CorDx

CorDx

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

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use

For use with anterior nasal swab specimens

INSTRUCTIONS FOR USE (IFU)

For technical support, please email Support@CorDx.com or contact 858-999-1582.

1. INTENDED USE

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.

This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the identification and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A, and influenza B infection.

Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 and/or influenza infection and should seek follow-up care with their physician or healthcare provider.

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. SUMMARY AND EXPLANATION

Influenza is a highly contagious, acute viral infection of the respiratory tract with symptoms such as headache, chills, dry cough, body aches or fever. It is a communicable disease that is easily transmitted through aerosolized droplets containing live virus from coughing and sneezing. The causative agents of the disease are immunologically diverse single strand RNA viruses known as influenza viruses. Influenza type A viruses are typically more prevalent than influenza type B viruses and are associated with most known influenza epidemics, while influenza type B

infections are usually milder. Diagnosis is difficult because the initial symptoms are like those caused by other infectious agents.

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is based by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals with COVID-19 may have a range of symptoms including fever and/or symptoms of acute respiratory illness (i.e. cough, dyspnea) although some individuals experience mild symptoms or are asymptomatic. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

Accurate diagnosis and prompt treatment of patients infected with SARS-CoV-2 and influenza virus can have a positive effect on public health.

3. PRINCIPLE OF THE TEST

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test is a rapid, immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 nucleocapsid protein and Influenza A and B proteins in anterior nasal swab specimens.

The test strip enclosed in a 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. 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 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.

4. REAGENTS AND MATERIALS PROVIDED

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test kit configurations are indicated below:

Components	1 test/kit	2 tests/kit	4 tests/kit	5 tests/kit	8 tests/kit	10 tests/kit	20 tests/kit	25 tests/kit
Test cassette	1	2	4	5	8	10	20	25
Swab	1	2	4	5	8	10	20	25
Tube with sample processing solution	1	2	4	5	8	10	20	25
Quick reference instructions (QRI)	1	1	1	1	1	1	1	1

5. MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, timer or stopwatch

6. WARNINGS AND PRECAUTIONS AND SAFETY INTERPRETATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in symptomatic individuals with SARS-CoV-2 negative results at least twice over three days (with 48 hours between tests) . You may need to purchase additional tests to perform this serial (repeat) testing.**
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use.
- Do not use the test kit after its expiration date.
- Do not touch swab tip when handling the swab.
- Exposure to hand sanitizer may cause false positive results with this test.
- When collecting a sample, only use the swab provided in the kit.
- Once opened, the test cassette should be used within 60 minutes. If the pouch is open for more than an hour, invalid test results may occur.
- Testing should be performed in an area with good lighting.
- **Do not read test results before 10 minutes or after 30 minutes. Results read before 10 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- **Faint lines may appear on the test strip prior to running the test when tests are stored opened at hot and humid conditions. Do not read or interpret test results until after the sample has been added to the test cassette and the test has been allowed to run for 10 minutes.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Hazard Category (mixture)	GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
3	Mild skin irritation	Cause mild skin irritation (H316)	• Triton X-100 / 0.5% • Proclin 300 / 0.05%	N/A

- For more information on EUAs please visit: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization**.
- For the most up to date information on COVID-19, please visit: **www.cdc.gov/COVID19**

7. STORAGE AND STABILITY

Store the test kit between 36~86°F (2~30°C) in a place out of direct sunlight. Reagents and materials must be used at room temperature (59~86°F/15~30°C). The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is labeled on the package.

8. QUALITY CONTROL

Each CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid 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.

9. TEST PROCEDURES

TEST PRE-CAUTIONS

- Only the components provided in the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test kit should be used.
- Transport media should not be used.
- It is recommended to use the test kit immediately after opening. The unsealed cassette is valid for 1 hour. Once the sample has been collected, it should be processed within 1 hour.

PREPARING FOR THE TEST

(1) Read all the instructions before you start the test.

(2) **Check the test's expiration date (EXP).**
Do not use an expired test.

(3) Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
(4) Use a flat level surface (such as a table or countertop) for testing.
(5) Use a timer during the test.
(6) Make sure you have all the test components before you begin.
(7) Bring test kit to room temperature (59~86°F /15~30°C).
(8) Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

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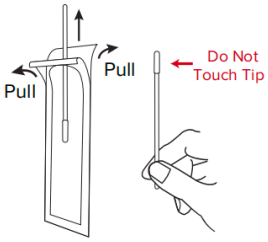
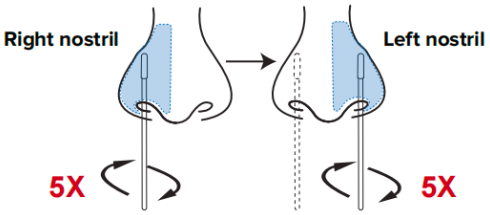
STEP 1: COLLECT SAMPLE



(1) Remove the swab from the pouch.
Note: Be careful not to touch the swab tip (soft end) with your hand.

