

TEST SET INSTRUCTION 933

Prevent 360 – for capillary blood analysis
with Mitra® sticks in Mitra Devices



YOU RECEIVE



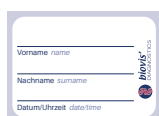
1 x Request form



2 x Lancets



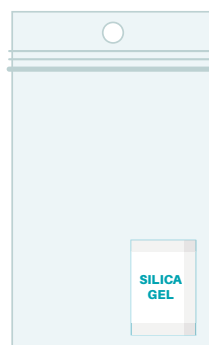
2 x Mitra Devices
incl. Mitra®-Sticks
(3x10µl, 3x30µl)



2 x Name label



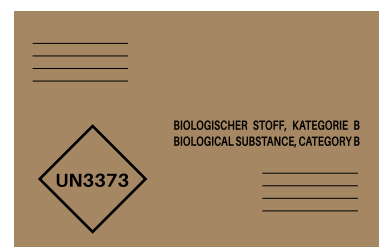
2 x Sterile plasters



2 x Plastic bag
with silica gel



2 x Disinfectant wipes



1 x Shipping bag

Test duration: **15-30 minutes**
Drying time: **8-24 hours**
Time: **morning (empty stomach)**



Purpose:

The Test Set 933 is intended for the independent collection of blood from a fingertip ("capillary blood") for testing with the biovis Prevent 360 test procedure. Only use the test set in accordance with the instructions. Read the enclosed instructions for use carefully and follow all steps precisely. **Blood must be taken on an empty stomach, i.e. no food for the last 8 hours, except water up to 1 hour before the blood sample is taken.** Further information on the intended use and safety in accordance with Regulation (EU) 2017/745 (MDR) can be found at the end of the test instructions.



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biovis.de



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

REF

Order number: Test set 933



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 933



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 SET INSTRUCTION 933

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. Lay out all the materials in front of you as shown in the picture. To do this, take the two Mitra Devices out of the plastic bags and set them aside. (The bags and the silica gels will be needed later for shipping.)



2. Label the name labels with the name and date of the sample collection and stick them onto the Mitra Devices.

If you have received barcodes, please use them to label the samples.

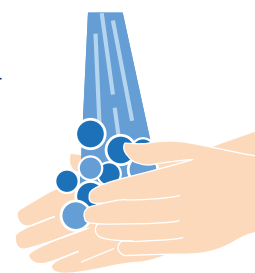


3. Open the Mitra Devices by folding the two upper parts outwards.

Place the opened Mitra Devices on a clean surface.



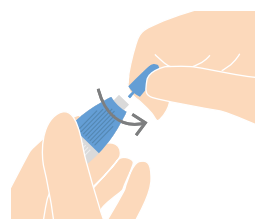
4. Wash your hand with warm water. If your hands are still cold, you can move your fingers or swing your arms next to your body.



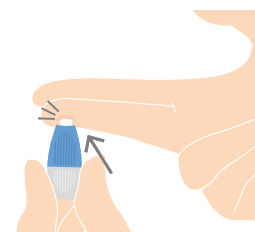
5. Take the disinfectant wipe out of the packaging and use it to disinfect the tip of your ring or middle finger.



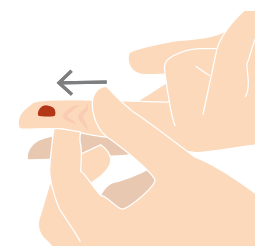
6. Take the lancet, turn the protective cap once around its own axis and pull it off.



7. 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.



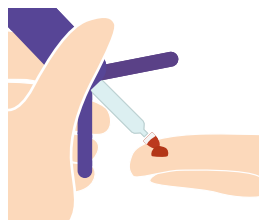
8. Hold your hand horizontally and massage your finger from the bottom to the puncture site until a blood drop is formed. Remove the first blood drop with a towel.



Prevent 360 - for capillary blood analysis with Mitra® sticks in Mitra Devices

9. Take one of the Mitra Devices and guide one of the Mitra Sticks to the drop of blood and wait until the white tip is completely saturated with blood. Repeat this with the other Mitra Sticks.

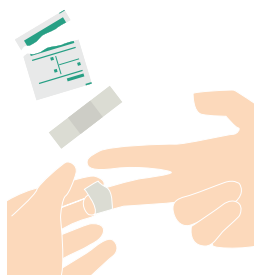
Repeat this with the second Mitra Device.



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.

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



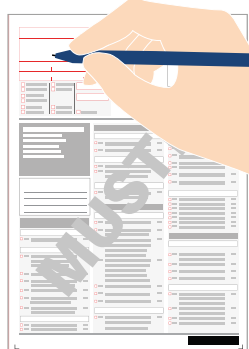
11. Leave the two Mitra devices to dry at room temperature in a **dark place** (e.g. a darkened room) for **8 to (maximum) 24 hours**.



12. 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.



13. Once the samples have dried after 8–24 hours, seal the Mitra devices and pack them back into the plastic bags. Take the silica gels and remove the plastic packaging. Pack one silica gel into the bag with each Mitra device. Seal the bags carefully. Then pack everything into a shipping bag together with the completed and signed request form.



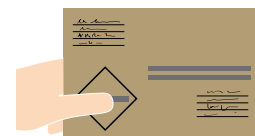
14. Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope. You can remove the sticker with the test set name if you wish to do so for reasons of discretion.



15. 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.

If you have any further questions, please contact your practice.



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

- The Test Set 933 is intended for the independent collection of blood from a fingertip ('capillary blood') for testing with the biovis Prevent 360 test procedure.
- The test set contains two sterile lancets, two disinfectant wipes, two name labels, two Mitra Devices including three Mitra®-Stick™ (3 x 10 µl, 3 x 30 µl), 2 sterile plasters and the "Test request" form.
- This test set is intended for independent use by adults in a home environment. It offers a simple and safe way to independently collect capillary blood samples for further analysis by biovis Diagnostik MVZ GmbH.
- The capillary blood samples (6 Mitra®-Sticks™) and 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) using modern, high-performance chromatography methods (LC-MS).
- The samples obtained cannot and must not be used to diagnose diseases by the user themselves or by independent third parties, but must be sent to biovis Diagnostik MVZ GmbH for further analysis by qualified medical professionals.

Safety instructions for test set 933 for obtaining capillary blood for biovis Prevent 360 in accordance with Regulation (EU) 2017/745 (MDR):

- Only use the test set in accordance with the instructions. Read the enclosed instructions for use carefully and follow all steps precisely. Improper use can lead to inaccurate results and injuries from the lancets.
- Store the test set in a cool, dry place away from light. Ensure that it is kept out of the reach of children
- Before use, check the expiry date on the test set packaging. Do not use the test set after the expiry date, as the reliability of the results may be compromised.
- Before and after use, wash your hands thoroughly with soap and water to avoid the risk of contamination.
- Do not use the set if the packaging is damaged or opened.
- Avoid contact of the test materials with the eyes. If this happens, rinse the eyes immediately with clean water and seek medical attention if symptoms persist.
- The test set is intended for single use only. Do not reuse the components and do not share it with others.
- If you are unsure about how to use the test set or notice any unusual symptoms, consult a healthcare professional.
- After use, dispose of the remaining components of the test set (waste) in accordance with local regulations for household waste.