Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

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COVID-19 Antigen Test
(Nasal pharyngeal swab specimens)
176653-1

IVD See external Label 15-30°C ∑= 1 Test

INTENDED USE

The Cortez Diagnostic, Inc. COVID-19 Antigen Test is a is a rapid chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal pharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

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.

The Cortez Diagnostic, Inc. COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory 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 definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Cortez Diagnostic, Inc. COVID-19 Antigen Test is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests. The Cortez Diagnostic, Inc. COVID-19

INTRODUCTION

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and they are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. The two highly pathogenic viruses, SARS-CoV and MERS-CoV, cause severe respiratory syndrome in humans, and the other four corona viruses (HCoV-NL63, HCoV-229E, HCoV-OC43 and HKU1) induce only mild upper respiratory diseases in immunocompetent hosts, although some of them can cause severe infections in elderly individuals1.

In December 2019, a pneumonia outbreak was reported in Wuhan, China. On 31 December 2019, the outbreak was traced to a novel strain of coronavirus which was given the interim name 2019-nCoV by the World Health Organization (WHO), later renamed SARS-CoV-2 by the International Committee on Taxonomy of Viruses.The virus is transmitted mainly via respiratory droplets that people sneeze, cough, or exhale. The incubation period of SARS-CoV-2 is currently estimated at between two and 14 days. Common symptoms of COVID-19 infection include fever, dry cough and respiratory symptoms such as shortness of breath and breathing difficulties. More serious cases develop severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock that can lead to the death of the patient. People with existing chronic conditions seem to be more vulnerable to severe illness.

This COVID-19 Antigen Test is a Driven Flow® immunoassay for the detection of nucleocapsid protein antigen from SARS-CoV-2.

TEST PRINCIPLE

This device[2,3] is a chromatographic immunoassay. A progressive compression structure is built into the device to accelerate the reactions. This device detects SARS-CoV-2 nucleocapsid protein antigen through visual interpretation of color lines.

The Test has two pre-coated lines, "C" Control line (coated with Goat x Rabbit IgG, acting as an internal Control,) "T" Test line (coated with antibodies against COVID-19 proteins) on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Another critical component is the conjugate pad with Colloidal gold- labeled anti-COVID-19 antibodies. A bottle with lysing buffer is included in this kit to lyse and deactivate the virus. If the COVID-19 virus is present in the specimen, the lysed proteins of COVID-19 will bind to anti-COVID-19 antibodies, forming antibody-antigen complexes and then move across the membrane surface pushed via progressive compression force.

This complex migrates on the membrane test line, where it will be captured by the anti-SARS-CoV-2 antibodies. A colored test line (burgundy color) would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no burgundy color appears in the test line. The C line should always be visible after testing as a confirmation that the test is working properly.

During testing, the progressive structure progressively forces the specimen to mix with conjugated compounds thoroughly, and then flow onto the surface of the membrane strip which mobilizes the colored antibody conjugates. The reaction time can be as quick as three to seven (3-7) minutes.

MATERIALS AND COMPONENTS

Materials provided with the test kit

- Individually pouched test devices
- Swab Sample Extraction Tubes: Containing liquid extraction reagent
- Sterile nasal swabs
- Package Insert

Materials required but not provided

- Timer
- COVID-19 Antigen Control

PRECAUTIONS

- For in vitro diagnostic use.
- For prescription use only

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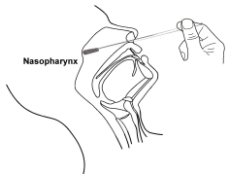
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- The instructions must be followed exactly to obtain accurate results.
- Do not remove the test from its sealed pouch until prior to use.
- Do not use expired devices and reagents.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Sample collection and handling procedures require specific training and guidance.
- To obtain the most sensitive results, directly test patient specimens without transport media.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.

KIT STORAGE AND STABILITY

1. Store the kit at 15-30°C out of direct sunlight. Kit materials are stable until the expiration date printed on the label.
2. Do not freeze the kit.
3. Exposing the kit to temperatures over 86°F (30°C) may reduce the shelf life or cause malfunction of the device.



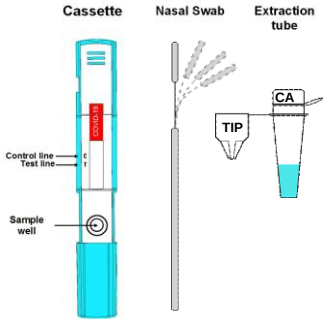
SPECIMEN STORAGE

- Specimens should be tested as soon as possible after collection; or Stored at 2-8°C for 72 hours.
- If long-term storage is required, store at -20 °C for up to 3 months, or store at -80 °C for 1 year.
- Avoid repeat freezing and thawing.

