



Happy Holidays



Phlebotomy Hours

Christmas Week

Monday, December 24th ACC open 7:00 a.m. to 1 p.m.

Fanny Allen CLOSED

Tuesday December 25th All patient service centers CLOSED

Wednesday, December 26th ACC and Fanny Allen **7 a.m. to 5 p.m.**

Thursday, December, 27th ACC and Fanny Allen **7 a.m. to 5 p.m.**

Friday, December 28th ACC and Fanny Allen **7 a.m. to 5 p.m.**

Saturday, December, 29th Regular hours

Sunday, December, 30th Regular hours

New Year

Monday, December 31st ACC open 7:00 a.m. to 1:00 p.m.

Fanny Allen CLOSED

Tuesday, January 1st All patient service centers CLOSED

Medical Center Campus

Ambulatory Care Center (ACC)

Laboratory Services

Main Pavilion, Level 2 (Orange Level)

Regular Hours

Monday through Friday, 7:00 a.m. to 7:00 p.m.

Saturday, 9:00 a.m. to 1:00 p.m.

Fanny Allen Campus

Laboratory

Regular Hours

Monday through Friday, 7:00 a.m. to 7:00 p.m.

Saturday, 8:30 a.m. to 1:00 p.m.

Sunday, 9:00 a.m. to 1:00 p.m.

If you have a patient with an immediate need or require a timed test during closed hours above, please instruct patients to go to the Ambulatory Care Center information desk inside the front entrance on level 3 (street level), and a phlebotomist will be paged. Patients will need to go to registration prior to having samples drawn.

Phlebotomy Cards

We now have available business sized phlebotomy cards and holders. If you would like a set for your office please contact laboratory customer service.

January 2008

Holiday Phlebotomy Hours

Phlebotomy cards

Test News

Poly stat@ Mono Test

Testing for Vitamin D

Compliance Update

New LCD's

Sed Rate

Homocysteine

Acid Phosphatase; Total

& Prostatic

Plasma vs Serum Glucose

Attachments

Cystic Fibrosis Gene Mutation

Factor V Leiden Mutation

Prothrombin G20210A Mutation

Genetic Informed Consent Form

Infectious Mononucleosis Poly stat® Mono Test

We have received a notice from the manufacturer of the Mononucleosis Poly stat® Mono test used in the laboratory. The notice states that while the assay meets all documented specifications, “this assay has not been established for patients under 18 years of age”¹. This statement will be added to each test result.

The assay used is a qualitative membrane strip based immunoassay that detects heterophile antibodies in blood. It is important to recognize that in children and adolescents heterophile antibody response is less frequent than in adults. Specifically, children under 4 years of age most often will not develop a heterophile antibody response to Epstein-Barr virus and viral-specific serology should be used for diagnosis in this age group or in other patients who have atypical clinical presentations or severe prolonged illnesses with negative heterophile antibody tests. In addition, antibody concentrations decline after the acute illness has resolved but may be detectable for up to 9 months after the onset of illness. Therefore, a positive monospot test is not diagnostic of active disease.²

If you have any questions concerning this issue, please contact Dr. Greg Sharp in the laboratory
gregory.sharp@vtmednet.org

¹ Medical Device Alert, Polymedco Poly stat® Mon Cassette, Polymedco inc., November 6, 2007

² Peter J, Ray CG: Infectious mononucleosis. *Pediatr Rev* 1998;19(8):276-279

Testing for Vitamin D Deficiency

A number of recent news stories and articles in clinical journals have raised interest in the importance of Vitamin D both in its traditional role in calcium and bone metabolism, as well as an independent predictor of risk for cancer and other chronic diseases. A recent review in the New England Journal of Medicine discusses the nature of vitamin D deficiency, its role in skeletal and non skeletal health, and suggests strategies for its prevention and treatment.¹

The conclusion of the article is that in most circumstances, providing children and adults with approximately at least 800 IU of vitamin D3 per day or its equivalent should guarantee vitamin D sufficiency unless there are mitigating circumstances. If measurement is deemed indicated, however, serum 25-hydroxyvitamin D is the barometer for vitamin D status: the serum 1,25 dihydroxyvitamin D assay should only be used rarely and only for specific clinical indications. As long as the combined total of 25-hydroxyvitamin D2 and D3 (the D2 and D3 indicate plant or animal source for the precursor) is greater than 30 ng/mL, the patient has sufficient vitamin D. The optimal range for 25-hydroxyvitamin D is not well established: in the quoted article it is considered to be 30-60 ng/mL, while Mayo Medical Laboratories reports an optimal range of 25-80 ng/mL. Physicians should use these guidelines in combination with their clinical judgement according to the specific clinical situation.

