

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K262432

B Applicant

CorDx, Inc.

C Proprietary and Established Names

CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test; CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SCA	Class II	21 CFR 866.3987 - Multi-Analyte Respiratory Virus Antigen Detection Test	Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test and CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test (hereafter referred to as the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test).

B Measurand:

Protein antigens from SARS-CoV-2, Influenza A and Influenza B

C Type of Test:

Qualitative Lateral Flow Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test:

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test:

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

C Special Conditions for Use Statement(s):

OTC – Over the counter Use

D Special Instrument Requirements:

Not Applicable

II Device/System Characteristics:

A Device Description:

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a rapid, immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 nucleocapsid protein and influenza (Flu) A and B proteins in anterior nasal swab specimens. The test package components for each of the devices are as follows:

- CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test
 - 1/2/4/5/8/10/20/25 Test cassettes
 - 1/2/4/5/8/10/20/25 Swabs
 - 1/2/4/5/8/10/20/25 Tubes with sample processing solution
 - 1 Quick Reference Instructions (QRI)
- CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test
 - 2/10/25 Test cassettes
 - 2/10/25 Swabs
 - 2/10/25 Tubes with sample processing solution
 - 1 Quick Reference Guide (QRG)

The test device is composed of a test strip and cassette housing. The test strip, which is enclosed in the cassette housing, is comprised of the following components: sample pad, reagent pad, reaction membrane, and absorbent pad. The reagent pad contains latex particles conjugated with monoclonal antibodies against the proteins of Flu A, Flu B and SARS-CoV-2; the reaction membrane contains the secondary antibodies for the proteins of Flu A, Flu B and SARS-CoV-2.

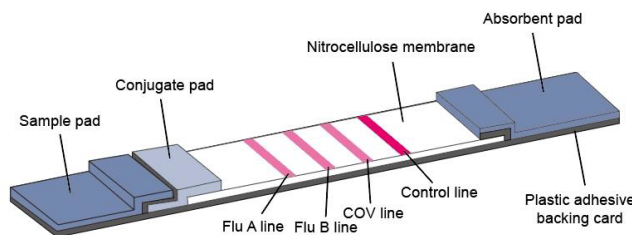


Fig. 1 Diagram of Test Device

B Principle of Operation:

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test employs membrane based lateral flow technology in a sandwich design to detect proteins from SARS-CoV-2, influenza A, and influenza B. Following sample collection, the individual's anterior nasal swab sample is placed

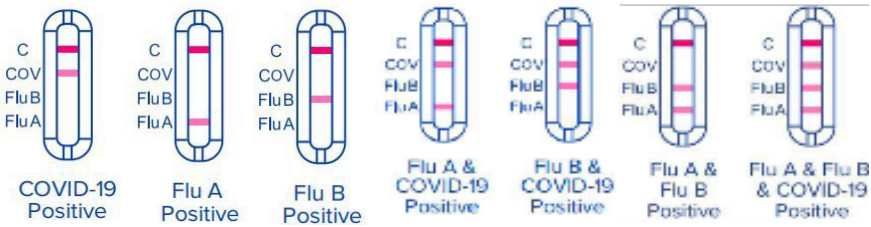
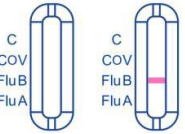
in the tube with sample processing solution, to lyse the sample and solubilize viral proteins. After lysis, the sample is loaded onto the test cassette sample well.

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 Flu A, Flu B proteins and/or SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex forms between the anti-Flu A/Flu B/SARS-CoV-2 conjugate and the viral antigen and will be captured by the specific anti-Flu A/Flu B/SARS-CoV-2 monoclonal antibody coated on the test line region (Flu A/Flu B/COV line). Absence of the test line (Flu A/Flu B/COV 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.

If the control line does not appear, the sample result is invalid. Test results are read visually without the need for any instrument.

Result Interpretation:

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test may give three possible results, positive, negative, or invalid:

POSITIVE	 If the control line (C) is visible and one or more lines appear(s) for any of the viruses, the test is positive for that or those viruses.
NEGATIVE	 If the control line (C) is visible but no other lines appear, the test is negative.
INVALID	 If the control line (C) is not visible the test is invalid, even if any test line is visible.

III Substantial Equivalence Information:

A Predicate Device Name(s):

WELLlife COVID-19 / Influenza A&B Home Test;
WELLlife COVID-19 / Influenza A&B Antigen Test

B Predicate 510(k) Number(s):

K243256

C Comparison with Predicate(s):

Device & Predicate Device(s):	Subject Device (K262432)	Predicate (K243256)
Device Trade Name	CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test; CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test	WELLlife COVID-19 / Influenza A&B Home Test; WELLlife COVID-19 / Influenza A&B Antigen Test
Intended Use/Indications For Use	<u>CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test:</u> The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of	<u>WELLlife COVID-19 / Influenza A&B Home Test:</u> WELLlife COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. 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. All negative results are presumptive and should be confirmed with an FDA cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening

	breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. <u>CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test:</u> The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider. Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.	respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out coinfection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up. <u>WELLlife COVID-19/ Influenza A&B Antigen Test:</u> The WELLlife COVID-19/ Influenza A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older. All negative results are presumptive and should be confirmed with an FDA cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers. Positive results do not rule out coinfection with other respiratory pathogens. Test results should not be used as the sole basis for treatment or
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		other patient management decisions.
General Device Characteristic Similarities		
Regulation Number	21 CFR 866.3987	Same
Assay Technique	Lateral Flow immunochromatographic assay, visually read	Same
Analytes	SARS-CoV-2, influenza A, and influenza B, protein antigens	Same
Intended Specimen	Anterior nasal swab specimen	Same
Sample Collection Method	Nasal swab supplied in the kit	Same
Usage	Single use test	Same
Assay Result	Qualitative (positive, negative or invalid)	Same
Storage Temperature	Store at 36-86°F /2-30°C	Same
General Device Characteristic Differences		
Time to Result	10-30 min	10-20 min

IV Standards/Guidance Documents Referenced:

Document #	Title	Publisher	Applicable Study
ISO 11135:2014	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
EP05-A3	Evaluation of Precision of Quantitative Measurement Procedures	CLSI	Precision
EP12-A2	User Protocol for Evaluation of Qualitative Test Performance	CLSI	Precision
EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents	CLSI	Reagent stability

Document #	Title	Publisher	Applicable Study
EP37	Supplemental Tables for Interference Testing in Clinical Chemistry	CLSI	Interference

V Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The multi-lot precision for the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test was evaluated to assess variability across multiple sources of analytical variability, including different testing days, operating runs, operators, and test kit lots. A panel of samples, including one negative sample and seven positive sample combinations: single positive samples (SARS-CoV-2, Flu A, and Flu B separately), doubly co-spiked samples (SARS-CoV-2 + Flu A, SARS-CoV-2 + Flu B, and Flu A + Flu B), and a triply co-spiked sample (SARS-CoV-2 + Flu A + Flu B) were tested. Positive samples were prepared at three concentration levels, including approximately 0.8x LoD, 2x LoD, and 5x LoD. All samples were prepared in pooled negative swab matrix (PNSM).

Testing was performed using three reagent lots and two operators over 10 non-consecutive day. Six panel sets were tested per day, with panel assignments alternated between operators throughout the study to ensure balanced operator representation across concentration levels and reagent lots. A total of 96 tests were performed per study day.

Results for this study are shown in Table 1 below. The results demonstrated 100% concordance with the expected result across sample types, device test lines and lots with negative samples, 2x LoD and 5x LoD samples. The expected lot-to-lot imprecision was observed with 0.8x LoD samples.

Table 1: Precision Study Results

Analyte Concentration	Analyte	Test Lines	# Positives / # Total			# Positives / # Total (% Positive Rate)
			Lot 1	Lot 2	Lot 3	
0	Negative	COV	0/40	0/40	0/40	0/120 (0%)
		Flu A	0/40	0/40	0/40	0/120 (0%)
		Flu B	0/40	0/40	0/40	0/120 (0%)
0.8x LoD	SARS-CoV-2	COV	7/10	6/10	5/10	18/30 (60%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	0/10	0/10	0/10	0/30 (0%)
	Flu A	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	7/10	6/10	5/10	18/30 (60%)
		Flu B	0/10	0/10	0/10	0/30 (0%)
	Flu B	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	7/10	6/10	5/10	18/30 (60%)
	SARS-CoV-2 + Flu A	COV	5/10	6/10	6/10	17/30 (56.7%)
		Flu A	7/10	4/10	5/10	16/30 (53.3%)
		Flu B	0/10	0/10	0/10	0/30 (0%)

