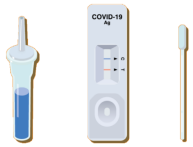
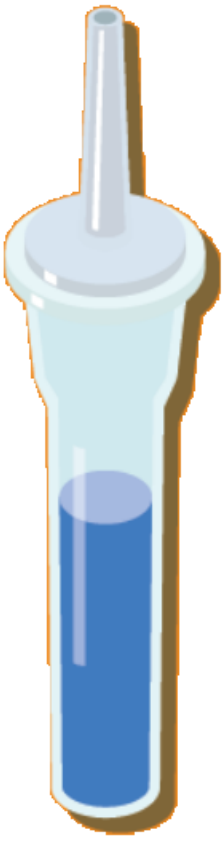
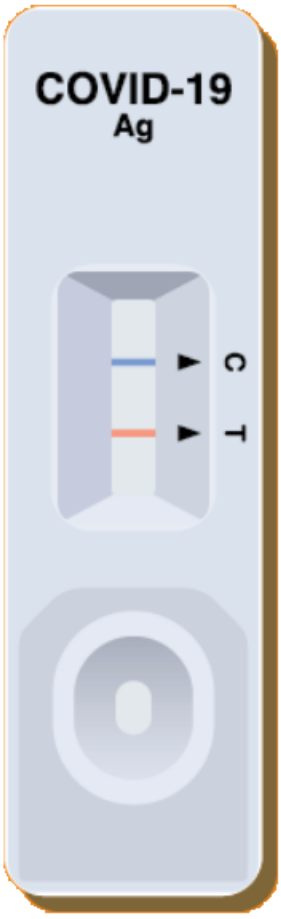


CorDx COVID-19 Multiplex Rapid Test Instructions

CorDx COVID-19 Multiplex Rapid Test

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Contents

INTENDED USE

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider 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 SARSCoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous in vitro detection 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.

These viral antigens are generally detectable in anterior nasal swab specimens 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.

All negative results are presumptive, and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control measures 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 each respiratory infection.

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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.

PRINCIPLE OF THE TEST

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 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 protein of Flu A, Flu B and SARSCoV-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.

REAGENTS AND MATERIALS PROVIDED

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

Components	2 tests/kit	10 tests/kit	25 tests/kit
Test cassette	2	10	25
Swab	2	10	25
Tube with sample processing solution	2	10	25
Instructions for use (IFU)	1	1	1
Quick reference guide (QRG)	1	1	1

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, timer or stopwatch
- CorDx Tyfast Flu A/B & COVID-19 Multiplex Control Swab Kit for additional quality control REF #: CUS294-10

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Serial testing should be performed in individuals with SARS-CoV-2 negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. 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.
- 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 results.
- Do not use the test kit after its expiration date.
- Do not reuse the test cassette, processing solution, or swab.

- Do not use the test if the pouch is damaged or open.
- Do not interchange or mix components from different kit lots.
- Do not open the kit contents until ready for use. If the pouch is open for more than an hour, invalid test results may occur.
- Do not touch swab tip when handling the swab.
- Exposure to hand sanitizer may cause false positive results with this test.
- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.
- Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.
- Inadequate or inappropriate sample collection, storage and transport may yield false test results.
- Only use the nasal swabs provided in the kit. Do not touch the swab tip prior to testing.
- Dispose of test kit contents in accordance with federal, state, and local regulations.
- 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/emergencypreparednessandresponse/mcmlegalregulatoryandpolicyframework/emerg authorization**
- For the most up to date information on COVID-19, please visit: **www.cdc.gov/COVID19**

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.

INTERNAL QUALITY CONTROL

Each CorDx Tyfast Flu A/B & COVID-19 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.

EXTERNAL QUALITY CONTROL

In point-of-care (POC) or CLIA Waiver laboratory settings external controls should be tested with each new lot, shipment received, and with each new untrained operator, or to conform with local regulations, accrediting groups, or the lab's standard Quality Control procedures.

Applicable external controls for use with the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test at the Point of Care (POC): CorDx Tyfast Flu A/B & COVID-19 Multiplex Control Swab Kit from CorDx, Inc. REF #: CUS294-10

This control kit consists of a positive control swab (contains influenza A, influenza B and SARSCoV-2 recombinant antigen) and a negative control swab. To perform a positive or negative control test, complete the steps in the Test Procedures section, treating the control swab in the same manner as a patient swab.

TEST PROCEDURES

TEST PRE-CAUTIONS

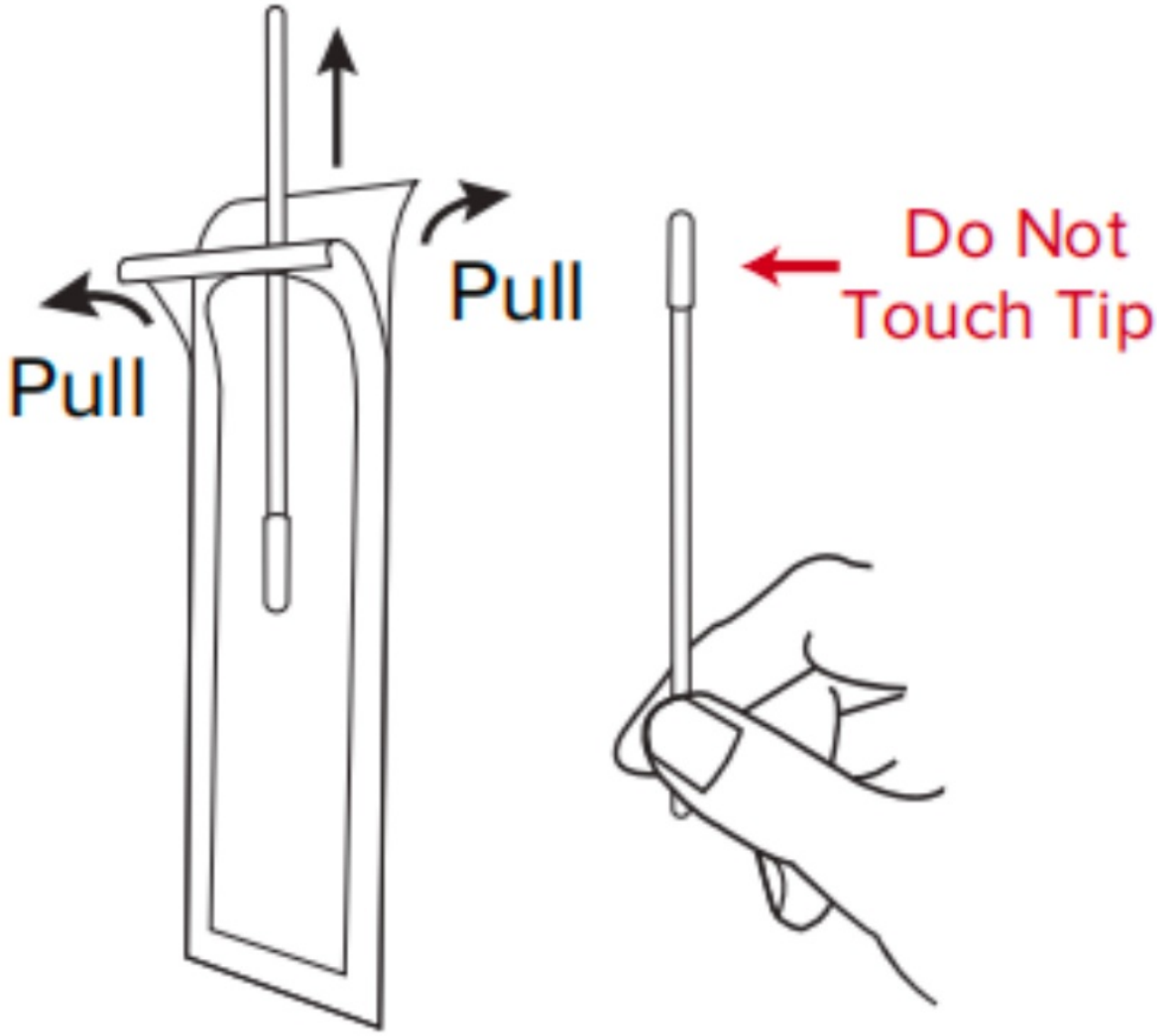
- Only the components provided in the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test kit should be used.
- Transport media should not be used. Use of viral transport media with this test may result in inaccurate results.
- It is recommended to use the test kit immediately after opening. The unsealed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

