

ACCU-TELL® **SARS-CoV-2 Ag Cassette** **(Nasopharyngeal Swab)**

For professional in vitro diagnostic Use only

For Nasopharyngeal Swab Sample

This package insert is applied to the below products:

Catalog No.	Product Name
ABT-IDT-B367	SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab)

A rapid test for the qualitative detection of SARS-CoV-2 antigen in Nasopharyngeal swab.

For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, 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® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasopharyngeal 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 is 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 particles and anti-SARS-CoV-2 Nucleocapsid protein coated on 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.

SPECIMEN COLLECTION AND PREPARATION

Nasopharyngeal swab

Insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

MATERIALS

Materials provided

Test cassettes
Extraction Reagent
Extraction Tubes
Dropper tips
Sterile Swabs
Package Insert
Workstation

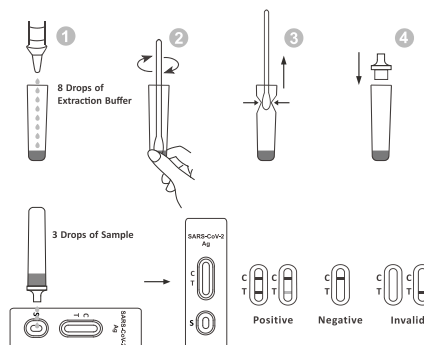
Materials required but not provided

Timer

TEST PROCEDURE

Allow the test, specimen, 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. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add **8 drops** of solution (Approx. 300 μ L) to the Extraction Tube. See illustration 1.
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 2.
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 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add **3 drops** of the solution (**approx. 80 μ L**) 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 colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) is for professional in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 Antigen in Nasopharyngeal swab. 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® SARS-CoV-2 Ag Cassette (Nasopharyngeal 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. 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.
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 reagent 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

ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR (RT-PCR comparator assay was Thermo fisher taqpath and RT-PCR reagent kit was NxTAG® CoV Extended Panel Assay) is used as the reference method for ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab). Specimens were considered positive if PCR indicated a positive result.

Method	RT-PCR		Total Results
	Results	Positive	Negative
ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab)	Positive	112	3
	Negative	5	360
Total Results		117	363
			480

Relative Sensitivity: 95.7% (95%CI*:90.3%-98.6%)* Relative Specificity: 99.2% (95%CI*:97.6%-99.8%)* Relative accuracy: 98.3% (95%CI*:96.7%-99.3%)*

*** Confidence Intervals**
Detection Limit

The LOD for ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) was established using limiting dilutions of a viral sample inactivated. The material (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of **1.15x10⁷ TCID₅₀/mL**. The Estimated LOD is **1000 TCID₅₀/mL**.









Cross Reactivity

ACCU-TELL® SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii (PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens. The results showed no cross reactivity.

BIBLIOGRAPHY

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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. Trends Microbiol 2016;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



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EC REP



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