Analyte Concentration	Analyte	Test Lines	# Positives / # Total			# Positives / # Total (% Positive Rate)
			Lot 1	Lot 2	Lot 3	
	SARS-CoV-2 + Flu B	COV	6/10	6/10	5/10	17/30 (56.7%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	4/10	4/10	6/10	14/30 (46.7%)
	Flu A + Flu B	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	5/10	6/10	5/10	16/30 (53.3%)
		Flu B	4/10	6/10	4/10	14/30 (46.7%)
	SARS-CoV-2 + Flu A + Flu B	COV	5/10	5/10	6/10	13/30 (53.3%)
		Flu A	5/10	4/10	5/10	14/30 (46.7%)
		Flu B	6/10	5/10	6/10	17/30 (56.7%)
2.0x LoD	SARS-CoV-2	COV	20/20	20/20	20/20	60/60 (100%)
		Flu A	0/20	0/20	0/20	0/60 (0%)
		Flu B	0/20	0/20	0/20	0/60 (0%)
	Flu A	COV	0/20	0/20	0/20	0/60 (0%)
		Flu A	20/20	20/20	20/20	60/60 (100%)
		Flu B	0/20	0/20	0/20	0/60 (0%)
	Flu B	COV	0/20	0/20	0/20	0/60 (0%)
		Flu A	0/20	0/20	0/20	0/60 (0%)
		Flu B	20/20	20/20	20/20	60/60 (100%)
	SARS-CoV-2 + Flu A	COV	20/20	20/20	20/20	60/60 (100%)
		Flu A	20/20	20/20	20/20	60/60 (100%)
		Flu B	0/20	0/20	0/20	0/60 (0%)
	SARS-CoV-2 + Flu B	COV	20/20	20/20	20/20	60/60 (100%)
		Flu A	0/20	0/20	0/20	0/60 (0%)
		Flu B	20/20	20/20	20/20	60/60 (100%)
	Flu A + Flu B	COV	0/20	0/20	0/20	0/60 (0%)
		Flu A	20/20	20/20	20/20	60/60 (100%)
		Flu B	20/20	20/20	20/20	60/60 (100%)
	SARS-CoV-2 + Flu A + Flu B	COV	20/20	20/20	20/20	60/60 (100%)
		Flu A	20/20	20/20	20/20	60/60 (100%)
		Flu B	20/20	20/20	20/20	60/60 (100%)
5.0x LoD	SARS-CoV-2	COV	10/10	10/10	10/10	30/30 (100%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	0/10	0/10	0/10	0/30 (0%)
	Flu A	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	10/10	10/10	10/10	30/30 (100%)
		Flu B	0/10	0/10	0/10	0/30 (0%)
	Flu B	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	10/10	10/10	10/10	30/30 (100%)
	SARS-CoV-2 + Flu A	COV	10/10	10/10	10/10	30/30 (100%)
		Flu A	10/10	10/10	10/10	30/30 (100%)
		Flu B	0/10	0/10	0/10	0/30 (0%)
	SARS-CoV-2 + Flu B	COV	10/10	10/10	10/10	30/30 (100%)
		Flu A	0/10	0/10	0/10	0/30 (0%)
		Flu B	10/10	10/10	10/10	30/30 (100%)
	Flu A + Flu B	COV	0/10	0/10	0/10	0/30 (0%)
		Flu A	10/10	10/10	10/10	30/30 (100%)
		Flu B	10/10	10/10	10/10	30/30 (100%)

Analyte Concentration	Analyte	Test Lines	# Positives / # Total			# Positives / # Total (% Positive Rate)
			Lot 1	Lot 2	Lot 3	
	SARS-CoV-2 + Flu A + Flu B	COV	10/10	10/10	10/10	30/30 (100%)
		Flu A	10/10	10/10	10/10	30/30 (100%)
		Flu B	10/10	10/10	10/10	30/30 (100%)

2. Linearity:

This is a qualitative assay and therefore, linearity is not applicable.

3. Analytical Specificity/Interference:

a. *Cross-reactivity and Microbial Interference:*

Cross-reactivity and microbial interference studies were conducted to determine if pathogens likely to be present in direct nasal swab samples would cause false results by cross reacting or interfering with the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test. A panel of viruses, bacteria, and fungi were evaluated in these studies. Dilutions for testing were made in PNSM. Each organism spiked sample was tested in three replicates in the absence (for cross-reactivity) or presence (for microbial interference) of 3x co-spike LoD for SARS-CoV-2, Flu A virus, and Flu B virus. Cross-reactivity with SARS-CoV-2 was observed with SARS-CoV when tested $\geq 1.60 \times 10^4$ TCID₅₀/mL but was not observed at 1.60×10^3 TCID₅₀/mL.

There was no cross-reactivity or microbial interference observed for any other organisms.

The results of cross-reactivity and microbial interference studies are summarized in Table 2.

Table 2: Cross-Reactivity and Microbial Interference Study Results

Pathogens	Concentration Tested	# Positive / # Total*	
		Cross Reactivity	Microbial Interference
SARS-CoV-1	8.00×10^5 TCID ₅₀ /mL	3/3**	N/A
	1.60×10^5 TCID ₅₀ /mL	3/3**	N/A
	1.60×10^4 TCID ₅₀ /mL	1/3**	N/A
	1.60×10^3 TCID ₅₀ /mL	0/3	3/3
MERS-coronavirus	1.51×10^5 TCID ₅₀ /mL	0/3	3/3
Human coronavirus OC43	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Human coronavirus 229E	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Human coronavirus NL63	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Adenovirus (AV71)	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Adenovirus Type 7	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Cytomegalovirus	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Epstein Barr Virus Human gammaherpesvirus 4	$> 2.5 \times 10^3$ CEID ₅₀ /mL	0/3	3/3
Human Metapneumovirus (hMPV)	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Human Parainfluenza virus 1	1.50×10^5 TCID ₅₀ /mL	0/3	3/3
Human Parainfluenza virus 2	1.50×10^5 TCID ₅₀ /mL	0/3	3/3

