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 $\geq$ 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