

Lab Updates

March 2008

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Creatinine Standardization

Changes in Reference Range and Laboratory Estimation of Glomerular Filtration Rate (GFR)

UMass Memorial Medical Center Laboratories

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M **MEASUREMENT OF CREATININE CONCENTRATIONS** provides information on two parameters: kidney function and muscle mass. When kidney function is impaired, Creatinine levels in blood increase. Minor changes in Creatinine concentrations may indicate kidney impairment. Abnormally high levels of Creatinine are a warning of possible malfunction of the kidneys, sometimes even before a patient reports any symptoms. Chronic Kidney Disease (CKD) is defined as having some type of kidney abnormality or decreased kidney function for 3 months and longer. There are many causes of CKD. High risk groups include those with diabetes, hypertension, and family history of kidney disease. A cornerstone of diagnosis of CKD is the determination of GFR. GFR is a measure of efficiency with which substrates are cleared from the body by the kidneys. Estimation of GFR is of great importance with increasing emphasis on the early detection and measurement of CKD.

The National Kidney Disease Education Program (NKDEP), in collaboration with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Communities Confederation of Clinical Chemistry (EC4), has launched the Creatinine Standardization Program to reduce inter-laboratory variation in Creatinine assay calibration and provide more accurate estimates of glomerular filtration rate (GFR). Some of the important recommendations include the calibration of Creatinine assay using the new NIST standard that is traceable to Gas Chromatography-isotope dilution Mass Spectrometry (GC-IDMS) and reporting Creatinine based estimates of GFR using modification of diet in renal disease (MDRD) algorithm, which takes age, gender and race in to account. This effort is part of a larger NKDEP initiative to help health care providers better identify and treat chronic kidney disease in order to prevent or delay kidney failure and improve patient outcomes.

UMass Memorial Laboratories validated their Creatinine assay traceable to the new international standard and **effective March 3, 2008**, will begin reporting both Creatinine as well as modified MDRD equation for calculated GFR, based on this new standard. Extensive internal validation studies showed that these new standards will result in slightly lower patient values than those currently being reported. The average bias was -0.05 for Creatinine and 1.0 for GFR in both males and females.

New IDMS-Traceable MDRD Study Equation for the Calculation of GFR:

$GFR (mL/min/1.73 m^2) = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if African American})$
(conventional units); where S_{Cr} is serum Creatinine.

Since the patient's race is not usually available to the laboratory, the factor for African-American patients will be noted on the report so that clinicians can adjust the

calculated result. The equation has not been validated in children and will only be reported for patients > 16 years of age. The equation is normalized for an average adult body surface area of 1.73 m²; weight and height adjustment is not necessary. Results are reported in mL/min/1.73 m² and will only be reported numerically for values below 60.

Based on internal studies done by the laboratory, separate reference ranges for Creatinine will be adopted for males and females. The new reference range for males will be 0.60-1.30 mg/dL and females will be 0.50-1.20 mg/dL.

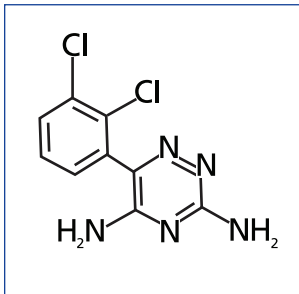
If you have questions, comments or suggestions, please contact:

Dr. L.V. Rao, Director at 508-334-7593 or
via email at RaoL@ummhc.org

Ms. Judy Rennell, Manager at 508-334-3803 or
via email at Rennellj@ummhc.org



Changes in Lamotrigine (Lamictal) Testing



Lamotrigine is an anticonvulsant drug used in the treatment of epilepsy and bipolar disorder. For epilepsy it is used to treat partial seizures, primary and secondary tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome.