Pathogens	Concentration Tested	# Positive / # Total*	
		Cross Reactivity	Microbial Interference
Parainfluenza virus 3	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Parainfluenza virus 4	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Enterovirus Type 68	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Rhinovirus 1A	1.00 x 10 ⁵ PFU/mL	0/3	3/3
<i>Bordetella pertussis</i>	> 1 x 10 ⁴ CFU/mL	0/3	3/3
<i>Candida albicans</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Chlamydia pneumoniae</i>	1.10 x 10 ⁶ IFU/mL	0/3	3/3
<i>Corynebacterium sp.</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Escherichia coli</i>	> 2.5 x 10 ⁴ CFU/mL	0/3	3/3
<i>Hemophilus influenzae</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Lactobacillus sp.</i>	> 1 x 10 ⁴ CFU/mL	0/3	3/3
<i>Legionella pneumophila</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Moraxella catarrhalis</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Mycoplasma pneumoniae</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Mycobacterium tuberculosis</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Neisseria meningitidis</i>	1.05 x 10 ⁵ CFU/mL	0/3	3/3
<i>Neisseria sp.</i>	> 1 x 10 ⁴ CFU/mL	0/3	3/3
<i>Pneumocystis jirovecii</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Pseudomonas aeruginosa</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Staphylococcus aureus</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Staphylococcus epidermidis</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Streptococcus salivarius</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Streptococcus pneumoniae</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
<i>Streptococcus pyogenes</i>	1.10 x 10 ⁶ CFU/mL	0/3	3/3
Measles	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Mumps	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Live RSV strain A	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Live RSV strain B	1.50 x 10 ⁵ TCID ₅₀ /mL	0/3	3/3
Human coronavirus HKU1	2.61 x 10 ⁶ GE/mL	0/3	3/3
Pooled Negative Swab Matrix (PNSM)	NA	0/3	0/3
3x Positive in PNSM	NA	NA	3/3

*Represents the same results for each of the three analytes. 0/3 and 3/3 represent 0 positive and 3 positive results respectively for all the three analytes tested.

**Results represent only for SARS-CoV-2 test line; Flu A and B test lines showed 0 positives for both Flu A and B.

b. Endogenous and Exogenous Interfering Substances Study:

Interfering substances studies were conducted to assess the effect on the performance of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test in the presence of potentially interfering substances that might be present in anterior nasal swab specimens. Each potentially interfering substance was tested in PNSM at the targeted initial concentrations in the absence (negative) and presence (positive) of co-spiked analytes (SARS-CoV-2, Flu A, and Flu B) at 3x LoD. Three (3) replicates were tested for each sample prepared using one lot of the candidate test kit. Interference (false positive results) was observed for FluMist

Quadrivalent Live Intranasal Influenza Virus Vaccine for Flu A and Flu B. No interference was observed for the remaining substances at the concentrations tested. The results of the endogenous and exogenous interference are summarized in Table 3.

Table 3: Potential Interfering Substances Study Results

Potential Interfering Substance	Concentration	Cross-Reactivity (without analyte) (# Positive / # Total)			Interference (with analyte) (# Positive / # Total)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Mucin	2.5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	3.0 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Naso GEL (NeilMed)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Corticosteroid (Dexamethasone)	1 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Nasal Corticosteroid (Triamcinolone)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Nasal gel (Galphimia glauca, Histanium hydrochloricum, Luffa operculata, Sulfur)	1.25 % v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic allergy relief (Histaminum hydrochloricum)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zicam Nasal Spray (Galphimia glauca, Luffa operculata)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Homeopathic Nasal Spray (Alkalol)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tobramycin	4 µg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Mupirocin	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
Anti-viral drug (Remdesivir)	10 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3

Potential Interfering Substance	Concentration	Cross-Reactivity (without analyte) (# Positive / # Total)			Interference (with analyte) (# Positive / # Total)		
		SARS-CoV-2	Flu A	Flu B	SARS-CoV-2	Flu A	Flu B
Fluticasone Propionate	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3	3/3	3/3	3/3
FluMist/ FluMist Live intranasal influenza virus vaccine 15%	15% v/v	0/3	3/3	3/3	NT*	NT*	NT*
FluMist/ FluMist Live intranasal influenza virus vaccine 1.5%	1.5% v/v	0/3	3/3	3/3	NT*	NT*	NT*
FluMist/ FluMist Live intranasal influenza virus vaccine 0.5%	0.5% v/v	0/3	3/3	0/3	NT*	NT*	NT*
FluMist/ FluMist Live intranasal influenza virus vaccine 0.25%	0.25% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Zanamivir	282 ng/mL	0/3	0/3	0/3	3/3	3/3	3/3
Zinc (Therazine throat spray)	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Body & Hand Lotion	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Body Lotion, with 1.2% dimethicone	0.5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Lotion	5% w/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% ethyl	5% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer cream lotion	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	0/3	0/3	0/3	3/3	3/3	3/3
Hand soap liquid gel	10% w/v	0/3	0/3	0/3	0/3	0/3	0/3
PNSM	/	0/3	0/3	0/3	0/3	0/3	0/3

