MEDICAL CENTER OF CENTRAL GEORGIA
MEDICAL LABORATORIES COMMUNIQUE'

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CHEMISTRY

New "Urine Drug Screen Panel with Pain Management Drugs": A new urine drug panel incorporating the pain management drugs oxycodone, oxymorphone, methadone, propoxyphene and buprenorphine along with traditional opiates (morphine, codeine, hydrocodine, hydromorphone and heroin) will be offered starting July 18th.

The "Opiate" assay in the commonly used medical urine drug 7 panel does not efficiently detect oxycodone or oxymorphone. The medications methadone, propoxyphene and buprenorphine are not detected by the "Opiate" assay.

This new panel will offer physicians:

1. Improved screening for drug overdoses
2. A screening test to assist in meeting "Pain Management" standards for controlled substance monitoring.

The tests included in this panel and their detection limits:

Medical Urine Drug Screen with Pain Management Drugs with or without Ethanol (two separate panels)

1. Amphetamines – 1000 ng/mL
2. Barbiturates – 300 ng/mL
3. Benzodiazepines – 300 ng/mL
4. Cannabinoids – 50 ng/mL
5. Cocaine & metabolite – 300 ng/mL
6. Phencyclidine - 25 ng/mL
7. Opiates (analogues of morphine) – 300 ng/mL
8. Oxycodone/Oxymorphone – 100 ng/mL
9. Methadone – 300 ng/mL
10. Propoxyphene – 300 ng/mL
11. Buprenorphine - 5 ng/mL

(12). Ethanol (optional) – 40 mg/dL

Specimen Integrity checks include

1. Creatinine
2. pH

New Test – Anti-CCP: The laboratory will offer this new test effective July 18, 2012. Cyclic Citrullinated Peptide Antibodies (Anti-CCP) is useful for evaluating patients suspected of having rheumatoid arthritis (RA). The assay in use, Abbott Architect, is a second generation assay with a sensitivity of ~ 78% for RA and fewer than 5% false positives in healthy controls. Most studies show much improved specificity for Anti-CCP compared to RF.

Blood ACTH and IgE: The laboratory will cease performing these assays July 9th at MCCG. This change is necessitated due to the elimination of these products by our supplier. Both tests will be sent out to our reference laboratory (ARUP Laboratories) for testing.

Method Changes July 18th: Several methods will change due to discontinuation of product availability for one of the laboratory immunoassay analyzers as follows:

1. PSA Method Change: The laboratory will change the method for performance of PSA effective July 18th. The new method, Abbott Architect, will have the same normal ranges and performance schedule as the previous method. However, as a tumor marker, serial studies are recommended to be performed using the same method**. In order to accommodate serial interpretation with the new method** the laboratory will implement the following procedure for the 1st year of new method performance:

- All "diagnostic" PSA Orders will be reviewed for prior test performance at MCCG, using the old Immulite method. If prior testing was performed the sample will be assayed by both methods with both results reported so that a new patient baseline may be established.
- "Screening" PSA Test Results if **elevated** will be reviewed for prior test performance at MCCG. If prior testing was performed the results by both the new and old method will be reported so that a new patient baseline may be established.

Test performance by the "old Immulite" method will require referral to a reference laboratory. This will add approximately 3 days to the turnaround time for the assay. Test performance at MCCG is not possible due to the manufacturer's discontinuation of the Immulite PSA product for the instrumentation we have at MCCG.

2. Intact Parathyroid Method: The new assay "normals" are 12 – 88 pg/mL. See Test Information Guide for details.

3. Anti-TPO Method Change: The new assay "normals" are <5.61 IU/mL. See Test Information Guide for details.

4. Homocysteine Method Change: The new assay "normals" are 5-15 umol/L. See Test Information Guide for details.

5. DHEA-S Method Change: The new assay "normals" vary with age and gender. Please see the Lab Guide Information on the back of newsletter.

6. C-Peptide Method Change: The new assay "normals" are 1-5 ng/mL for fasting serum / plasma samples and 35-116 ng/mL for 24 hr urine collections. See Test Information Guide for details.

7. Anti-Thyroglobulin Antibody: The new assay "normals" are <4.11 IU/mL. See test Information Guide for details.

COMPLIANCE CORNER

Frequency limitations for Glycated HB /HBA1C tests:

CMS's Medicare National Coverage Determinations Manual, Pub 100-03, Ch 1, pt 3 § 19021, states that it is not considered reasonable and necessary to perform an HBA1c test more often than every 3 months on a controlled diabetic patient unless documentation supports the medical necessity of testing in excess of national coverage guidelines.

For more information on this coverage decision (CPT83036): www.cms.gov/medicare-coverage-database.

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Test Information Guide – New Tests

Intact - PTH:
Specimen: Heparin plasma or serum with separator.
Minimum Volume: 0.5 mL
Alternate test names: PTH Intact
Stability: Plasma-8hrs@ RT or 48 hrs @ 2-8C
Serum- 4hrs@ RT, 8 hrs @ 2-8C
Availability: Monday – Sunday, 24/7, Stat
Turnaround Time: 2 hours from receipt in lab
Reference Range: 12-88 pg/mL
CPT: 83970
Limitations: Avoid lipemic and hemolyzed samples
Interpretative Information:

	PTH (pg/mL)	Ca (mg/dL)
Normal Parathyroid Function:	12 – 88	Normal
Hypoparathyroidism:	< 27	Low
Primary Hyperparathyroidism:	> 88	High
Secondary Hyperparathyroidism:	> 88	Normal/Low
Nonparathyroid Hypercalcemia:	< 27	High

Anti-CCP:
Specimen: Serum with or without separator; lithium heparin with separator.
Minimum Volume: 0.5 mL
Alternate test names: Cyclic Citrullinated Peptide Antibodies
Stability: Samples may be stored for up to 22 hrs at RT; up to 7 days at 2-8C
Availability: M-F 9 -9; Saturday and Sunday 9-2
Turnaround Time: 4 hrs.
Reference Ranges: < 5.0 U/mL
CPT: 86200
Method: Chemluminescent Immunoassay
Interpretative Information:
<5.0 U/mL is negative
Results will be reported 0.5 U/ml-200 U/mL

Anti-TPO
Specimen: Serum or plasma (Lithium heparin, sodium heparin) with separator.
Minimum Volume: 0.5 mL
Alternate test names: Anti-Thyroid Peroxidase Antibody
Stability: Analysis within 8 hrs at RT; up to 72 hr 2-8C
Availability: M-F 9-9; Sat-Sun 9-2
Turnaround Time: 4 hrs
Reference Ranges: <5.61 IU/mL
CPT: 86376
Method: Chemluminescent Immunoassay
Interpretative Information: Reportable Range
3.0 IU/mL-2000 IU/mL

Homocysteine:
Specimen: Fasting >/= 4hrs preferred, non-fasting samples will not be rejected. Heparin plasma (lithium or sodium) with gel separator
Minimum Volume: 0.5 mL
Alternate test names: None
Stability: Plasma must be separated from cells within one hour: if centrifugation is not possible within 1 hr, keep sample on Wet Ice for up to 6 hrs.
Availability: M-F 9am-9pm; Sat-Sun 9am-2pm
Turnaround Time: 4 hrs

(Homocysteine continued)
Reference Ranges: 5-15 umol/L
CPT: 83090
Method: Chemluminescent Immunoassay
Interpretative Information: Men tend to have higher levels than women. Postmenopausal women tend to have higher levels than premenopausal women.

DHEA-S:
Specimen: Serum with separator preferred. Plasma collected in Sodium Heparin can be used.
Minimum Volume: 0.5 mL
Alternate test names: Dehydroepiandrosterone sulfate
Stability: On or off the clot for up to 8 days @ 2-8C
Availability: M-F 9am - 9pm, Sat/Sun 9am – 2 pm
Reference Ranges:
*F*emale: 20-24 yrs = 134-407 ug/dL, 25-44 yrs = 75-511 ug/dL, 45-54 yrs = 56-283 ug/dL, >55yrs = 34-182ug/dL.
Male: 20-24 yrs = 238-539 ug/dL, 25-44 yrs = 140-592 ug/dL, 45-54 yrs = 146-450 ug/dL, 55-64 yrs = 49-362 ug/dL, >65 yrs = 229-284 ug/dL.
CPT: 82627
Method: Chemluminescent Immunoassay
Interpretative Information: Avoid grossly hemolyzed samples.

C-Peptide:
Specimen: Fasting >/= 4hrs preferred; non-fasting specimen will not be rejected. Serum with separator; Heparin (lithium or sodium) with or without separator.
24 hr Urine Samples without preservative stored at 2-8 during collection.
Minimum Volume: 0.5 mL serum or plasma
Alternate test names: Connecting Peptide of Insulin
Stability: 8 hrs @ 15-30C; 48 hrs @ 2-8C
Availability: M-F 9-9; Sat-Sun 9-2
Turnaround Time: 4 hrs.
Reference Ranges: Fasting serum values 1-5 ng/mL.
24 Hr Urine values 35-116 ng/mL
CPT: 84681
Method: Chemluminescent Immunoassay

Anti-TG (TGAB):
Specimen: Serum or plasma (Lithium or sodium heparin) with separator
Minimum Volume: 0.5 mL
Alternate test names: Anti-Thyroglobulin Antibody
Stability: 8 hrs@ RT; up to 72 hrs. @ 2-8C
Availability: M-F 9-9; Sat-Sun 9-2
Turnaround Time: 4 hrs
Reference Ranges: < 4.11 IU/mL
CPT: 86800
Method: Chemluminescent Immunoassay
Interpretative Information: Elevated thyroglobulin Ab levels may interfere with the measurement of serum thyroglobulin concentration. In cancer patients with elevated TGAB serial serum thyroglobulin studies are not recommend for assessment.