



PCR GARGLING KIT

IN VITRO DIAGNOSTIC MEDICAL DEVICE

PCR GARGLING KIT is a unique self-sampling device based on the principle of gargling of the oral cavity and pharynx. The self-sampling device is intended for collecting samples, which are then tested in a professional laboratory for the presence of viruses infecting the oral cavity and upper respiratory tract. The kit was primarily developed for the detection of SARS-CoV-2 virus, which causes covid-19. The evaluation is performed in the laboratory by detection based on nucleic acid amplification such as **RT-PCR and RT-LAMP** methods. In the transport medium, viruses remain vital and can also be used for culture tests.

WHY PCR GARGLING KIT?

The kit is fully validated and meets **CE IVD certification**. The sampling kit was developed and manufactured by a Czech pharmaceutical company **AUMED, a.s.** Company production capacity is up to **100,000 kits per day**. **The collection by gargling is of the same quality as the common collection from the nasopharynx, however, the collection by gargling is pleasant compared to the common collection from the nasopharynx and does not irritate the mucous membranes.** Instead of pushing the sticks into the nose, it is enough to gargle a sip of ordinary water for 20-30 seconds and then empty this content from the mouth into the enclosed collection tube containing the transport powder. The user then closes the tube and packs it according to the instructions. The user will perform this procedure either at the sampling point or at home, from where he will then deliver the sample to the sampling point, to the laboratory or, for example, to his doctor.

WHY GARGLING?

1. Irrigation of the oral cavity and the pharynx by gargling is a reliable method of self-sampling for virological testing, including the SARS-CoV-2 virus.
2. This new method of diagnostic self-collection is functionally comparable and does not differ statistically from the collection performed by healthcare professionals using nasopharyngeal swabs.
3. Self-sampling by gargling is safe, simple, and easy to do, even by an instructed layman.
4. There is no need for assistance from medical staff during self-sampling.
5. It is a completely painless way of sampling from the pharynx and oral cavity which does not irritate the mucosa, even when a repeated sampling is performed.
6. The collected sample is stabilized with a special buffer and storage or transport to laboratories at a reduced temperature is not necessary.
7. Viruses remain stable in the solution for a long period of time over a wide range of temperatures (from 4–37 °C) for at least 1 week.



More information can be found at:
www.aumed.cz
www.aumedtest.cz

AUMED a.s.
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143 14 Praha

SELF-SAMPLING INSTRUCTIONS

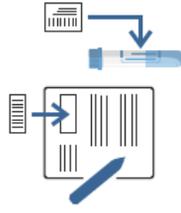
Strictly follow the instruction during self-sampling.

➡ Aumed a.s. Komořanská 326/63, Praha



CAUTION BEFORE USE:

The self-sampling is best done in the morning before performing your regular oral hygiene. Wash your hands properly before using the test. Store the collected sample at 4-37 °C, it will be stable for at least 1 week. **Do not expose to frost!**



01.

Before using the test, fill out the application form, which is located on the other side of this instructions. **Stick the barcode onto the transport tube and paper application form.** Write your name and birth number on the label on the transport tube.



06.

Spit the contents of your mouth into the measuring cup.



02.

Fill tap water in the enclosed measuring cup to the **5 ml** line.



03.

Take the breath and cough. This will increase the possibility of infection detection in the lower respiratory tract.



04.

Pour the contents of the measuring cup into your mouth – do not swallow! If you accidentally swallow repeat the procedure from step 2.

20–30 s



05.

Gargle from 20 to 30 seconds. You can gargle intermittently. However, keep total recommended minimal gargling time.



08.

Close the tube and shake it slightly.



10.

Place the packet tube with absorption insert into the larger bag and seal it.



11.

Place the tube in a sealed outer bag in the undamaged box. Attach a completed application form with the stuck barcode. Take the box to the collection point.

Self-sampling set contains: transport plastic test tube, disposable water measuring cup, application form and self-collection instructions, 2x bar code, large and small plastic bag, transport box, absorption insert