

INSTRUCTION OMICSNAP TUBE

Molecular genetic stool tests



YOU SHOULD HAVE RECEIVED FROM YOUR PRACTICE:

The sample tube may already be inside the transport tube.



1 x Request form



1 x Transport tube



1 x OmicSnap Tube



1 x Stool collector



1 x Name label

Test implementation: 15-30 min

Purpose:

The OmicSnap Tube is intended for the independent collection of stool samples by lay persons. It enables the collection of a defined amount of stool and the stabilisation of the sample for further laboratory diagnostic determination in nucleic acid-based procedures by biovis Diagnostik MVZ GmbH. It is not intended for immediate self-interpretation. Further information on the intended use and safety instructions in accordance with Regulations (EU) 2017/745 and 2017/746 can be found at the end of the instructions.

IF YOU HAVE ANY
FURTHER QUESTIONS,
PLEASE CONTACT THE
MEDICAL PROFESSIONALS
YOU TRUST.

Manufacturer:
biovis Diagnostik MVZ GmbH
Brüsseler Str. 18
65552 Limburg-Eschhofen
Tel.: +49 6431 21248 0
Fax: +49 6431 21248 66
info@biovis.de
biovis.de

Order number: KV10021CP

Only for taking samples, if the sample is sent to biovis Diagnostik MVZ GmbH for examination and analysed there in accordance with the current specifications.

Batch number - see label on OmicSnap

Storage temperature: 15-25°C

In-house medical device of biovis Diagnostik MVZ GmbH according to Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR)

Use by - see sticker OmicSnap

IMPORTANT INFORMATION

General information

- The OmicSnap Tube contains a stabiliser liquid. This must not be poured out, otherwise the stool sample cannot be analysed in the laboratory.
- Ensure that the OmicSnap Tube is kept out of the reach of children.
- Avoiding contamination: The stool collector, the stool sample, and the sample tube must not come into contact with cleaning agents, disinfectants, toilet water, or other substances, as this can interfere with the laboratory analysis. The stool sample should also not be mixed with urine. Therefore, please be sure to use the enclosed stool collector!
- If you are suffering from an acute intestinal infection, consult your doctor to find out whether it is advisable to have the examination at this time or whether you should wait until you feel better.
- Avoid making any sudden changes to your lifestyle, such as changing your diet or travelling abroad. In this case, wait a while to prevent any potential influences.
- Please follow the test instructions carefully.

Contraindications

Representative molecular genetic stool testing is not possible in the following situations:

- During antibiotic therapy
- While taking humic acids
- During and shortly after fasting
- During menstruation
- During or shortly after the use of contrast agents for radiological examinations
- During or shortly after cytotoxic chemotherapy

What you need to consider before performing the test:

At least 4 weeks beforehand

(preferably 6 weeks):

- Do not take antibiotics
- Do not have a colonoscopy

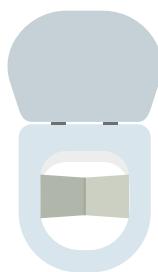
1 week beforehand, if possible, otherwise at least 3 days beforehand (consult your practice if necessary):

- Do not take medication for constipation. This includes prokinetics and laxatives (including high-dose magnesium/vitamin C).
- You should not suffer from severe or unusual diarrhoea and should not receive enemas.
- Do not take proton pump inhibitors (e.g. omeprazole, pantoprazole) and/or oral X-ray contrast agents.
- Do not take humic acids.
- Do not take any medication that inhibits or stimulates digestion (e.g. MCP).
- If you have been taking probiotics and prebiotics for a long time, you can continue to use them as usual. However, if you have only been taking them for a short time, you should stop taking them approximately one week before the test.

Other medicines and dietary supplements may continue to be taken. Please follow the test instructions carefully.

TEST INSTRUCTIONS

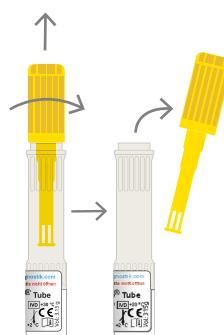
1. Place all the materials in front of you. Place the stool collector on the toilet seat.



IMPORTANT

The stool and the stool collector must not come into contact with the toilet bowl, water, or cleaning agents.

2. Place the OmicSnap Tube upright, to prevent the liquid from escaping. Unscrew the **yellow cap** **counterclockwise** and remove the sample lance.

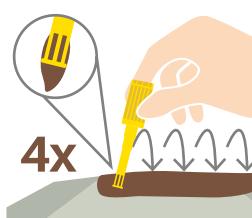


IMPORTANT

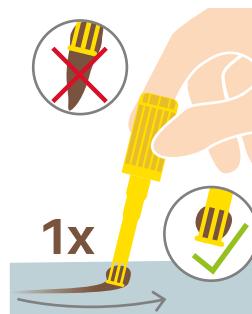
The white cap with the white sticker must absolutely remain untouched. Please do not open.

3. Insert the sample lance at four different spots into the stool sample, until the sample lance is filled.

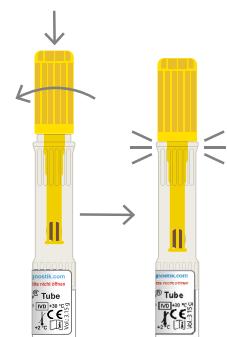
Please do not use the sample lance as a spoon to transfer the stool into the sample tube.