PREPARING FOR THE TEST

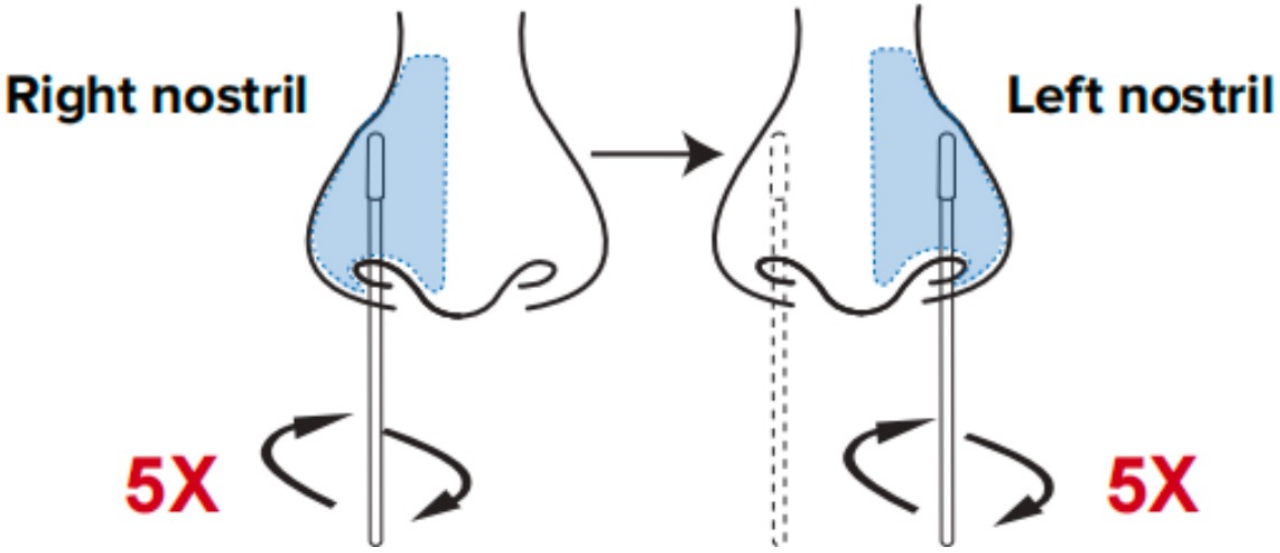
1. Read all the instructions before you start the test.
2. Check the test's expiration date (EXP). Do not use an expired test.
3. Use a flat level surface (such as a table or countertop) for testing.
4. Use a timer during the test.
5. Make sure you have all the test components before you begin.
6. Bring test kit to room temperature (59~86°F /15~30°C).
7. Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

STEP 1: COLLECT SAMPLE

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

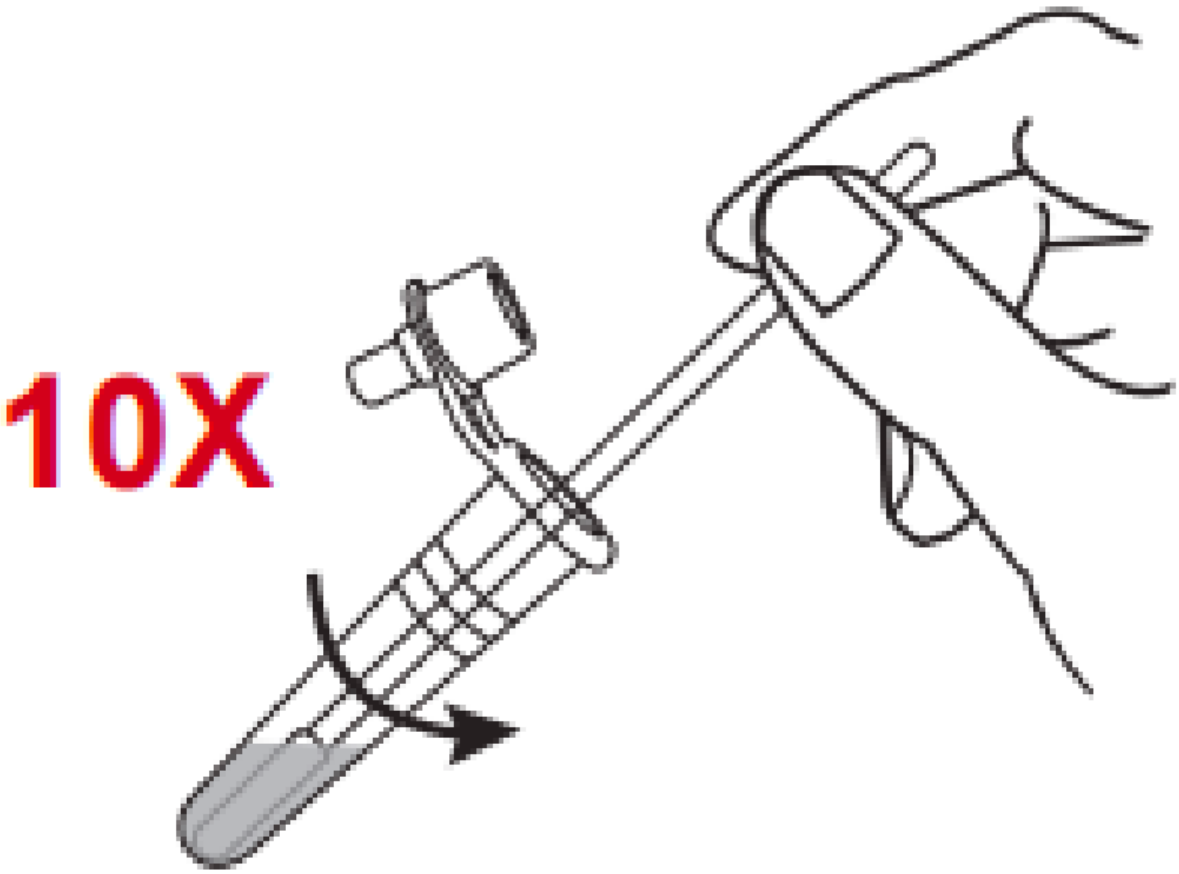
from both nostrils.

Did you swab BOTH nostrils?

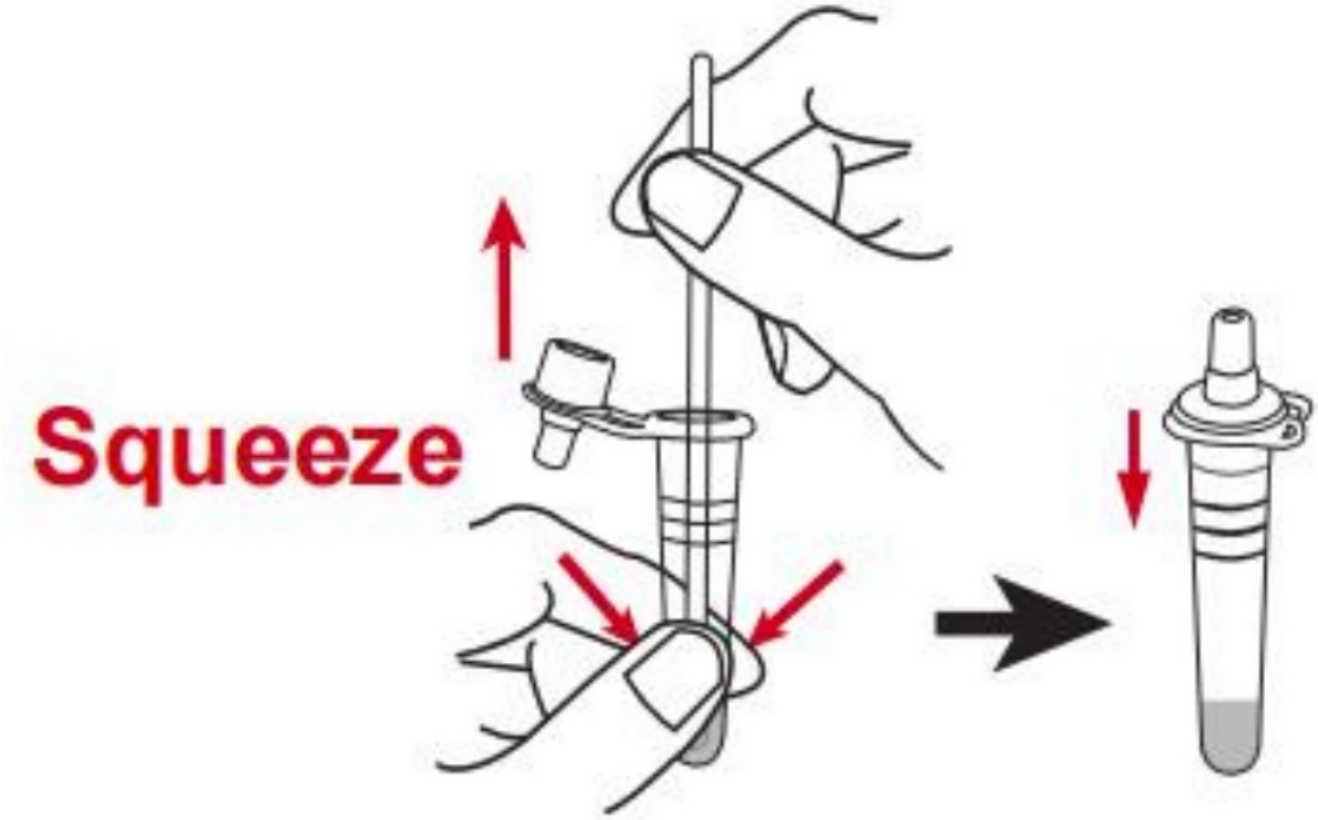
Inaccurate test results may occur if the nasal sample is not properly collected.

