June 1, 2026

CorDx, Inc.
Aiiso Ally Yang
COO & VP
5900 Windward Parkway
Alpharetta, Georgia 30005

Re: K253882/CW250025
Trade/Device Name: CorDx Tyfast COVID-19 Ag Rapid Test Rx
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple Point-Of-Care Device To Directly Detect SARS-CoV-2 Viral Targets From Clinical Specimens In Near-Patient Settings
Regulatory Class: Class II
Product Code: QVF
Dated: December 4, 2025
Received: December 4, 2025

Dear Aiiso Ally Yang:

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,

JOSEPH BRIGGS -S

Joseph Briggs, PhD.
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)*
K253882

Device Name
CorDx Tyfast COVID-19 Ag Rapid Test Rx

Indications for Use *(Describe)*
The CorDx Tyfast COVID-19 Ag Rapid Test Rx is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory tract infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the CorDx Tyfast COVID-19 Ag Rapid Test Rx and followed up with a molecular test.

A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established from September 2023 to December 2023, when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

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.

510(k) Summary
CorDx Tyfast COVID-19 Ag Rapid Test Rx
CorDx, Inc.

510(k) Number: K253882/CW250025

Preparation Date: May, 2026

Submitter

Submitter Name: CorDx, Inc.
Submitter Address: 5900 Windward Pkwy, Alpharetta, GA 30005, USA
Submitter Contact: Aiiso Ally Yang
Submitter Contact Email: hx@cordx.com
Submitter Contact Phone: 858-888-3866

A. Device

1. Device Trade Name: CorDx Tyfast COVID-19 Ag Rapid Test Rx
2. Measurand: Nucleocapsid protein antigen from SARS-CoV-2
3. Type of Test: Qualitative lateral flow immunoassay
4. Product Code: QVF
5. Classification: Class II
6. Classification Name: Simple Point-Of-Care Device To Directly Detect Sars-Cov-2 Viral Targets From Clinical Specimens In Near-Patient Settings
7. Regulation Number: 21 CFR 866.3982
8. Panel: Microbiology

B. Predicate Device

K231187, Nano-Check COVID-19 Antigen Test

C. Intended Use

1. Intended use/Indications for use

The CorDx Tyfast COVID-19 Ag Rapid Test Rx is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory tract infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the CorDx Tyfast COVID-19 Ag Rapid Test Rx and followed up with a molecular test.

A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established from September 2023 to December 2023, when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

2. **Special conditions for use statement(s)**

   Rx - For Prescription Use Only

3. **Special instrument requirements**

   None

D. Device Description

The CorDx Tyfast COVID-19 Ag Rapid Test Rx uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 nucleocapsid protein antigen in anterior nasal swab specimens.

The test device is composed of a cassette housing and a test strip. The test strip, which is enclosed in the cassette housing, is comprised of the following components: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains colloidal-gold conjugated monoclonal antibody against the nucleocapsid protein antigen of SARS-CoV-2; the reaction membrane contains the secondary monoclonal antibody for the nucleocapsid protein antigen of SARS-CoV-2.

When the sample extract is added into the sample well, conjugates dried onto the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the viral antigen, will be captured by the specific anti-SARS-CoV-2 monoclonal antibody coated on the test line region (T). Absence of the test line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

E. Substantial Equivalence Comparison With Predicate

The following table provides a comparison of the characteristics of the CorDx Tyfast COVID-19 Ag Rapid Test Rx to the predicate device, the Nano-Check COVID-19 Antigen Test, K231187.

Comparison with the Predicate Device

Device & Predicate Device(s)	Predicate (K231187)	Subject Device
Device trade name	Nano-Check COVID-19 Antigen Test	CorDx Tyfast COVID-19 Ag Rapid Test Rx
Characteristic Similarities		
Intended use/ Indications for use	The Nano-Check™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleoprotein protein antigens directly in anterior nasal swab	The CorDx Tyfast COVID-19 Ag Rapid Test Rx is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigen directly in anterior nasal swab specimens from

