

Corewell Health LaboratoryDearborn • Farmington Hills • Grosse Pointe • Royal Oak • Taylor • Trenton • Troy • Wayne

HUMAN PAPILLOMAVIRUS (HPV) - TESTING UPDATE**Date: February 3, 2025**

Human Papillomavirus (HPV) Genotypic testing, formerly HPV DNA DETECTION, (LAB 1231019, HPVHR), will be updated to expand acceptable sources and collection methods. Additionally, a new HPV assay has been implemented for cervical screening that specifically calls out HPV 16, HPV 18, HPV 45, and two groups of other HR-risk HPV genotypes (see test option #1 below). The following three HPV tests will be available, and the corresponding testing algorithm will be driven by the clinician specified specimen source and collection method/device.

1. HPV High-Risk Screen with HPV Genotype Reflex – Cervical Source (LAB1231770)

Detection of 14 high-risk (HR) HPV genotypes:

- HPV Genotype 16
- HPV Genotype 18
- HPV Genotype 45
- Other HR genotypes-A: (31, 33, 52 and 58)
- Other HR genotypes-B: (35, 39, 51, 56, 59, 66, and 68)

Collection Information:

- Acceptable Source: Clinician-collected cervical
- Collection Device: Cervical brush
- Container: ThinPrep® PreservCyt® Solution

2. HPV High-Risk Screen with HPV Genotype Reflex – Vaginal Source (LAB1231772)

Detection of 14 HR HPV genotypes:

- HPV Genotype 16
- HPV Genotype 18
- Other HR HPV - includes 31,33,35,39,45,51,52,56,58,59,66,68

Collection Information:

- Acceptable Source: Clinician-collected vaginal
- Collection Device: Cervical brush
- Container: ThinPrep® PreservCyt® Solution

3. Self-Collect HPV High-Risk Screen with HPV Genotype Reflex (LAB1231853)**Testing Restricted to HPV only –Co-testing Not Available: PAP or STI (ICNG, TV)**

Detection of 14 HR HPV genotypes:

- HPV Genotype 16
- HPV Genotype 18
- Other HR HPV - includes 31,33,35,39,45,51,52,56,58,59,66,68

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Collection Information:

- Acceptable Source: Patient Self-collected vaginal
- Collection Device: Rovers® Evalyn® Brush
- Collection Instructions: Patients must use the Evalyn Brush in a healthcare setting to self-collect a vaginal specimen following the Evalyn Brush collection instructions. A trained healthcare staff member must immediately suspend the Evalyn Brush into a vial of ThinPrep PreservCyt solution following transport instructions. The ThinPrep PreservCyt vial can then be transported to the lab at 2 to 30°C.
- Rovers® Evalyn® Brush Collection [Evalyn Brush Self Collection.pdf](#) and [Transport Instructions](#)

If you have questions, please contact your Corewell Health Laboratory Customer Service Department:

- Corewell Health Reference Lab East Customer Service: 800-551-0488 or 248-551-1155, Option 5
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Date Submitted: 1/23/2025**Submitted by:** Dr. Josh Shirley, D(ABMM), Technical Director, Microbiology and Molecular Pathology

Self collection instructions for Rovers® Evalyn® Brush

The Evalyn® Brush is to be used for the collection of vaginal specimens for use with the **cobas®** HPV or **cobas®** HPV Tests. Users should read and carefully follow these instructions. If you have any questions or difficulties with the collection process described below, please ask your healthcare provider for more information.

Should unexpected events not described in these instructions occur during self-collection, inform your healthcare provider.

WARNINGS:

- Inform your healthcare provider if you have used any substances such as vaginal creams, gels, lubricants, etc. within 24 hours prior to collection.
- The brush should not touch any other surface prior to inserting into vagina.

DO NOT USE:

- During pregnancy or within three months after giving birth
- If you have recently undergone gynecological surgery
- In case of unusual bleeding or pelvic pain



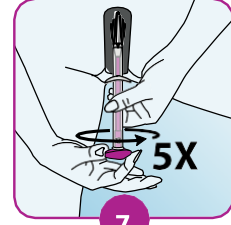
1

Wash your hands before usage.



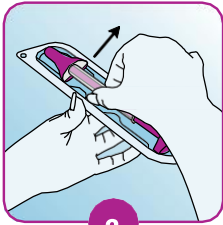
4

Obtain the sample whilst in a standing position. Assume a comfortable stance (e.g. as if you were about to insert a tampon).



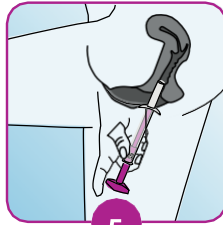
7

Turn the pink plunger five rotations in the same direction. After each rotation, you will hear a click. This helps you count the rotations. After turning the plunger five times, carefully remove the Evalyn Brush.



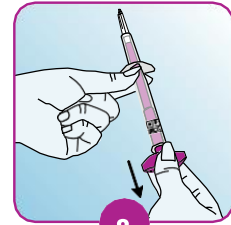
2

Remove the Evalyn Brush from the packaging. Do not throw the packaging away, as it is necessary for sending the Evalyn Brush to the laboratory after usage.



5

Spread your labia with one hand, and with the other, insert the Evalyn Brush into your vagina until the wings touch your labia.



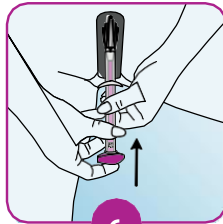
8

Hold the transparent casing with one hand, and with your other hand, pull on the pink plunger until the white brush disappears into the casing. When doing so, do not touch the top part of the Evalyn Brush above the wings.



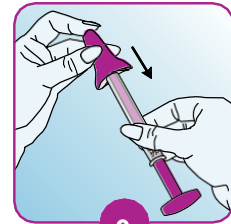
3

Press the sides of the pink cap with your thumb and index finger to remove the pink cap from the Evalyn Brush. Ensure that you do not touch the white brush of the Evalyn Brush with your hands!



6

Hold the transparent casing with one hand, and with your other hand, push the pink plunger in the direction of the transparent casing. You will hear and feel a click when the brush is in the right position with the pink plunger directly against the casing.



9

Hold the transparent end to ensure the white brush does not extend again. Place the pink cap back on the Evalyn Brush using your thumb and index finger. You will hear a click when it is properly in place.



10

Put the Evalyn Brush back inside the packaging. After collection, hand over the swab for processing.

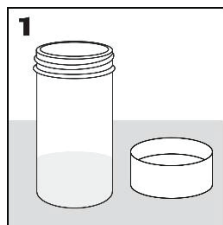
Sample suspension instructions for Rovers® Evalyn® Brush

Sample handling instructions for self-collected sample using Rovers Evalyn® Brush for testing with the cobas® 4800 HPV Test or cobas® HPV.

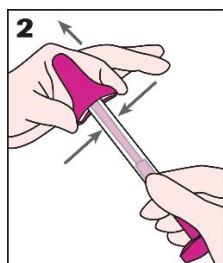
Self-collected sample must be placed into medium after sample has been collected.

- Read all instructions before starting sample suspension.
- For sample collection, follow the collection device manufacturer's Instructions for use.
- Once the sample has been collected, continue with the following instructions to preserve the sample:

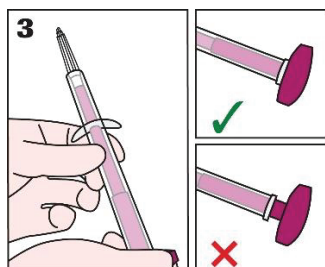
Handle the collected sample with care.



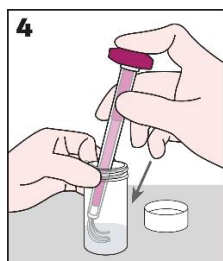
1. Carefully uncap the vial containing medium and place it on a stable, flat surface.



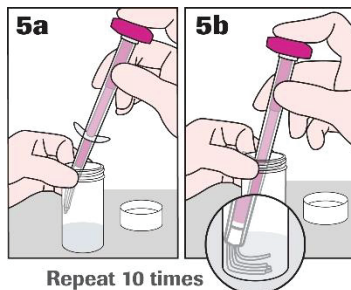
2. Remove the pink cap from the Evalyn Brush **taking care not to touch the exposed end.**



3. Press the pink plunger down until it clicks into place to expose the white brush. **Take care to keep the exposed brush from touching anything** (e.g., fingers, surfaces).



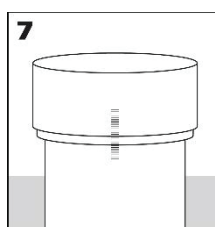
4. Hold the vial with one hand then with the other hand place the white brush into the vial so that the **bristles are fully immersed in the medium and the wings are past the opening of the vial.**



5. Holding onto the vial, vigorously plunge the brush, **smashing** the white brush **against the bottom and interior wall** of the vial **10 times to maximize sample release.** Be careful not to splash.



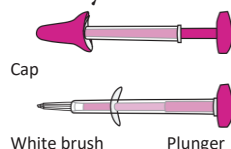
6. Remove the white brush by carefully drawing the brush up along the inner wall of the primary vial until the brush is no longer submerged in the medium. **Hold the brush against the inner vial wall to drain fluid** off the brush. Place the Evalyn brush back inside the packaging and discard.



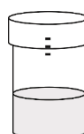
7. Re-cap the vial and tighten until the lines on the cap and vial meet or slightly overlap to prevent leakage. Store upright.

8. The sample can now be processed with the cobas® 4800 HPV Test or cobas® HPV.

Glossary



Evalyn Brush: The self collection device used to collect sample.



Vial: A container which contains 20 mL of clear solution. The specimen you collect will need to be transferred into this container and this container will be sent to the lab for processing.

Medium: What the liquid that comes in the vial is called.