Fastep® COVID-19 Antigen Pen Home Test

(Nasal swab)

1. INTENDED USE

The Fastep COVID-19 Antigen Pen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.
This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two (2) years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.
The Fastep COVID-19 Antigen Pen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 definitive cause of disease. Individuals who test positive with the Fastep COVID-19 Antigen Pen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.
All 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 measures such as isolating from others and wearing masks. 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 who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.
Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All 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 Fastep COVID-19 Antigen Pen Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The Fastep COVID-19 Antigen Pen Home Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

2. EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The Fastep® COVID-19 Antigen Pen Home Test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in anterior nasal swab specimens.

The Fastep® COVID-19 Antigen Pen Home Test is a single test comprised of a base and a test pen with an integrated sample swab and test strip. The Test Strip is composed of several materials which, in combination, can detect SARS-CoV-2 antigens.

The sample should be collected with the sample swab after removing the swab protector. The swab containing the sample is then inserted directly into the base which has a built-in buffer, resulting a sample mixture. The sample mixture liquid will move up the Test Strip across the nitrocellulose membrane containing two reagent lines, contacting the Test Line first and then the Control Line. If SARS-CoV-2 antigen is present in the sample, it will bind to the anti-SARS-CoV-2 conjugate particles and then be captured on the Test Line, forming a colored line indicating a SARS-CoV-2 antigen positive test result. The sample mixture liquid will continue to move up the Test Strip and will bind to the Control Line, forming a colored line, to indicate the test was run correctly and establishes assay validity. The Control Line will appear on all valid tests whether the Test Line gives a reactive or non-reactive result. If a colored

Control Line does not appear, the test is invalid, and the specimen must be retested. The liquid will continue to be drawn up to the absorbent pad of the Test Strip until the color on the membrane has cleared within 15 minutes after the start of the test.

3. MATERIAL

Materials Provided

Material	1Test Kit	2 Test Kit	4 Test Kit	20Test Kit
Foil Package containing Base and Test Pen	1	2	4	20
Package insert	1	1	1	1

Materials Required But Not Provided

Clock, timer, or stopwatch

4. QUALITY CONTROL

Each Fastep® COVID-19 Antigen Pen Home Test has a built-in internal procedural control. The pink line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct pink Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed using a new sample and new test kit.

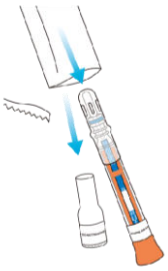
External run controls are not required to use the Fastep® COVID-19 Antigen Pen Home Test in a home setting.

5. TEST PROCEDURE

- Check expiration date printed on test.
- The test should be used at room temperature.
- Make sure that all packaging is intact. Do not use the test if the foil packaging is visibly damaged.
- Do not open the foil package until you are ready to perform the test. Use the test within 1 hour of opening.
- Ensure you have a flat surface area, such as a table top.
- Wash your hands with soap and water for 20 seconds or use hand sanitizer.

1) Remove the Test Pen and the Base from the packaging.

USE THE TEST WITHIN 1 HOUR OF OPENING.



2) Remove Swab cap from the Test Pen.

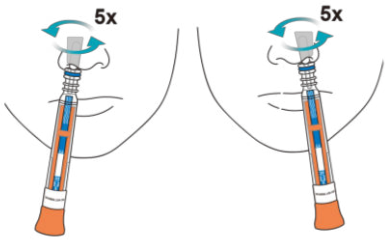
Discard the Swab Cap.

3) Gently insert the Swab end of the Pen in one nostril about 1/2 - 3/4 of an inch. Firmly rub the swab at least 5 times

against the inside walls of the nostril in a circular motion. Do not just spin the swab.

Instructions for swabbing children: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to hold the child's head while swabbing.

