CovAb™

SARS-CoV-2 Ab Test

For Emergency Use Authorization (EUA) only

For prescription use only

For in vitro diagnostic use only

Version 4.0

INTENDED USE

The CovAb™ SARS-CoV-2 Ab 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 (gingival crevicular fluid – GCF). The CovAb™ SARS- CoV-2 Ab Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The CovAb™ SARS-CoV-2 Ab Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Testing is limited to laboratories certified under t he Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet 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 W aiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of total SARS-CoV-2 antibodies. The duration of time antibodies are present in oral fluid post- infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the CovAb™ SARS-CoV-2 Ab Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False-positive results for CovAb™ SARS-CoV-2 Ab Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different SARS-CoV-2 antibody assay.

Samples should only be tested from individuals who are 15 days or more post symptom onset.

The CovAb™ SARS-CoV-2 Ab Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

BACKGROUND

Coronaviruses (CoV) are a large family of viruses that cause illnesses 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.

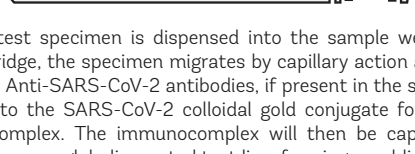
Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Several known coronaviruses are circulating in animals that have not yet infected humans.

The 2019 Novel Coronavirus (SARS-CoV-2) was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The disease caused by SARS-CoV-2 is known as Coronavirus Disease (COVID-19). Patients infected 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]. There is an urgent need for rapid tests to manage the ongoing pandemic.

PRINCIPLES OF THE PROCEDURE

The CovAb™ SARS-CoV-2 Ab Test is a lateral-flow chromatographic immunoassay that can detect antibodies specific to the SARS-CoV-2 virus in oral fluid specimens.

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. Anti-SARS-CoV-2 antibodies, 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. If the control line is absent, it indicates an invalid result and the sample should be re-tested with a different test cartridge.

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 SARS-CoV-2 infection.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only. For prescription use only. For use under Emergency Use Authorization only.
2. Test cartridges are single-use only. Do not reuse test cartridges.
3. This product has not been FDA-cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
4. This product has been authorized only for detecting the presence of total antibodies to SARS-CoV2, not for any other viruses or pathogens.
5. 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. All human oral fluid specimens should be handled as potentially infectious material. The Centers for Disease Control and the National Institutes of Health recommend that potentially infectious agents be handled at Biosafety Level 2.
7. 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.
8. 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.
9. This test should be performed at 18 to 30°C (64 to 86°F). If test kit stored refrigerated, ensure that the pouch and sample solution are brought to operating temperature before performing the test.
10. Specimens from patients with active oral infections and/or bleeding gums were not tested and could provide erroneous results.
11. Do not use expired kit components or tests.
12. Do not open the sealed test cartridge pouch until you are ready to conduct the test.
13. The person tested should not eat, drink, or smoke within 30 minutes of collecting an oral fluid sample and performing the test.
14. If desiccant packet is missing, DO NOT USE. Discard test device and use a new test device.

15. Do not use any test device if the cartridge pouch has been perforated.
16. Do not mix reagents from different lot numbers of kits.
17. Avoid contamination of collection swab and sample solution with foreign matter.
18. Do not use the collection swab if the package has been opened or if the swab is dropped.
19. Do not touch the collection swab pad with fingers before or after specimen collection.
20. Test results should be read at 15 minutes. Reading after 20 minutes may give erroneous results.
21. Only interpret the test results where there is adequate lighting.
22. Wash hands thoroughly after performing the test.
23. Do not reuse the collection swab or specimen collection tube.
24. Each test device is for single use only.

SAFETY PRECAUTIONS

1. Oral fluid specimens may be infectious. Use universal precautions when performing this assay.
2. Wear protective clothing such as laboratory coats, disposable gloves and safety glasses when handling patient samples. Wash hands thoroughly before and after handling specimens and kit reagents.
3. Dispose of all samples and materials used in the test procedure in a biohazard waste container. 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.
5. Use freshly prepared 10% bleach to decontaminate surfaces in the event of a spill of collected specimen.

STORAGE AND STABILITY

The CovAb™ 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.

SPECIMEN STORAGE AND STABILITY

If testing cannot be performed immediately after collection, specimen should be stored at 2-8°C for up to 24 hours.

REAGENTS AND MATERIALS

REAGENTS AND MATERIALS PROVIDED

Instructions for use (this document)

Each box of fifty (50) tests contains 50 Single Test kits.

