January 30, 2026

Hangzhou Clongene Biotech Co., Ltd.
℅ Jenny Xia
LSI International, Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877

Re: K253318
Trade/Device Name: Clungene RSV Antigen Rapid Test
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: Class I
Product Code: GQG
Dated: September 29, 2025
Received: September 30, 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,

JOSEPH BRIGGS -S

Joseph Briggs, 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

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)*
K253318

Device Name
Clungene RSV Antigen Rapid Test

Indications for Use *(Describe)*
The Clungene RSV Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. The test is intended for in vitro diagnostic use as an aid in the diagnosis of RSV infections. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or patient management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an FDA-cleared molecular assay.

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.

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510(k) SUMMARY
K253318

1. Date: January 29, 2026
2. Submitter: Hangzhou Clongene Biotech Co., Ltd.
   No.1 Yichuang Road, Yuhang District,
   Hangzhou 311121 Zhejiang, 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: Clungene RSV Antigen Rapid Test
5. Classification: Class II

Product Code	**CFR #**	**Panel**
GQG	21 CFR 866.3480 Respiratory Syncytial Virus Serological Reagents	Microbiology

6. Predicate Devices:
   K240280, Nano-Check RSV Test

7. Intended Use
   The Clungene RSV Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. The test is intended for in vitro diagnostic use as an aid in the diagnosis of RSV infections.
   Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or patient management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an FDA-cleared molecular assay.

8. Device Description
   The Clungene RSV Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. The nasopharyngeal swab from individuals is processed by the extraction buffer in buffer tube. After the extracted sample is added into the specimen well, the respiratory syncytial virus (RSV) nucleoprotein antigen in the sample will react with anti-RSV antigen antibody conjugated with color micro particles to form an antigen-antibody labeled complex. This complex migrates on the membrane via capillary action until the test line, where

it will be captured by the pre-coated anti-RSV antigen antibody. If the specimen contains RSV nucleoprotein antigen, a colored line will appear in the test line (T) region indicating a positive result. If the specimen does not contain RSV nucleoprotein antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line (C) region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The test result should be read at 15-20 minutes after adding the extracted sample is added into the specimen well. One line in the control line region (C), and another line in the test line region (T) indicates a positive result, regardless of color intensity. When only One line is present in the control region(C) and no line is present in the test line region (T) results are negative result. If the control line(C) fails to appear, the result is invalid, and the operator should review the procedure and repeat the test with a new test cassette.

Contents	Amount	Description
Test cassettes	25	Each sealed foil pouch containing one test device and one desiccant
Buffer tubes	25	Tube sealed with foil film containing 0.3 mL of extraction buffer
Sterile Swabs	25	Single use nasopharyngeal swabs for specimen collection
Positive Control Swab	1	Non-infectious recombinant RSV nucleocapsid protein is dried on the swab tip
Negative Control Swab	1	Non-infectious recombinant Group C Streptococci is dried on the swab tip
Work Station	1	/
Instructions for Use	1	/
Quick Reference Instructions	1	/

9. Substantial Equivalence Information

A summary comparison of features of the Clungene RSV Antigen Rapid Test and the predicate device is provided in the following table.

Device & Predicate Device	**Predicate device (K240280)**	**Candidate device**
	Nano-Check RSV Test	Clungene RSV Antigen Rapid Test
Regulation Number	21 CFR 866.3480	Same
Regulatory Class	Class II	Same
Product Code	GQG	Same
Intended Use	The Nano-Check RSV Test is a rapid immunochromatographic	The Clungene RSV Antigen Rapid Test is a lateral flow immunoassay intended for

	assay for the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in anterior nasal swab specimens from patients with signs and symptoms of respiratory infections. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients aged 6 months to 6 years old, and adults over 60 years of age. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as an FDA-cleared molecular assay.	the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. The test is intended for in vitro diagnostic use as an aid in the diagnosis of RSV infections. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or patient management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an FDA-cleared molecular assay.
Indication Type	Prescription Use Only	Same
Technology	Immunochromatographic assay	Same
Test Result Type	Qualitative	Same
Specimen Type	Anterior nasal swab	Nasopharyngeal swab
Test Target	Nucleoprotein of RSV	Same
Instrumentation	None	Same
Device Format	Cassette	Same
Result Interpretation	Visual determination of the presence or absence of colored line at the Test line and a colored line at the Control line indicate the presence or absence of RSV	Same

Time to Result	15 minutes	15-20 minutes

10. Performance Summary

Analytical Performance

a. Limit of Detection (LoD)

To determine the Limit of Detection (LoD) of the Clungene RSV Antigen Rapid Test, four respiratory syncytial virus (RSV) strains were tested. Contrived samples were prepared by spiking each RSV strains (two RSV A and two RSV B strains) into pooled negative nasal fluid matrix, which had been confirmed as RSV negative by RT-PCR prior to use.

