

Lab Updates

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CHANGES IN MATERNAL SERUM SCREENING

Effective September 13th, 2006, the performing site for Maternal Serum Quad testing will change from FBR to ARUP. With this change we are able to offer electronic reporting of Quad 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 from 8:30 AM to 5:00 PM. There will be no changes in the sample requirements or turn around times. The new updated history form for this test can be obtained from laboratory Customer Service at 508-334-2863.

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 our customer service line at 508-334-2863

RECOMMENDATIONS FOR USE OF MOLECULAR DIAGNOSTIC REQUISITION & GENETIC CONSENT FORM

Use the Molecular Diagnostics test requisition to order any molecular test. There is a consent form on the bottom of the requisition. Please note that some specialized Molecular testing will require additional patient information forms which are available through customer service. Please be sure the ordering physician's name is legible. Indicate symptomatic vs. asymptomatic status. If symptomatic, please list symptoms. If there is a positive family history note this in the appropriate section, and also note if there is a known gene mutation in the family. Complete all additional questions within a test section (see Cystic Fibrosis and Fragile X). Responses to these questions are essential in properly calculating risk for the patient.

Sign the Consent Verification section attesting that the test is for diagnostic purposes or that consent obtained is necessary. Please remember to submit a signed Genetics Test Consent form.

Tips for Using Genetics Consent Form

- Include specimen type and tests ordered on the form.
- Have patient and witness sign and print their names, and date the form.
- Both Molecular Diagnostic Requisitions and Genetics Test Consent forms are available on our website or by calling the laboratory customer service at 508-334-2863.
- As a service to our providers, we have Genetic Counselors available in the laboratory Monday-Friday afternoons for questions regarding molecular or genetic testing. They can be reached through our customer service line at 508-334-2863.

CHANGES IN ADRENOCORTICOTROPIC HORMONE TEST (ACTH)

Effective September 13, 2006, ACTH testing will be performed by using chemiluminescent immunometric assay technology. As ACTH was previously sent out to a reference lab, bringing this test in house will greatly improve overall turnaround time.

Plasma ACTH assays are useful in the differential diagnosis of pituitary Cushing's disease, Addison's disease, autonomous ACTH producing pituitary tumors, hypopituitarism with ACTH deficiency and ectopic ACTH syndrome.

In normal individuals, ACTH reaches a peak in the early morning (6:00-8:00 a.m.) and levels become lowest late in the day and near the beginning of the sleep period. Because of this diurnal rhythm, it is customary to draw plasma ACTH samples between 8:00-10:00 a.m. However, discrimination of patients with Cushing's disease from normal individuals may be best made on samples obtained in the evening (10:00 p.m. to midnight).

Recommended sample collection guidelines: Collect into iced, plastic lavender-top (EDTA) tube, noting time of collection. After venipuncture, immediately immerse the tubes in an ice bath. Separate plasma from cells by centrifugation. Transfer the plasma into a plastic transport tube. The specimen should be frozen immediately and maintained frozen until tested. To avoid delays in turnaround time when requesting multiple tests on frozen samples, please submit separate frozen specimens for each test requested.

The reference range (typically established in the morning) is less than 46 pg/mL.

CHANGES IN 17 ALPHA –HYDROXY PROGESTERONE RESULTING

The manufacturer of the 17 Alpha-Hydroxy Progesterone test recently identified a high bias in the test results due to a drift in the calibration from the gravimetric standard. This resulted in 10-20% higher values in both patient and control results. Effective August 11, 2006, this high bias was corrected with a new calibrator lot. Should you feel it necessary that this test be repeated on a given patient, please notify client services at 508-334-2863 and submit a new sample which will be performed at no charge.

CHANGES IN HEPATITIS B SURFACE ANTIBODY TESTING

Effective September 13th, 2006, Hepatitis B Surface Antibody (Anti-HBs) testing results will be reported quantitatively. This test was previously reported qualitatively only. There are no changes in specimen collection and turnaround time.