(2) Insert the entire soft end of the swab into the nostril no more than 3/4 of an inch (1.5 cm).
Firmly and slowly rotate the swab 5 times, brushing against the inside walls of the nostril to ensure both mucus and cells are collected.

- Do not push the swab further if you meet resistance.
- For young children do not insert more than 1/2 inch.



Using the **same swab**, repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils.

STOP

Did you swab BOTH nostrils?
Inaccurate test results may occur if the nasal sample is not properly collected.

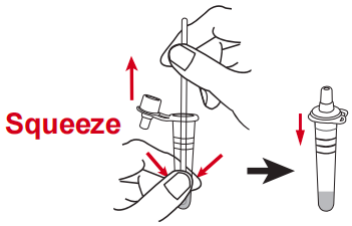
STEP 2: PROCESS SAMPLE

(3) Insert the swab into the tube until it touches the bottom.

Rotate the swab at least **10 times** while pressing the swab head against the bottom and side of the tube.

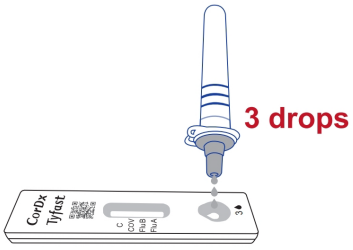
(4) Remove the swab while squeezing the sides of the tube.

Attach the dropper tip firmly onto the tube.



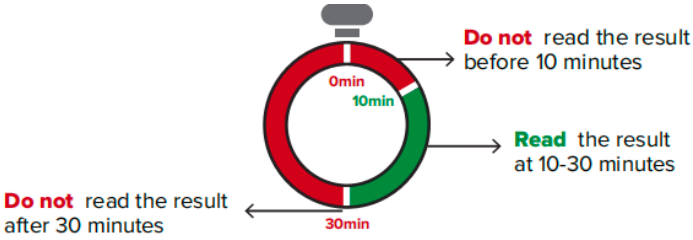
STEP 3: ADD SAMPLE

(5) Slowly squeeze the tube and dispense 3 drops of solution into the sample well.
Note: Invalid results can occur if less than 3 drops are added to the sample well.



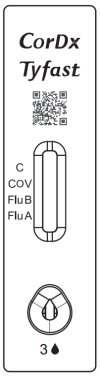
STEP 4: READ RESULT

(6) Wait 10 minutes.
Read the result after 10 minutes but before 30 minutes.



Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

10. INTERPRETATION OF RESULTS

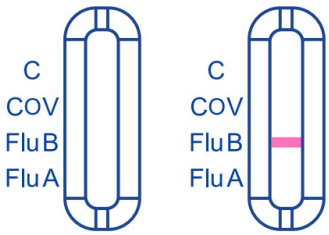


C =Control line

COV = COVID-19 line
Flu B = Influenza B line
Flu A = Influenza A line

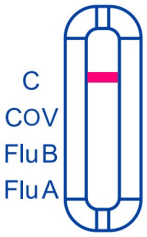
Look for lines next to C, COV, Flu B, and Flu A.
FOR EASE OF USE, HOLD TEST CASSETTE NEXT TO THE IMAGES BELOW

INVALID RESULT



If the control line (C) is not visible the test is **invalid**, even if any test line is visible. Re-test with a new swab and new test device.

NEGATIVE RESULT



If the control line (C) is visible, but no other lines appear the test is **negative**.

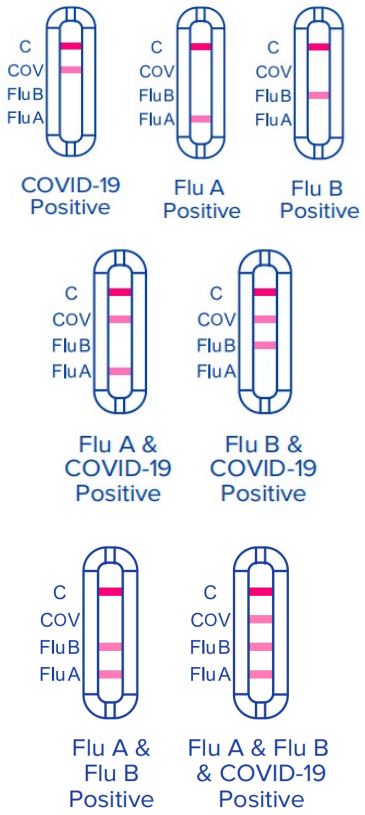
COVID-19 Negative Result

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

If you still have COVID-19, Flu B, Flu A, or symptoms, you should seek follow-up care with your healthcare provider.

