Billings Clinic℠

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

Test Updates

The January Issue of the Laboratory Communiqué was delayed to coincide with the February 3 "Go-Live" of our two new molecular tests, HPV, High Risk and HPV 16 18/45 on the GenProbe Panther System which performs our GC/CT testing.

HPV, HR

The APTIMA® HPV Assay is an *in-vitro* nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) from the 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The high-risk types detected by the assay include: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The APTIMA® HPV Assay does not discriminate between the 14 high-risk types.

HPV 16 18/45

The APTIMA® HPV 16 18/45 Genotype Assay is an *in-vitro* nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) of human papillomavirus (HPV) types 16, 18 and 45 in cervical specimens. The APTIMA® HPV 16 18/45 Genotype Assay can differentiate HPV 16 from HPV 18/45, but does not differentiate between HPV 18 and HPV 45.

HPV Epidemiology

HPV is a small, double-stranded DNA virus. Of the more than 100 genotypes of HPV identified, approximately 40 are known to infect the urogenital tract and of these, 14 genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) have been found to be present in the majority of cervical cancers and are considered to be high-risk for carcinogenesis. Persistent infection with these high-risk genotypes has been suggested to be the main risk factor for development of high-grade cervical neoplasia and cancer.

HPV Information

HPV CPT Code

HPV High Risk CPT 87621

HPV, 16 18/45 CPT 87621

Testing Schedule:

Performed: Monday-Friday

HPV Results:

Negative for any of the HPV 14 high-risk types

Positive for at least one of the HPV 14 high risk types

Invalid

HPV 16 18/45 Results:

Negative for HPV 16, Negative for HPV 18/45

Negative for HPV 16, Positive for HPV 18/45

Positive for HPV 16, Negative for HPV 18/45

Positive for HPV 16, Positive for HPV 18/45

Invalid

Methodology:

The APTIMA® HPV and HPV 16 18/45 Assays involve three steps, which take place in a single tube: target capture; target amplification by Transcription-Mediated Amplification (TMA); and detection of the amplification products (amplicons) by the Hybridization Protection Assay (HPA). The assay incorporates an Internal Control (IC) to monitor nucleic acid capture, amplification and detection as well as operator or instrument error.

Specimen:

Cervical specimens in ThinPrep® Pap Test vials containing PreservCyt® Solution and collected with broom-type or cytobrush/spatula collection devices.

Hepatitis C Virus (Anti-HCV) with Reflex to HCV RNA by PCR, Serum

BC Test Code 4812

This test requires 2 aliquots of 1.5 mL serum in each plastic vial for a total of 3.0 mL. If the HCV test is *"Reactive"*, the test is reflexed to HCV RNA by PCR and sent to Mayo Laboratories for testing.

If we do not have the second aliquot for the reflex HCV RNA by PCR, the test may be cancelled QNS. There is a limitation to the number of freeze/thaw cycles of a serum before it is considered unacceptable for testing. This scenario can happen if there is only one aliquot of serum submitted for the test.

The on-line Billings Clinic Test Catalog states:

Draw blood in a serum gel tube(s). Aseptically spin down within 1 hour of draw and send 3 mL of serum divided into 2 plastic vials each containing 1.5 mL of serum. Send specimens frozen in plastic vials.

Hepatitis B Surface Antibody Titer

A change has been made to the Interpretation comment for this test:

Interpretation Guide:

Anti-HBs level after vaccination:

<8.00 mIU/mL: Individual is considered not immune to

HBV infection

8.00 to <12.00 mIU/mL (Grayzone) : The immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors, and the use of diagnostic information. Consider revaccination 3 months after the first series.

= or >**12.00** mIU/mL: Positive for antibody to Hepatitis B. No further vaccination necessary.

Urinalysis

Coming soon to the Hematology/Urinalysis Department will be the Siemens CLINITEK® AUWI System, a fully automated chemical and microscopic testing instrument.

This system combines two of the most widely used urine analyzers: the CLINITEK Atlas® Automated Urine Chemistry Analyzer and the Sysmex UF-1000i™ Urine Cell Analyzer. Together they offer complete, unattended operation from start to finish.

The urine chemistry will continue to be the dry pad test measurement method using the Siemens Multistix strips. The color change on these strips is measured by reflectance photometry with dual readings at reactive and reference wavelengths. The specific gravity is measured by a refractive index method. The clarity of the specimen is measured by transmitted and scattered light.

The UF-1000i is a flow cytometer which allows us to automate the urine microscopic, thereby providing efficiencies in testing by reducing hands-on-time, minimizing manual urine microscopic analyses and improving overall TAT. The UF-1000i bases its objective analysis on both physical and chemical particle

CLINITEK® AUWI

Chemical Parameters Reported:

Clarity
Color
Specific Gravity
pH
Bilirubin
Urobilinogen
Ketones
Glucose
Protein
Occult Blood
Nitrate
Leukocyte Esterase

UF-1000i Reported Parameters:

RBC
WBC
Epithelial Cells
Hyaline Casts
Bacteria

And flagged parameters…

Pathological Casts
Crystals
Small Round Cells
Sperm
Yeast

properties. The UF-1000i has the following features and benefits:

- Standardizes urine microscopics
- Reliable identification analysis and auto identification of normal samples eliminates the need for further manual steps
- Measures formed elements in urine by fluorescent flow cytometry
- Unmatched sensitivity with fluorescence, forward scatter, impedance and cluster analysis
- Automatically classifies 10 formed elements found in urine
- Cell counting capabilities of up to 80,000 particles reduces review rate
- Separate bacteria channel for improved discrimination
- Temperature and pH normalization provides a more accurate result
- Analyzing more of the sample provides fully quantitative results that eliminates subjective interpretation

Implementation of the new Siemens® CLINITEK AUWI will require some lab renovation which should occur in the near future. Additional information on a Go-Live date and any changes in urinalysis reporting will be shared in a later Communiqué and/or a New Test Letter.

For more information about Billings Clinic Laboratory please call (406) 657-4060. www.billingsclinic.com.

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