pseudomonas aeruginosa	4.93 x 10^8 CFU/mL	No cross-reactivity	No Interference
Respiratory syncytial virus	2.09 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Rhinovirus	1.00 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Staphylococcus aureus	9.23 x 10^8 CFU/mL	No cross-reactivity	No Interference
Staphylococcus epidermidis	6.84 x 10^8 CFU/mL	No cross-reactivity	No Interference
Streptococcus pneumoniae	7.22 x 10^7 CFU/mL	No cross-reactivity	No Interference
Streptococcus pyogenes	4.60 x 10^8 CFU/mL	No cross-reactivity	No Interference
Streptococcus salivarius	1.35 x 10^8 CFU/mL	No cross-reactivity	No Interference

The sequence homology was compared between the SARS-CoV-2 nucleocapsid protein and the structural proteins of SARS coronavirus (SARS-CoV) and with given the substantial homology rate (91.5%), there is high probability of cross-reactivity between the nucleocapsid proteins of SARS-CoV-2 and SARS-CoV. The Flow*flex* Plus COVID-19 + Flu A/B Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Endogenous and Exogenous Interference Substances

The following medically relevant endogenous and exogenous interferents that may be encountered in the collected samples from the upper respiratory tract were evaluated. Substances that are commonly found on the hands were also tested. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 virus (USA-WA1/2020), Influenza A H1N1 virus (Strain: Brisbane/02/18) and Influenza B virus (Washington/02/19) at a low concentration (3 x LoD). The performance of Flow*flex* Plus COVID-19 + Flu A/B Home Test was not affected by any of the interference substances tested at the concentration listed in the table below.

Table 14. Summary of interference substance study on Flow*flex* Plus COVID-19 + Flu A/B Home Test

Interfering Substance	Conc. of Interfering Substance applied to dry swab	Cross-reactivity Results	Interference Results
Beclomethasone	5 mg/mL	No cross-reactivity	No interference
Biotin	3500 ng/mL	No cross-reactivity	No interference
Dexamethasone	5 mg/mL	No cross-reactivity	No interference
Dyclonine Hydrochloride	1.5 mg/mL	No cross-reactivity	No interference
FluMIST (Influenza Vaccine Live, Intranasal)	1.5% ~ 15% v/v	Cross-reactivity with Flu A and Flu B	No interference
	0.75% v/v	Cross-reactivity with Flu A	No interference
	0.375% v/v	No cross-reactivity	No interference
Flunisolide	5 mg/mL	No cross-reactivity	No interference
Hand sanitizer	15% v/v	No cross-reactivity	No interference
Hand Soap	15% v/v	No cross-reactivity	No interference
Homeopathic Allergy Relief medicine (histaminum hydrochloricum)	15% w/v	No cross-reactivity	No interference
Homeopathic nasal wash	15% v/v	No cross-reactivity	No interference
Leukocytes	4.8×10^6 cells/mL	No cross-reactivity	No interference
Molnupiravir	10 mg/mL	No cross-reactivity	No interference
Mucin	2.5 mg/mL	No cross-reactivity	No interference
Mupirocin	10 mg/mL	No cross-reactivity	No interference
Nasal corticosteroids (Budesonide)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (fluticasone furate)	5% v/v	No cross-reactivity	No interference
Nasal corticosteroids (fluticasone propionate)	5% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Mometasone furoate)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Triamcinolone Acetonide)	15% v/v	No cross-reactivity	No interference
Nasal gel	15% v/v	No cross-reactivity	No interference
Nasal Spray (Cromolyn Sodium)	15% v/v	No cross-reactivity	No interference
Nasal Spray (Oxymetazoline HCl)	15% v/v	No cross-reactivity	No interference
Nasal Spray (Phenylephrine HCl)	15% v/v	No cross-reactivity	No interference

Nasal Wash (Saline nasal wash: sodium chloride & preservatives)	15% v/v	No cross-reactivity	No interference
Oral Anesthetic Cough Lozenge (Menthol)	3 mg/mL	No cross-reactivity	No interference
Oseltamivir Phosphate	5% w/v	No cross-reactivity	No interference
Remdesivir	10 mg/mL	No cross-reactivity	No interference
Sore Throat & Cough Lozenges (Benzocaine, Dextromethorphan HBr)	3 mg/mL	No cross-reactivity	No interference
Sore Throat Spray (Phenol)	5% w/v	No cross-reactivity	No interference
Tobramycin	50 µg/mL	No cross-reactivity	No interference
Whole Blood	2.5%	No cross-reactivity	No interference
Zanamivir	5 mg/mL	No cross-reactivity	No interference
ZICAM Nasal Decongestant, Cold Remedy Nasal Spray (Galphimia glauca, Luffa operculata, Sabadilla)	15% v/v	No cross-reactivity	No interference

High Dose Hook Effect

No high dose hook effect was observed on the Flow*flex* Plus COVID-19 + Flu A/B Home Test when tested with SARS-CoV-2 virus at a concentration of 3.80 x 10^6 $TCID_{50}$/mL, Flu A virus at a concentration of 1.51 x 10^6 $TCID_{50}$/mL, or Flu B virus at a concentration of 1.55 x 10^4 $TCID_{50}$/mL, respectively.

Competitive Interference

For co-infection, ~ 2 x LoD influenza A and/or influenza B were tested in the presence of high levels of SARS-CoV-2; and ~ 2 x LoD SARS-CoV-2 was tested in triplicate in the presence of high levels of influenza A and/or influenza B. No competitive interference was observed between SARS-CoV-2 and influenza A and B as listed in the Table below.

Table 15. Results of Competitive Interference

Assigned Sample Panel #	High concentration analyte		Low concentration analyte		Low concentration analyte Percent Positivity
	Virus	Spiked Concentration ($TCID_{50}$/mL)	Virus	Concentration 2xLoD ($TCID_{50}$/mL)	
1	Flu A/ Brisbane/02/18 (H1N1)	1.12 x 10^5	Flu B/ Washington/02/19 (Victoria)	1.03 x 10	100%
2	Flu A/ Brisbane/02/18 (H1N1)	1.12 x 10^5	SARS-CoV-2 (USA-WA1/2020)	2.53 x 10^3	100%

3	Flu B/ Washington/02/19 (Victoria)	1.00×10^4	Flu A/ Brisbane/02/18 (H1N1)	3.02×10^3	100%
4	Flu B/ Washington/02/19 (Victoria)	1.00×10^4	SARS-CoV-2 (USA-WA1/2020)	2.53×10^3	100%
5	SARS-CoV-2 (USA-WA1/2020)	1.41×10^5	Flu A/ Brisbane/02/18 (H1N1)	3.02×10^3	100%
6	SARS-CoV-2 (USA-WA1/2020)	1.41×10^5	Flu B/ Washington/02/19 (Victoria)	1.03×10	100%
7	Flu A/ Brisbane/02/18 (H1N1)	1.51×10^6	Flu B/ Washington/02/19 (Victoria)	1.03×10	100%
			SARS-CoV-2 (USA-WA1/2020)	2.53×10^3	100%
8	Flu B/ Washington/02/19 (Victoria)	1.00×10^4	Flu A/ Brisbane/02/18 (H1N1)	3.02×10^3	100%
			SARS-CoV-2 (USA-WA1/2020)	2.53×10^3	100%
9	SARS-CoV-2 (USA-WA1/2020)	1.41×10^5	Flu A/ Brisbane/02/18 (H1N1)	3.02×10^3	100%
			Flu B/ Washington/02/19 (Victoria)	1.03×10	100%

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Index of Symbols

	Manufacturer
	Contains sufficient for <*n*> tests
	*In vitro* diagnostic medical device
	Consult instructions for use
	Temperature limit
	Do not use if package is damaged

	Date of manufacture
	Catalogue number
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	Do not reuse

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