July 3, 2025

Innovita (Tangshan) Biological Technology CO., LTD.
℅ Jenny Xia
Regulatory Consultant
LSI International Inc.
504 East Diamond Avenue, Suite H
Gaithersburg, Maryland 20877

Re: K250398
Trade/Device Name: Innovita Flu A/B Antigen Rapid Test
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza Virus Antigen Detection Test System
Regulatory Class: Class II
Product Code: PSZ
Dated: February 11, 2025
Received: February 12, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K250398

Device Name
Innovita Flu A/B Antigen Rapid Test

Indications for Use *(Describe)*
The Innovita Flu A/B Antigen Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection and differentiation of influenza A and B viral nucleoprotein antigens directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection.

The test is intended for use as an aid in the differential diagnosis of acute influenza A and B viral infections. The test is not intended to detect influenza C antigens. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the December 2023, and July 2024 influenza season when influenza A/H1N1pdm09, influenza A/H3N2 and influenza B/Victoria viruses were the predominant influenza viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If an infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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

1. Date: July 1, 2025
2. Submitter: INNOVITA (Tangshan) Biological Technology Co., Ltd.
   No. 699 Juxin Street, High-tech Industrial Development Zone,
   Qian'an, Hebei, 064400, China.

3. Contact person: Jenny Xia
   LSI International Inc.
   504 East Diamond Ave., Suite H
   Gaithersburg, MD 20877
   Telephone: 301-525-6856
   Fax: 301-916-6213
   Email: jxia@lsi-consulting.org

4. Device Name: Innovita Flu A/B Antigen Rapid Test

5. Classification: Class II

Product Code	**CFR #**	**Panel**
PSZ	21 CFR 866.3328 Influenza Virus Antigen Detection Test System	Microbiology

6. Predicate Devices:
   K191514, CareStart Flu A&B Plus

7. Intended Use
   The Innovita Flu A/B Antigen Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection and differentiation of influenza A and B viral nucleoprotein antigens directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection.

   The test is intended for use as an aid in the differential diagnosis of acute influenza A and B viral infections. The test is not intended to detect influenza C antigens. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

   Performance characteristics for influenza A were established during the December 2023, and July 2024 influenza season when influenza A/H1N1pdm09, influenza A/H3N2 and influenza B/Victoria viruses were the predominant influenza viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If an infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

8. Device Description

The Innovita Flu A/B Antigen Rapid Test is a double antibody sandwich immunoassay-based test. The test device consists of the specimen zone and the test zone. The specimen zone contains monoclonal antibody against the Flu A/Flu B antigen labeled with latex microspheres and chicken IgY antibody conjugated with latex microspheres. The test line contains the other monoclonal antibody against Flu A/Flu B antigen. The control line contains rabbit anti-chicken IgY antibody.

After the specimen is applied into the specimen well of the device, antigen in the specimen forms an immune complex with the binding reagent in the specimen zone. Then the complex migrates to the test zone. The test line in the test zone contains antibody from a specific pathogen. If the concentration of the specific antigen in the specimen is higher than LoD of Flu A or Flu B, it will be captured at Flu A or Flu B line and form a red-purple line. In contrast, if the concentration of the specific antigen is lower than LoD, it will not form a red-purple line. The test also contains an internal control system. A red-purple control line (C) should always appear after the test is completed. Absence of a red-purple control line indicates an invalid result. The product contents are listed below.

Contents	Amount	Description
Test cassette	25	Each sealed foil pouch containing one test device and one desiccant
Extraction diluent	25	Vials with 500μLof solution, mainly composed of Tris-HCl buffer (pH8.4), NaCl and Triton X-100.
Swab	25	Nasopharyngeal swab
Influenza A Positive Control	1	Swab is coated with non-infectious recombinant influenza A antigen
Influenza B Positive Control	1	Swab is coated with non-infectious recombinant influenza B antigen
Negative Control	1	Swab contains inactivated Staphylococcus aureus
Package Insert	1	
Quick Reference	1	

9. Substantial Equivalence Information

A summary comparison of features of the Innovita Flu A/B Antigen Rapid Test and the predicate device is provided in the following table.

