COVID-19 Antigen Test

Rapid Mono-Test for the determination of SARS-CoV-2 Antigen

4BShopLab

A - INTENDED USE

Immunochromatographic Rapid Test for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal swab of individuals suspected of COVID-19 in acute phase or with symptoms typical of such disease.

For "in vitro" diagnostic use only.

B - INTRODUCTION

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which was first identified amid an outbreak of respiratory illness cases in Wuhan City, Hubei Province, China and has since then caused a global pandemic.

Those who are infected with COVID-19 may have little to no symptoms. Symptoms of COVID-19 are similar to a cold or flu and may take up to 14 days to appear after exposure to SARS-CoV-2. Symptoms have included: fever, cough, difficulty breathing, pneumonia in both lungs.

In addition to the current molecular tests for SARS CoV 2 which require time and compl ex equipment, the chromatographic antigen test is a simple and rapid method that determines a dominant antigen protein (NCP) of the virus The rapid antigenic chromatographic test, although with a sensitivity lower than the molecular tests , represents an eff ective means of monitoring the infection , easy to use manual ly and quick.

C - PRINCIPLE OF THE TEST

The assay is based on the well-known principle of the immunochromatographic lateral flow and use anti-NCP monoclonal antibodies. The cassette is composed of three parts: a membrane to deposit the sample, a conjugate consisting of colloidal gold activated with a monoclonal antibody and a second membrane on which are adhered, in two different areas, a second capture monoclonal antibody and a reagent of internal control (polyclonal anti Mouse IgG).

If the sample, extracted from the swab with the extraction reagent, contains the antigen, this is fixed by the red coloured conjugate, dragged by capillarity towards the bottom of the reaction strip and captured by the second monoclonal antibody generating a red coloured band at the T mark (test line).

The conjugate continues to migrates reaching the control area, where it binds the anti Mouse antibody, generating a second red band at the C mark (control line).

D - COMPONENTS

Code COVAG.CE contains reagents individually packaged in Aluminium foil bag (1 Mono-test/bag) for a total of 25 tests.

	Total Number	Mono Test
Aluminium foil bag	n. 25	n. 1
Test cassette	n. 25	n. 1
Swab	n. 25 nasopharyngeal swabs	n. 1 nasopharyngeal swabs
Extraxtion tube (with buffer)	n. 25	n. 1
Dropper	n. 25	n. 1
Quick user guide	n. 25	n. 1
Package insert	n. 1	-

E - MATERIALS REQUIRED BUT NOT PROVIDED

1 - Timer.

2 - Personal Protective Equipment (PPE): protective lab coat, disposable gloves, FFP2 protective mask and face shield.

3 - Specific container for laboratory/hospital waste of potentially infectious materials.

F - WARNINGS AND PRECAUTIONS

1 - For "in vitro" diagnostic use only.

2 - Do not use the kit after the expiration date.

3- Wear PPE to perform both swab and test.

4 - Avoid touching the reagent membrane and sample the window surfaces.

5 - Both the swab and test shall be carried out by skilled and properly trained technical personnel only in in an environment suitable for handling potentially infectious materials.

6 - The test has to be performed at room temperature.

7 - Swabs and all the material used for the test must be treated with disinfectant agents approved for COVID-19 and discarded in the appropriate waste container.

8. Store the kit at 2-30°C. Do not freeze.

9 - Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.

10 - Avoid cross-contamination between samples.

11 - Do not use the kit after the expiration date stated on the external container labels.

12 - Accidental spills of samples during the operations have to be adsorbed with paper tissues soaked in sodium hypochlorite and then rinsed with water. Papers should then be discarded in Specific container for laboratory/hospital waste for biological materials.

13 - Do not reuse the used Test Cassette, used extraction tube, used dropper and used swab.

G - SPECIMEN: PREPARATION AND RECOMMANDATIONS

1 - Blow your nose before carrying out the nasopharyngeal swab.

