

# INSTRUCTION TEST SET 903

## Cryptopyrrole



### YOU RECEIVE

The sample tubes may be located in the transport tubes.

Test duration: **10 minutes**  
Time: **in the morning (fasting)**



1 x Request form



1 x Transport tube  
(light-protected)



1 x Urine monovette



1 x Name label

### ADDITIONALLY:



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

### Intended use:

The T903 test set is intended for the independent collection of urine samples by lay persons. The test set enables laboratory diagnosis of cryptopyrrole by biovis Diagnostik MVZ GmbH. It is not intended for immediate self-interpretation. Further information on the intended purpose 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](http://biovis.de)

**REF** Order number: Test set 903

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 903

Use by - see sticker Test set 903

# TEST INSTRUCTIONS

## Note

Certain factors can distort the test results. If any of the following apply to you, please postpone the test:

- Menstrual bleeding (at least 1 day without bleeding)
- Cold symptoms (wait at least 1-2 weeks)
- Extreme physical exertion/fasting (wait at least 1-2 weeks)

In addition, please note the following:

- Do not take any dietary supplements containing vitamin B6, zinc, and manganese (multivitamin preparations) for **1 week** prior to the test.
- Avoid alcohol and nicotine for **24 hours beforehand** and do not take any dietary supplements containing magnesium.
- Do not drink more than 0.5 litres in the **12 hours** prior to the test.
- The sample must be taken on an empty stomach.

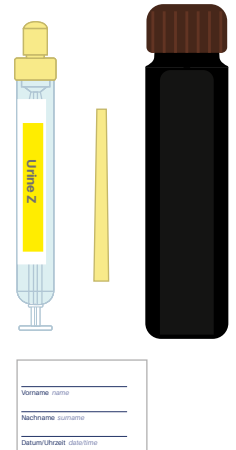
## IMPORTANT

Use the **first morning urine**. The first morning urine is the urine collected after getting up in the morning. You should not have emptied your bladder for at least 4 hours, preferably 8 hours, beforehand.

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.

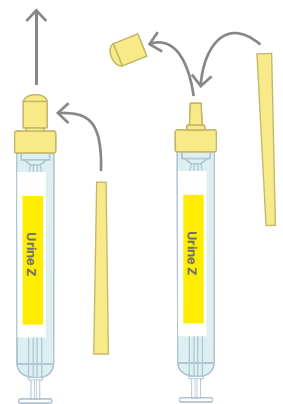
If this is not the case, label the urine monovette with your name, date of birth and date of sample collection.



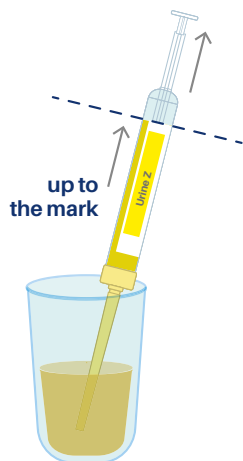
2. Use the urine collection cup (not included in the test set) to collect all of your morning urine. If the urine cup is already full but your bladder is not completely empty, discard the remaining urine in the toilet.



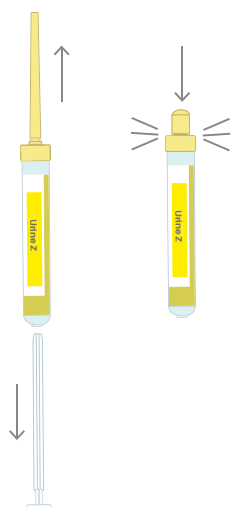
3. Now take the urine monovette and hold it by the lower part of the yellow cap. With your other hand, twist off the front tip of the cap. Take the yellow, straw-like tip and place it on the top of the urine monovette.



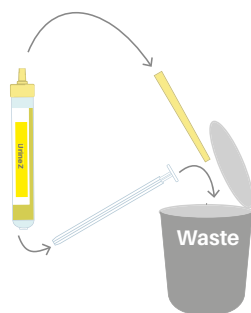
**4.** Dip the yellow, straw-like tip into the urine and pull on the plunger until the urine monovette is completely full. The plunger must click into place noticeably.



**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 immediately after taking the sample.

**The sample must be protected from light during storage!**



**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 back into the mailing bag.

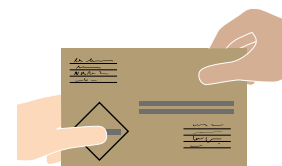
Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the envelope.

You can remove the sticker with the test set name if you wish to do so for reasons of 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 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 use according to Regulation (EU) 2017/746 (IVDR):**

- The T903 test set is an in vitro diagnostic medical 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 cryptopyrrole by HPLC. 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 cryptopyrroluria.
- 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 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 the use of 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 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 collection of a urine sample by laypersons and does not have its own analysis function; it is not intended for use as a self-test for diagnosis. Reuse may lead to falsified results and, under certain circumstances, to health risks.
- Please note the contraindications and other information listed above, which must be taken into account 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 biological samples: The urine sample is potentially infectious.
- The samples should be returned on the day they are taken, if possible. Until dispatch, the filled sample must be stored at room temperature (10–30 °C) and protected from light.
- No shipping 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 labeled 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.