

TEST INSTRUCTION T928

Acid-stabilised second morning urin



YOU RECEIVE

The sample tubes may be located in the transport tubes.



1 x Request form



1 x Centrifuge tube
(with stabiliser plate)



1 x Transfer pipette



1 x pH test strip incl. bag



1 x Transport tube



1 x Name label

ADDITIONALLY



1 x Mailing bag



1 x Urine beaker

Purpose:

The T928 'Acid-stabilised urine' test kit is intended for the collection of urine by laypersons. It offers a simple and safe way to collect urine for further analyses by biovis Diagnostik MVZ GmbH.

Further information on the intended use and safety instructions in accordance with Regulation (EU) 2017/745 and 2017/746 can be found at the end of the instructions.



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

REF Order number Test set T928

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 T928

Storage temperature 10-30°C

Inhouse 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 T928

Contraindications

In the following situations a representative determination of hormones and neurotransmitters is not possible:

- Severe illnesses (renal insufficiency, liver cirrhosis, severe infections)
- During antibiotic therapy
- During and shortly after a fasting programme
- During menstruation
- During pregnancy and up to two weeks after the birth
- Immediately after travelling by air with a time difference (except for airline staff)

Food

- The last meal should be eaten the evening before. Remain fasting until the sample collection.
- Foods with a high content of certain amino acids can significantly influence the test results. Depending on the profile being examined, these foods should be avoided for **2 days prior to sample collection**.

This includes:

Tryptophan: *Brie, Edam, pork fillet, pork liver, peanuts, cashew nuts, lima beans, soybeans, tuna*

Phenylalanine/Tyrosine: *Brie, Camembert, Appenzeller, Tilsit, Edam, Gouda, Emmental, Parmesan, almonds, peanuts, peas, lima beans, soybeans, pork, tuna, caviar, skate*

TMA/TMAO: All fish and seafood, including sauces based on fish or shellfish

- **At least 16 hours before starting and during the collection, the following should be strictly avoided:** *alcohol, coffee and caffeinated beverages or energy drinks, tea, and nicotine.*

Medications and supplements

- Some supplements and common medicines affect tryptophan or catecholamine metabolism and should be discontinued 7 days before use if possible. These include tryptophan, 5-HTP, griffonia and others, and antidepressants such as SSRIs, SNRIs and MAO inhibitors. If discontinuation is not possible, this must be considered when interpreting the results.
- If TMAO metabolism is part of your analysis, omega-3 supplements must also be discontinued at least 2 days prior to testing.
- **Please consult with your practice.**

Important Notes

- **Stay fasting** until the sample is taken. Your last meal should be in the evening at the latest.
- **Do not exercise** on the morning of the sample collection.
- Avoid excessive drinking before the sample collection! Water and fruit tea are allowed in moderation (max. 0.5 litres).
- The pH test strip is initially red and changes colour in an acidic environment.
- Ensure that the pH test strip do not come into contact with your fingers or any liquids before use.
- The test strip is for single use only.
- If the pH test strip turns red, discard the test kit and use a new one. You can obtain a replacement test kit from your practice.

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Acid-stabilised second morning urine

IMPORTANT

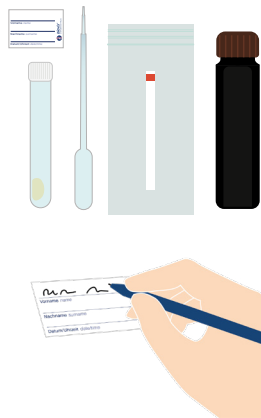
Use the second morning urine. The second morning urine should be collected at least 2 to 4 hours after the first morning urine, no earlier.

Please avoid excessive drinking during this time. Water and fruit tea are allowed in moderation (max. 0.5 litres).

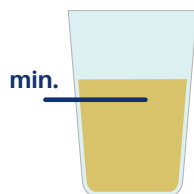
1. Place all the materials in front of you as shown in the picture.

The practice should have already applied a barcode to the sample tubes for you.

If this is not the case, write your name and the date or time of the sample collection on the name label and attach it to the tube.



2. Fill the urine beaker about halfway with urine



IMPORTANT

Use the midstream urine. Midstream urine refers to a urine sample collected from the continuous stream of urine. The first and last part of the urine are not collected.

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

Ensure that the centrifuge tube is positioned vertically so that the stabiliser plate cannot escape.



4. Hold the transfer pipette by the top end and squeeze it.

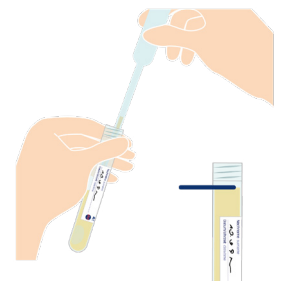
Dip the pipette into the urine and release the grip to draw the urine up.



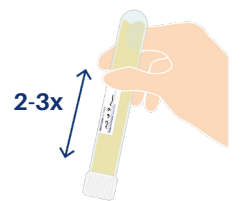
5. Fill the urine into the tube.

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

Then close the tube.



6. Invert the tube 2-3 times and then open it again.

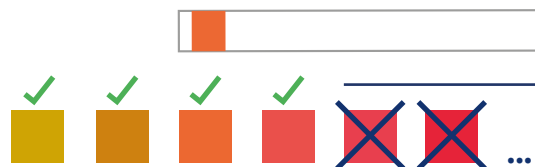
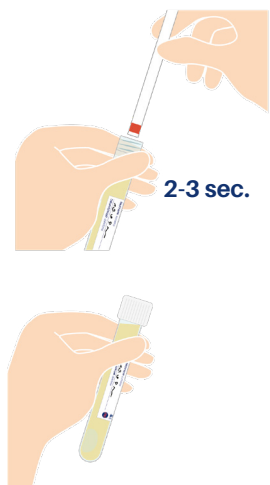


7. Now, determine the pH of the urine sample in the tube.

Take a pH test strip from the packet and dip it into the urine for 2-3 seconds.