The study was conducted in two phases. In the initial screening phase, serial 10-fold dilutions of each RSV strain were prepared in the negative matrix and tested in triplicate using three lots of the test kit. The lowest concentration demonstrating 100% positivity (3 out of 3 replicates) for each strain was identified and was selected for further refinement.

In the LoD determination phase, 2-fold dilutions were prepared around the preliminary LoD concentration identified in the screening phase. Operators tested 20 replicates of each dilution using three lots of the test kit. The final LoD for each RSV strain was established as the lowest concentration achieving at least 95% positivity.

The results are presented in the table below.

RSV Subtype	**Strain**	**LOD ($TCID_{50}$/mL)**	**Positive Rate**
A	RSV-A (2006 Isolate)	1.5×10^2	60/60 (100%)
	RSV-A (ATCC-2012-10)	6.4×10^3	60/60 (100%)
B	RSV-B (ATCC-2012-11)	1.9×10^2	60/60 (100%)
	RSV-B (B WV/14617/85)	2.2×10^3	60/60 (100%)

b. Inclusivity

An inclusivity study was performed to demonstrate that the Clungene RSV Antigen Rapid Test can detect a broad range of RSV strains. In addition to the strains evaluated in the LoD study, five strains of RSV A and four strains of RSV B were tested in the study. Serial 10-fold dilutions of these RSV strains were prepared with the negative matrix and tested in triplicate using three lots of the test kit. The lowest concentration at which the device demonstrated 100% positivity (3 out of 3 replicates) was chosen for further study. Further characterization was performed by evaluating 2-fold dilutions of the RSV strains around the preliminary LoD. Operators tested 3 replicates using three lots of the test kit. The lowest concentration of each strain that resulted in 100% detection (3/3) is presented in the table below.

RSV Subtype	**Strain**	**Lowest Concentration with 100% Detection**
A	RSV-A (A2)	1.6×10^3 $TCID_{50}$/mL
	RSV-A(Long)	8.0×10^2 PFU/mL
	RSV-A (1/2015 Isolate #1)	6.3×10^1 $TCID_{50}$/mL
	RSV-A (2/2015 Isolate 2)	1.2×10^1 $TCID_{50}$/mL

	RSV-A (A2023/06-12NSMM)	7.0×10^2 $TCID_{50}$/mL
B	RSV-B(CH93(18)-18)	3.2×10^2 $TCID_{50}$/mL
	RSV-B (B1)	7.0×10^2 $TCID_{50}$/mL
	RSV-B (18537)	1.2×10^3 $TCID_{50}$/mL
	RSV-B (9320)	1.4×10^3 $TCID_{50}$/mL

c. High-dose Hook Effect

A high-dose hook effect study was conducted to determine if a Hook Effect would be observed at high analyte concentration (i.e., a false negative at high concentrations of RSV). Four different RSV strains were diluted to four or five different concentrations in pooled negative nasal fluid matrix and tested in three replicates using three lots of the Clungene RSV Antigen Rapid Test. Concentrations ranged from 10,000x LoD (the maximum virus concentration possible, undiluted from the viral stock) to 1x LoD diluted in negative clinical matrix. All tested samples demonstrated 100% positivity, as expected. The Clungene RSV Antigen Rapid Test did not display a Hook Effect for the tested RSV concentrations.