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected

	exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
POSITIVE RESULT 	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. **NOTE:** Any red line, no matter how faint, should be considered an indication of a positive result. **COVID-19 Positive Result:** **Repeat testing does not need to be performed if you have a positive result at any time.** **Dual Positive Result:** **It is possible to have more than one positive test line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one positive test line is observed, retest with a new sample and new test kit. If you continue to have a "dual positive" result, you should contact your healthcare provider to be tested with a molecular assay to confirm your results.** *A positive test result means that the virus that causes COVID-19, Flu A and/or Flu B virus(es) was detected in the sample, and it is very likely you have the respective infection(s) and are contagious. Please contact your doctor/primary care physician and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).* *Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. If you tested positive with the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test, you should self-isolate and seek follow-up care with your physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.*

Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing**	**Day 2 (Second Test)**	**Final Interpretation**
SARS-CoV-2 (+) Influenza A and/or B (-)	NO	Not needed	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 * Positive for Influenza A and/or B *
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (-)	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 * Positive for Influenza A and/or B *
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 * Positive for Influenza A and/or B *
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 * Positive for Influenza A and/or B *

**It is possible to have more than one positive test line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one positive test line is observed, retest with a new sample and new test kit. If you continue to have a "dual positive" result, you should contact your healthcare provider to be tested with a molecular assay to confirm your results.*

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

11. LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2023 and February 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 and Influenza as compared to a molecular test, especially in samples with low viral load.
- All antigen test negative results, for SARS-CoV-2 or influenza, are presumptive and confirmation with a molecular assay may be necessary.

- If the individual continues to have symptoms of COVID-19 or Influenza, and both the individual's first and second tests are negative, the individual may not have COVID-19 or Influenza infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that causes COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with COVID-19 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exist. Wet testing with HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- False results due to cross-reactivity between Influenza B and SARS-CoV-2 can occur with this test at high viral loads/titers. If your test is positive for both SARS-CoV-2 and Influenza B, follow up testing with a molecular test (RT-PCR) should be performed by your healthcare provider to confirm results.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2 and influenza. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

12. PERFORMANCE CHARACTERISTICS

12.1 Limit of Detection (LoD) - Analytical Sensitivity

A preliminary LoD was first determined by three (3) replicates tested a serial of samples with ten-fold or two-fold dilutions (were diluted in Pooled Negative Swab Matrix (PNSM)) of gamma irradiated SARS-CoV-2 (USA-WA1/2020), Influenza A H1N1, Influenza A H3N2, Influenza B Victoria lineage, and Influenza B Yamagata lineage. The isolate dilutions were tested by adding fifty (50) µL to the head of the nasal swab and extracting the swab per the instructions for use. The LoD was confirmed by testing twenty (20) replicates at the preliminary LoD for each target analyte.

The First WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of SARS-CoV-2 antigen.

Virus	LoD in PNSM	LoD per Swab	Positive Replicates (n=20)
SARS-CoV-2	4.0×10^2 $TCID_{50}$/mL	2.0×10^1 $TCID_{50}$/swab	20/20
Influenza A H1N1	2.4×10^7 $CEID_{50}$/mL	1.2×10^6 $CEID_{50}$/swab	20/20
Influenza A H3N2	2.6×10^5 $CEID_{50}$/mL	1.3×10^4 $CEID_{50}$/swab	20/20
Influenza B Victoria	4.2×10^6 $CEID_{50}$/mL	2.1×10^5 $CEID_{50}$/swab	20/20
Influenza B Yamagata	3.7×10^4 $CEID_{50}$/mL	1.8×10^3 $CEID_{50}$/swab	20/20
WHO Standard (NIBSC 21/368)	2.5×10^2 IU/mL	1.25×10^1 IU/swab	20/20

12.2 Inclusivity (Analytical Reactivity)

For SARS-CoV-2:

The inclusivity of the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test in detecting currently available SARS-CoV-2 variants, e.g. Alpha B1.1.7, SARS-CoV-2 (USA-WA1/2020), Brazil P.1, Beta B.1.351, Delta B.1.617.2, Omicron B.1.1.529, Omicron XBB, and B.1.595, was determined as assessed by its Limit of Detection. Serially diluted heat-irradiated SARS-CoV-2 variants (obtained from commercial sources) were spiked into Pooled Negative Swab Matrix (PNSM) to determine the LoD for each tested variant using one lot of tests.