Clinical interpretation following testing algorithm:

Anti-HBs Assay Result	Result Text	Clinical Interpretation of Immune Status
<5.00 mIU/mL	Negative	Patient is considered to be not immune to infection with HBV.
≥ 5.00 mIU/mL and <12.0 mIU/mL	Indeterminate	Unable to determine if anti-HBs is present at levels consistent with immunity. Patient's immune status should be further assessed by considering other clinical information or retesting another specimen drawn at a later time.
≥12.0 mIU/mL	Positive	Anti-HBs detected at >10 mIU/mL. Patient is considered to be immune to infection with HBV. It has not been determined what the clinical significance is for values greater than ≥ 12 mIU/mL, other than the individual is considered to be immune to HBV infection.

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 or

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

CHLAMYDIA AND NEISSERIA GONORRHEA URINE COLLECTION

Effective September 13, 2006, we will no longer accept urine samples for Chlamydia and Neisseria Gonorrhoea unless they are collected in the specialized Genprobe urine collection tube. Urines not stabilized in the Genprobe media will be cancelled and a new sample will be requested. A standard urine collection cup is no longer acceptable as it does not provide the optimum sample for detection. Genprobe urine collection kits can be ordered individually or in boxes of 50. Further order information can be obtained by contacting Customer Service at 508-334-3845.

REFERENCE RANGE CHANGES

Effective date September 13, 2006, please note the following changes in reference ranges.

The new reference ranges for Cadmium Exposure:

Cadmium, blood: 0.0-5.0µg/L	<u>CPT Codes</u> 82300
Cadmium, urine: 0.0-2.6 µg/L	82300
Creatinine, random urine: Not established	82570
Cadmium per gram of creatinine: 0.0-3.0 µg/g crt	
*β ₂ Microglobulin, urine: 1-160 µg/L	82232

β_2 Microglobulin per gram of creatinine: 0-300 $\mu\text{g/g}$ crt

* β_2 Microglobulin, urine units are changing

The new reference ranges for Sex Hormone Binding Globulin:

Age	Male	Female	CPT Codes
1-30 days	13-85 nmol/L	14-60 nmol/L	84270
31-364 days	70-250 nmol/L	60-215 nmol/L	
1-3 years	50-180 nmol/L	60-190 nmol/L	
4-6 years	45-175 nmol/L	55-170 nmol/L	
7-9 years	28-190 nmol/L	35-170 nmol/L	
10-12 years	23-160 nmol/L	17-155 nmol/L	
13-15 years	13-140 nmol/L	11-120 nmol/L	
16-17 years	10-60 nmol/L	19-145 nmol/L	
18 years and older	11-80 nmol/L	30-135 nmol/L	
Tanner Stage I	26-286 nmol/L	30-173 nmol/L	
Tanner Stage II	22-169 nmol/L	16-127 nmol/L	
Tanner Stage III	13-104 nmol/L	12-98 nmol/L	
Tanner Stage IV	11-60 nmol/L	14-151 nmol/L	
Tanner Stage V	11-71 nmol/L	23-265 nmol/L	

The new reference ranges for Fragile X:

Negative: The individual's allele(s) is in the normal range; and therefore is predicted to be neither affected with nor a carrier of Fragile X. Methylation pattern is normal for the gender.

CPT Codes 83890, 83898 x 2, 83909, 83891, 83892 x 2, 83894, 83897, 83896, 83912

TUBE RECALL

This is to inform you that the manufacturer for one of our tubes has notified us of a product recall.

The recall is for Sodium Citrate Additive Greiner Bio-One Blood Collection, Blue Top, 3.2 ml blood collection tube **lot #B050609 only**. This lot has been recalled due to an inadequate amount of Sodium Citrate in the tube making them unsuitable for laboratory testing. Please do not use tubes of this lot number. Return them with the courier and ask for replacement by faxing an order to UMass Memorial Laboratories Materials Management at 508-334-0277.

We apologize for any inconvenience. Please contact customer service if you have any questions at 508-334-2863.