June 5, 2026

Assure Tech., LLC
% Jenny Xia
Director
LSI International, Inc.
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K260754
Trade/Device Name: Fastep COVID-19 Antigen Pen Home Test; Fastep COVID-19 Antigen Pen Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Class: Class II
Product Code: QYT
Dated: March 6, 2026
Received: March 9, 2026

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260754

Device Name
Fastep COVID-19 Antigen Pen Home Test; Fastep COVID-19 Antigen Pen Test

Indications for Use *(Describe)*

Fastep COVID-19 Antigen Pen Home Test:
The Fastep COVID-19 Antigen Pen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for use by individuals aged 14 years and older testing themselves, or adults testing individuals aged 2 years or older.

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

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

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

Performance characteristics for SARS-CoV-2 were established from September 2023 to February 2025 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Fastep COVID-19 Antigen Pen Test:
The Fastep COVID-19 Antigen Pen Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for use by individuals aged 14 years and older testing themselves, or adults testing individuals aged 2 years or older.

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

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

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

Performance characteristics for SARS-CoV-2 were established from September 2023 to February 2025 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Background Information:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

A. 510(k) Number

K260754

B. Submitter's Information

Name:	Assure Tech., LLC
Address:	1521 Concord Pike, Suite 201, Wilmington, DE 19803
Contact Person:	Jenny Xia LSI International Inc. 504E Diamond Ave., Suite H Gaithersburg, MD 20877 jxia@lsi-consulting.org
Date:	May 21, 2026

C. Proprietary and Established Names

Fastep COVID-19 Antigen Pen Home Test

Fastep COVID-19 Antigen Pen Test

D. Classification

Product code:	QYT
Classification Regulation:	21 CFR 866.3984 - Over-The-Counter Test to Detect SARS-Cov-2 From Clinical Specimens
Classification:	Class II
Review Panel:	Microbiology

II. Submission/Device Overview:

A. Purpose for Submission

To obtain 510(k) clearance for the Fastep COVID-19 Antigen Pen Home Test/Fastep COVID-19 Antigen Pen Test.

B. Measurand

Nucleocapsid protein antigen from SARS-Coronavirus 2 (SARS-CoV-2).

C. Type of Test

Qualitative lateral flow immunoassay.

III. Intended Use/Indications for Use:

A. Intended Use

Fastep COVID-19 Antigen Pen Home Test:

The Fastep COVID-19 Antigen Pen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for use by individuals aged 14 years and older testing themselves, or adults testing individuals aged 2 years or older.

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

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

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

Performance characteristics for SARS-CoV-2 were established from September 2023 to February 2025 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Fastep COVID-19 Antigen Pen Test:

The Fastep COVID-19 Antigen Pen Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for use by individuals aged 14 years and older testing themselves, or adults testing individuals aged 2 years or older.

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

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

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

Performance characteristics for SARS-CoV-2 were established from September 2023 to February 2025 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

B. Indications(s) for Use:

See Intended Use above.

C. Special Conditions for Use Statement(s):

OTC – Over the Counter.

D. Special Instrument Requirements:

Not applicable.

IV. Device/System Description

The Fastep COVID-19 Antigen Pen Home Test/Fastep COVID-19 Antigen Pen 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/ Fastep COVID-19 Antigen Pen 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 in 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 (T) first and then the Control Line (C). 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.

V. Substantial Equivalence Information:

A. Predicate Device Name(s):

Flowflex COVID-19 Antigen Home Test

B. Predicate 510(k) Number(s):

K230828

C. Comparison with Predicate Device

Device	Candidate Device	Predicate (K230828)
Device Trade Name	Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test	Flowflex COVID-19 Antigen Home Test

Indications For Use/ Intended Use	The Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. This test is for use by individuals aged 14 years and older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek appropriate follow-up care from their healthcare provider. Performance characteristics for SARS-CoV-2 were established from September 2023 to February 2025 when SARS-CoV-2 Omicron variant was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens. Performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 of the SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary. This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.
General Device Characteristic Similarities		
Disease	COVID-19	Same
Intended Use Population	Individuals with symptoms of COVID-19	Same

