Flow*flex*® COVID-19 Antigen Home Test Package Insert for Healthcare Providers

REF L031-118B5	REF L031-125N5	English
REF L031-125M5	REF L031-125P5	

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. *For in vitro diagnostic use only.*

INTENDED USE

The Flow*flex* COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The Flow*flex* COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established during December 2022 to March 2023 when COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

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.

PRINCIPLE

The Flow*flex* COVID-19 Antigen Home Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab specimens.

When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the colored anti-SARS-CoV-2 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 monoclonal antibodies immobilized at the 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 antibodies.
Extraction Buffer	1, 2, 5 or 25 single use buffer tubes, each with an integral dispensing tip	Detergent solution with 0.02% sodium azide.
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
Package Insert	1 English Instructions for use 1 Spanish Instructions for use	

Materials Required But Not Provided

- Timer
- Flow*flex* Web App (Optional) - if using the Web App, ensure you have an internet connection and go to www.flowflexcovid.com prior to starting the test. Ensure you are using a compatible web browser (Chrome, Firefox, Edge, or Safari) and your electronic device has a camera.

REAGENT STORAGE

- The kit can be stored at temperatures between 36-86°F (2-30°C).
- The test must remain in the sealed pouch until use and should be run at temperatures not to exceed 40°C (104°F).
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- 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 (C) 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

- Read the COVID-19 Antigen Home Test Package Insert carefully before performing a test. Follow directions for use. Failure to follow directions may produce inaccurate test results.
- For *in vitro* diagnostic use.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **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.**
- If you have symptoms longer than 6 days, follow up with healthcare provider.
- You should not use this test if you have no symptoms.
- This product has been designed only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- **INVALID RESULTS**, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test cassette. Gently squeeze the tube and dispense 4 drops of solution into the sample well of test cassette.
- **Do not use on anyone under 2 years of age.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. For children age 2 to 13 years, samples should be collected and tested by an adult.
- Wear a safely mask or other face-covering when collecting a specimen from a child or another individual.

- Leave the test cassette sealed in its pouch until just before use. Once opened, the test cassette should be used within 60 minutes.
- Do not use the test after the expiration date shown on the test cassette pouch. The use of expired tests can lead to incorrect results.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use. Do not use with multiple specimens.
- Make sure there is sufficient light when reading and interpreting test results.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test. Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Accurate results are dependent on adequate product storage, and adherence to the specimen collection and testing procedures. Failure to follow test procedures can lead to incorrect results.
- Do not touch the swab tip when handling the swab.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.
- The healthcare provider will consider additional information such as the patient's personal medical history and symptoms, current disease prevalence in the community, and additional test results if applicable, to help determine what steps are best for diagnosis and treatment if needed.
- False positive test results are more likely when prevalence of SARS-CoV-2 is low in the community.
- Discuss any test results with a healthcare provider if any of the following occur:
  - The patient has high risk for severe illness based on age or medical condition.
  - The patient has a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results).
  - The patient is performing this test on behalf of a person who has any of the above conditions.
- The performance characteristics for SARS-CoV-2 were established during December 2022 to March 2023 when COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- The reagent solution in the tube contains a harmful chemical (see table below). If the 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		
Chemical Name	**Harms (GHS) code for each ingredient**	**Concentration**
TX-100	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazard (Category 1), H400	1%
ProClin 300	Acute toxicity, Oral (Category 4), H302 Acute toxicity, Inhalation (Category 4), H332 Skin corrosion (Category 1B), H314 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317	0.02%

If INHALED: Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

If SKIN Contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTED: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

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

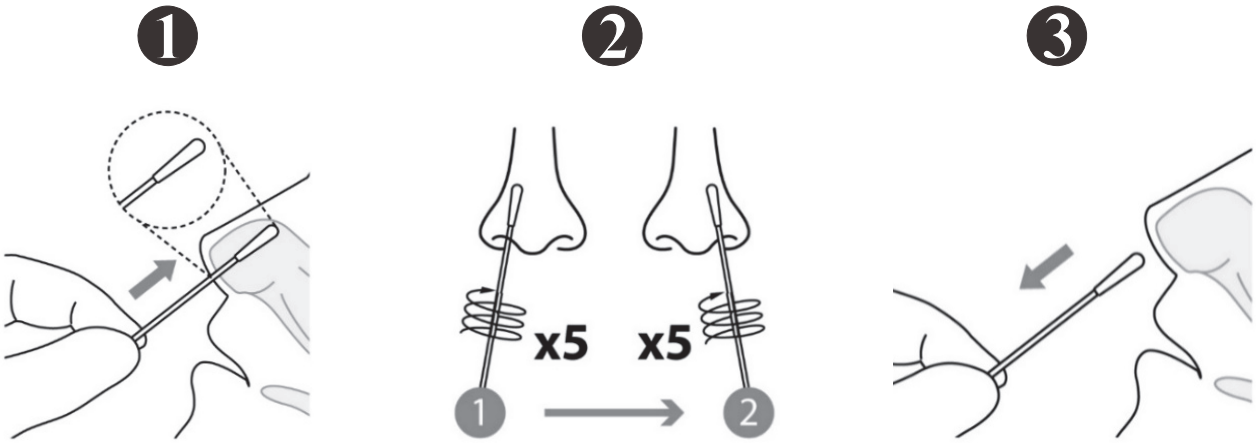
SAMPLE COLLECTION AND HANDLING

- The Flow*flex* COVID-19 Antigen Home Test is performed using anterior nasal swab specimens.
- Wash or sanitize your hands. Make sure they are dry before starting the test.
- Open the test cassette pouch and lay the cassette on a clean, flat surface.
- To collect an anterior nasal swab sample:

1. Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

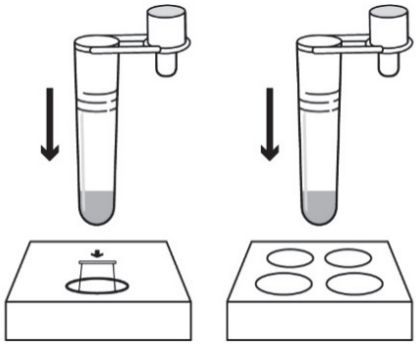
   Note: A false negative result may occur if the nasal swab specimen is not properly collected.

2. Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril using the same swab.
3. Remove the swab from the nostril and place into the extraction buffer tube.

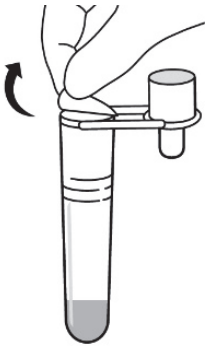


TEST PROCEDURE

1. Punch through the perforated circle on the kit box to form a tube holder. For 25 test quantity kit box the tube holder is included.

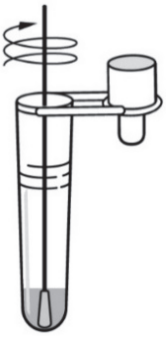


2. Remove the foil from the top of the extraction buffer tube. Place the tube in the tube holder.

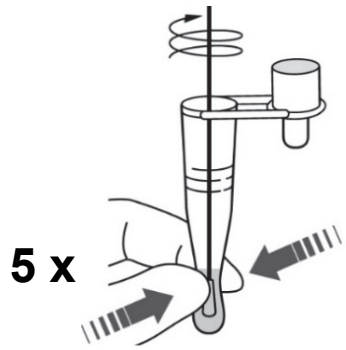


3. Immediately place the swab into the tube and swirl for 30 seconds.

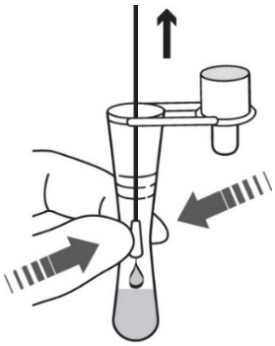
30 sec.



4. Rotate the swab 5 times **while squeezing the tube**.



5. Remove the swab **while squeezing the tube** to extract as much liquid as possible. Dispose the swab in the trash.



6. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

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

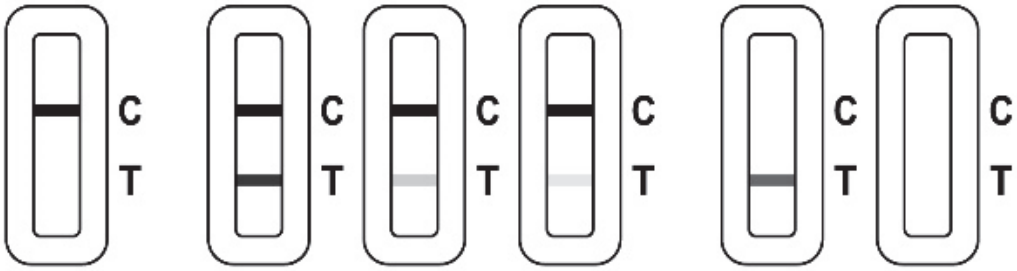
7. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose the tube in the trash.

   Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.

8. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash.

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

INTERPRETATION OF RESULTS



Negative **Positive** **Invalid**

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Interpretation
With Symptoms	Positive	N/A	Positive for COVID-19
	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

NEGATIVE: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you must test again in 48 hours if the individual has symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

POSITIVE: If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red or pink test (T) line with the control line (C) should be read as positive. **Repeat testing does not need to be performed if patients have a positive result at any time.**

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-

isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Flow*flex* COVID-19 Antigen Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

INVALID: If the control (C) line is not visible, the test is not valid. Re-test with a new swab and a new test cassette.

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 2023. The clinical performance has not been established in 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.
2. This test is only for use by individuals who show symptoms of COVID-19 within the 6 days of symptom onset.
3. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
4. If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up with a Healthcare Provider may be needed.
5. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
6. 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.
7. Incorrect test results may occur if a specimen is incorrectly collected or handled.
8. This test detects both viable (live) and nonviable 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 same sample.
9. The Flow*flex* COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
10. Test results should be correlated with other clinical data available to the physician.
11. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of Flow*flex* COVID-19 Antigen Home Test was established in a prospective all-comers clinical study conducted between December 2022 and March 2023. 799 nasal swabs from symptomatic individuals were self-collected by adults and most individuals between 14 and 18 years of age, or pair-collected by another study participant from symptomatic patients age < 14 (within 6 days of onset) suspected of COVID-19. The study was conducted in a simulated home setting environment at nine study sites in U.S. All adults and all minors ≥ 14 years of age performed the test unassisted and interpreted the result, using only the Summary instructions. The investigational sample was collected after the collection of the nasopharyngeal swab for comparator testing. The Flow*flex* COVID-19 Antigen Home Test results were compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the tables below:

Table 1. Performance of the Flow*flex* COVID-19 Antigen Home Test in Symptomatic subjects

Flow*flex* COVID-19 Antigen Home Test	**RT-PCR method**		
	Positive	**Negative**	**Total**
Positive	212	4	216
Negative	24	559	583
Total	236	563	799
Positive Percent Agreement (PPA)	89.8% (212/236) (95%CI: 85.2% - 93.4%)		
Negative Percent Agreement (NPA)	99.3% (559/563) (95%CI: 98.2% - 99.8%)		

Table 2. Cumulative PPA results by days since symptom onset

Days Since Symptom Onset	**# Specimens Tested**	**# Cumulative Positive Flow*flex* COVID-19 Antigen Home Test**	**Cumulative Positive RT-PCR**	**Cumulative PPA**
0 to 1 day	203	47	53	88.7%
0 to 2 days	496	137	146	93.8%
0 to 3 days	643	169	184	91.9%
0 to 4 days	727	190	209	90.9%
0 to 5 days	774	204	227	89.9%
0 to 6 days	799	212	236	89.8%

Symptomatic Patient Age Distribution:

A total of 799 symptomatic patients participated in the study. Ages of symptomatic patients ranged from 2 years to 83 years. The table below shows age distribution and the positive results broken down by age of the symptomatic patient:

Table 3. Age distribution of symptomatic subjects and specimen positivity

Age Group	Flow*flex* COVID-19 Antigen Home Test (N=799)		
	Total	Total Positive	Prevalence
2-13 years	99	13	13.1%
14- 24 years	81	27	33.3%
25- 64 years	514	156	30.4%
≥ 65 years	105	41	39.0%
Total	799	236	29.5%

Usability Study

A total of 431 subjects were enrolled in the usability study for the Flow*flex* COVID-19 Antigen 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. Subjects performed 96.2% (409/425) of steps/tasks correctly compared to healthcare professionals.

After the completion of the test, the subject (or Parent/Legal Guardian) completed a usability test and a satisfaction questionnaire. Specifically, 98.8% of subjects indicated that it was easy to see and understand the test results. Untrained lay users missed 7.9% of results compared to a healthcare provider, suggesting that lay users should carefully inspect the test cassette for faint lines.