For *in vitro* diagnostic use only. Rx Only

- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.

TEST COMPONENTS



SPECIMEN COLLECTION & PREPARATION

IMPORTANT: Proper specimen collection, storage, and transport are critical for the performance of this device.

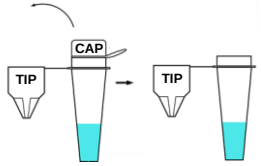
Use standard clinical methods to collect nasal pharyngeal specimens.

1. Nasal Pharyngeal Specimen:

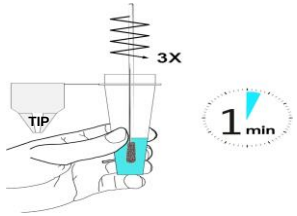
Tilt the patient's head back 70 degrees. Have the patient close his/her eyes as this helps minimize discomfort. Gently insert the swab through one of the nostrils and horizontally into the nasal passage up to the measured distance on the swab shaft or until resistance is met. Rotate the swab 2-3 times and then hold the swab in place for 5-10 seconds for better specimen absorption.

SPECIMEN TRANSFER TO EXTRACTION TUBE

1. Remove the white cap from tube.



2. After collecting specimens with swab, insert the swab head into the liquid in extraction tube and swirl a minimum of three (3) times then leave in place for one (1) minute.



3. When removing swab, squeeze the sides of extraction tube pressing the swab head against the inside of extraction tube to extract as much liquid as possible into the tube. Then close the dropper tip and tightly seal the extraction tube

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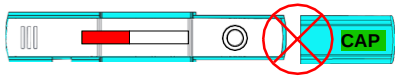
with specimen.

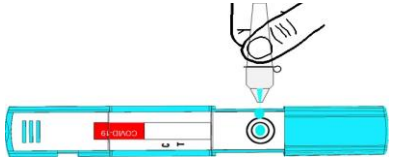
ASSAY PROCEDURE

1. Prior to testing, specimen and all components of the kit must be equilibrated to room temperature.
2. Remove the cassette from the foil pouch. Do not open pouch until ready to perform the test.

***Note: Do not pull the cap off the device.**

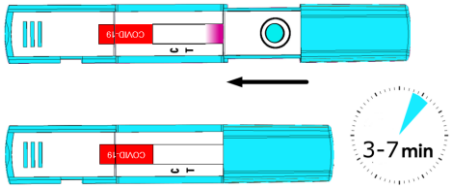


3. Squeeze the extraction tube and apply two (2) drops vertically into the sample well of the cassette.



4. Wait until the Burgundy color flow appears in the Result Window near the T line before closing the cap.

5. Close the cap of test device with force until it clicks. Start the timer. Read the result in three to seven (3-7) minutes.



INTERPRETATION OF THE TEST RESULT

Negative	C T
Positive	C T
Invalid	C T C T

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen (T).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
4. If the test is invalid, a new test should be performed with a new sample and a new extraction tube and test device.
5. Invalid results may relate to insufficient volume of specimen and/or incorrect testing procedure. Review the procedure and repeat the test using a new test device.

*The presence of any line no matter how faint the result is considered positive.
*Positive results should be considered in conjunction with the clinical history and other data available.

PERFORMANCE CHARACTERISTICS

Clinical Agreement Study

211 clinical samples were collected and evaluated in triplicate in the United States. The clinical findings compared to a COVID-19 molecular assay are shown as follows:

Method		PCR		Total
COVID-19 Antigen Test	Results	Positive	Negative	Results
	Positive	37	3	40
	Negative	3	168	171
Total Results		40	171	211

Relative Sensitivity: 92.5% 95% CI (85.2 – 99.8%)
Relative Specificity: 98.2% 95% CI (94.9 – 99.6%)

Analytical Performance

a) Limit of Detection (LoD):
The limit of detection was determined with inactivated SARS-CoV-2 viral culture and has been evaluated **at 2.8 x10³ TCID50/mL.**

b) Cross-Reactivity:
Cross-reactivity and potential interference was evaluated by testing various microorganisms, viruses and negative matrixes. The final concentration of the organisms and viruses are documented in the Table below.