	Predicate device	Candidate device

Device & Predicate Device	CareStart Flu A&B Plus K191514	Innovita Flu A/B Antigen Rapid test
Regulation Name	Influenza virus antigen detection	Same
Regulatory Class	Class II	Same
Product Code	PSZ	Same
Assay Target	Influenza A and B nucleoprotein	Same
Intended Use	The CareStart Flu A&B Plus is an in vitro rapid immunochromatographic assay for the qualitative detection of influenza virus type A and B nucleoprotein antigens directly from nasopharyngeal swab specimens of symptomatic patients. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and B viral infections. This test is intended to distinguish between influenza type A and/or B virus in a single test. This test is not intended to detect influenza type C viral antigens. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the basis for treatment or other patient management decisions. Performance characteristics for influenza A and B were established during the 2018-2019 influenza season when influenza A/H3N2, A/H1N1pdm09, and B/Victoria were the predominant	The Innovita Flu A/B Antigen Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection and differentiation of influenza A and B viral nucleoprotein antigens directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. The test is intended for use as an aid in the differential diagnosis of acute influenza A and B viral infections. The test is not intended to detect influenza C antigens. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the December 2023, and July 2024 influenza season when influenza A/H1N1pdm09, influenza

	influenza viruses in circulation. When other influenza viruses are emerging, performance characteristics may vary. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to received and culture specimens.	A/H3N2 and influenza B/Victoria viruses were the predominant influenza viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If an infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Specimens Type	Nasopharyngeal swabs	Same
Assay Result	Qualitative	Same
Technology	Immunochromatographic assay	Same
Instrumentation	None	Same
Device Format	Cassette	Same
Detection Format	Visual determination of presence or absence of colored line indicators for the test line and control line on the test strip indicate the presence of influenza A and/or B antigen.	Same
Time to Result	10 minutes	10 ~30 minutes

10. Performance Summary

Analytical Performance

a. Limit of Detection (LoD)

To determine the Limit of Detection (LoD) of Innovita Flu A/B Antigen Rapid Test, four influenza A virus with two common currently or recently circulating influenza A subtypes (i.e., H3N2, H1N1) and four influenza B virus with two genetic lineages (i.e., Victoria lineage and Yamagata lineage) were tested in this study. In this study, each influenza virus strain of the panel was serially diluted to the concentration at which at least one negative result was obtained from replicate testing.

The estimated LoD for each virus strain was confirmed by testing twenty replicates per lot with three different lots. The results presented in the table below.

Strain Type	Strain	LOD ($TCID_{50}$/mL)	LOD Per Swab ($TCID_{50}$/Swab)	Positive Rate
Flu A virus (H3N2)	A/Virginia/ATCC6/2012	2.23×10^3	1.12×10^2	60/60 (100%)
	A/Baltimore/JH-0586/2022	2.50×10^3	1.25×10^2	60/60 (100%)
Flu A virus (H1N1)	A/Dominican Republic/7293/2013 pdm09	5.00×10^2	2.50×10^1	58/60 (96.67%)
	A/Virginia/ATCC1/2009 TC isolate	8.00×10^2	4.00×10^1	60/60 (100%)
Flu B virus (Victoria lineage)	B/New Jersey/1/2012	2.20×10^3	1.10×10^2	59/60 (98.33%)
	B/Michigan/01/2021	1.43×10^3	7.15×10^1	60/60 (100%)
Flu B virus (Yamagata lineage)	B/Brisbane/9/14	1.26×10^2	6.30×10^0	59/60 (98.33%)
	B/Panama/45/90	9.50×10^2	4.75×10^1	60/60 (100%)

b. Inclusivity

To determine the detectability of the Innovita Flu A/B Antigen Rapid Test, twenty-nine strains of influenza A virus representing each of three common currently or recently circulating influenza A subtypes (i.e., H1N1 and H3N2) and twelve strains of influenza B virus representing each of two influenza B genetic lineages (i.e., Yamagata lineage and Victoria lineage) were tested in this study. In this study, each influenza virus strain was serially diluted to a concentration near the LoD and tested in replicates of 10 with the Innovita Flu A/B Antigen Rapid Test. All viruses were detected in all ten replicates per lot with three different lots at the concentrations shown below.