Based on the results, the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test detects SARS-CoV-2 variants with LoD at the concentrations tested. The assay can detect these variants near the LoD of the original SARS-CoV-2 virus and thus displaying comparable sensitivity and acceptable inclusivity for the variants tested.

SARS-CoV-2 Variant	Concentration ($TCID_{50}$/ mL)	SARS-CoV-2 Variant	Concentration ($TCID_{50}$/ mL)
Alpha B1.1.7	5×10^3	Delta B.1.617.2	6.25×10^2
USA-WA1/2020	1.25×10^3	Omicron B.1.1.529	6.25×10^2
Brazil P.1	1×10^4	Omicron XBB	5×10^3
Beta B.1.351	5×10^3	B.1.595	7.813×10^1

For Influenza A & Influenza B:

A selection of temporal, geographic and genetically diverse Influenza strains were tested. An abbreviated LoD study was conducted on a total of 20 Influenza A strains, 5 Influenza B strains and by testing a series of ten-fold dilutions of each virus spiked into PNSM with the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test. All strains exhibited established Limits of Detection (LoD), confirming the assay's capability to detect target analytes across a diverse range of strains, as following:

Virus	Strain	LoD
Influenza A (H1N1)	A/Brownsville/39H/2009	4.0×10^2 $TCID_{50}$/mL
	A/Massachusetts/15/2013	4.0×10^6 $CEID_{50}$/mL
	A/Bangladesh/3002/2015	6.5×10^5 $CEID_{50}$/mL
	A/Michigan/45/2015	2.5×10^7 $CEID_{50}$/mL
	A/St. Petersburg/61/2015	2.3×10^6 $CEID_{50}$/mL
	A/Hawaii/66/2019	7.4×10^7 $CEID_{50}$/mL
	A/Wisconsin/588/2019	2.8×10^4 FFU/mL
	A/Dominican/Republic/7293/2013	1.3×10^4 $TCID_{50}$/mL
	A/Iowa/53/2015	7.3×10^6 $CEID_{50}$/mL
	A/Idaho/07/2018	1.6×10^3 $TCID_{50}$/mL
Influenza A (H3N2)	A/New York/21/2020	2.6×10^5 FFU/mL
	A/Tasmania/503/2020	1.3×10^5 FFU/mL
	A/Hong Kong/2671/2019	6.2×10^6 $CEID_{50}$/mL
	A/Singapore/INFIMH-16-0019/2016	2.2×10^5 $CEID_{50}$/mL

Virus	Strain	LoD
	A/Hong Kong/45/2019	1.5 x 10^4 FFU/mL
	A/Ohio/09/2015 (H1N1v)	7.0 x 10^6 $CEID_{50}$/mL
	A/Minnesota/19/2011 (H1N2v)	4.0 x 10^7 $CEID_{50}$/mL
	A/Indiana/08/2011 (H3N2v)	2.0 x 10^3 $TCID_{50}$/mL
	A/northern pintail/Illinois/10OS3959/2010 (H7N3)	1.4 x 10^6 $CEID_{50}$/mL
	A/mallard/Wisconsin/2576/2009 (H5N1)	8.0 x 10^5 $CEID_{50}$/mL
Influenza B (Victoria Lineage)	B/Colorado/6/2017	1.6 x 10^5 $CEID_{50}$/mL
	B/Florida/78/2015	8.5 x 10^5 $CEID_{50}$/mL
Influenza B (Yamagata Lineage)	B/Texas/06/2011	4.0 x 10^6 $CEID_{50}$/mL
	B/Wisconsin/1/10	7.05 x 10^1 $TCID_{50}$/mL
Influenza B (non-Victoria non-Yamagata)	B/Maryland/1/1959	8.9 x 10^1 $CEID_{50}$/mL

12.3 Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross Reactivity and Microbial Interference studies were conducted to determine if other respiratory pathogens/flora that could be present in a direct nasal swab samples could cause a false-positive test result or interfere with a true positive result. A panel of viruses, bacteria, fungi, and pooled nasal wash was used for these studies. Final target organism concentrations were $\geqslant$1.43 x 10^5 $TCID_{50}$/mL, 1.00 x 10^5 PFU/mL, or 1.43 x 10^5 $CEID_{50}$/mL for viruses, and $\geqslant$1.00 x 10^6 CFU/mL or $\geqslant$1.00 x 10^6 IFU/mL for bacteria and fungi. When the target concentration was not achievable due to the titer of the stock culture, the highest concentration possible was tested without dilution. For organisms for which a specific titer was not provided, it was assumed the stock concentration was 10^4 .