Make sure you have removed the swab cap (see step 2)

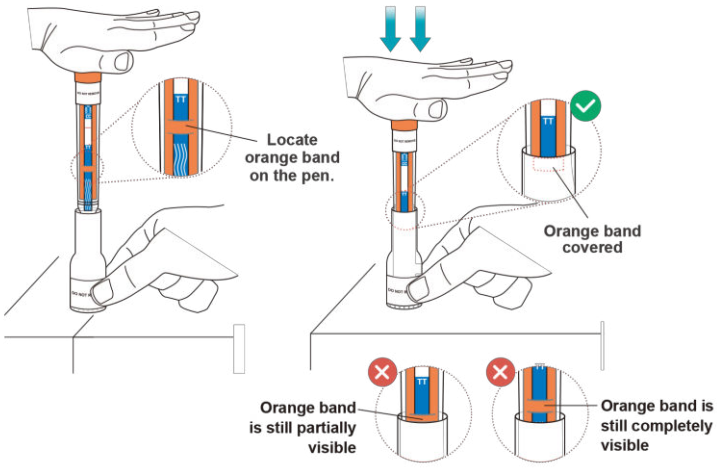


4) Repeat the process with the same swab in the other nostril.

Did you swab both nostrils? If not, inaccurate results can occur.

5a) Place the Base on a flat surface. Place the swab end of the Pen into the base.

5b) **Press firmly** on the test pen to insert it all the way into the base so that the orange band is completely covered by the base.

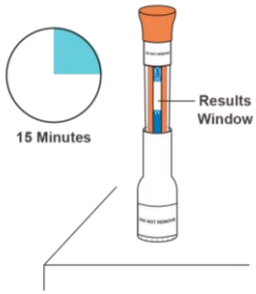


WARNING: Failure to insert the test pen all the way into the base can lead to inaccurate results.

6) Leaving the test upright, set a timer and read the results at 15 minutes. After test is completed, dispose of used materials in trash.

WARNING: Do not read results earlier than 15 minutes. Do not read the results after 30 minutes.

After test is completed, dispose of used materials in trash.



6. RESULT INTERPRETATION

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

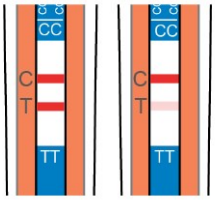
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	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.

For more information on EUAs please visit:
www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.

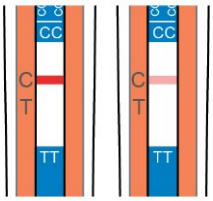
WARNING: Do not read results earlier than 15 minutes. Do not read the results after 30 minutes. Inaccurate test interpretations may occur.

Locate the letters CC and TT at the top and bottom of the results window. After the 15 minutes has elapsed, a pink line should always appear at the control (CC) region; this is a control line and signals that the test is working properly.



COVID-19 Positive (+): If the Control (C) line and the Test (T) line are visible, the test is 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 your sample and it is very likely you have COVID-19 and are 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 definite cause of disease. Individuals who test positive with the [Test Name] 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.



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 should:**

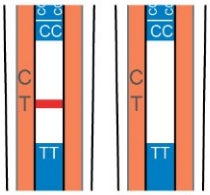
• Test again in 48 hours if the individual has symptoms on the first day of testing.

• Test 2 more times at least 48 hours apart if the individual does not have 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.



***Invalid*:** If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

WARNING: The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for the test line to show up.

7. STORAGE AND STABILITY

- Store the Fastep® COVID-19 Antigen Pen Home Test at 2-30°C / 36-86°F when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

8. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing a test. Failure to follow instructions may produce inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 6 days, you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 14 years should be tested by an adult.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- 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.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.
  If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name/CAS	GHS Code for applicable Ingredient	Concentration (%)
Sodium Azide/ 26628-22-8	*Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310*	*0.02%*

- For more information on EUAs please visit:
  https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authoriza

tion
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- This test may give false negative results when tested in conditions of <15% humidity.

9. LIMITATIONS

- 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 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between August, 2022, and January, 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient'sfirst and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- 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.
- These test results are shown as lines of color. Because these 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).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- 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.

10. PERFORMANCE CHARACTERISTICS

Clinical Performance: Prospective Serial Testing Study at National Institutes of Health:

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.
Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.
Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table below.