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.



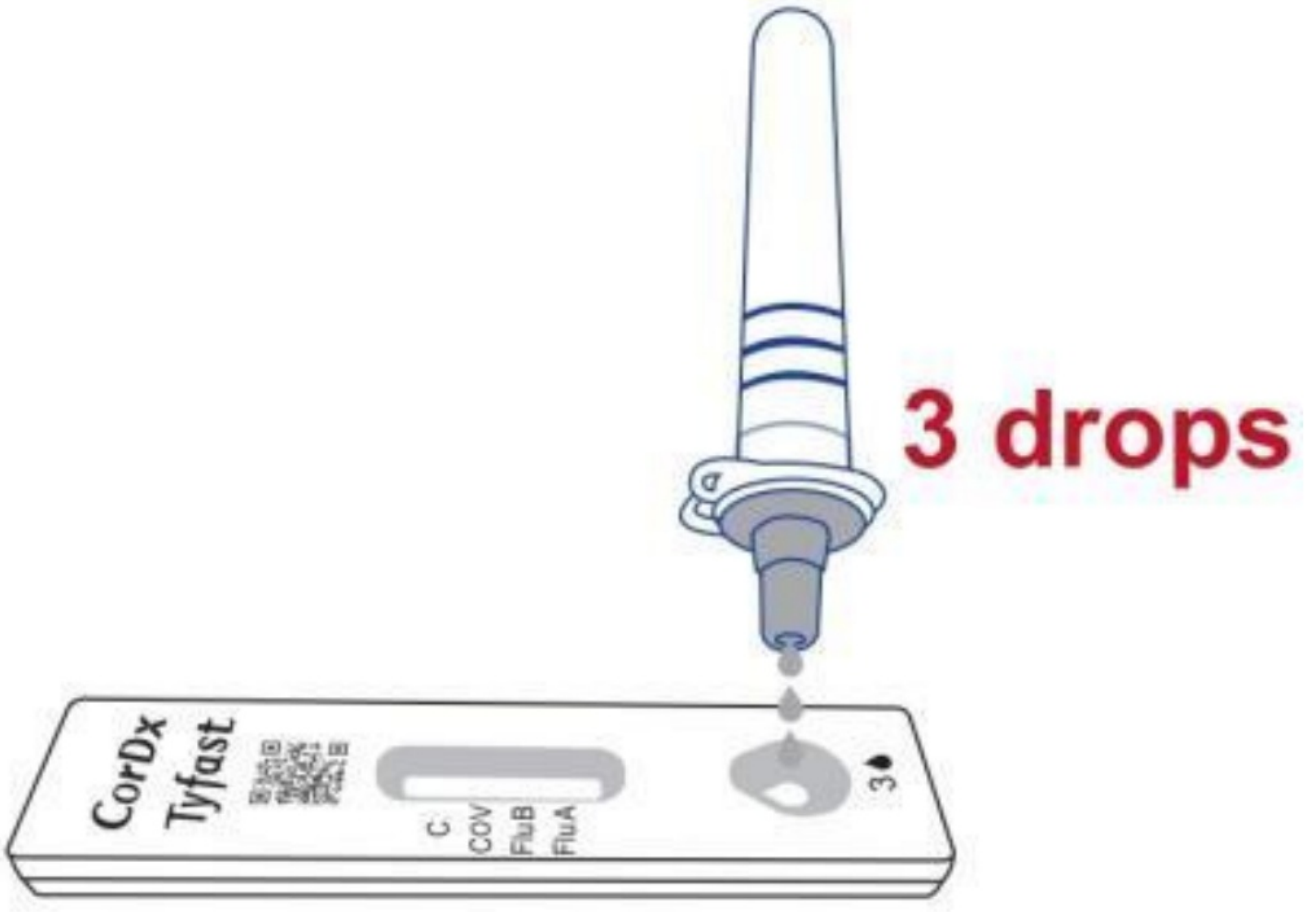
4. Remove the swab while squeezing the sides of the tube.
   Attach the dropper tip firmly onto the tube.



STEP 3: ADD SAMPLE

5. Slowly squeeze the tube and dispense 3 drops of solution into the sample well.

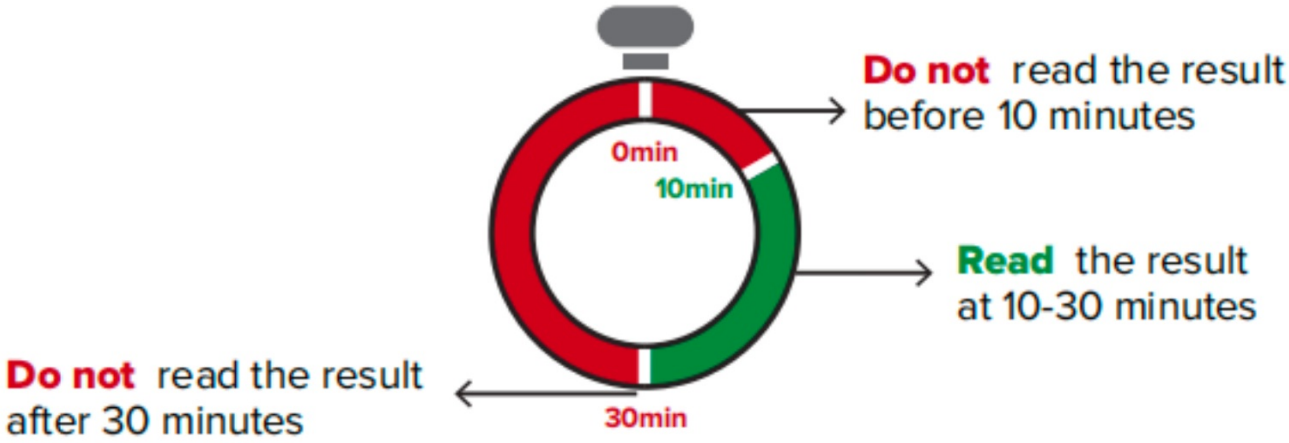
   Note: Invalid results can occur if less than 3 drops are added to the sample well.



STEP 4: READ RESULT

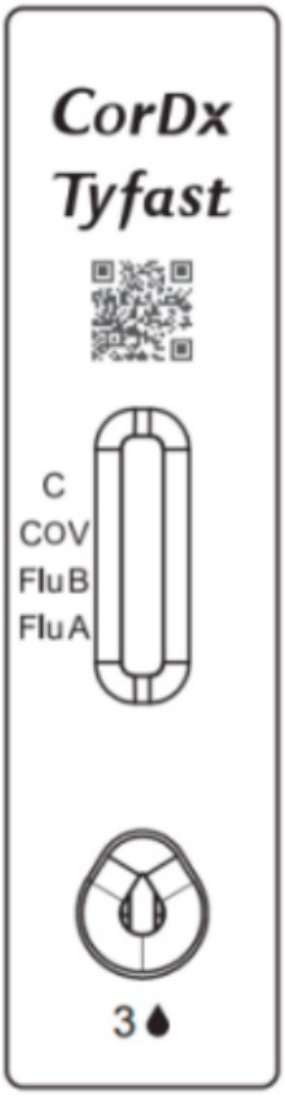
6. **Wait** 10 minutes.

   Read the result after 10 minutes but before 30 minutes.