Test Name: 25-Hydroxyvitamin D2 and D3

Test Code: VD2D3

Sample Requirements: Draw blood in a plain, red-top tube(s). Spin down and send 0.5 mL of serum refrigerated. Minimum volume, 0.25 mL

Test Name: Vitamin D, 1,25-Dihydroxy

Test Code: VD125

Sample Requirements: Draw blood in a plain, red-top tube(s) or a serum gel tube(s) from a fasting patient (4-hour fast preferred but not required). Spin down and send 1.2 mL of serum refrigerated. Specimen Minimum Volume: 0.65 mL

¹Holick, Michael F. Vitamin D Deficiency. New England Journal of Medicine 2007;357:266-281.

COMPLIANCE UPDATE

Medicare Coverage Decisions

There are 3 *new* Medicare Local Coverage Decisions (LCDs) effective December 1, 2007.

Sedimentation Rate, Westergren (ESR)
Homocysteine Level, Serum
Acid Phosphatase; Total & Prostatic

These new coverage decisions discuss the indications for ordering these tests and list the ICD-9 codes that support medical necessity.

The Medicare Local Coverage Decisions (LCD) for Reticulocytes has been *retired*.

Reticulocyte Count

The effective date was May 31, 2007.

To view any of these coverage decisions in their entirety, go to <http://www.NGS Medicare.com/>

If you have questions regarding these new coverage limitations please contact Janet Schroeter (847-9435) or Kathy Nadeau (847-0930).

Plasma Versus Serum Glucose

Please be aware that both the Basic Metabolic Panel (BMP) and the Comprehensive Metabolic Panel (CMP) include a serum glucose. It is not necessary to order a plasma glucose in addition as long as the sample is spun within 2 hours of collection.

The sooner the sample is spun and separated from the cells the better. We would recommend that it is spun within 2 hours. There is a **7% per hour loss of glucose** if the serum is allowed to sit on the cells. Another option would be for you to draw a gray top tube in addition to a tiger top, if spinning or transport is an issue.



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FLETCHER ALLEN HEALTH CARE

PATHOLOGY & LABORATORY MEDICINE

CYSTIC FIBROSIS MUTATION ANALYSIS: TEST UPDATE

TEST NAME: Cystic Fibrosis Mutation Analysis, 70 Mutation Panel

ASSAY INFORMATION:

Beginning January 8, 2008, mutation analysis for Cystic Fibrosis diagnosis and carrier state will be done at Mayo Medical Laboratories. Mayo Medical Laboratories tests for 70 of the most common mutations. The screen includes all 25 of the mutations recommended by the American College of Obstetrics and Gynecology. Detection rates vary by ethnicity.

Mayo Medical Laboratories tests for 70 of the most common CF mutations. The screen includes all 25 of the mutations recommended by the American College of Obstetrics and Gynecology (ACOG) and is suitable for use in prenatal screening. Detection rates vary by ethnicity.

DETECTION RATES FOR CLASSIC FORMS OF CYSTIC FIBROSIS BY POPULATION:

Racial or Ethnic Group	Carrier Frequency	Mutation Detection Rate*	Residual Risk after a negative test result
African American	1/65	77%	1/279
Ashkenazi Jewish	1/25	99%	1/2401
Asian American	1/90	54%	1/194
Mixed European	1/25	80%	1/120
Eastern European	1/30	75%	1/117
Romanian specifically	1/30	65%	1/183
French Canadian	1/25	91%	1/267
Hispanic American	1/46	81%	1/238
Northern European	1/25	91%	1/267
Southern European (Italian)	1/25	77%	1/105

This test will replace the current send-out to Genzyme and represents a large cost savings to our patients and clients.

METHOD:

The multiplex PCR-based assay from TM Bioscience

As before, we recommend obtaining informed consent for genetic testing. Informed consent should be documented in the patient chart. There is no need to send consent forms to the laboratory. For your convenience, blank forms are available at http://www.fahc.org/pathology/Services/lab_forms.html, in the Laboratory Services Directory or by fax from Lab Customer Service (847-5121). A black form is also included in this packet.

ORDERING INFORMATION:

Test Name: Cystic Fibrosis Mutation Analysis

Test Code: CFIB

Sample Requirements:

Blood: Draw 3.0 mL blood in lavender-top (EDTA) tube, invert several times to mix. Forward whole blood promptly at room temperature. Minimum volume: 0.5 mL

Amniotic Fluid: Obtain 20 ml of amniotic fluid. Transfer specimen to 2 screw-capped sterile centrifuge tubes. Send specimen refrigerated. Specimen cannot be frozen. Minimum volume: 10 mL

Chorionic Villi: Obtain 20 mg of chorionic villus specimen. Send specimen refrigerated in transport media in 15-mL tube.

