

Laboratory Update

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HPV Self-Collected Specimens

MercyOne is now offering FDA-Clearance, Self-Collected HPV PCR testing. To remain compliant with the FDA Clearance, the following conditions must be met:

1. The swab is to be collected in a healthcare setting.
2. The swab is a Copan FLOQSwab, which we have available for distribution. Each order includes instruction sheets that should be given to the patient along with the swab. Orders can be placed at [Order Supplies | MercyOne](#) using the designated client ID. Please order the 'FLOQ Swab for HPV Self-Collection' (part number 000080).
3. Before sending it to the lab, the swab will be broken at the score and placed into a ThinPrep pap vial labeled with 2 patient identifiers, collection date and time.

It is crucial that Paper or Electronic Orders state '**Self Collection**'. This will ensure the following interpretive comment is added to the results:

'The validity of this test is largely dependent on the patients' ability to properly collect the sample. Providers should give detailed verbal instructions as well as provide their patients with the "self-collection" written instructions.' The sample must be collected in a licensed health care facility and sent with a courier to the lab on the same day as the collection takes place.

Note: *Positive HPV results will require a follow-up visit with a speculum exam. A negative-HR-HPV result does not exclude the possibility of future cytologic HSIL or underlying CIN2-3 or cancer.*

Patients should refrain from using feminine hygiene products for approximately 24 hours prior to self-collection of the vaginal brush. Use of carbomer-containing feminine hygiene products has been associated with invalid results by the human papillomavirus (HPV) detection/genotyping assay. The vaginal HPV self-collection should not be ordered if active menstrual bleeding or vaginal product use has occurred within 2 days.