Strain	Substitute strain	Inclusivity
Flu A virus (H1N1)	A/California/08/2009 pdm09	1.6×10^4 $CEID_{50}$/mL
	A/California/04/2009 (H1N1) pdm09	1.1×10^2 $TCID_{50}$/mL
	A/Michigan/272/2017	9.6×10^3 $TCID_{50}$/mL
	A/New Hampshire/02/2010 (H1N1) pdm09	1.8×10^4 $CEID_{50}$ /mL
	A/South Carolina/2/2010 (H1N1) pdm09	2.5×10^5 $CEID_{50}$ /mL
	A/St. Petersburg/61/2015	9.3×10^5 $CEID_{50}$ /mL
	A/Michigan/45/2015 (H1N1) pdm09	$1\times10^4$$CEID_{50}$/mL
	A/Baltimore/JH-22377/2022	1.6×10^5 $TCID_{50}$/mL

	A/Massachusetts/15/2013 (H1N1) pdm09	1.6×10^4CEID$_{50}$/mL
	A/Iowa/53/2015 (H1N1) pdm09	2.9×10^4CEID$_{50}$/mL
	A/Bretagne/06091/2023	5.5×10^3 PFU/mL
	A/Bangladesh/3002/2015 (H1N1) pdm09	1.3×10^4CEID$_{50}$/mL
	A/California/07/2009 pdm09	2.3×10^4 CEID$_{50}$/mL
Flu A virus (H3N2)	A/Perth/16/2009	1.1×10^5TCID$_{50}$/mL
	A/Baltimore/JH-286/2021	2.8×10^5 TCID$_{50}$/mL
	A/Baltimore/JH-335/2022	8.9×10^4 TCID$_{50}$/mL
	A/Baltimore/JH-0440/2022	2.8×10^4 TCID$_{50}$/mL
	A/Hong Kong/8/68	1.58×10^3 CEID$_{50}$/mL
	A/Wisconsin/67/2005 (H3N2)	1.5×10^5 CEID$_{50}$/mL
	A/Aichi/2/68	2.3×10^3 CEID$_{50}$/mL
	A/Alaska/232/2015	2.6×10^4 CEID$_{50}$/mL
	A/Michigan/15/2014	9.3×10^3 FFU/mL
	A/Switzerland/9715293/2013	1.6×10^5 CEID$_{50}$/mL
	A/California/2/2014	5.8×10^2 TCID$_{50}$/mL
	A/Texas/71/2017	9.3×10^3 FFU/mL
	A/Indiana/08/2011 (H3N2) v	8.1×10^2 TCID$_{50}$/mL
	A/Minnesota/11/2010 (H3N2) v	2.2×10^4 CEID$_{50}$/mL
	A/Singapore/INFIMH-16-0019/2016	2.2×10^4 CEID$_{50}$/mL
	A/Hong Kong/4801/2014	9.6×10^5 CEID$_{50}$ / mL
Flu B virus (Victoria lineage)	B/Baltimore/JH002/2021	1.6×10^4 TCID$_{50}$/mL
	B/Florida/78/2015	2.8×10^4 TCID$_{50}$/mL
	B/Colorado/6/2017	1.6×10^4 CEID$_{50}$/mL
	B/New Hampshire/01/2021	1.3×10^2TCID$_{50}$/mL
	B/Brisbane/60/2008	1×10^4 CEID$_{50}$/mL
	B/Hong Kong/286/2017	2.7×10^3TCID$_{50}$/mL
	B/Maryland/15/2016	1.3×10^3 TCID$_{50}$/mL
Flu B virus (Yamagata lineage)	B/Guangdong/120/00	1.68×10^2TCID$_{50}$/mL
	B/Texas/6/11	3.8×10^2TCID$_{50}$/mL
	B/Wisconsin/1/2010 BX-41A	1.8×10^5 CEID$_{50}$/mL
	B/Florida/4/2006	5×10^4 CEID$_{50}$/mL
	B/Massachusetts/2/2012	1.0×10^4TCID$_{50}$/mL

c. Specificity / Cross Reactivity and Microbial Interference

The potential cross-reactivity of a panel of common organisms was evaluated with influenza negative samples using the Innovita Flu A/B Antigen Rapid Test. Potential microbial interference was evaluated with samples containing influenza A or influenza B at concentrations 2X LoD. A total of 49 organisms were tested. All influenza negative samples gave negative results at the tested concentrations showing no cross-reactivity with Innovita Flu A/B Antigen Rapid Test. All samples with influenza A or influenza B tested positive showing no microbial interference at the concentrations tested.

