

# InstaCOVID Ag

## COVID-19 ANTIGEN TEST

METHOD – Lateral Flow Assay  
PRODUCT CODE – RC26



### INSTRUCTIONS FOR USE

**INTENDED USE: Test for qualitative detection of COVID-19 (SARS-CoV-2) Antigen using lateral flow assay method.**

#### SUMMARY

*InstaCOVID Ag* is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in human nasopharyngeal specimens. *InstaCOVID Ag* provides only an initial screening test, and not sole basis for the diagnosis; confirmatory testing is required, if negative.

As per advisory from ICMR, those who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR or rapid antigen testing (RAT) to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

#### PRINCIPLE

The device uses an advanced and sensitive method of lateral flow immunoassay technology for detection of specific antigens of SARS-CoV-2 in nasopharyngeal swab. The anti-SARS-CoV-2 monoclonal antibody is pre-stripped on the nitrocellulose membrane on the test region (T line) and goat anti-mouse antibody on the control region (C line).

#### KIT COMPONENTS

1. *InstaCOVID Ag* test device pouches with silica – 25
2. Disposable Extraction tubes – 25
3. Nylon-flocked nasopharyngeal swab - 25
4. Instructions for use leaflet – 1
5. Lysis buffer sufficient for 25 tests – 1

#### REAGENT PREPARATION, STORAGE & STABILITY

The device is single ready to use device. The test should be stored at 2-30 °C and is stable till the expiry date indicated on the label.

#### STORAGE AND HANDLING REQUIREMENT

*InstaCOVID Ag* does not require any specific installation. The storage temperature for InstaCOVID Ag test kit pouch is +2°C to +30°C /35.6-86°F. *InstaCOVID Ag* should be stored in cool and dry place away from direct sunlight, and is stable until the expiration date printed on the outer box. Do NOT freeze. The storage temperature for viral lysis buffer is +2°C to +30°C /35.6-86°F. Nasopharyngeal swab and virus extraction tubes can be stored up to +40°C /104°F.

#### MATERIALS REQUIRED BUT NOT PROVIDED

Timer/watch

#### SPECIMEN & PRESERVATION

##### Nasopharyngeal swabs:

Place the nasal swab into the sampling tube where the pharyngeal swab has been collected. In this way, there is a pharyngeal swab and a nasal swab in a sampling tube, so-called nasopharyngeal swab tube. Place the swab specimen in the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

#### ASSAY PROCEDURE

1. Transfer ~300 µL (8 to 10 drops of the lysis buffer from lysis buffer vial) of Lysis Buffer into the Extraction Tube.
2. Bring the Lysis Buffer placed in the Extraction Tube at room temperature.
3. Insert the swab into the Extraction Tube. Once the sample is collected in the extraction buffer, it is stable only for one hour.
4. Break the swab at the groove and discard what remains of the swab.
5. After dipping in the lysis buffer, stir the swab more than 5 times with slight pressure from finger on the walls of Extraction Tube giving an effect of squeezing on swab while stirring.
6. Gently press on the walls of the virus extraction tube giving an effect of squeezing to extract all the nasopharyngeal material. Please note that if the liquid sample from the swab is not extracted properly, then it may result in lesser sample volume.
7. Close the labelled collection tube, wipe the tube with a surface-disinfectant wipe, and insert the tube into an open biohazard bag.
8. NO TRANSPORT MEDIUM IS ALLOWED.

Follow the directions below in next section for direct processing of the swab specimen.

#### INSTRUCTION FOR USE OF INSTACOVID AG

1. Bring *InstaCOVID Ag* to room temperature.
2. Cut open the pouch, take out the InstaCOVID Ag test kit.
3. Place test kit on a flat surface.

#### FOR LESS VISCOUS SAMPLES:

1. 2 (two) full mucous-free drops of the sample from the Extraction Tube are added into InstaCOVID Ag sample well. Wait around 1 minute till the sample gets completely absorbed and check that sample is flowing properly to the upper portion of the cassette through the result window. If required, add 1-2 more full drops of the sample and wait for the control line to appear.
2. **Please ensure that at any time while sample addition the sample should not overflow from the sample well.** Please make sure to add maximum 1-2 drops of sample at a time and wait for at least 1 minute between two additions.
3. Wait for 10 minutes to read the results.