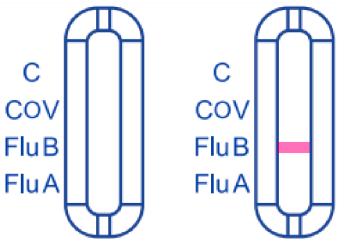


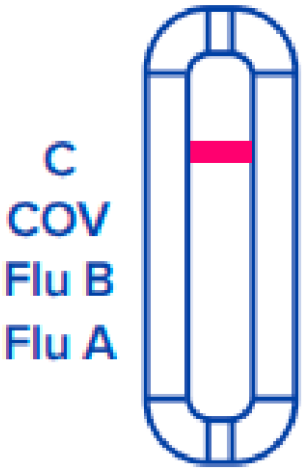
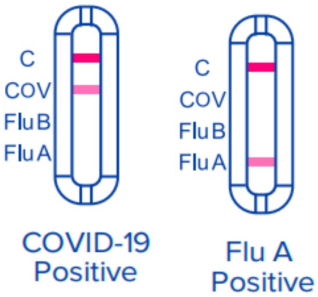
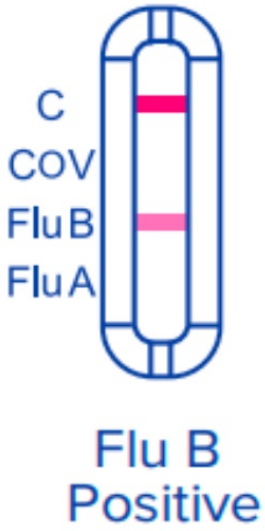
Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

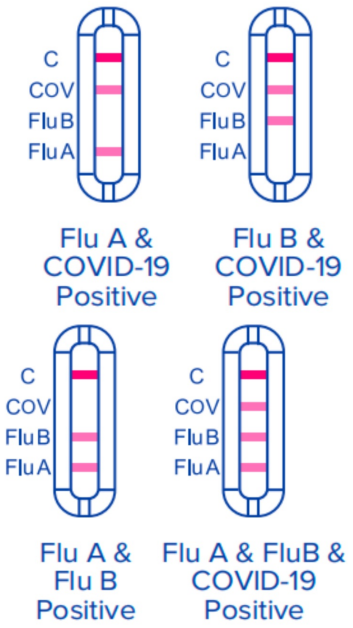
INTERPRETATION OF RESULTS



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, y ou 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 det ected in the sample. A negative result does not rule out COVID-19. There is a hi gher 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 sympto ms, 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. All negative results should be treated as presumptive and confirmation with a m olecular assay may be necessary if there is a high likelihood of SARS-CoV-2 inf ection, 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 infe ction. Negative results do not rule out SARS-CoV-2 infection and should not be used a s the sole basis for treatment or patient management decisions, including infecti on control decisions.
POSITIVE RESULT  	If the Control line (C) is visible and one or more lines appear(s) for any of the vir uses, the test is **positive** for that or those viruses. *A positive result does not rule out co-infections with other pathogens or identify any specific influenza A subtype, influenza B lineage, or SARS-CoV-2 variant.* **NOTE**: Positive test lines are usually very prominent but at times may vary in sh ade and intensity. A line of any intensity or thickness that appears in the Flu A, F lu B, or COV region is considered a positive result. The intensity of the C line sh ould not be compared to that of the test line for the interpretation of the test resu lt. Take time to look at test lines very carefully. If you see a very light or faint test li ne appear, this is considered a **POSITIVE** result.

	**NOTE**: 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 patient sample and new test kit. Repeatable “dual positive” results should be confirmed by an FDA-cleared molecular assay before reporting results. **COVID-19 Positive (+) Result:** **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. The agent detected may not be the definite cause of disease. Individuals who test positive with the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test should self- isolate and seek follow up care with their 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 negative SARS-CoV-2 results. Please follow the table below when interpreting test results with symptoms. Serial (repeat) SARS-CoV-2 testing does not need to be performed if patients have a positive SARS-CoV-2 result.

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 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

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from Sep 2023 to Feb 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 SARS-CoV-2 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 patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have SARS-CoV-2 infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that cause COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS-CoV-2 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Use of CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is limited to laboratory personnel and CLIA waived users. Not for home use.
- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens as well as SARS-CoV-2 antigen from direct anterior nasal swab samples only.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV2. 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 sample.
- 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.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.

- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available.
- Positive test results do not exclude co-infections with other pathogens.
- Positive test results do not identify specific coronavirus, influenza A and B subtypes and strains.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
- If differentiation of specific coronavirus or influenza A, influenza B subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- False results due to cross-reactivity between Influenza B and SARS-CoV-2 can occur with this test at high viral loads/titers. If the test is positive for both SARS-CoV-2 and Influenza B, follow up with molecular testing (RT-PCR) should be conducted to confirm results.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for

Patients, and authorized labeling are available on the FDA website:
https://www.fda.gov/medicaldevices/covid19emergencyuseauthorizations-medicaldevices/in-vitro-diagnostics-euas

However, to assist in using the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test (“your product” in the conditions below). the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test Instructions for Use and Quick Reference Guide. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7 OIR/OPEQ/CDRH (via email: **CDRHEUA-Reporting@fda.hhs.gov**) and CorDx by contacting Technical Services (via email at **Support@CorDx.com** or via phone at **858-999-1582**).

- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- CorDx, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The Letter of Authorization refers to “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation” as “Authorized Laboratories”.

PERFORMANCE CHARACTERISTICS

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 detection using the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test.

Virus	LoD in PNSM	LoD per Swab	Positive Replicates (n=20)
SARS-CoV-2	4.0 x 102 TCID50/mL	2.0 x 101 TCID50/swab	20/20
Influenza A H1N1	2.4 x 107 CEID50/mL	1.2 x 106 CEID50/swab	20/20
Influenza A H3N2	2.6 x 105 CEID50/mL	1.3 x 104 CEID50/swab	20/20
Influenza B Victoria	4.2 x 106 CEID50/mL	2.1 x 105 CEID50/swab	20/20
Influenza B Yamagata	3.7 x 104 CEID50/mL	1.8 x 103 CEID50/swab	20/20
WHO Standard (NIBSC 21/368)	2.5 x 102 IU/mL	1.25 x 101 IU/swab	20/20

Inclusivity (Analytical Reactivity)

For SARS-CoV-2:

The inclusivity of the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test on 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, were determined as assessed by its Limit of Detection. Serial 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 Multiplex Rapid Test detects SARSCoV-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 these variants tested.

For Influenza A & Influenza B:

A selection of temporal, geographic and genetically diverse Influenza were tested. An abbreviated LoD study has been 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 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.

Virus	Strain	LoD
Influenza A (H1N1)	A/Brownsville/39H/2009	4.0 x 102 TCID50/mL
	A/Massachusetts/15/2013	4.0 x 106 CEID50/mL
	A/Bangladesh/3002/2015	6.5 x 105 CEID50/mL
	A/Michigan/45/2015	2.5 x 107 CEID50/mL
	A/St. Petersburg/61/2015	2.3 x 106 CEID50/mL
	A/Hawaii/66/2019	7.4 x 107 CEID50/mL
	A/Wisconsin/588/2019	2.8 x 104 FFU/mL
	A/Dominican/Republic/7293/2013	1.3 x 104 TCID50/mL
	A/Iowa/53/2015	7.3 x 106 CEID50/mL
	A/Idaho/07/2018	1.6 x 103 TCID50/mL
Influenza A (H3N2)	A/New York/21/2020	2.6 x 105 FFU/mL
	A/Tasmania/503/2020	1.3 x 105 FFU/mL
	A/Hong Kong/2671/2019	6.2 x 106 CEID50/mL
	A/Singapore/INFIMH-16-0019/2016	2.2 x 105 CEID50/mL
	A/Hong Kong/45/2019	1.5 x 104 FFU/mL
	A/Ohio/09/2015 (H1N1v)	7.0 x 106 CEID50/mL
	A/Minnesota/19/2011 (H1N2v)	4.0 x 107 CEID50/mL
	A/Indiana/08/2011 (H3N2v)	2.0 x 103 TCID50/mL
	A/northern pintail/Illinois/10OS3959/2010 (H7N3)	1.4 x 106 CEID50/mL
	A/mallard/Wisconsin/2576/2009 (H5N1)	8.0 x 105 CEID50/mL
Influenza B (Victoria Lineage)	B/Colorado/6/2017	1.6 x 105 CEID50/mL
	B/Florida/78/2015	8.5 x 105 CEID50/mL

Virus	Strain	LoD
Influenza B (Yamagata Lineage)	B/Texas/06/2011	4.0 x 106 CEID50/mL
	B/Wisconsin/1/10	7.05 x 101 TCID50/mL
Influenza B (non-Victoria non-Yamagata)	B/Maryland/1/1959	8.9 x 101 CEID50/mL

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 ≥1.43 x 105 TCID50/mL, 1.00 x 105 PFU/mL, or 1.43 x 105 CEID50/mL for viruses, and ≥1.00 x 106 CFU/mL or ≥1.00 x 106 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 104

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 ≥7.90 x 101 TCID50/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 TCID50/mL. These results are notunexpected 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 102 TCID50/mL; Influenza A: 1 x LoD 2.60 x 105 CEID50/mL; Influenza B: 1 x LoD 3.70 x 104 CEID50/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 105 TCID50/mL	0/3	3/3