Table: **Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined**.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Clinical Performance:

The Fastep® COVID-19 Antigen Pen Home Test was evaluated for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic individuals. A total of 429 evaluable symptomatic subjects were enrolled, and each were currently experiencing symptoms associated with COVID-19 within 6 days of symptom onset. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils) or had one sample collected from them by another individual. Each subject then had a nasopharyngeal sample collected by one of the study personnel. Test results from the Fastep® COVID-19 Antigen Pen Home Test were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. As shown, the controlled analysis approach was used to assess the impact of the higher than anticipated low viral load on Multiple Percent Positive Agreements (PPA). The PPA is calculated based on inclusion of 10%, 12.5%, 15%, 17.5% and 20% of the weak or low positives per the protocol. At 10% low positives, the PPA was 81.9% and the NPA was 99.1% with 95% confidence interval bounds of 71.5%-89.1% for PPA and 97.4%-99.7% for NPA respectively. This was the basis of the authorization. At 20% low positives, the PPA was 76.3% with 95% confidence interval bounds of 65.9%- 84.2%.

Controlled Analysis Low Positive Azure Fastep COVID-19 Antigen Pen Home Test Performance Against a Highly Sensitive EUA Authorized RT-PCR assay

Controlled Analysis Low Positive PPA Table

	Overall	10% Low Positive	12.5% Low Positive	15% Low Positive	17.5% Low Positive	20% Low Positive
High Positive Samples	64	64	64	64	64	64
Low Positive Samples	28	8	10	12	14	16
Total Comparator Positive For PPA	92	72	74	76	78	80
True Positive by Device	63	59	59	60	61	61
PPA	68.5%	81.9%	79.7%	78.9%	78.2%	76.3%
95% CI (XX% - XX%)	58.4% - 77.1%	71.5% - 89.1%	69.2% - 87.3%	68.5% - 86.6%	67.8% - 85.9%	65.9% - 84.2%
NPA	99.1% (334/337)					
95% CI (XX% - XX%)	97. 4%-99. 7%					

30.4% (28/92) of all the evaluable positives in this study were low positives

When all study participants are included, the PPA is 68.5% and the NPA is 99.1% with the 95% confidence interval bounds of 58.4% to 77.1% for the PPA and 97.4% to 99.7% for the NPA, respectively.

The specimen positivity breakdown based on the age of the patient:

Age	Fastep COVID-19 Antigen Pen Home Test		
	Total #	Total Positive	Positivity Rate
2-13	40	8	20.0%
14-24	71	15	21.1%
25-64	280	39	13.9%
65+	38	4	10.5%
Total	**429**	**66**	**15.4%**

The table below shows the positive results broken down by days since symptom onset:

Days Since Symptom Onset	Specimens Tested	RT-PCR Positive (+)	COVID-19 Antigen Pen Home Test Positive (+)	PPA	95%CI
0	8	2	2	100%	34.2%-100%
1	70	20	17	85.0%	64.0%-94.8%
2	123	23	13	56.5%	36.8%-74.4%
3	107	25	17	68.0%	48.4%-82.8%
4	68	11	7	63.6%	35.4%-84.8%
5	39	9	5	55.6%	26.7%-81.1%
6	14	2	2	100%	34.2%-100%

Analytical Sensitivity (Limit of Detection):

A preliminary LoD was determined by evaluating different concentrations of a Gamma Irradiated (USA_WA1/2020) diluted in Pooled Negative Nasal Wash (PNW). 50µL of the spiked sample preparation was pipetted onto the swab that were then processed per IFU. The LoD was confirmed as the lowest concentration of SARS-CoV-2 that was detected >95% of the time (i.e., concentration where 19 out of 20 test results were positive). The LoD of Fastep® COVID-19 Antigen Pen Home Test was confirmed to be 7.9×10^2 $TCID_{50}$/mL based upon the testing procedure for this study, which equates to 39.5 $TCID_{50}$/swab.

NIH/RADx Variant Testing:

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of

clinical specimens that were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the Fastep® COVID-19 Antigen Pen Home Test detected 100% of live virus Omicron samples at a Ct-value of 27.7 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 28.5) were not detected by the Fastep® COVID-19 Antigen Pen Home Test in this study.

