LIMITATION OF TEST

- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained. A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly - Therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by an RT-PCR (Reverse Transcription - Polymerase Chain Reaction) test.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule out other Corona Virus infections, except the SARS-CoV-2.

WARNINGS AND PRECAUTIONS

- Specimen should be tested as soon as possible after collection.
- Do not re-use the test kit.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not use the test kit if the expiry date printed on the pouch is exceeded.
- Do not use the extraction buffer tube of another lot.
- Do not smoke, drink or eat while handling specimen.
- Remove the test cassette from the pouch only at the time of conducting the test.
- Wear personal protective equipment, such as PPE, masks, gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- This product is strictly for medical professional use only and not intended for personal use.

EC REP

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STRUMED®
STRUCTURED INNOVATION

iNSTAXPLOR® COVID-19 RAPID ANTIGEN TEST

IFU No.:10-184-0001-R7

STRUMED®
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INTENDED USE

The iNSTAXPLOR® COVID-19 Ag is a rapid chromatographic immunoassay for the qualitative detection of antigens specific to SARS-CoV-2 in nasal/nasopharyngeal swabs containing samples collected from a human nasopharynx. This test is recommended for administration by qualified healthcare workers and certified laboratories only, as an aid for rapid differential diagnosis of SARS-CoV-2 infection in patients with the associated clinical symptoms. This product provides only a preliminary test result. The interpretation of the results should be done by trained health professionals and cannot be the sole basis for the diagnosis of SARS-CoV-2 infection; Negative results should be ascertained using confirmatory tests such as RT-PCR (Reverse Transcription - Polymerase Chain Reaction).

TEST PRINCIPLE

The principle of iNSTAXPLOR® COVID-19 Ag Test is an antigen-capture immunochromatographic assay for the detection of SARS-CoV-2 antigens in nasal/nasopharyngeal swab samples. Monoclonal anti-SARSCoV-2 Antibodies are conjugated to colloidal gold and deposited on the conjugate pad. Monoclonal anti-SARS-CoV-2 Antibodies are also coated and immobilised on the Test band "T" of the Nitrocellulose membrane. When the sample is added, the gold-antibody conjugate is rehydrated and SARS-CoV-2 antigens, if any in the sample, will interact with the gold conjugated antibodies to form an immunocomplex. This immunocomplex will migrate towards the test window where they will be captured by the immobilised antibodies in case of presence of SARS-CoV-2 antigens in the sample, forming a visible coloured line in the "T" band which indicates a positive result. If SARS-CoV-2 antigens are absent in the sample, no coloured line will appear in the "T" band, which indicates a negative result. To serve as a procedural control, a Control band "C" has been designed, where a coloured line must always appear at the test completion. Absence of a coloured line in the "C" band is an indication of an invalid result.

KIT CONTENTS

iNSTAXPLOR COVID-19 Ag test cassette (individually packet with desiccant) x 25 Nos

Buffer Bottle x 2 Nos

Extraction buffer tube x 25 Nos

Nozzle Cap x 25 Nos

Sterile Nasopharyngeal Swab x 25 Nos

Instructions for use x 1 No

KIT STORAGE AND STABILITY

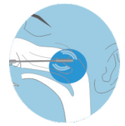
- Store the kit at 2-28°C without direct exposure to sunlight and moisture.
- Kit materials are stable until the expiry date.
- Do not freeze the kit.
- Shelf life: 24 months (Please refer expiry date printed on the pouch)

DETAILED TEST PROCEDURE

- Add 10 drops of buffer from Buffer bottle to the Extraction Buffer tube.
- Insert a sterile nasopharyngeal swab into the nostril of the patient and reach the surface of the posterior nasopharynx.
- Rotate the swab a few times against the nasopharyngeal wall.
- Withdraw the sterile swab from the nasal cavity carefully.
- Insert the swab in to the Buffer-filled Extraction buffer tube.
- While squeezing the sides of the Buffer tube, stir the swab more than 10 times.
- Remove the swab while squeezing the liquid from the swab, by pressing the tube sides.
- Cover the Extraction Buffer tube with nozzle cap and close tightly.
- Mix well and wait for 2 Minutes.
- Remove the test cassette from the foil pouch and place it on a flat surface.
- Apply 2 drops of specimen from the Extraction Buffer tube in to the well of the test cassette.
- Read the test result in 15-30 minutes.

TEST PROCEDURE SUMMARY

ADD 10 DROPS OF BUFFER



COLLECT NASAL SWAB SAMPLE

INSERT SWAB IN BUFFER TUBE

STIR 10 TIMES, WHILE SQUEEZING THE TUBE

REMOVE SWAB WHILE SQUEEZING TUBE

CLOSE TUBE WITH NOZZLE CAP, MIX WELL AND WAIT FOR 2 MINUTES

APPLY 2 DROPS OF SPECIMEN IN TO WELL OF THE CASSETTE

READ THE TEST RESULT IN 15-30 MINUTES

TEST RESULTS

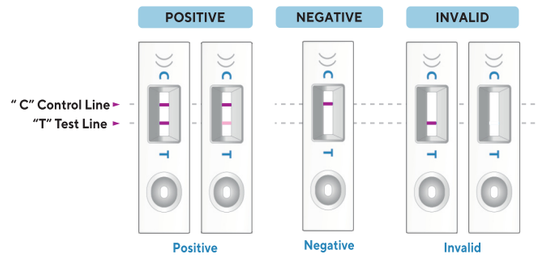


TABLE NO.:-1

In House Evaluation of iNSTAXPLOR COVID 19 Rapid Antigen Test

	Patients Tested	iNSTAXPLOR Results	Sensitivity (%)	Specificity (%)
No. Of RTPCR Positive	100	98	98%	100%
No. Of RTPCR Negative	100	100		

- As per the above table No.1, we tested 100 positive and negative samples and we obtained a Sensitivity of 98% and Specificity of 100%.