

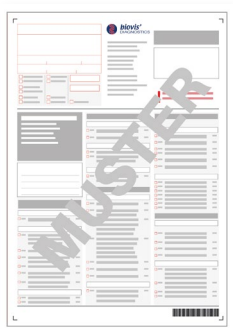
# INSTRUCTIONS TEST SET 919

## Food intolerances



**biovis**  
DIAGNOSTICS

### YOU RECEIVE:



1 x Request form



2 x Disinfectant wipes



2 x Sterile plaster



2 x Lancets



1x Name label



1 x Blood collection tube with capillary



1 x Transport tube

Test implementation: **20-30 min.**



### Purpose:

The Test set 919 is intended for the independent collection of capillary blood samples by lay persons. The test set enables sample collection for further laboratory diagnostic determination of IgG4 antibodies to various foods 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.

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

**Manufacturer:**  
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Fax: +49 6431 21248 66  
info@biovis.de  
[biovis.de](http://biovis.de)

**REF** Order number: Test set 919

**Storage temperature:** 10-25°C

**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.

**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 919

**Use by** - see sticker Test set 919

# TEST INSTRUCTIONS

## What you should consider before performing the test:

If you have taken cortisone or other immunosuppressants at the time of testing or within the previous three weeks, testing is not recommended. During pregnancy (and in some cases also during breastfeeding), false-negative results may occur, which is why testing may not be recommended. Please discuss this with your practice if necessary.

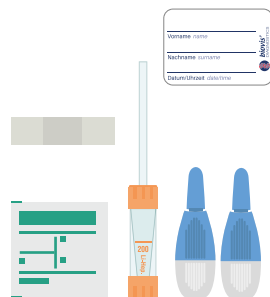
In the weeks before the sample is taken, you should have regularly consumed the foods to which you (may) be allergic.

## Contraindications:

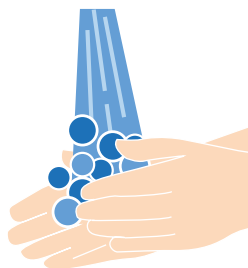
Taking cortisone and/or immunosuppressants.

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

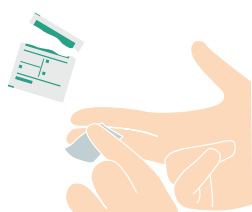
Also, keep a clean cloth handy.



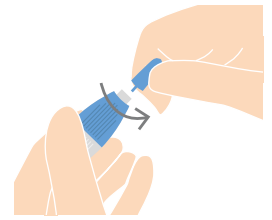
**2.** Wash your hands thoroughly with warm water. If your hands are still cold, you can move your fingers or swing your arms alongside your body.



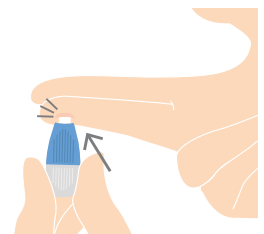
**3.** Remove the disinfectant wipe from the packaging and use it to disinfect the tip of your ring or middle finger.



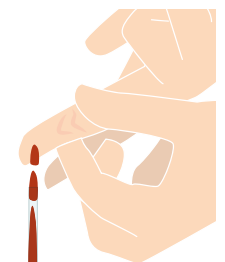
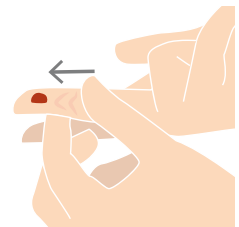
**4.** Take the lancet, turn the protective cap once around its axis and pull it off.



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



**6.** Hold your hand horizontally and massage your finger from below to the puncture site until a drop of blood forms. Hold your finger at an angle to the capillary of the blood collection tube so that the blood can flow into it. Continue massaging your finger. Fill the tube up to the mark.

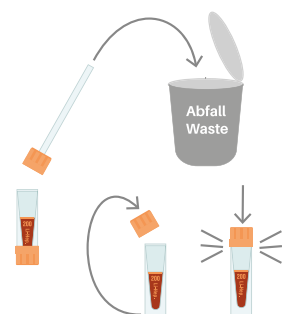


**Tap the tube gently on the table several times to allow the blood to flow in.**

**Do not squeeze the blood out of your finger.**

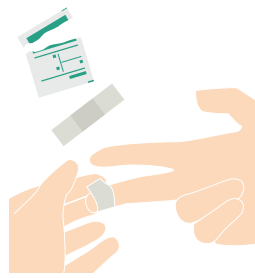


**7.** Grasp the upper orange cap and pull to remove the capillary tube. Pull off the orange cap at the bottom of the tube and use it to seal the upper opening.



To do this, press the cap onto the opening until you hear a click.

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



**9.** The practice should have already labeled the sample tube with a barcode for you.

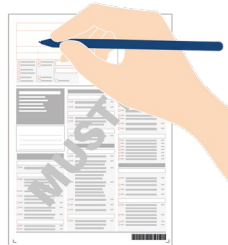
If not, write your name and the date of sample collection on the name label and attach it to the tube.



**10.** 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.



**11.** Place the sample tube and the completed and signed request form back into the envelope.

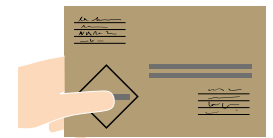
Pull on the marked tab to remove the adhesive strip that has already been used. Use the inner adhesive strip to seal the shipping bag.

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



**12.** 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 purpose according to Regulation (EU) 2017/746 (IVDR):**

- Test Set 919 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 IgG4 antibodies to various foods using ELISA. The 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 food intolerances.
- The product is intended for single use outside of clinical facilities.
- Samples are collected 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 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 10-25 °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 only intended for the one-time collection of a capillary blood sample by lay persons 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 of collection 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 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.