JULY, 2018

THE University of Vermont MEDICAL CENTER

Pathology & Laboratory Medicine

Communiqué

IN THIS ISSUE

LABORATORY TEST CATALOG

To view a complete listing of tests available at UVMMC, please visit **http://uvmlabs.testcatalog.org**

Browse by Name

A B C D E F G H I J K L

Search

Lupus Anticoagulant Cascade

Laboratory Phlebotomy Site Hours

Independence Day Holiday

Wednesday July 4

All collection sites are closed

Regularly scheduled hours will apply to any days not specifically addressed above, please call 847-5121 or 1-800-991-2799 for assistance.

Successful Laboratory Inspections

The Department of Pathology and Laboratory Medicine was inspected by the College of American Pathologists (CAP) and the American Association of Blood Banks (AABB). The unannounced inspection lasted for a day and a half. There were 15 inspectors from Eastern Maine Medical Center in Bangor Maine scrutinizing all sections of the Clinical and Anatomic Laboratories as well as the Fanny Allen Lab and the Electron Microscopy facility. The inspectors left us with high praise for the quality of work performed by our department. At the summation, comments included "*Your Quality Program is Amazing*" and "*Your lab is so clean, bright and organized*". It was a great team effort. This certification is valid for 2 years and we will be inspected again in 2020.

Clayton Wilburn, MD
Medical Director
Clinical Chemistry
Phone: 847-9657

TB by Quantiferon Test Kit Change

The manufacturer of our current interferon gamma release assay (IGRA) Quantiferon Gold for the detection of latent tuberculosis (TB) is discontinuing the current 3-tube IGRA. It is being replaced with the manufacturer's new 4-tube IGRA Quantiferon Gold Plus. This new IGRA still utilizes the same Nil and Mitogen control tubes, but instead of there being only one TB tube, there are two TB tubes. The difference is in the T-cell types that are stimulated to produce a positive reaction. Whereas the Quantiferon Gold IGRA only stimulated CD4 T-cells, the Quantiferon Gold Plus stimulates both CD4 and CD8 T-cell responses. In the new 4-tube IGRA the TB1 tube will measure CD4 T-cell response and the TB2 tube will measure the combined response of CD4 and CD8 T-cells. The inclusion of CD8 T-cell response allows for increased detection of latent TB in immunosuppressed patients and children and adolescents.

The Immunology Laboratory is in the process of validating the new 4-tube IGRA assay. We expect to be using the new 4-tube IGRA assay by mid-September of 2018. When the switch occurs, we will no longer be accepting the old 3-tube Quantiferon Gold assay. For those who receive the IGRA tubes directly from UVMMC, we will be assisting in the conversion from the 3-tube to the 4-tube assay. For those who obtain their IGRA tubes from another source, plan your ordering such that the 3-tube assay will no longer be accepted by mid-September of 2018 and use of the new 4-tube system will begin.

As we move closer to the implementation of the new Quantiferon Gold Plus 4-tube IGRA, we will be sending further communication with an exact date for the switch over and changes to the ordering and resulting of the test. If you have any questions about this up-coming change, please contact Dr. Clayton Wilburn in the chemistry laboratory.

Effects of Biotin Supplements on Laboratory Testing

THE ISSUE:

Increased prevalence of hyper-supplementation of biotin, vitamin B7, in the general population has raised concern over its effect on the results of many routine laboratory medicine tests, as outlined in a recent FDA Safety Notification.[1] For over a decade manufacturers of many laboratory medicine tests have utilized biotin-streptavidin bonding in their immunoassays. Biotin-streptavidin is one of the strongest non-covalent bonds in nature that is resistant to extremes of pH and strong surfactants, as well as being relatively biologically/chemically inert. For these reasons, it is used in immunoassay platforms to isolate properly captured antigens to facilitate sensitive and specific measurements.

The recommended daily intake for biotin is just 0.03 mg, and at this level there is no risk of interference with biotin-streptavidin containing laboratory assays. However, it is not uncommon for many supplements, including multi-vitamins, to contain 1, 5, 10, or 20 mg of biotin in a daily dose. Some patients may even be taking up to 300 mg/day for conditions such as multiple sclerosis. At these quantities of ingestion, the serum biotin level can reach concentrations that directly interfere with biotin-streptavidin containing laboratory assays. Depending on the measuring principles of the assays, the results could be falsely raised or lowered.

WHAT WE ARE DOING:

We have identified all tests performed at UVMMC that may be effected by biotin supplementation. Based on recent studies obtained from the lab test manufacturers, we have determined how increased biotin concentrations could effect each individual test. The list of all tests performed at UVMMC that could be effected by biotin supplementation and how the presence of excess biotin would effect the result is given in the table at the end of this communication.

Moving forward, all tests performed at UVMMC that may be effected by biotin supplementation will be resulted with an additional comment. This comment will identify the test as being susceptible to biotin interference and state whether the result could either be falsely raised or lowered by the presence of excess biotin. Below is an example of such a comment:

"The results of this assay can be falsely elevated due to the consumption of Biotin."

In addition, we will be adding a note in the UVMMC Joint Test Catalog for all tests that could be

effected by biotin supplementation and how the presence of excess biotin would effect the result. The note for each test will also include the following statement:

"Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw."

WHAT YOU CAN DO:

Ask each of your patients about biotin supplementation, remember that it can be present in a general multi-vitamin or dietary supplement or be called a hair and nail supplement, and document their usage including daily dose in the EHR. Instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw when ordering the tests effected by biotin supplementation listed in this communication. For patients taking more than 20 mg/day, consult Dr. Clayton Wilburn to discuss how long a patient would need to abstain from their supplement to ensure testing is not effected.

If your patient's test results do not fit with their clinical presentation or you have concern that biotin supplementation could be effecting the result, do not hesitate to contact Dr. Clayton Wilburn in the laboratory for help.

If you have any questions or concerns about the information provided in this communication, please contact Dr. Clayton Wilburn in the Chemistry Laboratory.

Table of UVMMC Laboratory Tests Effected by Biotin Supplementation:

Test Name	Test Code	Effect on Result	Comment
Cortisol	CORTI	Falsely Elevated	The results of this assay can be **falsely elevated** due to the consumption of Biotin. Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw.
Cortisol Stimulation Baseline	CORB	Falsely Elevated	
Cortisol Stimulation 30 Minutes	COR30	Falsely Elevated	
Cortisol Stimulation 60 Minutes	COR60	Falsely Elevated	
Folate(FOL)	FOL	Falsely Elevated	
Hepatitis A Total Antibody with Reflex	HAAB2	Falsely Elevated (Falsely Positive)	
Homocysteine	HCY	Falsely Elevated	
Testosterone	TESTO2	Falsely Elevated	
Estradiol	ESTRA	Falsely Lowered	The results of this assay can be **falsely lowered** due to the consumption of Biotin. Please instruct patients to discontinue the use of vitamins or supplements that contain Biotin 12 hours before blood draw.
HCG for Accutane Monitoring	HCGAC2	Falsely Lowered	
HCG for Pregnancy	HCGS	Falsely Lowered	
HCG Quantitative	HCGTUM	Falsely Lowered	
Hepatitis A Antibody, IgM	HAIGM2	Falsely Lowered (False Negative)	
Hepatitis B Surface Antibody	HBABQ2	Falsely Lowered (False Negative)	
Hepatitis B Surface Antigen	HBSAG	Falsely Lowered (False Negative)	
Hepatitis B Core Antibody	HBCOR	Falsely Lowered (False Negative)	
Hepatitis C antibody	HCSCR2	Falsely Lowered (False Negative)	
HIV 1 & 2 Antibody	HIVSCN	Falsely Lowered (False Negative)	
HIV, Rapid 1 & 2 Antibody	HIVSS2	Falsely Lowered (False Negative)	
NT-proBNP	NTBNP	Falsely Lowered	
Parathyroid Hormone, Intact	PTHIN	Falsely Lowered	
Parathyroid Hormone, Intact, Intraoperative	PTHOP	Falsely Lowered	
Sex Hormone Binding Globulin	SHBG2	Falsely Lowered	
Troponin I	TROPI	Falsely Lowered	
Thyroid Stimulation Hormone	TSH3	Falsely Lowered	
Vitamin B12	B12	Falsely Lowered	

REFERENCE: Biotin (Vitamin B7): Safety Communication - May Interfere with Lab Tests. FDA Safety Alerts for Human Medical Products. https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586641.htm

Bronwyn Bryant, MD
Phone: 847-0031

Lynch Syndrome Screening on Endometrial Cancer Resections

On May 1, 2018, GYN Pathology began performing Universal Screening for Lynch Syndrome on hysterectomy specimens found to be positive for endometrial cancer, in accordance with NCCN, SGO, and ACOG guidelines.

