

# Lab Updates

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## September 2006

### CHANGES IN MATERNAL SERUM SCREENING

Effective October 24, 2006, the performing site for Maternal Serum Quad/Triple testing and Amniotic Fluid AFP testing will change from FBR to ARUP. With this change we are able to offer electronic reporting of testing results allowing results to be available in Meditech upon completion. Abnormal results will continue to be called during normal office hours Monday through Friday 8:30 - 5:00. Requests for re-calculations can be made through our customer service center which is staffed 24 hours a day. There will be no changes in the sample requirements or turn around times.

With this October 24<sup>th</sup> change, please discard the FBR requisitions and write in QUAD or TRIPLE maternal testing on the standard outpatient requisition and attach a completed maternal patient history form. We have attached an updated patient history form to this newsletter that can be replicated as needed.

**Please note** that ARUP uses a different cut-off for calling a result abnormal. While FBR uses a cut-off of 1:200, ARUP uses a cut-off of 1:150. ARUP uses the 1:150 cut-off because the difference in Down syndrome detection between these two cut-offs is minimal, while the false positive rate difference is more significant. With a 1:200 cut-off, the detection rate for the general population is 84% with a false positive rate of 6.2%. Using a 1:150 cut-off, the detection rate is 81% with a false positive rate of 4.9%. Note that ARUP, like FBR, reports the calculated risk, so an individual provider could still choose to use a 1 in 200 cut-off, although patients with a risk of less than 1 in 150 will be reported as screen normal. ARUP has found that most cases of Down syndrome actually have a risk of 1 in 110 or higher.

Trisomy 18 detection should remain unchanged because ARUP and FBR employ the same methodology and algorithm for detection.

If you have any questions regarding the above information or this testing please contact our Genetic Counselors through Customer Service at 508-334-2863 or Susan Mills, Referral Testing Manager, at 508-334-4925, or via email at MillsS@ummhc.org.

**PATIENT HISTORY FORM FOR MATERNAL SERUM / AMNIOTIC FLUID TESTING**

*(This is not a requisition please submit an outpatient requisition identifying the ordered testing)*

**REQUIRED PATIENT INFORMATION FOR ALL MATERNAL TESTING– This information is critical for proper risk calculation. There can be a delay in reporting if this information is not provided.**

Patient Last Name \_\_\_\_\_ Patient First Name \_\_\_\_\_ MI \_\_\_\_\_

Date of Birth \_\_\_\_\_ MR# \_\_\_\_\_

Specimen Collection Date \_\_\_\_\_ Sample type :  Serum  Amniotic Fluid

First day of LMP \_\_\_/\_\_\_/\_\_\_ If ultrasound was done \_\_\_\_\_ Wks. On \_\_\_/\_\_\_/\_\_\_

Physician/ Genetic Counselor \_\_\_\_\_ Phone # \_\_\_\_\_

Comments or Special Instructions \_\_\_\_\_

**QUAD**  **Triple**  **AFP**  **Amniotic AFP**  **Acetylcholinesterase**

A. Current weight \_\_\_\_\_ lbs.

B. Due date (EDC) \_\_\_/\_\_\_/\_\_\_ Determined by: Last menstrual period  Ultrasound

C. Is current pregnancy: Singleton  Twins  Triplets  Unknown

D. What is the patient's race?

Caucasian  African-American  Hispanic  Asian  Unknown  
Other, specify \_\_\_\_\_

E. Does the patient require insulin to control diabetes? No Yes Unknown

F. Is there a family history of neural tube defect? No Yes Unknown  
If yes, relationship to fetus? \_\_\_\_\_

G. Is there a family history of aneuploidy (e.g. Down syndrome, Trisomy 18 or 13)? No Yes Unknown

If yes, specify aneuploidy \_\_\_\_\_  
Relationship to fetus? \_\_\_\_\_

H. Is this an *in vitro* fertilization pregnancy? No Yes Unknown  
If yes, age of egg donor (if not the patient) \_\_\_\_\_ yrs. Date of Birth \_\_\_\_\_

I. Has patient taken valproic acid or carbamazepine during this pregnancy? No Yes Unknown  
If yes, specify \_\_\_\_\_

J. Is this a repeat sample? No Yes Unknown

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### **CHANGES IN TESTING FOR PNH**

The sugar (sucrose) water and Ham tests have been used for many years for the confirmation of Paroxysmal Nocturnal Hemoglobinuria (PNH), a severe hemolytic disease associated with thrombotic manifestations. It is known, however, that these tests are relatively insensitive. As of November 15, 2006, we will no longer offer the sugar water and Ham tests.

