CorDx Tyfast COVID-19 Ag Rapid Test

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 **+1-800-711-5355**.

1. 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.

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.

IMPORTANT! How to Use This Test

- **Do not use this test when you have symptoms for more than 5 days or if you have no symptoms.**
- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

2. EXPLANATION OF THE TEST

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.

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. The test kit includes the: test cassette, swab, tube with sample processing solution, tube holder (back of the box) and the user instructions.

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.

3. MATERIALS AND REAGENTS PROVIDED

The CorDx Tyfast COVID-19 Ag Rapid Test kit configurations are indicated below:

Reagent/Material	2 tests/kit	4 tests/kit	5 tests/kit	8 tests/kit	10 tests/kit	12 tests/kit	20 tests/kit
Test cassette	2	4	5	8	10	12	20
Swab	2	4	5	8	10	12	20
Tube with sample processing solution	2	4	5	8	10	12	20
Tube holder (back of box)	2	2	2	2	2	2	2
Quick reference instructions (QRI)	1	1	1	1	1	1	1

4. MATERIALS REQUIRED BUT NOT PROVIDED

Timer or clock

5. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- **Do not use this test when you have symptoms for more than 5 days or if you have no symptoms.**
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- If you skipped or incorrectly performed one or more steps, repeat the test with a new sample and cassette.

- This product is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- 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.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Once opened, the test card should be used within 60 minutes.
- 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.
- If uncertain how to proceed, contact Technical Assistance at **Support@CorDx.com.**
- When collecting an anterior nasal swab sample, only use the swab provided in the kit.
- Inadequate or inappropriate specimen collection may yield false negative test results.
- Testing should be performed in an area with good lighting.
- If you are prescribed eye-glasses or contact lenses for vision correction, you must wear them when performing and interpreting the test.
- Dispose of all materials in household waste.
- **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 as compared to a molecular test, especially in samples with low viral load.**
- 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*.**

Chemical Name	Harms (GHS Code) for each ingredient	Concentrations
Triton X-100	Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H318)	0.5%
ProClin 300	Harmful if swallowed (H302) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%
EDTA-$Na_2 \cdot 2H_2O$	Harmful if swallowed (H302) May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled (H373)	0.5%

- For the most up to date information on COVID-19, please visit: *www.cdc.gov/COVID19*

6. STORAGE AND STABILITY

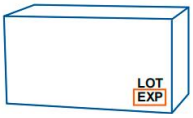
Store the CorDx Tyfast COVID-19 Ag Rapid Test between 36-86°F (2-30°C) in a place out of direct sunlight and out of reach of children. Reagents and devices must be used at room temperature (59-86°F/15-30°C). The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date assigned at manufacturing is on the package.

7. QUALITY CONTROL

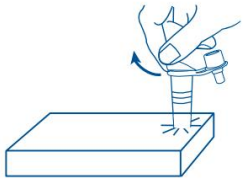
Each CorDx Tyfast COVID-19 Ag Rapid Test has a built-in "Control" region which serves as an internal procedural control when a colored line appears in the control line region ("C line"). The "C line" should always appear if the test has been performed correctly. If the "C line" does not appear at 10 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.

8. TEST PROCEDURES

TEST PREPARATION

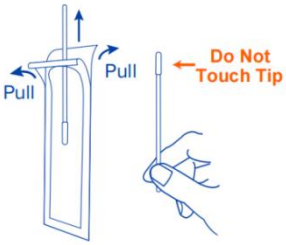


- Check the Expiration Date on the package. ***Do not use an expired test kit!***



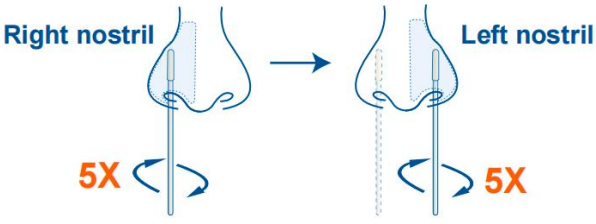
- Remove the test cassette from the pouch and place it on a clean, flat surface.
- Insert the tube in the pre-made hole on the back of the kit box.
- Remove the foil from the top of the tube.

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) Carefully insert the swab tip into one nostril about **1/2** to **3/4 inch**. 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.

