

INSTRUCTION TEST SET 928

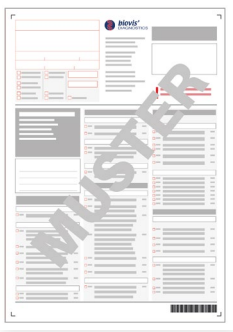
Acid-stabilised second morning urine



YOU RECEIVE:

The sample tube may already be inside the transport tube.

Test implementation: **20-30 min**



1 x Request form



1 x Centrifuge tube
(with stabiliser sheet)



1 x Transfer pipette

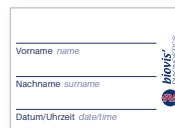
ADDITIONALLY:



1 x pH test strip incl. bag



1 x Transport tube



1 x Name label



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

Intended use:

The Test Set 928 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 metabolites by biovis Diagnostik MVZ GmbH. It is not intended for immediate self-interpretation.

Manufacturer:
biovis Diagnostik MVZ GmbH
Brüsseler Str. 18
65552 Limburg-Eschhofen
Tel.: +49 6431 21248 0
Fax: +49 6431 21248 66
info@biovis.de
biovis.de



Order number: Test set 928

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)

Batch number - see label on Test set 928

Use by - see sticker Test set 928

IMPORTANT INFORMATION

What you should consider before performing the test:

- Please remain fasting until the sample is taken. Your last meal should be in the evening at the latest.
- Do not exercise in the morning on the day of the sample collection.
- Please do not drink excessively in the period leading up to the sample collection! Water and fruit tea are permitted in moderation (max. 0.5 litres).
- The pH test strip is already red at the start and changes colour in an acidic environment.
- Make sure that the pH test strip does not come into contact with your fingers or liquids before use.
- The test strip may only be used once.
- If the pH test strip turns red, discard the test set and use a new one. You can obtain this from your practice.

Medications and dietary supplements

- Some dietary supplements and conventional medicines affect tryptophan or catecholamine metabolism and should, if possible, be discontinued **7 days** in advance. In addition to tryptophan, 5-HTP, Griffonia, etc., these also include antidepressants such as SSRIs, SNRIs and MAO inhibitors. If these cannot be discontinued, this must be taken into account when evaluating the results!
- If TMAO metabolism is part of your analysis, you must also stop taking omega-3 supplements at least 2 days before the test.
- **Please discuss this with your practice.**

Food

- The last meal should be eaten the evening before. Remain fasting until the sample is taken.
- Foods that are high in certain amino acids can have a significant impact on the test results. Depending on the profile being tested, these foods should be avoided for **2 days before the sample** is taken.
These include:
Tryptophan: Brie, Edam, pork fillet, pork liver, peanuts, cashews, lima beans, soybeans, tuna
Phenylalanine/tyrosine: Brie, Camembert, Appenzeller, Tilsiter, Edam, Gouda, Emmentaler, Parmesan, almonds, peanuts, peas, lima beans, soybeans, pork, tuna, caviar, ray
TMA/TMAO: All fish and seafood, including fish/shellfish-based sauces
- **At least 16 hours before the start and during collection, the following should also be strictly avoided:** Alcohol, coffee and caffeinated drinks or energy drinks, tea, nicotine

Contraindications

In the following situations, it is not possible to obtain representative measurements of hormones and neurotransmitters:

- severe illnesses (renal insufficiency, liver cirrhosis, severe infections)
- during antibiotic therapy
- during and shortly after fasting
- during menstruation
- during pregnancy and up to two weeks after giving birth
- immediately after air travel involving time differences (except for flight personnel)

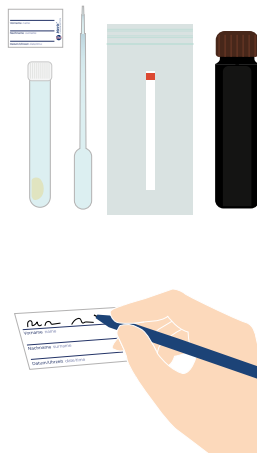
TEST INSTRUCTIONS

IMPORTANT

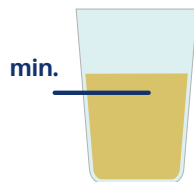
Use your second morning urine sample. The second morning urine sample is collected no earlier than 2-4 hours after the first morning urine sample in the morning - not before! Please do not drink excessive amounts during this time. Water and fruit tea are allowed in moderation (max. 0.5 litres).

