



COVID-19 Antigen Test

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



4BShopLab



Designed for patients with suspected COVID-19



Made in Italy



Results in 10-15 minutes



High Reliability Nasal:

Concordance with the Molecular Test $\geq 95\%$

High Reliability Nasopharyngeal:

Concordance with the Molecular Test $\geq 98\%$



Each Mono-Test is individually packaged in aluminium foil bag with reagents



Test easy to use manually and to interpret.
Usable in any context



Test for large-scale analysis



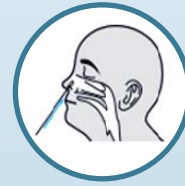
Moderate costs compared to the RT-PCR method



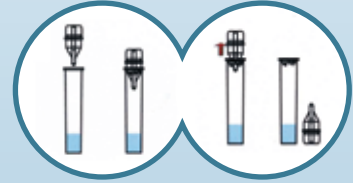
Product and scientific support specialist

ASSAY PROCEDURE NASAL

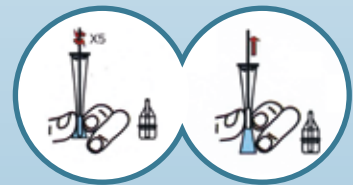
Simple nasal swab sample collection



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



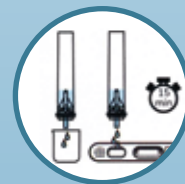
Insert the swab into the lysis buffer tube.
Squeeze the tube and stir the swab,
make sure all the liquid from the swab is removed



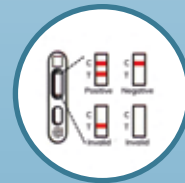
Mix the tube by gently shaking,
let stand for 1 minute



Discard the first two drops and
add three drops of processed specimen vertically
into the SAMPLE well, let stand for 15 minutes



Read the test result

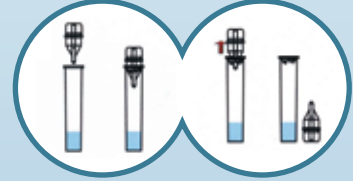


ASSAY PROCEDURE NASOPHARYNGEAL

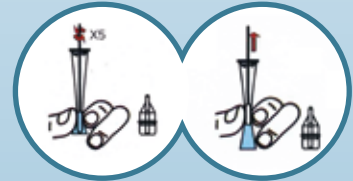
Collect nasopharyngeal swab from the patient in accordance with standard operating procedure



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



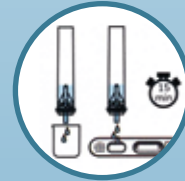
Insert the swab into the lysis buffer tube.
Squeeze the tube and stir the swab, make sure all the liquid from the swab is removed



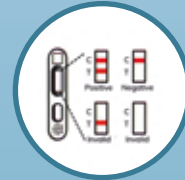
Mix the tube by gently shaking, let stand for 1 minute



Discard the first two drops and add three drops of processed specimen vertically into the SAMPLE well, let stand for 15 minutes



Read the test result



TECHNICAL SPECIFICATIONS



Sample: nasal/nasopharyngeal swab

Test time: 15 minutes

Storage: 2°C - 30°C

Kit components:

- 25 rapid Mono-Test for the determination of SARS-CoV-2 Antigen packaged in aluminium foil bags
- 1 package insert

Mono-Test components:

- 1 test cassette
- 1 swab
- 1 extraction tube (with buffer)
- 1 dropper
- 1 quick user guide

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. The rapid antigenic chromatographic test, although with a sensitivity lower than the molecular tests, represents an effective means of monitoring the infection, easy to use manually and quick.

The test can be used in any context meeting the requirements specified in

the package insert and in local regulations.

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.

4BShopLab

DISTRIBUTOR

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MANUFACTURER

Dia.Pro - Diagnostic Bioprobes Srl



MADE IN ITALY

EN ISO 13485:2013 Certified