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

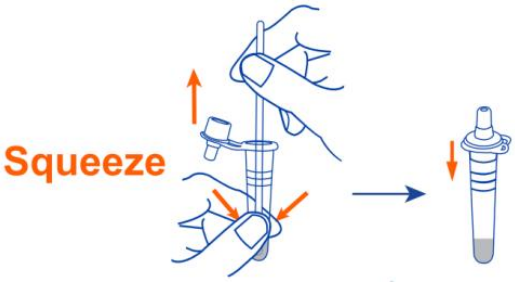
Note: Failure to swab properly may cause Incorrect results.

STEP 2: PROCESS SAMPLE

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

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

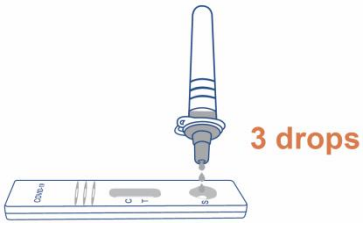
(6) Remove the swab **while squeezing the sides of the tube** to express as much liquid as possible from the swab.



(7) Attach the dropper tip firmly onto the tube.

STEP 3: ADD SAMPLE

(8) Gently squeeze the tube and dispense 3 drops of solution in the sample well.

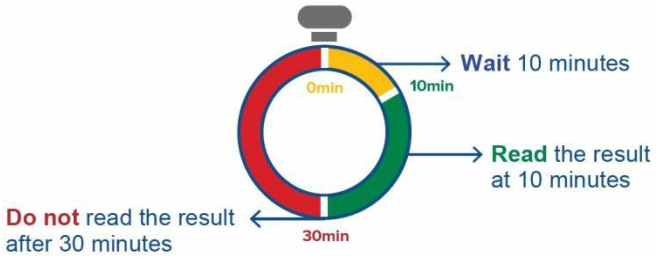


Note: Invalid results can occur if less than 3 drops are added to the sample well.

STEP 4: READ RESULT

(9) **Wait** 10 minutes.
(10) **Read** the result at 10 minutes.

Do not read the result after 30 minutes.



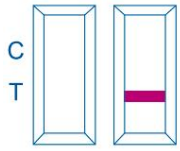
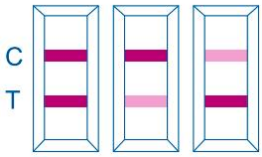
Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

9. TEST INTERPRETATION

If you are prescribed eye-glasses or contact lenses for vision correction, you must wear them when performing and interpreting the test.
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

 **INVALID**	***Invalid*** If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.
 **POSITIVE**	***COVID-19 Positive (+)*** If the Control (C) line and the Test (T) line are visible, the test is positive. **NOTE: Any red or pink line in the correct, indicated locations, no matter how faint, should be considered an indication of a positive result. See examples of different color grades of the test lines (T) in the images.** **Repeat testing does not need to be performed if patients have a positive result at any time.** A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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. Individuals who test positive with the CorDx Tyfast COVID-19 Ag Rapid Test should self-isolate and seek follow up care with their physician or healthcare provider.
 **NEGATIVE**	***COVID-19 Negative (-)*** If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **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.** A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

10. LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2023 and December 2023. 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.

- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision - such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- Positive test results do not exclude co-infection with other pathogens.
- Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV. If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state and local public health departments, is required.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment is necessary.
- Accurate results are dependent on adequate product storage, and adherence to the specimen collection and testing procedures.

11. PERFORMANCE CHARACTERISTICS

11.1 Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LoD) of the CorDx Tyfast COVID-19 Ag Rapid Test was established using serial dilutions of two different SARS-CoV-2 materials, i.e. Heat-Inactivated SARS-CoV-2 virus (Isolate: USA-WA1/2020, Lot# 329181) in Pooled Negative Swab Matrix (PNSM) and UV-Inactivated SARS-CoV-2 virus (Isolate: USA-WA1/2020, Lot# 325796) in Pooled Nasal Cavity Wash.