Human coronavirus 229E	1.5 x 105 TCID50/mL	0/3	3/3
Human coronavirus NL63	1.5 x 105 TCID50/mL	0/3	3/3
Adenovirus (AV71)	1.5 x 105 TCID50/mL	0/3	3/3
Adenovirus Type 7	1.5 x 105 TCID50/mL	0/3	3/3
Cytomegalovirus	1.5 x 105 TCID50/mL	0/3	3/3
Epstein Barr Virus	>2.5 x 103 CEID50/mL	0/3	3/3
Human metapneumovirus 4 Type B2	1.5 x 105 TCID50/mL	0/3	3/3
Parainfluenza virus 1	1.5 x 105 TCID50/mL	0/3	3/3
Parainfluenza virus 2	1.5 x 105 TCID50/mL	0/3	3/3
Parainfluenza virus 3	1.5 x 105 TCID50/mL	0/3	3/3
Parainfluenza virus 4b	1.5 x 105 TCID50/mL	0/3	3/3
Enterovirus 68	1.5 x 105 TCID50/mL	0/3	3/3
Respiratory syncytial virus A	1.5 x 105 TCID50/mL	0/3	3/3
Respiratory syncytial virus B	1.5 x 105 TCID50/mL	0/3	3/3
Rhinovirus	1.00 x 105 PFU/mL	0/3	3/3
Bordetella pertussis	>1 x 104 CFU/mL	0/3	3/3
Candida albicans	1.1 x 106 CFU/mL	0/3	3/3
Chlamydia pneumoniae	1.1 x 106 IFU/mL	0/3	3/3
Corynebacterium sp.	1.1 x 106 CFU/mL	0/3	3/3
Escherichia coli	>2.5 x 104 CFU/mL	0/3	3/3
Haemophilus influenzae	1.1 x 106 CFU/mL	0/3	3/3
Lactobacillus sp.	>1 x 104 CFU/mL	0/3	3/3
Legionella pneumophila	1.1 x 106 CFU/mL	0/3	3/3
Moraxella catarrhalis	1.1 x 106 CFU/mL	0/3	3/3
Mycoplasma pneumonia	1.1 x 106 CFU/mL	0/3	3/3
Mycobacterium tuberculosis	1.1 x 106 CFU/mL	0/3	3/3

Neisseria meningitidis	1.05 x 105 CFU/mL	0/3	3/3
Neisseria sp. (subflava)	>1 x 104 CFU/mL	0/3	3/3
P. jiroveci-S. cerevisiae	1.1 x 106 CFU/mL	0/3	3/3
Pseudomonas aeruginosa	1.1 x 106 CFU/mL	0/3	3/3
Staphylococcus aureus (Protein A Producer)	1.1 x 106 CFU/mL	0/3	3/3
Staphylococcus epidermidis	1.1 x 106 CFU/mL	0/3	3/3
Streptococcus salivarius	1.1 x 106 CFU/mL	0/3	3/3
Streptococcus pneumonia	1.1 x 106 CFU/mL	0/3	3/3
Streptococcus pyogenes	1.1 x 106 CFU/mL	0/3	3/3
Measles	1.5 x 105 TCID50/mL	0/3	3/3
Mumps	1.5 x 105 TCID50/mL	0/3	3/3
Coronavirus MERS	1.51 x 105 TCID50/mL	0/3	3/3
SARS-CoV	7.90 x 103 TCID50/mL	3/3	N/A
	7.90 x 102 TCID50/mL	3/3	N/A
	7.90 x 101 TCID50/mL	3/3	N/A
	7.90 TCID50/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.

Competitive Interference

The competitive interference testing was performed with different combinations of low (3 x LoD) and high concentrations (the highest concentration achievable exceeding 105 PFU/mL, CEID50/mL, or TCID50/mL) of influenza A (H3N2), influenza B (Yamagata), and SARS-CoV-2 (WA1) on the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test 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.

Endogenous/Exogenous Interference Substances Studies

The CorDx Tyfast Flu A/B & COVID-19 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-spike 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 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
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 Inf luenza 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 Alc ohol	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
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

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 Result	Flu A Result	Flu B Result
SARS-CoV-2 Neat	7.9 x 105 TCID50/mL	3/3	0/3	3/3
SARS-CoV-2 1:2	4.0 x 105 TCID50/mL	3/3	0/3	2/3
SARS-CoV-2 1:4	2.0 x 105 TCID50/mL	3/3	0/3	0/3
Influenza A H1N1 Neat	9.7 x 108 CEID50/mL	0/3	3/3	0/3
Influenza A H3N2 Neat	2.6 x 108 CEID50/mL	0/3	3/3	0/3
Influenza B Victoria Neat	2.1 x 109 CEID50/mL	3/3	0/3	3/3
Influenza B Victoria 1:2	1.1 x 109 CEID50/mL	0/3	0/3	3/3
Influenza B Yamagata Neat	7.3 x 107 CEID50/mL	0/3	0/3	3/3

Red text: False positive results.

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 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 evaluable subjects were within 5 days post symptoms onset. The subjects either self-collected a dual anterior nares (AN) sample or had a dual AN sample collected from him/her by another individual for the investigation test and test the sample using the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test. 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 CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test (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 O nset	Number of Subj ect samples tes ted	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.

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 test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

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

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

Performance of the antigen test with serial testing in 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 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	47/51	44/47
	(59.6%)	(92.2%)	(93.6%)
2	58/62	59/60	43/43
	(93.5%)	(98.3%)	(100%)
4	55/58	53/54	39/40
	(94.8%)	(98.1%)	(97.5%)
6	27/34	26/33	22/27
	(79.4%)	(78.8%)	(81.5%)
8	12/17	12/17	7/11
	(70.6%)	(70.6%)	(63.6%)
10	4/9	3/7	

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.

TECHNICAL SUPPORT

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

SYMBOLS

	Do not re-use	REF	Catalogue number		Keep away from sunlight
	Keep dry		Consult instructions for use	30℃ 86℉ 2℃ 36℉	Store at 36~86℉/2~30℃
	Manufacturer	Rx only	Prescription use only		Do not use if package is da maged and consult instructi ons for use

CorDx, Inc.
9540 Waples St. #C San Diego, CA 92121 www.CorDx.com

For use under Emergency Use Authorization (EUA) only.

For in vitro diagnostic use.

For use with anterior nasal swab specimens.

Store the kit at 36~86°F/2~30°C.

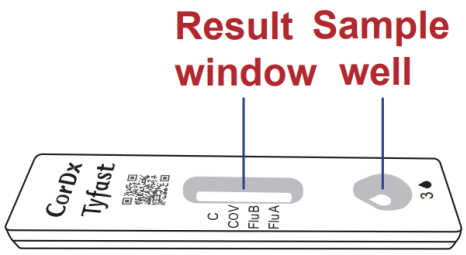
Bring the kit to room temperature (59~86°F/15~30°C) before the test.

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate results.

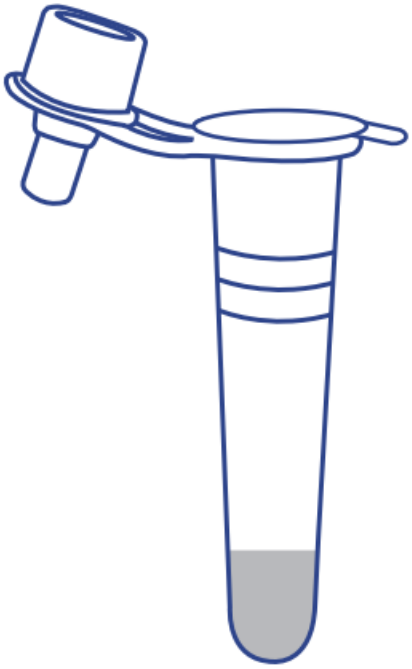
Refer to the Instructions for Use (IFU) for more complete information.

KIT CONTENTS

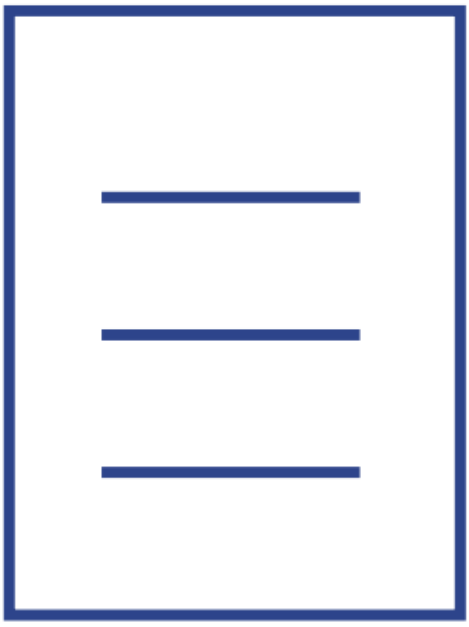
- Test cassette



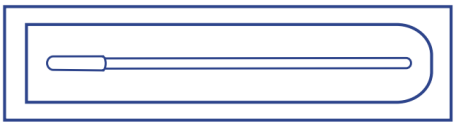
- Tube with sample processing solution

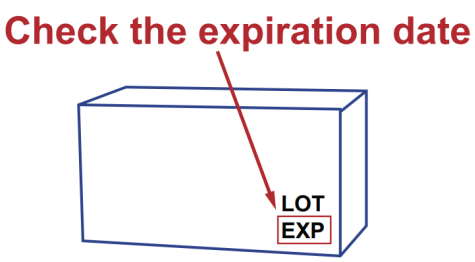


- QRG & IFU



- Swab





TEST PROCEDURES

- Only the components provided in the test kit should be used.
- Transport media should not be used. Use of viral transport media with this test may result in inaccurate results.
- 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.

