FAQs for HPV Samples and Testing

MaineHealth is dedicated to providing patient-centered care and working collaboratively to ensure our communities are the healthiest in America. HPV screening and testing recommendations are rapidly evolving. To support best practices and regulatory compliance, MaineHealth NorDx must ensure testing is performed using FDA-cleared test systems aligned with appropriate specimen types.

Please refer to the FAQs below for additional information regarding regulatory requirements and operational changes surrounding HPV testing.

What test system is used for molecular HPV detection at MaineHealth?

MaineHealth NorDx uses the Hologic Aptima HPV test for the detection of high-risk HPV genotypes. The test platform has excellent performance characteristics and is well established as a leader in the field of high-risk HPV genotype detection from cervical specimens as a co-test with PAP smear. The test was not optimized or designed to be used on vaginal or self-collected specimens. This test recently received FDA clearance for primary screening indication on February 4, 2026.

Are self-collect and home-collect the same thing?

No. Self-collection refers to a patient collecting their own vaginal specimen while in a healthcare setting, such as a clinic under the direction of a healthcare provider. Home-collection refers to a patient collecting their own vaginal specimen outside of a healthcare setting, such as at home, and returning the specimen for testing.

These two collection methods are regulated separately by the FDA and require specific validation and clearance.

Can self-collect kits that are FDA cleared for one HPV test be used with a different platform?

No. The Hologic Aptima HPV test does not have intended use for self-collect. Using a collection method that is cleared for other testing platforms does not obviate the need for an FDA cleared test with self-collect intended use.

Are provider-collected vaginal specimens acceptable for testing by NorDx?

No. The Hologic Aptima HPV test *cannot* be tested with vaginal specimens of any kind. The test is only cleared for cervical specimens.

Why is self-collection allowed on other Hologic Aptima tests?

NorDx offers numerous Hologic Aptima tests that target vaginal pathogens (*e.g. Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis*, bacterial vaginitis, vulvovaginal candidiasis) which are appropriately detected in self-collected vaginal specimens and have been scrutinized through clinical trials submitted through the FDA. The performance characteristics are well established for vaginal self-collection on these assays.

Can cervical specimens still be collected and tested locally?

Yes! Cervical specimens collected by providers using approved collection methods will continue to be tested locally using the Hologic Aptima HPV test.

How are clients able to order testing for these self-collected vaginal HPV specimens?

Since early April 2026, we have been live with VHPV (LAB9488) to LabCorp. The test catalog page is here.

Are there specific collection requirements for LabCorp's Test?

Yes, LabCorp requires vaginal collection with a Copan FLOQswab, swirled in a ThinPrep vial. The swab is to be discarded and the ThinPrep vial sent for HPV testing.

"Vaginal HPV Collection Kits" will be available from client supply but will need to be written on the client supply form. Each kit comes with collection and processing instructions.

What test should be ordered for post-hysterectomy patients requiring PAP and HPV?

Post-hysterectomy patients who require vaginal cytology (PAP) and HPV whereby the specimen is collected by traditional methods (vaginal brush), should continue to place

orders for a vaginal PAP and HPV regardless of diagnosis as they do currently. Those specimens will be tested by NorDx and temporarily be reported with a disclaimer recognizing the non-validated source.

NorDx is working to validate this specimen type, (not self-collected vaginal specimen), post-hysterectomy specimens with vaginal cytology, on our in-house HPV assay so that it will be able to be reported without the disclaimer. There is no expected completion date for that at this time.

Please refer to the NorDx test catalog at https://nordx.testcatalog.org/ for any processing or specimen collection questions and NorDx Customer Solutions if you have any questions – 207-396-7830.