

# T933 TEST INSTRUCTIONS

## Prevent 360 - for capillary blood analysis with Mitra®-Sticks



### YOU RECEIVE




1 x Request Form




6 x Tubes incl.  
Mitra®-Sticks  
(3x10µl, 3x30µl)



2 x Lancets

Test implementation: **15-30 mins**  
Drying time: **8-24 h**  
Time: **in the morning**  
(on an empty stomach) 



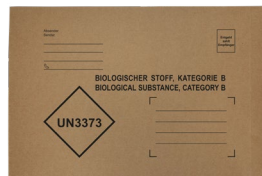
Here you will  
find the test  
instruction video: 



2 x Desinfectant wipes



2 x Sterile plasters



1 x Mailing bag

#### Purpose:

The T933 test set is designed for the self-collection of blood from a fingertip („capillary blood“) for analysis using the biovis Prevent 360 test method. Use the test set only as instructed. Carefully read the enclosed instructions for use and follow all steps precisely. **Very important: The blood sample must be taken while fasting, meaning: No food intake in the last 8 hours, except for water up to 1 hour before the blood collection.** Further information on the intended purpose and safety according to Regulation (EU) 2017/745 (MDR) can be found at the end of the test instructions.





#### 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**




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


 Order number Test set T933

 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.

 Batch number - see label on test set T933

 Storage temperature 10-30°C

 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 T933

# TEST INSTRUCTION

## IMPORTANT

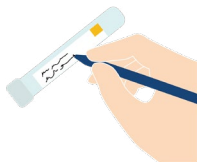
The sample must be taken on an empty stomach. Do not eat or drink anything for 8 hours beforehand. Water is allowed up to 1 hour before the sample collection.

The samples must be dried in a dark place for 8 to (a maximum of) 24 hours. Do not perform the test on Fridays, during the weekend, or on public holidays.

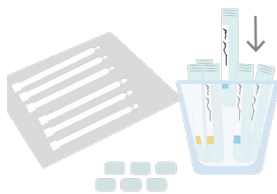
1. Place all the materials in front of you as shown in the picture.



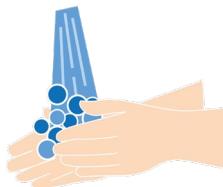
The practice should have already labeled the sample tubes with a barcode for you. If not, label the sample tube with your name and date of sample collection.



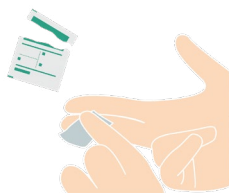
2. Remove the 6 Mitra®-Sticks from the tubes and place the sticks on a clean surface. Place the empty tubes upright in a container.



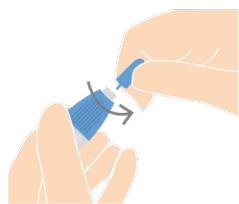
3. Wash your hand with warm water. If your hands are still cold, you can move your fingers or swing your arms next to your body.



4. Take the disinfectant wipe out of the packaging and use it to disinfect the tip of your ring or middle finger.

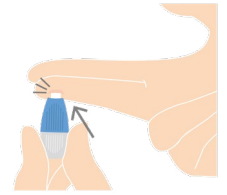


5. Take the lancet, turn the protective cap once around its own axis and pull it off.

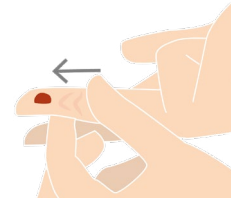


## capillary blood analysis - Prevent 360

6. Place the lancet on the side of your fingertip and press it against your finger so that the tip of the lancet shoots into your finger.

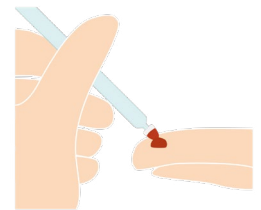


7. Hold your hand horizontally and massage your finger from the bottom to the puncture site until a blood drop is formed.



Remove the first blood drop with a towel.

8. Take a Mitra®-Stick out of the tube and hold it with the white tip pointing downwards. Gently touch the tip to the drop of blood. The tip should be completely saturated with blood. Then insert the soaked Mitra®-Stick back into the tube with the tip facing the lid.



