

INSTRUCTION TEST SET 912

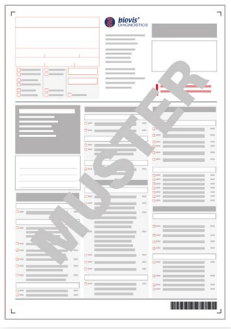
Gludorphin and Casomorphin



YOU WILL RECEIVE:

The sample tube may already be inside the transport tube.

Test implementation: **10 min**
Time: **in the morning**
(on an empty stomach!)



1 x Request form



1x Centrifuge tube
(contains a stabiliser sheet
that must not be removed!)



1 x Transfer pipette

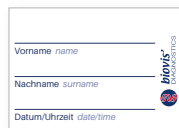


1 x International
shipping bag

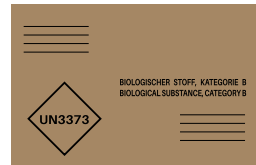
ADDITIONAL:



1 x Transport tube



1x Name label



1 x Shipping bag



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

Purpose:

The T912 test set is intended for the independent collection of urine samples by lay persons. The test set enables the stabilisation of the sample for further laboratory diagnostic determination of gliadorphin and casomorphin peptides 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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REF Order number: Test set 912

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 912

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)

Use by - see sticker Test set 912

IMPORTANT INFORMATION

What you need to know before performing the test:

Your kidney function must be intact.

1-2 weeks beforehand

- No extreme diets or fasting before the test
- No antibiotic therapy

3-5 days before

- Foods containing gluten and casein must be consumed before the test; otherwise, eat light, familiar foods, consuming peas, lentils, and beans only in moderation.
- Avoid protein shakes
- Completely avoid all types of soy products
- Avoid strongly spiced and heavily processed foods and excessive caffeine consumption
- No alcohol consumption, no green tea (herbal teas are allowed)
- No dietary supplements (B6, zinc, magnesium, copper, manganese, niacin, vitamin C) on the day of the test or, ideally, 24 hours beforehand; no enzyme preparations (DPP-IV enzymes), digestive enzymes (e.g. bromelain, papain, lipase), lactase preparations; no probiotics, prebiotics, or fibre supplements (e.g. linseed or psyllium husks).

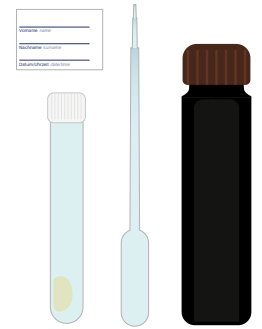
IMPORTANT

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

The sample must be taken on an empty stomach. Your last meal should have been at least 8 hours ago.

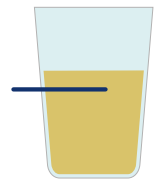
Do not perform the test during menstruation.

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



The practice should have already labelled the Centrifuge Tube with a barcode for you. If this is not the case, label the tube with your name and the date of collection and attach the label to the tube.

2. Fill the urine cup up to the mark.

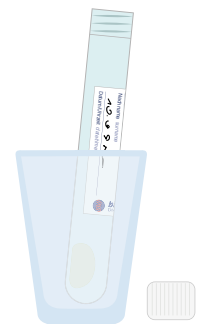


IMPORTANT

Use the **midstream urine**.

Midstream urine is a urine sample obtained from the middle of the stream. The first and last parts of the urine are not collected.

3. Open the centrifuge tube and set the cup aside.



NOTE

Make sure to position the centrifuge tube vertically so that the stabiliser sheet cannot escape.

4. Hold the transfer pipette at the top and squeeze it together. Dip the pipette into the urine and release the grip so that the urine is drawn up. Pour the urine into the centrifuge tube. Repeat the process until the centrifuge tube is filled to the mark. Then reseal the centrifuge tube.



5. Place the centrifuge tube in the transport tube (light-protected).



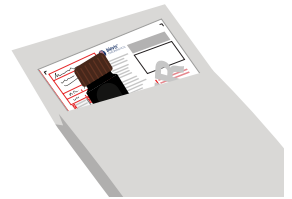
6. Fill out the request form legibly (in digital or block letters).

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

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



7. Shipping by post: Place the sample tube and the completed and signed request form in the enclosed white shipping bag. Take the shipping bag to a post office on the day of sample collection and send the sample by **express delivery**. The sample must arrive at the laboratory within 48 hours!



Shipping via the doctor's office (after prior consultation with the doctor's office): Hand in the filled sample tube and the completed and signed request form at the doctor's office on the day of collection. The doctor's office will then ship the sample using our delivery service to ensure that the sample arrives at the laboratory within 48 hours.



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 T912 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 intended for the standardised, non-invasive collection of urine samples by lay persons for the subsequent determination of gliadorphin and casomorphin peptides using LC-MS/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 intolerances associated with gastrointestinal or neurological diseases and neurologically induced developmental disorders.
- The product is for single use outside 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 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 kit 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 10-25 °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 lay persons to collect a urine sample 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 biological samples: The urine sample is potentially infectious.
- Avoid direct contact with skin and mucous membranes. Wash your hands thoroughly with soap and water before and after taking the sample.
- The samples must be returned on the day of collection. The samples must arrive at the laboratory within 48 hours. Until dispatch, the filled sample must be stored in a refrigerator (2-8 °C).
- 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 that due to 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.