Device & Predicate Device(s)	Predicate (K231187)	Subject Device
	specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Nano-Check™ COVID-19 Antigen Test and followed up with a molecular test. The test does not differentiate between SARS-CoV or SARS-CoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established during the 2022-2023 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.	individuals with signs and symptoms of upper respiratory tract infection. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the CorDx Tyfast COVID-19 Ag Rapid Test Rx and followed up with a molecular test. A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other respiratory pathogens and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established from September 2023 to December 2023, when SARS-CoV-2 Omicron was dominant. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.
Regulation number	21 CFR 866.3982	Same
Target population	Individuals with signs and symptoms of upper respiratory tract infection	Same
Intended use setting	Prescription use only	Same
Sample type	Anterior nasal swab specimens	Same
Analyte	SARS-CoV-2 Nucleocapsid protein	Same
Test type	Lateral flow immunoassay	Same
Test result	Qualitative (positive, negative, invalid)	Same
Detection format	Test cassette, visually read without an instrument	Same
Characteristic Differences		
Reading time	15 - 30 minutes	10 - 30 minutes

F. Performance Characteristics

1. Analytical Performance

a. Analytical sensitivity (Limit of detection)

1) Limit of Detection in pooled negative Nasal Wash Matrix
UV-inactivated SARS-CoV-2 virus (Isolate: USA-WA1/ 2020) was spiked into pooled negative Nasal Wash Matrix and serially diluted. Each dilution was tested in triplicate on the CorDx Tyfast COVID-19 Ag Rapid Test Rx to find the initial LoD range. The final LoD was confirmed to be $1.25x10^4$ $TCID_{50}$/mL by testing 20 individual replicates with concentrations at the initial LoD and at concentrations above and below the initial LoD.

2) Limit of Detection in Pooled Negative Swab Matrix
The Limit of Detection (LoD) of the CorDx Tyfast COVID-19 Ag Rapid Test Rx in the Pooled Negative Swab Matrix (PNSM) was established by testing serial dilutions of heat-inactivated SARS-CoV-2 virus (Isolate: USA-WA1/ 2020) spiked in PNSM. The preliminary LoD determined by testing a 10-fold dilution series of five replicates per concentration was confirmed by testing 20 replicates. The confirmed LoD for the CorDx Tyfast COVID-19 Ag Rapid Test Rx in PNSM was $1.00x10^4$ $TCID_{50}$/mL.

3) Limit of Detection by testing the WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368)
This study was designed to determine the Limit of Detection (LoD) for the CorDx Tyfast COVID-19 Ag Rapid Test Rx using the WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in Pooled Negative Swab Matrix (PNSM). The preliminary LoD determined by testing a 2-fold dilution series of three replicates per concentration was tested with an additional 17 replicates, for a total of 20 replicates, to confirm the LoD. Concentrations above and below the preliminary LoD were also tested with 20 replicates to further verify the LoD. The LoD for the CorDx Tyfast COVID-19 Ag Rapid Test Rx was $5.00x10^2$ IU/mL.

b. Analytical reactivity (Inclusivity)

The inclusivity of the CorDx Tyfast COVID-19 Ag Rapid Test Rx was determined for detecting SARS-CoV-2 Alpha, Beta, Delta and Omicron variants as assessed by its Limit of Detection. Serially diluted Heat-irradiated SARS-CoV-2 Alpha (Lineage B1.1.7), Brazil (Lineage P.1), Beta (Lineage B.1.351), Delta (Lineage B.1.617.2), Omicron (Lineage B.1.1.529, XBB), and B.1595 variants were spiked into Pooled Negative Swab Matrix (PNSM) to determine the LoD for each tested variant using one kit lot.

Based on the results, the CorDx Tyfast COVID-19 Ag Rapid Test Rx detects SARS-CoV-2 variants with LoD at the concentrations as indicated in the table below. The assay can detect these variants near the LoD of the original SARS-CoV-2 virus and thus displays comparable sensitivity and acceptable inclusivity for these variants tested.

