

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.

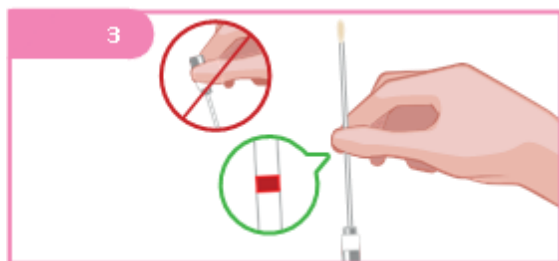
In the 2 days prior to self-collection of a vaginal sample, sexual intercourse and ultrasound scans or gynecological examinations should be abstained from.



Wash your hands with soap and water before starting.



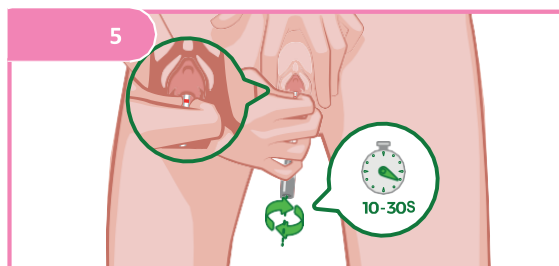
Twist and pull cap to remove the swab from the tube.



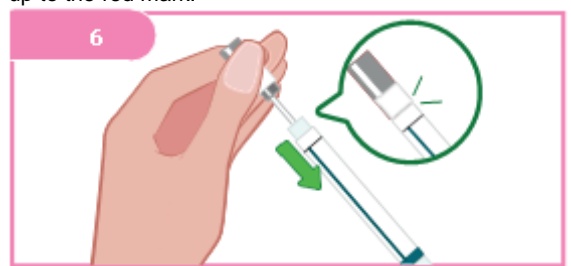
Hold the swab at the red mark



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.

Suspension of self-collected specimen

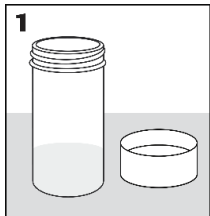
Sample suspension instructions for Copan FLOQSwabs® #552C.RM

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

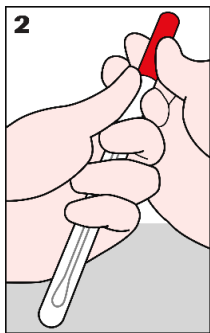
Self-collected sample must be placed into medium after sample has been collected.

- 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:

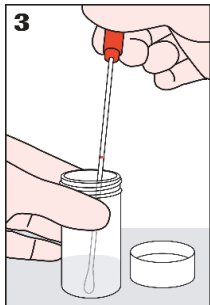
Handle the collected sample with care.



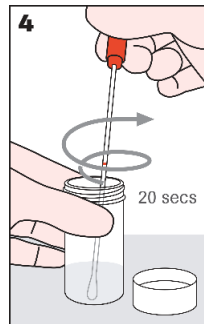
1. Carefully uncap the vial containing medium and place it on a stable, flat surface.



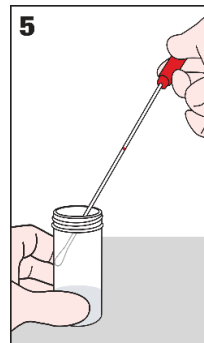
2. Slowly pull the FLOQSwab cap off to remove the swab from the tube. **Minimize touching the inner walls of the tube as you remove the FLOQSwab.**



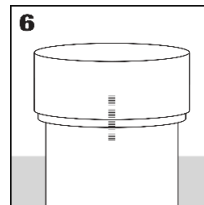
3. Hold the vial with one hand then with the other hand place the FLOQSwab tip into the vial until the FLOQSwab **tip is fully immersed in the medium and touching the bottom** of the vial.



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.



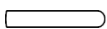
6. Re-cap the vial and tighten until **the lines on the cap and vial meet or slightly overlap** to prevent leakage. Store upright.

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

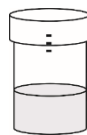
Glossary



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.