Patient Use	Over the counter use/self-testing	Same
Usage	Single use test	Same
Test Result	Qualitative	Same
Test Principle	Lateral flow immunoassay	Same
Instrument	No	Same
Development Time	15-30 min	Same
Result Interpretation	Visually read	Same
Sample Type	Direct anterior nasal swab specimen	Same
Analyte	SARS-CoV-2 nucleocapsid protein	Same
General Device Characteristic Differences		
Swab Format	Integrated sample swab	Individual packed disposable nasal swab
Tube holder	No	Yes

VI. Performance Summary

A. Analytical Performance:

1. Precision

Precision studies were carried out for samples with concentrations of 0, 0.16x LoD, 1x LoD and 3x LoD of Gamma-irradiated SARS-CoV-2. These samples were prepared by spiking Gamma-irradiated SARS-CoV-2 in negative nasal fluid. All sample aliquots were randomized and blindly labeled by the person who prepared the samples and did not take part in the sample testing. For each concentration, tests were performed with five replicates per day per lot for 5 days in a randomized order by each operator at three different POC testing sites. There are two different operators at each site.

Table 1: Summary Results of Multi-Lot Precision Study

Sample	Number of Positives / Number of Samples Tested (%)			Total number of positives / Total number of samples (%)
	Lot 1	Lot 2	Lot 3	
Negative	0/150 (0.0%)	0/150 (0.0%)	0/150 (0.0%)	0/450 (0.0%)
C_5 sample (0.16x LoD)	5/150 (3.3%)	5/150 (3.3%)	4/150 (2.6%)	14/450 (3.1%)
C_{95} sample (1x LoD)	142/150 (94.6%)	144/150 (96%)	145/150 (96.6%)	431/450 (95.8%)
Moderate positive (3x LoD)	150/150 (100.0%)	150/150 (100.0%)	150/150 (100.0%)	450/450 (100.0%)

2. Limit of Detection (LoD)

The LoD of the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test was established by using limiting dilutions of Gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020). The virus was spiked into negative nasal fluid that was confirmed as SARS-CoV-2 negative by RT-PCR.

At each dilution, 50 µL of sample was added to pen swabs and then tested following the procedures for sample testing in the IFU. Testing was performed with 9 replicates per concentration. The estimated LoD was found from testing the initial 7 different concentrations. Using this preliminary concentration, the LoD was confirmed with testing 20 replicates each at 0.5X, 0.75X, 1X, 1.25X and 1.5X LoD, using three device lots by three different operators. A total of 180 tests were performed at each of the five confirmation concentrations. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (concentration at which at least 19 out of 20 replicates tested positive) for each lot.

The Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test LoD in negative nasal fluid is 7.9×10^2 $TCID_{50}$/mL.

The WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test. The LoD was found to be 750 IU/mL (37.5 IU/swab) for the WHO SARS-CoV-2 standard.

3. Cross Reactivity (Analytical Specificity) and Microbial Interference

The potential cross-reactivity of common organisms was evaluated with SARS-CoV-2 negative samples using the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test. Potential microbial interference was evaluated with samples containing Gamma-irradiated SARS-CoV-2 virus (USA-WA1/2020) sample at concentration of 2x LoD (low positive samples).

No cross-reactivity or interference was observed with the following microorganisms at the specified concentrations.

Table 2: Summary Results of Cross Reactivity Study

Microorganism	Conc. Tested	Units	Cross-Reactivity	Interference
Bordetella pertussis	1.28×10^6	CFU/mL	No	No
Candida albicans	2.28×10^6	CFU/mL	No	No
Chlamydia trachomatis	6.25×10^6	CFU/mL	No	No
Chlamydia pneumoniae	4.50×10^7	IFU/mL	No	No
Haemophilus influenzae	1.28×10^8	CFU/mL	No	No
Legionella pneumophila	3.50×10^7	CFU/mL	No	No
Mycoplasma pneumoniae	2.25×10^6	CFU/mL	No	No
Mycobacterium tuberculosis	3.03×10^7	CFU/mL	No	No
Pseudomonas aeruginosa	1.73×10^8	CFU/mL	No	No
Saccharomyces cerevisiae	7.65×10^7	CFU/mL	No	No
S. aureus MSSA	2.31×10^9	CFU/mL	No	No