*NT: Not Tested

c. Competitive Interference Study:

A competitive inhibition study was conducted to evaluate the potential for a high concentration of one target analyte to interfere with the detection of another target analyte at low concentration. Testing was performed with different combinations of low (3x LoD) and high concentrations (1000x LoD or the highest concentration achievable) of co-spiked virus (SARS-CoV-2, Flu A, and Flu B) solutions. All testing conditions were tested in 3 replicates using a single lot of the candidate test. No competitive interference was observed between SARS-CoV-2, Flu A, and Flu B as listed below in Table 4.

Table 4: Competitive Interference Study Results:

Test Conditions			Test Results (# Positive / # Total)		
Flu A	Flu B	SARS-CoV-2	Flu A	Flu B	SARS-CoV-2
High	Low	Neg	3/3	3/3	0/3
High	Neg	Low	3/3	0/3	3/3
High	Low	Low	3/3	3/3	3/3
Low	High	Neg	3/3	3/3	0/3
Neg	High	Low	0/3	3/3	3/3
Low	High	Low	3/3	3/3	3/3
Low	Neg	High	3/3	0/3	3/3
Neg	Low	High	0/3	3/3	3/3
Low	Low	High	3/3	3/3	3/3
PNSM			0/3	0/3	0/3

4. Detection Limit and Assay Reportable Range:

a. **Limit of Detection (LoD):**

i. *Single Analyte LoD:*

Analytical sensitivity studies were conducted to determine the limit of detection (LoD) for the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test. The LoD is defined as the lowest concentration at which 95% of the replicates tested are positive. A preliminary LoD was established independently for SARS-CoV-2, Flu A, and Flu B by testing serial ten-fold or two-fold dilutions of the viral stock diluted into negative clinical matrix (PNSM) and spiked onto sterile swabs. Three replicates were tested at each dilution. The LoD was confirmed by testing an additional 20 replicates with concentrations at the preliminary LoD or at concentrations below the preliminary LoD for each virus. The results of the LoD study are summarized in Table 5.

Table 5: Limit of Detection Study Results

Virus	LoD in PNSM	LoD per Swab	# Positive / # Total	% Detected
SARS-CoV-2 (USA-WA1/2020)	2.55x10 ² TCID ₅₀ /mL	1.28x10 ¹ TCID ₅₀ /swab	57/60	95.0%
Influenza A H1N1 (A/Indiana/02/2020)	3.64x10 ⁶ CEID ₅₀ /mL	1.82x10 ⁵ CEID ₅₀ /swab	57/60	95.0%
Influenza A H3N2 (A/Montana/08/2023)	4.88x10 ⁵ FFU/mL	2.44x10 ⁴ FFU/swab	57/60	95.0%
Influenza B Victoria (B/Washington/02/2019)	1.05x10 ⁶ CEID ₅₀ /mL	5.25x10 ⁴ CEID ₅₀ /swab	57/60	95.0%
Influenza B Yamagata (B/Phuket/3073/2013)	4.13x10 ⁵ CEID ₅₀ /mL	2.07x10 ⁴ CEID ₅₀ /swab	57/60	95.0%

ii. Co-Spike LoD:

A co-spike equivalency study was conducted to assess whether the co-spiked LoDs of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test are equivalent to the LoDs of the individually tested analytes. Co-spiked samples were prepared in PNSM and spiked with SARS-CoV-2, Flu A, and Flu B viruses either at 1x LoD or 0.3x LoD for all three assay analytes. For each concentration level, 20 replicates were tested. All replicates produced 100% positive results for each analyte at 1x LoD. As expected, the positive rate dropped at 0.3x LoD. Thus, there was no impact on the sensitivity when all analytes were co-spiked supporting the use of co-spiked samples in subsequent analytical studies.

iii. International Standard Material NIBSC code: 21/368 – Limit of Detection:

The LoD was established using the 1st International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in PNSM. Initially, a preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head in three replicates. Following this, a confirmatory LoD test with an additional 20 replicates was conducted at the preliminary LoD concentration. To determine LoD concentration, another 20 replicates of three targeted dilutions bracketing the LoD concentration (3x LoD, 1x LoD, and 1/3x LoD) were prepared in PNSM and tested. It was determined that the LoD of the 1st International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in PNSM was confirmed to be 2.50×10^2 IU/mL (1.25×10^1 IU/swab).

b. High Dose Hook Effect:

A High Dose Hook Effect study was conducted to determine if a hook effect (a false negative result) would be observed at high concentrations of the analytes. Undiluted stock of each virus (heat-inactivated SARS-CoV-2, Flu A H1N1, Flu A H3N2, Flu B Victoria lineage, and Flu B Yamagata lineage) was applied separately to the swab and tested in triplicate using a single candidate test lot. No hook effect was observed for any of the tested analytes as shown in Table 6 below.

