

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.

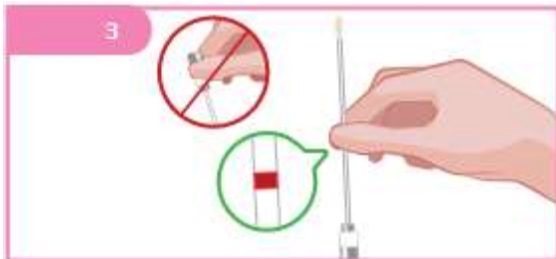
In the 2 days prior to self-collection of a vaginal sample, sexual intercourse and ultrasound scans or gynecological examinations should be abstained from.



Wash your hands with soap and water before starting.



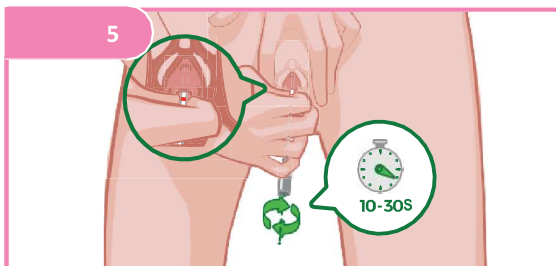
Twist and pull cap to remove the swab from the tube.



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.

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



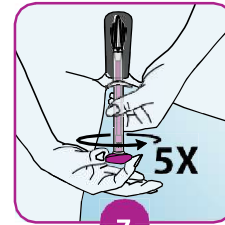
1

Wash your hands before usage.



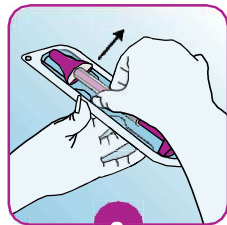
4

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.



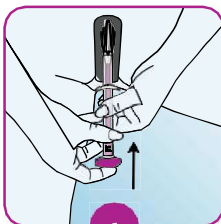
8

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.



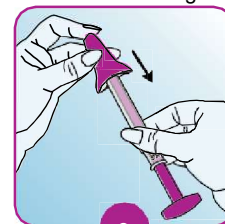
3

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!



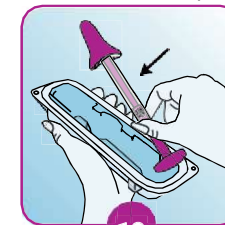
6

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.

Suspension of self-collected specimen

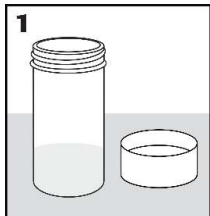
Sample suspension instructions for Copan FLOQSwabs® #552C.RM

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

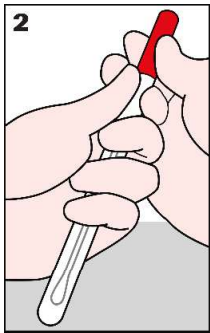
Self-collected sample must be placed into medium after sample has been collected.

- **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:

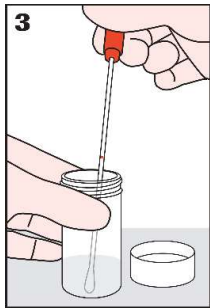
Handle the collected sample with care.



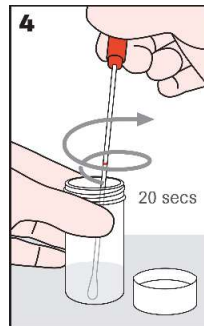
1. Carefully uncap the vial containing medium and place it on a stable, flat surface.



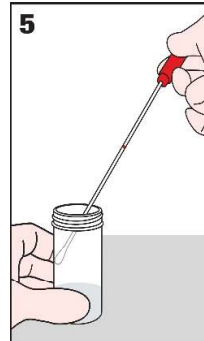
2. Slowly pull the FLOQSwab cap off to remove the swab from the tube. **Minimize touching the inner walls of the tube as you remove the FLOQSwab.**



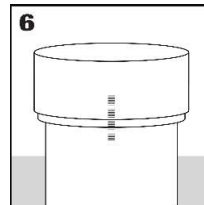
3. Hold the vial with one hand then with the other hand place the FLOQSwab tip into the vial until the FLOQSwab **tip is fully immersed in the medium** and **touching the bottom** of the vial.



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.



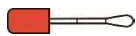
5. Carefully draw the FLOQSwab up along the inner vial wall until the tip is no longer immersed in the medium. Hold the tip against the inner vial wall to drain fluid off of the swab. Place the FLOQSwab into the tube and discard.



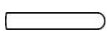
6. Re-cap the vial and tighten until **the lines on the cap and vial meet or slightly overlap** to prevent leakage. Store upright.

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

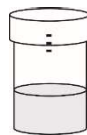
Glossary



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.

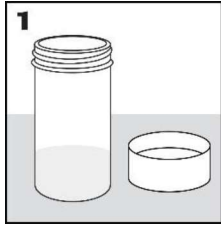
Sample suspension instructions for Rovers® Evalyn® Brush

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

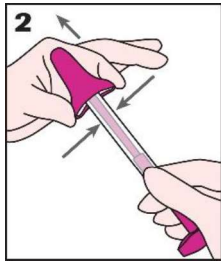
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- Read all instructions before starting sample suspension.
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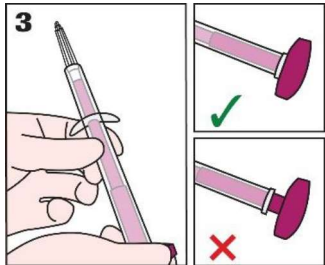
Handle the collected sample with care.



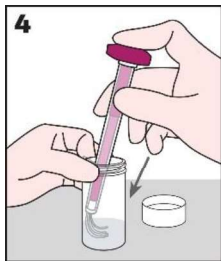
1. Carefully uncap the vial containing medium and place it on a stable, flat surface.



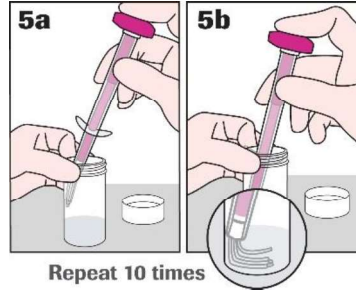
2. Remove the pink cap from the Evalyn Brush **taking care not to touch the exposed end.**



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).



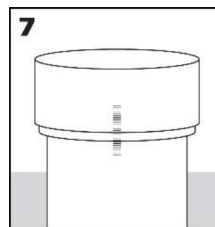
4. Hold the vial with one hand then with the other hand place the white brush into the vial so that the **bristles are fully immersed in the medium and the wings are past the opening of the vial.**



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.



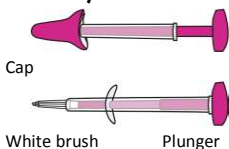
6. Remove the white brush by carefully drawing the brush up along the inner wall of the primary vial until the brush is no longer submerged in the medium. **Hold the brush against the inner vial wall to drain fluid** off the brush. Place the Evalyn brush back inside the packaging and discard.



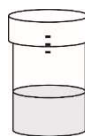
7. Re-cap the vial and tighten until **the lines on the cap and vial meet or slightly overlap** to prevent leakage. Store upright.

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.