Cross-Reactivity

Dilutions for cross-reactivity testing were made in Pooled Negative Swab Matrix (PNSM). Each organism was tested in replicates of three (3) without SARS-CoV-2, Influenza A virus and Influenza B virus present in the sample.

No cross-reactivity was observed for any of the organisms tested, except for SARS-CoV which exhibited cross-reactivity when tested $\geqslant$ 7.90 x 10^1 $TCID_{50}$/mL. A titration of SARS-CoV was performed to find the concentration at which cross reactivity was no longer observed. Cross reactivity was no longer observed for SARS at 7.90 $TCID_{50}$/mL. These results are not unexpected in that the COVID-19 Ag Test targets the nucleocapsid protein which is present on both the SARS-CoV and SARS-CoV-2 viruses. Organisms that did not cause cross-reactivity were further evaluated for microbial interference.

Microbial Interference

For microbial interference testing, the 2 x organism solution was further mixed 1:1 with PNSM spiked with gamma irradiated SARS-CoV-2, live Influenza A, and live Influenza B in PNSM at 6 x LoD to achieve final concentrations of 1 x target organism and 3 x Co-spike LoD solution (SARS-CoV-2: 1 x LoD 4.00 x 10^2 $TCID_{50}$/mL; Influenza A: 1 x LoD 2.60 x 10^5 $CEID_{50}$/mL; Influenza B: 1 x LoD 3.70 x 10^4 $CEID_{50}$/mL).

SARS-CoV-2, Influenza A and Influenza B were detected in all samples tested in the presence of interfering organisms and proved no interferences with the organisms.

Organism	Concentration Tested for Cross Reactivity & Microbial Interference	Test results (# Pos/Total)	
		Cross Reactivity	Microbial Interference
Human coronavirus OC43	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus 229E	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Adenovirus (AV71)	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Adenovirus Type 7	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Cytomegalovirus	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Epstein Barr Virus	>2.5 x 10^3 $CEID_{50}$/mL	0/3	3/3
Human metapneumovirus 4 Type B2	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 1	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 2	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 3	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4b	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Enterovirus 68	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus A	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus B	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Rhinovirus	1.00 x 10^5 PFU/mL	0/3	3/3
Bordetella pertussis	>1 x 10^4 CFU/mL	0/3	3/3
Candida albicans	1.1 x 10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	0/3	3/3
Corynebacterium sp.	1.1 x 10^6 CFU/mL	0/3	3/3
Escherichia coli	>2.5 x 10^4 CFU/mL	0/3	3/3
Haemophilus influenzae	1.1 x 10^6 CFU/mL	0/3	3/3
Lactobacillus sp.	>1 x 10^4 CFU/mL	0/3	3/3
Legionella pneumophila	1.1 x 10^6 CFU/mL	0/3	3/3
Moraxella catarrhalis	1.1 x 10^6 CFU/mL	0/3	3/3
Mycoplasma pneumonia	1.1 x 10^6 CFU/mL	0/3	3/3
Mycobacterium tuberculosis	1.1 x 10^6 CFU/mL	0/3	3/3
Neisseria meningitidis	1.05 x 10^5 CFU/mL	0/3	3/3
Neisseria sp. (subflava)	>1 x 10^4 CFU/mL	0/3	3/3
P. jiroveci-S. cerevisiae	1.1 x 10^6 CFU/mL	0/3	3/3
Pseudomonas aeruginosa	1.1 x 10^6 CFU/mL	0/3	3/3
Staphylococcus aureus (Protein A Producer)	1.1 x 10^6 CFU/mL	0/3	3/3
Staphylococcus epidermidis	1.1 x 10^6 CFU/mL	0/3	3/3
Streptococcus salivarius	1.1 x 10^6 CFU/mL	0/3	3/3
Streptococcus pneumonia	1.1 x 10^6 CFU/mL	0/3	3/3
Streptococcus pyogenes	1.1 x 10^6 CFU/mL	0/3	3/3
Measles	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Mumps	1.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus MERS	1.51 x 10^5 $TCID_{50}$/mL	0/3	3/3
SARS-CoV	7.90 x 10^3 $TCID_{50}$/mL	3/3	N/A
	7.90 x 10^2 $TCID_{50}$/mL	3/3	N/A
	7.90 x 10^1 $TCID_{50}$/mL	3/3	N/A
	7.90 $TCID_{50}$/mL	0/3	3/3