Readability Study

The readability study for the Flow*flex* COVID-19 Antigen 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 (92/92) and positive results at 5 x LoD with 100% accuracy (61/61). As the Test Line intensity became fainter with low positive samples at 1.5 x LoD, the agreement was 95% (86/91); 4 of 61 lay users with age related vision impairments found it difficult to determine the positive results for low positive samples at 1.5 x LoD.

Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the Flow*flex* COVID-19 Antigen Home Test was determined using limiting dilutions of heat-inactivated SARS-CoV-2 virus (USA-WA1/2020). 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 300 µL of PBS. The swab eluates were combined and mixed thoroughly to create a negative clinical nasal swab matrix pool. SARS-CoV-2 virus was diluted in this negative clinical matrix pool 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 LoD from the dilution series was confirmed with 20 replicates each for two lots.

SARS-CoV-2 Concentration	Number of Positives/Total	% Detected
1.52 x 10^3 $TCID_{50}$/mL (76 $TCID_{50}$/swab)	40/40	100%

Based on this testing, the LoD of Flow*flex* COVID-19 Antigen Home Test was confirmed as 1.52 x 10^3 $TCID_{50}$/mL (76 $TCID_{50}$/swab) in nasal matrix.

The analytical sensitivity of the Flowflex COVID-19 Antigen 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).

Nasal swabs from healthy donors were collected. Each collected swab was eluted with 300 µL of PBS. The swab eluates were combined and mixed thoroughly to create a negative clinical nasal swab matrix pool. The WHO International Standard for SARS-CoV-2 antigen was diluted in this negative clinical matrix pool 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 each for two lots.

WHO International Standard SARS-CoV-2 Concentration	Number of Positives/Total	% Detected
625 IU/mL (31 IU/swab)	40/40	100%

The analytical sensitivity of the Flow*flex* COVID-19 Antigen Home Test with the WHO International Standard for SARS-CoV-2 antigen was confirmed as 625 IU/mL (31 IU/swab) in nasal matrix.

Multi-lot Precision Study

Three lots of the Flow*flex* COVID-19 Antigen Home Test were evaluated for precision. The test sample panels consisted of three samples at negative, low positive (1.5 x LoD) and positive (5 x LoD). The sample panel was tested in a blinded manner by three operators for ten non-consecutive days. The agreement of the obtained results with expected results was 100% across all lots, operators, and days. No variability was observed between the three independently manufactured lots.

Analytical Reactivity Study

Analytical reactivity study was conducted using contrived samples prepared in pooled negative clinical matrix spiked with SARS-CoV-2 virus or each variant respectively.

SARS-CoV-2 virus and variants	Flow*flex* COVID-19 Antigen Home Test	
	Analytical reactivity	**Positive rate (n=5)**
SARS-CoV-2 virus (USA-WA1/2020)	1.52 x 10^2 $TCID_{50}$/mL	100%
Variant B.1.1.7 (Alpha variant)	4.20 x 10^2 $TCID_{50}$/mL	100%
Variant B.1.351 (Beta variant)	1.05 x 10^3 $TCID_{50}$/mL	100%
Variant P.1 (Gamma variant)	4.20 x 10^2 $TCID_{50}$/mL	100%
Variant B.1.617.2 (Delta variant)	1.05 x 10^3 $TCID_{50}$/mL	100%
B.1.1.529 (Omicron variant)	5.01 x 10^2 $TCID_{50}$/mL	100%
BA.2.3 (Omicron variant)	2.45 x 10^3 $TCID_{50}$/mL	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) at a low concentration.

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

Microorganism		Concentration Tested	Cross-reactivity Results	Interference Results
Virus	Adenovirus	2.82 x 10^6 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Enterovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Human coronavirus HKU1	Clinical specimens (between Ct values 13.7 and 24.6)	No cross-reactivity	No Interference
	Human Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Influenza A	1.51 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Influenza B	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	MERS-coronavirus	1.05 x 10^5 $TCID_{50}$/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
	Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
	Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No Interference
Bacteria	*Bordetella pertussis*	1.16 x 10^9 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 CFU/mL	No cross-reactivity	No Interference
	Haemophilus influenzae	3.87 x 10^7 CFU/mL	No cross-reactivity	No Interference
	Legionella pneumophila	3.27 x 10^9 CFU/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
	Staphylococcus aureus	9.23 x 10^7 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 10^7 CFU/mL	No cross-reactivity	No Interference
	Pseudomonas aeruginosa	4.93 x 10^8 CFU/mL	No cross-reactivity	No Interference
Yeast	*Candida albicans*	1.31 x 10^7 CFU/mL	No cross-reactivity	No Interference