Omicron pool 2 - Live Dilution		Assay #1	Assay #2	Fastep COVID-19 Antigen Pen Home Test
	Ct-N2 Ave.	Percent Positive (n=5)	Percent Positive (n=5)	Percent Positive (n=5)
Dilution 1	19.4	100	100	100
Dilution 2	20.6	100	100	100
Dilution 3	21.6	100	100	100
Dilution 4	22.4	100	100	100
Dilution 5	23.3	100	100	100
Dilution 6	24.5	0	100	100
Dilution 7	25.6	0	100	100
Dilution 8	26.5	0	0	100
Dilution 9	27.7	0	0	100
Dilution 10	28.5	0	0	0
Dilution 11	29.4	0	0	0
Dilution 12	30.3	0	0	0

Cross-Reactivity and Microbial Interference:

Cross reactivity and potential interference of Fastep® COVID-19 Antigen Pen Home Test was evaluated by testing 33 commensal and pathogenic microorganisms (bacteria, viruses, and pooled human nasal wash) that may be present in the nasal cavity. Each organism and virus were tested in the absence and presence of inactivated SARS-CoV-2. All testing samples were prepared in a pooled negative nasal wash matrix, and each cross-reacting organism was tested in replicates of three (3). No cross reactivity or interference was observed for any of the organisms tested, except for SARS-coronavirus which exhibited cross-reactivity when tested at 7.9 x 10^3 $TCID_{50}$/mL. A titration of SARS-CoV was performed to find the concentration at which cross-reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 7.9 $TCID_{50}$/mL, which is below the analytical limit of detection of the test. These results are not unexpected in that the Fastep® COVID-19 Antigen Pen Home Test targets the nucleocapsid protein which is present on both SARS-CoV and SARS-CoV-2 viruses.

Organism	**Concentration Tested for Cross Reactivity**	**Concentration Tested for Microbial Interference**	**Cross-reactivity result**	**Microbial Interference result**
Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus OC43	1.70×10^5 $TCID_{50}$/mL	8.50×10^4 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus NL63	1.17×10^5 $TCID_{50}$/mL	5.85×10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
inactivated	1.00×10^5 $TCID_{50}$/mL	1.00×10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference

SARS-coronavirus				
"Live" SARS Coronavirus	7.90 × 10^3 $TCID_{50}$/mL	7.90 × 10^3 $TCID_{50}$/mL	Cross-reactivity	NA
"Live" SARS Coronavirus	7.90 × 10^2 $TCID_{50}$/mL	7.90 × 10^2 $TCID_{50}$/mL	Cross-reactivity	NA
"Live" SARS Coronavirus	79.0 $TCID_{50}$/mL	79.0 $TCID_{50}$/mL	Cross-reactivity	NA
"live" SARS Coronavirus	7.9 $TCID_{50}$/mL	7.9 $TCID_{50}$/mL	No Cross-reactivity	No Interference
inactivated MERS-Coronavirus	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
live MERS-Coronavirus	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Adenovirus	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human metapneumovirus 4 Type B2	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 1	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 2	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 3	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 4b	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza A	1.43 × 10^5 $CEID_{50}$/mL	1.43 × 10^5 $CEID_{50}$/mL	No Cross-reactivity	No Interference
Influenza B	1.43 × 10^5 $CEID_{50}$/mL	1.43 × 10^5 $CEID_{50}$/mL	No Cross-reactivity	No Interference
Enterovirus 68	1.43 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Respiratory syncytial virus	1.0 × 10^5 pfu/mL	1.0 × 10^5 pfu/mL	No Cross-reactivity	No Interference
Rhinovirus	2.57 × 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL	No Cross-reactivity	No Interference
Haemophilus influenzae	1.00 ×10^6 cfu/mL	1.00 ×10^6 cfu/mL	No Cross-reactivity	No Interference
Streptococcus pneumonia	1.00 × 10^6 cfu/mL	1.00 x 10^6 cfu/mL	No Cross-reactivity	No Interference
Streptococcus pyogenes	1.00 × 10^6 cfu/mL	1.00 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Candida albicans	1.00 × 10^6 cfu/mL	1.00 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Bordetella pertussis	>1.0 × 10^4 cfu/mL	>1.0 × 10^4 cfu/mL	No Cross-reactivity	No Interference
Mycoplasma pneumonia	1.00 × 10^6 cfu/mL	1.00 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Chlamydia pneumoniae	1 × 10^6 ifu/mL	1 × 10^6 ifu/mL	No Cross-reactivity	No Interference
Legionella pneumophila	1.00 × 10^6 cfu/mL	1.00 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Mycobacterium tuberculosis	1.0 × 10^6 cfu/mL	1.0 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Pneumocystis carinii	1.00 × 10^6 Nuclei/mL	1.00 × 10^6 Nuclei/mL	No Cross-reactivity	No Interference
P. jiroveci-S. cerevisiae	1.0 × 10^6 cfu/mL	1.0 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Staphylococcus aureus subsp. *aureus*	1 × 10^6 cfu/mL	1 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Staphylococcus epidermidis	1.0 × 10^6 cfu/mL	1.0 × 10^6 cfu/mL	No Cross-reactivity	No Interference
Pooled Negative Matrix	N/A	N/A	No Cross-reactivity	No Interference

