For *in vitro* diagnostic use only
For use under an Emergency Use Authorization

Fastep COVID-19 Antigen Home Test (Nasal swab)

1. INTENDED USE

The Fastep COVID-19 Antigen Home Test is lateral flow immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2.

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 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested 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 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 definite cause of disease. Individuals who test positive with the Fastep COVID-19 Antigen 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 from their physician or healthcare provider.

The Fastep COVID-19 Antigen Home Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The Fastep COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.
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 the CDC.

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. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

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

The Fastep COVID-19 Antigen Home Test Kit is comprised of a sample collection (nasal swab), Sample Buffer Tube, and Test Cassette with a 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 provided nasal swab. The swab containing the sample is then added directly into the Sample Buffer Tube containing Sample Buffer and mixed. Remove the swab, Insert the nozzle to the buffer tube, and add the sample mixture liquid into the sample well on the test cassette. 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-SARSCoV-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	1 Test Kit	2 Test Kit	4 Test Kit	5 Test Kit	25 Test Kit
Test device	1	2	4	5	25
Sterile Nasal swab	1	2	4	5	25
Package insert	1	1	1	1	1
Extraction buffer with attached dropper cap (0.4mL per buffer vial)	1	2	4	5	25

Materials Required But Not Provided
Clock, timer, or stopwatch

4. QUALITY CONTROL

Each Fastep COVID-19 Antigen Home Test has a built-in internal procedural control. The red line appearing at the “C” position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct red Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed using a new sample and new test kit.
External run controls are not required to use the Fastep COVID-19 Antigen Home Test in a home setting.

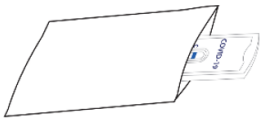
5. TEST PROCEDURE

- All test materials must be at room temperature before use.
- Exposure to humidity may decrease the stability of the test. The test should be performed immediately after removing it from the pouch.

1 Check expiration date printed on test.
For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit At-Home OTC COVID-19 Diagnostic Tests

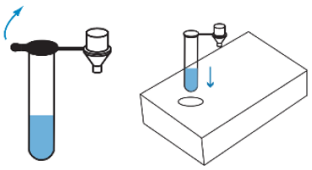
2 Wash your hands thoroughly.

3 Open the pouch



4 Peel off the aluminum foil cover of the extraction buffer and insert the extraction buffer into the tube holder.

Note: 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. **Wear a face mask if swabbing other.**

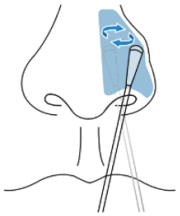


5 Open the swab packaging. Remove the swab from the stem.
Be careful not to touch the soft, fabric tip of the swab.

6 Insert the swab about ½ to ¾ inch into the nostril (collect the anterior nasal swab specimen).

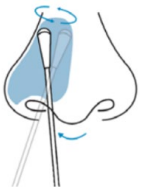
Note: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

7 Circle the swab against the nasal wall **5 times**.
Do not just spin the swab.

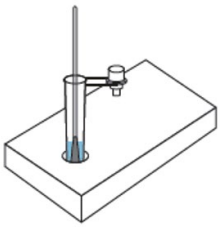


8 Pull the swab out of the nose while rubbing it against the walls and repeat the process with the same swab in the other nostril.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.
Collect specimen and immediately perform test according to instructions.

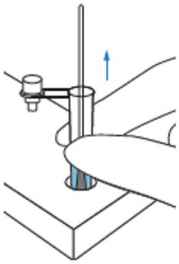


9 Place swab into the tube that you previously placed in the tube holder.



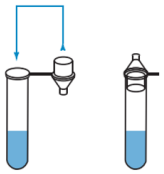
10 Remove the tube from the tube holder. Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.

WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.
Failure to rotate the swab 10-15 times may lead to incorrect results.



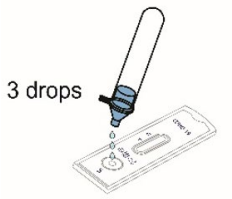
11 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

12 Secure the dropper cap onto the buffer tube.



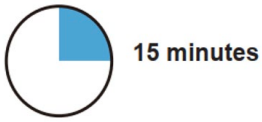
13 Invert the tube and add 3 drops of the solution to the sample well by gently squeezing the tube.
Do **NOT** add test sample to the rectangular results window.
Do **NOT** touch the sample well with dropper tip.
Do **NOT** hold the dropper tube more than ¼ inch above sample well.

