

Laboratory Communiqué

July, 2011

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Summer Schedule

Phlebotomy

Our sample collection areas will be closed on the following holidays:

Independence Day

Monday July 4, 2011

Labor Day

Monday September 5, 2011

Ambulatory Care Center (ACC): **Closed**

Fanny Allen Campus: **Closed**

Blair Park: **Closed**

University Health Center (UHC): **Closed**

Regularly scheduled hours will apply to any days not specifically addressed above.

To view our regularly scheduled Patient Service Center hours, please go to

<http://www.fletcherallen.org/drawsites> or call Laboratory Customer Service for assistance.

Couriers

We do not operate our normal courier schedule on holidays. We have asked offices with a routine courier pick-up what their office hours will be over the summer. We adjust staffing and manage pick-up times according to your schedules.

If you have not notified us of your holiday needs please contact Laboratory Customer Service. We will have couriers available on-call for stat sample pick-up. If you require a pick-up on any of the days listed, please contact lab Customer Service to arrange for a pick-up.

CONTACT INFO

Call 802-847-5121

800-991-2799

Email: labmarketing@vtmednet.org

Or visit: www.FletcherAllen.org/lab

TABLE OF CONTENTS

Laboratory Operations

Summer Schedule.....1

The Sun Sets on Maple.....2

Test Changes

AFP Tumor Marker.....2

GTT Update.....2

Amikacin Assay.....3

Chemistry Analyte Maximum Reportable Range.....4

Cryoglobulins Collection.....4

PTH Sample Stability.....4

DHEA-S Methodology.....5

FLM Change to Lamellar Body Count.....5

H. pylori and CMV IgG Antibody Change.....6

Quad Marker Method.....6

S. pneumoniae Antigen Detection, Urine.....6

Thyroid Antibody: Thyroglobin Antibody and Thyroperoxidase Antibody Change.....7

Platelet Aggregation.....8

IT Update

The Sun Sets on Maple

On June 1, 2011, Fletcher Allen Health Care decommissioned the Maple software system. Since our EHR went live 2 years ago now we have been transitioning users away from Maple and onto Prism. Although it is sad to see Maple go, the additional functionality and depth offered by Prism replaces the limited scope of Maple that only accessed laboratory, radiology and appointments.

Test Changes

AFP Tumor Marker Change

On April 8, 2011, the Chemistry Laboratory changed the method used for AFP tumor marker (Test order code: AFPTUM) testing. The method changed from the Centaur® (Siemens Diagnostic) to the Access® 2 (Beckman Coulter). Comparisons between the two methods show excellent correlation. The new method is noted by a comment and there has been a clinically insignificant change in the reported reference range. If you have any questions concerning this change please contact [Dr. Greg Sharp](mailto:gregory.sharp@vtmednet.org) (gregory.sharp@vtmednet.org).

Glucose Tolerance Test: Encouraging Eating a Snack Following a Three Hour Test

In a recent review of glucose levels recorded at the end of the three-hour glucose tolerance test, we noticed that a small but significant percentage of patients had a critically low serum glucose level of less than 50 mg/dl. Although some patients may not exhibit hypoglycemic symptoms, people with levels this low should not drive an automobile without first eating a snack to raise the glucose level.

In order to alleviate this issue, we strongly encourage all patients to have a snack prior to leaving the phlebotomy area following a three-hour glucose tolerance test. While we have some snacks available in our Outpatient Phlebotomy areas, we also encourage patients to bring a snack that they would find appealing. We would greatly appreciate your assistance in further encouraging your patients to bring a snack along when they present for their glucose tolerance tests.

Greg Sharp, MD

Test Changes

Amikacin Assay Change

Amikacin Assay Information: Beginning July 18, 2011, the Chemistry Laboratory will send all samples for amikacin analysis to Mayo New England in Andover, Massachusetts. This change was prompted by our vendor's announcement that it will no longer support this assay. There will be no changes to the reference range for this assay. Please note the sample type has changed. *Please review the test information listed in the table below.* Fletcher Allen couriers transport samples to Mayo New England each evening (except for Saturday). Samples sent to Mayo New England will generally have results available the following morning.

Clinical Application: Amikacin is an aminoglycoside used to treat severe blood infections by susceptible strains of gram-negative bacteria. Aminoglycosides induce bacterial death by irreversibly binding bacterial ribosomes to inhibit protein synthesis. Amikacin is minimally absorbed from the gastrointestinal tract, and thus can be used orally to reduce intestinal flora.

Method: This assay is performed by enzyme-multiplied immunoassay technique (EMIT) using an Olympus analyzer: The EMIT assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in biological fluids. The assay is based on competition for antibody binding sites between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6P-DH does not interfere, because the coenzyme functions only with the bacterial enzyme employed in the assay.