Table 1. LoD Concentrations of SARS-CoV-2 Variants

SARS-CoV-2 Variant	Concentration ($TCID_{50}$/ mL)	SARS-CoV-2 Variant	Concentration ($TCID_{50}$/ mL)
Alpha B1.1.7	$2.5x10^4$	Omicron B.1.1.529	$3.125x10^3$

Brazil P.1	$2.5x10^4$	Omicron XBB	$2.5x10^4$
Beta B.1.351	$2.5x10^4$	B.1.595	$3.906x10^2$
Delta B.1.617.2	$3.125x10^3$		

c. Linearity

Not applicable, this device is a qualitative assay.

d. Analytical specificity (Cross-reactivity) and microbial interference

Cross-reactivity and microbial interference studies were performed to determine if the CorDx Tyfast COVID-19 Ag Rapid Test Rx reacts with non-SARS-CoV-2 respiratory pathogens and other microorganisms that are likely to be encountered in the clinical sample. Each microorganism was evaluated in the absence and presence of inactivated SARS-CoV-2 virus (3x LoD) to see if false positive and false negative test results may occur. Study results showed that no cross-reactivity or interference occurs with the following microorganisms at the concentration tested in the table below.

Table 2. Microorganisms and Concentrations Tested in the Study

Microorganisms	**Concentration Tested**
Human coronavirus 229E (Inactive)	$1x10^5$ $TCID_{50}$/mL
Human coronavirus 229E (Live)	$2.81x10^4$ $TCID_{50}$/mL
Human coronavirus OC43 (Inactive)	$1x10^5$ $TCID_{50}$/mL
Human coronavirus OC43 (Live)	$1x10^5$ $TCID_{50}$/mL
Human coronavirus NL63 (Inactive)	$1x10^5$ $TCID_{50}$/mL
Human coronavirus NL63 (Live)	$1x10^5$ $TCID_{50}$/mL
MERS-coronavirus (Inactive, UV)	$1x10^5$ $TCID_{50}$/mL
MERS-coronavirus (Inactive, Heat)	$1x10^5$ $TCID_{50}$/mL
SARS-coronavirus (Gamma-irradiated virus in Vero E6 cells in DMEM) (Inactive)	$1x10^5$ PFU/mL
SARS-coronavirus (Gamma-irradiated virus in PBS) (Inactive)	$1x10^7$ PFU/mL
Adenovirus (e.g., C1 Ad. 71) (Live)	$1x10^6$ $TCID_{50}$/mL
Human Metapneumovirus 3 (hMPV-3) Type B1 (Inactive)	$1x10^5$ $TCID_{50}$/mL
Human Metapneumovirus 3 (hMPV-3) Type B1 (Live)	$1x10^5$ $TCID_{50}$/mL
Parainfluenza virus Type 1 (Inactive)	$1x10^7$ $TCID_{50}$/mL
Parainfluenza virus Type 1 (Live)	$1x10^5$ $TCID_{50}$/mL
Parainfluenza virus Type 2 (Inactive)	$1x10^5$ $TCID_{50}$/mL
Parainfluenza virus Type 2 (Live)	$1x10^5$ $TCID_{50}$/mL
Parainfluenza virus Type 3 (Inactive)	$1x10^7$ $TCID_{50}$/mL
Parainfluenza virus Type 3 (Live)	$1x10^6$ $TCID_{50}$/mL
Parainfluenza virus Type 4A (Inactive)	$1x10^5$ $TCID_{50}$/mL
Parainfluenza virus Type 4A (Live)	$1x10^5$ $TCID_{50}$/mL
Influenza A /Perth/16/09 (H3N2) (Inactive)	$1x10^5$ $TCID_{50}$/mL
Influenza A/California/07/09 (H1N1) (Inactive)	$1x10^5$ $TCID_{50}$/mL
Influenza A /Hong Kong/2671/19 (Live)	$1x10^5$ $TCID_{50}$/mL
Influenza A/Indiana/02/ 2020 (H1N1) pdm09 (Live)	$1x10^7$ $CEID_{50}$/mL
Influenza B/Brisbane/60 /08 (Victoria lineage) (Inactive)	For Cross reactivity: $4.68\ x10^4$ $TCID_{50}$/mL For Interference: $2.34\ x10^4$ $TCID_{50}$/mL
Influenza B/Wisconsin/01 /10 (Yamagata lineage) (Inactive)	$1x10^5$ $TCID_{50}$/mL
Influenza B/Washington/ 02/19 (Victoria lineage) (Live)	$1\ x10^4$ $TCID_{50}$/mL
Influenza B/Florida/4/ 2006 (Yamagata lineage) (Live)	$1x10^7$ $CEID_{50}$/mL