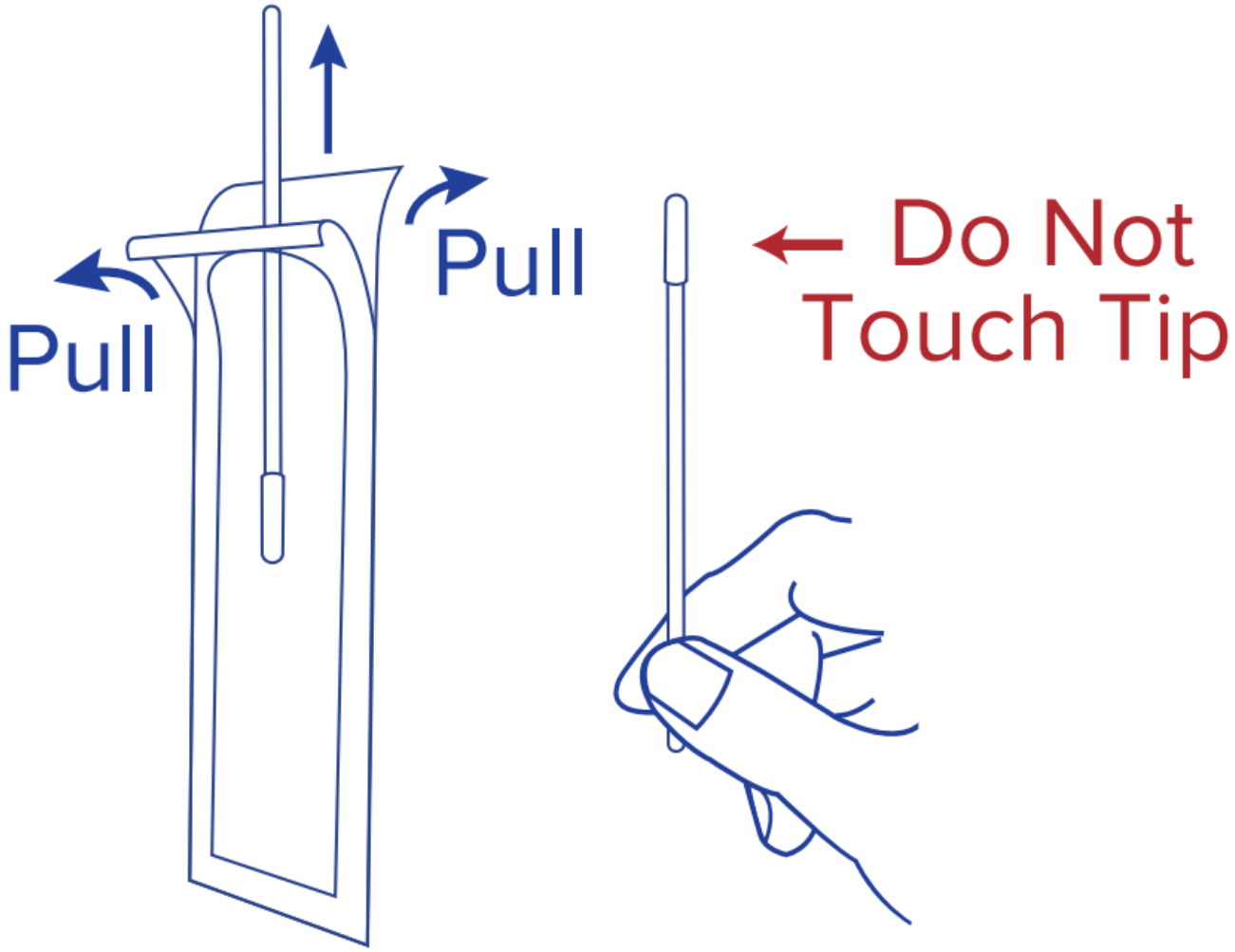
PREPARING FOR THE TEST

- Read all the instructions before you start the test. Failure to follow the instructions may result in inaccurate test results.
- Check the test's expiration date (EXP). Do not use an expired test.
- Use a flat level surface (such as a table or countertop) for testing.
- Use a timer during the test.
- Make sure you have all the test components before you begin.
- Bring test kit to room temperature (59~86°F /15~30°C).
- Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

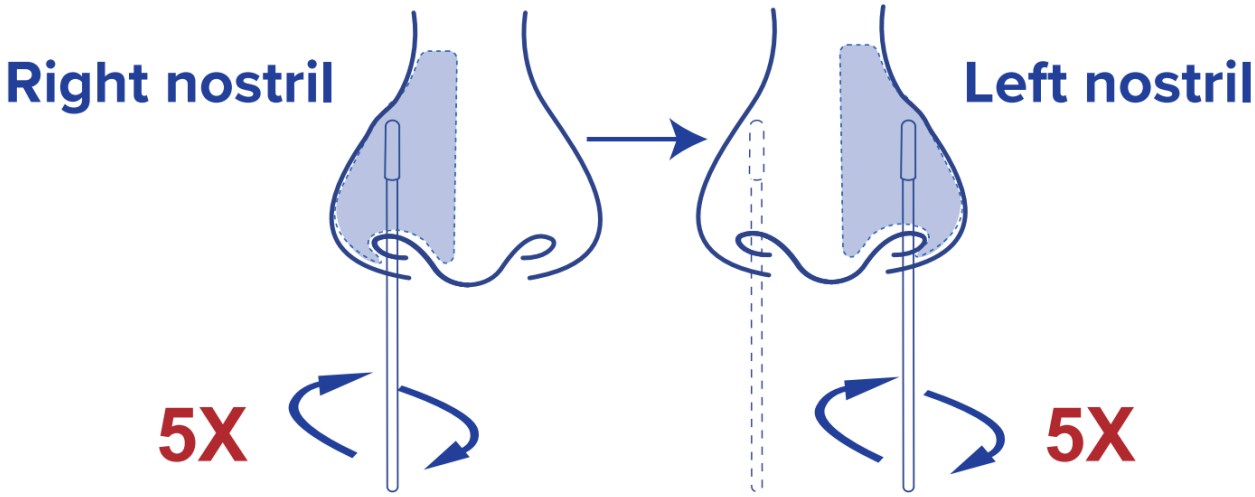
PERFORMING THE TEST

- Read all the instructions before you start the test.
  Failure to follow the instructions may result in inaccurate test results.
- Check the test's expiration date (EXP).
  Do not use an expired test.
- Use a flat level surface (such as a table or countertop) for testing.
- Use a timer during the test.
- Make sure you have all the test components before you begin.
- Bring test kit to room temperature (59~86°F /15~30°C).
- Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

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

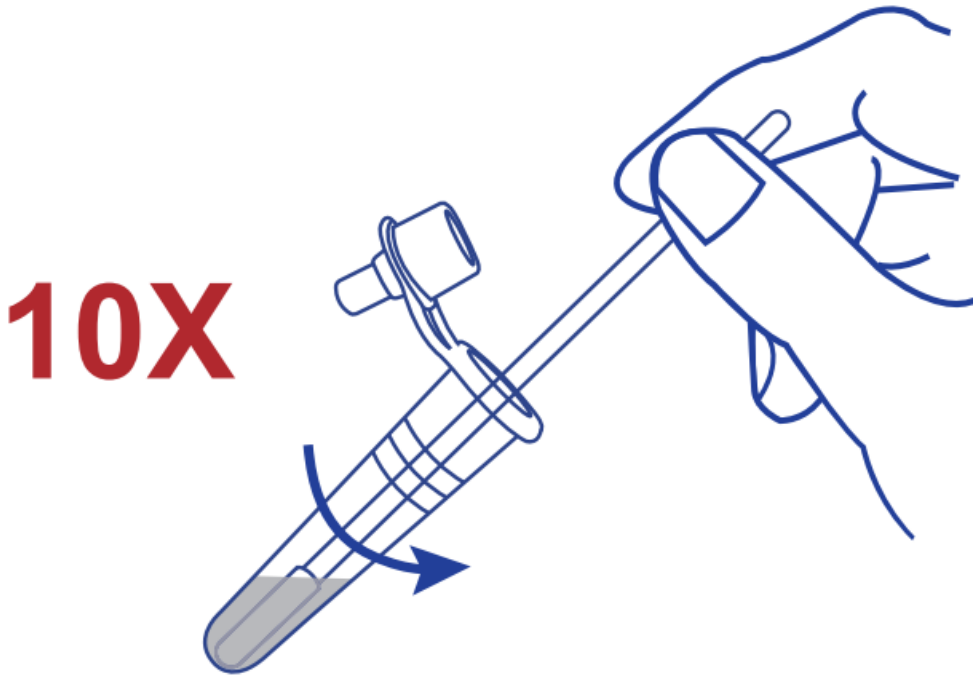


Using the same swab, repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils.

