

Laboratory Communiqué

October, 2011

Laboratory Operations

Thanksgiving Holiday Hours: Laboratory Service Center

Thursday, November 24:	CLOSED ALL SITES	
Friday, November 25:	Ambulatory Care Center	7:00 a.m. - 5:30 p.m.
	Fanny Allen Campus	7:00 a.m. - 5:30 p.m.
	UHC Campus	7:00 a.m. - 5:30 p.m.
	Blair Park	CLOSED

Patients who require a stat or timed draw outside regular hours should come to the Ambulatory Care Center Registration area, on Level 3 (street level), and a phlebotomist will be paged.

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, 847-5121 or 1-800-991-2799.

CONTACT INFO

Call 802-847-5121
800-991-2799

Email: labmarketing@vtmednet.org

Or visit: www.FletcherAllen.org/lab

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Carbohydrate Antigen 19-9 (CA19-9)

Assay Information: As of October 31, 2011, the Chemistry Laboratory will perform the Carbohydrate Antigen 19-9 (CA 19-9) assay. CA 19-9 is currently sent to Mayo Medical Laboratories, which utilizes the same instrument, the Beckman Coulter Access® 2 (Beckman Coulter, Inc., Brea, CA). Correlations between the two laboratories' results have been excellent with essentially identical values. A notice will be attached to the report when the location of testing is changed. If there is concern about results for a particular patient, please contact the Dr. Greg Sharp in the Chemistry Laboratory at 847-5115.

Carbohydrate Antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen that may be elevated in patients with gastrointestinal malignancies such as cholangiocarcinoma, pancreatic cancer, or colon cancer. It has been used for the management of patients who have been diagnosed with cancers of the exocrine pancreas. It is important to recognize that it is neither sensitive nor specific enough to be used as a cancer screen and that a single measurement may be of limited value. Serial monitoring should begin prior to therapy. Patients must be able to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen even in the presence of malignancy. Results of this assay should not be considered absolute evidence of the presence or absence of malignant disease, and should always be interpreted in conjunction with other clinical and diagnostic information. Patients exposed to animal antigens either in the environment or as part of therapy or diagnosis may develop antibodies which may interfere with the assay reagents to produce unreliable results.

CA 19-9 Test Information:

Test Name:	CA 19-9
Test Code:	C199
Tests Translation Code:	FAH5493
CPT Code:	86301
Sample Requirements:	Collect 3.5 mL serum gel tube, submit 1.0 mL serum frozen. Minimum Volume 0.8 mL.
Days Performed:	Monday, Wednesday, and Friday
Analytical Time:	Same day
Expected Value:	Less than 55 U/mL
Price:	Please contact Laboratory Customer Service for pricing information, 847-5121 or 1-800-991-2799.
Effective Dates:	October 31, 2011

Estimated Glomerular Filtration Rate – Abnormal Value

For a number of years the estimated glomerular filtration rate (GFR) has been added to creatinine reports to facilitate detection, evaluation, and management of chronic kidney disease.⁽¹⁾ An estimated GFR of less than 60 mL per minute per 1.73 m² is associated with a graded increase in the risk of each of the major adverse outcomes of chronic kidney disease including impaired kidney function, progression to kidney failure and premature death caused by cardiovascular disease. To emphasize this factor, on October 31, 2011, estimated GFR values that are less than 60 mL per minute per 1.73 m² will be marked as abnormal.

1. Lesley A. Stevens, M.D., Josef Coresh, M.D., Ph.D., Tom Greene, Ph.D., and Andrew S. Levey, M.D., Assessing Kidney Function – Measured and Estimated Glomerular Filtration Rate. N Engl J Med 2006; 354:2473-2483

Free Light Chains, Serum

Assay Information: On September 14, 2011, the Chemistry Laboratory began offering Serum Free Light Chains (Kappa Free Light Chains, Lambda Free Light Chains and Kappa/Lambda Ratio) testing. This assay is based on Rate Nephelometry and performed on the Image® 800(Beckman Coulter). Previously this test was sent to Mayo Medical Laboratories which uses Rate Nephelometry technology. Serum Free Light Chains testing will be performed Monday through Friday with results available the same day. If you have any questions concerning this change, please contact Dr. Gregory Sharp in the laboratory (847-5115) or by email gregory.sharp@vtmednet.org.

