Tell Me Fast COVID-19 Antigen Test

Saliva/Nasal (Anterior & Mid Turbinate)
Format: Cassette Catalog Number: B230C Instructions for Use

INTENDED USE

Biocan Tell Me Fast COVID-19 Antigen Test is a rapid qualitative membrane-based immunochromatographic in vitro assay intended for detection of SARS-CoV-2 (COVID19) antigens with human saliva (oral fluid) and nasal swab (anterior nares or mid turbinate). This test is intended for in vitro diagnostic use at point of care settings and laboratories and is a preliminary screening test and final diagnosis should be based after examination with other qualified assays like molecular diagnostics test.

Results are for the identification of SARS-CoV-2 antigen which 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. Negative results, from patients with symptom onset beyond ten 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.

SUMMARY

Human coronaviruses are common throughout the world. Seven different coronaviruses, that scientists know of, can infect people and make them sick. Some human coronaviruses were identified many years ago and some have been identified recently. Human coronaviruses commonly cause mild to moderate illness in people worldwide. Three newer human coronaviruses, MERS-CoV, SARS-CoV and 2019-nCoV, frequently have been known to cause severe illness. Human coronaviruses can sometimes cause lower-respiratory tract illnesses, such as pneumonia or bronchitis. Severe illness more common in people with cardiopulmonary disease, diabetes, weakened immune systems, and older adults. Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through droplets. So far, there are seven types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus (COVID-19) (2019), all pathogens of human respiratory infections. Among them, the COVID-19 was discovered in 2019 from Wuhan virus pneumonia outbreak. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea, lack of smell and taste and so on. These manifestations can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome (ARDS), septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

PRINCIPLE OF THE TEST

Biocan Tell Me Fast COVID19 Antigen Test is a lateral flow chromatographic immunoassay. The test consists of a burgundy colored conjugate pad containing mouse monoclonal anti-SARS-CoV-2 nucleocapsid antibody conjugated to colloidal gold, rabbit IgG conjugated to colloidal gold and a nitrocellulose membrane containing test band (T bands) and a control band (C band). The T band is pre-coated with mouse monoclonal anti-SARS-CoV-2 nucleocapsid antibody for the binding and detection of SARS-CoV-2 nucleocapsid viral antigen, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 virus, if present in the specimen, will bind to the mouse monoclonal anti- SARS-CoV-2 antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse monoclonal anti-SARS-CoV2 antibody, forming a pink colored T band, indicating a Covid-19 antigen positive test result. Absence of test band (T) suggests a negative result. The test contains an internal control (C band) which should exhibit a pink colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on of the test band. If the control line does not appear, the test result is not valid. The presence of the pink control band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

PRECAUTIONS

- Specimen processing should be performed in accordance with pertaining national biological safety regulations and following the recommended WHO guidelines on biosafety and biosecurity**.** For laboratory in vitro diagnostic research use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

MATERIALS PROVIDED
- Test cassette with desiccant in individual pouch (1 tests per box)
- Specimen Extraction tubes prefilled with diluent buffer (1 per box)
- Sterile Swabs (1 per box)
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Disposable gloves
- Timer
- External controls

SPECIMEN COLLECTION AND PREPARATION

Specimen collection should be done by trained staff or the patient themselves after reviewing and following the collection instructions, taking into consideration safe laboratory practices. Specimen should be tested immediately after collection. Saliva (oral fluid), anterior nare and mid turbinate swab can be done by the patient themselves. Careful and successful sample collection is important to get accurate results. When you collect the samples wear gloves and

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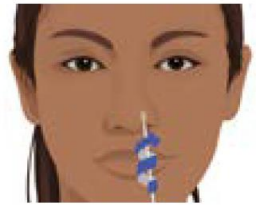
a mask to protect yourself if the patient coughs or sneezes. Cough is not uncommon while you are tickling the Nasal swab area and wash your hands and change gloves between each patient. Refer to below image and instructions.

