



1. Test Method & Application Area

Epigenetic test for detecting endometrial carcinoma in peri- and postmenopausal women with abnormal bleeding, with a significant reduction in the false-positive rate compared to sonography.

2. Material

- Sample collection vials: Copan MSwab® (or eNAT®)
- Collection swabs: Copan “regular” or “L-shaped” FLOQSwabs®

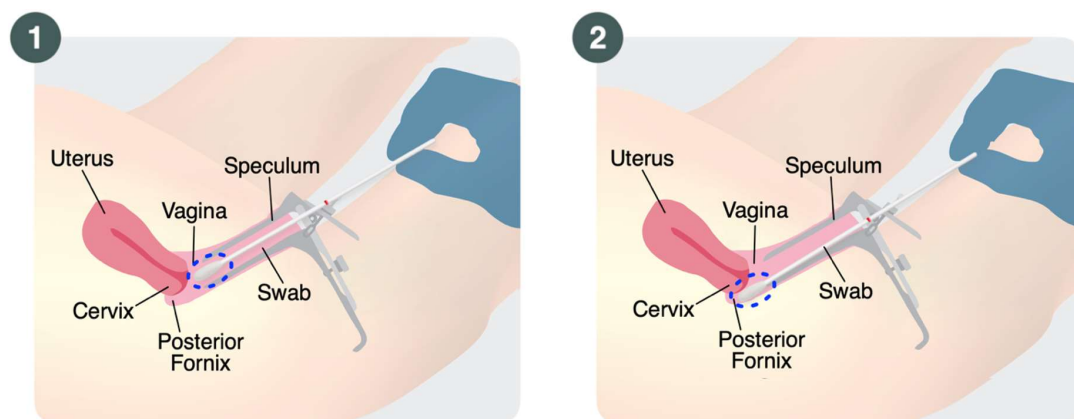
3. Preparation of the Patient

- The presence of blood or cell debris in the vagina does not interfere with the WID®-easy test, so there is no need to remove blood, mucus, or cell debris beforehand.
- Sample collection for the WID®-easy test should be done before other sample collections (e.g., Pap smear) or examinations (e.g., transvaginal ultrasound).

4. Sample Collection

As appropriate sample collection is crucial for downstream analysis, please make sure, that every member of the sample collecting staff is well informed beforehand.

1. Please label a sample vial (name & date of birth) and fill out a requisition form.
2. Visualize the cervix and the posterior fornix (speculum with little or no lubricant).
3. Insert the collection swab into the upper vaginal area, near the cervix (see Figure 1).
4. Hold the collection swab in this position and slowly rotate it 360° degrees once (for 2-3 seconds).
5. Then insert the collection swab into the posterior vaginal fornix, as shown in Figure 2.
6. Again, hold the collection swab in position and slowly rotate it 360° degrees (for 2-3 seconds).



Optimal positions for sample collection: Figure 1: In the upper vaginal area and Figure 2: In the area of the posterior fornix.





7. Transfer the FLOQSwab® into the sample tube and, holding the tube away from the face, break the swab at the red-marked break point using the tube edge. Screw on the lid of the tube.
8. Shake the sample tube by 10x full rotations and store at room temperature (2-25°C).

5. Patient Data (Referral Form)

The referral form must contain the following data:

- Patient data: Surname, first name & date of birth, Residential address of the patient.
- Insurance number (NIN), as unique person identifier.
- Referrer data: Practice address, stamp & signature.
- Accurate and complete clinical information is important for optimal test results! Therefore, please provide information on all fields listed on the requisition form as necessary.

6. Packaging Requirements & Shipping

Please note that the shipment of medical samples is considered hazardous material transport, and the postage and customs effort are determined accordingly. Therefore, compliance with packaging regulations and correct labeling is essential to guarantee minimal sample transportation time.

- Waterproof primary container (= Copan sample vial).
- Waterproof secondary packaging with water absorbing inlay (e.g. screwable plastic container).
- Sufficiently sturdy outer packaging (e.g. padded envelope for postal shipment).
- Please label the envelope containing samples with the term "**EXEMPT HUMAN SPECIMEN**".
- Please enclose a fully completed requisition form for each sample.
- For transfers from non-EU-countries: Please observe the national and/or EU customs regulations. Fill out the necessary customs documents and include them with the shipment (usually, the customs documents are provided by your transportation service provider). Please ensure that the customs documents are prominently and easily removable from the outside. The customs tariff number for sample shipments is: **38229000** (Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 3006; certified reference materials: other)
- Samples sent under this number will be customs cleared at 0% of their commercial value. However, please still fill in a commercial value greater than 0.
- Any deviation from the requirements specified here may result in the return of the sample shipment by the customs office or the transportation service providers.
- The Copan MSwab® tubes preserve methylation, DNA and RNA up to 14 days at room temperature. The Copan eNAT® tubes even for up to 28 days.

7. Criteria for Acceptance and Rejection of Samples

Please note that the laboratory can only accept samples that are:

- Clearly identifiable.
- Assignable to a requisition form.
- Fixed in the container appropriate for the respective test.





Missing or incorrect information on the requisition form will be requested or corrected by telephone if possible. However, this may lead to delays in processing.

8. Price and Billing

The price per test is € 250 and will be billed to the referrer. Costs for postal sample delivery, due to changes in the exchange rates and medical treatment are not included or covered by Tyrolpath.

9. Contact & Further Information

The DNA extraction will be performed shortly after reception of the sample. The samples will be analyzed within 12 working days after sample reception.

To transmit the reports, a secure transmission method will be established. Please contact us in advance to discuss and set up this transmission method with you.

For further information about the scientific test principle please visit www.sola-diagnostics.com online. Detailed information on handling the sample collection system can be found in the package insert from the Copan company.

For any further questions, please feel free to contact us at the following extensions:

+43 5442/666 11

Extension – 260 Sample Collection & Logistics

Extension – 210 Sample Reception & Referral