Method: Rate nephelometry measures the increase in the intensity of light as it is scattered by particles suspended in a semi-disposable cuvette when a beam of light is passed through the cuvette. The light source for the rate nephelometer is a 670 nm laser. The detector is placed at a 90 degree angle from the laser beam to measure light scatter. The particles are formed by the immunoprecipitin reaction that occurs when a specific antibody is brought into contact with the specific antigen. The resulting formation of antigen-antibody complexes and the consequent change in intensity of scattered light occurs at a rate that gradually increases at first then rapidly and finally proceeds through a peak rate of change for that analyte. The electronics system derives the peak value for the rate of change from the scattered light signal then converts that value into concentration units using stored calibration information.

Clinical Significance: Immunoglobulin molecules consist of two identical heavy chains which define the immunoglobulin class and two identical light chains (kappa or lambda). Each light chain is covalently linked to a heavy chain and the two heavy chains are linked covalently at the hinge region. In healthy individuals, the majority of light chain in serum exists in this form, bound to heavy chain. However, low levels of free light chain (flc) are found in serum of normal individuals due to the over-production and secretion of free light chain by the plasma cells.

Elevated serum levels of monoclonal free light chain are associated with monoclonal gammopathies such as multiple myeloma, Waldenstrom's macroglobulinemia, monoclonal gammopathy of undetermined significance, primary amyloidosis and light chain deposition disease.

This automated, nephelometric assay is reported to be more sensitive than immunofixation for detection of monoclonal free light chains.

The specificity of this assay for detection of monoclonal light chains relies on the ratio of free kappa and lambda light chains. Once an abnormal free light chain kappa/lambda ratio has been demonstrated and a diagnosis made, the quantitation of the monoclonal light chain is useful for the monitoring of disease activity.

Limitations:

- Moderate lipemia may interfere with the ability to perform testing.
- Diagnosis cannot be made and treatment must not be given on the basis of free light chain measurement alone. Clinical history and other laboratory findings must be taken into account.
- Monoclonal free light chains can be highly variable: the amino acid composition of the light chain produced during an individual B cell disease state will influence the level at which a sample may show antigen excess with the free light chain assay.

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Free Light Chains Test Information:

Test Name:	Free Light Chains, Serum
Test Code:	SFLC
Tests Translation Code:	FAH5486
CPT Code:	83883 x 3
Sample Requirements:	Collect 3.5 mL serum gel tube, submit 0.5 mL serum. Stable for 7 days refrigerated. Markedly lipemic or hemolyzed samples will not be accepted.
Days Performed:	Monday—Friday, Run starts at 10 am
Analytical Time:	Same day
Expected Value:	Kappa free light chain: 0.33—1.94 mg/dL Lambda free light chain: 0.57—2.63 mg/dL Kappa/Lambda FLC ratio: 0.26—1.65
Price:	Please contact laboratory Customer Service for pricing information, 847-5121 or 1-800-991-2799.
Effective Date:	September 14, 2011

References:

Freelite human kappa free kit for use on the Beckman Coulter Immage/Immage 800 product insert, November 2005.

Freelite human lambda free kit for use on the Beckman Coulter Immage/Immage 800 product insert, November 2005.

Mayo Medical Laboratories Test Catalog, 2011. Mayo Medical Laboratories, Rochester, MN.

Microalbumin Name Change

Effective November 2, 2011, the name of our microalbumin assay name will change to albumin, urine. Urine albumin testing will include the following: urine albumin (mg/dl), urine creatinine (mg/dl) and an albumin/creatinine ratio (ug/mg).