Microorganism	Concentration Tested	Negative sample			Flu A positive sample			Flu B positive sample		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Human rhinovirus 1A	6.6×10^6 PFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human parainfluenza virus 1 (HPIV-1)	3.2×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Acinetobacter calcoaceticus	6.2×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human adenovirus 1	3.2×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human mastadenovirus B7	1.78×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Bordetella pertussis	3.08×10^6 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Candida albicans	7.3×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Chlamydophila pneumoniae	4.6×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human coronavirus 229E	3.2×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Beta coronavirus 1 (Human coronavirus OC43)	1.0×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Corynebacterium diphtheriae	1.28×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human Coxsackievirus B4	3.2×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Cytomegalovirus	1.4×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Enterococcus faecalis	1.78×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Escherichia coli	2.88×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Gardnerella vaginalis	9.92×10^6 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Haemophilus influenzae	3.36×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Klebsiella pneumoniae subsp. *pneumoniae*	1.04×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Lacticaseibacillus casei	4.32×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Legionella pneumophila subsp. *pneumophila*	1.12×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Listeria monocytogenes	2.28×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Measles virus	1.78×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human Metapneumovirus 27 (hMPV-27) Type A2	7.6×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Moraxella (Branhamella) *catarrhalis*	8.8×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mumps virus	9.84×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mycobacterium tuberculosis	3.32×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mycoplasma pneumoniae	6.6×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Neisseria gonorrhoeae	2.8×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+

Neisseria meningitidis	1.44×10^6 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Neisseria sicca	8.4×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human parainfluenza. virus 2	1.78×10^6 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human parainfluenza virus 3	3.2×10^7 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Proteus vulgaris	1.04×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Pseudomonas paraeruginosa	6.4×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Human respiratory syncytial virus B	5.6×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Rubella	1.78×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
SARS-CoV-2	3.16×10^5 $TCID_{50}$/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Serratia marcescens subsp. *marcescens*	2.64×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Staphylococcus aureus subsp. *aureus*	1.16×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Staphylococcus epidermidis	2.12×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus agalactiae	1.28×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus anginosus	2.32×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus dysgalactiae subsp *equisimilis*	1.12×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus mutans	4.42×10^9 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus pneumoniae	3.4×10^6 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus pyogenes	2.8×10^7 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus sanguinis	1.52×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus constellatus	4.28×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Streptococcus intermedius	8.34×10^8 CFU/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+

d. Interfering Substances

Potentially interfering substances present in respiratory specimens or that may be artificially introduced into the oropharynx or nasopharynx cavity were studied with the Innovita Flu A/B Antigen Rapid Test. The positive samples were prepared using the influenza A and B virus strains diluted to concentrations 2X LoD. Each influenza strain combined with each interfering substance was evaluated separately. Negative samples were prepared by adding each interfering substance to the negative nasal fluid. Each positive and negative sample, combined with each interfering substance, was tested in triplicate for each lot with three different lots. None of the tested potential interfering substances showed false positive or false negative test results using Innovita Flu A/B Antigen Rapid Test with influenza positive and negative samples at the concentrations specified below.

Potentially interfering substances	Concentration Tested	Negative sample	Flu A positive sample	Flu B positive sample

		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Acetaminophen	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Acetyl salicylic acid	15 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Beclomethasone	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Benzocaine	5 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Budesonide	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Chlorpheniramine maleate	5 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Dexamethasone	1 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Dextromethorphan HBr	2 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Diphenhydramine HCl	5 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Ephedrine HCl	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Flunisolide	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Fluticasone	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Guaiacol Glyceryl Ether	20 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Histamine Dihydrochloride	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Menthol	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mometasone	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mucin	3 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Mupirocin	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
OTC Throat drop (Halls)	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
OTC Throat drop (Ricola)	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
OTC Nasal spray (Afrin)	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
OTC Nasal spray (Vicks Sinex)	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
OTC Nasal spray (Zicam)	15%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Oxymetazoline HCl	10 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Phenylephrine HCl	5 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Phenylpropanolamine	5 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Tobramycin	1 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Triamcinolone	1 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+
Whole Blood	3%	3-	3-	3-	3+	3+	3+	3+	3+	3+
Zanamivir	1 mg/mL	3-	3-	3-	3+	3+	3+	3+	3+	3+

The biotin interfering effects using Innovita Flu A/B Antigen Rapid Test were tested. No interference was observed with biotin concentrations up to 4000 ng/mL.

e. Precision/Reproducibility Study

A precision study was performed to evaluate the precision of the Innovita Flu A/B Antigen Rapid Test. The study was performed at three external testing sites consisting of seven samples at various virus concentrations including near the respective LoD (i.e., true negative, high negative influenza A, low positive influenza A, moderate positive influenza A, high negative influenza B, low positive influenza B, and moderate positive influenza B). These samples were tested by six (6) untrained operators at 5 replicates per day and last over 5 days, i.e., 5 replicates x 6 operators x 5

days= 150 replicates per concentration and a total of 1050 data points collected. Three (3) test lots were used in this study, so lot-to-lot variability was also assessed. Fifty (50) µL of the prepared sample were applied to kit swabs, shipped and stored frozen at -20°C until testing. The results were 100% agreement between expected and read result within replicates, by lot, by operator, by day, between sites and overall.

