# PACKAGE CONTENTS:





2 sample tube

**3** saline solution

4 transfer tube

5 transport tube

6 2 x sealing sticker

7 sample tube holder

8 package insert



# INSTRUCTION FOR USE CORONA TEST-SET

For independent sampling and evaluation in the laboratory using a patented test procedure

Open the page:  ${\bf homekit.lead-horizon.com}$ , there you will be guided through the process.

The administration of the test consists of two procedural parts:

1) Activation of the product

Carrying out the test

Please note that we are obliged to register your test result in the national reporting system. Should you require a certificate, the performance of your test with the video camera must be documented (obligatory proof of identity). Otherwise, you can skip this section.

## USAGE:

Verify your test kit with your sample number and email address. We will send you a link to verify your email and enter your personal data in the next step.

#### 1. Information about the customer

Now enter vour personal data. that vour data for evaluation result delivery. sonal is reauired and

## 2. Proof of identity

The next step is the proof of identity. You also have the option of using the test set without proof of identity. Please note that in this case we can only provide you with your result, but not with a certificate. For proof of identity, please have your official photo ID ready and allow access to your camera. Please take a photo with yourself and your ID below or next to your face. Use the camera of your smartphone or your webcam from your PC/laptop/tablet for this purpose.

#### 3. Mouthwash

In the next step, you will be asked to carry out the following instructions: Please insert the sample tube (2) into the holder (7) provided. In the next step, take the saline solution into your mouth and rinse thoroughly for 1 minute with your mouth closed. Then fill the saline solution into the sample tube (2) with the transfer tube (4). Then close the sample tube (2) with the red cap and stick one of the two sealing stickers (6) over the side of the cap. Then hold your sample tube (2) with the sample number clearly legible into the camera. If the proof of identity was skipped, the rinsing process takes place without recording.

# 4. Packing the test set

Now put the closed and sealed sample tube (2) into the transport tube (5). Please close the transport tube (5) well and return it to the test kit. Dispose of the saline solution (3) and the transfer tube (4). Keep the slip of paper with your sample number safe and DO NOT return it. Close the box with the 2nd sealing sticker.

#### 5. Send test set

Label your test set with the laboratory address and send it to the address displayed in the WebApp or bring it directly to the drop-off point. Please be sure to keep your receipt with the shipment number. From the time we receive your sample in the laboratory, we need a maximum of 24 hours to evaluate your sample.

#### POSSIBLE TEST RESULTS:

- positive (with SARS-CoV-2 infected)
- negative (not infected)
- indifferent (no result could be achieved)

The laboratory is obliged to register all results in the national epidemiological reporting system. The sample is evaluated by a certified partner laboratory of LEAD Horizon GmbH using the PCR-method. After sampling, the user does not receive any information about his pathological condition. The test result is only generated by the evaluation of the sample in the certified laboratory using the PCR-method and made available to the user.

#### CONTENTS:

# STORAGE:

- 2,5 ml 0,9% NaCl solution (3)
- Store at 4° 25°C!
  Best before: see packaging
- 2 ml transport buffer (2)

## IMPORTANT INFORMATION:

- Sampling by the user, evaluation in the laboratory
- Mandatory proof of identity with official photo ID by camera for a certificate
- Internet-enabled computer with webcam or smartphone required
- In-vitro diagnostic

## INTENDED USE:

The Corona Test Set is used for the detection of a SARS-CoV-2 infection. Only the sample is taken by the user. The molecular biological analysis of the sample is not carried out by the user. The molecular biological analysis of the sample using the PCR method is carried out by a certified partner laboratory of LEAD Horizon GmbH. The test result is sent to the user by e-mail only after the molecular biological analysis in the laboratory. The Corona Test Set includes a kit for sample collection, postage costs and the services of a certified molecular biological partner laboratory of LEAD Horizon GmbH. Various definitions can be found in the FAQs at www.lead-horizon.com/haeufig-gestellte-fragen.

# DISPOSAL:

- The excess saline solution can be disposed of in the drain
- Dispose of transfer tubes in paper waste
- Dispose of the saline solution container in the residual waste