Additionally, the following new nomenclature will be used to categorize albuminuria:

Normal	Less than 30 ug/mg creatinine
High	30-300 ug/mg creatinine
Very High and Nephrotic	Greater than 300 ug/mg creatinine

This new nomenclature is based on a 2011 National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus (Sacks DB, ed.), which in turn drew on the work of a collaboration initiated by Kidney Disease: Improving Global Outcomes, an international foundation dedicated to improving patient care and outcomes in kidney disease

(Levey AS, et al. The definition, classification, and prognosis of chronic kidney disease: a KDIGO Controversies Conference report. *Kidney Int* 2011;80:17-28). If you have any questions concerning this change, please contact Dr. Greg Sharp (gregory.sharp@vtmednet.org) in the Laboratory.

Opiate Screening Assay Change in Text

Immunoassay screens for opiates are generally optimized to recognize morphine and are much less sensitive to some semi-synthetic opiates such as oxycodone and oxymorphone. To emphasize this difference in sensitivity, a statement has been included with opiate screens that states “This assay does not detect oxycotin or oxycodone” to emphasize this lack of sensitivity and the fact that a negative screen might not indicate a lack of compliance. However, a review of opiate immu-

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noassay screen results and opiate confirmations would indicate that although less sensitive to oxycodone and oxymorphone, the opiate screening assay may be positive in patients with only these opiates in the urine, and that a positive urine opiate screen in patients taking oxycodone may not indicate abuse of other opiates. The statement will thus be changed to indicate a decreased sensitivity for these substances rather than an inability to detect them. This emphasizes the importance of consideration of both screening and confirmatory results in the interpretation of urine drug testing.

Quad Marker Interpretations in PRISM

As of October, 31, 2011, the interpretation portion of the Quad Marker report will file in the EHR of those accounts ordering in PRISM or with an interface (ATLAS). The result will state, "Refer to supplemental report for complete interpretive information" and the printed report will be handled as it had been previously. As part of this change a message will also be filed when the sample is received in the laboratory. These changes should enhance the mechanics of handling and reporting of results. If you have any questions concerning these changes, please contact Dr. Greg Sharp (gregory.sharp@vtmednet.org) in the Laboratory.

Troponin and CK-MB Assay Change

This fall, as part of a major change in the instrumentation used for high volume biochemical analysis, the laboratory will change the analyzer used for CK-MB and troponin analysis from the ADVIA Centaur® (Siemens Healthcare Diagnostics, Deerfield, IL) to the Ortho Vitros® 5600 (Ortho Clinical Diagnostics, Rochester, NY). Preliminary correlations look very good for these assays, but there may be small changes in reference range and other aspects of these tests. As the time for the transition approaches, more detailed information concerning these changes will be made available electronically. If you have any questions concerning these changes, please contact Dr. Greg Sharp (gregory.sharp@vtmednet.org) in the Laboratory.

HCG Assay Change

This fall, as part of a major change in the instrumentation used for high volume biochemical analysis, the laboratory will change the analyzer used for HCG analysis from the ADVIA® Centaur (Siemens Healthcare Diagnostics, Deerfield, IL) to the Ortho Vitros® 5600 (Ortho Clinical Diagnostics, Rochester, NY). Preliminary correlations look very good for these assays, but there may be small changes in reference range and other aspects of these tests. As the time for the transition approaches, more detailed information concerning these changes will be made available electronically. If you have any questions concerning these changes, please contact Dr. Greg Sharp (gregory.sharp@vtmednet.org) in the Laboratory.

Compliance Updates

Advance Beneficiary Notice of Noncoverage (ABN) Form Update

The Centers for Medicare and Medicaid Services (CMS) has revised the ABN form.

This new form must be used as of November 1, 2011. Please contact Laboratory Customer Service (847-5121 or 1-800-991-2799) for the new forms.