Sample	Positive Percent Agreement						Total Positive Percent Agreement (95% Confidence Intervals)	
	Site 1/Lot 1		Site 2/Lot 2		Site 3/Lot 3			
	Flu A	Flu B	Flu A	Flu B	Flu A	Flu B	Flu A	Flu B
Negative swab sample	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%) (0%-2.5%)	0/150 (0%) (0%-2.5%)
Flu A high negative swab sample (0.1×LOD)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%) (0%-2.5%)	0/150 (0%) (0%-2.5%)
Flu A Low positive swab sample (1×LOD)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	150/150 (100%) (97.5%-100%)	0/150 (0%) (0%-2.5%)
Flu A moderate positive swab sample (3×LOD)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	150/150 (100%) (97.5%-100%)	0/150 (0%) (0%-2.5%)
Flu B high negative swab sample (0.1×LOD)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%) (0%-2.5%)	0/150 (0%) (0%-2.5%)
Flu B Low positive swab sample (1×LOD)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/150 (0%) (0%-2.5%)	150/150 (100%) (97.5%-100%)
Flu B moderate positive swab sample (3×LOD)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/150 (0%) (0%-2.5%)	150/150 (100%) (97.5%-100%)

f. Prospective Clinical Study

The prospective clinical study was carried out during the 2023-2024 influenza season at three clinical sites in the U.S. and compared against an FDA-cleared influenza A and B molecular assay. A total of 1109 subjects with flu-like symptoms were enrolled in the study. Of those, 8 specimens were unevaluable (eight samples were lost in transit to the laboratory). A total of 1101 nasopharyngeal swab specimens were considered evaluable. Two nasopharyngeal swabs were collected from each subject. At all sites, the first collected nasopharyngeal swab was eluted in 3 ml of viral transport media and transported to the central laboratory for testing an FDA-cleared molecular assay as a comparator method. The second collected nasopharyngeal swab was tested directly with the Innovita Flu A/B Antigen Rapid Test according to the product instructions.

The following tables show the number of influenza A and influenza B positive cases and its percentage in four subject age categories, as observed during the clinical study.

Age Group	Positivity Rates for Influenza A based on an FDA-cleared molecular test during the Clinical Study		
	Number of Subjects	Number of Influenza A Positives	Influenza A Positivity Rate
≤5 Years of Age	463	121	26.1%
6-21 Years of Age	399	95	23.8%
≥22 Years of Age	239	21	8.8%
Total	1101	237	21.5%

Age Group	Positivity Rates for Influenza B based on an FDA-cleared molecular test during the Clinical Study		
	Number of Subjects	Number of Influenza B Positives	Influenza B Positivity Rate
≤5 Years of Age	463	14	3.0%
6-21 Years of Age	399	19	4.8%
≥22 Years of Age	239	9	3.8%
Total	1101	42	3.8%

The performance of the Innovita Flu A/B Antigen Rapid Test for influenza A and influenza B as compared to the comparator method is presented in the tables below.

Innovita Flu A/B Antigen Rapid Test - Influenza A	Molecular Comparator		
	Positive	Negative	Total
Positive	203	4	207
Negative	34	860	894
Total	237	864	1101
Positive Percent Agreement (PPA)	85.7% (95% CI: 80.6%-89.5%)		
Negative Percent Agreement (NPA)	99.5% (95% CI: 98.8%-99.8%)		

Innovita Flu A/B Antigen Rapid Test - Influenza B	Molecular Comparator		
	Positive	Negative	Total
Positive	36	0	36
Negative	6	1059	1065
Total	42	1059	1101
Positive Percent Agreement (PPA)	85.7% (95% CI: 72.2%-93.3%)		
Negative Percent Agreement (NPA)	100% (95% CI: 99.6%-100%)		

11. Conclusion

Based on the data submitted in this traditional 510(k) submission, the Innovita Flu A/B Antigen Rapid Test has been shown to be substantially equivalent in terms of

intended use, technological characteristics, and assay performance to the predicate device.