San Francisco Department of Public Health - San Francisco Health Network

OPERATING PROCEDURE

FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test Kit

PURPOSE

The FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. The FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. 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.

Individuals who test positive should self-isolate and consult their doctor as additional testing may be necessary and for public health reporting.

Negative results are presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. 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. Negative 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.

Individuals should provide all results obtained with this product to their doctor or healthcare provider for public health reporting. Doctors or healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Flowflex COVID-19 Antigen Home Test is intended for self-use or lay user testing another in a non-laboratory setting. The Flowflex COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SCOPE

This document is to be used by trained staff as a Procedure Manual for performing the FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test. FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization. Refer to the FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test package insert and Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#Individual%20EUAs for further details.

TESTING PERSONNEL

Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

REAGENTS & MATERIALS

A. Materials Provided

Test Cassette
Disposable Nasal Swab
Extraction Buffer Tube

B. Materials Required but not Provided

Clock, timer or stopwatch

STORAGE AND STABILITY

- **Store kit at temperatures between 2-30°C** (36-86°F) **in a temperature monitored environment.**
- The FlowFlex SARS-CoV-2 COVID-19 Low Level Nasal Non-Invasive Swab Antigen Rapid Test is stable until the expiration date marked on the outer packaging and containers.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE
- **Do not use after the expiration date**

PRECAUTIONS AND WARNINGS

1. 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.

2. For in vitro diagnostic use.
3. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
4. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
5. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
6. This product has been designed only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
7. Inadequate or inappropriate sample collection may yield false test results.
8. To obtain accurate results, the test must be performed as indicated in this Instructions for Use.
9. INVALID RESULTS, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test device. Gently squeeze the tube and dispense 4 drops of solution into the sample well of test device.
10. Swabs in the kit are approved for use with Flowflex COVID-19 Antigen Home Test. Do not use other swabs.
11. Do not use on anyone under two years of age. Keep test kit and materials out of the reach of children and pets, before and after use.
12. Do not open the kit contents until ready to use. If the test cassette is open for an hour or longer, invalid test results may occur.
13. Do not use the test after the expiration date shown on the test cassette pouch.
14. Do not use the test if the pouch is damaged or open.
15. Do not reuse any kit components. Do not use with multiple specimens.
16. Make sure there is sufficient light when reading and interpreting test results.
17. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
18. 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
19. Inadequate or improper nasal swab sample collection may result in false negative test results.
20. Do not touch the swab head when handling the swab
21. Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.
22. The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
23. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
24. Do not ingest any kit components.
25. The reagent solution in the tube contains hazardous ingredients (see table below). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222

Hazardous Ingredients for the Reagent Solution

Chemical Name	Hams (GHS) code for each ingredient	Concentration
TX-100	Acute Toxicity, oral (category 4), H302 Skin irritation (category 2), H3-15 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazared (category 1), H400 Long-term (chronic) aquatic hazard (category 1), H410	1%
Sodium Azide	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.02%

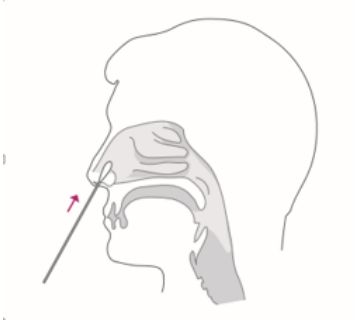
SPECIMEN REQUIREMENTS

Specimen Collection and Preparation:

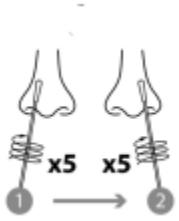
- The Flowflex COVID-19 Antigen Home Test is performed using anterior nasal swab specimens.
- Wash or sanitize your hands. Make sure they are dry before starting the test.

To collect an anterior nasal swab sample (follow below)

1. Gently insert the entire absorbent tip of the swab head 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



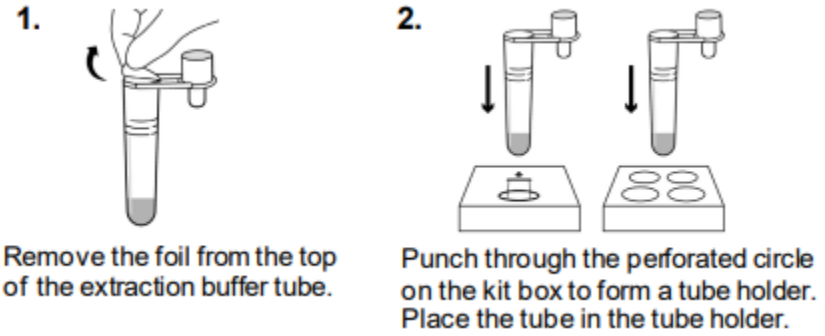
2. Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril using the same swab



