

INSTRUCTIONS TEST SET 901

Breath test Lactose malabsorption



YOU WILL RECEIVE

The sample tubes may be in the transport tubes.

Test implementation: **3 hours**
Time: **in the morning**
(on an empty stomach)



1 x Request form



1 x Test protocol



1 x 50 g Lactose
(for test solution)



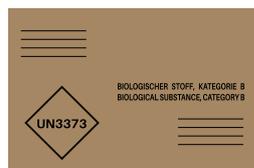
1 x Mouthpiece with bag
and sampling device



5 x Sample tubes



5 x Transport tubes



1 x Mailing bag

Purpose:

The Test Set 901 is intended for the independent collection of breath samples by laypersons. The test set enables laboratory diagnosis of hydrogen and methane concentrations in the breath before and after oral administration of lactose 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.**

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biovis.de

REF Order number: Test set 901

Storage temperature: 15-25°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 (IVDR)

LOT Batch number - see label on Test set 901

Use by - see sticker Test set 901

IMPORTANT INFORMATIONS

General information

- **CAUTION: The sampling device contains a sharp needle.**
- Pay attention to the expiry date on the packaging. Do not use expired test sets.
- Do not open the rubber cap of the breath tube. Otherwise, the vacuum in the tube will be lost.
- The breath tubes are located in the transport tubes. Remove the breath tubes from the transport tubes to perform the test.
- The pre-punched hole in the breath bag is necessary for performing the test.
- The filled tubes should be returned to the laboratory on the day of the test implementation if possible.
- As the powder may take a little longer to dissolve, we recommend preparing the test solution the evening before and storing it in the refrigerator overnight.
- During pregnancy and breastfeeding, the test should only be carried out in consultation with your practice.

Side effects

- Please note that the test takes about 3 hours in total and may cause symptoms such as abdominal pain, flatulence, diarrhoea, and nausea, as well as dizziness, headaches, or weakness.

Contraindications

- Intestinal obstruction
- Acute gastrointestinal infections
- Antibiotic therapy
- SIBO, irritable bowel syndrome
- Severe lung/respiratory diseases
- Chronic inflammatory bowel disease (during acute flare-up or after recent surgery)
- Patients who are unable to perform the test correctly (e.g. infants)
- Possibly diabetes mellitus type 1/2 (Talk to your doctor. Whether the test can be performed must be decided on an individual basis).

Instructions for performing the test on children:

- The **dosage of the test solution** must be adjusted to the child's body weight. Weigh out the appropriate amount of test solution. The weighed amount can be taken undiluted or dissolved in water. (For children weighing 25 kg or more, the entire test solution can be used.)

Dosage: 2 g per kg body weight

Example:

For a body weight of 15 kg: $15 \times 2 \text{ g} = 30 \text{ g}$ → Use 30 g of the test solution.

What you need to consider before performing the test:

4 weeks before

Do not take antibiotics.
Do not have a colonoscopy.

2 weeks before

You should not suffer from severe or unusual diarrhoea and should not have any enemas. Do not take proton pump inhibitors (e.g. omeprazole, pantoprazole) and/or oral X-ray contrast agents.

1 week before

(if possible, otherwise at least 3 days before)

Do not take probiotics and/or laxatives. These include prokinetics and laxatives (including high doses of magnesium/vitamin C).

3 days before

Do not take any medication that inhibits or promotes digestion (e.g. MCP). Do not take any H₂-receptor antagonists (e.g. cimetidine, ranitidine).

2 days before

If you have undergone various breath tests (sorbitol, lactose intolerance), there should be at least 2 days between them.

24 hours before

Do not eat foods that are high in fibre or cause flatulence. These include legumes, cabbage, leeks, and beans. Foods containing fructose, lactose, and sorbitol as well as alcohol should also be avoided.

For more information on permitted foods or recipe suggestions, please refer to the nutrition flyer about breath tests on our homepage.



12 hours before

You must not eat anything from this point onwards, including sugary or diet drinks. You should also avoid mouthwash, toothpaste and chewing gum. If possible, do not take any blood pressure/cardiovascular medication or diabetes medication; consult your practice if necessary.

6 hours before

Do not smoke. If possible, do not use asthma spray.

Immediately before and during the test

Avoid any kind of sports or strenuous activity before or during the test, including running up stairs.

The samples should be taken before brushing your teeth. You should also refrain from using mouthwash, chewing gum, and other breath-freshening substances. Do not use adhesive agents for dentures.

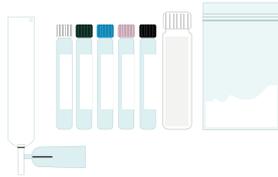
12 hours before and during the test, you must not eat anything.

TEST INSTRUCTIONS

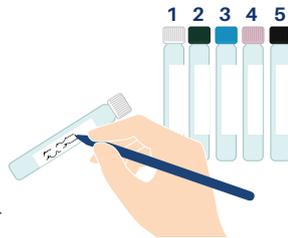
IMPORTANT

The test should be carried out in the morning, 1-2 hours after getting up, if possible. One hour after the start of the test, you may drink small amounts of still mineral water and unsweetened tea.

1. Place all the materials in front of you and make sure that the sampling equipment is complete.

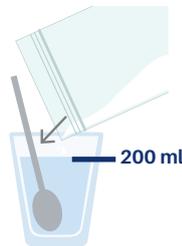


2. Label the tubes with your name and date of birth and arrange them in order (No. 1-5).



If you have received bar-codes, use them to label the samples.

3. Dissolve the entire contents of the test solution in **200 ml of warm water** and set aside until you need the test solution.

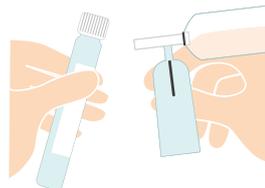


You can also prepare the test solution the evening before and store it in the refrigerator.

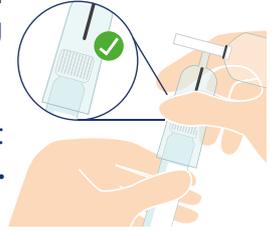
The reference sample must be taken before drinking the test solution!



4. Hold the mouthpiece with the breathing bag in one hand and the labelled **sample tube no. 1** in the other hand.

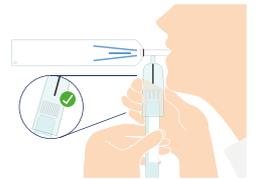


5. Insert the sample tube with the cap into the sampling device.

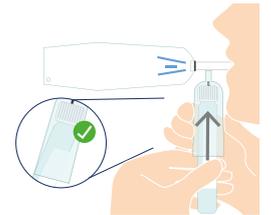


Caution: The needle must not pierce the rubber stopper yet.

6. Place the mouthpiece in your mouth and breathe in normally, then exhale through the mouthpiece into the bag so that it fills slowly and the air flows out through the hole at the end of the bag.



7. Just before you run out of air, press the sample tube lightly onto the sampling device while exhaling. The needle will pierce the rubber stopper and your breath will flow into the tube. Remove the sample tube from the sampling device and prepare it for shipping.



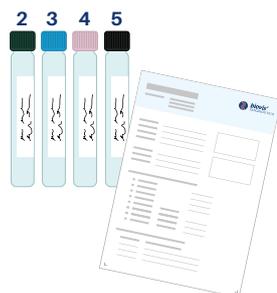
IMPORTANT

Do not take deep breaths, just breathe normally! The bag must be filled with breath during sample collection. Your mouth must always remain in contact with the mouthpiece.

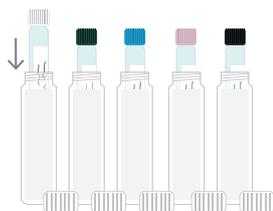
8. After taking the reference sample, drink the **test solution**. Note the time of ingestion on the test protocol.



9. After 30, 60, 120 and 180 minutes, take **samples 2-5** as described above. Record the times of each sample on the test protocol. Also record any symptoms that occur in the test protocol.



10. Place the sample tubes into the transport tubes.



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

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



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

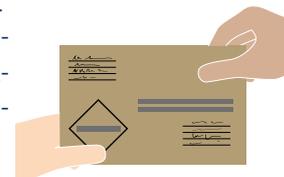
12. Place the sample tube and the completed and signed request form back into the envelope.



Pull on the marked tab to remove the already-used adhesive strip. Use the inner adhesive strip to seal the envelope securely. You may remove the test label from the envelope if you prefer more discretion.

After taking the sample, the remaining materials from the test set can be disposed of in your household waste, unless local regulations stipulate otherwise. It is not necessary to return them to us.

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



Please do not send 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 901 is an in vitro diagnostic medical device (IVD) in accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). It is intended for the standardised, non-invasive collection of breath samples by laypersons for subsequent determination by gas chromatography of the hydrogen and methane concentrations in the breath before and after oral administration of lactose. Quantitative analysis is carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and is used as a diagnostic aid in cases of suspected lactose intolerance.
- 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 point-of-care diagnosis 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 15-25 °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 single use by laypersons to collect breath samples and does not have its own analysis function; it is not intended for use as a self-test for diagnosis. Reuse may lead to false results and, under certain circumstances, to health risks.
- People with known primary homozygous lactose intolerance should not perform the test.
- Observe the contraindications listed above and other instructions that must be followed before performing the test! If in doubt, discuss the use of the test with your doctor before performing it. If you have any health problems, consult a doctor.
- The samples should be returned on the day of collection 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 of the test set (waste) 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.

TEST PROTOCOL



biovis'
DIAGNOSTICS

Atemgastest **Fructose malabsorption**
Lactose malabsorption
Fructose-sorbitol intolerance
Sorbitol intolerance

Last name: _____

First name: _____

Date of birth: _____

Address: _____

Body weight: _____

Height: _____

Date the test was performed: _____

Practice stamp:

Barcode (if available):

Please enter the corresponding time here:

Step

1. Collect reference sample (tube no. 1)

2. Drink test solution

3. Tube no. 2 (After 30 minutes)

4. Tube no. 3 (After 60 minutes)

5. Tube no. 4 (After 120 minutes)

6. Tube no. 5 (After 180 minutes)



Test time

Please enter your complaints here:

Time:

Type and duration of symptoms:
