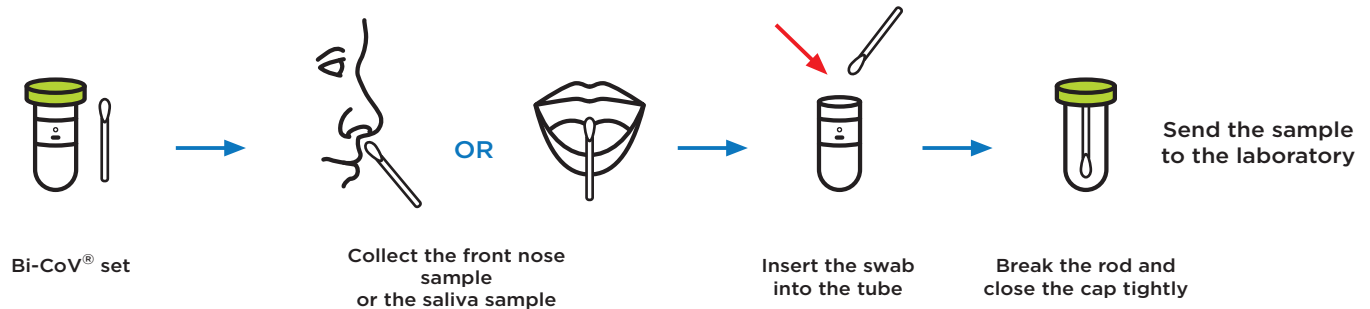


Instructions for use – Sampling kit Bi-CoV[®] set (Bioinova) with GeneProof SARS-CoV-2 PCR kits

Instructions for sampling



1. Open the package (tear the foil and paper on the opposite side from the swab) to remove the plastic rod with the swab.
2. Open the plastic tube with the solution by turning the cap.
3. Collect the **front nose** sample or the **saliva** sample.
4. Insert the swab with the sample into the tube with the solution, break the plastic rod and close the cap tightly.
5. Label the tube and send it to the laboratory.

INSTRUCTIONS FOR SAMPLING FROM THE FRONT NOSE:

Blow your nose first. Then insert the swab into the front nose (ca. 2 cm deep) and turn it three times in each direction.

INSTRUCTIONS FOR SAMPLING FROM THE ORAL CAVITY (SALIVA):

Tested person must not brush teeth, use mouthwash, drink, eat, use chewing gum or smoke at least 30 minutes before the sampling.

The tested person sniffs and coughs heavily to clear the throat to get mucus and saliva from the nasopharynx and throat to get to the oral cavity. Insert the swab into the oral cavity to the collected material (on or under the tongue, near the molars, etc.) eventually wipe around the palatoglossal arches.

Instructions for PCR analysis in laboratory

INSTRUCTIONS FOR SAMPLE PREPARATION FOR PCR TEST:

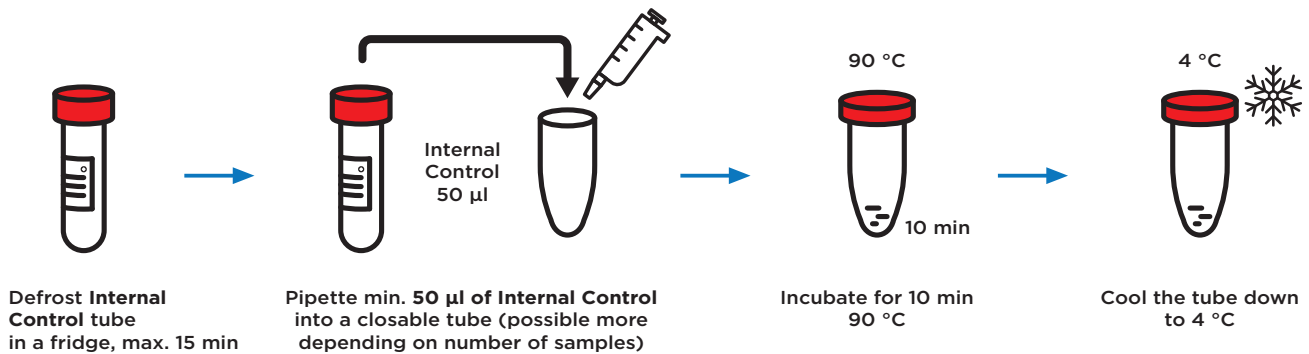
- The sample is ready for PCR testing upon receipt in the laboratory (without RNA extraction step).
- To increase the sensitivity of the PCR test, a short centrifugation is recommended (10,000-12,000 g, 3-5 minutes).
- The required amount of sample can be taken without having to remove the swab.

INSTRUCTIONS FOR USE WITH GENEPROOF PCR KITS

GeneProof SARS-CoV-2 PCR Kit, REF COV2/GP/100

GeneProof SARS-CoV-2 Screening PCR Kit, REF COV2S/GP/100

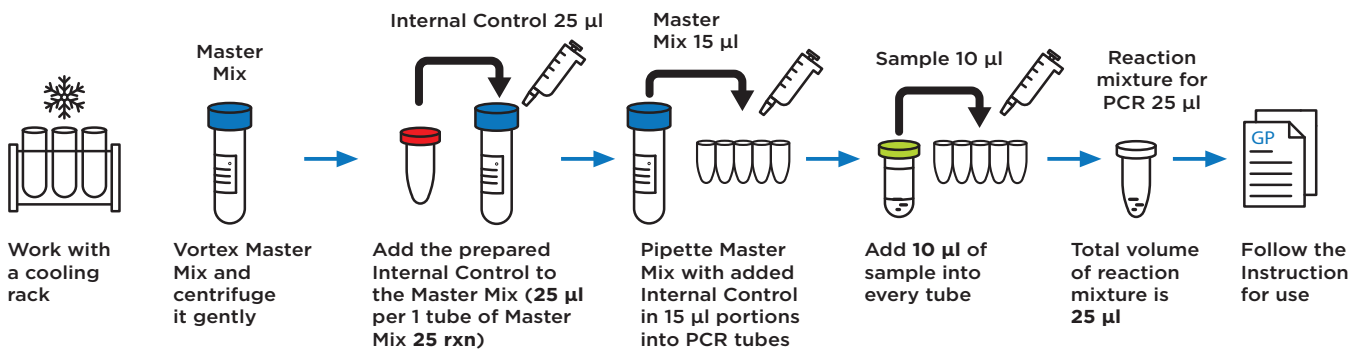
INTERNAL CONTROL TREATMENT:



- 1. Defrost the** Internal Control (IC) tube (in a fridge, no longer than 15 min).
- Gently **vortex and** shortly **centrifuge** the melted IC.
- Pipette min. 50 µl** into a closable tube (depending on number of samples).

- 4. Incubate** the tube with the pipetted Internal Control for **10 min** at **90 °C**. During the incubation vortex and centrifuge the tube (in the middle and at the end of the process.)
- 5. Cool the tube down to 4 °C.**

PREPARATION FOR PCR TEST (work with a cooling rack):



- After thawing, gently vortex and centrifuge shortly the Master Mix tube.
- Add the prepared Internal Control to the Master Mix (**25 µl** per 1 tube of Master Mix **25 rxn**) and **homogenize** thoroughly!
- Pipette Master Mix with Internal Control added in **15 µl** portions into PCR tubes. *

- Add **10 µl** of sample (clinical material collected in Bi-CoV sampling solution) to each PCR tube. The total volume of the reaction mixture is **25 µl**.
- Follow the **GeneProof PCR kit Instructions for use**.
- Always use **1× Positive Control** and **1× Negative Control** per 1 run.

* **WARNING** - after adding IC to MM, it will **signal HEX channel in positive and negative control** simultaneously. The MM thus prepared is stable at 5 °C (± 3 °C) for 8 hours. When stored at -20 °C (± 5 °C), the MM is stable for 2 repeated freeze / thaw cycles.