Sola Diagnostics GmbH

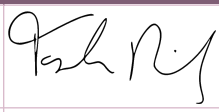
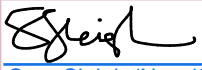
WID®-easy PCR Kit: Sampling Instructions

Document Code	SI-WIDeasy-UKCA-001	**Version**	1.1
Applies To	WID®-easy PCR Kit — UK-CA marked		
Effective Date	Per Approved By signature	**Document Owner**	Quality Director
Legal Manufacturer	Sola Diagnostics GmbH, Innsbruck, Austria		

Revision History

Version	Effective Date	Approved By	Description of Change
1.0	2026-08-20	Quality Director	Initial controlled release
1.1	Per Approved By signature	Quality Director	Check of swab and tube before use; leak check; labelling of the tube, collection date and pairing with the request form; three collection restrictions of the Instructions for Use; statement on who provides swab and medium removed; return as instructed by the supplier of the sampling kits; “sampling kit” used throughout

Document Approval

Stage	Role	Signature	Date
Prepared By	Quality Director		2026-11-17
Reviewed By	Clinical Affairs	 Sara Sleigh (Nov 17, 2026 11:19:53 GMT)	2026-11-17
Approved By	Quality Director		2026-11-17

Scope and regulatory positioning

These sampling instructions apply to the UK-CA marked WID®-easy PCR Kit, which has been registered as an in vitro diagnostic within Great Britain (England, Scotland, Wales). They describe the collection of the cervicovaginal specimen from which DNA is subsequently isolated and bisulfite-converted for analysis. Sampling is performed by qualified clinical personnel; the WID®-easy PCR Kit is not applied to the specimen directly.

These sampling instructions must be read in conjunction with the Instructions for Use for the UK-CA marked WID®-easy PCR Kit, published at wid-easy.info, in particular the section “Limitations of Use”. In the event of any discrepancy, the Instructions for Use take precedence.

Translations of this document are derived from the English original. The English version is the reference text and prevails in the event of any discrepancy.

Materials

- Sampling is carried out using the Copan FLOQswab™ (552C.80PB) and eNAT medium (608C) from Copan. A corresponding sampling kit (608CS01R) is also available.
- Before use, check that the swab and the eNAT® tube are undamaged and within their expiry date. Do not use a damaged or expired swab or tube. Use one tube per patient.

Before sampling

IMPORTANT It is important that the vagina is not cleaned ahead of any sample taking & that minimal (preferably no) lubricant is used when inserting the speculum.

The sample collection for the WID®-easy test takes place

- ✓ before taking a sample for another test, e.g., for a PAP smear.
- ✓ before inserting another substance into the vagina or near the cervix, such as acetic acid or Lugol iodine, for visual inspection (VIA).
- ✓ before transvaginal sonography.
- ✓ or at the earliest three days after these measures.

Also note

- Do not collect samples: during the menstrual cycle or within 24 hours after sexual intercourse without a condom.
- Use of lubricant should be avoided if possible.
- The aim is to collect vaginal secretions using the swab rather than to scrape cells from the cervix.
- Avoid cleaning the vagina of blood or other secretions before taking the sample.

Taking the sample

1. Insert the speculum to visualise the cervix and the posterior fornix.
2. Insert the Copan swab into the vagina and first take a sample in the upper vaginal area, if possible without touching the cervix (see Fig. 1).
3. Hold the swab in this position whilst rotating it slowly once through 360 degrees (for 2-3 seconds).
4. Re-position the swab into the posterior fornix of the vagina, as depicted in the Fig. 2.
5. Again, hold the swab in position whilst rotating it slowly through 360 degrees for 2-3 seconds.

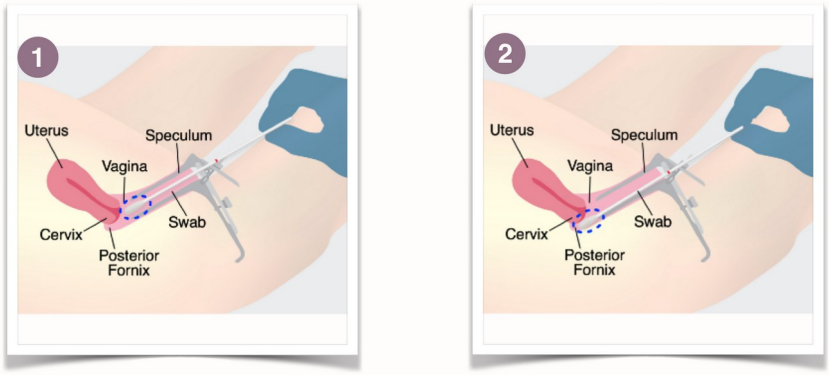


Fig. 1 and Fig. 2: Swab positions — upper vaginal area (1) and posterior fornix (2).

Transferring the swab into the eNAT® tube

1. Remove the swab from the vagina.
2. Unscrew and remove the cap from the eNAT® tube, taking care not to spill the medium.
3. Insert the swab into the tube until the breaking point (red mark) reaches the level of the opening of the tube (Fig. A).
4. Bend the swab shaft at a 180 degree angle to break it off at the breaking point holding the tube away from the face (Fig. B). If needed, gently rotate the swab shaft to complete the breakage and discard the upper part of the swab shaft into clinical waste.
5. Replace the cap on the tube and close tightly (Fig. C). Check that the tube does not leak.
6. Flick-mix the tube 10 times and store the sample in an upright position for at least 5 minutes at room temperature.
7. Label the tube with the patient identification and check that it matches the request form. Note the collection date on the request form. Place the tube and its request form together in one specimen bag before you sample the next patient.
8. Store locally at room temperature until shipment to the Laboratory.
9. Please return the collection tube to your laboratory, following the instructions you received from the supplier of your sampling kits.

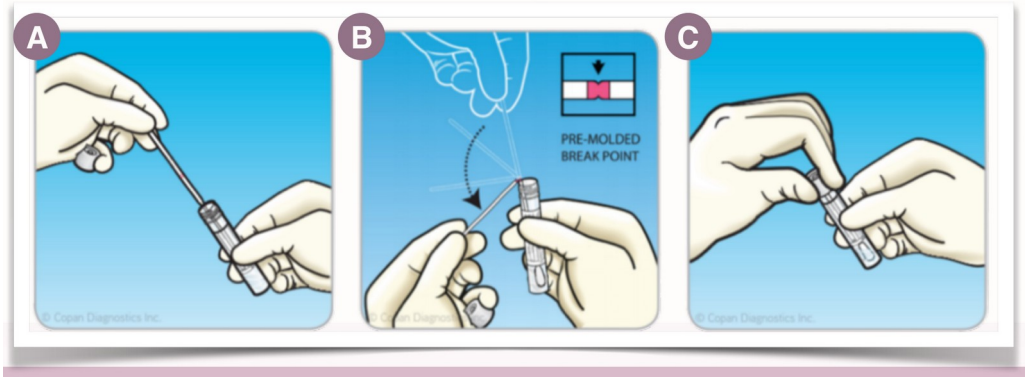


Fig. A, B and C: Inserting the swab, breaking it at the pre-moulded break point, and closing the tube.

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Status:	Signed
Transaction ID:	CBJCHBCAABAADqJ745qkDp8yV_SYpkFs6fguY6yX-BvB

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Document e-signed by David Tschabitscher (tschabitscher@sola-diagnostics.com)
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2026-11-17 - 10:59:05 AM GMT

Email viewed by Sara Sleigh (sleigh@sola-diagnostics.com)
2026-11-17 - 11:19:42 AM GMT

Document e-signed by Sara Sleigh (sleigh@sola-diagnostics.com)
Signature Date: 2026-11-17 - 11:19:53 AM GMT - Time Source: server - Signature Appearance Selected: DRAW

Document emailed to tschabitscher@sola-diagnostics.com for signature
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