The linear epitope cross-reactivity of HKU1 with SARS-CoV-2, Influenza A and Influenza B were investigated by In Silico Analysis. There is a very low expectation of cross-reactivity between the

SARS-CoV-2, Influenza A and Influenza B nucleoprotein with HKU1 viral proteins, however, cross-reactivity cannot be ruled out.

12.4 Competitive Interference

The competitive interference testing was performed with different combinations of low (3 x LoD) and high concentrations (the highest concentration achievable exceeding 10^5 PFU/mL, $CEID_{50}$/mL, or $TCID_{50}$/mL) of influenza A (H3N2), influenza B (Yamagata), and SARS-CoV-2 (WA1) to determine if the assay can detect target analytes across a variety of analyte concentration combinations. All testing conditions have been tested in 3 replicates.

False positive results were observed for two of three (2/3) replicates on Influenza B with a high SARS-CoV-2 concentration (666.67x), but no false positve result was observed on Influenza B with a lower SARS-CoV-2 concentration (500.33x).

Test Conditions			Results (# Pos/Total)		
Flu A	**Flu B**	**SARS-CoV-2**	**Flu A**	**Flu B**	**SARS-CoV-2**
333.33x	3x	Negative	3/3	3/3	0/3
333.33x	Negative	3x	3/3	0/3	3/3
333.33x	3x	3x	3/3	3/3	3/3
3x	666.67x	Negative	3/3	3/3	0/3
Negative	666.67x	3x	0/3	3/3	3/3
3x	666.67x	3x	3/3	3/3	3/3
3x	Negative	666.67x	3/3	2/3	3/3
Negative	3x	666.67x	0/3	3/3	3/3
3x	3x	666.67x	3/3	3/3	3/3
3x	Negative	500.33x	3/3	0/3	3/3
Negative	3x	500.33x	0/3	3/3	3/3
3x	3x	500.33x	3/3	3/3	3/3

Red text: False positive results.

12.5 Endogenous/Exogenous Interference Substances Studies

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. Negative specimens were evaluated in triplicate to confirm that the potentially interfering substances were not cross-reactive with the test. Specimens containing 3x single analyte LoD co-spiked solution were also evaluated in the presence of interfering substances in triplicate to confirm that SARS-CoV-2, influenza A and influenza B could still be detected.

Interfering substances testing was performed using a panel of endogenous and exogenous substances tested at concentrations recommended by the FDA.

The results showed that that the test device was not interfered by the substances at the concentrations tested.

Viruses unspiked

Potential Interfering Substance	Concentration Tested	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	4% v/v	0/3	0/3	0/3

Potential Interfering Substance	Concentration Tested	SARS-CoV-2	Flu A	Flu B
Mucin (Porcine Stomach, Type II)	0.50%	0/3	0/3	0/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	0/3	0/3	0/3
NasoGEL (NeilMed)	5% v/v	0/3	0/3	0/3
Nasal Drops (Phenylephrine)	15% v/v	0/3	0/3	0/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	0/3	0/3
Nasal Spray (Cromolyn)	15% v/v	0/3	0/3	0/3
Zicam	5% v/v	0/3	0/3	0/3
Homeopathic nasal wash (Alkalol)	10% v/v	0/3	0/3	0/3
Sore Throat Phenol Spray	15% v/v	0/3	0/3	0/3
Tobramycin	4 ug/mL	0/3	0/3	0/3
Mupirocin	10 mg/mL	0/3	0/3	0/3
Fluticasone Propionate	5% v/v	0/3	0/3	0/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	0/3	0/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine *	15% v/v	0/3	3/3	3/3
Zanamivir	282 ng/mL	0/3	0/3	0/3
Body and Hand Lotion	0.5% w/v	0/3	0/3	0/3
Body Lotion, with 1.2% Dimethicone	0.5% w/v	0/3	0/3	0/3
Hand Lotion	5% w/v	0/3	0/3	0/3
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	0/3	0/3	0/3
Hand Sanitizer Cream Lotion **	15% v/v	3/3	3/3	3/3
Hand Sanitizer, 80% Ethanol	15% v/v	0/3	0/3	0/3
Hand Soap Liquid Gel	10% w/v	0/3	0/3	0/3