WARNING: Adding other than the recommended number of drops may result in inaccurate results.



14 Set a timer and read the results at 15 minutes.

WARNING: Do not read the result before 15 minutes or after 30 minutes.



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

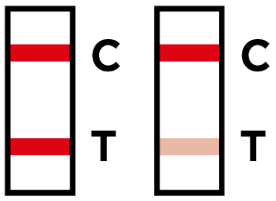
6. RESULT INTERPRETATION

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.

WARING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.
Look at the result window and locate the letters C and T on the side of the window. A red line should always appear at the C position; 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. Any faint visible red test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you 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 your doctor/primary care physician or your local health authority immediately and 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 NIDS 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.

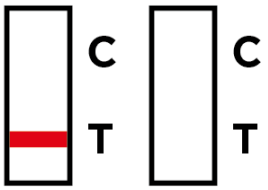
COVID-19 Negative (-): If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

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 your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your 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.

7. STORAGE AND STABILITY

- Store the Fastep COVID-19 Antigen 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.
- Ensure all kit components are at room temperature before use.
- The Test Device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 60 minutes. Use beyond one hour may not produce accurate results.
- Test samples immediately after collection. Swabs should be placed in extraction buffer within 60 minutes of collection.

8. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in 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 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- For in vitro diagnostic use only.
- Do not use kit past its expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit At-Home OTC COVID-19 Diagnostic Tests
- Do not mix components of different test kit lots.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not use this test on anyone under 2 years of age.
- 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.
- Keep the test device on flat surface during testing. Improper handling and setup may yield inaccurate results.
- For best results, read test in a well-lit area.
- 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.
- 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.
- Test components are single-use. Do not re-use.
- Once opened, the test card should be used within 60 minutes.
- Do not use the Extraction Buffer if it is discolored or turbid.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Specimens should be tested immediately after collection and should not be stored.
- Inadequate or improper nasal swab sample collection may yield false-negative test results.
- 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 devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE) and gloves when running the test and handling a patient's test device. Change gloves between tests.
- Dispose of used specimens and test components in accordance with Federal, State, and Local requirements.
- In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., 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 or eye, 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-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

9. LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between July 5, 2022 and July 25, 2022. 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.
- 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.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- The performance of the Fastep COVID-19 Antigen Home Test was evaluated using the procedures provided in Instruction for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- 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's first 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.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- 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

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:

Fastep COVID-19 Antigen Home Test 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 204 symptomatic subjects were enrolled, and each were currently experiencing symptoms associated with COVID-19 within 5 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 mid-turbinate sample (from both nostrils) collected by one of the study personnel. Test results from the Fastep COVID-19 Antigen Home Test were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. As shown, the positive percent agreement (PPA) is 85.4%, and the negative percent agreement (NPA) is 99.4% with the 95% confidence interval bounds of 71.6% to 93.1% for the PPA and 96.5% to 99.9% for the NPA, respectively.

Summary of the Performance of the Fastep COVID-19 Antigen Home Test Compared to RT-PCR

Fastep COVID-19 Antigen Home Test	RT-PCR		Total
	Positive	Negative	
Positive	35	1	36
Negative	6	157	163
Total	41	158	199
Positive Percent Agreement (PPA)	(35/41) x 100% = 85.4% (95% CI = 71.6 to 93.1%)		

Negative Percent Agreement (NPA)	(157/158) x 100% = 99.4% (95% CI = 96.5 to 99.9%)

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

Age	Fastep COVID-19 Antigen Home Test		
	Total #	Total Positive	% Positivity Rate
>2 and <14 years of age	30	4	16.7%
14-24 years of age	25	6	24.0%
>24-64 years of age	122	20	19.7%
≥65 years of age	22	6	27.3%

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

Days Since Symptom Onset	Specimens Tested	RT-PCR Positive (+)	Fastep COVID-19 Antigen Home Test Positive (+)	**PPA**
0	11	1	1	100.0%
1	42	9	8	88.9%
2	75	14	12	85.7%
3	44	9	9	100.0%
4	18	5	4	80.0%
5	5	3	2	66.7%

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). 50 uL of the virus dilutions were added to swabs and swabs processed per the test's 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 replicates were positive). The Fastep COVID-19 Antigen Home Test LoD was confirmed to be 2.8×10^2 $TCID_{50}$/mL of original sample concentration, which is equivalent to 14 $TCID_{50}$/Swab based upon the testing procedure.