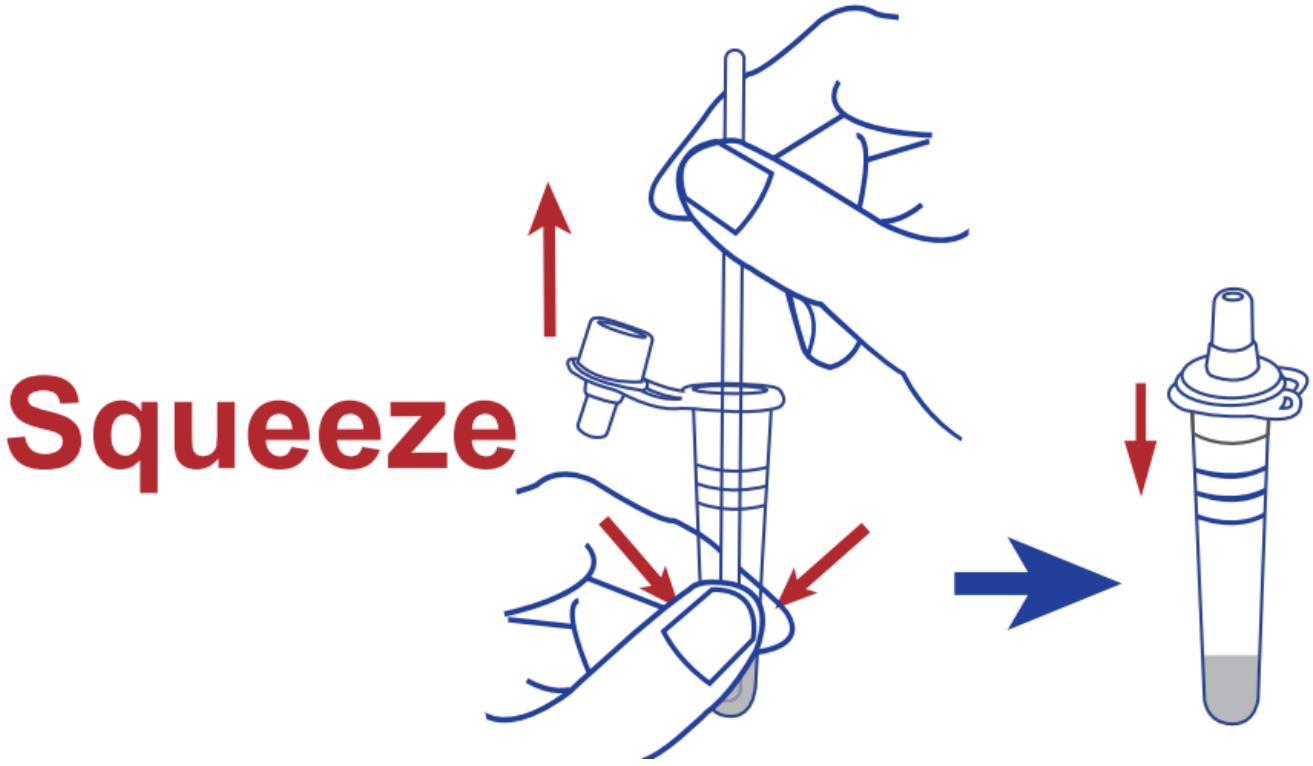
STOP Did you swab BOTH nostrils?

Inaccurate test results may occur if the nasal sample is not properly collected.

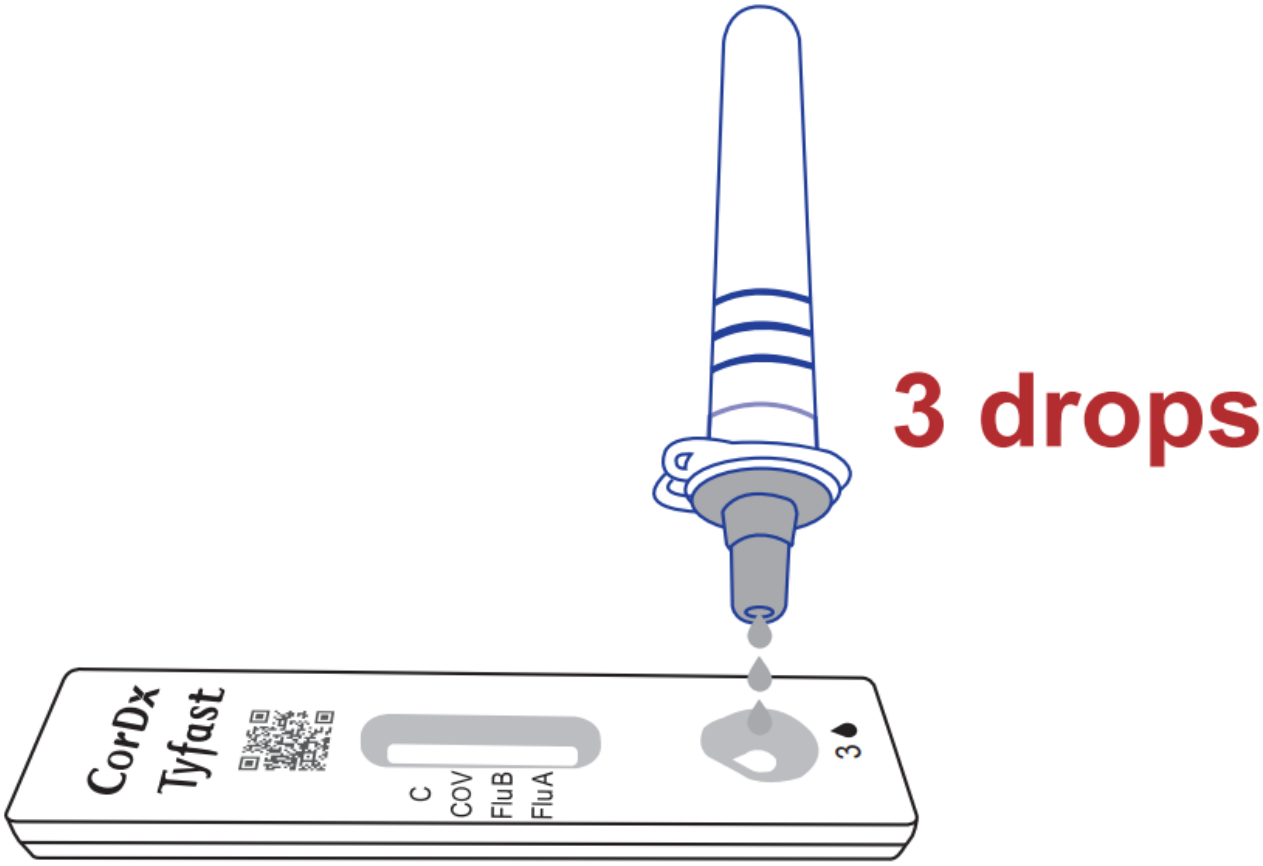
3. Insert the swab into the tube until it touches the bottom.
   Rotate the swab at least 10 times while pressing the swab head against the bottom and side of the tube.



