Beaumont

March 21, 2016

Beaumont Laboratory

Human Papillomavirus Testing at Beaumont Health

Dear healthcare provider,

The purpose of this memo is to provide a clear understanding of best practice HPV testing at Beaumont Laboratory. Beaumont Laboratory (all eight hospitals) has agreed to standardize to the Roche cobas 4800 HPV test. The Roche cobas 4800 HPV test has numerous advantages when compared to the Hologic Aptima mRNA and Qiagen/Digene hybrid capture II HPV tests. These are as follows:

Category	Roche cobas 4800 HPV	Qiagen-Digene HCII HPV	Hologic Aptima mRNA HPV
FDA-approved for Primary Screening	Yes	No	No
False Positives Results Due To Low-Risk Genotype Cross-Reactivity (1)	No	Yes	Yes
HPV 16/18 Genotyping (2)	Yes	No	Yes
Direct Sample Testing (3)	Yes	No	No
Cellularity Control (4)	Yes	No	No
Sample Volume Required (5)	1 mL	4 mL	2 mL

(1) Qiagen (6,11,40,42,53-55,66); Hologic (26,67,70,82). False positive results will lead to unnecessary patient management.
(2) Hologic HPV 16/18 genotyping **cannot** distinguish genotypes 18 and 45. Patients infected with HPV 45 will therefore be managed as if HPV genotype 18 positive. Roche HPV 16/18 genotyping is automatically included at no additional charge.
(3) Direct testing from the liquid based cytology vial reduces specimen-to-specimen contamination and specimen labeling errors.
(4) A cellularity control ensures that sufficient clinical material was in the liquid based cytology vial. False negative test results due to poor sample collection **cannot** be excluded with the Qiagen and Hologic tests.
(5) Hologic requires 1ml of sample for initial testing and another 1ml of sample for high-risk genotype testing. This increases the chance that the patient will need repeat specimen collection due to insufficient sample volume.

Implementation of the Roche cobas 4800 HPV test at each affiliate is anticipated as follows:

- ***Beaumont - Royal Oak, Grosse Pointe and Troy:*** the Roche cobas 4800 HPV test has been in use for several years - no additional changes are anticipated.

- ***Beaumont – Dearborn, Taylor, Trenton and Wayne:*** the Roche cobas 4800 HPV test is anticipated to be in use by June 2016. Until that time, the Hologic Aptima mRNA HPV test will continue to be used.

- ***Beaumont – Farmington Hills:*** the Roche cobas 4800 HPV test is anticipated to be in use by 2018 once the existing Qiagen/Digene hybrid capture II HPV test contract expires.

As these implementation timelines draw closer, additional educational efforts will be provided to minimize disruption to your practice and daily routine.

We appreciate your effort in making this transition as smooth as possible.

Sincerely,

Mark Kolins, MD	Corporate Chair, Laboratory Services
David Grossman, MD	Chief, Laboratory Services, Beaumont Troy
Vaishali Pansare, MD	Chief, Laboratory Services, Beaumont Grosse Pointe
Michael Schaldenbrand, MD	Chief, Laboratory Services, Beaumont Oakwood
Gil Herman, MD	Chief, Laboratory Services, Beaumont Farmington Hills
Bobby Boyanton, MD	Medical Director, Microbiology; Associate Medical Director, Molecular Pathology, Beaumont Royal Oak

References:

1. Castle PE, *et al.* Comparison of human papillomavirus detection by Aptima HPV and cobas HPV tests in a population of women referred for colposcopy following detection of atypical squamous cells of undetermined significance by Pap cytology. *J Clin Microbiol* 2015 Apr;53(4):1277-81.
2. Rebolj M, *et al.* Comparison of three human papillomavirus DNA assays and on mRNA assay in women with abnormal cytology. *Gynecol Oncol* 2014 Dec;135(3):474-80.
3. Moss SM, *et al.* Comparison of the performance of HPV tests in women with abnormal cytology: results of a study within the NHS cervical screening programme. *Cytopathology* 2015 Dec;26(6):373-80.
4. Ratnam S, *et al.* Aptima HPV E6/E7 mRNA test is a sensitive as Hybrid Capture 2 Assay but more specific at detecting cervical precancer and cancer. *J Clin Microbiol* 2011 Feb;49(2):557-64.
5. Wright TC, *et al.* Primary cervical cancer screening with human papillomavirus: end of study results from the ATHENA study using HPV as the first-line screening test. *Gynecol Oncol* 2015 Feb;136(2):189-97.
6. Rao A, *et al.* Comparison of hybrid capture 2 High-Risk HPV results in the low positive range with cobas HPV Test results from the ATHENA study. *J Clin Virol* 2013 Sep;58(1):161-7.
7. Wright TC Jr, *et al.* Interlaboratory variation in the performance of liquid-based cytology: insights from the ATHENA trial. *Int J Cancer* 2014 Apr;134(8):1835-43.