Endogenous and Exogenous Interference Substance studies

The following substances, naturally present in respiratory specimens or artificially introduced into the respiratory tract, were evaluated

at the concentrations listed below. The positive (3x LoD SARS-CoV-2) and negative specimens were tested with the addition of potentially interfering substances. None of the potentially interfering substances listed in the table below were found to affect the test performance of the Fastep® COVID-19 Antigen Pen Home Test at the concentrations tested.

Substance	Conc. Tested	Cross-reactivity result	Interference result
Human Whole Blood (EDTA tube)	4% v/v	No Cross-reactivity	No Interference
Mucin (porcine stomach, type II)	0.50%	No Cross-reactivity	No Interference
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No Cross-reactivity	No Interference
Naso GEL (NeilMed)	5% v/v	No Cross-reactivity	No Interference
Nasal Drops (Phenylephrine)	15% v/v	No Cross-reactivity	No Interference
Nasal Spray (Oxymetazoline)	15% v/v	No Cross-reactivity	No Interference
Nasal Spray (Cromolyn)	15% v/v	No Cross-reactivity	No Interference
Zicam	5% v/v	No Cross-reactivity	No Interference
Homeopathic (Alkalol)	10% v/v	No Cross-reactivity	No Interference
Sore Throat Phenol Spray	15% v/v	No Cross-reactivity	No Interference
Tobramycin	4 µg/mL	No Cross-reactivity	No Interference
Mupirocin	10 mg/mL	No Cross-reactivity	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Cross-reactivity	No Interference
Fluticasone Propionate	5% v/v	No Cross-reactivity	No Interference
Body & Hand lotion (Cerave)	0.5%w/v	No Cross-reactivity	No Interference
Body Lotion with 1.2% dimethicone	0.5%w/v	No Cross-reactivity	No Interference
Hand Lotion (Eucerin)	5% w/v	No Cross-reactivity	No Interference
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	No Cross-reactivity	No Interference
Hand Sanitizer cream lotion (vaseline)	15% v/v	No Cross-reactivity	No Interference
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	No Cross-reactivity	No Interference
Hand Soap liquid gel (soft soap)	10% w/v	No Cross-reactivity	No Interference

High-Dose Hook Effect

The Fastep® COVID-19 Antigen Pen Home Test was tested up to at 7.90×10^5 $TCID_{50}$/mL of gamma irradiated, inactivated SARS-CoV-2 isolate USA-WA1/2020 stock virus and no hook effect was observed.

Flex Studies

A robust use of Fastep® COVID-19 Antigen Pen Home Test was demonstrated by seven (7) flex studies as follows;

- Delay in Reading Results Flex Study
- Disturbance While Testing Flex Study
- Lighting Flex Study
- Open Kit Stability Flex Study
- Non-Level Surface Flex Study
- High Heat and Humidity Flex Study
- Low Heat and Humidity Flex Study

11. LITERATURE REFERENCES

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2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

12. GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at 1-800-281-9867

(Available Hours: Mon. to Fri.: 9:00 a.m.- 5:00 p.m. PST) or hometest@azure.bio

Azure Biotech Inc.
10400 Main Street
Houston, TX 77025
United States
hometest@azure.bio

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