DATE: January 13, 2020
TO: UCH Medical Staff, House staff, Patient Care Centers, and Outpatient Clinics
FROM: Kathleen G. Beavis, MD, Medical Director of Microbiology and Immunology Laboratories
Tatjana Antic, MD, Medical Director of Cytopathology
Maryam Siddiqui, MD, Vice Chair Clinical Operations, Department of Ob/Gyn
RE: HPV Genotyping test for CERVICAL Specimens

Effective January 16, 2020, the Clinical Microbiology and Immunology Laboratories will perform the Roche Cobas® HPV test on cervical specimens; this test includes genotyping of high-risk subtypes.

The Cobas® HPV Genotyping Test is an FDA-cleared assay for the detection of Human Papillomavirus in cervical specimens. The test utilizes PCR and nucleic acid hybridization for the detection of 14 high-risk subtypes in a single analysis, including specific identification of HPV16 and HPV18.

**Targets detected by the Cobas® HPV Genotyping Test include:**
- Detection and specific identification of HPV16
- Detection and specific identification of HPV18
- Concurrent detection of 12 other high-risk HPV subtypes (31,33,35,39,45,51,52,56,58,59,66 and 68) without specific identification.

Results will be reported as positive for HPV 16, HPV 18, and/or Other High-Risk HPV, or Negative if none of the targets is detected. Results will be flagged in EPIC if abnormal.

**Specimen and transport requirements: Unchanged**
Cervical specimens should be collected using an endocervical brush/spatula, which should be placed in the ThinPrep Pap Test PreservCyt transport, agitated, removed and discarded. The HPV assay can be performed on the same sample collected for liquid-based ThinPrep Pap test. Transport to Anatomic Pathology (tube station 212 or 230) if cytology is included or to Microbiology (tube station 906) if only HPV is ordered.

**Test ordering information: Unchanged**
1. Order PAP alone, PAP with HPV reflex, Pap and HPV (co-testing), or HPV alone based on age appropriate criteria or history.
2. To order only primary HPV cervical screening in women ≥ 30 years old, use order code HPVA.

**Testing for HPV from other sources or Primary HPV testing:**
1. HPV testing of the anal and/or vaginal canals: Unchanged. This testing is currently performed on another platform. Continue to order HPVAN (anal) or HPVAV (vaginal) and collect specimen with Dacron® swab or spatula/brush and transport in the PreservCyt vial.

Testing Schedule and turnaround time:
Testing will be performed Monday through Friday.

If you have any questions, please contact Scott Matushek, Laboratory Manager, in the Clinical Microbiology and Immunology Laboratories at 773-702-4116 or Lia Colbert, Chief Cytotechnologist at 773-702-7948.