** Interference (false positive results) was observed for FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine for influenza A and influenza B. Users who have received nasally administered vaccine recently should not use this test.*

*** Interference (false positive results) was observed for hand sanitizer cream lotions for SARS-CoV-2, influenza A, and influenza B. Users are directed to ensure that hands are dry before performing the test*

Viruses spiked

Potential Interfering Substance	Concentration Tested	SARS-CoV-2	Flu A	Flu B
Human Whole Blood (EDTA tube)	2% v/v	3/3	3/3	3/3
Mucin (Porcine Stomach, Type II)	0.50%	3/3	3/3	3/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	3/3	3/3	3/3
NasoGEL (NeilMed)	5% v/v	3/3	3/3	3/3
Nasal Drops (Phenylephrine)	15% v/v	3/3	3/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	3/3	3/3	3/3
Nasal Spray (Cromolyn)	15% v/v	3/3	3/3	3/3
Zicam	5% v/v	3/3	3/3	3/3

Potential Interfering Substance	Concentration Tested	SARS-CoV-2	Flu A	Flu B
Homeopathic nasal wash (Alkalol)	10% v/v	3/3	3/3	3/3
Sore Throat Phenol Spray	15% v/v	3/3	3/3	3/3
Tobramycin	4 ug/mL	3/3	3/3	3/3
Mupirocin	10 mg/mL	3/3	3/3	3/3
Fluticasone Propionate	5% v/v	3/3	3/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3	3/3	3/3
FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine	0.25% v/v	3/3	3/3	3/3
Zanamivir	282 ng/mL	3/3	3/3	3/3
Body and Hand Lotion	0.5% w/v	3/3	3/3	3/3
Body Lotion, with 1.2% Dimethicone	0.5% w/v	3/3	3/3	3/3
Hand Lotion	5% w/v	3/3	3/3	3/3
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	3/3	3/3	3/3
Hand Sanitizer Cream Lotion	1.75% v/v	3/3	3/3	3/3
Hand Sanitizer, 80% Ethanol	15% v/v	3/3	3/3	3/3
Hand Soap Liquid Gel	10% w/v	3/3	3/3	3/3

12.6 High Dose Hook Effect

No hook effect was observed for any of the tested analytes. However, false positive results were observed when testing SARS-CoV-2 and Influenza B Victoria.

Spike Analyte	Concentration	SARS-CoV-2	Flu A	Flu B
SARS-CoV-2 Neat	7.9×10^5 $TCID_{50}$/mL	3/3	0/3	3/3
SARS-CoV-2 1:2	4.0×10^5 $TCID_{50}$/mL	3/3	0/3	2/3
SARS-CoV-2 1:4	2.0×10^5 $TCID_{50}$/mL	3/3	0/3	0/3
Influenza A H1N1 Neat	9.7×10^8 $CEID_{50}$/mL	0/3	3/3	0/3
Influenza A H3N2 Neat	2.6×10^8 $CEID_{50}$/mL	0/3	3/3	0/3
Influenza B Victoria Neat	2.1×10^9 $CEID_{50}$/mL	3/3	0/3	3/3
Influenza B Victoria 1:2	1.1×10^9 $CEID_{50}$/mL	0/3	0/3	3/3
Influenza B Yamagata Neat	7.3×10^7 $CEID_{50}$/mL	0/3	0/3	3/3

Red text: False positive results.

13. Clinical Study

A prospective study was completed at five sites in the United States for clinical validation of the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test for the detection of the SARS-CoV-2/Flu A/Flu B in anterior nasal (AN) swab samples from September 2023 to February 2024. The study evaluated the candidate test's performance in symptomatic individuals (those suspected of COVID-19/Flu A/Flu B).

A total of 756 subjects were enrolled in the study, of which 748 subjects were evaluable within 5 days post symptoms onset (DPSO). The subjects enrolled either self-collected a dual anterior nares (AN) sample or had a dual AN sample collected from him/her by another individual for testing.

A matched nasal swab sample was also taken from each study subject by a healthcare professional for testing on a high-sensitivity, FDA 510(k)-cleared RT PCR method as the comparator.

Test results from the investigational test were compared to highly sensitive molecular FDA 510(k)-cleared SARS-CoV-2/Flu A/Flu B assay to determine the test performance.

