

INSTRUCTION TEST SET 926

Native stool



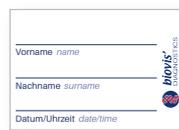
YOU RECEIVE:

The sample tubes may be located in the transport tube.

Test implementation: **5-10 min.**



1 x Request form



2 x Name label



2 x Stool collector



2 x Transport tube



2 x Stool tube

Purpose:

The Test Set 926 is intended for the independent collection of stool samples by lay persons. The test set enables laboratory diagnostic determination of various stool analyses 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.

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Order number: Test set 926

Storage temperature: 10-30°C

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.

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

Batch number - see label on Test set 926

Use by - see sticker Test set 926

IMPORTANT INFORMATIONS

General information:

- **Avoiding contamination:** The stool collector, stool sample, and sample tube must not come into contact with cleaning agents, disinfectants, toilet water, or other substances, as this may 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 short-term changes in your lifestyle, such as a change in diet or travelling to other countries. In this case, wait a while to prevent possible influences.

What you need to consider before performing the test:

At least 4 weeks beforehand

(preferably 6 weeks)

- Do not take antibiotics.
- No colonoscopy.

1 week before if possible, otherwise at least 3 days before (please 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 have 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.

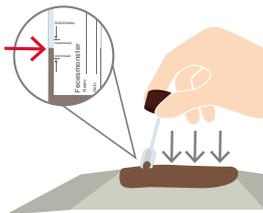
2. The practice should have already labelled the sample tube with a barcode for you.

If not, write your name and the date of sample collection on the name label and attach it to the sample tube.



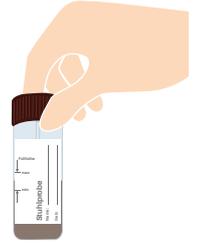
3. Unscrew the stool tube (brown lid) and remove the spoon.

4. Take stool samples from at least 4 different spots and fill the stool tube until it is at least filled to the mark.



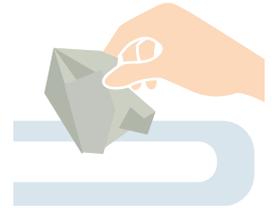
5. Screw the lid with the spoon back onto the tube.

Repeat the process with the second stool sample tube.



6. Optional step: If you have received additional stool tubes from your practice, such as an OmicSnap(Meta) tube or another special stool tube (e.g. for histamine or occult blood), use the same stool sample. Again, take stool samples from 4 different spots. Please follow the separate test instructions for each tube.

7. 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.



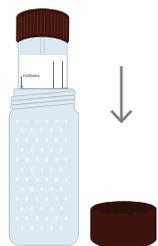
8. Please fill in the request form legibly (in digital or printed letters).

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

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



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

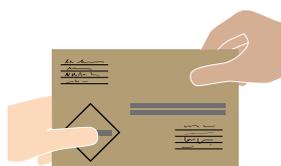


Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope.



You may remove the test label from the envelope if you prefer more discretion.

10. 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.

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 Test Set 926 is a medical in vitro diagnostic (IVD) device 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 the subsequent determination of various parameters that can be measured in unstabilised stool. The qualitative, semi-quantitative, and quantitative analyses are carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and are used as a diagnostic aid for gastrointestinal complaints. A complete list of the relevant parameters is not possible here due to space constraints, but can be found in the service specifications of biovis Diagnostik MVZ GmbH.
- The product is intended for single use outside clinical facilities.
- Samples are taken in accordance with the enclosed instructions.
- The test set is not intended for immediate diagnosis at the point of care or for self-interpretation by the user, but is explicitly intended for sample collection followed by laboratory testing. 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 test set 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 test set in a cool, dry place away from light. The storage temperature is 10-30°C.
- Ensure that the test set 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 test set.
- Do not use if the packaging is damaged or incomplete.
- The test set 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 test set 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.
- 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 test set 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.