CorDx, Inc.
% Jinjie Hu
President and Principal Consultant
Axteria Biomed Consulting Inc.
8040 Cobble Creek Circle
Potomac, Maryland 20854

June 21, 2024

Re: K240728
Trade/Device Name: CorDx Tyfast COVID-19 Ag Rapid Test; CorDx COVID-19 Ag Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-the-counter test to detect SARS-CoV-2 from clinical specimens
Regulatory Class: Class II
Product Code: QYT
Dated: March 18, 2024
Received: March 18, 2024

Dear Jinjie Hu:

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.

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,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2024.06.21 10:54:26 -04'00'

Silke Schlottmann, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
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)*
K240728

Device Name
CorDx Tyfast COVID-19 Ag Rapid Test; CorDx COVID-19 Ag Rapid Test

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

SUBMITTER: CorDx, Inc.
9540 Waples St. # C,
San Diego, CA 92121

Contact person: Jinjie Hu,
Axteria BioMed Consulting Inc.
8040 Cobble Creek Circle
Potomac, MD 20854
Tel: 1-(301)814-4985
Email: jinjie.hu@axteriabiomed.com

Date prepared: March 22, 2024

Purpose of Submission:

To obtain a substantial equivalence for the CorDx Tyfast COVID-19 Ag Rapid Test (also known as CorDx COVID-19 Ag Test in EUA)

A. 510(k) Number:
K240728

B. Purpose for Submission:
New Device

C. Measure:
Antigen of SARS-CoV-2

D. Type of Test:
Qualitative chromatographic immunoassay

E. Applicant:
CorDx, Inc.

F. Proprietary and Established Names:
CorDx Tyfast COVID-19 Ag Rapid Test

G. Regulatory Information:

1. Regulation:
   21 CFR 866.3984 - Over-The-Counter Test to Detect SARS-Cov-2 From Clinical Specimens

2. Classification:
   Class II

3. Product Code:
   QYT

4. Panel:
   Microbiology

H. Intended Use:

1. Intended use(s):
   The CorDx Tyfast COVID- 19 Ag Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

   This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

   The CorDx Tyfast COVID- 19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

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

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

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

The CorDx Tyfast COVID-19 Ag Rapid Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting.

2. Special condition for use statement(s):
   This device is intended for over-the-counter (OTC) use.

3. Special instrument requirements:
   None

I. Device Description:

The CorDx Tyfast COVID-19 Ag Rapid Test is a rapid, immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 from anterior nasal swab specimens. This test does not differentiate between SARS-CoV and SARS-CoV-2. The test kit includes the: test cassette, swab, tube with sample processing solution, tube holder (back of the box) and the Quick Reference Instructions (QRI).

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

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-2 conjugate and the viral antigen will be captured by the specific anti-SARS-2 monoclonal antibody coated on the test line region (T). Absence of the test line (T) 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACON Laboratories, Inc. K230828, Flowflex COVID-19 Antigen Home Test

2. Predicate K number(s): K230828

3. Comparison with predicate

Parameter	CorDx Tyfast COVID-19 Ag Rapid Test	Predicate (K230828) Flowflex COVID-19 Antigen Home Test	Similarity or Difference
Intended Use	The CorDx Tyfast COVID- 19 Ag Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The CorDx Tyfast COVID- 19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.	The Flowflex COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.	Same

Parameter	CorDx Tyfast COVID-19 Ag Rapid Test	Predicate (K230828) Flowflex COVID-19 Antigen Home Test	Similarity or Difference
	This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from September, 2023, to December, 2023, when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-10 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider. The performance characteristics for SARS-CoV-2 were established from December 2022 to March 2023 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.	
Intended Use Environment	Over the counter use/self-testing	Over the counter use/self-testing	Same
Intended Use population	Individuals with symptoms of COVID-19	Individuals with symptoms of COVID-19	Same
Organism detected	SARS-CoV-2	SARS-CoV-2	Same
Analyte	Nucleocapsid protein antigen from SARS-CoV-2	Nucleocapsid protein antigen from SARS-CoV-2	Same
Regulation number	21 CFR 866.3984	21 CFR 866.3984	Same
Principle of the Technology	Qualitative lateral flow immunoassay	Qualitative lateral flow immunoassay	Same
Sample type	Anterior nasal swab specimens	Anterior nasal swab specimens	Same
Detection format	Test cassette, visually read without an instrument.	Test cassette, visually read without an instrument.	Same
Assay Result	Qualitative (positive, negative, invalid)	Qualitative (positive, negative, invalid)	Same