Subject Demographics

	Subjects (by lay-user collection and testing) (N=75)	Subjects (Self-collecting and testing) (N=673)	Overall (N=748)
Age			
Mean (SD)	8.3 (5.5)	42.5 (16.3)	39.1 (18.7)
Median [Min, Max]	8 [2, 34]	40 [14, 90]	38 [2, 90]
Age Group			
≥2-<14 years of age	70 (93.3%)	0 (0.0%)	70 (9.4%)
14-24 years of age	3 (4.0%)	87 (12.9%)	90 (12.0%)
>24-64 years of age	2 (2.7%)	513 (76.2%)	515 (68.9%)
≥65 years of age	0 (0.0%)	73 (10.8%)	73 (9.8%)
Sex at Birth			
Female	40 (53.3%)	420 (62.4%)	460 (61.5%)
Male	35 (46.7%)	253 (37.6%)	288 (38.5%)
Ethnicity			
Hispanic/Latino	48 (64%)	409 (60.8%)	457 (61.1%)
Not Hispanic/Latino	27 (36%)	263 (39.1%)	290 (38.8%)
Unknown/Prefer not to answer	0 (0%)	1 (0.1%)	1 (0.1%)
Race			
American Indian or Alaskan Native	0 (0.0%)	1 (0.1%)	1 (0.1%)
Asian	4 (5.3%)	12 (1.8%)	16 (2.1%)
Black or African American	6 (8.0%)	78 (11.6%)	84 (11.2%)
Native Hawaiian/Pacific Islander	0 (0.0%)	1 (0.1%)	1 (0.1%)
White	64 (85.3%)	572 (85.0%)	636 (85.0%)
Unknown/Prefer not to answer	1 (1.3%)	2 (0.3%)	3 (0.4%)
Other (Mixed race/biracial)	0 (0.0%)	7 (1.0%)	7 (0.9%)

SARS-CoV-2: Multiplex Rapid Test (Candidate) results vs. Comparator results

	Comparator Positives	Comparator Negatives	Total
Candidate Positives	98	1	**99**
Candidate Negatives	12	637	**649**
Total	**110**	**638**	**748**
Positive Percent Agreement (PPA) = (98/110) = 89.1% (95% CI: 81.9% - 93.6%)			
Negative Percent Agreement (NPA) = (637/638) = 99.8% (95% CI: 99.1% - 100%)			

SARS-CoV-2: Subjects on Days Post-Symptom Onset

Days post COVID-19 Symptoms Onset	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA
Day 0	5	1	2	40.0%	**50.0%**
Day 1	166	13	17	10.2%	**76.5%**
Day 2	237	25	27	11.4%	**92.6%**
Day 3	190	24	29	15.3%	**82.8%**
Day 4	109	25	25	22.9%	**100.0%**
Day 5	41	10	10	24.4%	**100.0%**
Total	**748**	**98**	**110**	**14.7%**	**89.1%**

Flu A: Multiplex Rapid Test (Candidate) results vs. Comparator results

	Comparator Positives	Comparator Negatives	Total
Candidate Positives	46	8	**54**
Candidate Negatives	9	684	**693**
Total	**55**	**692**	**747***
Positive Percent Agreement (PPA) = (46/55) = 83.6% (95% CI: 71.7% - 91.1%)			
Negative Percent Agreement (NPA) = (684/692) = 98.8% (95% CI: 97.7% - 99.4%)			

**1 Subject was unevaluable and excluded for Flu A analysis due to incorrect transport media used for sample collection.*

Flu B: Multiplex Rapid Test (Candidate) results vs. Comparator results

	Comparator Positives	Comparator Negatives	Total
Candidate Positives	27	1	**28**
Candidate Negatives	3	716	**719**
Total	**30**	**717**	**747***
Positive Percent Agreement (PPA) =(27/30) = 90.0% (95% CI: 74.4% - 96.5%)			
Negative Percent Agreement (NPA) = (716/717) = 99.9% (95% CI: 99.2% - 100%)			

**1 Subject was unevaluable and excluded for Flu B analysis due to incorrect transport media used for sample collection.*

14. SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2023 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 tests 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 symptomatic individuals is described in the table 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 the 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%)
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.

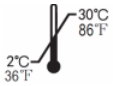
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

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.

15. TECHNICAL SUPPORT

For technical support, please email Support@CorDx.com or contact 858-999-1582.

16. SYMBOLS

	Do not re-use		Keep dry
	Store at 36~86℉/2~30℃		Keep away from sunlight
	Catalogue number		Consult instructions for use
	Manufacturer		Do not use if package is damaged and consult instructions for use

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