Close the tube again.

Immediately read the result of the pH test strip. Hold the strip next to the colour scale and compare the colour.



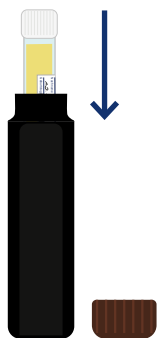
If the pH test strip turns red, discard the sample and the test kit, and repeat the test with a new kit on a different day.

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8. Place the tube into the transport tube.

The transfer pipette, urine cup, and pH test strip can be disposed of in the household waste.



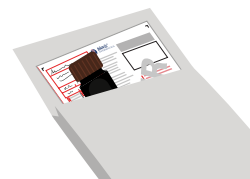
9. Please fill in the request form legibly (in digital or printed letters).

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

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

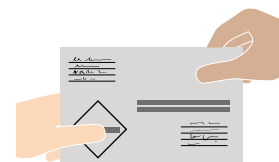


10. Pack the tube and the completed and signed request form in the mailing bag.



11. Preferably take the mailing bag to a post office or to your practice.

Please do not send on Fridays, weekends or public holidays and do not drop in letterboxes.



If you have any further questions, please contact the medical professionals you trust.

Purpose according to Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- The T928 „Acid-Stabilized Urine“ test kit is designed for the collection of so-called „midstream urine“ by laypersons. The test kit is provided to patients by healthcare professionals in the therapeutic practice. It offers a simple and safe way to collect midstream urine for further analysis by biovis Diagnostik MVZ GmbH. The kit is intended for independent use by adult laypersons in a home setting. Healthcare professionals at the practice are available to answer any questions.
- The kit contains a centrifuge tube („stabilized“), a transfer pipette, one pH test strip with a bag, a transport tube, and a name label. Additionally, the test kit includes the „Examination Request“ form and an envelope for returning the sample to the laboratory. A urine collection cup is part of the test kit but is provided separately by the therapeutic practice.
- The collected sample is ‘acid-stabilized midstream urine’.
- The patient collects urine into the primary container according to the test instructions. A portion of the urine sample collected in the primary container is transferred into the centrifuge tube using the transfer pipette. To stabilize the midstream urine for subsequent diagnostics, an acid-soaked filter paper is pre-inserted in the centrifuge tube. To confirm the stabilization of the urine, the pH value of the midstream urine transferred into the centrifuge tube is checked using a pH test strip and compared to the indicator colour scale provided in the test instructions. Midstream urine that does not meet the required pH value is discarded: the urine is disposed of in a toilet, and the centrifuge tube and pH test strips are disposed of in household waste.
- If the urine sample meets the acceptable pH value, the sample in the centrifuge

tube and the completed and signed examination request form are sent to the medical laboratory biovis Diagnostik MVZ GmbH for further analysis.

- At biovis Diagnostik MVZ GmbH, the urine sample is used to determine one or more of the measurement parameters requested in the examination order (see the full list of possible parameters below).
- The collected samples cannot and must not be used by the patient or independent third parties to diagnose diseases. They must be sent to biovis Diagnostik MVZ GmbH for further analysis by qualified medical professionals.

List of parameters derived from midstream urine collected with test set 928:

- | | |
|---|--------------------------------------|
| ▪ E408 Organic acids in urine | ▪ F630 Methyl group donors |
| ▪ E425 Organic acids of the citric acid cycle | ▪ F520 Inhibitory neurotransmitters |
| ▪ E435 Markers of vitamin metabolism | ▪ F550 Serotonin in urine |
| ▪ C410 Methylhistamine in urine | ▪ A125 Arabinitol in urine |
| ▪ C415 Histamine in urine | ▪ A685 Tryptophan Metabolism Plus |
| ▪ F500 Neurotransmitter Basics | ▪ A681 Bacterial uraemic metabolites |
| ▪ F510 Neurotransmitter Plus | ▪ A675 TMA and TMAO production |
| ▪ F610 NT-Tryptophan Metabolism | |
| ▪ F620 NT-Tryptophan Metabolism Plus | |

Safety instructions for the use of the test kit according to Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- Use the test kit only as instructed. Carefully read the enclosed instructions for use and follow all steps precisely. Improper use may lead to inaccurate results.
- Store the test kit in a cool, dry place, protected from light. Ensure it is kept out of the reach of children.
- Check the expiration date on the packaging before use. Do not use the test kit after the expiration date, as the reliability of the results may be compromised.
- Wash your hands thoroughly with soap and water before and after using the test kit.
- Do not use the test kit if the packaging is damaged or opened. Use the test kit only once and dispose of it properly afterward.
- The components of the test kit are intended for single use only. Do not reuse the components or share them with others.

- Avoid contact between the test kit components and your eyes. If contact occurs, immediately rinse your eyes thoroughly with clean water and seek medical attention if symptoms persist.
- If you are uncertain about the procedure or notice unusual symptoms, consult a medical professional, such as the healthcare provider who issued the test kit. After use, dispose of the test kit in accordance with local household waste regulations. Any remaining urine in the collection container can be flushed down the toilet; the container itself can be discarded with household waste.