Table 6: High Dose Hook Effect Study Results

Virus/Strain	Concentration	Conc. Units	# Positive / # Total		
			SARS-CoV-2	Flu A	Flu B
SARS-CoV-2: USA-WA1/2020	1.02E+08	TCID50/mL	3/3	0/3	0/3
Flu A H1N1pdm09: A/Indiana/02/2020	9.70E+08	CEID50/mL	0/3	3/3	0/3
Flu A H3N2: A/Montana/08/2023	2.60E+08	FFU/mL	0/3	3/3	0/3
Flu B Victoria: B/Washington/02/2019	2.10E+09	CEID50/mL	0/3	0/3	3/3

Virus/Strain	Concentration	Conc. Units	# Positive / # Total		
			SARS-CoV-2	Flu A	Flu B
Flu B Yamagata: B/Phuket/3073/2013	1.10E+09	CEID ₅₀ /mL	0/3	0/3	3/3

c. Inclusivity:

The inclusivity study was performed to determine if the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test can detect target analytes across a variety of strains by establishing analytical sensitivity for SARS-CoV-2 strains, Flu A strains, and Flu B strains on the candidate test kit. Studies were done by performing testing using one lot of the candidate device on a total of 1 SARS-CoV-2 strain, 20 Flu A strains, and 6 Flu B strains. Three replicates were tested per dilution for each virus. The lowest concentration in which all replicates tested positive was determined to be the analytical sensitivity. The results of the inclusivity study summarized in Table 7 below demonstrate that the test results can detect analytes across a range of viral strains.

Table 7: Inclusivity Study Results

Virus	Strain	Minimum Detectable Concentration
Influenza A (H1N1)	A/Brownsville/39H/2009	2.0 x 10 ² TCID ₅₀ /mL
	A/Massachusetts/15/2013	1.6 x 10 ⁶ CEID ₅₀ /mL
	A/Bangladesh/3002/2015	3.3 x 10 ⁵ CEID ₅₀ /mL
	A/Michigan/45/2015	5.0 x 10 ⁶ CEID ₅₀ /mL
	A/St. Petersburg/61/2015	9.3 x 10 ⁵ CEID ₅₀ /mL
	A/Hawaii/66/2019	1.9 x 10 ⁷ CEID ₅₀ /mL
	A/Wisconsin/588/2019	1.4 x 10 ⁴ FFU/mL
	A/Iowa/53/2015	2.9 x 10 ⁶ CEID ₅₀ /mL
	A/Idaho/07/2018	3.2 x 10 ² TCID ₅₀ /mL
	A/Dominican/Republic/7293/2013	5.0 x 10 ³ TCID ₅₀ /mL
	A/Ohio/09/2015 (H1N1)v	1.8 x 10 ⁶ CEID ₅₀ /mL
Influenza (H1N2)	A/Minnesota/19/2011 (H1N2)v	8.0 x 10 ⁶ CEID ₅₀ /mL
Influenza A (H3N2)	A/Hong Kong/2671/2019	3.1 x 10 ⁶ CEID ₅₀ /mL
	A/Singapore/INFIMH-16-0019/2016	1.1 x 10 ⁵ CEID ₅₀ /mL
	A/New York/21/2020	1.3 x 10 ⁵ FFU/mL
	A/Tasmania/503/2020	3.3 x 10 ⁴ FFU/mL
	A/Alaska/232/2015	6.5 x 10 ⁴ CEID ₅₀ /mL
	A/Indiana/08/2011 (H3N2)v	8.1 x 10 ² TCID ₅₀ /mL
Influenza A (H7N3)	A/northern pintail/Illinois/100S3959/2010 (H7N3)	3.5 x 10 ⁵ CEID ₅₀ /mL
Influenza A (H5N1)	A/mallard/Wisconsin/2576/2009 (H5N1)	4.0 x 10 ⁵ CEID ₅₀ /mL
Influenza B (non-Victoria non-Yamagata)	B/Maryland/1/1959	2.2 x 10 ¹ CEID ₅₀ /mL