Test Information:

Test Name(s):	Amikacin Random, Amikacin Peak, and Amikacin Trough
Test Code(s):	AMIKN, AMIKPN, and AMIKTN
MAYO Number:	81752, 82112, and 81593
CPT Code:	80150
Method:	Enzyme-multiplied immunoassay (EMIT)
Sample Requirements:	Collect 8.0 mL RED TOP TUBE. Submit 1.0 mL serum. Minimum Volume 0.25 mL Serum gel tube is not acceptable.
Days performed:	Sunday through Friday
Analytical Time:	1 Day
Expected Value:	Amikacin, peak: 20-35 mcg/mL Amikacin, trough: Less than 8.0 mcg/mL
Patient Price:	Please contact Laboratory Customer Service for pricing information.
Effective Date:	July 18, 2011

References: *Amikacin, Peak, Serum*, Mayo Foundation for Medical Education and Research, Rochester, MN, 1995-2011, Web. April, 2011.

Syva Company, Siemens Healthcare Diagnostics, *EMIT Amikacin Assay*, Package Insert, Newark, DE, February 2007.

Test Changes

Chemistry Analyte Maximum Reportable Range

The analyzers in the Clinical Chemistry Laboratory are designed to directly measure biochemical analytes in the range in which they are commonly present in patients. When the analytes are at levels that exceed this range, the sample can be diluted to bring the result within the measurable range of the analyzer. We recently conducted a study to ensure that the results generated were indeed an accurate reflection of the amount of analyte in these samples. As a result of this study we have made changes in the maximum dilution we will use to obtain a final result. Analytes that exceed this value will be reported as greater than the maximum value. A chart showing these changes is reproduced below.

CK is a special case. In some clinical situations the enzyme can be elevated to an extraordinarily high value, and it has often been requested to dilute the sample to a final result regardless of the level. Our study indicates that at a level exceeding 30,000 U/L there is a significant decline in the recovery and accuracy of the reported results and at a level exceeding 75,000 U/L the inaccuracy of the result makes performing a dilution a pointless exercise. We therefore will routinely dilute elevated CK samples to a level of 30,000 U/L and on specific request to the Pathology Resident to 75,000 U/L. Dilutions beyond this level will not be performed. However, samples may be sent to Mayo Medical Laboratories for further dilutions. If you have any questions concerning this change please contact Dr Greg Sharp (Gregory.sharp@vtmednet.org).

Test Name	Previous Max Value	New Max Value
Alcohol	300 mg/dL	600 mg/dL
Amylase	20,000 U/L	5,000 U/L
Bilirubin, Total	100 mg/dL	40 mg/dL
Digoxin	20.0 ng/mL	8.0 ng/mL
LDH	37,000 U/L	18,500 U/L
Lipase	40,000 U/L	10,000 U/L
CK	30,000 U/L	30,000 U/L

Cryoglobulins Collection Change

Due to unique handling requirements, effective June 6, 2011, patients requiring cryoglobulin testing should be directed to the Ambulatory Care Center for phlebotomy. Proper sample collection and processing is critical to ensure the accuracy of results for this assay. If you have any questions please contact Lab Customer Service (labcustomerservice@vtmednet.org).

PTH Sample Stability

A PTH sample stability study was performed in order to extend the amount of time that a sample can sit before centrifugation. Our recommendation is to centrifuge samples within 2 hours of collection but we will now accept PTH Samples within 4 hours of collection, spun or unspun. Our procedure has been updated with these changes.

PTH Sample Requirements: Collect 5.0 mL serum gel tube (red top tube is also acceptable), allow specimen to clot at room temperature. Spin and separate sample within 4-hours of collection. Submit 1.0 mL in a plastic vial. Minimum volume is 0.6 mL. Submit specimen frozen. Serum removed from the gel is stable 24 hours refrigerated.

Test Changes

DHEA-S Methodology Change

On April 8, 2011 the Chemistry Laboratory changed the method used for DHEA-S testing. The method changed from the Immulite® 2500 (Siemens Diagnostic) to the Access® 2 (Beckman Coulter). Comparisons between the two methods show excellent correlation, although the new results are a few percent lower than those performed by the previous methodology (See table below). The new method is noted by a comment, and new age, and sex specific reference ranges will be reported. If you have any questions concerning this change please contact [Dr. Greg Sharp](mailto:gregory.sharp@vtmednet.org) (gregory.sharp@vtmednet.org).