Organism	Concentrations	Cross-Reactive Results
Adenovirus type1	1.14 x 10^5 PFU	Negative
Adenovirus type 7	6.69 x 10^6 PFU	Negative
Bordetella pertussis	1.17 x 10^6 CFU	Negative
Candida albicans	2.13 x 10^6 CFU	Negative

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Organism	Concentrations	Cross-Reactive Results
Chlamydia pneumoniae		Negative
Cytomegalovirus	2.9 x 10^5 PFU	Negative
Enterovirus	1.06 x 10^5 PFU	Negative
Haemophilus influenzae	4.4 x 10^6 CFU	Negative
Human corona virus 229E	8.82 x 10^5 PFU	Negative
Human corona virus NL63	1.19 x 10^5 PFU	Negative
Human corona virus OC43	6.69 x 10^5 PFU	Negative
Human metapneumovirus	1.19 x10^5 PFU	Negative
Human parainfluenza type 1	2.92 x 10^5 PFU	Negative
Human parainfluenza type 2	1.06 x 10^5 PFU	Negative
Human parainfluenza type 3	5.96 x 10^5 PFU	Negative
Human parainfluenza type 4	8.05 x 10^5 PFU	Negative
Pooled human nasal wash-to represent diverse microbial flora in the human respiratory tract	N/A	Negative
Human corona virus HKU1 In-silico (protein blast)	N/A	Negative
Influenza A (H1N1)	1.0 x 10^5 PFU	Negative
Influenza B	1.75 x 10^5 PFU	Negative
Legionella pneumophila	1.88 x 10^6 CFU	Negative
MERS-coronavirus (protein blast)	6.23 x 10^5 PFU	Negative
Moraxella catarrhalis	9.4 x 10^6 CFU	Negative
Mycobacterium tuberculosis avirulent	6.86 x 10^6 CFU	Negative
Mycobacterium tuberculosis In-silico (protein blast)	N/A	Negative
Mycoplasma pneumoniae	3.16 x 10^6 CFU	Negative
Pneumocystis jirovecii	1.56 x 10^6 CFU	Negative
Respiratory syncytial virus Type B	1.97 x 10^5 PFU	Negative
Rhinovirus Type 1A	2.92 x 10^5 PFU	Negative
SARS-coronavirus (In silico) (protein blast)	1 x 10 ^5 PFU	Negative
Streptococcus pneumoniae	2.78 x 10^6 CFU	Negative
Streptococcus pyogenes	1.64 x 10^6 CFU	Negative

C) Endogenous Interference Substances Studies:

A study was performed demonstrate that twenty-six (26) potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the Cortez Diagnostic, Inc. COVID-19 Antigen Test

Analyte	Concentration
Chloraseptic, (Benzocaine, Menthol)	0.7 g/mL
Chlorpheniramine	5 mg/mL
Crest Prohealth Advanced	25%
Cromolyn	15% v/v
Flonase-Fluticasone	5%
4-Acetamidophenol	10 mg/mL
Ephedrine	20 mg/mL
Guaiacol glyceryl ether	20 mg/mL
Halls Relief Cherry Flavor - Menthol	0.8 mg/mL
Listerine Cool Mint	25 %
Mucin	2.5mg/mL
Mupirocin	10 mg/mL
Nasocort Allergy 24-hour-Triamcinolone	5%
Naso GEL (NeilMed)	5% v/v
Neo-Synephrine-Phenylephrine hydrochloride	5%
Oseltamivir Phosphate (Tamiflu)	5 mg/mL
Oxymetazoline	15% v/v
Phenylephrine	15% v/v
Phenylpropanolamine	20 mg/mL
Phenol	15% v/v
Rhinocort-Budesonide Glucocorticoid	5%
Saline Nasal Spray	15%
Tobramycin	1.25 mg/mL
Zanamivir	282.0 ng/mL
Zicam Cold Remedy	5%
Whole Blood	5%

QUALITY CONTROL

Built-in Control:

The Cortez Diagnostic, Inc. with Driven Flow® COVID-19 Antigen Test has a built-in (internal) procedural control, the C line. For daily quality control, it is recommended to record the result for each test run. The appearance of a burgundy red C line for COVID-19 Antigen Test indicates that the test has been performed correctly, including that the proper volume of specimen has been absorbed and the specimen flow has

occurred. If the C line does not appear within 3 minutes, the test result is considered invalid.

External Controls

It is recommended that the external positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

*External controls, not included in this kit, may be purchased and used to verify that all reagents and procedures are performing properly.

The failure to obtain a negative result with the Negative Control or a positive result with the Positive Control likely indicates that the test was not performed properly or that the test reagents were not functioning properly.

LIMITATIONS OF PROCEDURE

- This Cortez Diagnostic, Inc. COVID-19 Antigen Test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Use of viral transport media may result in deceased test sensitivity, and directly testing specimens is recommended.
- The contents of this kit are to be used for the qualitative detection of SARS antigens from nasopharyngeal swab.
- The performance of the Cortez Diagnostic, Inc. COVID-19 Antigen Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

REFERENCES

1. Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-ncov/index.html
2. US patent 9,377,457, Progressive compression driven flow cartridge for analyte detecting strip and method.
3. US patent 9,702,872, Rapid diagnostic test device by driven flow technology.

ISO 13485:2016

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EC REP	**CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands.** www.cepartner4u.eu