CovAbScreen™

SARS-CoV-2 Ab Test

COVYDx, Inc.

INTENDED USE

The CovAbScreen™ SARS-CoV-2 Antibody Test is a lateral-flow immunoassay intended for the qualitative detection of total antibody (including IgG, IgA and IgM) to SARS-CoV-2 in oral fluid from patients with suspected COVID-19 infection. The CovAbScreen™ SARS-CoV-2 Antibody Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating a recent or prior infection, or vaccination. Results from the CovAbScreen™ SARS-CoV-2 Antibody Test should not be used as the sole basis for diagnosis.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results must be combined with clinical observations, patient history, and epidemiological information. The sensitivity of the CovAbScreen™ SARS-CoV-2 Antibody Test early after infection is unknown. False-positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Results are for the detection of total SARS-CoV-2 antibodies. IgG, IgA, and IgM antibodies to SARS-CoV-2 are generally detectable in blood and oral fluid several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

For professional use only. For *in vitro* diagnostic use only.

BACKGROUND

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV)[1-5]. SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Several known coronaviruses are circulating in animals that have not yet infected humans.

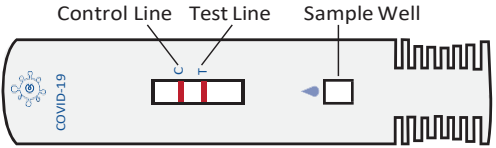
2019 Novel Coronavirus (SARS-CoV-2) is identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 report a mild to severe respiratory illness with symptoms of fever, cough, shortness of breath, but can also be asymptomatic. Symptomatic, pre-

symptomatic, and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission[6]. Currently, no specific treatments are available for COVID-19. There is an urgent need for rapid tests to manage the ongoing pandemic.

PRINCIPLES OF THE PROCEDURE

The CovAbScreen™ SARS-CoV-2 Antibody Test is a lateral-flow chromatographic immunoassay that can detect antibodies against the SARS-CoV-2 virus.

The test uses a SARS-CoV-2-specific protein (spike protein S1 domain) bound to a detector and a cocktail of anti-human IgA, IgM, and IgG antibodies for capture. The test control line employs Streptavidin bound to a detector and Biotin coupled Bovine Serum Albumin.



When a test specimen is dispensed into the sample well of the test cartridge, the specimen migrates by capillary action along the cartridge. The anti-SARS-CoV-2 antibody, if present in the specimen, will bind to the SARS-CoV-2 colloidal gold conjugate forming an immunocomplex. The immunocomplex will then be captured by the anti-immunoglobulin coated test line, forming a reddish-purple colored test line, indicating a SARS-CoV-2 virus antibody-positive test result.

The control line will capture Streptavidin colloidal gold. If the control line is present, it indicates that the test cartridge ran properly.

Information regarding the immune response to SARS-CoV-2 is limited and still evolving.

At this time, it is unknown how long antibodies may persist following infection or vaccination.

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use.
2. Read the product insert completely before using this assay. Follow the instructions carefully, as not doing so may result in inaccurate or invalid test results.

3. Testing prior to 14 days after onset of symptoms may produce a false negative test result.
4. Biotin or hair growth supplements may produce invalid test results. Pause intake for 3-5 days prior to testing.
5. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate or invalid test results.
6. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch and sample solution are brought to operating temperature before performing the test.
7. Do not use expired kit components or tests.
8. Do not open the sealed test cartridge pouch until you are ready to conduct the test.
9. The person tested should not eat, drink, or smoke within 10 minutes of collecting an oral fluid sample and performing the test.
10. If preservative bag is missing, DO NOT USE. Discard test device and use a new test device.
11. Do not use any test device if the cartridge pouch has been perforated.
12. Do not mix reagents from different lot numbers of kits.
13. Avoid contamination of collection swab and sample solution with foreign matter.
14. Do not use the collection swab if the package has been opened or if the swab is dropped.
15. Do not touch the collection swab pad with fingers before or after specimen collection.
16. Test results should be read between 15 and 20 minutes. Reading after 20 minutes may give erroneous results.
17. Only interpret the test results where there is adequate lighting.
18. Do not reuse the collection swab or specimen collection tube.

