Bioinova

INSTRUCTIONS FOR USE

Kit for specimen collection, transport, and RNA isolation

Bi-CoV®

Intended Use:

Bi-CoV® is a sampling kit used for a non-invasive collection of biological material from the front nose or oral cavity by soaking saliva into the inserted swab and subsequent specimen transport to the laboratory for PCR detection of SARS-CoV-2. Alternatively, nasopharyngeal or oropharyngeal swab specimens can be used as biological material. Sample collection is performed by health care workers, the set is also suitable for self-sampling. The collection and transport solution ensures a gradual decomposition of the viral particles, release of the nucleic acids (RNA) into the solution and their protection against degradation. **The sample is ready for PCR analysis without the need to perform RNA isolation in the diagnostic laboratory.**

Packaging:

10 sets (Cat. No. BI001-10)
25 sets (Cat. No. BI001-25)
50 sets (Cat. No. BI001-50)
25 sets (Cat. No. BI001-25L)

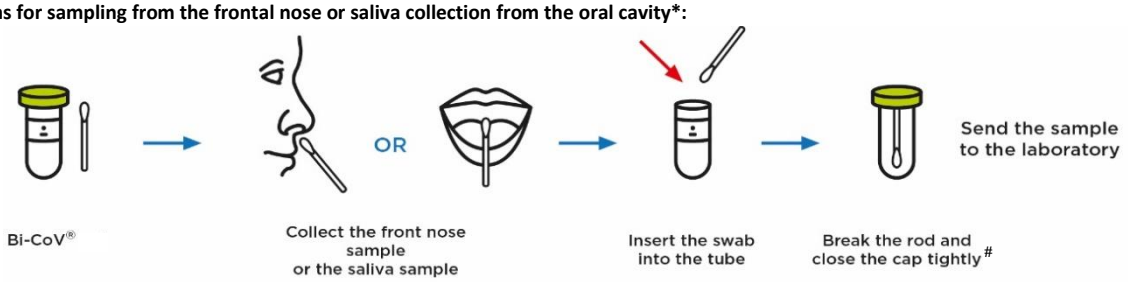
For one sampling:

- 2 ml plastic vial (BI001-25L: 10–13 ml plastic test tube) with 1 ml of collection/transport solution
- radiation-sterilized swab for taking a sample from the frontal nose or oral cavity (or nasopharyngeal/oropharyngeal sampling**)**

Ingredients:

The exact composition is part of a trade secret. The concentrations of the chemicals are so low that they do not meet the criteria for classification in accordance with the Regulation (EC) No 1272/2008 of the European Parliament and of the Council as amended (refer to the Harmonized Classification).

Instructions for sampling from the frontal nose or saliva collection from the oral cavity*:



Collection from the frontal nose:

1. Before sampling, the nose should be blown.
2. Open the package (tear the foil and paper on the opposite side from the sampling swab) to remove the plastic rod with the swab.
3. Open the plastic tube with the solution by turning the cap.
4. Insert the swab 2 cm deep while rubbing gently the nasal walls of the nostrils 3x in each direction.

Collection from the oral cavity (saliva):

1. Tested person must not brush teeth, use mouthwash, drink, eat, use chewing gum or smoke at least 30 minutes before the sample collection.
2. The tested person sniffs and clears the throat to get mucus and saliva form the nasopharynx and throat gets to the oral cavity.
3. Open the package (tear the foil and paper on the opposite side from the swab) to remove the plastic rod with the swab.
4. Open the plastic tube with the solution by turning the cap.
5. Insert the swab into the oral cavity to the collected saliva place (on or under the tongue, near the molars, etc.), and allow the material to soak in (or wipe around the palatoglossal arches).

- Insert the swab with the collected biological material into the tube with the solution, break the plastic rod. #If necessary, the collected material on the swab can be rinsed into the collection solution by a circular movement in the solution for at least 10 seconds. The swab can then be removed and discarded. Close the cap tightly.
- Label the tube and send it to the diagnostic laboratory.
- The sampling must be performed carefully to obtain a representative and analysable material.
- CAUTION: Direct contact with the biological material can be dangerous. While collecting the sample, use personal protective equipment.

***From nasopharynx or oropharynx**, the collection is performed by a circular movement of the swab on the posterior wall of the nasopharynx or oropharynx.

Storage and other information:

- Storage possible at room temperature if used up within 2 months, in other cases store at 2-8 °C. Avoid exposure to direct sunlight.
- For immediate use after opening.
- The product can be used as long as the packaging is not damaged.
- For single use only.
- Dispose of the used material as infectious waste.

Instructions for sample preparation for PCR test:

- After collection, the sample is transported to the laboratory for qualitative evaluation by PCR. The required amount of sample can be taken without having to remove the swab.
- To increase the sensitivity of the PCR test, a short centrifugation is recommended (10,000-12,000 g, 3-5 minutes).
- Serious incidents possibly related to the product (e.g. serious deterioration of health) shall be reported to the manufacturer and national competent authority.
- The sample is intended for detection of SARS-CoV-2 by PCR analysis.
- Keep out of reach of children.

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