The preliminary LoD determined by testing a 10-fold or 2-fold dilution series of five replicates per concentration was confirmed by testing 20 replicates for each of three device lots. The confirmed LoDs for the CorDx Tyfast COVID-19 Ag Rapid Test was specified in the table below:

SARS-CoV-2	Concentration ($TCID_{50}$/ mL)
USA-WA1/2020 (Heat-Inactivated)	$1.0x10^4$
USA-WA1/2020 (UV-Inactivated)	$1.25x10^4$

11.2 Inclusivity (Analytical Reactivity)

The inclusivity of the CorDx Tyfast COVID-19 Ag Rapid Test was determined on detecting SARS -CoV-2 Alpha, Beta, Delta and Omicron variants as assessed by its Limit of Detection. Serial diluted variants 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), B.1595, Omicron B.1.1.529, BA.1 (NIBSC 21/368), USA-WA1/2020 (Heat-Inactivated) and USA-WA1/2020 (UV-Inactivated) were spiked into pooled negative sample matrix (PNSM) to determine the LoD for each tested variant.

Based on the results, the CorDx TyFast COVID-19 Ag Rapid Test detects SARS-CoV-2 variants with LoD at the concentrations as indicated. 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.

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 B.1.1.529, BA.1 (NIBSC 21/368)	$5.0x10^2$
Beta B.1.351	$2.5x10^4$	Omicron XBB	$2.5x10^4$
Delta B.1.617.2	$3.125x10^3$	B.1.595	$3.906x10^2$
USA-WA1/2020 (Heat-Inactivated)	$1.0x10^4$	USA-WA1/2020 (UV-Inactivated)	$1.25x10^4$

11.3 Cross Reactivity (Analytical Specificity) and Microbial Interference

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 (3xLoD) to see if false positive and false negative test results may occur. Study results showed that no cross reactivity or interference was observed with the following microorganisms at the concentration tested in the table below.

Substance	Concentration	Cross Reactivity (Pos# / 3)	Interference (Pos# / 3)
Human coronavirus 229E	$2.81x10^4$ $TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
MERS-coronavirus	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
SARS-coronavirus (Gamma-irradiated virus in Vero E6 cells in DMEM)	$1x10^5$ PFU/mL	0/3	3/3
SARS-coronavirus (Gamma-irradiated virus in PBS)	$1x10^7$ PFU/mL	0/3	3/3
Human Adenovirus 1	$1x10^6$ $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus 3 (hMPV-3) Type B1	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 1	$1x10^7$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 2	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 3	$1x10^7$ $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 4A	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Influenza A /Hong Kong/2671/19 (H3N2)	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Influenza A/Indiana/02/2020 09(H1N1)	$1x10^7$ $CEID_{50}$/mL	0/3	3/3
Influenza B/Washington/02/19 (Victoria lineage)	$1.0 x10^4$ $TCID_{50}$/mL	0/3	3/3
Influenza B/Florida/4/2006 (Yamagata lineage)	$1x10^7$ $CEID_{50}$/mL	0/3	3/3
Enterovirus B111 2015 isolate	$1x10^6$ $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus	$1x10^6$ $TCID_{50}$/mL	0/3	3/3

Rhinovirus Type 1A	$1x10^5$ $TCID_{50}$/mL	0/3	3/3
Haemophilus influenzae type b (Eagan)	$1x10^7$ CFU/mL	0/3	3/3
Streptococcus pneumoniae Z022	$1x10^7$ CFU/mL	0/3	3/3
Streptococcus pyogenes Z018	$1x10^7$ CFU/mL	0/3	3/3
Candida albicans Z006	$1x10^7$ CFU/mL	0/3	3/3
Pooled human nasal wash –representative of normal respiratory microbial flora	NA	0/3	3/3
Bordetella pertussis A639	$1x10^7$ CFU/mL	0/3	3/3
Mycoplasma pneumoniae M129	$1x10^7$ CFU/mL	0/3	3/3
Chlamydia pneumoniae	$1x10^7$ IFU/mL	0/3	3/3
Legionella pneumophila Philadelphia	$1x10^7$ CFU/mL	0/3	3/3
Staphylococcus aureus MRSA; COL	$1x10^7$ CFU/mL	0/3	3/3
Staphylococcus epidermidis MRSE; PR62A	$1x10^7$ CFU/mL	0/3	3/3

To estimate the likelihood of cross reactivity for organisms that were not available for wet testing, *in silico* analysis using the Basic local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. Human coronavirus HKU1, Mycobacterium tuberculosis and Pneumocystis jirovecii were analyzed as shown below.

- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus has not been done and cross -reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Based on the *in silico* sequence homology analysis, no significant homology was found between the SARS-CoV-2 Nucleocapsid protein and the Mycobacterium tuberculosis, indicating an unlikelihood of cross-reactivity.
- No significant homology was found between the SARS-CoV-2 Nucleocapsid protein and the Pneumocystis jirovecii, indicating an unlikelihood of cross-reactivity.

11.4 Endogenous and Exogenous Interference

The following substances, naturally present in respiratory specimens or that may be artificially introduced, were evaluated.

The negative samples and positive samples (viral titer 3xLoD) 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 potentially interfering substances listed in the table below at the tested concentration.

Substance	Concentration Tested	Virus Spiked (Pos# / 3)	Virus Unspiked (Pos# / 3)
Whole Blood	4%	3/3	0/3
Mucin	0.5%	3/3	0/3
Chloraseptic (Methol/Benzocaine)	1.5 mg/mL	3/3	0/3
Naso GEL (NeilMed)	5% v/v	3/3	0/3
CVS Nasal Drops (Phenylephrine)	15% v/v	3/3	0/3
Afrin (Oxymetazoline)	15% v/v	3/3	0/3
Fluticasone Propionate	5% v/v	3/3	0/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3	0/3
Chloraseptic (Menthol/Benzocaine)	3mg/ml	3/3	0/3
Gericare Saline Nasal Spray (Sodium chloride with preservatives)	15% v/v	3/3	0/3
CVS Health Budesonide Allergy Nasal Spray (Budesonide)	15% v/v	3/3	0/3

CVS Nasal Spray (Cromolyn)	15% v/v	3/3	0/3
Zicam	5% v/v	3/3	0/3
Homeopathic (Alkalol)	10% v/v	3/3	0/3
Sore Throat Phenol Spray	15% v/v	3/3	0/3
Tobramycin	4 µg/mL	3/3	0/3
Mupirocin	10 mg/mL	3/3	0/3
Boiron Galphimia glauca	15% v/v	3/3	0/3
Boiron Histaminum Hydrochloricum	15% v/v	3/3	0/3
Nasonex 24HR Allergy Nasal Spray (Mometasone)	15% v/v	3/3	0/3
HealthA2Z Fluticasone Propionate Nasal Spray (Fluticasone)	15% v/v	3/3	0/3
Luffeel Nasal Spray (Luffa opperculata, Sulfur)	1.25 %	3/3	0/3

11.5 High Dose Hook Effect

No hook effect was observed for specimens containing SARS-CoV-2 viral concentration as high as $4.57x10^6$ $TCID_{50}$/ mL.

11.6 Precision

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 kit. The study includes a sample panel consisting of a negative sample, a low positive (2 x LoD) sample, and a medium positive (4.0x LoD) sample. The low positive and medium positive sample were prepared by spiking UV-inactivated SARS-CoV-2 in the negative sample matrix (NSM).
Each operator applied 50 µL of each coded sample to each dry nasal swab. Then, the operator processed the sample per the IFU of the proposed device. The sample panel was tested in a blinded manner by two operators for 10 non-consecutive days. All three lots were tested by each operator on each testing day. Each sample level was tested in triplicate in each run per operator per day (i.e., 3 lots x 2 operators x 3 replicates/run x 1 run X 10 days). A total of 180 tests were run per panel member. The agreement of obtained results with expected results was 100% across all lots, operators, and days. Variability in results was not observed between the three independently manufactured lots.

11.7 WHO International Standard for SARS-CoV-2 Antigen - NIBSC 21/368

This study was designed to determine the Limit of Detection (LoD) for SARS-CoV-2 Antigen tests using the First 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 confirmed by testing 20 replicates. The confirmed LoD for the CorDx Tyfast COVID-19 Ag Rapid Test was $5.00x10^2$ IU/mL which is equivalent to $2.50x10^1$ IU/swab based upon the testing procedure of the study.

