

Instructions for Use of the CoronaOne Swab Kit in case of suspected SARS-CoV-2

Read the entire package insert carefully before starting to use this medical product. Although the product is designed for easy use, always use it according to the enclosed information.

APPLICATION

The CoronaOne smear kit contains the necessary accessories to perform a smear test in the throat and nose area. The included applicator stick is a sterile, ready-to-use system for taking patient samples. The applicator rods are suitable for short-term contact with the human body. The swab kit should be used according to the instructions for use.

SUMMARY AND PRINCIPLES

One of the routine procedures for the diagnosis of COVID-19 infections involves taking samples on applicator sticks. This procedure can be performed using the supplied applicator sticks and accessories. The fiber types for the tips of the applicator rod include viscose, polyester and cotton. Slide Applicator Sticks have been sterilized with ethylene oxide or gamma rays.

INTENDED USE

The CoronaOne smear kit is intended as an aid in the diagnosis of COVID-19 ("coronavirus") infection. A nasopharyngeal and throat swab is taken. The swab kit itself is used for the smear; the laboratory in-vitro sample analysis is performed in a laboratory.

MATERIALS PROVIDED

Please check the contents of the CoronaOne swab kit immediately upon receipt. The following components must be contained and undamaged:

- 1 instruction manual
- 2 nitrile gloves sterile, size L
- 1 Tongue spatula sterile
- 1 swab in the test tube
- 1 transfer form
- 1 sample bag with adhesive strip, labelled
- 1 sample bag with pressure seal, unlabeled
- 1 Dangerous goods sticker "UN 3373 - biological substances"

An incomplete or damaged swab kit must not be used to perform a swab. In this case, please contact our customer service (mail@coronaone.de).

DUTY TO REGISTER

The mere suspicion of a disease with Sars-CoV-2 / COVID-19 is subject to notification according to § 6 para. 1 No. 5a IfSG (occurrence of a threatening disease). For further information on the coronavirus, please contact your local health authority.

EXPIRY OF THE PRODUCT

Sterility of the contents of unopened and undamaged units is guaranteed.

The applicator stick must not be used if (1) the product is visibly damaged or dirty, (2) the expiration date has expired, (3) the product is visibly leaking or (4) other signs of closure are visible.

TAKING OF SAMPLES

NOTE: During the collection and handling of microbiological samples the enclosed gloves must be worn.

1. Open the sample tube and pull out the applicator rod.
2. take the sample, first in the nasopharynx, then in the throat During collection, the end of the applicator rod (the tip) must only touch the collection site to avoid the risk of contamination. Do not touch the tongue during throat swabbing, use the tongue spatula to push the tongue down.
3. place the applicator stick in the transport test tube for the sample.
4. send the sample to the laboratory for immediate analysis

Samples taken for testing must be collected and handled in accordance with published manuals and guidelines. The relevant requirements for the shipping and handling of samples must be strictly in accordance with local and national regulations. The sending of samples to medical facilities must be in accordance with the institution's internal guidelines.

TECHNICAL NOTES

A slight yellowing of the applicator tip is a well-known phenomenon. This can be due to many factors: the type of raw material, the sterilization treatment of the product, the natural aging of the product. Yellowing of the product is therefore not necessarily an indication of its deterioration.

PRECAUTIONS

1. strictly follow the instructions for use.
2. apply only little pressure during removal, otherwise the material of the rod could break.
3. the adhesion of the fiber to the rod has been tested for instantaneous sampling: prolonged contact between the applicator rod and the sampling area may cause the fiber to separate.
4. if the applicator bar is subjected to chemical or physical sterilization or micro biostatic treatment, this may alter its intended function.
5. the applicator rod must not be reused or re-sterilized

CUSTAINMENT

Store the applicator stick at 2 - 30°C. If the product is stored at other temperatures, it may not retain its specified properties. The sample taken must be taken to the laboratory uncooled within 24 hours. The sample can be used for 72h when cooled to 4°C.

RESTRICTIONS

1. the swab kit may only be used after express consent has been given for a test for the novel coronavirus by a recognised medical practitioner
2. the swab kit and especially the swab may only be used by the intended patient The sample may only be taken from the posterior nasal cavity and throat of the intended patient.
3. not suitable for users who suffer from epilepsy or other diseases that can lead to uncontrolled movements.
4. only suitable for users who are in full possession of their mental and physical faculties during use.
5. not suitable for other purposes that are not in accordance with the intended use. The applicator rod is suitable for nasopharyngeal and pharyngeal sampling to detect viruses.
6. wear protective gloves or other generally recognised protective equipment in the laboratory for handling clinical specimens. Follow bio-safety recommendations when handling or analysing patient samples.
7. the condition, transport time and volume of samples collected for culture will affect the reliability of the test result. It is recommended that the instructions



regarding specimen collection be followed.
8. unless otherwise instructed, the applicator sticks should only be used by qualified personnel.

NOTES

1. this product is intended for a single use for personal use by one person Its reuse may lead to risks of infection and/or unreliable results.
2. at no time should the contents of the swab kit be touched without the gloves provided
3. keep out of the reach of children.
4. for in vitro diagnostic (IVD) use only.
5. the swab must be taken in the correct order according to the instructions for use and without delay between steps
- 6 Do not re-sterilize unused applicator strips.
7. do not repackage.
- 8) The suitability of this product for use with any rapid diagnostic kits or diagnostic instruments must be verified by the user prior to use.
9. do not use the applicator bar if there is visible damage (i.e. if the tip or rod of the applicator bar is broken).
10. do not press too hard or bend the rod too much while taking samples, otherwise the rod of the applicator rod could break off.
11. strictly follow the instructions for use. The manufacturer and distributor are not liable for inappropriate or improper use of the product.
12. a negative result of the analysis does not completely rule out an infectious disease. At the very beginning of the disease, the result may be inaccurate (false negative). If you are in doubt about your test result, you must consult a doctor for further tests.
13. the product should only be used by trained and qualified personnel, unless otherwise directed by your doctor.
- 14 All specimens are considered potentially infectious and should be handled with appropriate precautions. After use, dispose of test tubes and applicator strips in accordance with laboratory regulations for infectious waste.

WASTE DISPOSAL

Unused applicator sticks are considered as non-hazardous waste and can therefore be disposed of as such.
The disposal of used applicator sticks or other contaminated disposable waste material must be carried out in accordance with the regulations for infectious or highly infectious products. The laboratory must ensure that waste or liquid waste products are treated and disposed of according to their characteristics and degree of danger, as specified in the applicable regulations. Dispose of the gloves after use in household waste.

This package insert was edited last on April 25th, 2020.

Private Label Manufacturer

MEUS Srl
Via Leonardo da Vinci, 24/B, Piove di Sacco, IT
35028 (PD)
Tel +39 049 9719511
Fax +39 049 9719542 / 049 9719543
E-mail: info@vacutestkima.it
Webseite: <http://www.kima.it/en/meus/>

Distributor

Cedric-Pascal Sommer CoronaOne
Rheinsberger Str. 76,
10115 Berlin
Tel +349 179 4388820
E-mail: mail@coronaone.de
Webseite: <http://www.coronaone.de>

