# SARS-CoV-2 Antigen Rapid Test (Swab)
## Package Insert

| REF ISCO-ACO502 | English |
|---|---|

*In vitro* diagnostic rapid test for qualitative detection of Nucleocapsid Protein antigens of SARS-CoV-2.

## INTRODUCTION

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.

## INTENDED USE

The ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) is a *lateral flow* immunoassay for the qualitative detection of Nucleocapsid protein antigens of SARS-CoV-2 in swab specimens from individuals suspected of COVID-19 by their healthcare provider.

The SARS-CoV-2 antigen is able to be detected in the upper respiratory tract during the acute phase of infection. The ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) tests for the SARS-CoV-2 nucleocapsid protein antigen in upper respiratory specimens. While a positive result indicates the existence of the viral antigen, further evaluation of patient history and diagnostics are necessary to confirm these results. A patient may experience concurrent infection with other viruses or a bacterial infection which are not ruled out by a positive SARS-CoV-2 antigen result. Detection of the antigen does not surely certify it as the cause of the disease.

Negative results should be treated as presumptive and confirmation with a molecular assay may be necessary for patient management. Negative results do not rule out SARS-CoV-2 infection 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.

## PRINCIPLE

The ACRO™ SARS-CoV-2 Antigen Rapid Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in swab specimens.

The swab specimens require a sample preparation step. The extracted specimen is added to the sample well of the test cassette to initiate the test. When the specimen migrates in the test strip, SARS-CoV-2 antigens (if present) bind to anti-SARS-CoV-2 nucleocapsid protein conjugated to the indicator and capture particles in the conjugate pad, forming an immune complex. The complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

The presence of two colored lines in the control line region "C" and test line region "T" indicates SARS-CoV-2 Antigen positive. The presence of one colored lines in the control line region "C" indicates SARS-CoV-2 Antigen negative. No appearance of a colored line in the control region "C" indicates an invalid test.

## KIT COMPONENTS

•Test cassettes •Sterile swabs •Extraction buffer •Extraction tubes and tips (Optional)
•Workstation •Procedure card •Package insert

## STORAGE AND STABILITY

Store the kit at 2-30°C. **DO NOT FREEZE.** The kit is stable through the expiration date printed on the packaging. The test must remain in the sealed pouch until use.

Kit components must be at room temperature (15–30 °C) when used for testing.

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
4. Do not use kit beyond its expiration date.
5. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
6. Do not eat, drink or smoke in the area where the specimens or kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage and disposal of patient samples and used kit contents.
8. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
9. Wash hands thoroughly after handling.
10. Proper sample collection, storage and transport are essential for correct results.
11. Do not reuse the used test cassette.
12. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
13. Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
14. All components of this kit should be discarded as biohazard waste according to local regulations.

## QUALITY CONTROL

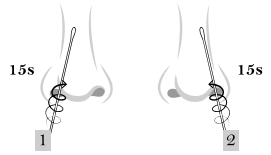
**Procedural Controls**

This test includes a positive procedural control within the test strip and is found at the "C" Control area. A visible line at the marked "C" area indicates the specimen volume has correctly traveled up the test strip and the technician adequately handled the test. A clear or light pink background elsewhere on the test strip should not contain any dark color, which shows that this negative procedural control confirms an adequately-working test.

**External Quality Control**

Good Laboratory Practice (GLP) compliance dictates the use of external positive and negative controls. [1] It is recommended to use these controls; however, they are not currently included with this test kit.

## SPECIMEN COLLECTION AND HANDLING




**Nasal Swab Specimen Collection:**

Insert a sterilized swab into a nostril. Do not insert it more than half an inch. Slowly twist the swab, rubbing it along the insides of the nostril for 15 seconds. Using the same swab repeat the collection procedure in another nostril. Withdraw the swab; avoid excess volume and high-viscous nasal discharge.

Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

## SPECIMEN TRANSPORT AND STORAGE

For best performance, Swab specimens should be tested as soon as possible after collection.

If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at 2-8°C for up to 24 hours prior to testing.

## TEST PROCEDURE

**All test components should be balanced at room temperature before use.**

**Specimen Preparation**

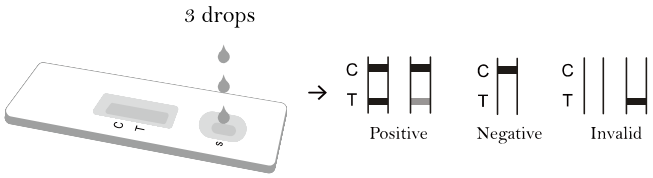
**Only extraction buffer and tubes provided in the kit are to be used for swab specimen preparation.**

1. Place the collected swab specimen into the extraction tube with extraction buffer. Press the swab against the tube and rotate the swab for **10-15 seconds**. (See procedure card for detailed information on specimen Preparation.)
2. Remove the swab while squeezing the swab head against the inside of the extraction tube to express as much liquid as possible from the swab. Discard the swab.

***NOTE**: Extracted specimen solution is stable for 2 hours at room temperature or 24 hours at 2-8°C.

**Test Reaction**

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen extraction tube, add **3 drops of extracted specimen** (approx.75-100µl) to the specimen well(S) and then start the timer.
3. Read the result in the test window **15 minutes** after sample application. Results should not be read after 20 minutes.




## TEST INTERPRETATION

**NEGATIVE:** **A negative specimen will give a single colored line in the control region (C) in the test window**, indicating a negative result. This control line means that the detection part of the test was done correctly, but no SARS-CoV-2 Antigen was detected.

**POSITIVE:** **A positive specimen will give two colored lines.** This means that SARS-CoV-2 Antigen was detected. Specimens with low levels of antigen may give a faint Line. Any visible colored line is considered a positive.

**INVALID:** **If no Control lines are seen, the test is invalid.** 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.

## TEST LIMITATIONS

1. The test is intended for direct swab specimens only. Viral Transport Media (VTM) should not be used with this test as it may cause false results.
2. When testing for detection of SARS-CoV-2 Nucleocapsid Protein Antigen, it is imperative to carefully follow the provided procedure, results interpretation, and specimen collection for a valid test result. Deviating from these instructions may lead to erroneous results.
3. The performance of the ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
5. The ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to re-sample the patient and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
8. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
9. 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.

10. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

## PERFORMANCE CHARACTERISTICS

**1. Clinical performance**

Clinical performance characteristic of the ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) was evaluated with 421 swab specimens. RT-PCR is used as the reference method.

The data was summarized in the table below:

**Nasal swab specimen**

| ACRO™ SARS-CoV-2 Antigen Rapid Test | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| SARS-CoV-2 Antigen | Positive | 105 | 2 | 107 |
| | Negative | 6 | 308 | 314 |
| Total | | 111 | 310 | 421 |
| Relative Sensitivity | | 105/111=94.6% (95%CI*: 88.6%~98.0%) | | |
| Relative Specificity | | 308/310>99.4% (95%CI*: 97.7%~99.9%) | | |
| Accuracy | | 413/421=98.1% (95%CI*: 96.3%~99.2%) | | |

*95% Confidence Intervals

**2. Detection limit**

ACRO™ SARS-CoV-2 Antigen Rapid Test was confirmed to detect 100$TCID_{50}$/ml of SARS-CoV-2.