In recent years, flow cytometry analysis of glycosyl phosphatidylinositol–anchored proteins (GPI-AP) became the standard test in diagnosing PNH. In addition, the PNH test developed and performed by the Flow Cytometry Laboratory at UMass Memorial is 10 to 100 fold more sensitive than conventional qualitative flow cytometry assay. Multiple GPI-AP protein (CD55, CD59, CD66b, and CD16) are analyzed on granulocytes. If classic PNH is identified, the red blood cells will be analyzed to determine the degrees of deficiency (PNH I, PNH II and PNH III, or mosaic).

Whenever PNH or PNH clones are suspected, please use the Hematology/Pathology or Clinical Laboratories requisition forms, and mark PNH under Other. Please collect 8-10 ml of peripheral blood in a purple top tube and deliver them to the flow cytometry laboratory on the day of collection. The PNH test is only valid when it is performed on peripheral blood samples; bone marrow samples will be rejected for this test. The assay is performed on a daily basis, and the turn around time is 1-2 days. Results will be reported in the anatomic pathology module in PCI under the Hematopathology section.

For any further questions or comments regarding PNH flow test, please contact:  
Sa Wang, MD, at 508-793-6174, or via email at [WangA@ummhc.org](mailto:WangA@ummhc.org) or  
Mary Andersen, Lab Manager at 508-793-6234, or via email at [AndersenM@ummhc.org](mailto:AndersenM@ummhc.org)

Dr. Liberto Pechet, Director, at 508-334-0265, or via email at [PechetL@ummhc.org](mailto:PechetL@ummhc.org)  
Diane Connor, Manager, at 508-334-7153, or via email at [ConnorD@ummhc.org](mailto:ConnorD@ummhc.org)

### **CHANGES IN PERFORMING THE RISTOCETIN COFACTOR ASSAY**

As of November 15, 2006, the Ristocetin Cofactor assay will be performed in-house. The normal range will be 58-172% instead of the previous normal range reported by ARUP of 44-195%. Please note that patients with blood type 0 may run 10-20% lower values than all other blood group patients. Please draw blood in a blue-top tube. The turn around time will be 7-10 days.

We offer 4 assays for the diagnosis of von Willebrand's disease: Ristocetin Co-factor (a functional assay), von Willebrand factor antigen (an immunologic assay), Factor VIII coagulant (decreased in most types of von Willebrand's disease), and Ristocetin-induced platelet aggregation (RIPA) (a semi quantitative platelet aggregation assay that also discriminates between von Willebrand's disease type IIB or platelet type von Willebrand's disease, and all other types). For patients with low values we suggest correlation with the blood group.

Once the diagnosis of von Willebrand's disease is established, von Willebrand multimers can be ordered to sub classify the condition into its various subtypes. This assay will be sent to our reference lab. Please do not order the multimers assay until the diagnosis of von Willebrand's disease had been established by the in-house panel described above.

For any further questions or comments, please contact:  
Dr. Liberto Pechet, Director, at 508-334-0265, or via email at [PechetL@ummhc.org](mailto:PechetL@ummhc.org)  
Diane Connor, Manager, at 508-334-7153, or via email at [ConnorD@ummhc.org](mailto:ConnorD@ummhc.org)

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## CHANGES IN REPORTING OF i-STAT POTASSIUM

Effective October 12, 2006, please note the following comment will be added to the reporting of i-STAT Potassium outcomes: ***i-STAT analyzer cannot determine presence of hemolysis in sample.***

### CRITICAL VALUE CHANGES

Our current critical value policy for Lead reporting is:

Test	Current Critical Value
Lead, venous (0 to 17 years)	10 micrograms/dL
Lead, venous (greater than 17 years)	25 micrograms/dL

Effective October 1, 2006, based on State guidelines and regulatory requirements, please note the following changes in Lead reporting:

Test	New Critical Value
Lead, capillary (less than 15 years)	Greater than or equal to 25 micrograms/dL
Lead, venous (less than 15 years)	Greater than or equal to 25 micrograms/dL
Lead, venous (greater than or equal to 15 years)	Greater than or equal to 15 micrograms/dL

### CLARIFICATION

In the August 2006 *Lab Updates*, in the section entitled "Recommendations for Use of the Molecular Diagnostics Requisition", it was not made clear that the last two bullet points were Either/Or possibilities.

**EITHER**

- Sign the Consent Verification attesting that:
  - a) the test is for diagnostic purposes or
  - b) a consent was obtained

**OR**

- Submit a signed Genetics Test Consent form with the sample.
- Both Molecular Diagnostic Requisitions and Genetics Test Consents are available on our [website](#) or by calling Customer Service at 508-334-2863.

### DID YOU KNOW.....?

JoLynn Reasoner, the Manager of Outreach Phlebotomy and Logistics at UMass Memorial Laboratories, is one of 17 persons nationally who sit on the Customer Advisory Board of Becton-Dickinson Diagnostics. The board was founded in 2003 to serve its customers by stimulating constructive discussion on issues affecting the clinical diagnostic market and arriving at creative solutions to emerging critical challenges. Its members are respected industry experts all working together for the benefit of our shared customers.