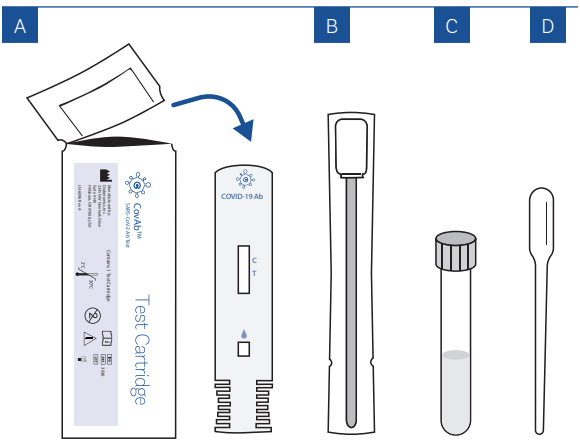
Each Single Test kit contains:

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

B. One (1) individually wrapped sterile 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
- Tube rack
- CovAb™ Control Kit (Cat. # 2039): 2 x 0.5 mL

EXTERNAL CONTROLS

External positive and negative controls are not included with the test kit. External controls are available for purchase separately

from Diabetomics, Inc. (Cat. #2039). To run the external controls, follow the instructions provided in the CovAb™ Control kit. External controls should be run before testing any samples with the CovAb™ SARS-CoV-2 Ab Test. If either of the positive or negative controls give incorrect results, re-test the controls on unused new cassettes. If incorrect results occur twice, do not use the kit to test clinical samples and contact Diabetomics, Inc.

PREPARATION AND SPECIMEN COLLECTION

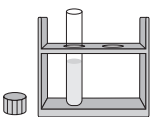
Consider any materials of human origin as infectious and handle using standard biosafety procedures.

PREPARING FOR THE TEST

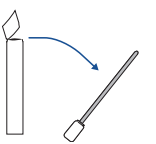
1. Read and make sure you understand these instructions before running the test.
2. Have a watch, clock, or timer available.
3. Wash and dry your hands before starting the test.
4. If the patient wears dentures or false teeth, have them take them out of their mouth before performing the test.
5. The patient should not eat or drink during the 30 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

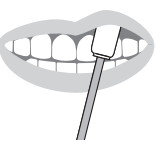
1 Open the sample collection tube and place it in a tube rack.



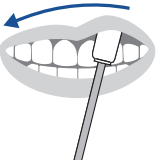
2 Tear open the package containing the swab and remove the swab by grasping the handle. Do not touch the cloth end of the swab.



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.

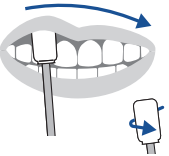


4 Apply moderate pressure to slowly and gently brush the entire length of the upper gum line with the flat side of the swab in one direction until reaching the other corner of the mouth.

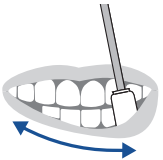


5 Using the same procedure, gently wipe the swab a second time back across the upper gum line to return to the starting position.

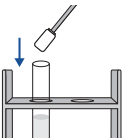
Turn the swab over.



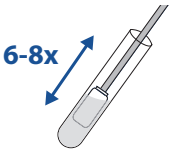
6 Using the other side of the swab's flat head, do the same process with the entire lower gum line. Gently wipe the swab against the entire length of the lower gum line in one direction, then back to the starting position.



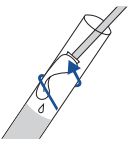
7 Immediately and carefully without splashing, insert the swab head into the tube containing the sample solution.



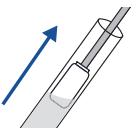
8 Grasp the swab handle firmly and slowly push the swab up and down inside the tube 6 to 8 times. This will mix the liquid in the tube with the liquid in the swab as much as possible.



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.

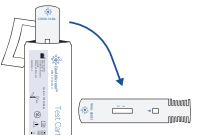


10 Remove the swab from the tube and discard it. The specimen is now ready for testing.

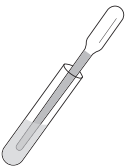


TEST PROCEDURE

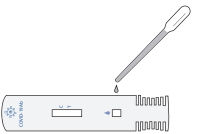
1 Remove the test cartridge from the foil pouch immediately before it is to be used and place it on a flat surface.



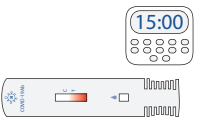
2 Use the transfer pipette to collect the liquid sample. Press the bulb completely and release to fill the pipette up to the line marking.



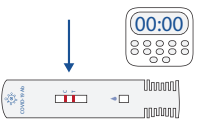
3 Deliver 5 drops of the liquid sample from the tip end of the transfer pipette into the sample well.



4 Start a timer for 15 minutes and allow the test to run.



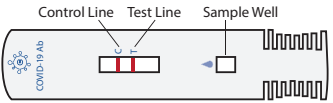
5 Read results in 15 minutes. DO NOT INTERPRET RESULTS AFTER 20 MINUTES. Discard the device after interpreting the result.