RSV Strain	**Concentration ($TCID_{50}$/mL)**	**Positive Agreement (RSV positive/Total tested)**
RSV-A (2006 Isolate)	1.5×10^6(10000×LoD)	100% (9/9)
	1.5×10^5 (1000×LoD)	100% (9/9)
	1.5×10^4 (100×LoD)	100% (9/9)
	1.5×10^3 (10×LoD)	100% (9/9)
	1.5×10^2 (1×LoD)	100% (9/9)
RSV-A (ATCC-2012-10)	6.4×10^6 (1000×LoD)	100% (9/9)
	6.4×10^5 (100×LoD)	100% (9/9)
	6.4×10^4 (10×LoD)	100% (9/9)
	6.4×10^3 (1×LoD)	100% (9/9)
RSV-B (ATCC-2012-11)	3.8×10^4 (200×LoD)	100% (9/9)
	1.9×10^4 (100×LoD)	100% (9/9)
	1.9×10^3 (10×LoD)	100% (9/9)
	1.9×10^2 (1×LoD)	100% (9/9)
RSV-B (B WV/14617/85)	8.9×10^5 (400×LoD)	100% (9/9)
	2.2×10^5 (100×LoD)	100% (9/9)
	2.2×10^4 (10×LoD)	100% (9/9)
	2.2×10^3 (1×LoD)	100% (9/9)

d. Specificity / Cross Reactivity and Microbial Interference

The potential cross-reactivity and microbial interference of the Clungene RSV Antigen Rapid Test were evaluated using a panel of common organisms. Cross reactivity was assessed by testing each organism with RSV negative samples, and

microbial interference was assessed by testing each organism with samples containing RSV at concentrations 2x LoD. A total of 56 organisms were tested across three device lots. All RSV negative samples gave negative results, and all RSV positive samples gave positive results at the tested concentrations, showing no cross-reactivity or microbial interference with the Clungene RSV Antigen Rapid Test.

Microorganism	**Concentration Tested**	**Cross Reactivity (negative / total test)**	**Microbial Interference (positive / total test)**
Adenovirus Type 1,Adenoid 71	1.6×10^{6} $TCID_{50}$/mL	9/9	9/9
Adenovirus Type 2,Adenoid 6 (NIAID 202-001-014)	1.1×10^{7} $TCID_{50}$/mL	9/9	9/9
Adenovirus Type 3,G.B.	8.9×10^{8} $TCID_{50}$/mL	9/9	9/9
Adenovirus Type B7	8.9×10^{5} $TCID_{50}$/mL	9/9	9/9
SARS-CoV-2, USA-WA1/2020	3.8×10^{5} $TCID_{50}$/mL	9/9	9/9
Human coronavirus OC43	1.6×10^{5} $TCID_{50}$/mL	9/9	9/9
Human coronavirus 229E	2.8×10^{5} $TCID_{50}$/mL	9/9	9/9
Human coronavirus NL63	1.8×10^{5} $TCID_{50}$/mL	9/9	9/9
Human herpesvirus 5 (Human Cytomegalovirus), Merlin, ATCC-2011-3	1.2×10^{5} $TCID_{50}$/mL	9/9	9/9
Human Parainfluenza virus type 1, C35	8.9×10^{5} $TCID_{50}$/mL	9/9	9/9
Human Parainfluenza virus type 2, Greer	8.9×10^{5} $TCID_{50}$/mL	9/9	9/9
Human Parainfluenza virus type 3	8.5×10^{6} $TCID_{50}$/mL	9/9	9/9
Human Parainfluenza virus type 4A, M-25	1.6×10^{5} $TCID_{50}$/mL	9/9	9/9
Measles virus, Edmonston	2.1×10^{5} $TCID_{50}$/mL	9/9	9/9
Mumps virus, 1	1.2×10^{6} $TCID_{50}$/mL	9/9	9/9
Rhinovirus 1A, 2060	2.2×10^{6} PFU/mL	9/9	9/9
Herpes simplex virus 1, Maclntyre	1.4×10^{6} $TCID_{50}$/mL	9/9	9/9
Varicellovirus Human herpesvirus 3,Ellen	2.9×10^{6} $TCID_{50}$/mL	9/9	9/9
Epstein-Barr Virus, P-3	3.2×10^{7} Copies/mL	9/9	9/9
Rotavirus A, WA (TC-adapted)	5.0×10^{6} $TCID_{50}$/mL	9/9	9/9
Enterovirus 68, 2007 Isolate	1.5×10^{5} $TCID_{50}$/mL	9/9	9/9
Enterovirus 71, H	8.9×10^{6} $TCID_{50}$/mL	9/9	9/9
MERS-CoV, Florida/USA-2_Saudi Arabia_2014	8.0×10^{5} $TCID_{50}$/mL	9/9	9/9

