

# **ACCU-TELL®** **COVID-19 Antigen Cassette** **(Nasal Swab)**

***For professional in vitro diagnostic Use only***

## ***For Nasal Swab Sample***

This package insert is applied to the below products:

Catalog No.:	Product Name
ABT-IDT-B374	COVID-19 Antigen Cassette (Nasal Swab)

A rapid test for the qualitative detection of COVID-19 antigen in a Nasal Swab.

For use only by individuals who have been given appropriate training for in vitro diagnostic use.

### **INTENDED USE**

ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in Nasal swab. The identification is based on monoclonal antibodies specific to the Nucleocapsid (N) protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

### **SUMMARY**

The novel coronaviruses belong to the  $\beta$  genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of other people getting infected; asymptomatic and symptomatic infected people can both be an infectious source. Based on the current epidemiological investigations, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

### **PRINCIPLE**

ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal Swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

### **REAGENTS**

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein conjugated gold colloid particles and anti-SARS-CoV-2 Nucleocapsid protein antibody coated onto the membrane.

### **PRECAUTIONS**

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
4. The used test should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves when handling the samples, avoid touching the

reagent membrane and sample well.

### **STORAGE AND STABILITY**

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

### **MATERIALS**

#### **Materials provided**

Test cassettes  
Exaction buffers  
Extraction Tubes  
Dropper tips  
Sterile Nasal Swabs  
Package Insert  
Workstation

#### **Materials required but not provided**

Timer

### **SPECIMEN COLLECTION AND PREPARATION**

#### **Nasal Swab**

Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually  $\frac{3}{5}$  to 1 of an inch (1.5 to 2.5cm) inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Take approximately 15 seconds to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. **Sample both nostrils with the same swab before testing.**

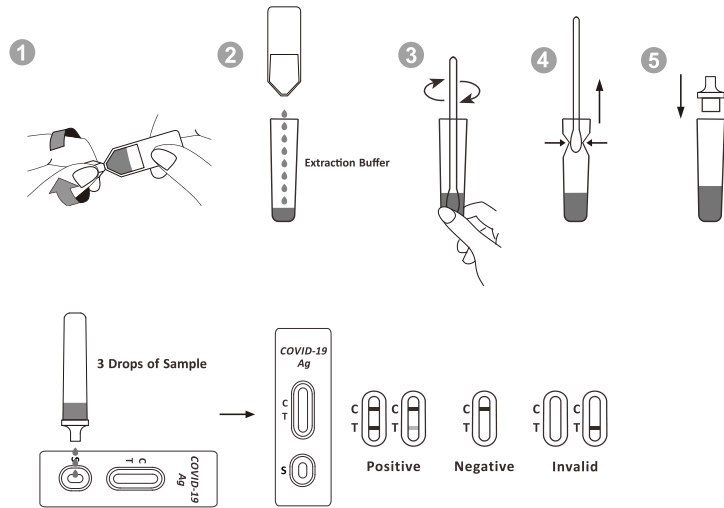
#### **Specimen Collection Instruction**



### **TEST PROCEDURE**

**Allow the test, specimen, and extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube in the workstation. Turn the hand over and add all extraction buffer to the extraction tube. See illustration 1&2.
3. Place the swab specimen in the extraction tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 3.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 4.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 5
6. Add **3 drops** of the solution (approx. 80µL) to the sample well and then start the timer. Read the result at **10 minutes**. Do not interpret the result after 20 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:** \*Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.

**\*NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that SARS-CoV-2 antigen is not present in the specimen, or is present below the detectable level of the test.

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

### QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control solutions are not provided in this kit. It is however recommended where possible, for positive and negative controls to be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

1. ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) is for use only by individuals who have been given appropriate training for in vitro diagnostic use. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
3. ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR, and/or should be interpreted and followed up in line with national/regional guidance. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the swab is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.

7. A positive result for SARS-CoV-2 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. Positive results may be due to current infection with acute non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E, SARS-CoV-1.
10. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. Extraction buffer has the ability to kill the virus, but it cannot inactivate 100% of the virus. The method of inactivating the virus can be referred to: what method is recommended by WHO/CDC, or it can be handled according to local regulations.

### PERFORMANCE CHARACTERISTICS

#### Sensitivity, Specificity and Accuracy

##### Nasal Swab:

ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) has been evaluated with specimens obtained from different clinical sites where the specimens were collected with Nasal Swabs. The Nasal Swabs were randomised and blind tested by operators following the instructions for use. RT-PCR (RT-PCR comparator assay was Thermo fisher taqpath and RT-PCR reagent kit was NxTAG® CoV Extended Panel Assay) was used as the reference method for ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab). Specimens were considered positive if PCR indicated a positive result.