INTERPRETATION OF TEST RESULT

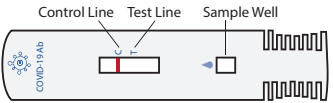
POSITIVE TEST RESULT

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 and SARS-CoV-2 antibodies were detected.



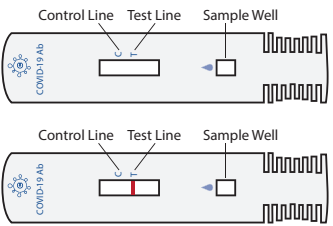
NEGATIVE TEST RESULT

When only the control line (C) is visible and there is no test (T) line, this indicates the samples is negative and SARS-CoV-2 antibodies were not detected.



INVALID TEST

For the test to be valid, there must be a visible control line (C). If there is no control line, the result is invalid. The invalid result should not be reported. Repeat the test with a new cartridge. (Wait 30 minutes before resampling). If repeated invalid results are observed, test with a different antibody test to SARS-CoV-2.



LIMITATIONS OF THE PROCEDURE

1. Samples should only be tested from individuals who are 15 days or more post symptom onset. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
2. Results from antibody testing should not be used as to diagnose or exclude SARS-CoV-2 infection.
3. 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.
4. Not for the screening of donated blood.
5. 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.
6. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
7. The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
8. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2020 and October 2020 and between May 2020 and June 2020 for lab-based studies conducted in the United States and in India, respectively. For point-of-care (POC) studies samples were collected between June 2020 and August 2020 in the United States. The clinical performance has not been established in 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.
9. Proper sample collection is critical for optimal test performance. The CovAb™ SARS-CoV-2 Ab Test must be used in accordance with the instructions in this product insert to obtain accurate results.
10. This test uses a biotin-streptavidin interaction for generating the Control Line. Testing samples collected from subjects with high doses of biotin intake may cause invalid or erroneous test results.

11. This test has not been validated in the presence of active oral infections and/or bleeding gums.
12. Testing at 37°C with 95% relative humidity (RH) may reduce test line color intensity. Testing at 40°C with 60% RH and 95% RH may reduce test line color intensity and may produce false negative results.
13. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of the prepared sample may yield erroneous results.
14. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
15. The test is limited to qualitative detection of antibodies specific for SARS-CoV-2. The color intensity of the test line does not correlate to SARS-CoV-2 antibody levels in the specimen.
16. 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.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The CovAb™ SARS-CoV-2 Ab Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist clinical laboratories using the CovAb™ SARS-CoV-2 Ab Test, ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

1. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify

the relevant public health authorities of their intent to run your product prior to initiating testing.

4. 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.

5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Diabetomics, Inc., (1-877-748-9355 or support@diabetomics.com) any suspected occurrence of false-positive or false-negative results and significant deviations from the established performance characteristics of your product of which they become aware.

6. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

7. Diabetomics, Inc., 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 authorized laboratories as the following: "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate 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."

PERFORMANCE CHARACTERISTICS

CLINICAL EVALUATION: Laboratory-based study

The clinical performance of the CovAb™ SARS-CoV-2 Ab Test was evaluated in a prospective study testing 155 oral fluid (GCF) samples collected from SARS-CoV-2 RT-PCR positive and negative individuals as indicated below. All samples were randomized and all test operators were blinded to the status of each sample.

Positive Percent Agreement: CovAb™ SARS-CoV-2 Ab 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 RT-PCR test. The sample collections ranged from 3 days to 218 days from onset of symptoms. Samples were tested with the CovAb™ SARS-CoV-2 Ab Test by lab technicians. Positive percent agreement (PPA) with SARS-CoV-2 RT-PCR-positive samples presented by days post onset of symptoms is summarized in the table below.

PPA-Laboratory Based Study:

Days from onset of symptoms	No. of RT-PCR positive subjects tested	CovAb™ SARS-CoV-2 Ab test results		
		No. of total antibodies positive subjects	Total antibodies PPA	95% CI
0 - 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	**73**			

Negative Percent Agreement: CovAb™ SARS-CoV-2 Ab Test Negative percent agreement (NPA) in SARS-CoV-2-negative samples.

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

NPA-Laboratory Based Study:

No. of RT-PCR negative subjects tested	CovAb™ SARS-CoV-2 Ab test results		
	No. of total antibodies negative subjects	Total antibodies NPA	95% CI
82	81	81/82 (98.78%)	93.39% - 99.97%

POINT-OF-CARE USE

A prospective study was conducted using oral fluid specimens (GCF) collected from subjects at a nursing home facility in Seattle, Washington, USA. A total of 151 subjects who tested positive or negative for SARS-CoV-2 by the molecular test were tested by 6 non-laboratorian operators using the CovAb™ SARS-CoV-2 Ab Test. The oral fluid (GCF) sample collections ranged from 8 days to 160 days from onset of symptoms. Positive percent agreement (PPA) with SARS-CoV-2 RT-PCR-positive samples and negative percent agreement (NPA) are summarized in the tables below.