Lamotrigine also acts as a mood stabilizer. Chemically unrelated to other anticonvulsants, lamotrigine has relatively few side-effects. The exact mechanism of action of lamotrigine has not been fully elucidated. It is thought to act by inhibiting release of glutamate, an excitatory neurotransmitter via inhibition of voltage-sensitive sodium channels. Lamotrigine has been successful in controlling rapid cycling and mixed bipolar states in people who have not received adequate relief from lithium, carbamazepine and/or valproate, possibly having significantly more antidepressant potency than either carbamazepine or valproate. It is useful as part of the treatment of some people with major (unipolar) depression, and has recently been reported to be a useful treatment for some people with post-traumatic stress disorder (PTSD) and borderline personality disorder (BPD).

Lamotrigine is 55% to 56% bound to proteins and salivary concentrations are approximately 46% of plasma. 94% is excreted in renal and its half-life is 13-59 hours (adults) and 7-66 hrs (Children).

Effective March 17, 2008, the Lamotrigine assay will be performed using highly specific HPLC methodology. There are no changes in specimen collection requirements or in the therapeutic range (3-14 mcg/mL). Concentrations that exceed 15 mcg/mL may contribute to adverse effects.



If you have questions, comments or suggestions, please contact:

Dr. L.V. Rao, Director at 508-334-7593 or
via email at RaoL@ummhc.org

Ms. R. Ambacher, Manager at 508-334-7316 or
via email at Ambacher@ummhc.org



Updates to the Lab Test Directory

17-Hydroxyprogesterone (17AOHP)

Methodology: Tandem Mass Spectrometry
Performed: Mon, Thu
Reported: 1 – 6 days
CPT: 83498



SPECIMEN REQUIREMENTS

Collect: Gold/SST (Serum or plasma must be separated from the cells ASAP and placed in a pour off tube).

Collection Notes: Also acceptable: plasma (EDTA or heparin).

Transport: Frozen if unable to deliver to the lab within 8 hours of collection.

Min. Volume: 0.5 mL Serum or Plasma

Parvovirus B19 DetectR™ (PARB19)

Methodology: Polymerase Chain Reaction
Performed: Mon, Wed, Fri
Reported: 1 – 4 days
CPT: 87798



SPECIMEN REQUIREMENTS

Collect: Gold/SST

Collection Notes: Plasma (EDTA) is acceptable as an alternate specimen.

Transport: Refrigerated. Serum or plasma should be frozen if beyond 3 days.

Min. Volume: 1.0 mL

EBV DNA Ultraquant® (EPBAR)

Methodology: Polymerase Chain Reaction
Performed: Mon - Fri
Reported: 1 – 4 days
CPT: 87799



SPECIMEN REQUIREMENTS

Collect: Lavender

Collection Notes: Other acceptable specimens: SST serum. If CSF, source must be noted.

Transport: Refrigerated. Serum or plasma should be frozen if beyond 3 days.

Min. Volume: 1 mL Plasma

Updates to the Lab Test Directory

Activated Partial Thromboplastin Time (PTT)

Methodology: Automated
Performed: Daily
Reported: Same Day
CPT: 85730



SPECIMEN REQUIREMENTS

Collect: Light Blue (3.2% Sodium Citrate)
Collection Notes: Stable unopened for 24 hrs. at room temperature—patient must not be on heparin—See Alternate collection notes for patients on heparin.
Transport: 1 full, unopened light blue top tube, room temperature
Min. Volume: 1 full, unopened light blue top tube
Alternate Collection: If patient is on heparin, call for stat courier and send unspun tube at room temperature to lab.
Notes: Must arrive within 3 hours of draw time.

Borrelia species DNA Detection by PCR (BORB) - Lyme Disease

Methodology: Polymerase Chain Reaction
Performed: Varies
Reported: 1 – 4 days
CPT: 87476



SPECIMEN REQUIREMENTS

Collect: Lavender
Collection Notes: Also acceptable: serum, CSF and skin punch biopsy
Transport: Refrigerated (3 days, freeze biopsy)
Min. Volume: 1ml Plasma

Creatine Kinase Isoenzymes (CPKI)

Methodology: Electrophoresis
Performed: Sun - Sat
Reported: 1 – 3 days
CPT: 82552 Creatine kinase isoenzymes;
82550 Creatine kinase, total



SPECIMEN REQUIREMENTS

Collect: SST
Collection Notes: Plasma samples no longer acceptable. CK-MB and CK-BB are quite labile. Specimens should be frozen if the assay cannot be performed within 24 hours. Repeated freeze/thaw cycles destroy CK activity.
Transport: Refrigerated (24 hours, then freeze).
Min. Volume: 1ml Serum

Please make a note of these changes on pages 8, 11, 42, 67, 80, and 155 in your copy of the *Directory of Tests and Services*.

Update: Special Coagulation Assays

Protein S Antigen and Protein S Antigen Free assay will be performed on new equipment starting **March 15, 2008**.

There are no changes in specimen collection requirements. Please note the following changes in the reference ranges:

Females/Males	
Protein S Antigen, Total	
Old reference range	73 – 130%
New reference range	60 – 140%
Protein S Antigen, Free	
Old reference range	60 – 126%
New reference range	60 – 141%



If you have questions, comments or suggestions, please contact:

Dr. Liberto Pechet, Director of Hematology at
508-334-0265 or via email at pechetL@umhc.org



Update: JAK2 Qualitative Assay for Bone Marrows

Effective February 20, 2008, In addition to JAK-2 quantitative assay in blood DNA, a qualitative assay in bone marrow DNA is now available in house. The report for JAK2 qualitative assay in bone marrow will indicate the presence or absence of the V617F mutation in JAK2 gene in the patient bone marrow.

This V617F mutation in JAK-2 (Janus Kinase 2) gene has been detected in 80-97% of polycythemia vera (PV), approximately 50% of idiopathic myelofibrosis (IMF), 30-50% of essential thrombocythemia (ET) cases and in smaller percentage of patients with other myeloproliferative disorders (MPDs).

Genomic DNA is isolated and amplified by polymerase chain reaction (PCR) followed by primer extension reactions. The resulting product is analyzed by Matrix Assisted Laser

Desorption Ionization-Time of Flight (MALDI-TOF) Mass Spectrometry.

The UMass Memorial *Molecular Diagnostics Test Requisition* should be used and sent with the sample. Copies of this requisition can be obtained by contacting Customer Service at 800-476-4431. The specimen requirement is 3 ml blood (minimum) drawn in a purple top (EDTA) tube. This assay will be performed twice a week and the TAT of this assay will be 3-5 days.

If you have questions, comments or suggestions, please contact:

Dr. Edward Ginns, 508-856-8134, or
via email at Edward.Ginns@umassmed.edu

Dr. Marzena Galdzicka, 508-856-4384, or
via email at Marzena.Galdzicka@umassmed.edu.



Update: Hepatitis B Quantitative Testing

As of March 3rd, 2008, the Hepatitis B Quantitative assay will be performed in-house in the UMass Memorial Molecular Diagnostics Laboratory. A conserved region of HBV DNA, isolated from patient plasma, is amplified and measured by Real-Time PCR. The analytical range of the assay is 1.7 to 8.3 log IU/mL of HBV DNA (50 to 200,000,000 IU/mL HBV DNA). This assay was validated (r statistic=0.98; 95%CI =0.97-0.98 at a p value<0.0001 in the Pearson correlation test) using samples previously measured by the Roche COBAS TaqMan HBV assay currently used for HBV quantification.

The specimen requirement and ordering mnemonic for HBV quantitative testing remain unchanged: one PPT tube is required, for ordering use mnemonic HEPBDNA.