SAFETY PRECAUTIONS

1. Specimens may be infectious. Use universal precautions when performing this assay.

2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.
3. Dispose of all samples and materials used in the test procedure in normal trash. Proper handling and disposal methods should be established according to local regulations.
4. Use routine laboratory precautions. Do not eat, drink, or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.

STORAGE AND STABILITY

The CovAbScreen™ SARS-CoV-2 Antibody Test kit should be stored in unopened pouches at 2 to 30°C (36 to 86°F). Do not freeze. Do not open pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch. If stored at 2-8˚C, ensure that the test device is brought to 18-30˚C (64 to 86°F) before opening.

REAGENTS AND MATERIALS

REAGENTS AND MATERIALS PROVIDED

Instructions for use (this document)

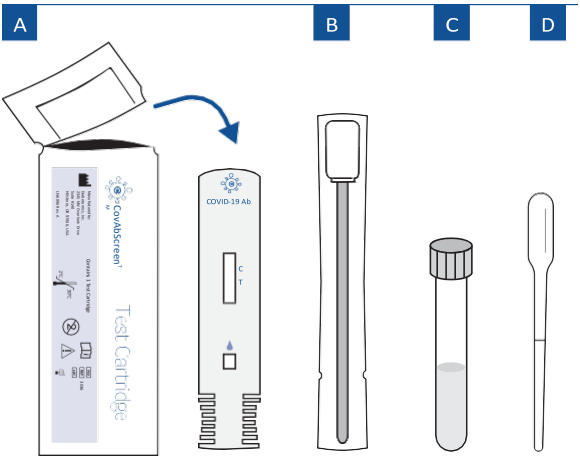
Each test kit contains:

A. One (1) test cartridge sealed in a foil pouch with preservative bag

B. One (1) individually wrapped oral fluid collection swab

C. One (1) tube containing 800 µL sample solution (buffer containing protein stabilizer and antimicrobial agent)

D. One (1) sample transfer pipette



OTHER REQUIRED, BUT NOT PROVIDED MATERIALS

- Timer

SUGGESTED, BUT NOT REQUIRED MATERIALS

CovAbScreen™ Controls Kit (Cat.# 2039)

Scan the QR Code to view Instructional video:

PREPARATION AND SPECIMEN COLLECTION

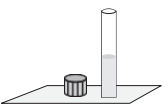
Consider any materials of human origin as infectious and handle using standard biosafety procedures.

PREPARING FOR THE TEST

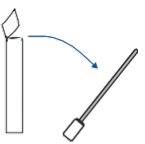
1. Read and make sure you understand these instructions before running the test.
2. Have a watch, clock, or timer available.
3. Wash and dry your hands before starting the test.
4. If the patient wears dentures or false teeth, have them take them out of their mouth before performing the test.
5. The patient should not eat or drink during the 10 minutes before starting the test. This includes chewing tobacco or chewing gum.
6. If a second oral sample is needed, wait until at least 30 minutes after collecting the first sample before collecting a new one.

COLLECTING THE SPECIMEN

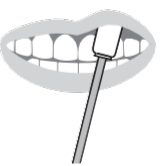
1 Open the sample collection tube and place it on a level surface.



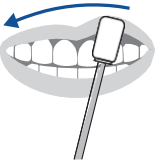
2 Tear open the package containing the swab and remove the swab by grasping the handle. Do not touch the cloth end of the swab.



3 Identify the upper gum line where the teeth and gum meet. Insert the swab into the back corner of the upper gum line in the mouth.

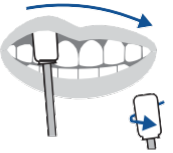


4 Apply moderate pressure to slowly and gently wipe the entire length of the upper gum line with the flat side of the swab in one direction until reaching the other corner of the mouth. Do not brush the gums.

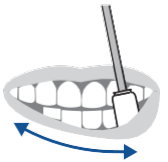


5 Using the same procedure, gently wipe the swab a second time back across the upper gum line to return to the starting position.

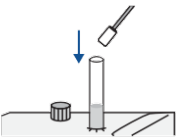
Turn the swab over.



