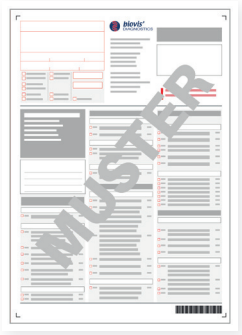
INSTRUCTIONS TEST SET 909

Histamine in stool

YOU RECEIVE

The sample tubes may be located in the transport tubes.

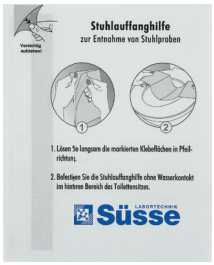
Test implementation: 1**5-30 min**



1 x Request form

1 x Transport tube

1 x Special histamine tube



1 x Stool collector

1 x Name label

1 x Mailing bag

Purpose:

The Test Set 909 is intended for the independent collection of stool samples by laypersons. The test set enables the sample to be stabilised for further laboratory diagnostic determination of histamine for more detailed analysis 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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biovis.de

REF Order number Test set 909

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 909

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).

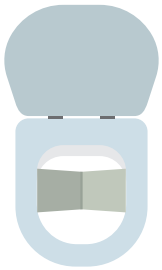
Use by – see sticker Test set 909

TEST INSTRUCTIONS

Note:

In the days before the test, please eat as you normally would and avoid any unusual or extreme behaviour. Also, do not take any antihistamines or high doses of biotin (> 5 mg/day) 24 hours before the test.

1. Place all the materials in front of you as shown in the picture. Place the stool collector on the toilet seat.



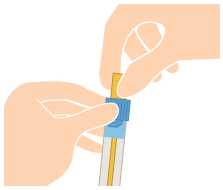
IMPORTANT

The stool sample should not come into contact with cleaning agents.

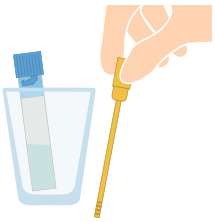
2. The practice should have already labelled the sample tube with a barcode for you.

If not, write your name and the date of sample collection on the name label and attach it to the sample tube.

3. Take the special histamine tube. Hold the blue cone insert with one hand and unscrew the yellow cap with the other hand.



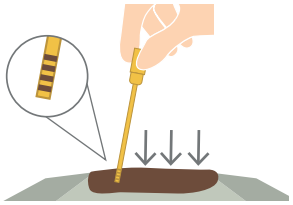
Make sure that the sample tube is positioned vertically so that the liquid cannot escape.



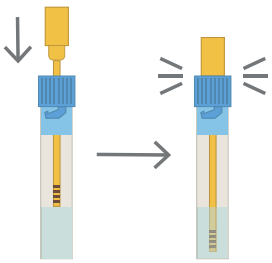
IMPORTANT

The blue cone insert remains closed on the stool sample tube.

4. Insert the stool sample at three different spots into the stool sample, until the grooves of the dosing tip are filled with stool sample.

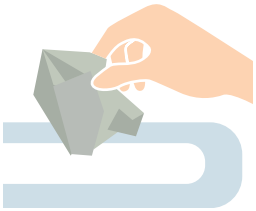


5. Put the dosing stick back into the tube and turn the yellow cap until you hear it click into place.



The dosing stick must not be pulled out again. If the sample has been pushed into the tube more than once and the liquid changes colour, the sample can no longer be measured.

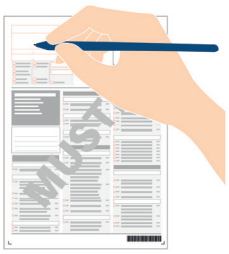
6. Remove the stool collector from the toilet seat. It is water-soluble and can be flushed away.



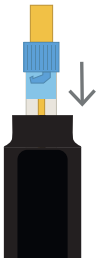
7. Please fill in the request form legibly (in digital or printed letters).

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

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



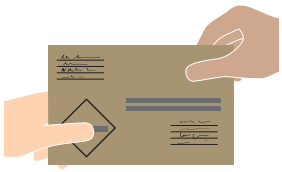
8. First pack the sample tubes in the transport tubes and then place them in the mailing bag with the completed and signed request form.



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 909 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 stool samples by lay persons for subsequent determination of the histamine concentration in stool 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 histamine intolerance.
- 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 2-30 °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 stool sample 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.
- Handling biological samples: The stool sample is potentially infectious.
- Avoid contamination: The stool collector and the sample tube must not come into contact with cleaning agents, disinfectants, or other substances, as this may interfere with the measurement in the laboratory.
- Avoid direct contact with skin and mucous membranes. Wash your hands thoroughly with soap and water before and after sampling.
- Samples should be returned on the day they are collected if possible. Until dispatch, the filled sample must be stored in a refrigerator (15-25 °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.