

CE



möLab[®]
point of care



Corona Antigen Test

Nasopharyngeal swab test

only **15**
minutes

PRODUCT MANUAL

INTENDED USE

The mö-screen Corona Antigen Cassette is an in-vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in a nasopharyngeal (NP) swab. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.

TEST PRINCIPLE

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in a nasopharyngeal (NP) swab. The test strip is composed of the following parts: the sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2 the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic cassette.

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample,, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T).

Absence of the T line suggests a negative result. To serve as a procedural control,, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

CORE ADVANTAGES OF THE TEST

- Full equipment -Test cassettes, sterile swabs, extraction tubes, dropper tips for extraction tubes, buffer, workstation, package insert
- Test results are easy to read
- High sensitivity and specificity

High accuracy (99,0%), sensitivity (97,3%) and specificity (>99,9%).

- Storage at 2 to 30 °C
- Long shelf life of up to 24 months



FAST



PRECISE

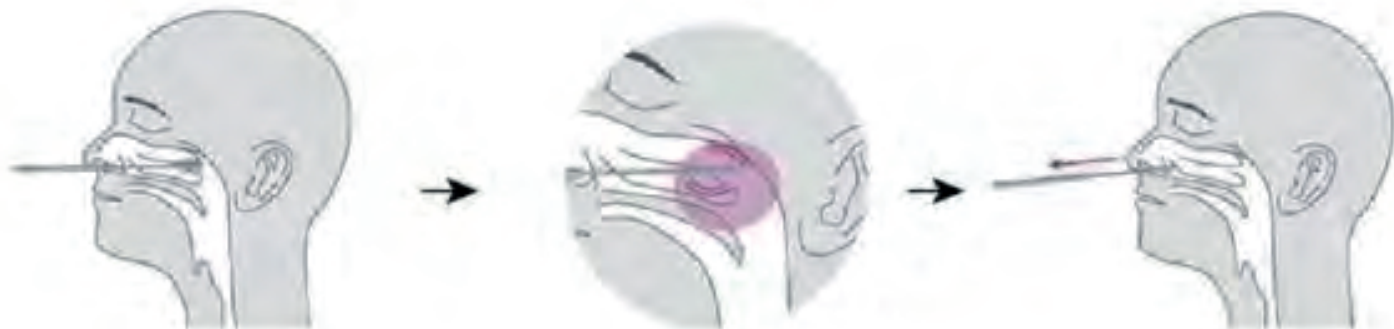


CONVENIENT

SPECIMEN COLLECTION

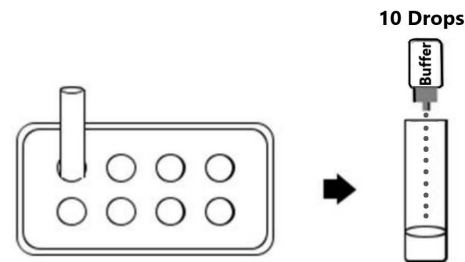
Use the nasopharyngeal swab supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx, that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.