**3. Cross Reactivity (Analytical Specificity) and Microbial Interference**

The following viral strains were tested at concentrations in following table and all found to be negative when tested with the ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab):

| Test items | | Test Concentration |
|---|---|---|
| Virus strain | Respiratory syncytial virus | 8.89 x $10^4$ $TCID_{50}$/ml |
| | Parainfluenza virus 3 | 1.58 x $10^8$ $TCID_{50}$/ml |
| | Parainfluenza virus 2 | 1.58 x $10^7$ $TCID_{50}$/ml |
| | Mumps | 1.58 x $10^4$ $TCID_{50}$/ml |
| | Measles | 1.58 x $10^4$ $TCID_{50}$/ml |
| | Influenza B | 3.16 x $10^6$ $TCID_{50}$/ml |
| | Influenza A H3N2 | 1 x $10^5$ $TCID_{50}$/ml |
| | Influenza A H1N1 | 3.16 x $10^5$ $TCID_{50}$/ml |
| | Human Rhinovirus 2 | 2.81 x $10^4$ $TCID5_{50}$/ml |
| | Human Rhinovirus 16 | 8.89 x $10^6$ $TCID_{50}$/ml |
| | Human Rhinovirus 14 | 1.58 x $10^6$ $TCID_{50}$/ml |
| | Human coronavirus OC43 | 1 x $10^6$ $TCID_{50}$/ml |
| | Human coronavirus NL63 | 1x $10^6$ $TCID_{50}$/ml |
| | Human coronavirus HKU1 | 1x $10^6$ $TCID_{50}$/ml |
| | Human coronavirus 229E | 5x $10^5$ $TCID_{50}$/ml |
| | MERS coronavirus Florida | 1.17x$10^4$$TCID_{50}$/ml |
| | Adenovirus type 7 | 1.58 x $10^5$ $TCID_{50}$/ml |
| | Adenovirus type 3 | 3.16 x $10^4$ $TCID_{50}$/ml |
| Bacteria | Arcanobacterium | 1.0x$10^8$ org/ml |
| | Corynebacterium | 1.0x$10^8$ org/ml |
| | Escherichia coli | 1.0x$10^8$ org/ml |
| | Moraxella catarrhalis | 1.0x$10^8$ org/ml |
| | Neisseria lactamica | 1.0x$10^8$ org/ml |
| | Neisseria subflava | 1.0x$10^8$ org/ml |
| | Pseudomonas aeruginosa | 1.0x$10^8$ org/ml |
| | Staphylococcus aureus subspaureus | 1.0x$10^8$ org/ml |
| | Staphylococcus epidermidis | 1.0x$10^8$ org/ml |
| | Streptococcus pneumoniae | 1.0x$10^8$ org/ml |
| | Streptococcus pygenes | 1.0x$10^8$ org/ml |
| | Streptococcus salivarius | 1.0x$10^8$ org/ml |
| | Streptococcus sp group F | 1.0x$10^8$ org/ml |
| Yeast | Candida albicans | 1.0x$10^8$ org/ml |

**4. Interference Substances**

The following substances that were evaluated had no impact on ACRO™ SARS-CoV-2 Antigen Rapid Test (Swab) at concentrations listed below.

| Substance | Concentration |
|---|---|
| Whole Blood | 20μl/ml |
| Mucin | 50μg/ml |
| Budesonide Nasal Spray | 200μl/ml |
| Dexamethasone | 0.8mg/ml |
| Flunisolide | 6.8ng/ml |
| Mupirocin | 12mg/ml |
| Oxymetazoline | 0.6mg/ml |
| Phenylephrine | 12mg/ml |
| Rebetol | 4.5μg/ml |
| Relenza | 282ng/ml |
| Tamiflu | 1.1μg/ml |
| Tobramycin | 2.43mg/ml |

**5. Repeatability and Reproducibility**

Repeatability and Reproducibility were evaluated using 3 standard controls. There were no differences observed within-run, between-run, between-lots, between-sites and between days.

## BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
| IVD | For in vitro diagnostic use only | Σ | Tests per kit | EC REP | Authorized Representative |
| 2°C 30°C | Store between 2-30°C | | Use by | | Do not reuse |
| | Do not use if package is damaged | LOT | Lot Number | REF | Catalog # |
| | Manufacturer | | Consult Instructions For Use | | |

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