Microorganism	Concentration Tested	Cross Reactivity (negative / total test)	Microbial Interference (positive / total test)
Influenza A (H1N1),Brisbane/59/07	3.6×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza A (H1N1),A/California/7/2009	2.3×10^7 $TCID_{50}$/mL	9/9	9/9
Influenza A (H3N2)，Brisbane/10/07	5.3×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza A (H3N2),Victoria/361/11	3.8×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza A (H3N2),Hong Kong/8/68	1.3×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza A (H3N2),Wisconsin/67/05	1.1×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza B(Yamagata),Yamagata/16/88	1.3×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza B (Yamagata),Victoria/504/00	6.3×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza B(Victoria),Malaysia/2506/04	1.9×10^6 $TCID_{50}$/mL	9/9	9/9
Influenza B (Victoria),Victoria/2/87	7.6×10^5 $TCID_{50}$/mL	9/9	9/9
Influenza B (Victoria) B/Florida/78/2015	2.8×10^6 $TCID_{50}$/mL	9/9	9/9
Human Metapneumovirus 16 Type A1 , IA10-2003	6.3×10^5 $TCID_{50}$/mL	9/9	9/9
Coxsackievirus, B4, J.V.B. (Benschoten)	1.6×10^6 $TCID_{50}$/mL	9/9	9/9
Bordetella pertussis	8.7×10^7 CFU/mL	9/9	9/9
Chlamydophila pneumonia, TW-183	9.1×10^6 IFU/mL	9/9	9/9
Mycoplasma pneumoniae M129-B7	4.2×10^5 CFU/mL	9/9	9/9
Pseudomonas aeruginosa	2.8×10^8 CFU/mL	9/9	9/9
Staphylococcus aureus	9.5×10^8 CFU/mL	9/9	9/9
Haemophilus influenzae	8.0×10^7 CFU/mL	9/9	9/9
Streptococcus pneumoniae	1.0×10^7 CFU/mL	9/9	9/9
Streptococcus pyogenes	1.3×10^8 CFU/mL	9/9	9/9
Streptococcus salivarius	1.3×10^7 CFU/mL	9/9	9/9
Streptococcus mutans	1.2×10^6 CFU/mL	9/9	9/9
Legionella pneumophila	1.6×10^6 CFU/mL	9/9	9/9
Klebsiella pneumoniae	5.8×10^7 CFU/mL	9/9	9/9
Staphylococcus epidermidis	1.2×10^9 CFU/mL	9/9	9/9

Microorganism	Concentration Tested	Cross Reactivity (negative / total test)	Microbial Interference (positive / total test)
Mycobacterium tuberculosis	1.2×10^7 CFU/mL	9/9	9/9
Candida albicans	3.6×10^6 CFU/mL	9/9	9/9
Corynebacterium diphtheriae	1.4×10^6 CFU/mL	9/9	9/9
Moraxella catarrhalis	2.2×10^8 CFU/mL	9/9	9/9
Lactobacillus sp.	5.0×10^7 CFU/mL	9/9	9/9
Neisseria meningitidis	8.8×10^7 CFU/mL	9/9	9/9
Escherichia coli EAEC	2.6×10^7 CFU/mL	9/9	9/9

e. Endogenous and Exogenous Interfering Substances

Potentially interfering substances that may be present in respiratory specimens or that may be artificially introduced into the specimen were evaluated with the Clungene RSV Antigen Rapid Test. The interferants were prepared in pooled negative nasal fluid (PNF) at their recommended concentration. Negative samples were prepared using virus-negative pooled nasal fluid (PNF) specimens containing each interfering substance, and positive samples were prepared by combining RSV-A at 2x LoD in PNF with each interfering substance individually. All samples were evaluated in triplicate per lot using three different lots of devices to confirm that the interfering substance did not produce false result in either presence or absence of RSV. None of the tested potential interfering substances showed false positive or false negative test results using the Clungene RSV Antigen Rapid Test with RSV positive and negative samples at the concentrations specified below.

Substance	Concentration Tested	Diluted with positive sample (positive/ total test)	Diluted with negative sample (negative / total test)
Purified mucin protein	2.5 mg/mL	9/9	9/9
Whole Blood	4%	9/9	9/9
Phenylephrine HCl	15% v/v	9/9	9/9
Oxymetazoline HCl	15% v/v	9/9	9/9
Sodium chloride with preservatives	15% v/v	9/9	9/9
Beclomethasone	0.5 mg/mL	9/9	9/9
Budesonide Nasal Spray	15% v/v	9/9	9/9
Mometasone furoate	0.5 mg/mL	9/9	9/9
Dexamethason	5 mg/mL	9/9	9/9
Flunisolide	5 mg/mL	9/9	9/9
Triamcinolone acetonide	5 mg/mL	9/9	9/9
Fluticasone propionate	5 mg/mL	9/9	9/9
Histamine dihydrochloride	10 mg/mL	9/9	9/9
Benzocaine	3 mg/mL	9/9	9/9

Substance	Concentration Tested	Diluted with positive sample (positive/ total test)	Diluted with negative sample (negative / total test)
Menthol	3 mg/mL	9/9	9/9
Zanamivir	5 mg/mL	9/9	9/9
Ribavirin	5 mg/mL	9/9	9/9
Oseltamivir Phosphate	5 mg/mL	9/9	9/9
Peramivir	100 µg/mL	9/9	9/9
Mupirocin	10 mg/mL	9/9	9/9
Tobramycin	5 µg/mL	9/9	9/9
D-Biotin	3500 ng/mL	9/9	9/9
Remdesivir	0.2 mg/mL	9/9	9/9
Molnupiravir	2.5 mg/mL	9/9	9/9
Paracetamol	50 µg/mL	9/9	9/9
Euphorbium Nasal Spray	15% v/v	9/9	9/9
Sinna Nasal Spray	15% v/v	9/9	9/9
Quantum HEALTH TheraZinc	15% v/v	9/9	9/9
Leukocytes	5×10^6 cells/mL	9/9	9/9

f. Precision/Reproducibility Study

A reproducibility study was performed to evaluate the reproducibility of the Clungene RSV Antigen Rapid Test. The study was performed at three external testing sites consisting of four samples at various virus concentrations including near the respective LoD (i.e., true negative, high negative, low positive, and moderate positive). These samples were tested by six untrained operators at 5 replicates per day for each of three lots over 5 days for a total of 450 replicates per concentration and a total of 1,800 data points collected. The results were 100% agreement between expected and read results within replicates, by lot, by operator, by day, between sites, and overall.

Sample	Expected Result/Total Tested			Total % Agreement with Expected Results (95% Confidence Intervals)
	Site A	Site B	Site C	
Negative swab sample	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%) (99.2%-100%)
RSV high negative swab sample (0.1×LOD)	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%) (99.2%-100%)
RSV low positive swab sample (1×LOD)	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%) (99.2%-100%)
RSV moderate positive swab sample (3×LOD)	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%) (99.2%-100%)

A lot-to-lot precision study was conducted at one external site. Test samples were contrived in negative nasal clinical matrix (NCM) and spiked with RSV-A strain to target four concentrations: true negative (NCM, unspiked), high negative (0.1x LoD), low positive (1x LoD), and moderate positive (3x LoD). The test samples were prepared by coating the viral solutions onto the swabs. The samples were randomized and blind-coded. The study was performed over twelve non-consecutive days by six untrained operators using three lots. Each operator performed two replicates at each concentration per day using one lot of the device. Two separate operators tested each lot every other day (i.e. operator 1 tested lot 1 on days 1, 3, 5, 7, 9, and 11, while operator 4 tested lot 1 on days 2, 4, 6, 8, 10, and 12). Each sample concentration was tested a total of 72 times (2 replicates x 12 days x 3 lots). Results are summarized below.

Sample	**Expected Result/Total Tested**			**Total % Agreement with Expected Results (95% Confidence Intervals)**
	Lot 1	**Lot 2**	**Lot 3**	
Negative swab sample	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%) (94.9%-100%)
RSV high negative swab sample (0.1×LOD)	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%) (94.9%-100%)
RSV low positive swab sample (1×LOD)	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%) (94.9%-100%)
RSV moderate positive swab sample (3×LOD)	24/24 (100%)	24/24 (100%)	24/24 (100%)	72/72 (100%) (94.9%-100%)

g.Internal Controls

The Clungene RSV Antigen Rapid Test has a built-in internal procedural control which monitors that sufficient volume of the sample is added and the reagent flow across the membrane occurred. Formation of a pinkish-red line in the control region on the strip confirms proper sample application and that the reagents are functioning appropriately. If no visible signal appears on the control line, the test result is invalid, and the operator is instructed in the labelling to test the sample again with another test device.

h.External Controls

The Clungene RSV Antigen Rapid Test contains one positive external control swab and one negative external control swab that allows for monitoring of the performance of the assay. The positive control swab contains noninfectious recombinant RSV nucleocapsid protein, and the negative control swab contains noninfectious recombinant Group C Streptococci.

Lot-to-lot precision of the external positive and negative control swabs was evaluated by testing ten replicates each of three lots of the external controls. For each external

control lot, all positive and negative controls produced 100% agreement with the expected results, as summarized below.

External Control	Control Lot No.	Test Result/Total Tests		% Agreement to Expected Result
		# Negative	# Positive	
External Positive Control	1	0/10	10/10	100%
	2	0/10	10/10	100%
	3	0/10	10/10	100%
External Negative Control	1	10/10	0/10	100%
	2	10/10	0/10	100%
	3	10/10	0/10	100%

i. Specimen Stability

Specimen stability was assessed using a negative sample (consisting of pooled negative human nasal fluid) and a contrived low positive sample (containing RSV-A strain at 2x LoD in the pooled negative human nasal fluid). Contrived samples on the swabs were stored at 2-8ºC, room temperature, 35ºC, and -20ºC and tested at the following timepoints: 1, 2, 3, and 4 hours for room temperature and 35ºC; 6, 12, 24, and 48 hours for 2-8ºC; and 1, 3, and 5 days for -20ºC. Three replicates of each concentration were tested in accordance with the package insert at each timepoint for each condition using three device lots by three operators.

Swabs were also stored at -20ºC for 24 hours, then transferred to room temperature for thawing, constituting one freeze-thaw cycle. The above was repeated to make two freeze-thaw cycles. After each freeze-thaw cycle, tests were performed in triplicate using three device lots by three operators.

The results obtained in these studies are summarized below.

Storage Temperature	Testing time post-storage	Test Results of Positive Swab Specimens			Test Results of Negative Swab Specimens		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
/	0h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
2-8℃	6h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	12h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	24h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	48h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
Room temperature	1h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	2h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	3h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	4h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
35℃	1h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	2h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	3h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	4h	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)

Storage Temperature	Testing time post-storage	Test Results of Positive Swab Specimens			Test Results of Negative Swab Specimens		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-20℃	Day 1	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	Day 3	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
	Day 5	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)

Freeze-thaw cycles	Test Results of Positive Swab Specimens			Test Results of Negative Swab Specimens		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
0 cycles	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
1 cycle	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)
2 cycles	+ (3/3)	+ (3/3)	+ (3/3)	- (3/3)	- (3/3)	- (3/3)

j. Prospective Clinical Study

The performance of the Clungene RSV Antigen Rapid Test in detecting RSV nucleoprotein antigen was evaluated in a multi-center, prospective study across five testing sites using nasopharyngeal (NP) swab samples collected from patients with signs and symptoms consistent with RSV. The study was conducted between November 2024 to April 2025. Informed consent was obtained for all patients prior to testing. Two NP swabs were collected from each subject. One swab (for comparator testing) was collected by the study operator and placed into transport media for comparator testing and the other swab was collected by the study operator and tested immediately with the Clungene RSV Antigen Rapid Test on site. The performance of the Clungene RSV Antigen Rapid Test with NP swabs was estimated based on the comparison with results obtained with an FDA cleared molecular test for RSV (positive percent agreement (PPA) and negative percent agreement (NPA)).

A total of 722 subjects with RSV symptoms were enrolled in the study and a total of 722 nasopharyngeal swab specimens were considered evaluable. Specimens were collected from patients between 0 to 97 years old. Of these, 20.2% (146/722) were from subjects less than 6 years old, 32.1% (232/722) were from patients 6 to 21 years old, and 47.6% (344/722) were from patients 22 years or older. There were 55.5% (401/722) females and 44.5% (321/722) males.

The clinical performance of the Clungene RSV Antigen Rapid Test, expressed as PPA and NPA, compared to the comparator method is presented below.

Clungene RSV Antigen Rapid Test	Comparator RT-PCR		
	Positive	Negative	Total
Positive	98	5	103
Negative	13	606	619
Total	111	611	722

Positive Percent Agreement (PPA)	88.3% (95% CI: 81.0%-93.0%)
Negative Percent Agreement (NPA)	99.2% (95% CI: 98.1%-99.6%)

Expected Values/Reference Range

A patient sample is expected to be negative for RSV.

11. Conclusion

Based on the data submitted in this traditional 510(k) submission, the Clungene RSV Antigen Rapid Test has been shown to be substantially equivalent in terms of intended use, technological characteristics, and assay performance to the predicate device.