Omicron 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 which 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 Home Test detected 100% of live virus Omicron samples at a Ct-value of 24.8 (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 27.4) were not detected by the FastepCOVID-19 Antigen Home Test in this study.

Omicron pool 2 - Live Dilution	Ct-N2 Ave.	Assay #1	Assay #2	Fastep COVID-19 Antigen Home Test
		Percent Positive (n=5)	Percent Positive (n=5)	Percent Positive (n=5)
Dilution 1	19.8	100	100	100
Dilution 2	20.8	100	100	100
Dilution 3	21.5	100	100	100
Dilution 4	22.7	100	100	100
Dilution 5	23.6	100	0	100
Dilution 6	24.0	60	0	100
Dilution 7	24.8	0	0	100
Dilution 8	25.8	0	0	0

Dilution 9	27.4	0	0	0
Dilution 10	28.1	0	0	0
Dilution 11	29.1	0	0	0

Cross-Reactivity and Microbial Interference:

Cross reactivity and interference of Fastep COVID-19 Antigen 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 the negative nasal wash. No cross reactivity or interference was observed for any of the organisms tested, except for SARS-coronavirus which exhibited cross-reactivity when tested as 7.9×10^3 $TCID_{50}$/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 0.79×10^1 $TCID_{50}$/mL. These results are not unexpected in that the Fastep COVID-19 Antigen Home Test targets the nucleocapsid protein which is present on both SARS-CoV and SARS-CoV-2 viruses.

Organism	Conc. Tested	Units	Cross-Reactivity Result	Microbial Interference Result
Human coronavirus 229E	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus OC43	8.50×10^4	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus NL63	5.85×10^4	$TCID_{50}$/mL	No Cross-reactivity	No Interference
SARS-coronavirus	7.9×10^3	$TCID_{50}$/mL	Cross-reactivity	Interference
MERS-coronavirus	1.0×10^6	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Adenovirus	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Human metapneumovirus 4 Type B2	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 1	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 2	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 3	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 4b	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza A	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza B	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Enterovirus 68	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Respiratory syncytial virus	1.0×10^5	pfu/mL	No Cross-reactivity	No Interference
Rhinovirus	1.43×10^5	$TCID_{50}$/mL	No Cross-reactivity	No Interference
Haemophilus influenzae	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Streptococcus pneumonia	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Streptococcus pyogenes	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Candida albicans	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Bordetella pertussis	5.0×10^3	cfu/mL	No Cross-reactivity	No Interference
Mycoplasma pneumonia	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Chlamydia pneumoniae	1.0×10^6	ifu/mL	No Cross-reactivity	No Interference
Legionella pneumophila	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Mycobacterium tuberculosis	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Pneumocystis carinii	1.0×10^6	nuclei/mL	No Cross-reactivity	No Interference

Organism	Conc. Tested	Units	Cross-Reactivity Result	Microbial Interference Result
P. jiroveci-S. cerevisiae	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Staphylococcus aureus subsp. aureus	1.0×10^6	cfu/mL	No Cross-reactivity	No Interference
Staphylococcus epidermidis	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 COVID-19 Antigen 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 Home Test was tested up to at $2.8x10^5$ $TCID_{50}$/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 Home Test was demonstrated by six (6) flex studies as follows;

- Delay in Reading Results Flex Study
- Disturbance While Testing Flex Study
- Lighting Flex Study
- Mixing Flex Study
- Non-Level Surface Flex Study
- Sample Volume Variability Flex Study
- High Heat and Humidity Flex Study
- Low Heat and Humidity Flex Study
- Specimen stability (Dry Swab)

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

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	*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
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