Compared the sequence homology 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* COVID-19 Antigen 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 the absence or presence of SARS-CoV-2 virus (USA-WA1/2020) at a low concentration. The performance of Flow*flex* COVID-19 Antigen Home Test was not affected by any of the interference substances tested at the concentration listed in the table below.

Interference Substance	Source/Item	Concentration Tested	Cross-reactivity Results	Interference Results
Beclomethasone	Sigma/ B0385	5 mg/mL	No cross-reactivity	No interference
Biotin	Sigma/ B4501	3500 ng/mL	No cross-reactivity	No interference
Budenoside	Rite Aid	15% v/v	No cross-reactivity	No interference
Cough Lozenge (Menthol)	Ricola	3 mg/mL	No cross-reactivity	No interference
Dexamethasone	Sigma/ D1756	10 mg/mL	No cross-reactivity	No interference
Dyclonine Hydrochloride	Sigma/PHR1849	2 mg/mL	No cross-reactivity	No interference
Flunisolide	Sigma/ 1274505	10 mg/mL	No cross-reactivity	No interference
Fluticasone furate	Flonase	5% v/v	No cross-reactivity	No interference
Fluticasone propionate	Flonase	5% v/v	No cross-reactivity	No interference
Hand Sanitizer	Hand in Hand	15% v/v	No cross-reactivity	No interference
Hand Soap	SoftSoap	15% v/v	No cross-reactivity	No interference
Homeopathic Allergy Relief (Histaminum Hydrochloricum)	Boiron	15% w/v	No cross-reactivity	No interference
Leukocytes	Lee Biosolutions	4.8×10^6 cells/mL	No cross-reactivity	No interference
Mometasone furoate	Nasonex	15% v/v	No cross-reactivity	No interference
Molnupiravir	BioSynth	10 mg/mL	No cross-reactivity	No interference
Mucin	Sigma/M3895	2.5 mg/mL	No cross-reactivity	No interference
Mupirocin	Sigma/M7694	10 mg/mL	No cross-reactivity	No interference
Nasal Decongestant	ZICAM	15% v/v	No cross-reactivity	No interference
Nasal Drops (Phenylephrine)	CVS Health	15% v/v	No cross-reactivity	No interference
Nasal Spray (Cromolyn)	NasalCrom	15% v/v	No cross-reactivity	No interference
Nasal Spray (Oxymetazoline HCl)	Afrin	15% v/v	No cross-reactivity	No interference
Nasal Spray (Sodium Chloride)	CVS Health	15% v/v	No cross-reactivity	No interference
Nasal Wash (Homeopathic)	ALKALOL	5% v/v	No cross-reactivity	No interference
NasoGEL	NeilMed	5% v/v	No cross-reactivity	No interference
Oseltamivir Phosphate (Tamiflu)	Sigma/SML1606	15% w/v	No cross-reactivity	No interference

Remdesivir	BioSynth	10 mg/mL	No cross-reactivity	No interference
Sore Throat & Cough Lozenge (Benzocaine, Dextromethorphan HBr)	CVS Health	3 mg/mL	No cross-reactivity	No interference
Sore Throat Spray (Phenol)	Chloraseptic	5% v/v	No cross-reactivity	No interference
Tobramycin	Sigma/LRAC4285	50 µg/mL	No cross-reactivity	No interference
Triamcinolone Acetonide	Goodsense	15% v/v	No cross-reactivity	No interference
Whole Blood	In-house	2.5 % v/v	No cross-reactivity	No interference

High Dose Hook Effect

No high-dose hook effect was observed when tested with a concentration up to 2.82×10^7 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 virus with Flow*flex* COVID-19 Antigen Home Test.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer		Date of manufacture
	Contains sufficient for <*n*> tests	REF	Catalogue number
IVD	*In vitro* diagnostic medical device		Use-by date
	Consult instructions for use	LOT	Batch code
	Temperature limit		Do not reuse

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Number: 1151531502
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