For detailed information with regard to the ABN process, please see the link below.

https://www.cms.gov/MLNProducts/downloads/ABN_Booklet_ICN006266.pdf

Compliance Updates

Physician Signature on Lab Requisitions

As some providers may be aware, CMS has begun the process of rescinding the requirement for physician signature on paper requisitions for laboratory orders. This is in response to the feedback from the Laboratory community as a whole indicating that this was an unreasonable burden and could negatively impact patient care.

This being said, the Fletcher Allen Health Care Laboratory will continue to request physician signatures on all paper lab requisitions when it is feasible and will not impact patient care.

The reason for this request include:

1. New York Medicaid continues to require physician signature on lab requisitions.
2. We are subject to government and other payer audits where we are required to provide signed orders for the laboratory testing we performed.

Without the actual paper requisitions signed by the ordering provider we must contact the ordering provider and request a copy of the progress notes that document the specific lab orders. This documentation must be collected and returned in a timely manner. If we cannot provide this documentation, then we must return any monies we received for the service we provided. If the original order is signed, any additional work disruptions for both the laboratory and the physician office staff will be minimized.

If you have questions, please contact the Laboratory Compliance staff (847-5121). Thank you for your efforts to comply with this request.

Medicare Preventative Services:

Medicare Initial Preventative Physical Examination (IPPE). Also known as “Welcome to Medicare Visit”

Please be aware that the IPPE benefit does not include any clinical laboratory tests.

Medicare Annual Wellness Visit (AWV)

Medicare does not usually pay for lab services associated with a general or routine medical exam (V70.0). If applicable and in addition to V70.0; please include all ICD-9-CM codes (signs, symptoms) related to the particular labs ordered at the time of the routine exam.

Example: A Lipid Panel is ordered and the physician is monitoring the patient’s Hyperlipdemia—add 272.4

Medicare does offer preventative screening as a covered benefit however; the benefits are subject to frequency limitations. See table on the following page.

If you ordered any of the testing in the table at the time of an annual wellness or routine exam, please use the appropriate ICD-9-CM codes to indicate you are screening so that the service may be covered.

Example: A Lipid panel is ordered as a screen for cardiovascular disease—add V81.2

If the service does meet the criteria of a covered service, please provide the patient with an Advance Notice of Noncoverage, so that they are aware of their financial liability for the testing requested.

Medicare Preventative Services Summary:

SERVICE	TESTING INCLUDED	ICD-9-CM CODES	FREQUENCY
Cardiovascular Disease Screenings	Lipid Panel Cholesterol Lipoprotein Triglycerides	Report one or more of the following codes: V81.0, V81.1, V81.2	Every 5 years
Diabetes Screening	Glucose, quantitative, blood (except reagent strip)	V77.1	Two screening tests per year for beneficiaries diagnosed with pre-diabetes. One screening per year if not previously diagnosed with pre-diabetes.
Screening Pap Tests	Conventional, Thin Prep or Image Assisted Pap tests	Low Risk: Report one of the following, V76.2, V76.47, V76.49, V72.31. High Risk: V15.89	Low Risk- Every 24 months High Risk: Annually
Colorectal Cancer Screening	Fecal Occult Blood	V76.41 or, V76.51	Beneficiaries age 50 and older Fecal occult blood annually
Prostate Cancer Screening	Prostatic Specific Antigen	V76.44	Male beneficiaries 50 and over annually
Human Immunodeficiency Virus (HIV) Screening	HIV-1 and/or HIV-2 screening by EIA or ELISA technique or HIV-1 and/or HIV-2 screening by rapid antibody test	No Increased Risk Factors: V73.89 Increased Risk: V73.89 and V69.8 Pregnant Women: V73.89 Plus one of the following codes: V22.0, V22.1, V23.9	One voluntary screening per year. Three voluntary screenings of pregnant Medicare beneficiaries : 1. When diagnosis of pregnancy is known. 2. During 3 rd trimester. 3. At labor, if ordered by the women's clinician.