Saliva (oral fluids) specimen:

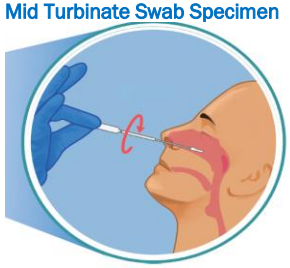
The patient should rinse the mouth thoroughly before collection of saliva sample. Collect the saliva (oral fluid) specimen with the sterile swab provided by swabbing the upper and lower gums all the way from the back to the front twice. Process the swab as soon as possible after collecting the specimen by placing in the specimen extraction buffer vial.

Anterior Nasal Swab Specimen



Insert the swab at least 1cm (0.5 inch) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nostrils with same swab. Place swab, tip first, into the extraction buffer vail.

Mid Turbinate Swab Specimen



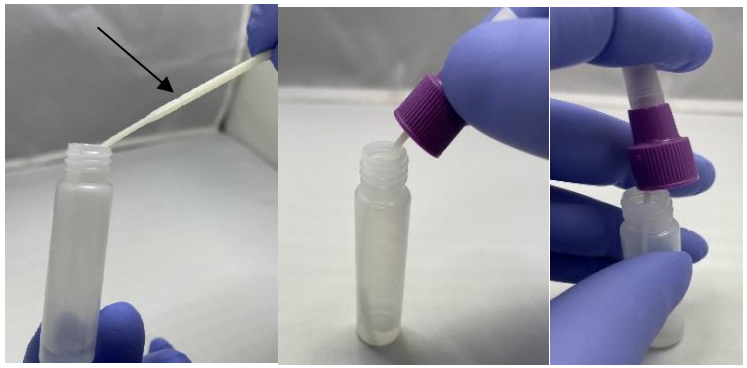
Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril parallel to the palate (not upwards) until resistance is met at turbinates. Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. Place swab, tip first, into the extraction buffer vail.

DIRECTIONS FOR USE

Allow the tests, swabs and controls to reach to room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay.

1. Open the specimen extraction tube and place the swab collected from the patient into the specimen extraction tube. Tilt the tube sidewards so that the entire swab can dip in the extraction buffer and then swirl the swab 5 to 10 times while pressing the head against the bottom and side of the tube.

2. Break the swab from the break point on the swab (see image below) and with the cap of the extraction tube press it down in the tube and close the specimen extraction tube and then shake it gently in a circular motion 5 to 10 times.



3. Take the test cassette out of the pouch and place it on a clean flat surface. Open the white top cap of the specimen extraction tube and transfer 3 drops solution from the extraction tube to the sample well of the test cassette.

After 10-15 minutes interpret the results. Do not read the results after 20 minutes.

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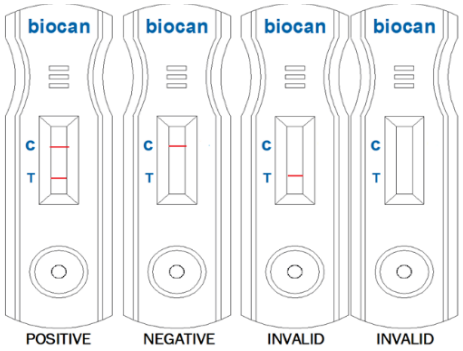
INTERPRETATION OF RESULTS



NEGATIVE: Only one pink band appears on control line (C).
POSITIVE: In addition to the pink control band, a pink band also appears on test line (T) which is located below the control line (C).
INVALID: No band appears on the control line. A total absence of the control colored band (PINK) regardless the appearance or not of the test lines. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.

NOTES ON THE INTERPREATION OF RESULTS

The intensity of the pink colored band in the result test line region (T) will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test. A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. External positive and negatives controls can also be provided.