It is important to note that the initial screening test, immunohistochemical (IHC) staining with antibodies against four mismatch repair proteins, done at the University of Vermont Medical Center is NOT considered a molecular test. However, any follow up molecular testing (e.g. MLH1-Promoter Methylation) requires preauthorization. The most common scenario in which this is encountered is in endometrial cancers that show the following IHC results: Loss of MLH1/PMS2 and retention of MSH2 and MSH6 proteins. In these cases the following comment will always be present in the surgical pathology report:

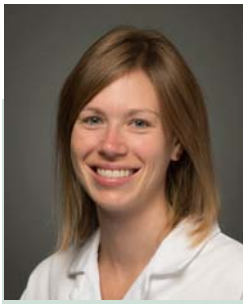
"The majority of endometrial cancers that have loss of MLH1/PMS2 protein are associated with somatic changes rather than an inherited mutation (Lynch syndrome). However, if additional testing to rule out Lynch syndrome is warranted in this individual, additional molecular testing, specifically MLH1 Promoter Methylation can be ordered upon obtaining preauthorization. "

MLH1 Promoter Methylation allows clinicians to definitively delineate Lynch Syndrome-associated cancer from microsatellite unstable (aka MSI-high) tumors that are sporadic (non-familial). However, this test will only be performed following preauthorization obtained from the treating clinician.

If you have any questions concerning this new Universal Screening protocol, please contact Dr. Bronwyn Bryant.

REFLEX TABLE

Initial Test	Reflex Criteria	Reflex Tests	Additional CPT Billed
Endometrial Cancer Resection	#1 All cases of endometrial cancer	#1 Immunohistochemical Testing (MLH1, PMS2, MSH2, MSH6) Performed at UVMMC	88342 x 4 for MMR
	#2 Loss of MLH1/PMS2 on IPEX	#2 MLH1 promoter methylation upon pre-authorization Performed at ARUP	81479



C. Wojewoda, MD
Medical Director
Microbiology
Phone: 847-5140

Urine Antibiotic Susceptibility Testing for Enterococcus Species

As of May 2, 2018, the Microbiology laboratory no longer routinely reports antibiotic susceptibility results on *Enterococcus* species in urine. Results are reported with a comment "Ampicillin or Amoxicillin are the drugs of choice for treating Enterococcus infections (including VRE) limited to the lower urinary tract". This is because ampicillin and amoxicillin concentrate to high enough levels in the bladder that all enterococci would be susceptible. Testing will still be performed for *Enterococcus* species for vancomycin to determine if the isolate is VRE or not for infection prevention purposes. If a patient is penicillin allergic, call the microbiology lab (847-2339) to request susceptibility results for Nitrofurantoin, Tetracycline, and Doxycycline. If you have anu questions concerning this change you can contact Dr. Christina Wojewoda in the microbiology laboratory.

Andrew Goodwin, MD
Medical Director
Coagulation and Hemostasis
Phone: 847-2377

Lupus Anticoagulant Cascade Change in Days Performed

Since June 4, 2018 the Thrombosis and Hemostasis Laboratory has performed the Lupus Anticoagulant Cascade testing (order code: LACASC) every Monday and Thursday. This change is necessary to balance the workload and allow for timely patient results. Please contact Dr. Andrew Goodwin in the laboratory should you have any questions.

John Lunde, MD
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Hematology
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Hemagram Name Change

UVMMC has used the terms Complete Blood Count and Hemagram interchangeably for many years. Generally, the Complete Blood Count (CBC) is a term with greater clinical recognition; additionally, in some laboratories, the Hemagram does not include a platelet count. For these reasons, on June 6, 2018 the laboratory updated all tests systems to say Complete Blood Count or Complete Blood Count with Differential. As always, these tests will include a platelet count.

The American College of Obstetricians and Gynecologists recommendations For Specific Conditions

SPINAL MUSCULAR ATROPHY

Screening for spinal muscular atrophy should be offered to all women who are considering pregnancy or are currently pregnant.

In patients with a family history of spinal muscular atrophy, molecular testing reports of the affected individual and carrier testing of the related parent should be reviewed, if possible, before testing. If the reports are not available, *SMN1* deletion testing should be recommended for the low-risk partner.

CYSTIC FIBROSIS

Cystic fibrosis carrier screening should be offered to all women who are considering pregnancy or are currently pregnant.

Complete analysis of the *CFTR* gene by DNA sequencing is not appropriate for routine carrier screening.

For couples in which both partners are unaffected but one or both has a family history of cystic fibrosis, genetic counseling and medical record review should be performed to determine if *CFTR* mutation analysis in the affected family member is available.

If a woman's reproductive partner has cystic fibrosis or apparently isolated congenital bilateral absence of the vas deferens, the couple should be provided follow-up genetic counseling by an obstetrician–gynecologist or other health care provider with expertise in genetics for mutation analysis and consultation.

REFERENCE: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Genetics/Carrier-Screening-for-Genetic-Conditions

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LABORATORY TOURS

Are you interested in coming down to the lab and seeing what it is all about, or do you have patients that would be interested in seeing what happens to their lab sample after it is collected? Call 847-9473 or email labambassador@UVMHealth.org for more information.