Microorganisms	Concentration Tested
Enterovirus B111 2015 (Inactive)	$1x10^6$ $TCID_{50}$/mL
Enterovirus Type 71 (Live)	$1x10^5$ $TCID_{50}$/mL
Respiratory syncytial virus (Live)	$1x10^6$ $TCID_{50}$/mL
Rhinovirus Type 1A (Inactive)	$1x10^5$ $TCID_{50}$/mL
Rhinovirus Type 1A (Live)	$1x10^5$ $TCID_{50}$/mL
Haemophilus influenzae type b (Eagan) (Live)	$1x10^7$ CFU/mL
Streptococcus pneumoniae Z022 (Live)	$1x10^7$ CFU/mL
Streptococcus pyogenes Z018 (Live)	$1x10^7$ CFU/mL
Candida albicans Z006 (Live)	$1x10^7$ CFU/mL
Pooled human nasal wash - representative of normal respiratory microbial flora	NA
Bordetella pertussis A639 (Live)	$1x10^7$ CFU/mL
Mycoplasma pneumoniae M129 (Live)	$1x10^7$ CCU/mL
Chlamydia pneumoniae TW-183 (Live)	$1x10^7$ IFU/mL
Legionella pneumophila Philadelphia (Live)	$1x10^7$ CFU/mL
Staphylococcus aureus MRSA; COL (Live)	$1x10^7$ CFU/mL
Staphylococcus epidermidis MRSE; PR62A (Live)	$1x10^7$ CFU/mL

In-silico analysis

Three microorganisms including Human coronavirus HKU1, Mycobacterium tuberculosis and Pneumocystis jirovecii were not commercially available for wet experiments. Thus, in silico sequence homology analyses were performed to predict potential cross-reactivity with these microorganisms.

The sequence analysis results showed that Homology exists between the SARS-CoV-2 Nucleocapsid protein and Human Coronavirus HKU1. BLASTP results showed 36 sequence IDs. Sequence ID AGT17773.1 and AGW27840.1 had the highest alignment score (199) and were 39.1% homologous across 76% of the sequences. While this is relatively low sequence homology, the possibility of cross-reactivity cannot be ruled out. No significant homology was found between the SARS-CoV-2 Nucleocapsid protein and the Mycobacterium tuberculosis or Pneumocystis jirovecii, suggesting that these two organisms would not cross-react or interfere with the CorDx Tyfast COVID-19 Ag Rapid Test Rx even if they were present in the samples.

e. Endogenous/Exogenous interference

Studies were performed to evaluate interference between the CorDx Tyfast COVID-19 Ag Rapid Test Rx and endogenous or exogenous substances which may be naturally present in respiratory specimens or that may be artificially introduced.

Negative samples and positive samples (viral titer 3x LoD) were tested in triplicate in the presence of the potentially interfering substances. The performance of the CorDx Tyfast COVID-19 Ag Rapid Test Rx was not affected by any of the interfering substances listed in the table below at the tested concentration.

Table 3. Potential Interfering Substances and Concentrations Tested

Potential Interfering Substance	Concentration Tested
No other substance	NA

Potential Interfering Substance	Concentration Tested
Whole Blood	4%
Mucin	0.5%
Chloraseptic (Methol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	10% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Chloraseptic (Menthol/Benzocaine)	3mg/ml
Gericare Saline Nasal Spray (Sodium chloride with preservatives)	15% v/v
CVS Health Budesonide Allergy Nasal Spray (Budesonide)	15% v/v
Nasonex 24HR Allergy Nasal Spray (Mometasone)	15% v/v
HealthA2Z Fluticasone Propionate Nasal Spray (Fluticasone)	15% v/v
Luffeel Nasal Spray (Luffa opperculata, Sulfur)	1.25 %
Boiron Galphimia glauca	15% v/v
Boiron Histaminum Hydrochloricum	15% v/v

f. High dose hook effect study

No hook effect was observed when testing specimens containing SARS-CoV-2 (Isolate: USA-WA1/ 2020) viral concentration as high as $4.57x10^6$ $TCID_{50}$/mL.

g. Matrix comparison

Matrix equivalency studies between negative clinical nasal swab matrix and the surrogate pooled nasal cavity wash matrix was conducted and demonstrated equivalent performance of the test with both matrices.

h. Sample stability

Study results confirmed that the dry swab specimen could be stored at room temperature for up to 2 hours after specimen collection by testing contrived samples prepared with the Pooled Nasal Swab Matrix (PNSM) using three kit lots.

i. Precision/Reproducibility

1) Precision and Repeatability

The repeatability/precision study includes a sample panel consisting of a negative sample, a low positive (2 x LoD) sample, and a medium positive (4.0x LoD) sample. The low positive and medium positive sample were prepared by spiking UV-inactivated SARS-CoV-2 in the negative sample matrix (NSM).