Virus	Strain	Minimum Detectable Concentration
Influenza B (Victoria Lineage)	B/Colorado/6/2017	4.0×10^4 CEID ₅₀ /mL
	B/Florida/78/2015	4.3×10^5 CEID ₅₀ /mL
Influenza B (Yamagata Lineage)	B/Wisconsin/1/2010	3.5×10^1 TCID ₅₀ /mL
	B/Florida/4/2006	1.8×10^4 CEID ₅₀ /mL
	B/Texas/06/2011	1.6×10^6 CEID ₅₀ /mL
SARS-CoV-2 (B.1.1.529, Omicron)	USA/MD-HP20874/2021	2.5×10^2 TCID ₅₀ /mL

d. Assay Reportable Range:

Not applicable; the device is a binary qualitative assay that is visually read.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. Controls:

i. Internal Controls:

Each CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test has a built-in “Control” region which serves as an internal procedural control indicated by the presence of a colored line in the control line region (“C line”). The “C line” should always appear if the test has been performed properly.

ii. External Controls:

External quality control materials are not included in the test kit but are available separately for optional use by professional users.

b. Stability:

i. Real-time Stability:

A real-time stability study was conducted to establish the shelf-life of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test. Three different lots were stored at four conditions 2°C, 15°C, 30°C and RT, and were tested at 3-month intervals from time 0 (within one month after production of the three device lots included in the study) up to 27 months. The testing panel consisted of a negative sample and a positive sample with co-spiked analytes at 2x LoD. The samples were prepared in pooled nasal wash matrix. Each sample was tested in five replicates across all three lots stored at specified storage duration. At the time of clearance, all study data met the protocol defined acceptance criteria and support storage of the test kits from 2-30°C for up to 24 months.

ii. Open-kit Stability:

An open-kit stability study was conducted to determine the stability of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test kit when left outside of its packaging. A test panel comprised of five (5) PNSM only negative control samples and five (5) low positive (2x LoD co-spiked) contrived samples were tested at zero (0) hours, one (1) hour, and two (2) hours after the device packaging was opened, with the one-hour and two-hour storage taking place at the worst-case condition for room temperature (i.e., $30 \pm 3^\circ\text{C}$). A single lot of the candidate test kit was used in the study. Results were acceptable for all conditions tested.

iii. Shipping Stability:

The purpose of this study was to evaluate the stability of the unopened CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test kit under extreme summer and winter temperature and humidity conditions that may be encountered during the shipping and handling of the test. A single test lot was exposed to simulated extreme summer shipping temperature and humidity condition (60°C and 85% RH) over an 8-day period with testing occurring every 24 hours and winter shipping temperature conditions (-10°C for 8 hrs and 18°C for 4 hrs) with testing occurring at the end of entire 12-hr simulation. Performance was assessed pre- (T0) and post-distribution (Td) across five replicates of PNSM negative sample and co-spiked moderate positive (5x LoD) sample contrived in PNSM. The test kit was stable at all shipping conditions tested.

6. Assay Cut-Off:

Not applicable as this is a qualitative visually read assay without numeric data.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See section C (clinical studies) below.

2. Matrix Comparison:

Not Applicable, the device only uses one matrix (i.e., anterior nasal swab). However, a matrix equivalency study was conducted between pooled negative nasal swab matrix (PNSM) and surrogate pooled negative nasal wash matrix (PNW) that was used in multiple analytical studies. The data demonstrated the equivalent performance of the test with both matrices.

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

A prospective clinical study to assess the performance of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test for the detection of SARS-CoV-2, Flu A, and Flu B protein antigens in self-collected anterior nasal swab samples when compared to an FDA cleared RT-PCR assay was conducted from April 2025 to May 2026 at seven (7) sites throughout the United States. Subjects who exhibited symptoms of infection consistent with COVID-19 or influenza at the time of collection were enrolled in the clinical study.

A total of A total of 632 subjects were enrolled in the study, of which 606 subjects were evaluable within 5 days post symptoms onset (DPSO). The subjects enrolled either self-collected a dual anterior nares sample or had a dual anterior nares sample collected from him/her by another individual for testing. A matched anterior nasal swab sample was also taken from each subject by a healthcare professional for testing on a highly sensitive, FDA 510(k) cleared RT PCR test as the comparator.

The subject demographics are shown in Table 8 below.

