INSTRUCTIONS TEST SET 927

Oestrogen metabolites (F325)

biovis' DIAGNOSTICS

YOU RECEIVE

The sample tube is located in the transport tube, if applicable

Test implementation: **10 min.**
Time: **in the morning (on an empty stomach)**

1 x Request form

1 x Transport tube (light-protected)

1 x Stabilised centrifuge tube (contains a stabiliser strip that must not be removed!)

ADDITIONALLY:

1 x Transfer pipette

1 x Name label

1 x Shipping bag

1 x Urine cup (Available from your practice. Alternatively, use a disposable cup.)

Intended use:

The Test Set 927 is intended for the independent collection of urine samples by lay persons. The test set enables the stabilisation of the sample for further laboratory diagnostic determination of oestrogen metabolites 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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REF Order number Test set 927

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 927

Storage temperature: 15-25°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 927

TEST INSTRUCTIONS

Note

The following conditions must be met when performing the test:

Please avoid the following 24 hours beforehand:

- Meat, dairy products, soy products, legumes, cucumbers, chocolate, alcohol, and nicotine.
- Sexual contact
- When taking hormonal preparations and using hormone creams, anti-ageing creams, and other hormone-containing preparations (e.g. including plant-based phytoestrogens or similar), the treating practice must decide on an individual basis whether these should be discontinued beforehand. Appropriate therapy can influence the test result and must be taken into account in the subsequent evaluation. In the case of hormonal contraception, a meaningful evaluation of the results is only possible to a limited extent.

Avoid making any sudden changes to your lifestyle, such as changing your diet or altering your intake of medication and dietary supplements. In the days leading up to the test, eat as you normally would and avoid extreme behaviour. In this case, wait a while to prevent any influences.

During pregnancy, breastfeeding, after childbirth, and in children and adolescents – i.e. during phases in which hormone levels deviate significantly from the typical adult profile, it is not possible to reliably interpret the results. Therefore, testing is not recommended.

IMPORTANT

Use the **second morning urine sample**. The second morning urine sample must be collected at least 2–4 hours after the first morning urine sample in the morning – not before! Please do not drink excessively during this time. Water and fruit tea are generally allowed in moderation (max. 1/2 litres).

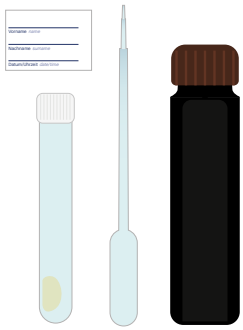
The sample must be taken **on an empty stomach**. The last meal should have been at least 8 hours ago.

Collect the urine sample during the luteal phase (second half of the cycle), preferably around the 21st day of the cycle.

If you are in the postmenopausal phase (at least 1 year after your last menstrual period), the timing is irrelevant.

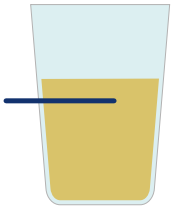
1. Place all the materials in front of you as shown in the picture.

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



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

3. Fill the urine cup (not included in the test set) at least halfway.



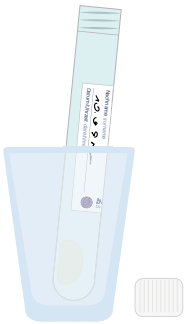
IMPORTANT

Use **midstream** urine.

Midstream urine is a urine sample obtained from the middle of the stream. The first and last parts of the urine are not collected.

4. Open the centrifuge tube and place the lid to one side.

Note:
Make sure to position the centrifuge tube vertically so that the stabiliser sheet cannot escape.

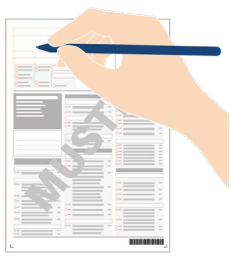


5. Hold the transfer pipette at the top and squeeze it together. Dip the pipette into the urine and release the grip so that the urine is drawn up. Pour the urine into the centrifuge tube. Repeat the process until the centrifuge tube is filled to the mark. Then reseal the centrifuge tube.

6. Place the centrifuge tube in the transport tube (light-protected).

7. Fill out the request form legibly (in digital or block letters).

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



In addition, fill in the information about your cycle phase and any hormone-containing medications you are taking on the request form and note the day of your cycle on which the sample was taken.

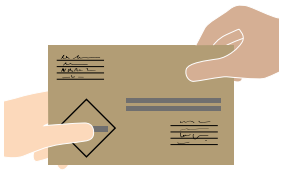
Fill in the declaration on the back and sign the request form.

8. Put the sample tube and the completed and signed request form back into the shipping bag.

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 kit name if you wish to do so for reasons of discretion.

9. 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 a Friday, at the weekend or on 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.

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

- The Test Set 927 is an in vitro diagnostic medical device (IVD) in accordance with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). It is used for the standardised, non-invasive collection of urine samples by lay persons for the subsequent determination of oestrogen metabolites (2-hydroxyoestron, 4-hydroxyoestron, 16-hydroxyoestron, 2-methoxyoestron, 4-methoxyoestron and two ratios) using LC-MS/MS. Quantitative analysis is carried out exclusively in the laboratory of biovis Diagnostik MVZ GmbH and is used for general cancer screening and cancer screening under hormone replacement therapy.
- 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 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 a urine sample 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.
- Please note the above instructions, which must be observed before performing the test! If in doubt discuss the use of the test with your doctor before performing it.
- Handling biological samples: The urine sample is potentially infectious.
- 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.