Testing Performed: Monday - Friday

Analytical Time: 5 days

Patient Price: Call laboratory Customer Service for pricing information.

Effective Date: January 8, 2007



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FACTOR V LEIDEN MUTATION :TEST UPDATE

TEST NAME: Factor V Leiden Mutation

ASSAY INFORMATION:

As of 1/02/2008 Factor V Leiden Mutation analysis will be performed in the Fletcher Allen Health Care Molecular Diagnostic laboratory, replacing the current assay that is sent to Mayo Medical Laboratories.

CLINICAL APPLICATION:

Factor V Leiden is a common gene mutation which causes activated protein C resistance and increases the risk of deep vein thrombosis and pulmonary embolism. It has also been associated with pregnancy complications. The prevalence of factor V Leiden is about 5% in Caucasians and much less in other ethnic groups. It is often observed in women with a history of VTE during pregnancy or in association with oral contraceptives or postmenopausal hormone use. Individuals who are heterozygous for factor V Leiden have a 3-8-fold increased risk for venous thrombosis; while those who are homozygous have a 12-34-fold increased risk. Factor V Leiden manifests as thrombosis mainly when there are additional inherited or acquired thrombosis risk factors. Heterozygosity for factor V Leiden is associated with a 2-3-fold increased risk of pregnancy loss, and possibly other pregnancy complications such as preeclampsia and fetal growth retardation.

Factor V Leiden status alone usually does not alter anticoagulation management of patients with venous thrombosis. Thorough assessment of other inherited and acquired risk factors, including genetic counseling are necessary for proper patient management. Such comprehensive clinical assessment is available at the Fletcher Allen Health Care Thrombosis and Hemostasis Program in the Hematology-Oncology Unit (847-4925).

The diagnosis of factor V Leiden is made by DNA analysis of the F5 gene, which encodes the factor V protein. The term "factor V Leiden" refers to the specific G-to-A substitution at nucleotide 1691 in the gene for factor V that predicts a single amino acid replacement (R506Q) at one of three APC cleavage sites in the factor Va molecule.

Informed consent for genetic testing is required before testing asymptomatic patients such as those presenting with a family history of factor V Leiden. Informed consent should be documented in the patient chart. Blank forms are available in your Laboratory Services Directory or you can request them by calling Laboratory Customer Service (847-5121)

METHOD:

Genomic DNA from a peripheral blood sample is amplified by real-time PCR. Sequence specific Fluorescence Resonance Energy Transfer (FRET) probes for the FV Leiden mutation are analyzed using melt curve analysis.

ORDERING INFORMATION:

Test Name: Factor V Leiden Mutation

Test Code: FACT5L

Sample Requirements: Collect 2.0 mL lavender top tube (EDTA), submit whole blood.

Testing Performed: Tuesday and Friday

Analytical Time: 1 day

Reference Range: No mutation identified

Patient Price: Call laboratory Customer Service for pricing information.

CPT Code(s):

83890 Molecular isolation or extraction

83896 x2 Nucleic acid probe, each

83900 Amplification of patient nucleic acid

83912 Interpretation and Report

Effective Date: January 2, 2008

References:

1. Simioni, P et al. (1997) The New England Journal of Medicine, Vol. 336, pp. 399-403.
2. Cripe, L et al. (1992) Biochemistry, Vol. 31, pp. 3777-3785.
3. Beauchamp, N et al. (1994) The British Journal of Haematology, Vol. 88, pp. 219-22.
4. Emmerich, J et al. (2001) Thromb Haemost, Vol. 86, pp. 809-816.
5. Kujovich, J.(2007) Gene Reviews Factor V Leiden Thrombophilia www.genetests.org
6. Cushman M. Epidemiology and risk factors for venous thrombosis. Seminars in hematology. 2007;44:62-69.



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PATHOLOGY & LABORATORY MEDICINE

PROTHROMBIN G20210A MUTATION :TEST UPDATE

TEST NAME: Prothrombin G20210A Mutation

ASSAY INFORMATION:

As of 1/02/2008, this assay will be done at Fletcher Allen Health Care Molecular Diagnostics laboratory, replacing the current assay sent to Mayo Medical Laboratories.

CLINICAL APPLICATION:

Prothrombin G20210A (“the prothrombin gene mutation”) is a common gene mutation that slightly increases the circulating prothrombin level (factor II) and increases the risk of deep vein thrombosis and pulmonary embolism. It is present in about 2% of Caucasian populations and is less common in other ethnic groups.). As with other thrombosis risk factors, the clinical expression of prothrombin G20210A is variable. There is a two-fold increase in relative risk for DVT in individuals who are heterozygous for the G20210A allele, and a higher risk for homozygotes. Prothrombin G20210A may also increase the risk of pregnancy loss and preeclampsia.