Microorganism	Conc. Tested	Units	Cross-Reactivity	Interference
S. aureus MRSA	2.38×10^9	CFU/mL	No	No
Staphylococcus epidermidis	3.05×10^9	CFU/mL	No	No
Streptococcus pneumoniae	1.81×10^8	CFU/mL	No	No
Streptococcus pyogenes	8.00×10^7	CFU/mL	No	No
Adenovirus	2.88×10^6	$TCID_{50}$/mL	No	No
Enterovirus 68	2.39×10^6	$TCID_{50}$/mL	No	No
Human coronavirus 229E	3.15×10^5	$TCID_{50}$/mL	No	No
Human coronavirus NL63	1.18×10^5	$TCID_{50}$/mL	No	No
Human coronavirus OC43	7.00×10^6	$TCID_{50}$/mL	No	No
Human coronavirus HKU1	1.25×10^5	$TCID_{50}$/mL	No	No
Human Metapneumovirus 9	1.00×10^5	$TCID_{50}$/mL	No	No
Influenza A Virus	2.63×10^5	$TCID_{50}$/mL	No	No
Influenza B Virus	3.78×10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 1	1.14×10^6	$TCID_{50}$/mL	No	No
Parainfluenza virus 2	1.25×10^5	$TCID_{50}$/mL	No	No
Parainfluenza virus 3	2.13×10^7	$TCID_{50}$/mL	No	No
Parainfluenza virus 4b	1.25×10^5	$TCID_{50}$/mL	No	No
Respiratory syncytial virus	3.78×10^5	$TCID_{50}$/mL	No	No
Rhinovirus	1.04×10^5	$TCID_{50}$/mL	No	No
MERS-coronavirus	4.00×10^5	$TCID_{50}$/mL	No	No
Negative Matrix	N/A*	N/A	No	No

*N/A=Not Applicable

4. Endogenous Interfering Substances

Substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test.

The SARS-CoV-2 target concentration in the positive samples was 2x LoD. All samples were tested in 3 replicates using three different device lots by three different operators. No interference was found for substances at the following tested concentrations.

Table 3: Summary Results of Endogenous Interfering Substances Study

Substance	Conc. Tested	Cross-Reactivity	Interference
Beclomethasone	15% v/v	No	No
Biotin	3500 ng/mL	No	No
Dexamethasone	15% v/v	No	No
Dyclonine Hydrochloride	2 mg/mL	No	No
Flunisolide	15% v/v	No	No
Hand sanitizer	15% v/v	No	No
Hand Soap	15% v/v	No	No
Homeopathic allergy relief (histaminum hydrochloricum)	15% w/v	No	No
Homeopathic nasal wash (alkalol)	5% v/v	No	No
Leukocytes	4.8×10^6cells/mL	No	No
Molnupiravir	10 mg/mL	No	No
Mucin	2.5 mg/mL	No	No
Mupirocin	10 mg/mL	No	No
Nasal corticosteroids(Budesonide)	15% v/v	No	No
Nasal corticosteroids(fluticasone furate)	5% v/v	No	No
Nasal corticosteroids (fluticasonepropionate)	5% v/v	No	No
Nasal corticosteroids(Mometasone furoate)	15% v/v	No	No
Nasal corticosteroids(Triamcinolone Acetonide)	15% v/v	No	No
Nasal decongestant (Galphimia glauca, Luffa opperculata, sabadilla)	15% v/v	No	No
Nasal gel	5% v/v	No	No
Nasal spray(Cromolyn sodium nasal solution)	15% v/v	No	No
Nasal spray (Oxymetazoline HCl)	15% v/v	No	No
Nasal spray (Phenylephrine HCl)	15% v/v	No	No
Nasal spray (Sodium Chloride & Preservatives)	15% v/v	No	No
Oral Anesthetic Cough Lozenge (Menthol)	3 mg/mL	No	No
Oseltamivir Phosphate (Tamiflu)	15% w/v	No	No
Remdesivir	10 mg/mL	No	No
Sore Throat & Cough Lozenges (Benzocaine, Dextromethorphan HBr)	3 mg/mL	No	No
Sore Throat Spray (Phenol)	5% v/v	No	No

Substance	Conc. Tested	Cross-Reactivity	Interference
Tobramycin	50 ug/mL	No	No
Whole Blood	2.5% v/v	No	No

5. Hook Effect

There is no hook effect at 7.9×10^5 $TCID_{50}$/mL corresponding to 1000x LoD, which is the highest concentration that was tested.