If you have questions, comments or suggestions, please contact:

Dr. Edward Ginns, 508-856-8134, or
via email at Edward.Ginns@umassmed.edu

Dr. Michael Mitchell, at 508-334-7160 or
via email at mitchelm@umhc.org

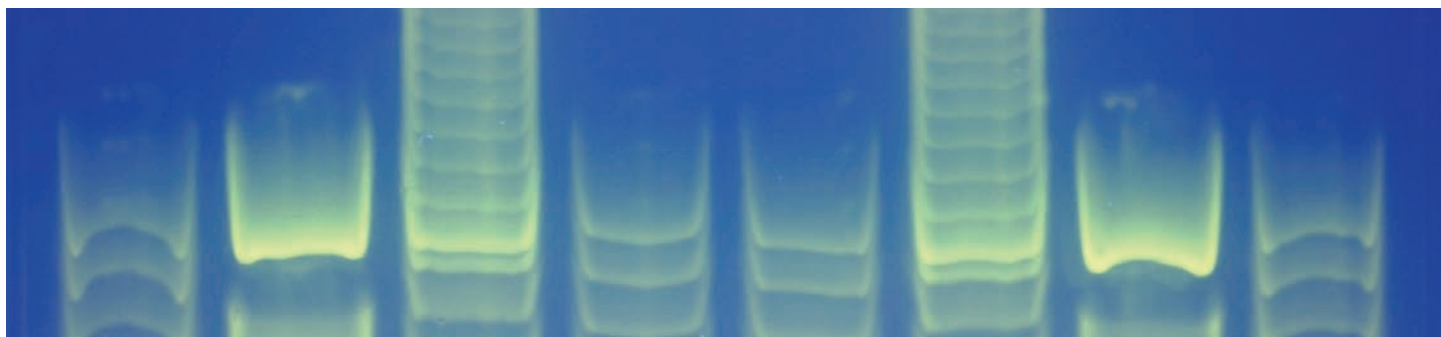
Dr. Marzena Galdzicka, 508-856-4384, or
via email at Marzena.Galdzicka@umassmed.edu.



Specimen Requirement *Changes/Clarifications*

Effective March 17, 2008

Test	Change/Clarification
Beryllium (BER)	6 ml Royal blue trace metal tube (serum or plasma)
Maternal Sequential # 1 (MSSEQ2)	HCG is being added to this testing. Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days gestation (Crown-Rump length (CRL) must be 4.2-7.9 cm) Unacceptable Conditions: Hemolyzed specimens. A crown-rump length greater than 7.9 cm
Maternal Sequential # 2 (MSSEQ1)	Specimen must be drawn between 15 weeks, 0 days and 22 weeks, 6 days gestation Unacceptable Conditions: Hemolyzed specimens.
Maternal Screen First Trimester Only (MSFIRST)	Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days gestation Unacceptable Conditions: Hemolyzed specimens. A crown-rump length greater than 7.9 cm.
Maternal Screen Integrated #1 (MSSINT1)	Specimen must be drawn between 10 weeks, 3 days and 13 weeks, 6 days gestation (Crown-Rump length (CRL) must be 3.6-7.9 cm) Unacceptable Conditions: Hemolyzed specimens
Maternal Screen Integrated #2 (MSSINT2)	Specimen must be drawn between 15 weeks, 0 days and 22 weeks, 6 days gestation
<i>Prior to submitting the above testing in yellow, sonographer certifications must be registered with the laboratory. Please contact Sue Mills, Manager at 508-334-4925.</i>	
Maternal Serum Screen AFP only (AFPM)	Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation
QUAD (QUAD)	Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation
Molybdenum (MOLY)	5ml royal blue trace metal tube (serum or plasma)



Featured Patient Service Center

We are one of the largest laboratory providers in New England

UMass Memorial Laboratories has opened a Patient Service Center (phlebotomy draw station) at 640 Bolton Street, Marlboro, Massachusetts.

The vision of UMass Memorial Laboratories is:

- To be a leading provider of laboratory services throughout New England, meeting the needs of patients and providers in the region, and
- To be one of the top ten academic medical center-based laboratories in the United States by 2008



Marlboro Lakeview PSC ***640 Bolton Street, Marlboro, MA***

The Marlboro Lakeview PSC is located at 640 Bolton Street, Marlboro, MA. The hours are Monday through Friday 8:00am-5:00pm, closed 12:15-1:15pm. The phone number at the Marlboro Lakeview PSC is 508-303-1990.

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If you don't believe it, put us to the test!