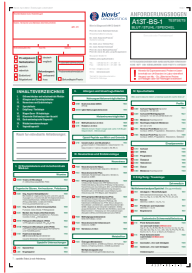


T911 TEST INSTRUCTION

Aromatogram - Flora status



YOU RECEIVE



1 x Request form



2 x Smear kit blue
(culture)



1 x Smear kit red
(PCR)



1 x pH Self-test



1 x Mailing bag

Purpose:

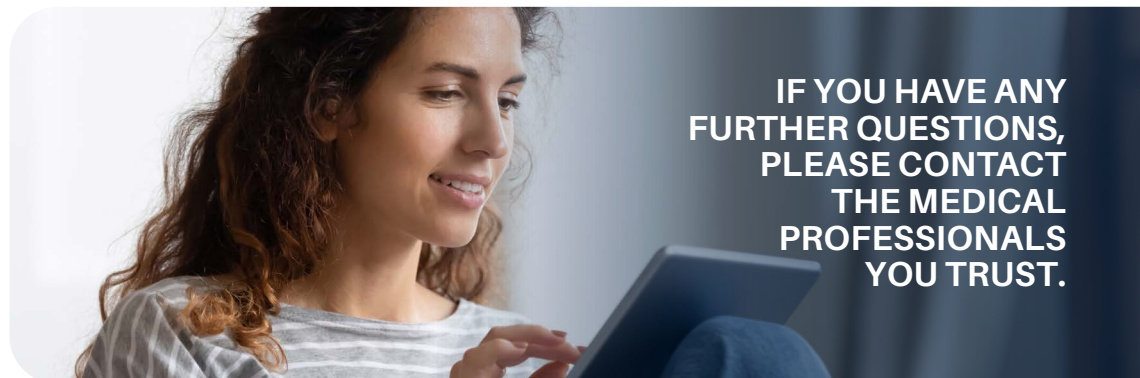
The T911 vaginal smear test set is designed for the independent collection of smear samples from the vaginal mucosa by the patient herself. It offers a simple and safe way to take vaginal smears independently for further analysis by biovis Diagnostik MVZ GmbH and to determine the vaginal pH value. Further information on the intended purpose in accordance with Regulation (EU) 2017/745 can be found at the end of the instructions.



Manufacturer:


 biovis Diagnostik MVZ GmbH
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Tel.: +49 6431 21248 0
Fax: +49 6431 21248 66
info@biovis.de


biovis.de




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


 Order number Test set T911

 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.

 Batch number - see label on test set T911

 Storage temperature 10-30°C

 In-house
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 T911

TEST INSTRUCTION

Aromatogram - Flora status

IMPORTANT

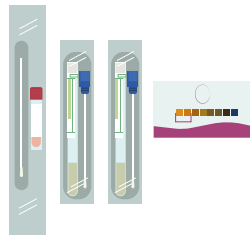
Do not perform the test during menstruation and wait at least 24 hours after sexual intercourse.

Shower before performing the test and do not use the toilet afterward.

Further information in accordance with Regulation (EU) 2017/745 can be found at the end of the instructions.

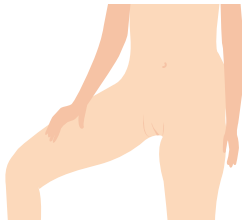
1. Place all the materials in front of you as shown in the picture.

Before performing the test, wash your hands thoroughly with soap.



2. Get into a comfortable position (for example, as if you were about to insert a tampon).

Please do not use any lubricant for the sample collection.



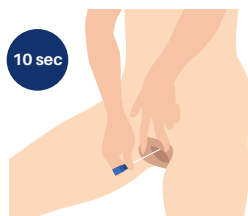
3. Open a blue smear kit and twist off the white sealing cap of the sample tube.

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



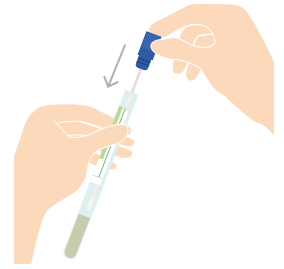
4. Use one hand to open your labia and, with the other hand, insert the blue swab into your vagina for about 10 seconds. The swab should be coated with vaginal fluid.

Please be sure not to touch any other areas outside the vagina with the swab, to prevent contamination of the sample.



5. Then insert the blue swab into the sample tube until it is sealed.

Repeat the procedure with the second blue swab set.