6. Inclusivity (Analytical Reactivity)

The inclusivity of the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test was evaluated with 7 strains of SARS-CoV-2 virus. These inactivated SARS-CoV-2 isolates were each diluted into negative nasal fluid at different concentrations. Each concentration was tested with 15 replicates to obtain detection limits. The following LoDs are verified.

Table 4: Summary Results of Inclusivity Study

SARS-CoV-2 Viral Strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2 virus (USA-WA1/2020)	7.90×10^2
B.1.1.7 (Alpha)	8.88×10^2
B.1.351 (Beta)	3.78×10^3
P.1 (Gamma)	3.15×10^3
B.1.617.2 (Delta)	1.04×10^3
B.1.1.529 (Omicron)	6.26×10^2
BA.2.3 (Omicron)	5.85×10^1
KP.2 (Omicron)	3.30×10^3
KP.3 (Omicron)	5.13×10^3
BA.2.86 (Omicron)	4.80×10^3

7. Stability

To determine the stability of the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test, three device lots were stored at 2-8°C and at 30°C and tested at specified time points. The real time stability study is ongoing. At the time of clearance, all study data met the protocol defined acceptance criteria and support storage of the test kits from 2-30°C (36-86°F) for up to 8 months.

B. Clinical Studies

A total of 1077 evaluable subjects were enrolled at 7 clinical study sites. Of the 1077 subjects, 109 were true positives (concordant positive results on both the investigational and comparator tests), and 947 were true negatives (concordant negative results on both the investigational and comparator tests). Twenty (20) subjects had discordant results in which the investigational test was negative, and the final comparator result was positive, and 1 subject had discordant results in which the investigational test was positive, and the final comparator result was negative.

Final analysis resulted in a Positive Percent Agreement (PPA) of 84.5% (95% CI: 77.3%-89.7%) and a Negative Percent Agreement (NPA) of 99.9% (95% CI: 99.4%-100.0%). The performance is shown in the following tables.

Table 5: Clinical Study Patient Demographics

Characteristics of the study population		No.	Percent (%)
Sex	Male	447	41.5%
	Female	630	58.5%
Education level	Associate degree (e.g., AA, AS)	109	10.1%
	Bachelor's Degree (e.g., BA, BBA and BS)	196	18.2%
	Doctorate (e.g., PhD, EdD)	9	0.8%
	High school diploma	348	32.3%
	Less than high school diploma	160	14.9%
	Master's Degree (e.g., MA, MS and Meng)	57	5.3%
	Professional Degree (e.g., MD, DDS, JD)	11	1.0%
	Some college, but no degree	178	16.5%
	Other	9	0.8%
Household Income	less than $15,000	239	22.2%
	$15,001 to $45,000	284	26.4%
	$45,001 to $90,000	248	23.0%
	$90,001 to $150,000	153	14.2%
	$150,001 to $300,000	85	7.9%
	over $300,000	19	1.8%
	Other	49	4.5%

Table 6: Clinical Performance Summary

Fastep COVID-19 Antigen Pen Home Test/Fastep COVID-19 Antigen Pen Test	Comparator Method		
	Positive	Negative	Total
Positive	109	1	110
Negative	20	947	967
Total	129	948	1077
Positive Agreement: (109/129) 84.5%; 95% Confidence Interval: 77.3%-89.7%			
Negative Agreement: (947/948) 99.9%; 95% Confidence Interval: 99.4%-100.0%			

Table 7: Clinical Performance by Age

Age Group (years)	Number of Subject Samples tested	Investigational Positives	Comparator Positives	Positivity Rate % (total positive/total tested)
≥ 2 - <14 years	219	6	11	5.0%
14 - 24 years	156	18	20	12.8%
> 24 - 64 years	637	75	87	13.7%
≥ 65 years	65	11	11	16.9%
Total	1077	110	129	12.0%