Parameter	**CorDx Tyfast COVID-19 Ag Rapid Test**	**Predicate (K230828) Flowflex COVID-19 Antigen Home Test**	**Similarity or Difference**
Time to Result	Time to result: 10 minutes after the extracted sample is added to the test cassette sample well.	Time to result: 15 minutes after the extracted sample is added to the test cassette sample well.	Different 5 minutes less reading time
Controls	-Internal procedural controls: Each CorDx Tyfast COVID-19 Rapid Ag Test has a built-in "Control" region which serves as an internal procedural control when a colored line appears in the control line region ("C line"). The "C line" should always appear if the test has been performed correctly. If the "C line" does not appear at 10 minutes, the test result is invalid. It is recommended to review the instructions again and repeat the test with a new sample and a new cassette. If the problem persists, please stop using the product and contact CorDx for technical support. -External controls: a separate external control kit is available for purchase from CorDx. The configurations of the CorDx Tyfast COVID-19 Ag Control Swab Kit from CorDx is: 10 positive swabs and 10 negative swabs per box. The COVID-19 antigen positive control swab is composed of SARS-COV-2 recombinant antigen extract dried onto a swab. The COVID-19 antigen negative control swab is composed of negative sample matrix dried onto a swab.	-Internal procedural controls: The Flowflex Plus COVID-19 Home Test has a built-in internal procedural control. The colored biotin labeled particle will bind to streptavidin on nitrocellulose membrane and the colored mouse monoclonal antibody labeled particle will bind to goat anti-mouse antibody on nitrocellulose membrane to form a colored Control line (C) in the control line region. Formation of the Control line serves as an internal control indicating that proper volume of specimen has been added and membrane wicking has occurred.	Different
Reagent Storage	Store at 36~86°F/2~30°C in a place out of direct sunlight and out of reach of children.	Store Flowflex COVID-19 Antigen Home Test between 2-30°C (36-86°F) until use.	Same

K. Standard/Guidance Document referenced (if applicable):

Document Title	Issued by	Applicable study
Reclassification order for DEN220028 and special controls under 21 CFR 866.3984 for Over- the-counter tests to detect SARS-CoV-2 from clinical specimens	FDA	All
ISO11135:2014, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO	Sterility
ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	ISO	Sterility
ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process	ISO	Biocompatibility
EP5-A3 Evaluation of Precision of Quantitative Measurement Procedures	CLSI	Precision
EP12-A2 User Protocol for Evaluation of Qualitative Test Performance	CLSI	Precision
EP25A Evaluation of Stability of In Vitro Diagnostic Reagents	CLSI	Reagent stability
EP37 Supplemental Tables for Interference Testing in Clinical Chemistry	CLSI	Interference

L. Test Principle:

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-2 conjugate and the viral antigen will be captured by the specific anti-SARS-2 monoclonal antibody coated on the test line region (T). Absence of the test line (T) 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.

M. Performance Characteristics

1. Analytical performance:

a. Precision Study by Lots

The purpose of the study was to assess lot-to-lot variability of three different lots of the CorDx Tyfast COVID-19 Ag Rapid Test kits. The study included a sample panel consisting of a negative sample, a low positive (2x LoD) sample, and a positive (4x LoD) sample. The positive samples were prepared by spiking UV-inactivated SARS-CoV-2 in pooled negative Nasal Wash Matrix. The study results demonstrated 100% consistent performance of the CorDx Tyfast COVID-19 Ag Rapid Test for the detection of SARS-CoV-2 virus antigen when performed under different conditions of variability (days, runs, operators, kit lots and sample replicates).

Table 1. Precision Study Results

Lot	Test result（#Neg/60，# Pos/60）		
	NEG	2xLoD	4xLoD
Lot 1	60/60	60/60	60/60
Lot 2	60/60	60/60	60/60

Lot 3	60/60	60/60	60/60
Total	180/180	180/180	180/180
Agreement	100%	100%	100%

b. 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 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 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 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 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 was $5.00x10^2$ IU/mL.

c. Inclusivity

The inclusivity of the CorDx Tyfast COVID-19 Ag Rapid Test 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 lot of kit.