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

The practice should have already labelled the sample tubes with a barcode for you. If this is not the case, write your name and the date of sample collection on the name label and stick it on the tube.



2. Fill the urine cup about halfway with urine.

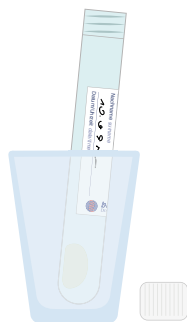


IMPORTANT

Use 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.

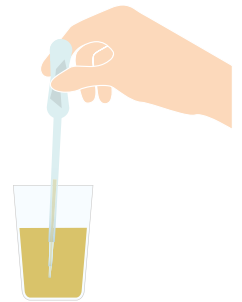
3. Open the centrifuge tube and set the lid aside.

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 loosen your grip so that the urine is drawn up.



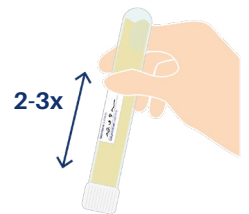
5. Fill the tube with urine.

Repeat the process until the tube is filled to the mark.

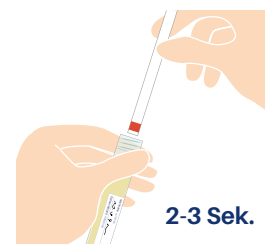
Then close the tube again.



6. Turn the tube upside down 2-3 times and open it again.

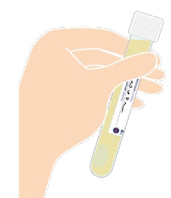


7. Now determine the pH value of the urine sample in the tube. To do this, take the pH test strip out of the bag and dip it into the urine for 2-3 seconds.



Close the tube again.

Then immediately read the result on the pH test strip. To do this, hold the test strip next to the colour scale and compare the colour.





If the pH test strip turns red, discard the sample and the test set and repeat the test with a new test set on another day.

8. Place the tube in the transport tube.

Transfer pipettes, urine cups and pH test strips can be disposed of in household waste.



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

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

Fill in 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 bag.

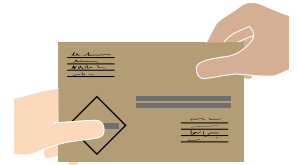
Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope.

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 as soon as possible at a post office or, after prior consultation, at your medical practice.

Please do not send it on a Friday, at the weekend or on public holidays, and do not put it in a letterbox.



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 doctor's surgery.

Intended use according to Regulation (EU) 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 protected 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 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 falsified results.
- Please note the instructions 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 complaints, 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 should be returned on the day of collection if possible. Until dispatch, the filled sample must be stored in the refrigerator (4-8 °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.

Restrictions and safety instructions for the use of the test set in accordance with Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- The Test Set 928 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 various urine metabolites 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 metabolic disorders. A complete list of the relevant parameters is not possible here due to space constraints, but can be found in the service specifications of biovis Diagnostik MVZ GmbH. It concerns the following tests, among others:
 - A125 D-Arabinol in Urine
 - A675 TMA and TMAO Formation
 - A685 Tryptophan Metabolism Plus
 - A681 Bacterial Uraemic Metabolites
 - C410 Methylhistamine in Urine
 - C415 Histamine in Urine
 - E408 Complete Profile of Organic Acids
 - E425 Organic Acids of the Citric Acid Cycle
 - E435 Vitamin Metabolism Marker
 - E520 Methylmalonic Acid
 - F500 Neurotransmitter Basic
 - F510 Neurotransmitter Plus
 - F520 Inhibitory Neurotransmitters
 - F550 Serotonin in Urine
 - F610 NT-Tryptophan Metabolism
 - F620 NT-Tryptophan Metabolism Plus
 - F630 Methyl Group Donors
- 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.

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.