Human Factors Assessment

A total of 113 subjects who were self-collecting and testing, or who were collecting a sample and performing the testing on another subject (child or adult), participated in the human factors assessment. The human factors assessment population included different genders, age groups, ethnicities, races and education levels. There were 63 subjects who self-collected and tested on the investigational test, and 50 lay-users (testers) who collected a sample from another individual and tested on the investigational test. The healthcare providers evaluated each

subject/tester's ability to correctly prepare the test components for testing, collect a sample, perform the test, and interpret the test results based on reading the Quick Reference Instructions (QRI). All enrolled subjects participating in the human factors assessment were required to complete a labeling and comprehension questionnaire, and each subject or tester was also provided with a panel of device representations with results for interpretation. The panel of device representations consisted of 5 investigational devices with mock results including one negative, one low positive at no more than 1.5 to 2x limit of detection (LoD), one positive at 5x LoD, an invalid result and either one additional low positive or negative result.

Overall, all 113 subjects who participated in the human factors assessment found the instructions clear and easy to follow and none of the subjects had difficulty collecting the sample or running the investigational test. The results of the subjects' interpretation of mock results are shown below.

Table 8: Summary Results of Human Factors Assessment

Interpreted Result	Confirmed Result		
	Low Positive/Positive	Negative	Invalid
Low Positive/Positive	279	3	0
Negative	1	162	9
Invalid	2	5	104
Sum	282	170	113
Accuracy	279/282	162/170	104/113
Percent Accuracy	98.9%	95.3%	92.0%
95% C.I.	(96.9%-99.6%)	(91.0%-97.6%)	(85.6%-95.8%)
Overall accuracy	545/565 = 96.5% (95% C.I.: 94.6%-97.7%)		

C. Other Supportive Performance Characteristics Data

1. Flex Studies

To evaluate the robustness of the Fastep COVID-19 Antigen Pen Home Test/ Fastep COVID-19 Antigen Pen Test, flex studies were conducted including evaluations of (1) delay in testing after sample collection, (2) device orientation, (3) various disturbance during testing, (4) lighting conditions, (5) reading time, (6) high heat and high humidity and low heat and low humidity conditions, and (7) sample volume. Tests were performed with both negative nasal fluid and contrived low positive 2x LoD samples. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous results.

2. Serial Testing

A prospective clinical study was conducted from January 2021 to May 2022 as part of the NIH Rapid Acceleration of Diagnostics (RADx) initiative. A total of 7,361 asymptomatic participants across the United States were enrolled in a decentralized study and assigned to one of three EUA-authorized SARS-CoV-2 OTC rapid antigen tests for serial testing every 48 hours over 15 days. Positive antigen results were considered positive.

At each testing time point, participants also collected a nasal swab for comparator testing using highly sensitive EUA RT-PCR assays. SARS-CoV-2 infection status was determined using a composite comparator method with at least two RT-PCR tests; discordant results were resolved using a third RT-PCR assay and majority rule. Symptom status was self-reported using the MyDataHelps app.

Of the 7,361 enrolled participants, 5,609 were eligible for analysis. Among 154 RT-PCR-positive participants, 97 (62%) were asymptomatic on the first day of infection and 57 (39%) were symptomatic. Pre-symptomatic individuals were included in the asymptomatic analysis if

they were asymptomatic on the first day of antigen testing. Antigen test performance with serial testing is summarized in the table below.

Table 9: 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	Symptomatic on First Day of Testing		
	Ag Positive / PCR positive (Antigen Test Performance % PPA)		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	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 performed 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.

3. Variant Monitoring Plan

A plan has been established to closely monitor the emergence of any circulating variants of concern. The plan includes the monitoring of publicly available databases and information from public health authorities, and a multi-tier approach that determines reactivity of the test with emerging variants (including silico analysis, use of antibody escape mutational profile, and wet testing).

VII. Conclusion

The information provided in this Premarket Notification demonstrates that the performance of the Fastep COVID-19 Antigen Pen Home Test and Fastep COVID-19 Antigen Pen Test is substantially equivalent in intended use, technological characteristics, and performance to the predicate device.