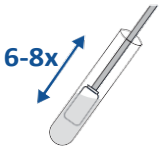
6 Using the other side of the swab's flat head, do the same process with the entire lower gum line. Gently wipe the swab against the entire length of the lower gum line in one direction, then back to the starting position.



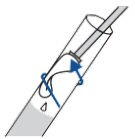
7 Immediately and carefully without splashing, insert the swab head into the tube containing the sample solution.



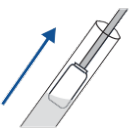
8 Grasp the swab handle firmly and slowly push the swab up and down inside the tube 6 to 8 times. This will mix the liquid in the tube with the liquid in the swab as much as possible.



9 Squeeze as much liquid from the swab as possible by pressing each side of the swab 2 to 3 times against the inside of the tube above the level of the liquid.

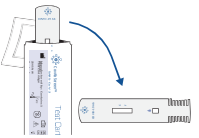


10 Remove the swab from the tube and discard. The specimen is now ready for testing.

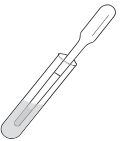


TEST PROCEDURE

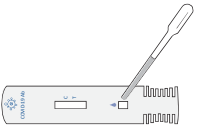
1 Remove the test cartridge from the foil pouch immediately before it is to be used and place on a flat surface.



2 Use the transfer pipette to collect the liquid sample. Press the bulb completely and release to fill the pipette.

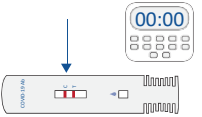


3 Deliver 5 drops of the liquid sample from the transfer pipette into the sample well.



4 Start a timer for 15 minutes and allow the test to run. The reading window will start to show a red color as the test runs.

5 At 15 minutes, evaluate the lines in the reading window on the cartridge. DO NOT INTERPRET RESULTS AFTER 20 MINUTES

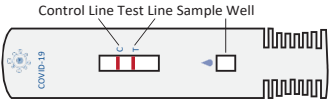


After interpreting the results, dispose of the kit and materials in the normal trash.

INTERPRETATION OF TEST RESULT

POSITIVE TEST RESULT

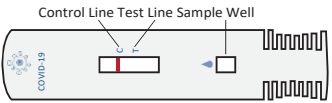
When there is a visible color line adjacent to both the test (T) line and the control (C) line, this indicates that the sample is positive for SARS-CoV-2 antibodies.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

NEGATIVE TEST RESULT

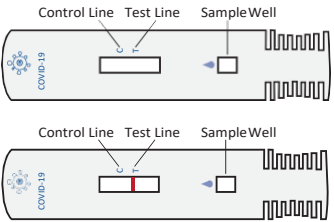
When only the control line (C) is visible, this indicates that there were insufficient or no SARS-CoV-2 antibodies to be detected.



Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

INVALID TEST

For the test to be valid, there must be a visible control line (C). If there is no control line, the sample added was inadequate.



PERFORMANCE CHARACTERISTICS

CLINICAL SENSITIVITY: CovAbScreen™ Antibody Oral Fluid (GCF) Test Positive percent agreement (PPA) in SARS-CoV-2-positive samples – laboratory-based study

Subjects: 73 subjects hospitalized for COVID-19 infection or suspected of COVID-19 and confirmed positive in a SARS-CoV-2 PCR test. The sample collections ranged from 3 days to 218 days from onset of symptoms. Samples were tested with the CovAbScreen™ SARS-CoV-2 Antibody Test by lab personnel. Positive percent agreement (PPA) with SARS-CoV-2 PCR-positive samples arranged by days post onset of symptoms is summarized in the table below.

Days from onset of symptoms	PCR-positive	Total Ab (IgA, IgM, IgG)-positive	PPA	95% CI
3-7 days	12	5	5/12 (41.67%)	15.17% - 72.33%
8-14 days	19	16	16/19 (84.21%)	60.42% - 96.62%
≥15 days	42	41	41/42 (97.62%)	87.43% - 99.94%
Total Subjects	73			

CLINICAL SPECIFICITY: CovAbScreen™ Antibody Oral Fluid (GCF) Test Negative percent agreement (NPA) in SARS-CoV-2-negative samples- laboratory-based study.