PERFORMANCE CHARACTERISTICS

An independent clinical evaluation and validation was conducted in a national reference laboratory and university on a total of 589 patients with majority of them symptomatic with SARS-CoV2 infection visiting the hospital (outpatients) for COVID19 testing and healthcare workers who came in contact with known COVID19 patients and small number of asymptomatic patients. All the participating patients were from the usual population seeking testing in the main testing center. For all 589 patients included in the study nasopharyngeal swabs were collected, tested and confirmed with reference SARS-CoV-2 RT PCR assays (CE & US FDA EUA approved) and also tested with Biocan Tell Me Fast COVID19 Antigen Test (RDT). All RDT testing was performed on site by technicians and health care workers. Out of the 589 patients tested with reference SARS-CoV-2 RT PCR, 180 were confirmed as positives and 409 were confirmed as negatives. For both the reference SAR-CoV-2 RT PCR tests the controls and patient specimens the threshold for RNase P as well as for the SARS-CoV-2 targets (N, E and ORF1ab) to be called positive is a Ct (cycle threshold) of ≤35. The results have been analysed for overall performance of the rapid antigen test especially taking into consideration the Ct values at different levels of the reference RT-PCR test.

Table: 1 Summary Results of Biocan Tell Me Fast COVID19 Antigen Test Strip in comparison to reference RT-PCR at various Ct Values

Comparative Reference RT-PCR at all Ct Values	**Tell Me Fast COVID19 Antigen Test Strip**		**Total**
	Positive	Negative	
Positive	155	25	180
Negative	-	409	409
Comparative Reference RT-PCR at Ct Value ≤30	**Tell Me Fast COVID19 Antigen Test Strip**		**Total**
	Positive	Negative	
Positive	155	18	173
Negative	-	409	409
Comparative Reference RT-PCR at Ct Value ≤28	**Tell Me Fast COVID19 Antigen Test Strip**		**Total**
	Positive	Negative	
Positive	148	9	157
Negative	-	409	409
Comparative Reference RT-PCR at Ct Value ≤25	**Tell Me Fast COVID19 Antigen Test Strip**		**Total**
	Positive	Negative	
Positive	112	-	112
Negative	-	409	409
Comparative Reference RT-PCR at Ct Value ≤23	**Tell Me Fast COVID19 Antigen Test Strip**		**Total**
	Positive	Negative	
Positive	84	-	84
Negative	-	409	409

Total number of patients tested by RT-PCR: 589
Total number of patients negative by RT-PCR: 409
Total number of patients positive by RT-PCR: 180
Total number of patients positive by Biocan Tell Me Fast COVID19 Antigen Test: 155
Total number of patients negative by Biocan Tell Me Fast COVID19 Antigen Test: 409

Table: 2 Summary Statistics of sensitivity and specificity of Biocan Tell Me Fast COVID19 Antigen Test Strip in comparison with reference RT-PCR and various CT Values

Measure (Comparision to Reference RT-PCR)	**Estimate**	**95% Confidence Interval**
Specificity (at all Ct Values)	100% (409/409)	99.0%-100%
Sensitivity (At all CT Values)	86.1% (155/180)	80.3%-90.4%
Sensitivity (At Ct ≤30)	89.6% (155/173)	84.1-93.3%
Sensitivity (At Ct ≤28)	94.3% (148/157)	89.4%-96.9%
Sensitivity (At Ct ≤25)	100% (112/112)	96.6%-100%
Sensitivity (At Ct ≤23)	100% (84/84)	95.6%-100%

For all positive patients tested there reference RT-PCT Ct value was recorded and stratified in the table above (Table 2) and below (Table 3) as per all Ct Values, ≤30, ≤28, ≤25 and ≤23 in order to properly analyse the detection ability of rapid antigen test and its relevance.