New DHEA-S	Reference Ranges
Females Age:	Reference Range: (ug/dL)
18-21	51 - 321
21-30	18 - 391
31-40	23 - 266
41-50	19 - 231
51-60	8 - 188
61-70	12 - 133
Over 71	7 - 177
Males Age:	Reference Range: (ug/dL)
18-21	24 - 537
21-30	85 - 690
31-40	106 - 464
41-50	70 - 495
51-60	38 - 313
61-70	24 - 244
Over 71	5 - 253

FLM Testing Change to Lamellar Body Count

The Chemistry Laboratory is discontinuing Fetal Lung Maturity Testing due to our vendor discontinuing support for the analyzer and reagents used for its Fetal Lung Maturity (TDx-FLM II) testing. As a result we began offering the Lamellar Body Count (LBC) on April 4, 2011 as a replacement.

The two technologically different methodologies have similar sensitivities and specificities and our correlations are similar to those in the literature¹. The result will be reported with a single cutoff of 50 K /cmm for maturity.

There is interference in the assay with blood and meconium and vaginal pool samples are discouraged. Sample handling for outside hospitals will change significantly. Samples should not be spun and are stable for 24 hours at 4 degrees. For more specific questions please contact Laboratory Customer Service (labcustomerservice@vtmednet.org).

Test Name:	Lamellar Body Count	Test Code:	FLMLBC
FAH Translation Code:	FAH5480	CPT Code:	83664
Method:	Automated Cell Counter		
Sample Requirements:	5.0 mL Amniotic Fluid in a sterile container submit on ice. Minimum volume: 1.0 mL. Do not spin. If sending sample from outside Fletcher Allen, sample must be received within 24-hours. Keep refrigerated. Please contact Customer Service prior to sending this test.		
Days performed:	Daily	Analytical Time:	Same day
Expected Value:	50 K/cmm or greater		
Effective Date:	April 4, 2011		

Reference:

1. Haymond S, Luzzi VI, Parvin CA et al. A direct comparison between lamellar body counts and fluorescent polarization methods for prediction respiratory distress syndrome. *Am J Clin OPathol.* 006;126:894-899

Test Changes

H. pylori and CMV IgG Antibody Change

On April 4, 2011, H.Pylori and CMV IgG Antibody testing moved from the Immulite® 2500 (Siemens Diagnostic) in Chemistry to the PhD™ (BioRad) system located in the Immunology section of the lab. Results from the PhD™ (BioRad) system are reported as Positive, Negative or Equivocal. Studies between the two methods for each test demonstrated excellent correlation. If you have any questions concerning this change please contact Dr. Greg Sharp (gregory.sharp@vtmendet.org) in the laboratory.

Quad Marker Method Change

On April 8, 2011 the methodology used for the analytes in the Quad Marker test changed to the Access® 2 (Beckman Coulter). This analyzer is widely used for this type of testing and will enable automation of all of the analytes on one platform. Values for AFP will remain the same. There will be a change in the absolute value of the results for the other analytes (beta-hCG, unconjugated estriol, inhibin), but the measured multiples of the median, used for the interpretation of risk, will remain the same. If you have any questions concerning this change please contact Dr. Greg Sharp (gregory.sharp@vtmendet.org) in the laboratory.

S. pneumonia AG Detection, Urine

On April 1st, 2011 the Microbiology Laboratory began offering the BinaxNOW® S. pneumoniae Urine Antigen Detection assay.

Clinical Application:

When the S. pneumoniae Urine Antigen Assay is used in conjunction with culture and other methods, it can aid in the diagnosis of pneumococcal pneumonia.

Test Information:

Test Name:	S. pneumoniae Urine Antigen Detection
Test Code:	SXPNAG
FAH Translation	FAH5474
CPT Code:	87899
Method:	Immunochromatographic Membrane
Sample Requirements:	10 mL random urine collected in a clean container
Test Note:	A negative result does not exclude infection with S. pneumoniae. Use result of Urine antigen test in conjunction with culture, other tests and clinical findings to make an accurate diagnosis. Recently administered S. pneumoniae vaccine may cause false positive results.
Days	Daily
Analytical Time:	Same day
Expected Value:	No S. pneumoniae antigen detected.
Effective Date:	April 1, 2011

References: Package Insert, Binax Now®
S. pneumoniae

Test Changes

Thyroid Antibody: Thyroglobin Antibody and Thyroperoxidase Antibody Change

On April 29, 2011, the Chemistry laboratory changed the methodology used for Thyroglobulin assays from the Immulite 2500 (Siemens Diagnostic) to the ADVIA Centaur (Siemens Diagnostic). There is a change in the values reported and our correlations indicate that the new assay is slightly more sensitive. The new assay had a slightly higher percentage of positives. In making this transition we compared 4 methods; two potential new assays, Mayo Medical Labs, and the old assay. Correlations were variable between all the assays but generally confirmed the results seen in a recent article comparing 5 automated assays ⁽¹⁾. Although all assays performed well, there was not good quantitative agreement between assays and they could not be used interchangeably. There is a distinct need for improved standardization in this area. If you have any questions concerning this change, please contact Dr. Greg Sharp (gregory.sharp@vtmednet.org) in the Laboratory.