Sample Preparation and Procedure

1. Place the extraction tube in the workstation and add 10 drops of buffer solution.

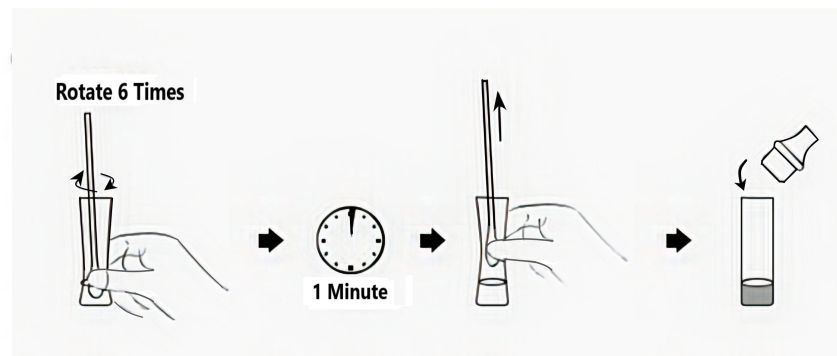


2. Place the swab in the extraction tube, rotating the swab at least 6 times.

3. Press the head of the swab against the bottom and side of the extraction tube.

4. Leave the swab in the extraction tube for 1 minute.

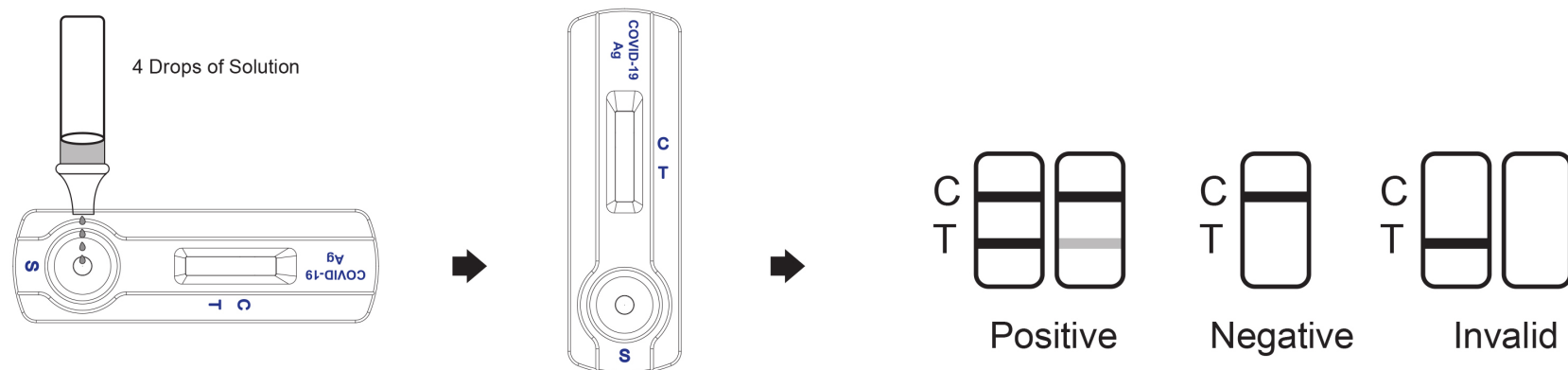
5. Lift up the swab and squeeze it well. This extracted solution is used as sample material.



Test Procedure

1. Remove the test cassette from the foil and place it on a clean, flat surface.
2. Add 4 drops of test sample into the sample window (S).
3. Wait for the colored band(s) to appear. The result should be read in 15 minutes.

Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

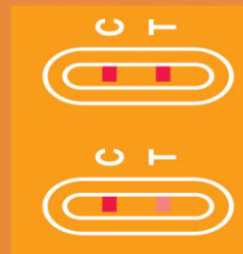
Wait for the colored line(s) to appear. Read results at **15 minutes**. Do not interpret results after 20 minutes!

Interpretation of results



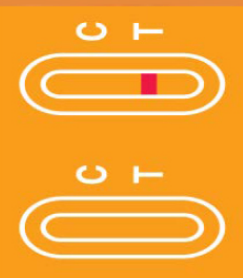
Negative

A coloured line appears in control area C.
No coloured line appears in test area T.



Positive

Two coloured lines appear, one in control area C and one in test area T.
The intensity of the test line T may vary depending on the concentration of the antigen in the sample. Any sign of a line should be considered a positive result.



Invalid

In the control area C, a red line must always appear when the test is performed.
If the line does not appear, the test is invalid in any case.
Please repeat the test with a new test cassette.



CERTIFICATION AUTHORITY



möLab Corona Antigen Test Kit has passed EU quality management system certification



möLab receives ISO13485 quality management system certificate



powerful brand trustworthiness: MöLab has been offering a large portfolio of innovative solutions in the field of medical diagnostics since 1985.

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THANK YOU

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