11.8 Usability and User Comprehension Studies

Of the 751 subjects enrolled in the clinical study, 104 were enrolled in the human factors arm of the study to evaluate the human user experience and comprehension of the CorDx Tyfast COVID-19 Ag Rapid Test and labeling. This subset of subjects included 53 self-collecting and 51 lay users collecting from another lay user.

The usability portion of the human factors assessment evaluated the ability of users to perform the entire test procedure in a simulated home-setting environment. The entire test procedure was performed by each individual participant using the kit. The participants were observed by study personnel during the whole procedure and any difficulties were recorded.

The user comprehension portion of the human factors assessment studied user comprehension of test results (interpreting mock positive, negative and invalid results) and instructions for use to verify that users can accurately interpret the test results and carry out any follow up actions. The participants were provided a panel of mock test devices to interpret following completion of the investigational testing.

Evaluation of the human user experience indicated acceptable usability of the CorDx Tyfast COVID-19 Ag Rapid Test. Of the subjects that participated in the human factors assessment, and none of the subjects had difficulty collecting the sample or running the investigational test. While most of the subjects reported no difficulty in interpreting the various mock test results, there were notable individual failures observed in the usability study. Specifically, 20.0% of the study subjects failed at squeezing the sides of the tube during sample extraction. The overall performance metrics for the mock test study were: Negative Percent Agreement (NPA): 97.4%, Positive Percent Agreement (PPA) at 1.9xLoD: 96.3%, PPA at 5xLoD: 98.1%, and Invalid Percent Agreement (IPA): 93.3%. A detailed breakdown of mock test Interpretation is provided below:

	Concentration	**TN**	**FP**	**FI**	**Total**	**NPA (%)**
Negative	N/A	148	2	2	152	97.4
		TP	**FN**	**FI**	**Total**	**PPA (%)**
Positive	1.9xLoD	154	5	1	160	96.3
	5xLoD	102	1	1	104	98.1
		TI	**FN**	**FP**	**Total**	**IPA (%)**
Invalid	N/A	97	7	0	104	93.3

12. CLINICAL PERFORMANCE

The clinical performance of the CorDx Tyfast COVID-19 Ag Rapid Test was evaluated in a prospective clinical study completed at five (5) sites throughout the United States. The study evaluated 693 evaluable symptomatic individuals aged 2 years or older who were either experiencing fever, or two or more symptoms associated with COVID-19, and presented within 5 days of symptom onset.

The subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Upon reviewing the CorDx Tyfast COVID-19 Ag Rapid Test's Quick Reference Instructions, the subject self-collected, or collected from another individual, an anterior nares sample and test the sample using the CorDx Tyfast COVID-19 Ag Rapid Test. A matched anterior 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.

Of the 693 symptomatic subjects, 118 (17.0%) were COVID-19 positive and 575 (83.0%) were COVID-19 negative by the comparator test.

Test results from the CorDx Tyfast COVID-19 Ag Rapid Test (investigational test) were compared to highly sensitive molecular FDA 510(k) cleared SARS-CoV-2 assay to determine the test performance.

Subjects	Comparator Positives	Comparator Negatives	Total
CorDx Tyfast COVID-19 Ag Rapid Test Positives	101	3	104
CorDx Tyfast COVID-19 Ag Rapid Test Negatives	17	572	589
Total	118	575	693
Positive Percent Agreement = 85.6% (95% CI: 78.1 to 90.8%)			
Negative Percent Agreement = 99.5% (95% CI: 98.5 to 99.8%)			

13. FREQUENTLY ASKED QUESTIONS (FAQ)

1) WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

a. Possible discomfort during sample collection.
b. Possible incorrect test result (see Warnings and Test Interpretation sections for more information).

Potential benefits include:

a. The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
b. The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

2) WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CorDx Tyfast COVID-19 Ag Rapid Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

3) HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.

4) WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

5) WHAT IF I HAVE A NEGATIVE TEST RESULT?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two

more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

6) WHAT DOES AN INVALID TEST RESULT MEAN?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

14. SERIAL TESTING

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

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

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

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

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

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		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. SYMBOLS

	Do not re-use		Caution		Consult instructions for use
	Catalogue number		Manufacturer		Keep dry
	Store at 36~86°F /2~30℃		Keep away from sunlight		*In vitro* diagnostic medical device
	Do not use if package is damaged and consult instructions for use				

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