Factors that predispose to thrombosis in patients with the G20210A mutation include whether the mutation is heterozygous or homozygous and the presence of coexisting genetic and acquired risk factors such as factor V Leiden and obesity.

The prothrombin gene mutation status alone usually does not alter anticoagulation management of patients with venous thrombosis. Thorough assessment of other inherited and acquired risk factors, including genetic counseling are necessary for proper patient management. Such comprehensive clinical assessment is available at the Fletcher Allen Health Care Thrombosis and Hemostasis Program in the Hematology-Oncology Unit (847-4925).

Detection of the mutation requires DNA analysis of the F2 gene that encodes prothrombin to identify the G to A transition mutation at nucleotide 20210A. The prothrombin G20210A is a common mutation within the 3’ -untranslated region of the prothrombin gene that may result in increased transcription of the gene.

Informed consent for genetic testing is required before testing asymptomatic patients such as those presenting with a family history of Prothrombin G20210A Mutation. Informed consent should be documented in the patient chart. Blank forms are available in your Laboratory Services Directory or from Laboratory Customer Service (847-5121)

METHOD:

Genomic DNA from a peripheral blood sample is amplified by PCR, and DNA mutations are detected using Fluorescence Resonance Energy Transfer (FRET) and melt curve analysis.

ORDERING INFORMATION:

Test Name: Prothrombin G20210A Mutation

Test Code: PROGMU

Sample Requirements: Collect 2.0 mL lavender top tube (EDTA), submit whole blood.

Testing Performed: Tuesday and Friday

Analytical Time: 1 day

Reference Range: No mutation identified

Patient Price: Call laboratory Customer Service for pricing information.

CPT Code(s):

83890 Molecular isolation or extraction

83896 x2 Nucleic acid probe, each

83900 Amplification of patient nucleic acid

83912 Interpretation and Report

Effective Date: January 2, 2008

References:

Leroyer, C et al. (1998) Thrombosis and Haemostasis Vol. 80, pp. 49-51.

Poort, S et al. (1996) Blood Vol. 88, pp. 3698-3703.

Poort, S et al. (1994) Thrombosis and Haemostasis Vol. 72, pp. 819-824.

McGlennen, R et al. (2002) The Archives of Pathology Laboratory Medicine Vol. 126, pp. 1319-1325.

Kujovich, J. (2007) Gene Reviews Prothrombin Thrombophilia www.genetests.org.

Epidemiology and risk factors for venous thrombosis. Seminars in hematology. 2007;44:62-69

Cushman M. Epidemiology and risk factors for venous thrombosis. Seminars in hematology. 2007;44:62-69.



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Addressograph

**VERMONT STATE
INFORMED CONSENT FOR GENETIC TESTING**

Genetic Testing has been recommended for me (or my child). I understand that the genetic testing requires analysis of the chromosomes, Deoxyribonucleic acid (DNA), Ribonucleic acid (RNA), or protein obtained from a sample of blood, skin, cheek brushings or other body tissues. I understand that no other tests than those authorized will be performed and that my biological sample will not be saved without my authorization.

I understand the specific test that I (or my child) is having and its accuracy. I understand that the results of this test may be inconclusive or uninformative (not tell me anything). I understand that incorrect information about family relationships may affect the test result. I understand that this test may reveal private information such as non-paternity (someone's father not being who they think they are) or adoption. I understand that such information, if obtained through this test, will NOT be revealed to me, my child, or to anyone else, under any circumstances.

I understand that I am responsible for the costs of genetic testing. If I choose to have my (or my child's) insurance company pay for the testing, it is my responsibility to contact the company to determine that they cover such testing. I know that if the insurance company pays for the testing they may have a right to learn the test results. I can choose not to have the insurance company pay for the testing, in which case I will pay for the test myself. I understand that in some cases payment is required before the genetic testing is performed.

Whether it is the insurance company or me that pays for the testing, the results may become part of my (or my child's) permanent medical record. Having this information in the medical record may make it more difficult for me (or my child) to get health, disability, long-term care or life insurance. I have also considered the possible financial impact of the test result.

I understand that Vermont law gives me certain protections from misuse of genetic information, including the right to sue if such misuse occurs.

I have explained to _____ the possible risks, benefits and limitations of the genetic test _____ (name of the test).

Provider Signature: _____ Date: _____

Institution: _____ Phone number: _____

I have read (or had read to me) the above information and received a copy of this page. All of my questions and concerns about genetic testing have been addressed. I know that I can contact the person above if I have additional questions.

Patient _____ Date: _____

If patient is a minor:

Parent or guardian: _____ Date: _____

Witness: _____ Date: _____