



# Laboratory Communiqué

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**The *Laboratory Communiqué* is a quarterly publication released by Billings Clinic Laboratory Services as an informational tool for medical staff and laboratorians.**

## In This Issue

### New Tests

**Cervista™ HPV, 16/18**

**Testing performed**

**Monday and  
Wednesday**

## New Testing

### Human Papillomavirus (HPV) 16/18

Billings Clinic Laboratory Services is pleased to announce the implementation of the only FDA approved HPV genotyping test, the Cervista™ HPV 16/18 assay from Hologic™, vendor for the ThinPrep® Liquid Based Pap Test.

In-house testing of Cervista™ HR-HPV, a highly accurate screening test for 14 high-risk human papillomavirus (HPV) types associated with cervical cancer, began in December 2010. In-house testing of HPV 16/18 genotyping began April 1, 2011.

We are now able to offer a high-risk HPV screening test that provides new levels of efficiency and responsiveness, including:

- ◆ 99.1% Negative Predictive Value (NPV) for CIN2+
- ◆ No cross-reactivity with common low-risk HPV types
- ◆ An internal control to assess both sample cellularity and contamination
- ◆ Requires only 2ml of specimen sample thereby limiting the “quantity insufficient” for testing cases
- ◆ Improved turn around time
- ◆ HPV 16/18 genotyping for positive Cervista™ HR-HPV results

HPV 16/18 are known to cause 70% of all cervical cancers and 79% of all adenocarcinomas in women. Recommendations for HPV genotypes 16 and 18 have been published by the American Society for Colposcopy and Cervical Pathology (ASCCP). Testing for HR-HPV may be used as a reflex for patients with ASCUS or as an adjunct to cytologic examination to determine follow-up intervals and referrals to colposcopy. Women 30 years of age or older, who are Pap-Negative and HR-HPV Positive should have repeat testing in 12 months. If the subsequent test results are the same, referral to colposcopy should be considered. In the Pap-Negative, HR-HPV negative group, return for screening in three years is acceptable management.

**The reflex to 16/18 is triggered by a Negative Pap test with a Positive HR-HPV test.**

## News Updates

### CMS Update on Physician Signature Requirement

### Vitamin D testing now a LCD test

Billings Clinic Laboratory Gyn requisitions have been revised to include the two new test options:

- ◆ DNA Pap (Liquid Based Pap with HR HPV)
- ◆ DNA Pap with reflex to 16/18

Cervista™ HR-HPV and HPV 16/18 genotyping assays from Hologic™ are FDA approved for cervical/vaginal samples only.

## Important News Updates

### CMS Update on Physician Signature Requirement

The Centers for Medicare and Medicaid Services will withdraw a requirement that laboratory requisition forms be signed by the ordering physician. According to the American Clinical Laboratory Association and American Association of Bioanalysts/National Independent Laboratory Association, top CMS officials told the associations on Feb. 11 that the requirement was deemed unworkable and would be rescinded before its April 1 effective date.

Once more definitive information is received from CMS we will inform our clients of our implementation intentions. Please contact Jena DeVries, Billings Clinic Laboratory Marketing Coordinator, with any questions regarding this topic at [jdevries@billingsclinic.org](mailto:jdevries@billingsclinic.org).

### Vitamin D testing now a Local Coverage Determination

Please be aware that as of February 8, 2011, Noridian has identified Vitamin D testing as a local coverage determination (LCD) test. Vitamin D testing will not be paid for by Medicare if used for screening purposes; it must have a medically necessary ICD-9 code. If you believe Medicare may not pay for a Vitamin D please obtain an Advanced Beneficiary Notice (ABN) from the patient and send a copy along with the order.

Additional information about LCDs and medically necessary ICD-9 codes can be found at: <https://www.noridianmedicare.com>

## Meeting News

NMLPW: April 24-30

ASCLS-MT Spring Meeting: April 13-16

4<sup>th</sup> Annual Billings Clinic Laboratory Services Fall Education Conference: Friday, October 14<sup>th</sup>

## Meetings

### National Medical Laboratory Professionals Week (NMLPW) is April 24-30, 2011

#### Fast Facts

- As Americans continue to age, more testing is required more frequently.
  - Beginning in January 1997, one baby boomer is turning 50 years of age about every 7 seconds
  - Almost 13% of the U. S. population is now over 65 years old
  - The over-85 category, which requires the greatest amount of health care services, is also growing rapidly
- Demand for medical laboratory testing is increasing due to:
  - Increases in the world population
  - Stronger emphasis on preventive medicine, including early detection and patient responsibility
  - An explosion of new medical technologies, such as genetic testing
- Expanding medical knowledge and technological developments have increased the need for medical laboratory testing. For example, 35 years ago, few organ transplants were performed. Today, they are becoming routine surgeries in many hospitals. Transplant patients need significant testing before the procedure, must be monitored immediately following, and require some follow up for years after the transplant.
- New and different pathogens are contributing to increased needs for laboratory testing. The identification of new diseases like AIDS, Lyme disease, and hepatitis C—and the resurgence of old foes like tuberculosis—pose serious threats to the public health.
- Unprecedented increases in international travel and immigration are resulting in the importation of rare or previously unknown diseases, especially parasitic infections and inherited disorders, which increases the need for laboratory testing.
- More than 10 billion laboratory tests are performed in the United States each year.
- Laboratory test results constitute a significant portion of the patient's medical records and are vital to the diagnosis and treatment of illness and disease.
- Thirteen percent of the current laboratory staff is likely to retire in

the next five years, according to the most recent ASCP Wage and Vacancy Report.

- 12,200 new laboratory professionals will be needed annually to meet the growing need of the world's population, but only 4,000 to 6,000 graduates will join the workforce each year.

This year the American Society for Clinical Pathology (ASCP) sponsored a 2011 Lab Week Contest designed to encourage laboratory teams across the country to "Take Center Stage" and showcase the important role they play in delivering quality patient care every day. Our laboratory submitted a video titled "**MISSION POSSIBLE**" that could be viewed on the ASCP Facebook page ([www.facebook.com/ASCP.Chicago](http://www.facebook.com/ASCP.Chicago)) from April 4-8. Visitors to the Facebook page could vote for as many videos as they wished. Prizes of a Lab Week Party would be awarded to the winner of each of the 10 USA regional areas.

### **The ASCLS-MT Annual Spring Meeting will be held April 13-16 in Great Falls**

This year the theme is titled "*On the Old North Trail to New Directions*" and will be hosted by Benefis Healthcare in Great Falls. Lodging for the Spring Meeting will be available at the Great Falls Inn located on the Benefis Healthcare East Campus. Susan Keeney is the General Chair and can be contacted with questions at [skeeney@bresnan.net](mailto:skeeney@bresnan.net)

### **Save the Date**

The 4<sup>th</sup> Annual Billings Clinic Laboratory Services Fall Education Conference will be held Friday, October 14<sup>th</sup> 2011 at the Mary Alice Fortin Health Conference Center located at Billings Clinic.

For more information about Billings Clinic Laboratory please call (406) 657-4060 or 1-866-232-2522. [www.billingsclinic.com](http://www.billingsclinic.com).



**Billings Clinic**

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