



# 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.

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## Welcome Bob Eytalis



Welcome to our new Lab Manager, Bob Eytalis. Originally from Illinois, Bob's most recent position was as Laboratory Director at Gila Regional Medical Center in Silver City, NM. With almost 30 years experience working in the clinical laboratory, including 20 years service in the Navy, Bob chose Billings Clinic because he was very impressed with everyone's positive attitudes during his interview. Bob also states that he had a desire to work at a larger health care facility and that Billings just felt like home. In his free time, Bob enjoys hiking with his dog Aldo, an Italian Spinone, cooking, and is delighted to be in a large community where there are many things to do.

## New Testing

### Human Papillomavirus (HPV) High Risk

On December 21, 2010 our laboratory implemented the FDA-approved Cervista™ HPV HR assay. This is an *in-vitro* diagnostic test for the qualitative detection of DNA from 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in cervical specimens. The Cervista™ HPV HR test is based on the Invader® chemistry, a patented technology owned by Hologic which uses a signal amplification method for the detection of specific nucleic acid sequences. It is approved for use utilizing the sample collected with the ThinPrep® Pap Test PreservCyt® Solution. The Cervista™ HPV HR has been approved for two uses:

## New Tests

### HPV, High Risk

BC # 9324

CPT Code 87621

Specimen: ThinPrep Pap vial

Days Run: Tuesday / Friday

- To screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.
- Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

Over 100 HPV types have been documented in the literature, approximately 40 of which infect the anogenital area and are transmitted sexually. Anogenital HPV is associated with virtually all cancers of the cervix. Cervical cancer has previously been shown to be highly preventable when cytological and HPV screening programs are employed to facilitate the detection and treatment of pre-cancerous lesions.

Of the sexually transmitted types of HPV, the 14 oncogenic genotypes mentioned above are considered high risk (HR) HPV types due to their strong association with cervical cancers (relative to low risk HPV types, which have little or no association with cervical cancer). Still, the vast majority of high-risk HPV infections are cleared. The identification of women with ASC-US cytology in conjunction with a high-risk HPV infection is a useful aid for clinicians to decide who should be monitored more aggressively. The Cervista™ HPV HR test cannot determine the specific HPV type present.

## Important News Update

### CMS Physician Signature Requirement delayed until April 1<sup>st</sup> 2011

As many of you may know, the Center for Medicare and Medicaid Services (CMS) has delayed its ruling which will require the signature of the ordering provider on *paper* laboratory requisitions until April 1<sup>st</sup>, 2011.

In the first calendar quarter of 2011, CMS will focus on developing educational and outreach materials to educate those affected by this policy. CMS has committed to educate physicians and laboratories and has committed to meet face-to-face with CLMA and other laboratory groups in January, 2011. Once the first quarter of 2011 educational campaign is fully underway, CMS will expect requisitions to be signed.

Billings Clinic Laboratory Services understands what a difficult process this will be for everyone and we are committed to making it a smooth transition for all involved. We will continue to update you as CMS moves forward with its campaign. You can access current CMS Transmittals on this topic at [www.cms.gov](http://www.cms.gov).

Once more definitive information is received from CMS we will inform you of our implementation intentions. Please contact Jena DeVries, Billings Clinic Laboratory Marketing Coordinator, with any questions

## Test Updates

New Sysmex 5000  
Hematology Instrument  
and test changes

## Meeting News

NMLPW: April 24-30

ASCLS-MT Spring  
Meeting: April 13-16

regarding this topic.

## New Collaborations

### Billings Clinic REI

Billings Clinic will begin offering in vitro fertilization (IVF) services as part of the hospital's assisted reproductive technology (ART) program starting in February 2011. This program will be the first IVF center in Montana, and will significantly expand the scope of fertility treatment options currently available for patients in Montana, Wyoming, North Dakota and South Dakota.

Billings Clinic Laboratory will be assisting the Reproductive, Endocrinology (REI), and Infertility department, and a visiting Embryologist to do laboratory testing and additional specimen processing.

### Cancer Human Biobank (caHUB)

In response to a critical and growing shortage of high-quality, well-documented human biospecimens for cancer research, the National Cancer Institute is developing a national, standardized human biospecimen resource called the cancer Human Biobank (caHUB). Currently, no centralized, standardized infrastructure of this type exists in the United States. caHUB will serve as a continuous and reliable source of high-quality human biospecimens and associated data for the broader cancer community, including basic and clinical researchers and the biotechnology and pharmaceutical industries that rely on human biospecimens for cancer diagnostics and drug development.

Billings Clinic Laboratory in collaboration with Oncology is submitting a proposal to submit 50 specimens a year to the caHUB. We will know soon whether our proposal is accepted.

## Test Updates

Due to the recent implementation of the new hematology Sysmex 5000 analyzer, the following reference ranges have been changed:

Platelet Count	Old Range	167 – 440 x10 <sup>3</sup> /uL
	New Range	153 – 407 x10 <sup>3</sup> /uL
MPV	Old Range	6.5 - 10.3 fL
	New Range	9.0 - 12.6 fL

New parameters have been added for the CBC/Diff:

Immature Granulocyte, %	Reference Range is 0 – 3%
Immature Granulocyte, abs	Reference Range is 0 – 0.2 x10 <sup>3</sup> /uL



**Laboratory Services**

**Contact Us**

**(406) 657-4060**  
**(866) 232-2522**

**Director/Pathologist:**  
Jeffrey Smith, MD

**Lab Director:**  
Mark Lubbers, MT ASCP

**Lab Manager:**  
Bob Eytalis, MT ASCP

**Technical Consultant:**  
Joni Gilstrap, MT ASCP  
Extension 4046

**Client Services  
Supervisor/Technical  
Liaison**  
Rebecca Schulz  
Extension 4861

**Laboratory Marketing  
Coordinator**  
Jena DeVries  
Extension 4888

**New parameters for the Reticulocyte Panel:**

Ret-He (replaces the CHR)	Reference Range is 29.3 – 35.8 pg
IRF (Immature Retic Fraction)	Reference Range is 3.0 – 15.9% Female 2.3 – 13.4% Male

IRF is expressed as a ratio of immature reticulocytes to total reticulocytes. This value provides a very early and sensitive index of marrow erythropoietic activity. A rise in the IRF has been shown to be one of the earliest indicators of hematopoietic recovery following bone marrow transplantation or intensive chemotherapy. The IRF can also be used as an early indicator of response to erythropoietin therapy in patients with chronic renal failure and other diseases.

RET-He (reticulocyte hemoglobin equivalent), which replaced the previous CHR, is a direct measure of the incorporation of iron into erythrocyte hemoglobin. This parameter supports:

- Direct analysis of an earlier stage of RBC development
- Assessment of anemia and the initial iron status of patients
- Accuracy and sensitivity in measurement of red cell production that supports effective monitoring of costly drug protocols for cell stimulation.

Any questions concerning the above changes should be forwarded to Stacey Baily or Dr. Ronald Linfesty at extension 4060.

**Meetings**

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

National Medical Laboratory Professionals Week (NMLPW) provides the profession with a unique opportunity to increase public understanding of and appreciation for, clinical laboratory personnel. The dates for the next NMLPW are April 24-30, 2011.

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

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2800 Tenth Avenue North  
P.O. Box 37000  
Billings, Montana 59107-7000

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