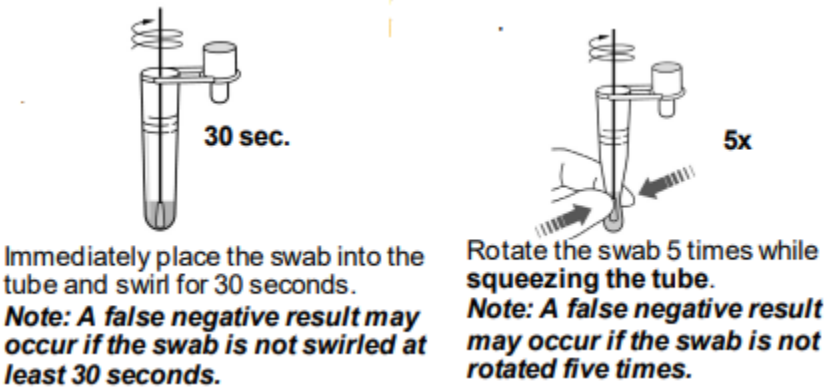
3. Remove the swab from the nostril and place into the extraction buffer tube.

Directions for Use

1. Punch through the perforated circle on the kit box to form a tube holder.
2. Remove the foil from the top of the extraction buffer tube. Place the tube in the tube holder.



3. Collect specimen, then immediately place the swab into the tube and swirl for 30 seconds.
4. Rotate the swab 5 times while squeezing the tube. Note: A false negative result may occur if the swab is not rotated 5 times.

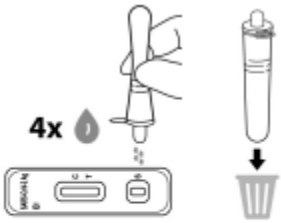


5. Remove the swab while squeezing the tube to extract as much liquid as possible. Dispose the swab in the trash.
6. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube. Note: A false negative result may occur if the swab is not swirled at least 30 seconds.

Remove the swab while **squeezing the tube**. Dispose the swab in the trash.

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

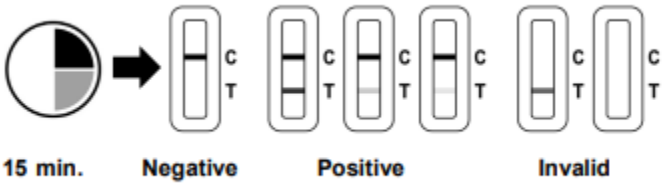
7. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose the tube in the trash. Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.



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: Only one red control line appears in the control line region (C). No apparent red line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should

be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

POSITIVE:* Two distinct red lines appear. One red line in the control line region (C) and the other red line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. * NOTE: The intensity of the red color in the test line (T) may vary depending on the level of the SARS-CoV2 antigen present in the specimen. Therefore, any shade of red in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, call (800) 838-9502 for assistance.

QUALITY CONTROL

Internal procedural controls are included in the test. A red 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

EXPECTED VALUE

Negative

REPORTING

Enter the result and procedural control result in a manual log or electronic form according to the facility procedure. All valid results must be reported to the appropriate public health authorities.

LIMITATIONS

1. The Flowflex COVID-19 Antigen Home Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection.
3. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
4. A false negative result may occur if the level of antigen in a sample is below the detection limit of the test.
5. A false negative result may occur if the sample was collected incorrectly or handled.
6. A false negative result may occur if the swab is not swirled at least 30 seconds or rotated five times

7. A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.
8. A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes
9. This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
10. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
11. Test results should be correlated with other clinical data available to the physician.
12. A positive or negative test result does not rule out co-infections with other pathogens such as other viral or bacterial infections.
13. Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
14. A negative test result is not intended to rule out other viral or bacterial infections.
15. If the differentiation of specific SARS viruses and strains is needed, additional testing is required, in consultation with state or local public health departments, is required. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and May 2021. Clinical performance has not been established with 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.

PERFORMANCE CHARACTERISTICS

Refer to the package insert for assay performance information.

REFERENCES

Flowflex COVID -19 Antigen Home Test Package Insert for HealthCare Providers Number: 1151390301 Effective Date: 2021-xx-xx