

# INSTRUCTION TEST SET BIO 1

## Cortisol/DHEA diurnal profile



### YOU RECEIVE

The sample tubes may be in the transport tubes.

Test implementation: **approx. 10 mins**  
Test duration: **1 day**  
Time: **8 am to 8 pm**



1 x Request form



1 x Transport tube



3 x Saliva tubes



3 x Name label



1 x Transport tube

### Purpose:

The Test Set Bio1 is intended for the independent collection of saliva samples by laypersons. The test set enables laboratory diagnosis of cortisol (and DHEA) levels throughout the day 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.

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**IF YOU HAVE ANY  
FURTHER QUESTIONS,  
PLEASE CONTACT THE MEDI-  
CAL PROFESSIONALS  
YOU TRUST.**

**REF** Order number: Test set BIO 1

**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 BIO 1

**Storage temperature:** 10-30°C

**In-house 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 BIO 1

# TEST INSTRUCTIONS

## Note

Sampling at 8 am, 12 pm and 8 pm is suitable for people who usually get up 1-2 hours before the first sample is taken at 8 am.

For all those who usually get up after 8 am or for shift workers:

- **The first sample should be taken 1-2 hours after getting up.**
- **The second sample should be taken 4 hours after the first.**
- **The third sample should be taken 8 hours after the second sample.**

## Example:

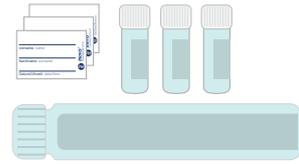
Get up: 10 am

- 1 Sampling 11 am
- 2 Sampling 3 pm } 4 hrs
- 3 Sampling 11 pm } 8 hrs

## IMPORTANT

- Saliva is collected at 8 am, 12 pm and 8 pm.
- The first sample should be taken in the morning on an empty stomach before brushing your teeth.
- The remaining samples must be taken at the earliest 30 minutes after ingesting solid/liquid food and after smoking.
- Make sure that the sample is saliva and not sputum from the throat or bronchial mucus.
- Bleeding gums can distort the result. If you notice that the saliva in the test tube is slightly pink in colour, rinse out the tube, wait a while and repeat the process.

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



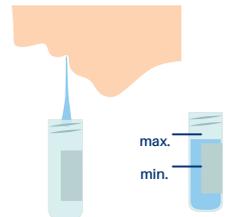
2. Rinse your mouth with clear water and **wait 5 minutes.**



3. Remove the stopper from the saliva tube by tilting it slightly to the side and then pulling it off.



4. Collect a sufficient amount of saliva in your mouth and transfer it into the tube. Repeat this process as often as necessary until the tube is filled at least halfway without foam formation (scale: 3.5 ml).



Then close the tube.



## NOTE

**If saliva production is insufficient, you may smell a lemon or lemon juice to stimulate saliva flow.**

**5.** Write your name and the date or time of the sample collection on the name label and attach it to the tube.

If you have received barcodes from the practice, please use them to label your samples. Additionally, please note the **time the sample was taken** on the tube.

**6.** Place the filled saliva tube into the transport tube.

**Repeat steps 2 through 6 with the other two tubes at the respective times.**



## IMPORTANT

**Store the sample in the fridge 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.

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 return envelope.

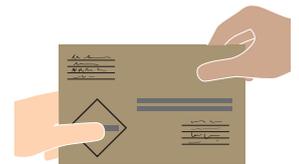
Pull on the marked tab to remove the already-used adhesive strip. Use the inner adhesive strip to seal the envelope securely.



You may remove the test label from the envelope if you prefer more discretion.

**9.** Drop off the shipping bag at a post office as soon as possible, or – after prior consultation – at your medical practice.

**Please do not send 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 TBio1 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 cortisol (and DHEA) levels throughout the day (3 measurement points for cortisol in the morning, at noon, and in the evening; 2 measurement points for DHEA in the morning and in the evening, depending on the profile) 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 Burnout and other stress-related illnesses.
- 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 (2-8°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.