

INSTRUCTIONS FOR USE

Kit for specimen collection, transport, and DNA/RNA isolation

Bi-Micro®

Intended Use:

Bi-Micro® is a sampling kit used for a collection of biological material from different anatomical locations (e.g. oral or nasal cavity) using the suitable swab and subsequent specimen transport to the laboratory for PCR diagnostics. The set is also suitable for self-sampling.

It is not necessary to perform DNA/RNA isolation in the diagnostic laboratory; the sample is already prepared for PCR analysis of viruses and some bacteria.

The solution in the kit ensures the gradual decomposition of viral particles and bacterial cells, the release of nucleic acids (DNA/RNA) into the solution and their protection from degradation. If necessary, the bacteria can be inactivated immediately by heating according to standard laboratory procedures.

Packaging:

10 sets (Cat. No. BI007-10)

25 sets (Cat. No. BI007-25L)

25 sets (Cat. No. BI007-25)

50 sets (Cat. No. BI007-50)

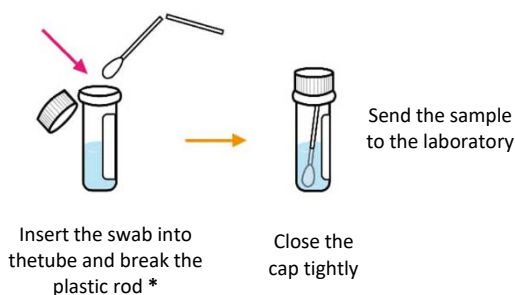
For one sampling:

- 2 ml plastic vial (BI007-25L: 10–13 ml plastic test tube) with 1 ml of collection/transport solution
- sterilized swab for taking a sample from different anatomical location

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 handling the collected sample:



- Collect the sample by a circular movement of the swab on the surface of the anatomical location.
- 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.

Storage and other information:

- Store at 2–8 °C, out of 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 quantitative or 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 events potentially related to the product (e.g. serious deterioration of health) must be reported to the manufacturer and national competent authority (if required locally).
- Keep out of reach of children.



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