

INSTRUCTION TEST SET 913

Hair mineral analysis



YOU RECEIVE

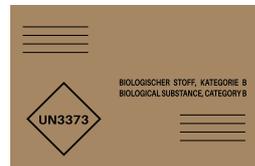
The sample tubes may already be inside the transport tubes.



1 x Request form



1 x Paper envelope



1 x Mailing bag

Purpose:

The Test Set 913 is intended for the independent collection of hair or nail samples by laypersons. The test set enables laboratory diagnosis of hair or nail mineral analyses 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
MEDICAL PROFESSIONALS
YOU TRUST.**

REF Order number: Test set 913

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 913

Storage temperature: 10-30°C

Inhouse 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 913

TEST INSTRUCTION

IMPORTANT

- Please send either hair or nails. If the materials are mixed, measurement will not be possible.
- Please use only untreated hair and nails. Hair treatments such as perms, dyeing or tinting, as well as nail polish, will affect the test result.
- If a sample of head hair is not possible, body or pubic hair can also be sent in.
- Armpit hair cannot be used!

1. Label the paper envelope with the name and type of material (head hair, pubic hair, fingernail). If you have received barcodes, use them to label the sample.

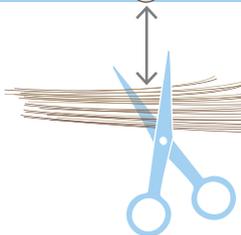
2. Sample collection

Hair from the head:

Wash your hair with a mild shampoo/soap and rinse thoroughly with clean water. Then dry your hair carefully.

Cut the hair at the lower back of the head in different places as close to the scalp as possible with clean scissors.

If the hair is longer than 4 cm: please trim the cut hair to 4 cm.

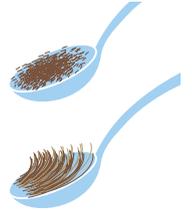


Body/pubic hair:

Wash the relevant area of the body with a mild soap and rinse thoroughly with clean water.

Then dry the hair carefully.

Cut the hair in different places as close to the skin as possible with clean scissors.



IMPORTANT

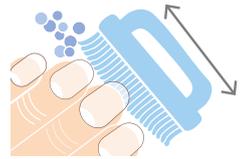
At least 1 tablespoon of hair is required.

Fingernails:

Wash your hands (using a nail brush if necessary) and dry them thoroughly.

If possible, cut the nails from all 10 fingers using clean scissors.

If cutting the nails once does not yield enough sample material, you can collect the nails over a period of 1-2 months.



IMPORTANT

At least 1 teaspoon of nails is required.

3. Place the sample material in the paper envelope and seal it.

biovis[®] DIAGNOSTICS

Sample ID: _____

Sample Name: _____

Sample Type:

Hair from Head

Hair from Pubic Area

Fingernails

Instructions for Sample Collection:

1. Wash hands thoroughly with soap and water.

2. Dry hands thoroughly.

3. Place sample in envelope and seal.

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

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

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



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

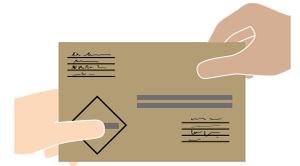
Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the mailing envelope.

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



6. 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 913 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 hair or nail samples by lay persons for subsequent determination by ICP-MS of 38 minerals, trace elements, and potentially toxic elements. Quantitative analysis is carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and is used to screen nutrient status and/or possible (heavy metal) contamination.
- 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 hair or nail sample and does not have its own analysis function; it is not intended for use as a self-test for diagnosis. Reuse can lead to inaccurate results and, in some circumstances, health risks.
- Wash your hands thoroughly with soap and water before and after taking the sample.
- Samples should be returned on the day they are collected if possible. Until dispatch, the filled sample must be stored at room temperature (10-30 °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.