Subjects: 82subjects who were SARS-CoV-2-negative based on a PCR test were tested with the CovAbScreen™ SARS-CoV-2 Antibody Test. Negative percent agreement (NPA) with SARS-CoV-2 negative samples is summarized in the table below.

Number of subjects	Total Ab (IgA, IgM, IgG)-positive	Total Ab (IgA, IgM, IgG)-negative	NPA	95% CI
82	1	81	81/82 (98.78%)	93.39% - 99.97%

Point-of-care CovAbScreen™ total Ab test clinical agreement-oral fluid (gingival crevicular fluid, GCF)

A total of 151 subjects who tested positive or negative for SARS-CoV-2 by the molecular test were tested by six non-laboratorian operators. The sample collections ranged from 8 days to 160 days from onset of symptoms. Samples were tested with the CovAbScreen™ SARS-CoV-2 Antibody Test. Positive percent agreement (PPA) with SARS-CoV-2 PCR-positive samples and negative percent agreement (NPA) are summarized in the tables below.

Days from onset of symptoms	PCR-positive	Total Ab (IgA, IgM, IgG)-positive	PPA	95% CI
0-7 days	0	NA	NA	NA
8-14 days	4	4	4/4 (100%)	39.76% - 100%
≥15 days	69	67	67/69 (97.10%)	89.92% - 99.65%
Total Subjects	73			

Number of subjects	Total Ab (IgA, IgM, IgG)-positive	Total Ab (IgA, IgM, IgG)-negative	NPA	95% CI
78	2	76	76/78 (97.4%)	91.04% - 99.69%

CROSS-REACTIVITY

The CovAbScreen™ SARS-CoV-2 Antibody Test was evaluated for potential cross-reactivity in conditions unrelated to SARS-CoV-2 infection. The results are summarized in the table below.

Cross-reactant (Positive serum samples)	Number of samples	Reactive (Positive)	Non-Reactive (Negative)
Influenza A	5	0	5
Influenza B	7	0	7
Haemophilus influenza	8	0	8
Respiratory Syncytial Virus (RSV)	9	0	9
Hepatitis C Virus (HCV)	5	0	5
Hepatitis B Virus (HBV)	5	0	5
Human Immunodeficiency virus (HIV)	5	0	5
Alpha coronavirus 229E	20	0	20
Alpha coronavirus NL63	17	0	17
Beta coronavirus OC43	17	0	17
Beta coronavirus HKU1	12	0	12
Rheumatoid factor (RF)	5	0	5

INTERFERENCE

The following potential interferents tested did not show interference with test results.

Matrix tested	Potential Interferent	Concentration tested
Gingival crevicular fluid	Ethanol	1% v/v
	Nicotine	0.01 mg/mL
	Caffeine	1 mg/mL
	Food	Custom
	Soda	Normal consumption
	Mouthwash	Normal Use
	Cough syrup	7%

LIMITATIONS OF THE PROCEDURE

1. This is for professional use only.
2. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for

SARS-CoV-2 is necessary.

3. Results from antibody testing should not be used as to diagnose or exclude SARS-CoV-2 infection.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains such as coronavirus HKU1, NL63, OC43, or 229E, or from vaccination with a SARS-CoV-2 vaccine.
5. Not for the screening of donated blood.
6. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
7. Proper sample collection is critical for optimal test performance. The CovAbScreen™ SARS-CoV-2 Antibody Test must be used in accordance with the instructions in this product insert to obtain accurate results.
8. This test uses a biotin-streptavidin interaction for generating the Control Line. Taking biotin supplements other than common multivitamins may cause invalid test results.
9. This test has not been validated in the presence of active oral infections and/or bleeding gums.
10. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of the prepared sample may yield erroneous results.
11. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
12. The test is limited to qualitative detection of antibodies specific for SARS-CoV-2. The color intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody levels in the specimen.
13. A negative result does not rule out disease or previous exposure and can occur if the quantity of antibodies for SARS-CoV-2 in the specimen is below the detection limit of the test.

REFERENCES

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GLOSSARY OF SYMBOLS


Manufacturer


Storage temperature


Do not reuse

For in vitro diagnostic use


Consult instructions for use


Caution

Component number

Batch code, lot number


Date of manufacture


Use by date

NOTES

CovAbScreen.com

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LN-6129 Rev. D