

Test Update

Self-Collect HPV DNA Detection with Genotyping, PCR, Vaginal UVM Medical Center

Effective 7/15/26, the UVMHC Laboratory will begin to offer vaginal self-collect HPV DNA Detection with Genotyping, PCR testing. The FDA-approved validation includes only samples **collected in a clinical setting**. At home, self-collect sampling is NOT allowed.

In-house validation studies were successfully completed and demonstrated excellent agreement with provider-collected cervical samples. This additional screening option is expected to improve access to cervical cancer screening for many patients. Individual clinics choosing to implement self-collection should be prepared to instruct patients on collection. We will continue to offer testing on provider-collected HPV samples.

Test Build Information:

New Orderable	Epic Code	Atlas Code	Mayo Test ID	Order LOINC	CPT Code(s)
Self-Collect HPV DNA Detection with Genotyping, PCR, Vaginal	LAB17722	LAB17722	FAH6307	6510-2	87626
Result Component(s):	Epic Code	Atlas Code	Mayo Test ID	Result LOINC	Notes
HPV High Risk Type 16, PCR	12301002674	PAP021	FAH6308	82456-5	
HPV High Risk Type 18, PCR	12301018870	PAP022	FAH6309	77400-0	
HPV other High Risk types. PCR	12301002439	PAP023	FAH6310	44550-2	
Specimen Requirements:					
Container	Specimen	Temperature	Collect/Submit Vol	Min Vol	Stability
ThinPrep Vial	Vaginal	Ambient	20 mL	20 mL	30 days
Collection Information:					
Provide patient with a labeled Copan FLOQSwab and the accompanying self-collection instruction pamphlet.					
Clinical staff must suspend the sample in PreservCyt immediately after collection, prior to transportation of sample.					

See final section below for clinic instructions for resuspension of the sample in ThinPrep solution. FLOQSwabs can be ordered by contacting Lab Operations Support, (802) 847-5121.

Result Interpretations and Follow-up

Results	Follow-up
Negative HPV	Repeat testing in 3 years
Positive HPV (other high-risk genotypes)	Return for provider-collected Pap
Positive HPV (types 16/18)	Refer to colposcopy

If you have any questions about these changes or would like additional information, please contact Dr. Hanna Loving (hanna.loving@uvmhealth.org).

UVM Medical Center

Pathology & Laboratory Medicine

Location

111 Colchester Ave.
Burlington, VT 05401

Lab Customer Service

802-847-5121
800-991-2799

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Instructions for use

Collection of self-collected specimen

Self collection instructions for Copan FLOQSwabs® (552C.RM)

The FLOQSwabs® 552C.RM 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 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.

Open the swab just before use and be careful not to touch any surfaces with the swab tip.

WARNINGS:

Inform your healthcare provider if you have used any substances such as vaginal creams, gels, lubricants, etc. within 24 hours prior to collection.

Do not use:

- during pregnancy or in the three months after giving birth
- if recently undergone gynecological surgery
- in case of unusual bleeding or pelvic pain

Specimen collection during the menstrual cycle has not been evaluated.

In the 3 days prior to self-collection of a vaginal sample, use of vaginal ovules, creams or washes, vaginal contraceptives or condoms should be avoided.

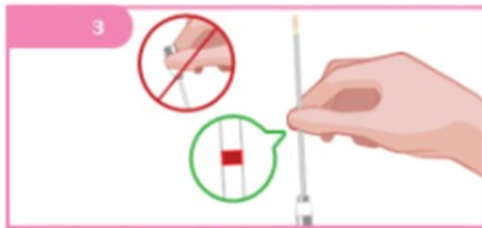
In the 2 days prior to self-collection of a vaginal sample, sexual intercourse and ultrasound scans or gynecological examinations should be abstained from.



Wash your hands with soap and water before starting.



Twist and pull cap to remove the swab from the tube.



Hold the swab at the red mark



Standing in a comfortable position, use the free hand to spread the skin of the vaginal opening, while carefully inserting the swab up to the red mark.



Gently rotate the swab for 10 to 30 seconds.
s= SECONDS



Place the swab back into the tube until you hear a CLICK.
After collection, hand over the swab for processing.

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Suspension of self-collected specimen

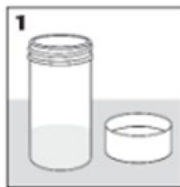
Sample suspension instructions for Copan *FLOQSwabs** #552C.RM

Sample handling instructions for self-collected sample using Copan *FLOQSwabs** #552C.RM for testing with the *cobas** 4800 HPV Test or *cobas** HPV.

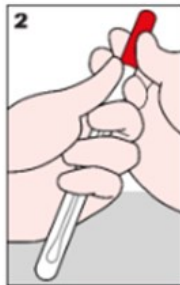
Self-collected sample must be placed into medium after sample has been collected.

- 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.



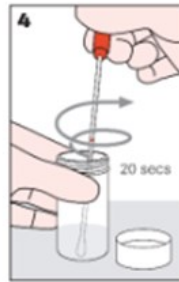
1. Carefully uncap the vial containing medium and place it on a stable, flat surface.



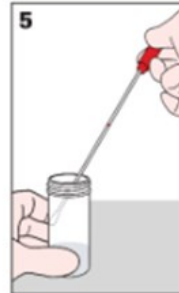
2. Slowly pull the FLOQSwab cap off to remove the swab from the tube. **Minimize touching the inner walls of the tube as you remove the FLOQSwab.**



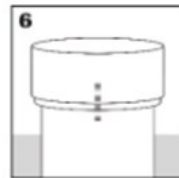
3. Hold the vial with one hand then with the other hand place the FLOQSwab tip into the vial until the FLOQSwab **tip is fully immersed in the medium and touching the bottom** of the vial.



4. Holding onto the vial, swirl the FLOQSwab along the inner vial wall for 20 seconds while ensuring the swab remains immersed in the medium. Be careful not to splash.



5. Carefully draw the FLOQSwab up along the inner vial wall until the tip is no longer immersed in the medium. **Hold the tip against the inner vial wall to drain fluid off of the swab.** Place the FLOQSwab into the tube and discard.



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

7. The sample can now be processed with the *cobas 4800 HPV Test or *cobas** HPV.**

Glossary



FLOQSwab/Swab: The self-collection device used to collect sample.



Tube: A protective container that the self-collected device will come in and can be used to temporarily store the collection device after the sample has been collected.



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.

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