Method	RT-PCR		Total Results
	Positive	Negative	
ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab)	96	2	98
	7	248	255
Total Results	103	250	353

Relative Sensitivity: 93.2% (95%CI\*:86.5%-97.2%)

Relative Specificity: 99.2% (95%CI\*:97.1%-99.9%)\*

Relative accuracy: 97.5% (95%CI\*:95.2%-98.8%)\*

\* Confidence Intervals

#### Detection Limit

The LOD for ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) was established using limiting dilutions of a viral sample inactivated. The material (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of  $1.15 \times 10^7$  TCID<sub>50</sub>/mL. The Estimated LOD is 1000 TCID<sub>50</sub>/mL.

#### Cross Reactivity

Cross reactivity of ACCU-TELL® COVID-19 Antigen Cassette (Nasal Swab) was evaluated by testing commensal and pathogenic microorganisms that may be present in the nasal cavity. Each of the organism, viruses, or yeast were tested in the absence or presence of inactivated SARS-CoV-2 virus. No cross-reactivity result was found with the following Cross-reactive substances when tested at the concentration or viral load presented in the table below.

Cross-reactive substances	Test Concentration or Viral Load
Parainfluenza Virus Type4a	$1.6 \times 10^4$ TCID <sub>50</sub> /mL
Human Cocksackievirus	$2.8 \times 10^6$ TCID <sub>50</sub> /mL
Mumps virus	$1.6 \times 10^5$ TCID <sub>50</sub> /mL
Rhinovirus	$2.8 \times 10^7$ TCID <sub>50</sub> /mL
Haemophilusparainfluenzae	$6 \times 10^7$ bacterial/ml
Staphylococcus aureus	$6 \times 10^7$ bacterial/ml
Neisseria meningitides	$6 \times 10^7$ bacterial/ml
Streptococcus sp. group A	$1 \times 10^9$ org/ml
Streptococcus sp. group B	$6 \times 10^7$ bacterial/ml









Streptococcus sp. group C	6 x 10 <sup>7</sup> bacterial/ml
Influenza A virus (H3N2)A/Aichi/2/68	2.3 x 10 <sup>8</sup> CEID <sub>50</sub> / mL
Adenovirus (e.g. C1 Ad. 71)-Type 7A	1.41 x 10 <sup>5</sup> U/ml
Enterovirus (e.g. EV68)	5.01 x 10 <sup>5</sup> TCID <sub>50</sub> /ml
Human Metapneumovirus (hMPV)	3.80 x 10 <sup>6</sup> TCID <sub>50</sub> /ml
Influenza A H1N1 (New Cal/20/99)	1.15 x 10 <sup>7</sup> U/ml
Influenza B (Florida/02/06)	1.41 x 10 <sup>5</sup> U/ml
Parainfluenza virus 1	9.12 x 10 <sup>8</sup> TCID <sub>50</sub> /ml
Parainfluenza virus 2	1.15 x 10 <sup>7</sup> U/ml
Parainfluenza virus 3	6.61 x 10 <sup>6</sup> U/ml
Parainfluenza virus 4	2.82 x 10 <sup>7</sup> U/ml
Respiratory syncytial virus-Type A	3.80 x 10 <sup>6</sup> U/ml
Rhinovirus (Type 1A)	3.55 x 10 <sup>5</sup> U/ml
Bordetella pertussis	1.13 x 10 <sup>10</sup> CFU/ml
Candida albicans	6.27 x 10 <sup>8</sup> CFU/ml
Haemophilus influenzae	5.43 x 10 <sup>8</sup> CFU/ml
Legionella pneumophila	1.88 x 10 <sup>10</sup> CFU/ml
Mycobacterium tuberculosis	6.86 x 10 <sup>7</sup> CFU/ml
Mycoplasma pneumoniae	3.16 x 10 <sup>8</sup> CCU/ml
Pneumocystis jirovecii (PJP)-S. cerevisiae Recombinant	3.45 x 10 <sup>8</sup> CFU/ml
Pseudomonas aeruginosa	8.44 x 10 <sup>9</sup> CFU/ml
Staphylococcus epidermis	1.21 x 10 <sup>10</sup> CFU/ml
Streptococcus pneumoniae	3.23 x 10 <sup>8</sup> CFU/ml
Streptococcus pyogenes	1.64 x 10 <sup>9</sup> CFU/ml
Streptococcus salivarius	8.17 x 10 <sup>8</sup> CFU/ml
Human coronavirus 229E	4.17 x 10 <sup>5</sup> TCID <sub>50</sub> /ml
Human coronavirus OC43	1.05 x 10 <sup>6</sup> TCID <sub>50</sub> /ml
Human coronavirus NL63	1.70 x 10 <sup>5</sup> TCID <sub>50</sub> /ml
MERS-coronavirus	3.16 x 10 <sup>6</sup> TCID <sub>50</sub> /ml
Staphylococcus aureus, Titered	1.84 x 10 <sup>10</sup> CFU/ml
Chlamydomonas pneumoniae, Titered	1.75 x 10 <sup>8</sup> IFU/ml
Pooled human nasal wash – representative of normal respiratory microbial flora	/



## BIBLIOGRAPHY

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol2016;24:490-502.

## GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse