

INSTRUCTION TEST SET 931

Multi-element analysis in saliva



biovis'
DIAGNOSTICS

YOU RECEIVE

The sample tube may already be inside the transport tube.

Test implementation: **approx. 15 min**
Time: **in the morning**
(on an empty stomach)



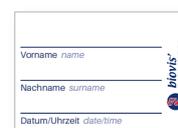
1 x Request form



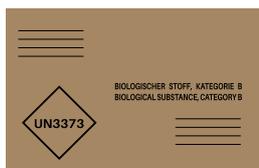
1 x Transport tube



1 x Saliva tube



1 x Name label



1 x Mailing bag



1 x Chewing gum*

*Ingredients: sweetener: xylitol, chewing gum base, flavouring, thickening agent: gum arabic, humectant: glycerine, emulsifier: lecithin (sunflower), colouring agent: calcium carbonate, coating agent: carnauba wax.

Purpose:

The Test Set 931 is intended for the independent collection of saliva samples by laypersons. The test set enables laboratory diagnosis of heavy metals 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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Fax: +49 6431 21248 66
info@biovis.de
biovis.de

REF Order number: Test set 931

MD 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.

LOT Batch number - see label on Test set 931

MD Storage temperature: 10-25°C

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

MD Use by - see sticker Test set 931

TEST INSTRUCTION

NOTE

- The sample must be taken in the morning on an empty stomach before brushing your teeth.
- Smoking should be avoided before the test is performed.
- Drinking water is allowed.
- Ensure that the sample is saliva and not sputum from the throat or bronchial mucus.
- Bleeding gums can distort the result. If you see that the saliva is pink, rinse out the tube and wait a while before refilling it.

1. Place all the materials in front of you as shown in the picture.



2. Rinse your mouth with clear water.



3. Remove the stopper from the saliva tube by tilting it slightly to one side and then pulling it off.



4. Collect a sufficient amount of saliva in your mouth and transfer it to the tube. Repeat the process until the tube is about half full without foaming.

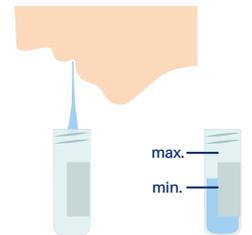
NOTE

A small amount of foam is normal and cannot be avoided. If saliva is not flowing sufficiently, you can smell a lemon or lemon juice. This stimulates saliva flow.

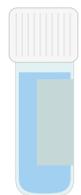
5. Take the chewing gum and chew intensively for 5-10 minutes, directly on the fillings if possible.



6. Collect a sufficient amount of saliva in your mouth again and transfer it to the saliva tube. Repeat the process until the tube is completely filled.



7. Seal the sample tube and dispose of the chewing gum in the household waste.



8. The practice should have already labelled the sample tubes 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 tube.



Place the filled saliva tube into the transport tube.

IMPORTANT

Store the sample in the refrigerator until dispatch.

9. 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.

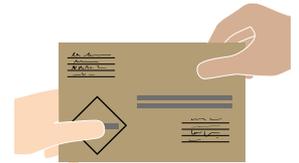
10. Place the sample tube and the completed and signed request form back into the shipping envelope.

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 can remove the sticker with the test set name if you wish to do so for reasons of discretion.

11. 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 931 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 saliva samples by lay persons for subsequent determination of multi-element analyses following increased abrasion by ICP-MS. 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 exposure.
- 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 10-25 °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 one-time use by laypersons to collect a saliva sample and does not have its own analysis function; it is not intended for use as a self-test for diagnosis.
- Individuals with known allergies or intolerances to xylitol or other ingredients in the chewing gum should not perform the test.
- Wash your hands thoroughly with soap and water before and after taking the sample.
- Samples should be returned on the day they are collected if possible. Until dispatch, the filled sample must be stored in a refrigerator (2-8 °C).
- 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.