Test Information:

Test Names:	Thyroperoxidase Antibody	Thyroglobin Antibody
Test Code:	TPO	ATGL
FAH Translation Code:	FAH5485	FAH5484
CPT Codes:	86376	86800
LOINC Code:	8099-4	8098-6
Method:	Chemiluminescence Immunoassay	
Sample Requirements:	Collect 3.5 mL whole blood in a serum gel tube and send 0.5 mL serum. Minimum serum volume 0.3 mL. Refrigerate sample.	
Days performed:	Monday through Friday	
Analytical Time:	Same day	
Expected Value:	Less than 61 U/mL	
Effective Date:	April 29, 2011	

Reference: 1. La'ulu, S., Slev, P. R. and Roberts, W. R. *Performance characteristics of 5 automated thyroglobulin autoantibody and thyroid peroxidase autoantibody assays.* Clinica Chimica Acta 376(2007):88-95.

Test Changes

Platelet Aggregation Test Update

Assay Information:

On of February 2011, the Special Coagulation Laboratory began offering Platelet Lumiaggregation. In addition to traditional platelet aggregation caused when an agonist reacts with platelet surface receptors, we will now be able to measure whether the dense granules of the platelet release their contents during the secondary wave of aggregation, and quantitate the release of ATP.

Method:

ATP release is measured by a sensitive luminescent (firefly luciferin-luciferase) assay for extra cellular ATP in combination with the simultaneous measurement of aggregation.

The ATP released by the platelet dense granules binds with luciferin-luciferase and generates light. A high gain photomultiplier tube measures luminescence simultaneously with aggregation on the Chrono-Log system.

Clinical Application:

Luminescent measurement of ATP secretion provides unequivocal evidence of normal or impaired dense granule release increasing the sensitivity of the test to secretion defects and storage pool deficiency.

Assay Limitations:

- Tests should be performed within 3 hours of venipuncture.
- Many drugs inhibit platelet function. Unless the aim of testing is to demonstrate drug induced inhibition, patients should be drug free for ten days to two weeks prior to testing.
- Further Clinical and Laboratory evaluation may be required to confirm diagnosis.
- Red Blood Cells in Platelet Rich Plasma (PRP) can inhibit the ability of the Aggregometer to detect changes in light intensity. This may cause the appearance of a decrease in platelet aggregation.
- Lipids in PRP can interfere with light transmission readings & prevent recording of aggregation.
- Platelet counts below 100,000/mL may cause problems with the setting of optical baseline, preventing the recording of aggregation

If you have any questions concerning this change, please contact Dr. Ted Bovill 656-2931 or by email at Edwin.Bovill@UVM.EDU

Test Changes

Platelet Aggregation Test Information:

Test Name:	Platelet Aggregation
Test Code:	PLTAGG
CPT Code:	85576 x 13
Method:	Aggregometer
Sample Requirements:	Must be scheduled a minimum of 2 weeks in advance with the Special Coagulation Lab. Unless the aim of testing is to demonstrate drug-induced inhibition, patients should be free of all drugs and supplements that affect platelets. Patient should have clear liquids only after midnight and scheduled for a 9:00 or 9:30 Am draw.
Days performed:	Monday –Thursday 9:00 or 9:30 with pre-scheduling.
Analytical Time:	Report available within 1-7 days.
Expected Value:	Interpretative Report
Test Note:	<p>Platelet Aggregation test includes a platelet count.</p> <p>A myriad of drugs inhibit platelet function, and a complete history of prescription and over-the-counter medications must be sought in all patients who represent with new onset mucocutaneous bleeding. The most likely culprits are non-steroidal anti-inflammatory drugs (NSAIDS), specific anti-platelet agents, selective serotonin reuptake inhibitors (SSRIs, anti-depressants), and some antibiotics. Furthermore, herbs, garlic, flavonoids in colored foods and drinks, and vitamin E may be implicated in unexpected bleeding. Thus, a thorough clinical history is essential to identify patients with drug-induced signs and symptoms. While platelet aggregometry may be useful to confirm the clinical suspicion, it is unnecessary in most cases. If mucocutaneous bleeding occurs, withdrawal of the implicated drugs, foods, or supplements is the best course of action.</p>
Effective Date:	February 23, 2011

References:

Patrono C. et al. Antiplatelet drugs: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines 8th edition. Chest 2008;122:199S-234S

