

INSTRUCTIONS TEST SET 922

DrySpot for vitamin D, fatty acids, DAO



YOU WILL RECEIVE:

Test implementation: **approx. 15 min**
 Drying time: **1-2 hours**
 Time: **in the morning**
(on an empty stomach)



1 x Request form



2 x Disinfectant wipes



2 x Sterile plaster



2 x Pipettes



2 x Lancets



1 x Sample carrier



1 x Protective cover for the sample carrier



1 x Silica gel

Intended use:

The Test Set 922 is intended for the independent collection of capillary blood samples by lay persons. The test set enables the stabilisation of the sample for further laboratory diagnostic determination of vitamin D, fatty acids, and/or serotonin by biovis Diagnostik MVZ GmbH. It is not intended for immediate self-interpretation. Further information on the intended purpose 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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REF Order number: Test set 922

Storage temperature: 15-25°C

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.

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

LOT Batch number - see label on Test set 922

Use by - see sticker Test set 922

TEST INSTRUCTIONS

What you should consider before performing the test:

- For DAO: If possible, do not take any supplements containing zinc, vitamin B6, copper or manganese for one week prior to the test, or at least three days prior.
- For fatty acids: If possible, do not take any omega-3 supplements for one week prior to the test, or at least three days prior if this is not possible. Avoid high-fat meals on the day before the test.
- For vitamin D: If possible, do not take any vitamin D supplements for 1 week prior to the test, or at least 3 days prior to the test.

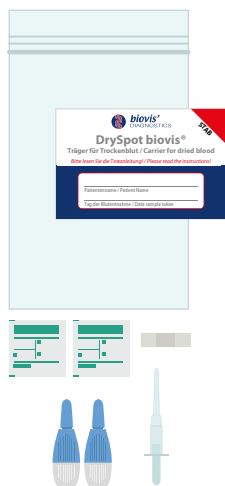
IMPORTANT

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

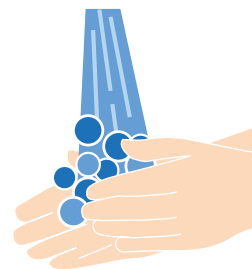
1. Place all the materials in front of you as shown in the picture.

The practice should have already labeled the sample carrier with a barcode for you.

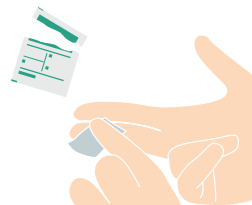
If this is not the case, label the sample carrier with your name and the date of sample collection.



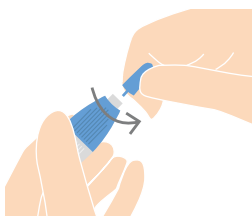
2. Wash your hands thoroughly with warm water. If your hands are still cold, you can move your fingers or swing your arms alongside your body.



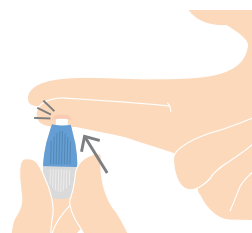
3. Remove the disinfectant wipe from the packaging and use it to disinfect the tip of your ring or middle finger.



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

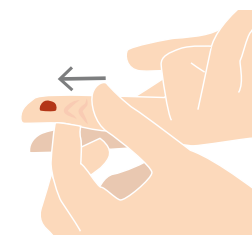


5. Place the lancet sideways on your fingertip and press it against your finger so that the tip of the lancet pierces your finger.

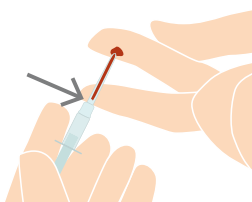


Wipe away the first drop of blood with a clean cloth.

6. Massage your finger from below to the puncture site until a drop of blood forms.

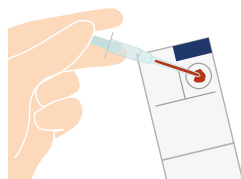


7. Now hold the pipette sideways to the drop of blood and wait until the blood has completely risen to the white band.



Do not squeeze the blood out of your finger.

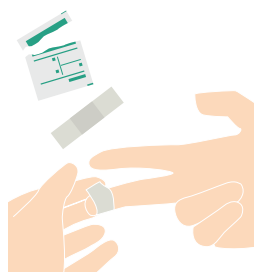
8. Hold the pipette over the sample carrier. Press down on the white plunger so that the blood is centred on the corresponding pre-punched field. One field must be filled for each test (fatty acids, vitamin D, DAO).



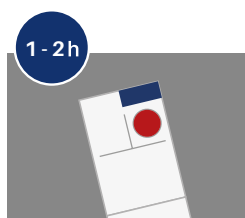
IMPORTANT

Make sure that you apply exactly one complete pipette filling of blood to the respective field. The blood must not be distributed over several fields. For additional fields, refill the pipette.

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



10. Allow the sample carrier to dry for at least **2 hours** at **room temperature** in a **dark place** (e.g. a darkened room).



IMPORTANT

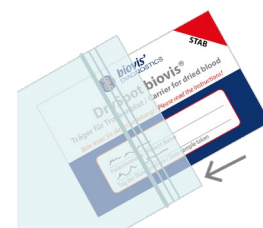
Avoid direct sunlight and place the sample carrier on a clean, dry piece of paper, for example, so that you do not contaminate it. A contaminated sample can affect the test results.

11. Fill out the request form legibly (digitally or in block letters). Write **your name, date of birth and date of collection** on the front.



Fill in the declaration on the back and sign the request form.

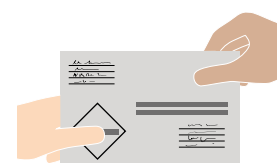
12. Once the samples have dried, place the sample carrier together with the silica gel in the protective sleeve. Then put everything back in the shipping envelope together with the completed and signed request form.



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

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

13. Please drop off the envelope at a post office or, after prior consultation, at your practice as soon as possible.



Please do not send it on a **Friday, at the weekend or on public holidays, and do not put it in the post box.**

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.

Intended use according to Regulation (EU) 2017/746 (IVDR):

- The Test Set 922 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, minimally invasive collection of capillary blood samples by lay persons for the subsequent determination of vitamin D by LC-MS/MS and/or fatty acids by GC-MS and/or serotonin by ELISA. The quantitative analyses are carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and are used as a diagnostic aid in cases of suspected deficiencies.
- The product is intended for single use outside of 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 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 the use of the test set in accordance with Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR):

- Only use the test set in accordance with the instructions. Read the enclosed instructions for use carefully and follow all steps precisely. 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 15-25 °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 collection of capillary blood samples by laypersons and does not have its own analysis function; it is not intended for use as a self-test for diagnosis. Reuse may lead to false results and, under certain circumstances, to health risks.
- Avoid direct contact with mucous membranes. Wash your hands thoroughly with soap and water before and after taking the sample.
- The samples should be returned on the day they are taken, if possible. Until dispatch, the filled sample should be stored at room temperature (10-30 °C).
- No shipping 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 labeled 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.