4. Remove the swab while squeezing the sides of the tube.
   Attach the dropper tip firmly onto the tube.

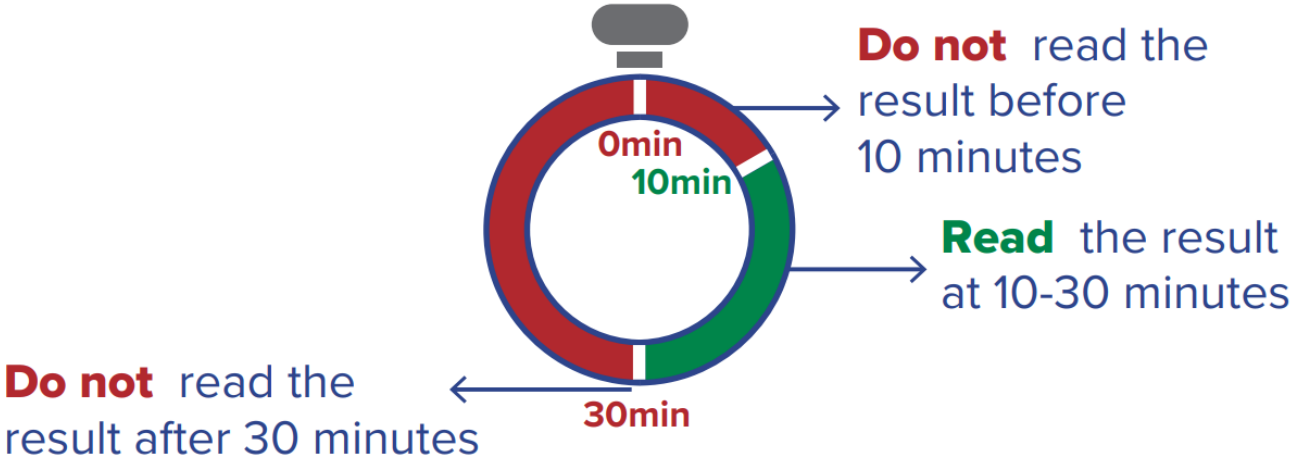


5. Slowly squeeze the tube and dispense 3 drops of solution into the sample well.



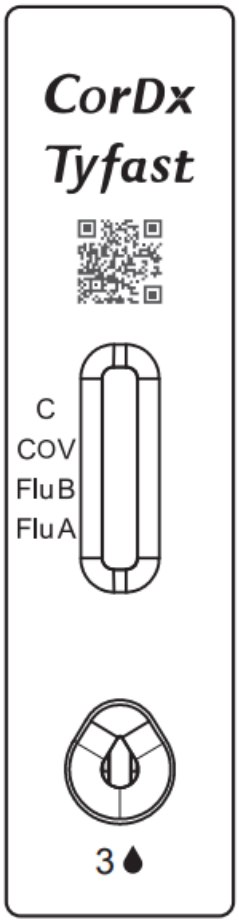
Note: Invalid results can occur if less than 3 drops are added to the Sample Well.

6. 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.

INTERPRETING RESULTS



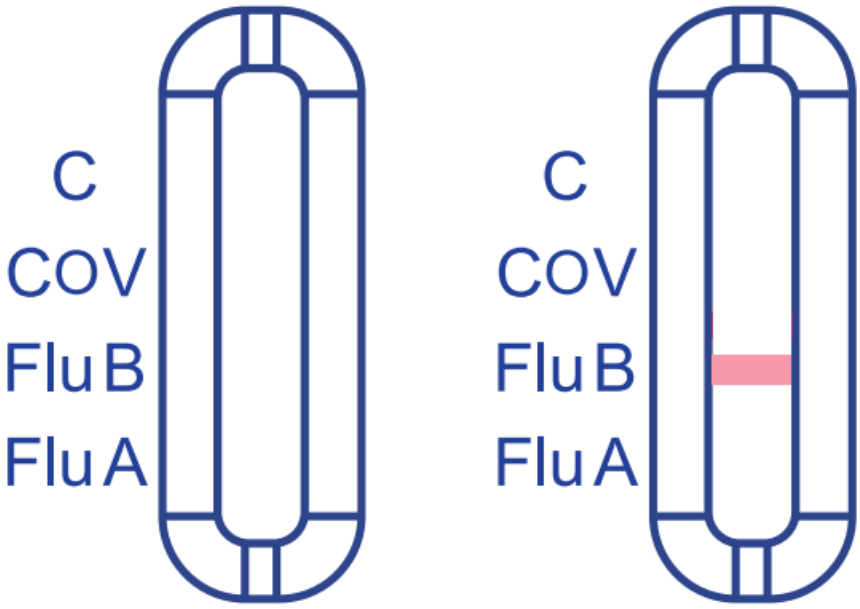
C = Control line
OV = COVID-19 line
Flu B = Influenza B line
Flu A = Influenza A line

Look for lines next to C, COV, Flu B, and Flu A.

FOR EASE OF USE, HOLD TEST CASSETTE NEXT TO THE IMAGES BELOW

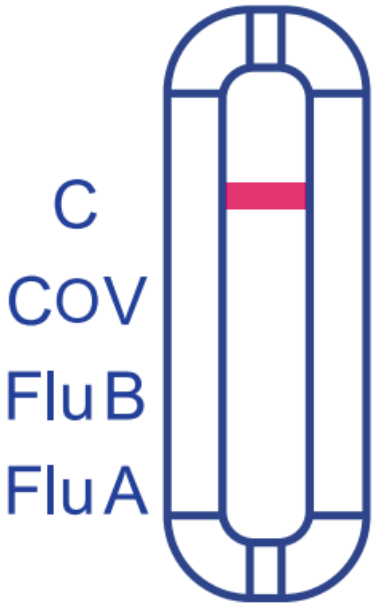
INVALID RESULTS

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 RESULTS

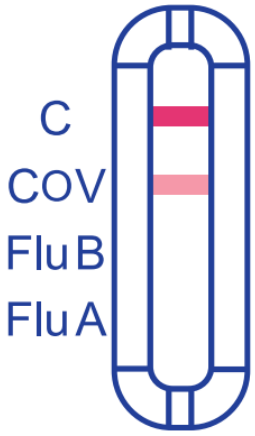
If the control line (C) is visible, but no other lines appear, the test is negative.



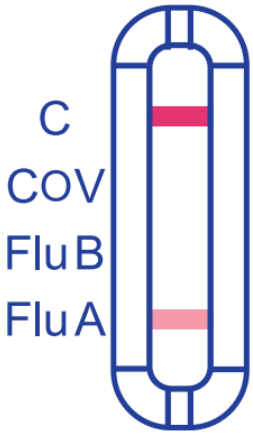
POSITIVE RESULTS

If the Control line (C) is visible and one or more lines appear(s) for any of the viruses, the test is positve for that or those viruses.

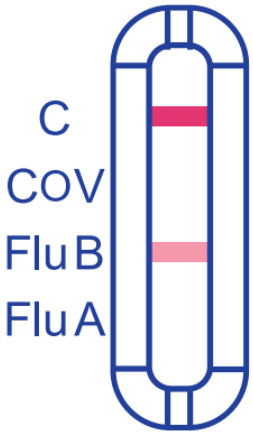
NOTE: Multiple lines may appear. The test is positive for all the tests at which a test line appears. Any red line, no matter how faint, should be considered an Indication of a positive result.



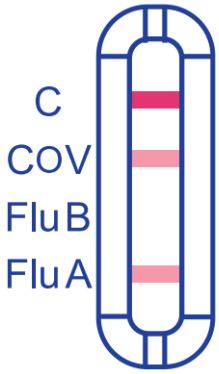
COVID-19 Positive



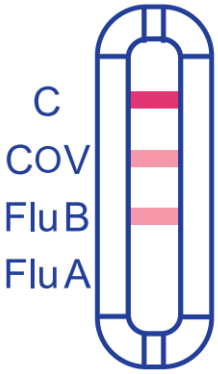
Flu A Positive



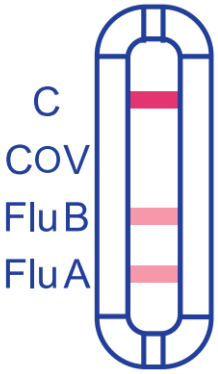
Flu B Positive



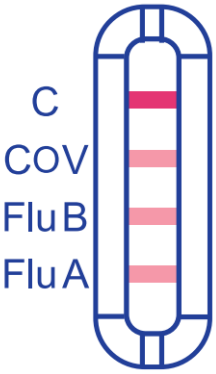
Flu A & COVID-19 Positive



Flu B & COVID-19 Positive



Flu A & Flu B Positive



Flu A & Flu B & COVID-19 Positive

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 patient sample and test kit. Repeatable “dual positive” results should be confirmed by an FDA-cleared molecular assay before reporting results.

SERIAL TESTING

Repeat Testing is needed for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B.
Repeat testing is needed to improve test accuracy for SARS-CoV-2.

Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing**	**Day 2 (Second Test)**	**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 (+)	Postive 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

EXTERNAL QUALITY CONTROL PROCEDURE

To perform a positive or negative control test, complete the steps in the TEST PROCEDURES section, treating the control swab in the same manner as a patient swab.

Minimally, CorDx recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

WARNINGS AND PRECAUTIONS

- Do not use the test kit after its expiration date.
- Do not reuse the test cassette, processing solution, or swab.
- Do not touch swab tip when handling the swab.
- Exposure to hand sanitizer may cause false positive results with this test.

- Failure to follow the test procedures may adversely affect test performance and/or invalidate the test result.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
- This test may only be used in symptomatic individuals.

EUA ˜ WARNINGS AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, and influenza A and 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.

INTENDED USE

Please see the Instructions for Use for the full intended use.

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact CorDx Technical Services at **Support@CorDx.com** or contact **858-999-1582**.

CUSTOMERS SUPPORT

CorDx, Inc.
9540 Waples St. #C
San Diego, CA 92121
PI2023001P Rev.06.2 04/2024

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

Documents / Resources

	CorDx COVID-19 Multiplex Rapid Test [pdf] Instructions COVID-19 Multiplex Rapid Test, COVID-19, Multiplex Rapid Test, Rapid Test, Test

References

- CorDx
- Coronavirus Disease 2019 (COVID-19) | CDC
- User Manual