Each operator applied 50 µL of each coded sample to each dry nasal swab. Then, the operator processed the sample per the IFU of the proposed device. The sample panel was tested in a blinded manner by two operators for 10 non-consecutive days. All three lots

were tested by each operator on each testing day. Each sample level was tested in triplicate in each run per operator per day (i.e., 3 lots x 2 operators x 3 replicates/run x 1 run X 10 days). A total of 180 tests were run per panel member. The agreement of obtained results with expected results was 100% across all lots, operators, and days. Variability in results was not observed between the three independently manufactured lots.

2) Reproducibility

The reproducibility/near cutoff study of the CorDx Tyfast COVID-19 Ag Rapid Test Rx was conducted using panels of blind coded contrived samples including a true negative sample, a high negative sample (0.1x LoD), a low positive sample (1.0x LoD) and a moderate positive sample (3.5x LoD), tested over 5 non-consecutive days by untrained operators at three testing sites.

The percent agreement relative to the expected results was 100% for the moderate positive samples, 96.7% for the low positive samples, 97.8% for the high negative samples and 100% for the true negative samples. Results are presented in the table below.

Table 4. Reproducibility Study Results

Sample	# of positive result/# of total tested (% positive rate)			Total sample count (% positive rate)
	Site 1	Site 2	Site 3	
True negative	0/30 (0.0%)	0/30 (0.0%)	0/30 (0.0%)	0/90 (0.0%)
High negative (0.1x LoD)	1/30 (3.3%)	0/30 (0.0%)	1/30 (3.3%)	2/90 (2.2%)
Low positive (1x LoD)	30/30 (100.0%)	29/30 (96.7%)	28/30 (93.3%)	87/90 (96.7%)
Moderate positive (3.5x LoD)	30/30 (100.0%)	30/30 (100.0%)	30/30 (100.0%)	90/90 (100.0%)

2. Clinical Performance

The clinical performance of the CorDx Tyfast COVID-19 Ag Rapid Test Rx was evaluated in a prospective clinical study conducted from September 2023 to December 2023 at four (4) sites throughout the United States.

The study enrolled a total of 693 evaluable subjects aged 2 years or older with symptoms associated with COVID-19. The clinical performance of the CorDx Tyfast COVID-19 Ag Rapid Test Rx was analyzed compared to a highly sensitive 510(k) Cleared SARS-CoV-2 RT-PCR assay. Results are listed in the table below.

Table 5. CorDx Tyfast COVID-19 Ag Rapid Test Rx Performance Within 5 Days of Symptom Onset Against the Comparator

CorDx Tyfast COVID-19 Ag Rapid Test	Comparator Positives	Comparator Negatives	Total
Positives	101	3	**104**
Negatives	17	572	**589**
Total	**118**	**575**	**693**

Positive Percent Agreement = 85.6% (95% CI: 78.1 to 90.8%)
Negative Percent Agreement = 99.5% (95% CI: 98.5 to 99.8%)

3. Serial Testing

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

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

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

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 (100.0%)
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 performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

4. Flex Studies

Using risk analysis as a guide, analytical flex studies were conducted on the CorDx Tyfast COVID-19 Ag Rapid Test Rx. The testing evaluated various sources of potential human errors and environmental factors that could affect the accuracy of results, including those related to sample handling, sample loading, results reading and extremes of operational conditions. The studies demonstrated that the test is robust to usage variation and environmental factors that may be encountered.

5. Clinical Cut-Off

Not applicable since there is no clinical cutoff related to the presence of SARS-CoV-2 in patient samples.

6. Expected Value/ Reference Range

Not applicable

G. Propose Labeling

The labeling supports the finding of substantial equivalence for this device.

H. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.