

# INSTRUCTION TEST SET 925

## Heavy metals in urine



### YOU RECEIVE

*The sample tubes may already be inside the transport tubes.*

Test implementation: **10 min**  
Test duration: **3-5 hours**  
(after chelation)



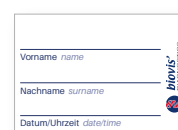
1 x Request form



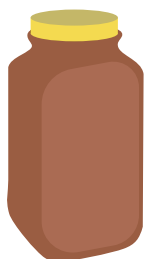
2 x Transport tube  
(light-protected)



2 x Urine monovette



2 x Name label

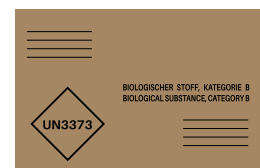


1 x 24-Hour urine  
collection container

### ADDITIONAL:



1 x Urine cup (Available from your practice.  
Alternatively, use a disposable cup.)



1 x Shipping bag

### Purpose:

The Test set 925 is intended for the independent collection of urine samples by lay persons. The test set enables laboratory diagnostic determination of heavy metals in urine 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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info@biovis.de  
[biovis.de](http://biovis.de)

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

**REF** Order number: Test set 925

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 (IVDR)

**LOT** Batch number - see label on Test set 925

Use by - see sticker Test set 925

# TEST INSTRUCTIONS

## Important information

The analysis of heavy metals in urine can be carried out before and/or after detoxification (e.g. chelation).

Please do not collect urine during menstruation.

## NOTE

There are various methods and substances for removing heavy metals. One well-known method is chelation therapy. However, this is a complex procedure and should only be carried out by experts, as side effects may otherwise occur. For this reason, we refrain from giving specific instructions regarding chelation itself and merely describe how to collect urine samples.

## Preparation & supporting measures

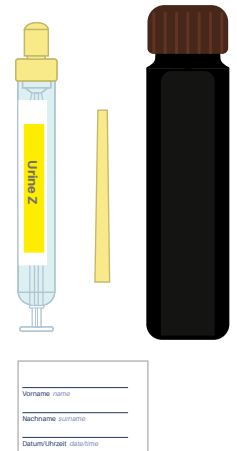
- Chelating agents also bind essential minerals and trace elements, so accompanying substitution therapy is recommended.
- Temporary alkalinisation of the urine can stabilise chelate complexes and reduce side effects.
- Before starting, the patient should be sufficiently stabilised, e.g.:
  - intact intestinal barrier
  - functioning blood-brain barrier
  - healthy liver and kidneys
  - support for the body's own detoxification processes:
    - phase I & II of the liver
    - homocysteine metabolism
    - urea cycle

## Collection of urine sample before detoxification

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

The practice should have already labelled the urine monovette with a barcode for you. Label the monovette additionally with „before“.

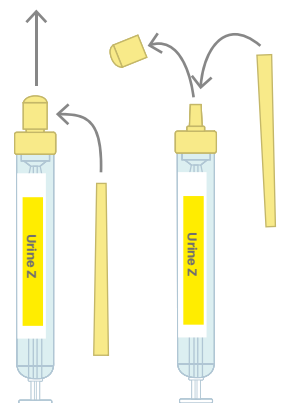
If this is not the case, label the urine monovette with your name, date of birth and date of sample collection. Also label the monovette with „before“.



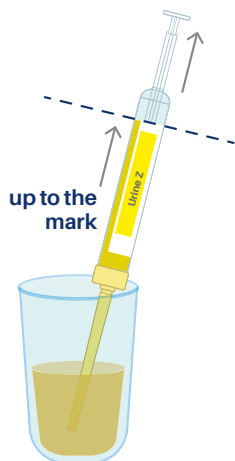
2. Use the urine collection cup (not included in the test set) to collect all of your morning urine. If the urine cup is already full but your bladder is not completely empty, discard the remaining urine in the toilet.



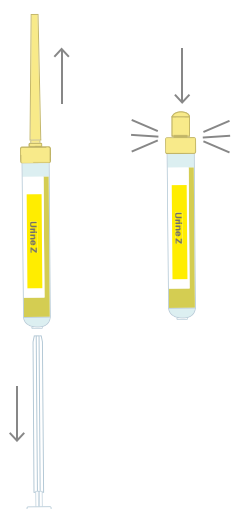
3. Now take the urine monovette and hold it by the lower part of the yellow cap. With your other hand, twist off the front tip of the cap. Take the yellow, straw-like tip and place it on the top of the urine monovette.