Repeat this with all 6 Mitra®-Sticks.



## IMPORTANT

Place the Mitra®-Sticks back into the tubes with the bloody tip facing upwards, i.e., towards the opening.

Do NOT screw the caps onto the tubes yet. Allow the sticks to dry while standing upright in the tubes.

## NOTE

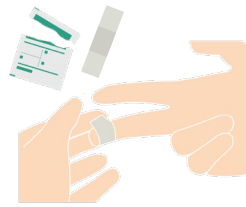
If the bleeding stops, you can use the second lancet to prick another fingertip.

Please also remove the first blood drop and do not squeeze the blood out of the finger.

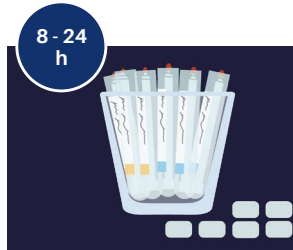


# TEST INSTRUCTION

**9.** Finally, clean the puncture site with the second disinfectant wipe and cover it with the plaster.



**10.** Allow the open, upright tubes with the Mitra®-Sticks to dry for **8 to 24 hours** at room temperature in a dark place (e.g., a dimly lit room).



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

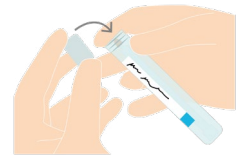


Write your **name, date of birth, and date and time of collection** on the front.

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

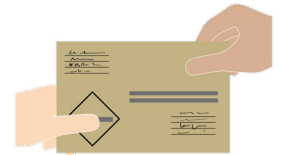
## capillary blood analysis - Prevent 360

**12.** Once the samples have dried after **8-24 hours**, close all the tubes. Pack everything together with the completed and signed request form in a mailing bag.



**13.** Preferably take the mailing bag to a post office or to your doctor/therapist.

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



### Purpose according to Regulation (EU) 2017/745 (MDR):

- The T933 test set is intended for the self-collection of blood from a fingertip („capillary blood“) for analysis using the biovis Prevent 360 test method.
- The test set contains two sterile lancets, two disinfectant wipes, 6 tubes including Mitra®-Stick™ (3 x 10 µl, 3 x 30 µl), 2 sterile plasters and the „Request Form“.
- This test set is designed for self-use by adults in a home environment. It provides a simple and safe method for collecting capillary blood samples independently for further analysis by biovis Diagnostik MVZ GmbH.

- The capillary blood samples (6 Mitra®-Sticks™), along with the completed and signed test request form, are sent to the medical laboratory biovis Diagnostik MVZ GmbH for further analysis. The analysis is used to determine a range of metabolic parameters (see the Prevent 360 brochure, available for download at [www.biovis.de](http://www.biovis.de)) using advanced high-performance chromatography methods (LC-MS).
- The collected samples cannot and must not be used for self-diagnosis or diagnosis by independent third parties; they must be sent to biovis Diagnostik MVZ GmbH for further analysis by qualified medical personnel.

### Safety instructions for the T933 test set for the collection of capillary blood for biovis Prevent 360 in accordance with Regulation (EU) 2017/745 (MDR):

- Use the test set only as instructed. Carefully read the enclosed instructions for use and follow all steps precisely. Improper use may lead to inaccurate results and injury from the lancets.
- Store the test set in a cool, dry place, protected from light. Ensure it is kept out of the reach of children.
- Before use, check the expiration date on the test set's packaging. Do not use the test set after the expiration date, as the reliability of the results may be compromised.
- Wash your hands thoroughly with soap and water before and after use to prevent contamination.
- Do not use the test set if the packaging is damaged or opened.
- Avoid contact of the test materials with the eyes. If contact occurs, rinse your eyes thoroughly with clean water and seek medical assistance if symptoms persist.
- The test set is for single use only. Do not reuse the components or share them with others.
- If you are unsure about using the test set or notice any unusual symptoms, consult a healthcare professional.
- After use, dispose of the remaining parts of the test set (waste) in accordance with local household waste regulations.