Table 8: Subject Demographics

	Subjects by lay-user (Tester) collection and testing (N=150)	Self-collecting and testing (N=456)	Overall (N=606)
Age: Mean (SD)	11.8 (12.9)	40.8 (17.9)	33.6 (20.9)
Age: Median [Min, Max]	9 [2, 83]	38 [14, 95]	30 [2, 95]
Age Group			
2 - <14 years of age	126 (84.0%)	0 (0.0%)	126 (20.8%)
14-21 years of age	12 (8.0%)	64 (14.0%)	76 (12.5%)
22-64 years of age	10 (6.7%)	338 (74.1%)	348 (57.4%)
≥65 years of age	2 (1.3%)	54 (11.8%)	56 (9.2%)
Sex at Birth*			
Male	86 (57.3%)	159 (34.9%)	245 (40.4%)
Female	64 (42.7%)	296 (64.9%)	360 (59.4%)
Ethnicity			
Hispanic/Latino	64 (42.7%)	112 (24.6%)	176 (29.0%)
Not Hispanic/Latino	81 (54.0%)	315 (69.1%)	396 (65.3%)
Unknown/Prefer not to answer	5 (3.3%)	29 (6.4%)	34 (5.6%)
Race			
American Indian or Alaskan Native	2 (1.3%)	5 (1.1%)	7 (1.2%)
Asian	19 (12.7%)	77 (16.9%)	96 (15.8%)
Black or African American	16 (10.7%)	89 (19.5%)	105 (17.3%)
Native Hawaiian/Pacific Islander	0 (0.0%)	1 (0.2%)	1 (0.2%)
White	59 (39.3%)	235 (51.5%)	294 (48.5%)
Unknown/Prefer not to answer	14 (9.3%)	19 (4.2%)	35 (5.4%)
Other (Mixed race/biracial)	40 (26.7%)	30 (6.6%)	70 (11.6%)

*One subject preferred not to answer sex at birth

The performance of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test when compared to the FDA cleared highly sensitive RT-PCR molecular assays are presented in the tables below.

Table 9: SARS-CoV-2 Clinical Performance

	Comparator Positive	Comparator Negative	Total
Candidate Positive	47	0	47
Candidate Negative	4	555	559
Total	51	555	606
Positive Percent Agreement (PPA) = (47/51) = 92.2% (95% CI: 81.5% - 96.9%)			
Negative Percent Agreement (NPA) = (555/555) = 100.0% (95% CI: 99.3% - 100.0%)			

Table 10: Influenza A Clinical Performance

	Comparator Positive	Comparator Negative	Total
Candidate Positive	45	1	46
Candidate Negative	7	553	560
Total	52	554	606
Positive Percent Agreement (PPA) = (45/52) = 86.5% (95% CI: 74.7% - 93.3%)			
Negative Percent Agreement (NPA) = (553/554) = 99.8% (95% CI: 99.0% - 100.0%)			

Table 11: Influenza B Clinical Performance

	Comparator Positive	Comparator Negative	Total
Candidate Positive	31	0	31
Candidate Negative	5	570	575
Total	36	570	606
Positive Percent Agreement (PPA) = (31/36) = 86.1% (95% CI: 71.3% - 93.9%)			
Negative Percent Agreement (NPA) = (570/570) = 100.0% (95% CI: 99.3% - 100.0%)			

2. Clinical Cut-Off:

Not Applicable. The candidate device is a qualitative assay with a visually read binary result without numeric raw data.

3. Usability and Readability Study:

a. Usability and User Comprehension Study:

A total of 55 evaluable subjects participated in the human factors assessment portion of the study to evaluate the usability of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test, and to evaluate the labeling and comprehension of the investigational test QRI, when performed by lay users in a simulated home environment.

Evaluation of the human user experience indicated high usability of the investigational test. Of the 55 subjects who participated in the usability and comprehension assessment, 53 (96.4%) found the instructions clear and easy to follow, 54 (98.2%) found the sample collection easy to perform, and all subjects had no difficulty reading the test results. Overall, 99.5% of all critical tasks associated with sample collection and running the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test kit were performed correctly. Among all non-critical tasks, 98.8% were performed correctly as shown in Table 12 below.

Table 12: Critical vs Non-critical Tasks Correctly Performed

Steps	Tasks performed correctly	Total number of tasks	Percentage of tasks performed correctly
Critical	438	440	99.5%
Non-Critical	163	165	98.8%
Total	601	605	99.3%

b. Readability Study:

All 55 subjects who participated in the human factors assessment also interpreted a panel of mock investigational tests with various results that reflected test concentration levels at 1.9x and 5x LoD in a blinded and randomized fashion.

An overall mock result interpretation accuracy of 98.2% across negative, invalid, and positive test results at both 1.9x LoD and 5x LoD was observed, indicating that lay users were able to correctly interpret test results, including low-intensity positive results. Thus, the readability study results are acceptable.

D Other Supportive Study/Device Information**1. Flex Studies:**

To assess the robustness and risk for false results of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (sample volume, reading time, other deviations from the procedure [delay in mixing, delay in addition of sample to the well, incubation time] and variability of environmental test conditions that the test may be subjected to when in use (lighting, disturbance during use, temperature and humidity stress conditions). Testing was performed with negative samples and contrived positive samples generated by diluting viruses into PNSM at a co-spiked concentration of 2x LoD. False results are observed with reading at less than 8 minutes, and the use of only 1 drop of extracted sample for testing. Thus, the studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

E Expected Values/Reference Range:

A patient sample is expected to be negative for influenza A, influenza B, and SARS-CoV-2.

VI Proposed Labeling:

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

VII Conclusion:

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