#### FOR MORE/VERY VISCOUS SAMPLES:

1. 2 (two) full mucous-free drops of the sample from the Extraction Tube are added into InstaCOVID Ag sample well. Wait around 1 minute till the sample gets completely absorbed and check that sample is flowing properly to the upper portion of the cassette through the result window. After sample gets completely absorbed, add 2 more full drops of the sample from extraction tube to sample well and again wait for around 1 minute for the sample to get completely absorbed.
2. **Please ensure that at any time while sample addition the sample should not overflow from the sample well.** Please make sure to add maximum 1-2 drops of sample at a time and wait for at least 1 minute between two additions.
3. Wait for 10 minutes to read the results.

#### INTERPRETATION OF RESULT

If SARS-CoV-2 antigen is present, they will be trapped in a specific location. The results can be visualised through naked eyes.

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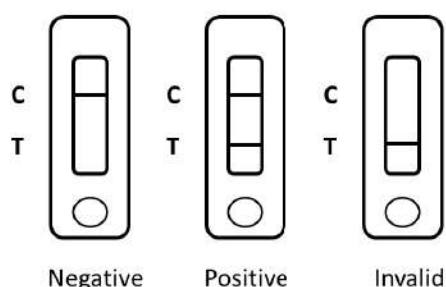


### INSTRUCTIONS FOR USE

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1. A violet/ black-coloured line at the top of the result window called control line suggest that test is valid.
2. A violet/ black-colored line may appear at the lower side of the result window called test line.
3. Even if the test line is broken and not uniform and even if the test line is very faint, the result must be interpreted as positive. **DO NOT READ AFTER 10 MINUTES.**
4. Consider the test invalid and reperform the test if control line does not appear.
5. The test should be used for the detection of SARS-CoV-2 antigen in nasopharyngeal swab specimens. This test cannot be used for any other viruses or pathogens.
6. This test is for qualitative assessment. Neither the quantitative value nor the viral load can be estimated.
7. Failure to follow the test procedure, interpretation of test results may be difficult.
8. The test may be negative, if the levels of antigens in the specimen is below the Limit of Detection (LoD). This could be due to poor technique in obtaining the specimen or too early in the disease status.
9. When using VTM, sensitivity can be reduced.
10. The test may give false positive if read after 10 minutes.
11. As with any laboratory investigation, the test results must always be correlated with other clinical data.
12. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
13. Positive test results do not rule out co-infections with other pathogens.

### PERFORMANCE CHARACTERISTICS



### WARNINGS AND PRECAUTIONS

1. Wear personal protective equipment (gloves, lab apron, and eye/face protection) before testing.
2. **InstaCOVID Ag** should be brought to room temperature before testing.
3. Do not use if any visible damage to the pouch or test device is found.
4. Do not open the foil pouch and expose it to the ambient environment until ready for immediate use. Premature exposure to ambient conditions may cause false positive, false negative, or invalid results.
5. Do not re-use the test kit. Do not use the test kit, if the pouch is damaged.
6. Do not use the Test Kit contents beyond the expiration date printed on the outside of the box.
7. Wash hands thoroughly after the tests are done.
8. Clean up spills thoroughly with an appropriate disinfectant. Take off contaminated cloths and wash before reuse.
9. Handle all specimens, as if they are infectious.
10. Dispose all specimens and test kit as biohazard waste.
11. **DO NOT ADD MORE THAN 2 DROPS OF SAMPLE.**
12. **DO NOT READ AFTER 10 MINUTES.**

### DISPOSAL OF TEST

**InstaCOVID Ag** is a one-time use in vitro diagnostic medical device kit and cannot be re-used or sterilized. For the unused devices and the discarded opened device, once the outer pouch is opened, it should be considered used, and it should be disposed of as per institutional policy for disposal of biomedical waste.

### LIMITATION OF TEST

1. **InstaCOVID Ag** cannot be used for quantifying SARS-CoV-2 antigen concentration.
2. The test procedure, precautions, and interpretation of results for this test must be followed strictly, when testing.

### QUALITY CONTROL

1. Consider test invalid if no line appears at the control line.
2. Do not read the test after 10 mins.

**Assay Cross Reactivity:** There no cross-reactivities of Influenza A, Influenza B, Adenovirus, Metapneumovirus, Parainfluenza virus, Respiratory syncytial virus, Streptococcus pyogenes, Candida albicans, Human coronavirus 229E, OC43, NL63, HKU1, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila.

**Interference** Not interfered for Oxymetazoline, Phenylephrine, Guaiacol glyceryl ether, Flunisolide Acetylsalicylic acid, mouth wash, whole blood and mucous.

The overall diagnostic performance of the kit; Positive Predictive Value= 95.31%, Negative Predictive Value= 69.86%, Sensitivity = 58.09% & Specificity = 97.14%,

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry