CE IVD

GARGTEST

WITH ELECTRONIC REQUEST FORM

Instructions for use of the gargling self-collection kit for testing the presence of viruses in the oral cavity and upper respiratory tract including SARS-CoV-2



www.gargtest.com

What is GARGTEST?

GARGTEST is a unique self-sampling device based on the principle of gargling of the oral cavity and pharynx. It was developed by researchers from the Institute of Molecular and Translational Medicine of the Faculty of Medicine and Dentistry, Palacký University in Olomouc, and the innovative companies IntellMed, s.r.o. and AUMED, a.s., 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 test is performed by this laboratory using commonly available nucleic acid isolation procedures and by detection based on nucleic acid amplification. In the transport medium, viruses remain vital and can also be used for culture tests.

What is GARGTEST not intended for?

- GARGTEST does not prove the presence of a virus on the point-ofcare (upon the sampling), it is only a kit for self-sampling biological material which must be further tested in a medical laboratory.
- GARGTEST is not suitable for the examination of bacterial flora, as the stabilizing solution contains substances that suppress the growth of bacteria, yeasts and fungi.



DISTRIBUTOR: **I.T.A.-Intertact, s.r.o.** www.ita-intertact.com ita@ita-intertact.com +420 224 810 196



VÝROBCE: IntellMed, s.r.o. www.intellmed.eu sales@intellmed.eu

Why gargling?

- 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.
- This new method of diagnostic selfcollection is functionally comparable and does not differ statistically from the collection performed by healthcare professionals using nasopharyngeal swabs.
- 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.
- 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.

Important notes

- Do not use the GARGTEST self-sampling set if it is damaged or has expired – see expiration date on the package.
- 2. The self-sampling set is intended for single use only.
- The fine powder at the bottom of the collection tube usually forms a hard, homogeneous layer. Disintegration of this layer does not damage the product and does not affect its performance. Do not inhale or ingest the powder.

VYROB Med, s.ro.

Samoodběrová sada GARGTEST obsahuie:

Plastic

tube

CONTAINS POWDER transport THATMUST NOT BE EATEN OR SPILLED

Before using the test, fill out the electronic test order form available on 1 the GARGTEST website.

SELF-COLLECTION PROCEDURE



Disposable water measuring cup



Self-collection instructions



Sterille three-part packaging: 1 x black plastic bag 1 x small plastic bag 1 x transport box

1 x absorbent pad

WARNING BEFORE USE

Please read instructions before before use to understand self-collective procedure. Make sure there is a barcode with an identification number on the sampling tube. You will need the barcode identification number to begin registration of the electronic test order form! You can fill the electronic order on this website. Wash your hands properly before using the test!

You will usually recieve your test results via text message. Therefore, it's necessary to provide your mobile telephone number in the test order form. The list of the testing laboratories is available on www.gargtest.com.



Carefully open the box and remove all contents. Do not damage the box as it will be used for transport your sample back to the laboratory or collection point.

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

5 ml

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

Pour the contents of the measuring cup into your mouth - do not swallow! If vou accidentaly swallow it doesn't matter and repeat the procedure from step 3.

5

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

Strictly follow the instructions

during collection.

11



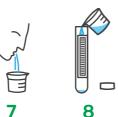
20-30 s

12

Place the packaged tube with the absorbent sealed outer bag in the pad into the larger bag and seal it

Place the tube in a undamaged box and then close it. Take the box to a sampling point. a collection point, your physician, or laboratory.

Store the collected sample at 4-30 °C; it will be stable for at least 1 week. Do not expose to frost!



Spit the contents of Carefully pour the your mouth into the liquid contents into measuring cup.

the enclosed plastic transport tube. The tube contains stabilizing powder which you must not spill.



Close the tube carefully and shake. Write your name and date of birth (foreigners only) on the label.



10

Very carefully close the transport tube and shake it slitghtly. Write your name and birth number on the label. For foreigners: Write your day of birth an the label