2 - Use the test to analyse the nasopharyngeal swab carried out, as described in the figure below, only by appropriately qualified technical personnel.

3 - Salivary swabs in particular and Oropharyngeal swabs show a much lower sensitivity respect to the antigenic test performed on a nasopharyngeal swab.

4 - Use the swab immediately after the collection.

5 - Discard the swab as material potentially infected.

H - ASSAY PROCEDURE

The assay has to be carried out according to what reported in the present instruction.

1 - Take out the Materials needed from the aluminium foil bag Take out the test card and lay it on a flat and stable surface.

2 - Collect nasopharyngeal swab from the patient in accordance with standard operating procedure.

3 - Pierce the sealing membrane of lysis buffer tube with the tip of nozzle cap.

4 - Unplug the nozzle cap from the tube and place it on the workbench with the protective cover facing down. Be careful not to touch the nozzle tip to avoid contamination.

5 - Insert the swab into the lysis buffer tube. Squeeze the tube and stir the swab for 6 TIMES.

6 - Keep squeezing the tube and remove the swab. Make sure all the liquid from the swab is removed.

7 - Install the nozzle cap with the protective cover facing up. Mix the tube by gently shaking for 10 TIMES. Let stand for 1 minute.

8 - Remove the protective cover. Squeeze the tube and discard the first two drops of processed specimen.

9 - Add three drops of processed specimen vertically into the SAMPLE well, and then let stand for 15 minutes.

10 - Read the test result immediately, the test result will be invalid after 30 Minutes.

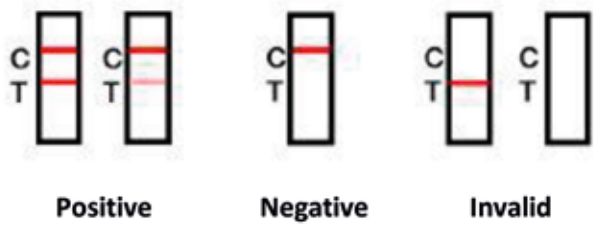
11 - Collect the material used in the aluminium foil bag and discard it in the specific container for laboratory/hospital waste of potentially infectious materials.

I - INTERPRETATION OF THE RESULTS

1 - **POSITIVE**: Two red line appear. One red line appears in the test region (T) and one red line in the control region (C). The test should be considered positive. Whenever there is even a faint line in the test region T.

2 - **NEGATIVE**: Only one red line appears in the control region (C).

3 - **INVALID**: No coloured band appears or only one coloured band appears in position T.



L - LIMITATIONS

1 - The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.

2 - This product is only used for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal swab, but not for quantitative detection.

3 - This product is only for the initial screening test. The disease diagnosis should be made in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.

4 - Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodology.

5 - In case of negative results, consider that the device shows a sensitivity lower than the molecular test.

6 - A negative result does not exclude the presence of a viral load less than the limit of sensitivity of the device.

7 - The test is not suitable for evaluating the results of antiviral pharmacological trials.

M - PERFORMANCES

Clinical studies of the device were conducted against molecular tests as reference.

On 550 samples examined, of which 50 positive and 500 negative in PCR tests, the tests showed a **sensitivity ≥ 96%** and a **specificity ≥ 98%.**

The **concordance** with the Molecular Test is **≥ 98%**.

The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the TIME.

(i.e., concentration at which at least 19 out of 20 replicates tested positive). The LOD is: 8.0×10^2 TCID50/mL.

No cross-reaction with the other member of the Coronavirus family or Flu viruses was found.

REFERENCES

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SIMBOLS

LEGENDA			
REF	Code of the product		Store Temperature
IVD	In Vitro Diagnostic Device		Instruction for Use
LOT	Lot Number		Manufacturer
	Expiration Date		Number of test
CE	CE Conformity Trade Mark		Date of manufacturing

DISTRIBUTOR

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