4. Remove excess stool from the top of the sample lance.



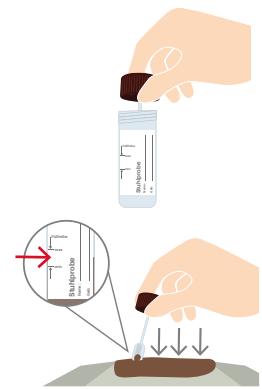
5. Return the sample lance back into the OmicSnap Tube and turn the yellow cap until resistance engages and it cannot be opened.



6. Then swirl the OmicSnap Tube back and forth several times.



7. **Optional step:** If you have received additional stool tubes from your practice, such as a native stool tube or an OmicSnapMeta Tube, use the same stool. Again, take stool samples from 4 different locations. Please follow the separate test instructions for each tube.



8. After you have collected all the necessary samples, remove the stool collector from the toilet seat. It is water-soluble and can be flushed away.



9. The practice should have already labelled the sample tubes with a barcode for you.

If not, write your name and the date or time of sample collection on the name label and attach it to the OmicSnap Tube. Please apply the name **label only to the tapered center of the tube** and do not stick it over one of the two thicker ends.



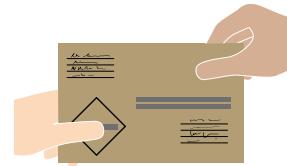
11. First pack the sample tubes in the transport tubes and then place them in the mailing bag with the completed and signed request form.

Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope.



12. Drop off the envelope at a post office as soon as possible, or - after prior consultation - at your medical practice.

Please do not send it on Fridays, weekends or public holidays and do not drop in letterboxes.



10. Please fill in the request form legibly (in digital or printed letters).

Write your **name, date of birth, and date of collection** on the front.



Complete the declaration on the back and sign the request form.

NOTE

Please observe the country-specific shipping conditions. These may differ from the procedure described here.

If you have any further questions, please contact your practice.

Purpose according to Regulation (EU) 2017/746 (IVDR):

- The OmicSnap Tube is a medical in vitro diagnostic device (IVD) in accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).
- It is used for the standardised, non-invasive collection of stool samples by lay persons for subsequent determination by nucleic acid-based methods of microbiome analyses and similar molecular genetic stool analyses. Depending on the parameter, qualitative, semi-quantitative or quantitative analyses are carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and are primarily used as a diagnostic aid in cases of suspected intestinal dysbiosis.
- The product is intended for single use outside of clinical facilities.
- Samples are collected in accordance with the enclosed instructions.
- The OmicSnap Tube is not intended for immediate point-of-care diagnosis or for self-interpretation by the user, but explicitly for sample collection with subsequent laboratory examination. The samples must be sent exclusively to biovis Diagnostik MVZ GmbH. They are intended exclusively for analysis by biovis Diagnostik MVZ GmbH in accordance with the valid service specifications. The test results are interpreted by medical professionals.

Restrictions and safety instructions for using the test set in accordance with Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- Only use the OmicSnap Tube as instructed. Read the enclosed instructions for use carefully and follow all steps exactly. Improper use or inadequately labelled samples may lead to invalid test results.
- Store the OmicSnap Tube in a cool, dry place away from light. The storage temperature is 15-25 °C.
- Ensure that the OmicSnap Tube is kept out of the reach of children.
- Do not use after the expiry date. The expiry date is indicated on the label of the OmicSnap Tube.
- Do not use if the packaging is damaged or incomplete.
- The OmicSnap Tube is intended for one-time use by laypersons to collect a stool sample and does not have its own analysis function; it is not intended for use as a self-test for diagnosis. Reuse can lead to inaccurate results and, in some cases, health risks.
- Please note the contraindications and other information listed above, which must be observed before performing the test! If in doubt, discuss the use of the OmicSnap Tube with your treating practice before performing it. If you have any health concerns, you should consult a doctor.
- Handling biological samples: The stool sample is potentially infectious.
- Avoidance of contamination: The stool collector and the sample tube must not come into contact with cleaning agents, disinfectants, or other substances, as this may interfere with the measurement in the laboratory.
- Avoid direct contact with skin and mucous membranes. Wash your hands thoroughly with soap and water before and after taking the samples.
- Samples should be returned on the day they are collected if possible. Until dispatch, the filled sample must be stored at room temperature (10-30 °C).
- Do not ship on Fridays, weekends, or public holidays.
- After use, dispose of the remaining components in accordance with local regulations for household waste.

Disclaimer:

biovis Diagnostik MVZ GmbH accepts no responsibility for incorrect or unevaluable results caused by improper use, incomplete or incorrectly labelled samples, failure to follow the instructions, or unsuitable storage or shipping conditions. The test is carried out at your own risk. The OmicSnap Tube is intended exclusively for standardised sample collection for subsequent analysis in the appropriate laboratory. The diagnosis and interpretation of the results is the sole responsibility of medical professionals. The product is not intended for self-analysis. Use outside the intended area of application is not permitted.