PPA-Point of Care Study:

Days from onset of symptoms	No. of RT-PCR positive subjects tested	CovAb™ SARS-CoV-2 Ab test results		
		No. of total antibodies positive subjects	Total antibodies 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	**73**			

NA - Not applicable

NPA-Point of Care Study:

No. of RT-PCR negative subjects tested	CovAb™ SARS-CoV-2 Ab test results		
	No. of total antibodies negative subjects	Total antibodies NPA	95% CI
78	76	76/78 (97.4%)	91.04% - 99.69%

ROBUSTNESS of the CovAb™ SARS-CoV-2 Ab Test:

Studies were performed to evaluate the robust use of this test for point of care settings. Varying reading time, amounts of sample (by evaluating swab handling after samples collection), varying amounts of Sample Diluent, temperature, humidity, device inclination, and lighting conditions were assessed. The results indicated that testing at 37°C with 95% relative humidity (RH) may reduce test line color intensity. Testing at 40°C with 60% RH and 95% RH may produce false negative results. Other results from this testing indicate that the test will perform as expected across environmental and use variations that may occur in POC settings.

CROSS-REACTIVITY

The CovAb™ SARS-CoV-2 Ab Test was evaluated for potential cross-reactivity in conditions unrelated to SARS- CoV-2 infection. SARS-CoV-2 antibody negative oral fluid (GCF) specimens were spiked with serum samples containing antibodies to potential cross-reactants and then tested with the CovAb™ SARS-CoV-2 Ab Test. No false positive results were observed. The results are summarized in the table below.

Potential cross-reactant (Positive serum samples)	Number of samples tested	CovAb™ SARS-CoV-2 Ab test results	
		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

POTENTIAL MICROBIAL INTERFERENCE

The CovAb™ SARS-CoV-2 Ab Test was evaluated for potential microbial interference from bacterial and viral microorganisms that may be present in oral fluid (GCF) specimens. SARS-CoV-2 antibody negative and positive GCF samples were evaluated with the CovAb™ SARS-CoV-2 Ab Test. To prepare the samples, SARS-CoV-2 antibody negative and positive GCF samples were spiked with microbial organisms and then tested with the CovAb™ SARS-CoV-2 Ab Test. No false positive or false negative results were observed at the microbial concentrations tested. The list of microbes and the concentration evaluated are summarized in the table below.

Virus/Bacteria	Type/strain	Concentration tested
Actinomyces viscosus	ATCC 43146	$>10^4$ CFU/mL
Prevotella oralis	ATCC 33269	$>10^4$ CFU/mL
Bordetella pertussis	ATCC BAA-589	$6.0x10^7$ CFU/ml
Candida albicans	ATCC 18804	$4.9x10^6$ CFU/mL
Chlamydolphia pneumoniae	AR-39 ATCC 53592	$7.0x10^6$ IFU/mL
Herpes Simplex Virus Type 1	ATCC VR-260	$8.0x10^6$ $TCID_{50}$/mL
Herpes Simplex Virus Type 2	ATCC VR-734	$8.0x10^5$$TCID_{50}$/ml
Lactobacillus johnsonii	ATCC 33200	$>10^4$ CFU/mL
Mycobacterium tuberculosis	ATCC 25177	$>10^4$ CFU/mL
Mycoplasma pneumonia	ATCC 15531	$8.0x10^5$ CFU/mL

Porphyromonas gingivalis	ATCC 49417	>10^4 CFU/mL
Staphylococcus aureus	ATCC 6538	1.7x10^6 CFU/mL
Staphylococcus epidermis	ATCC 12228	1.6x10^7 CFU/mL
Streptococcus pyogenes	ATCC 19615	1.8x10^6 CFU/mL
Streptococcus salivarius	ATCC 7073	>10^4 CFU/mL
Streptococcus mutans	ATCC 25175	4.4x10^5 CFU/mL

POTENTIAL INTERFERENCE

Because the CovAb™ SARS-CoV-2 Ab Test uses an oral fluid specimen potential interference evaluating exogenous substances that may be expected to be consumed orally was conducted. 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
	Whole blood	0.1-0.8% (v/v)
	Caffeine	1 mg/mL
	Food	Custom
	Soda	Normal consumption
	Mouthwash	Normal use
	Cough syrup	7%

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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

CovAb.com

IVD

Manufactured by Diabetomics, Inc.
2345 NE Overlook Drive, Suite #140
Hillsboro, OR 97006
Phone: (503) 924-5110 | Fax: (503) 924-5111

LN-6095 Rev. D