PORTABLE COVID-19 ANTIGEN LAB ®

In vitro diagnostic (IVD) medical device to aid in diagnosis and only for professional use.

1. DESCRIPTION

PORTABLE COVID-19 ANTIGEN LAB ® is a test for the qualitative detection of the presence of antigens characteristic to the Covid-19 coronavirus infection, using two cytology samples, nasal and oropharyngeal. The test is useful as a co-aid in medical judgement to decide on further qualitative and quantitative investigations for diagnosis.

2. INDICATIONS

PORTABLE COVID-19 ANTIGEN LAB ® is an antigen test that unambiguously detects the viral protein fraction of coronavirus and serves as an aid in the diagnosis of a symptomatic or asymptomatic infection with COVID-19. The search for antigens allows ascertaining the incubation stage or the early stages of infection, where the antibody response is still low and characteristic symptoms are not visible yet. The test, based on immunology methods to search for viral proteins in samples collected from the nasal cavity and the oropharyngeal cavity, helps doctors deliver a diagnosis for a possible early-stage infection and allows them to adopt possible protocols for hospitalization, quarantine and clinical therapy. The results of PORTABLE COVID-19 ANTIGEN LAB ® must never be used as the single base for diagnosis or for excluding an infection with SARSCoV-2 or to get information on the state of infection.

3. PRINCIPLE

PORTABLE COVID-19 ANTIGEN LAB ® is a non-invasive patient-side qualitative analytical immunological test that can help a doctor's diagnosis, performed with western blotting and chemocolorimetric results on a membrane coated with labelled antibodies against the specific antigen nucleocapsid located on the oral or nasal swab. In this test, a series of antibodies labelled for the specific protein is coated on a membrane. This membrane is submerged in a cell lysate derived from the immersion of two nasal and oropharyngeal samples in a lysis buffer. If the lysate contains the targeted marker proteins at a concentration higher than the minimum signal threshold over every single channel, they are captured on the membrane. The membrane is then immersed in a liquid that contains alkaline phosphatase-conjugated secondary antibodies, forming a sandwich that can be revealed by chemocolorimetry. The membrane is then immersed in the chemocolorimetry detection station, where a pink/purple strip is shown, one for every single type of targeted antigens, if the hybridomas are present. If there is 1 coloured line (in addition to the control line), the test is positive since it has detected the presence of the antigen nucleocapsid.

4. REAGENTS

The test includes antibodies against the antigen nucleocapsid, a buffer for cell lysis and a buffer for colorimetry detection.

5. PRECAUTIONS

1. Only for in vitro diagnostic for professional use.
2. Do not eat, smoke in the sample or kit handling area.
3. Handle all samples as if potentially infectious, observe the precautions established against microbiological risks for the entire time of the test and follow the standard procedures for a correct disposal of the samples.
4. Wear protective equipment, such as laboratory gowns, single use gloves, masks and safety glasses during sample analysis.
5. Used tests must be disposed of according to local law.
6. Humidity and temperature can have a negative impact on results. Keep the product at a temperature from 8°C to 35°C.
7. Do not use if the package is damaged.
8. In case any buffer comes in contact with the skin or with the eyes, rinse with plenty of water. See the technical data sheet.
9. Possible harmful substances present.
10. Do not exchange the preloaded syringes.
11. The blotting membrane must not come in contact with substances or solutions that are not supplied with the kit.
12. The blotting membrane must be put in the cuvette only and exclusively in the given order and for the time stated in the instructions for use. Any other handling contrary to the protocol can alter the results.
13. Once taken out of its packaging, the brush must come in contact only with the anatomical parts of interest and for which there is an intention to perform the qualitative assessment as an aid in diagnosis.

6. PRESERVATION AND STORAGE

The box of the kit must be kept at ambient temperature or refrigerated (8-35°C). The test is stable and results are reliable only and exclusively until the expiry date stated on the packaging. Each component of the test must remain in its packaging until use. **DO NOT FREEZE**. Never use beyond the expiry date.

7. SAMPLE COLLECTION AND PREPARATION

1. Take two samples using the two brushes in the packaging. Pass the first brush through the oral cavity and the second through the nasal cavity.
2. The test must be performed immediately after the sample is collected.

8. MATERIALS SUPPLIED WITH THE KIT

- Nb. 8 1,5ml cuvette;
- Nb. 2 0,5ml microtube;
- Nb. 3 preloaded syringes;
- Nb. 2 Pasteur pipette;
- Nb. 1 membrane for signal detection;
- Nb. 1 Cytobrush for the oral sample;
- Nb. 1 swab for the nasal sample;
- Instruction for a correct use

9. REQUIRED MATERIALS, NOT SUPPLIED WITH THE KIT

Watch or timer.

10. INSTRUCTION FOR USE

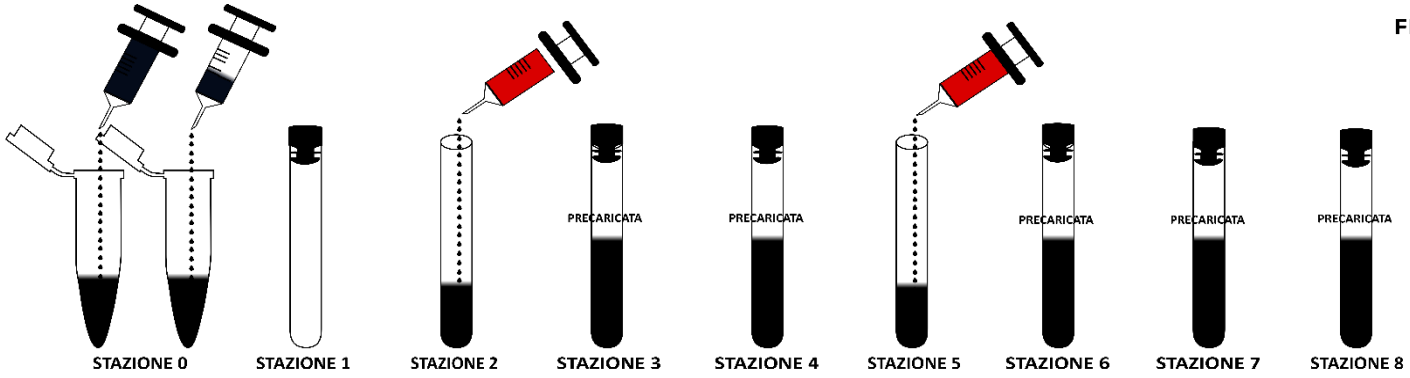
1. Bring the test to room temperature.
2. Open the packaging and **(see FIGURE 1);**

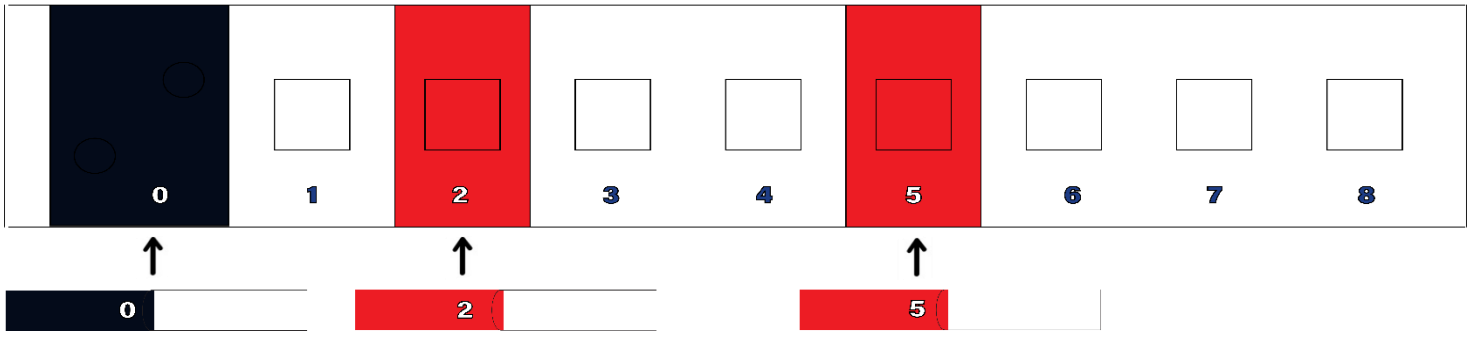
2.1 Take out the preloaded syringe with the cell lysis buffer, marked with 0, from the blue compartment and inject its contents, equally, in the two microtubes in **STATION 0**, and put it back in the blue compartment (**FIG. 1**);

2.2 Take out the preloaded syringe with the PBS/BSA buffer, marked with 2, from the red compartment. Fill in the cuvette in **STATION 2** (**FIG. 2**).

2.3 Take out the preloaded syringe with the PBS/BSA buffer, marked with 5, from the red compartment and fill in the cuvette in **STATION 5** (**FIG. 2**).

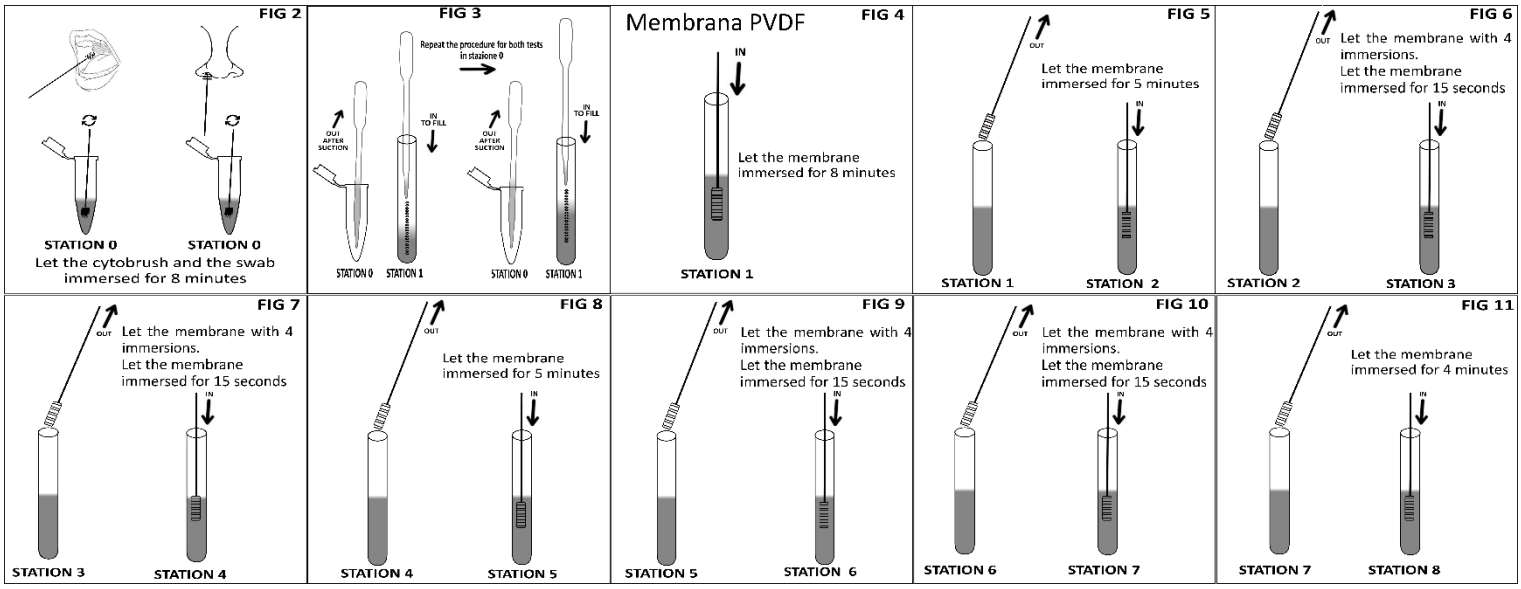
FIG 1



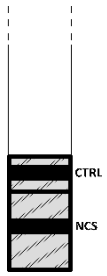
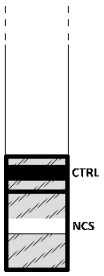
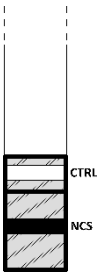
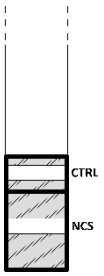


3. Take out a brush from the package, collect the sample from the oral cavity and insert the cytobrush immediately in a microtube in **STATION 0**. Rotate the cytobrush for about 10 times and let it immersed for **8 minutes**. **(FIG. 2).**
4. Take out the swab brush from the package, collect the sample from the nasal cavity and insert the cytobrush immediately in the second microtube in **STATION 0**. Rotate the cytobrush for about 10 times and let it immersed for **8 minutes**. **(FIG. 2).**

5. With the supplied Pasteur pipette, take out all the liquid in **STATION 0** and pour it in **STATION 1.** Repeat the step for both the test tubes in station 0 **(FIG. 3).**
6. Take out the membrane from its package, insert it in **STATION 1** and let it immersed in the cuvette for **8 minutes**. **(FIG. 4)**
7. Take out the membrane from **STATION 1** and insert it in **STATION 2**. Let it immersed in the cuvette for **5 minutes. (FIG. 5)**
8. Take out the membrane from **STATION 2** and insert it in **STATION 3**. Perform 4 immersions for washing and let it immersed for **15 seconds. (FIG. 6).**
9. Take out the membrane from **STATION 3** and insert it in **STATION 4**. Perform the 4 immersions for washing and let it immersed for **15 seconds. (FIG. 7).**
10. Take out the membrane from **STATION 4** and insert it in **STATION 5**. Let it immersed in the cuvette for **5 minutes. (FIG. 8)**
11. Take out the membrane from **STATION 5** and insert it in **STATION 6**. Perform the 4 immersions for washing and let it immersed for **15 seconds. (FIG. 9)**
12. Take out the membrane from **STATION 6** and insert it in **STATION 7**. Perform the 4 immersions for washing and let it immersed for **15 seconds. (FIG. 10)**
13. Take out the membrane from **STATION 7** and insert it in **STATION 8**. Let it immersed in the cuvette for **4 minutes. (FIG. 11)**
14. Read the result.



INTERPRETATION OF RESULTS

POSITIVE[1]	NEGATIVE[1]	NULL[1]
- The control line will colour up in light green - The NCS line will colour up in pink/purple	- The control line will colour up in light green - The NCS line will not colour up in pink/purple	- The control line will not colour up in light green - The NCS line may or may not colour up in pink/purple.
EXAMPLE	**EXAMPLE**	**EXAMPLE**
		 

[1]NOTE**:** The colour intensity in the test line area varies according to the protein concentration detected. Each colour tone in the test line area must be considered positive.

a) If the initial colouring is intense (pink/purple), read the result immediately after having extracted the membrane from station no. 8.
b) If the colouring is faded, close to white, let the membrane dry out for 1h and then read the result. If the colouring persists, consider the result as positive.

11. WARNINGS

PORTABLE COVID-19 ANTIGEN LAB ® is only for in vitro diagnosis. The test must be used for the detection of Covid-19 coronavirus specific proteins in collected samples. Positive or negative results require further clinical investigations for confirmation and they must be interpreted together with other clinical information the doctor has available. The declared performances are not guaranteed if samples, methods of extraction and detection instruments are used other than those stated by the manufacturer.

12. ANALITICAL SENSITIVITY

Analytical sensitivity of 10 pg/µl of viral spike and / or nucleocapsid protein.

13. ANALYTICAL SPECIFICITY

Specificity 100% spike protein and its cleaved forms S1, S2. Specificity 100% nucleocapsid.

14. INDEX OF SYMBOLS


See the instruction for use


Do not reuse


Do not use if the package is damaged


Temperature limits


Protect against heat sources and radioactive sources

IVD
Only for in vitro diagnosis


Attention. Before using the device, read the instructions for use carefully and, in particular, the warnings for safety.


Manufacturer


Manufacturing date

REF
Catalogue code

LOT
Lot number


Use by and not otherwise the stated date

15. QUALITY CONTROL

Stark S.a.r.l., the Quality Management System certified according to UNI CEI EN ISO 13485, warrants that every lot of PORTABLE COVID-19 ANTIGEN LAB ® has been tested according to preset specifications to guarantee a constant quality of the product.

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