OSF
SYSTEM LABORATORY

MEMORANDUM

To: All OSF System Laboratory Customer/Clients

From: OSF System Laboratory

Subject: HPV testing

Date: August 11, 2016

The OSF System Laboratory is switching HPV testing platforms with a planned implementation date of 8/15/2016. If this date is shifted, you will be notified. The current testing platform, QIAGEN's Digene HC,2 will be replaced by Roche's cobas 4800 HPV test. While the ordering process for HPV testing will remain the same (LAB1192), the new HPV assay will provide several advantages that will help us meet the needs of our patients. The assay will now provide clinicians and patients with Genotype-specific high risk HPV results, helping to guide patient management. The new platform will also allow for HPV testing to be performed in smaller batches, decreasing the current TAT of the assay. The new testing platform is also the only FDA-approved primary cervical cancer screening assay to detect high risk HPV, including genotyping for 16 and 18. We anticipate the change-over to be transparent.

The **cobas**® HPV Test is a qualitative *in vitro* test for the detection of Human Papillomavirus in cervical specimens collected by a clinician using an endocervical brush/spatula and placed in the ThinPrep® Pap TestTM PreservCyt® Solution. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

Women who test high risk HPV positive and 16/18 negative by the **cobas**® HPV Test (12 other HR HPV positive) should be evaluated by cervical cytology to determine the need for referral to colposcopy.

Thank you.

The OSF System Laboratory