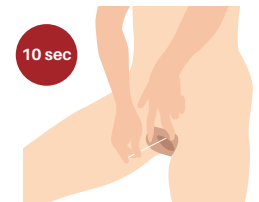
6. Open the red smear kit. Unscrew the red cap of the sample tube.

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



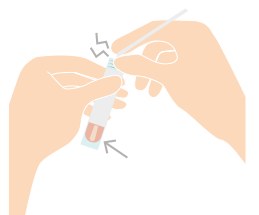
7. Use one hand to open your labia and, with the other hand, insert the red swab into your vagina for about 10 seconds. The swab should be coated with vaginal fluid.

Please be sure not to touch any other areas outside the vagina with the swab, to prevent contamination of the sample.



8. Then insert the red swab until it touches the bottom.

Grip the swab stick above the opening of the tube and bend the swab stick until it breaks at the break point.



9. Close the sample tube with the red cap until you hear a 'click'.

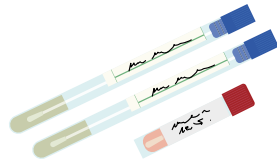


TEST INSTRUCTION

10. Now determine your vaginal pH level using the included pH self-test. Then, record the pH value on the request form.



11. Finally, label all the sample tubes with your name and date of birth.



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.

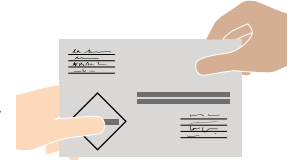
Aromatogram - Flora status

13. Pack all the sample tubes and the completed and signed request form in the mailing bag and seal it.



14. Preferably take the mailing bag to a post office or to your doctor/therapist.

Please do not send on Fridays, weekends or public holidays and do not drop in letterboxes.



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

- The vaginal smear test set T911 is intended for the independent collection of smear samples from the vaginal mucosa by the patient herself.
- The set contains three sterile smear sets for taking vaginal samples and a pH self-test to determine the vaginal pH value. In addition, the test kit contains the 'examination order' form and an envelope for returning the sample to the laboratory.
- This kit is intended for independent use by adult women in a domestic environment. It offers a simple and safe way to take vaginal smears independently for further analyses by biovis Diagnostik MVZ GmbH and to determine the vaginal pH value.
- The samples taken consist of vaginal secretions obtained using the sterile swabs. The pH test is determined by direct contact of the test strip with the vaginal fluid; the measured pH value is entered in the test order.
- The smear samples and the completed and signed examination order are sent to the medical laboratory biovis Diagnostik MVZ GmbH for further analysis. The vaginal smears are used for the cultivation and molecular-genetic analysis of various microorganisms that may be present in the vaginal mucus.
- The samples obtained cannot and must not be used for the diagnosis of diseases by the patient herself or independent third parties, but must be sent to biovis Diagnostik MVZ GmbH for further analysis by qualified medical personnel.

Safety instructions for the use of the smear set and the pH self-test according to Regulation (EU) 2017/745 (MDR):

- Only use the set in accordance with the instructions. Read the enclosed instructions for use carefully and follow all steps precisely. Improper use may lead to inaccurate results.
- Store the set in a cool, dry place away from light. Ensure that it is kept out of the reach of children.
- Check the expiry date on the packaging of the test set before use. Do not use the set after the expiry date, as the reliability of the results may be impaired.
- Wash your hands thoroughly with soap and water before and after use to avoid the risk of contamination.
- The smear sets are sterile packed. Do not use the set if the packaging is damaged or opened. Do not use the smear set and the pH test if you are currently suffering from an acute vaginal infection, severe irritation/discomfort, unusual bleeding, open wounds, or injuries in the vaginal region. In such cases, please contact a doctor at.
- If you are pregnant or suspect that you are pregnant, consult a doctor before using the set.
- Insert the swab carefully and without force into the vagina. Do not apply excessive pressure and stop using the swab immediately if you feel any pain or unusual discomfort.
- Each smear set and the pH test are intended for single use only. Do not use the components more than once and do not pass them on to others.
- Avoid contact of the test materials with the eyes. If this does occur, rinse the eyes thoroughly with clean water immediately and seek medical attention if discomfort persists.
- If you are unsure about the application or notice unusual symptoms, contact a healthcare professional.
- The self-test is not a substitute for professional medical diagnosis and treatment.
- After use, dispose of the smear set in accordance with local regulations for household waste. Do not flush any parts of the set down the toilet.