Based on the results, the CorDx TyFast COVID-19 Ag Rapid Test 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 2. 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	$3.125x10^3$		

d. Linearity/assay reportable range:

Not applicable. This is a qualitative device.

e. Cross-reactivity and microbial interference study

Cross reactivity (analytical specificity) and microbial interference studies were performed to determine if the CorDx Tyfast COVID-19 Ag Rapid Test 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 3: 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

Microorganisms	**Concentration Tested**
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
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 even if they were present in the samples.

f. Interference Study-other potential interference

This study was performed to evaluate interference between the CorDx Tyfast COVID-19 Ag Rapid Test 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 was not affected by any of the interfering substances listed in the table below at the tested concentration.

Table 4: Potential Interfering Substances and Concentrations Tested in the Study

Potential Interfering Substance	**Concentration Tested**
No other substance	NA
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

g. 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.

h. Traceability:

The tests were calibrated against the WHO International Standard for SARS-CoV-2 Antigen.

i. 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.

j. Sample Stability:

The 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.

k. Reagent Stability:

The real time stability study data demonstrated that the CorDx Tyfast COVID-19 Ag Rapid Test kit can be stored under recommended conditions of 2-30^{o}C for at least 24 months.

l. Shipping Stability:

The stability of the test kits under different stress shipping conditions was evaluated by testing 3 lots of test kits that went through the process of storing respectively at 7 different harsh temperature conditions and the process of dropping from various orientations. The kit components were stable under all conditions tested.

2. Clinical Performance:

a. Method comparison with predicate device:

Not applicable. See "3. Clinical Studies" for clinical performance.

3. Clinical Studies:

The clinical performance of the CorDx Tyfast COVID-19 Ag Rapid Test was evaluated in a prospective clinical study conducted from September 2023 to December 2023 at four (4) sites throughout the United States. The study evaluated 740 symptomatic individuals aged 2 years or older who were either experiencing fever or had two or more symptoms associated with COVID-19.

The performance of CorDx Tyfast COVID-19 Ag Rapid Test was analyzed compared to a highly sensitive 510(k)-cleared SARS-CoV-2 RT-PCR assay. Out of 740 enrolled individuals, 693 subjects were evaluable. Of the 693 subjects, 101 were true positives (concordant positive results on both the investigational and comparator tests) and 572 were true negatives (concordant negative results on both the investigational and comparator tests).

Twenty-one (21) subjects had discordant results in which the investigational test was negative, and the final comparator result was positive, and 3 subjects had discordant results in which the investigational test was positive, and the final comparator result was negative.

Table 5: CorDx Tyfast COVID-19 Ag Rapid Test Performance Against 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 10.8%)			
Negative Percent Agreement = 99.5% (95% CI: 98.5 to 99.8%)			

4. Other Supportive Studies

a. Usability Study

A total of 104 subjects were enrolled in the study and were observed during testing. All subjects successfully completed testing by receiving a Negative or Positive result. All subjects were issued a questionnaire to assess users' comprehension of the test. The questionnaire was completed by all the enrolled subjects. The questionnaire assessed the users' understanding of concepts such as the test purpose and interpretation of results. The results demonstrate the kit can be successfully utilized by lay users.

b. Readability Study

A total of 104 lay users with diverse gender, ages and educational background who met the study inclusion criteria, were enrolled for the Readability Study. Each lay user was asked to interpret blinded test panels with mock results including one negative, one low positive at 1.5 to 2x limit of detection (LoD), one positive at 5x LoD, an invalid result and either one additional low positive or negative result. Subjects with vision impairments (e.g., near sightedness/far sightedness, glaucoma, glasses/contacts, strength of prescription lens) were included in interpretation of these results. The results showed that the test results could be adequately interpreted by individuals without or with vision impairment.

c. Flex Studies

Flex studies were conducted to evaluate whether potential errors that lay users could make during testing would adversely affect the test performance. The studies included

dry swab testing delay flex study, extracted specimen testing delay flex study, swab rotation times flex study, extracted specimen volume flex study, reading time flex study, disturbance during testing flex study, lighting conditions flex study, temperature and humidity conditions flex study, and bubbles in sample chamber flex study. Tests were performed with weak positive sample swabs, which were generated by diluting inactivated SARS-CoV-2 virus at 2x LoD. The studies support that the test is robust in the intended use condition as stated in the IFU.

5. **Clinical Cut-off**

   Not applicable

6. **Expected value/ Reference Range:**

   Not applicable

N. Propose Labeling:

The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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