

INSTRUCTIONS TEST SET 924

Melatonin night-time saliva profile (O369)



YOU RECEIVE

The sample tubes may already be inside the transport tubes.

Test implementation: **5-10 min.**
Test duration: **approx. 4 hrs**
Time: **in the evening/at night**



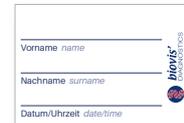
1 x Request form



1 x Transport tube



3 x Saliva tube



3 x Name label



1 x Mailing bag

Purpose:

The Test Set 924 is intended for the independent collection of saliva samples by laypersons. The test set enables laboratory diagnosis of melatonin in the night-time saliva profile at three different times 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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biovis.de

REF Order number: Test set 924

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 924

MD Storage temperature: 10-30°C

MD In-house medical device of biovis Diagnostik MVZ GmbH according to Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR)

MD Use by - see sticker Test set 924

TEST INSTRUCTION

Note

The sample should be taken at 10 p.m., midnight, and 2 a.m.

- You should go to sleep at around 10 p.m.
- It must be a normal night's sleep.
- The test is not suitable for people who sleep during the day (e.g. shift workers who work night shifts).
- Shift workers should only perform the test after they have worked day shifts for several days in a row and their sleep-wake rhythm has returned to night-time sleep.

IMPORTANT

- Take the saliva sample at 10 p.m., midnight, and 2 a.m.
- The sample must be taken either before brushing your teeth or at least 30 minutes after brushing your teeth.
- **Samples 2 and 3 must be taken in the dark.**
- Even small amounts of light affect melatonin production and thus distort the measurement. If it is not possible to take the sample in the dark, use the weakest possible light source.
- Ensure that the sample is saliva and not sputum from the throat or bronchial mucus.
- Bleeding gums can distort the result. If you see that the saliva is pink the next morning, rinse out the tube and repeat the test on another night.

1. Before going to bed, place all materials within easy reach.

In addition, have a bottle of clear water ready.

Set your alarm clock for midnight and 2 a. m.



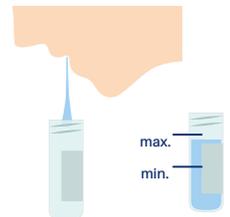
2. Rinse your mouth with clear water.



3. Remove the stopper from the saliva tube (10 p.m.) by tilting it slightly to one side and then pulling it off.



4. Collect a sufficient amount of saliva in your mouth and transfer it to the tube. Repeat the process until the tube is at least half full without foaming (scale: 3.5 ml).



Then seal the tube.



NOTE

A small amount of foam is normal and cannot be avoided. If saliva is not flowing sufficiently, you can smell a lemon or lemon juice. This stimulates saliva flow.

5. Place the filled saliva tube into the transport tube.

Repeat steps 2 to 5 at midnight and 2 a.m. Use the weakest possible light source.

6. The practice should have already labelled the sample tubes with a barcode for you. Also note the time of sample collection on the tube.

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



IMPORTANT

Place the samples in the refrigerator immediately after the last collection at 2 a.m. Store the sample in the refrigerator until dispatch.

7. 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.

Also note what time you went to bed.

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



8. Place the sample tube and the completed and signed request form back into the shipping envelope.

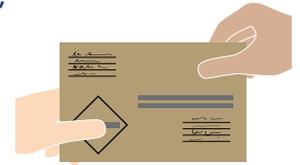
Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope.

You can remove the sticker with the test set name if you wish to do so for reasons of discretion.



9. Drop off the envelope at a post office as soon as possible, or - after prior consultation - at your medical practice.

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 Test Set 924 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 saliva samples by lay persons for subsequent determination of melatonin concentration over the course of the night (3 measurement points, depending on sleep behaviour, approx. 10 p.m., midnight and 2 a.m.) using ELISA. 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 sleep disorders.
- The product is intended for single use outside clinical facilities.
- Samples are taken 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 set in accordance with Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- Only use the test set as instructed. Read the enclosed instructions for use carefully and follow all steps exactly. 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 use by laypersons to collect a saliva sample and does not have its own analysis function; it is not intended for use as a self-test for diagnosis.
- Samples should be returned on the day they are collected if possible. Until dispatch, the filled sample must be stored in a refrigerator (4-8 °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 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.