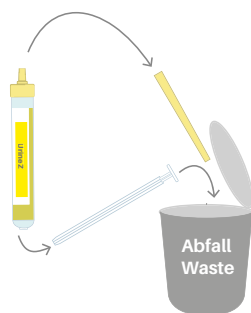
**4.** Dip the yellow, straw-like tip into the urine and pull on the plunger until the urine monovette is completely full. The plunger must click into place noticeably.



**5.** Remove the yellow, straw-like tip and reseal the urine monovette with the yellow cap.



**6.** Break off the drawn-out plunger at the designated break point. Dispose of the tip, plunger, and urine cup in your household waste.



**7.** Place the urine monovette in the transport tube after taking the sample.



## Obtaining the urine sample after detoxification

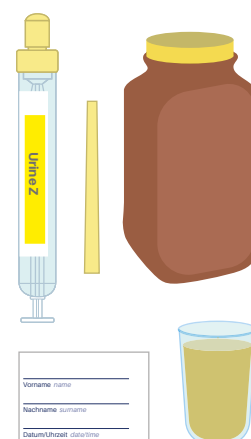
### IMPORTANT

Collect the urine in the collection container during and after the detoxification for 3-5 hours.

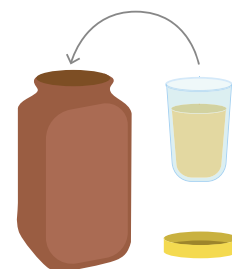
**1.** Place all the materials in front of you as shown in the picture.

The practice should have already labelled the urine monovette with a barcode for you. Label the monovette additionally with „after“.

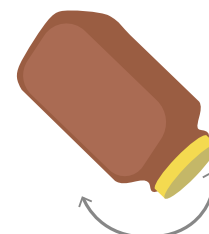
If this is not the case, label the urine collection tube with your name, date of birth and date of sample collection. Also label the collection tube with „after“.



**2.** Use the urine collection cup (not included in the test set) to collect all of the urine. Then transfer the urine to the collection container. Collect the urine during and after the detoxification for 3-5 hours.

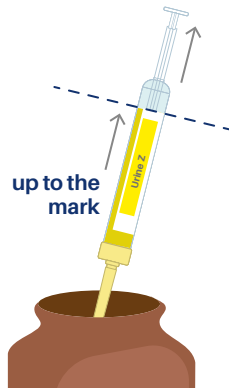


**3.** Swirl the collection container thoroughly **before** taking the urine sample.

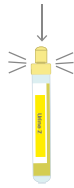


# TEST INSTRUCTIONS

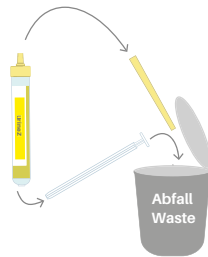
**4.** Dip the yellow, straw-like tip into the urine and pull on the plunger until the urine monovette is completely full. The plunger must click into place noticeably.



**5.** Remove the yellow, straw-like tip and reseal the urine monovette with the yellow cap.



**6.** Break off the drawn-out plunger at the designated break point. Dispose of the tip, plunger, and urine cup in your household waste.



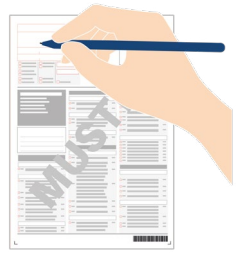
**7.** Place the urine monovette in the transport tube after taking the sample.



**8.** Fill out the request form legibly (in digital or block letters).

Please note **the name, date of birth and date of collection** on the front.

Fill out the declaration on the back and sign the request form.

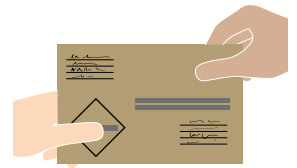


**9.** Put the sample tube and the completed and signed request form into the shipping bag.



**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 on a Friday, at the weekend or on 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.**

### **Intended purpose according to Regulation (EU) 2017/746 (IVDR):**

- The Test Set 925 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 urine samples by lay persons for the subsequent determination of heavy metals in urine using 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 heavy metal contamination.
- The product is intended for single use outside of clinical facilities.
- Samples are collected 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 explicitly for sample collection with subsequent 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 in accordance with the instructions. Read the enclosed instructions for use carefully and follow all steps precisely. Improper use or insufficiently 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 only intended for the one-time collection of a urine sample by lay persons 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.
- 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 with your doctor before performing it. If you have any health concerns, you should consult a doctor.
- Handling of biological samples: The urine sample is potentially infectious.
- Wash your hands thoroughly with soap and water before and after taking the sample.
- The samples should be returned on the day of collection if possible. Until dispatch, the filled sample should be stored at room temperature (10-30 °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 relevant 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.