CoviDx SARS-CoV-2 Rapid Antigen Test

For in vitro diagnostic use only.
Please read this package insert carefully prior to use and strictly follow the instructions.

INTENDED USE

CoviDx™ SARS-CoV-2 Rapid Antigen Test is a rapid immunoassay for the qualitative detection of the nucleocapsid protein in nasal swabs (NS), oropharyngeal swabs (OP), and nasopharyngeal swabs (NP) from patients suspected of a Coronavirus-19 (COVID-19) infection.

CoviDx™ SARS-CoV-2 Rapid Antigen Test aids in the clinical diagnosis of patients suspected of COVID-19. The test is intended for professional use and should be used in conjunction with other clinical evidence.

Negative results should be considered presumptive and do not preclude infection. Negative results should not be used as the sole basis for diagnosis, treatment, or other clinical and patient management decisions and should be confirmed with a molecular test for SARS-CoV-2.

CoviDx™ SARS-CoV-2 Rapid Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

SUMMARY

Coronaviruses are a family of viruses that can cause a range of respiratory illnesses from the common cold to MERS (Middle East Respiratory Syndrome) and SARS (Severe Acute Respiratory Syndrome). SARS-CoV-2 is a new coronavirus that was identified in December 2019 and can cause mild to severe illness (COVID-19). The clinical manifestations are fever, fatigue and other systemic symptoms, accompanied by dry cough and dyspnea which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multi-organ failure, and severe acid base metabolic disorder. SARS-CoV-2 transmission has been identified primarily through respiratory droplets (sneezing, coughing) and direct contact.

TEST PRINCIPLE

CoviDx™ SARS-CoV-2 Rapid Antigen test is a lateral flow immunochromatographic assay. Colloidal gold particles labeled with anti-SARS-CoV-2 antibody are fixed on the conjugate pad. Anti-SARS-CoV-2 antibody is immobilized on the “T” test line and Goat Anti-Mouse IgG is bound on the “C” control line of the nitrocellulose membrane. SARS-CoV-2 antigen in the sample will bind to anti-SARS-CoV-2 antibody conjugate in the sample pad forming a complex. This complex migrates through the nitrocellulose membrane by capillary action until it reaches the test line where it is captured by the immobilized anti-SARS-CoV-2 antibody, forming a red test line which confirms presence of SARS-CoV-2 antigen. No test line indicates the absence of SARS-CoV-2 antigen. The test contains an internal control (C line), and a red control line will form to indicate that the test was performed correctly and the test reagents are fully functional.

MATERIALS PROVIDED

25 single use pouched test devices
25 extraction tubes
25 extraction reagent vials
25 sterile swabs
1 workstation
1 package insert

MATERIALS NOT PROVIDED

Timer

KIT STORAGE AND STABILITY

CoviDx™ should be stored at 2-30°C out of direct sunlight. If stored at 2-8°C, ensure that the test device is brought to room temperature before testing. Do not freeze. Tests should be used within 1 hour of opening foil pouch. The test device is stable through the expiration date printed on the sealed pouch.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the CoviDx™ test past the expiration date.
3. Use standard precautions for collecting and handling a nasal, oropharyngeal, or nasopharyngeal swab sample.
4. All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. Use the swab provided in the kit to take a nasal or nasopharyngeal swab. If taking an oropharyngeal swab, use a polyester flocked oropharyngeal swab.
6. The extraction reagent contains a buffered salt solution (saline). If the extraction reagent comes into contact with the eye or skin immediately flush with copious amounts of water.
7. Adhere to the test instruction to obtain accurate results.
8. Do not remove the test from the foil pouch until ready to use. If the foil pouch is damaged do not use the test.
9. Allow all reagents and samples to reach room temperature before testing (15-30°C).
10. Do not replace the components in this kit with components from other kits.
11. The swab samples should be tested as soon as possible after collection, and within 1 hour.

SAMPLE COLLECTION

CoviDx™ SARS-CoV-2 Rapid Antigen test can be performed on nasal, oropharyngeal, or nasopharyngeal swabs. Use standard procedures for collecting a nasal, oropharyngeal, or nasopharyngeal swab.

Nasal swab sample collection:

Gently hold and tilt the patient's head with one hand. Carefully insert the swab into the left nostril and gently rotate the swab, ensuring that the swab tip is inserted about 2 cm (< 1 inch) into the nostril until resistance is met at the turbinates. Slowly rotate the swab in a circular path against the nasal wall. Be sure to collect any nasal drainage that may be present on the swab. Gently remove the swab and carefully insert the same swab into the right nostril repeating the collection procedure.

Oropharyngeal swab sample collection:

The patient should tilt their head slightly upward, open their mouth wide to expose both pharyngeal tonsils. Wipe both pharyngeal tonsils back and forth with slight force at least three times, and then wipe the posterior pharyngeal wall up and down at least three times.

Nasopharyngeal swab sample collection:

Gently hold the patient's head with one hand, carefully insert the swab into the nostril and slowly enter deep along the bottom of the lower nasal passage. When the top of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate and then slowly remove the swab.

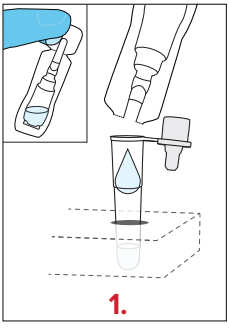
SAMPLE STORAGE

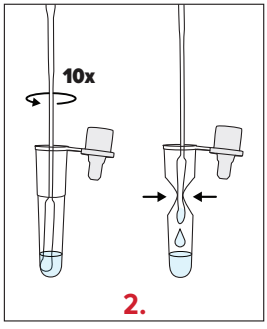
Freshly collected swab samples should be tested as soon as possible after collection, and within 1 hour of collection.

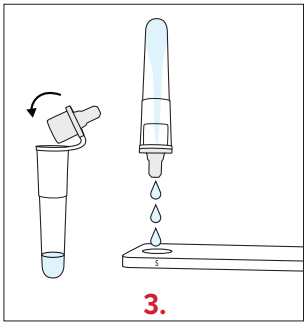
TEST PROCEDURE

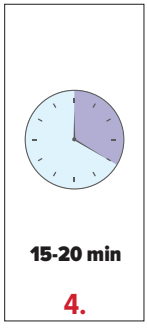
Before testing, read the instructions thoroughly. Allow all reagents and samples to reach room temperature before testing. Remove the test from the foil pouch just before testing and place on a flat surface.

1. Place an extraction tube in the cardboard workstation. Tear off top of extraction reagent vial and empty the entire contents into the extraction tube.
2. Add the swab to the extraction tube. Rotate the swab approximately 10 times, pressing the swab head against the extraction tube. Squeeze the swab head against the extraction tube to retain as much of the liquid as possible, then remove and discard swab. Immediately proceed to step 3.
3. Place cap on extraction tube, invert the extraction tube, and add 3 drops vertically to the sample well of the test device.
4. Read the test results at 20 minutes. Positive results can be read as early as 15 minutes. Do not read after 30 minutes.





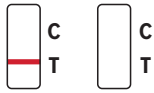




INTERPRETATION OF RESULTS

Positive

Negative



Invalid

Positive Result

A red line appears in both the test line region 'T' and the control line region 'C'.

A Positive result indicates the presence of SARS-CoV-2 antigen in the sample.

Even if the test line is weak or incomplete it should be interpreted as a positive result. Weak lines may be caused if the antigen concentration is low.

Negative Result

A red line appears in the control line region 'C' only. No line appears in the test line region "T".

A Negative result indicates the absence of SARS CoV-2 antigen in the sample, or the concentration is below the limit of detection of the test.

Invalid Result

A control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Control – CoviDx™ contains an internal control (C line). A red control line will form to indicate that the test was performed correctly and the test reagents are fully functional. The absence of a red control line indicates an invalid result. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

CLINICAL PERFORMANCE

A clinical evaluation of 288 prospectively collected oropharyngeal and nasopharyngeal swab samples from symptomatic patients with presumed COVID-19 were tested with CoviDx™ test and a high sensitivity PCR.

The study consisted of 179 males and 109 females, age range 8-86 years. All patients enrolled reported symptoms during the previous 14 days.

The clinical results are summarized in the following table:

		PCR test results		Total
		Positive (+)	Negative (-)	
CoviDx™ test results	Positive (+)	**45**	**0**	**45**
	Negative (-)	**3***	**240**	**243**
Total number		**48**	**240**	**288**

*3 patient samples had Ct values > 30

Sensitivity: 93.75% (95%CI: 83.16%-97.85%)
Sensitivity Threshold: 100% (95% CI: 92.1-100%) on samples with Ct < 30
Specificity: 100% (95%CI: 98.4-100%)
Accuracy: 99.0% (95%CI: 97.0-99.7%)

ANALYTICAL PERFORMANCE

CoviDx™ was demonstrated not to cross-react with positive samples of the following viruses and bacteria:

Drug names	Concentration	Test Result
Influenza B/Y Yamagata	1.00 x 10^2 $TCID_{50}$/mL	Negative
Influenza B/Victoria	1.07 x 10^5 $TCID_{50}$/mL	Negative
Influenza A H1N1	1.00 x 10^2 $TCID_{50}$/mL	Negative
Influenza A H3N2	1.15 x 10^2 $TCID_{50}$/mL	Negative
Adenovirus 3	1.24 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus 7	1.87 x 10^6 $TCID_{50}$/mL	Negative
Human coronavirus 229E	1.00 x 10^5 $TCID_{50}$/mL	Negative
Cytomegalovirus	1.00 x 10^5 $TCID_{50}$/mL	Negative
Enterovirus 71	2.55 x 10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 1	1.35 x 10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 2	6.31 x 10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 3	3.25 x 10^5 $TCID_{50}$/mL	Negative
Measles virus	6.31 x 10^5 $TCID_{50}$/mL	Negative
Mumps virus	6.31 x 10^6 $TCID_{50}$/mL	Negative
Respiratory syncytial virus	2.00 x 10^5 $TCID_{50}$/mL	Negative
Rhinovirus 1A	1.26 x 10^5 $TCID_{50}$/mL	Negative
Bordetella pertussis	1.30 x 10^6 CFU/mL	Negative
Chlamydophila pneumoniae	1.00 x 10^5 CFU/mL	Negative
Escherichia coli	1.00 x 10^5 CFU/mL	Negative
Haemophilus influenzae	1.20 x 10^6 CFU/mL	Negative
Mycobacterium sp.	1.00 x 10^5 CFU/mL	Negative
Mycoplasma pneumoniae	1.00 x 10^6 CFU/mL	Negative
Neisseria meninigitidis	1.00 x 10^5 CFU/mL	Negative
Neisseria gonorrhoeae	1.00 x 10^5 CFU/mL	Negative
Pseudomonas aeruginosa	3.70 x 10^6 CFU/mL	Negative
Staphylococcus aureus	2.20 x 10^6 CFU/mL	Negative
Streptococcus pneumoniae	1.00 x 10^6 CFU/mL	Negative
Streptococcus pyogenes	1.28 × 10^6 CFU/mL	Negative
Streptococcus salivarius	1.00 × 10^5 CFU/mL	Negative

INTERFERING SUBSTANCES

It was demonstrated there was no interference to the CoviDx™ test results with the following endogenous interfering substances and drugs within the given concentration range:

Interfering substance names	Concentration	Negative Interference Result	Positive Interference Result
Mucin	5%	Negative	Positive
Whole blood	5% (V/V)	Negative	Positive
α-interferon	500 thousand IU/mL	Negative	Positive
Zanamivir	500 ng/mL	Negative	Positive
Ribavirin	20 µg/mL	Negative	Positive
Oseltamivir	5 µg/mL	Negative	Positive
Peramivir	0.2 mg/mL	Negative	Positive
Lopinavir	8 mg/mL	Negative	Positive
Ritonavir	530 µg/mL	Negative	Positive
Umifenovir	4 µg/mL	Negative	Positive
Levofloxacin	30 µg/mL	Negative	Positive
Azithromycin	4.5 µg/mL	Negative	Positive
Ceftriaxone	0.8 mg/mL	Negative	Positive
Meropenem	1.1 mg/mL	Negative	Positive
Tobramycin	4 ng/mL	Negative	Positive
Phenylephrine	20 µg/mL	Negative	Positive
Oxymetazoline	0.1 mg/mL	Negative	Positive
Beclomethasone	0.1 mg/mL	Negative	Positive
Dexamethasone	2 mg/mL	Negative	Positive
Flunisolide	0.1 mg/mL	Negative	Positive
Triamcinolone acetonide	10.5 ng/mL	Negative	Positive
Budesonide	2.75 ng/mL	Negative	Positive
Mometasone	10 ng/mL	Negative	Positive
Fluticasone	55 µg/mL	Negative	Positive
Histamine hydrochloride	10 ng/mL	Negative	Positive
Sodium chloride	5%	Negative	Positive

HOOK EFFECT

CoviDx™ was demonstrated to show no hook effect at a concentration of 3.4×10^5 $TCID_{50}$/mL SARS-CoV-2 antigen.

LIMIT OF DETECTION

The limit of detection of CoviDx™ was determined to be: 1.7×10^2 $TCID_{50}$/mL.

LIMITATIONS OF THE TEST

1. CoviDx™ can only be used for the qualitative detection of SARS-CoV-2 antigen and cannot determine the quantity of SARS-CoV-2 antigens in samples.
2. CoviDx™ should be used for the detection of SARS-CoV-2 antigen in nasal, oropharyngeal, and nasopharyngeal swab samples only.
3. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. All results must be interpreted together with other clinical information including symptoms/signs, medical history, and other laboratory tests.
4. If the CoviDx™ test result is negative and clinical symptoms persist, it is recommended to repeat sampling or use other testing methods for testing. A negative result cannot preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
5. Inadequate sample collection, transportation and processing, low virus titer in the sample, or excessive freeze-thaw cycles may lead to false negative results.

REFERENCES

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LUMOS DIAGNOSTICS

IVD

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PM-083.2 MAR 2021