Table 3: Summary Statistics of PPA, NPA, OPA, PPV & NPV of Biocan Tell Me Fast COVID19 Antigen Test Strips in comparison with reference RT-PCR at various CT Values

Comparison to Reference RT-PCR	**PPA (Positive Percent Agreement)**	**NPA (Negative Percent Agreement)**	**OPA (Overall Percent Agreement)**	**PPV (Positive Predictive Value)**	**NPV (Negative Predictive Value)**

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At all Ct values	86.11%	100%	95.75%	100%	94.24%
At Ct ≤30	89.59%	100%	96.90%	100%	95.78%
At Ct ≤28	94.26%	100%	98.40%	100%	97.84%
At Ct ≤25	100%	100%	100%	100%	100%
At Ct ≤23	100%	100%	100%	100%	100%

Clinical Study (Saliva)

An evaluation was conducted from saliva samples obtained from a population of symptomatic and asymptomatic individuals and all results were confirmed by the RT-PCR (US FDA EUA). A total of 350 patient samples (50 PCR positive and 300 PCR negative) were collected. Summary results of Biocan Tell Me Fast COVID19 Antigen in comparison to reference RT PCR is showed in the following table:

	Tell Me Fast COVID19 Antigen Test		
RT PCR Results	Positive	Negative	Total
Positive	45	5	50
Negative	4	296	300
Total	49	301	350

Sensitivity: 91.8% Specificity: 98.7% Overall agreement: 97.43%

Cross-reactivity (Analytical Specificity)

Biocan Tell Me Fast COVID19 Antigen Test had no cross reactivity to the below listed Virus/bacteria. Each organism and virus were tested in triplicate. The final concentration of each organism is documented in the following table.

Potential Cross Reactant	Concentration tested	Cross Reactivity
Adenovirus type 1	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus type 7	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B	1.0 x 10^5 $TCID_{50}$/mL	No
Cytomegalovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No
Coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
Coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
MERS-CoV	1.0 x 10^5 $TCID_{50}$/mL	No
RSV Type A	1.0 x 10^5 $TCID_{50}$/mL	No
RSV Type B	1.0 x 10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Mumps virus	1.0 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza type 1	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza type 2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza type 3	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza type 4	1.0 x 10^5 $TCID_{50}$/mL	No
Epstein Barr virus	1.0 x 10^5 $TCID_{50}$/mL	No
Enterovirus type 71	1.0 x 10^5 $TCID_{50}$/mL	No
Measles virus	1.0 x 10^5 $TCID_{50}$/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No

Interference

Substances listed below were confirmed not to have interference or cross reaction with Tell Me Fast COVID19 Antigen Test.

- Mucin (4 mg/ml), Human Blood (2 %), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20 mg/ml), Biotin (0.35 mg/dL), Methanol (150 mg/dL), Acetylsalicylic Acid (3 mg/dL)

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.6 x 105 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the Tell Me Fast COVID19 Antigen Test.

Limit of Detection (Analytical Sensitivity)

As per independent laboratory evaluation Biocan Tell Me Fast COVID19 Antigen test for Anterior and Mid Turbinate samples meets the WHO recommended Analytical sensitivity/Limit of detection at an acceptable level which is equivalent to 10^6 genomic copies/mL or Ct ≈ 25-30 and desirable level which is equivalent to 10^4 genomic copies/mL or Ct≈>30

For the Saliva samples the LOD study was performed using cultured SARS-CoV-2 virus, which was β-propiolactone and heat inactivated and spiked into saliva specimen. The Limit of detection is 1.51 *10 TCID50/ml

LIMITATIONS

1. This test provides a preliminary diagnosis for COVID-19 infection. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and confirmed with other qualified assays.
3. Tell Me Fast COVID-19 Antigen test should be used only with specimen swabs as specified in the intended use. The use of swab specimens taken from other sites or the use of other samples such as urine has not been established. The quality of the test depends on the quality of the sample; proper swab specimens must be obtained.
4. A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test. Therefore, it is recommended that all negative Tell Me Fast COVID-19 Antigen test results undergo confirmatory testing using other method like PCR.

CE

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	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Protect from light and moisture		Do not reuse

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