MEDICAL CENTER OF CENTRAL GEORGIA
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MICROBIOLOGY

Discontinuation of Fecal Trypsin Testing: The laboratory will no longer perform testing for trypsin in fecal specimens. As this test is not available from our reference laboratories it will be unavailable. The absence of trypsin in fecal material was used as presumptive evidence of pancreatic deficiency although the test lacked specificity. It was also used as a screening method for cystic fibrosis.

The recommended replacement test is **"Pancreatic Elastase in Stool",** a sendout test referred to Mayo Medical Laboratories. This assay allows the diagnosis or exclusion of pancreatic exocrine insufficiency, which can be caused by chronic pancreatic, cystic fibrosis, pancreatic tumor, cholelithiasis or diabetes mellitus. The test requires 1 gram random formed stool. Pancreatic enzyme supplementation therapy should be discontinued prior to sample collection. Watery, diarrheal stool is not recommended for testing. The analytic time is one day for this test but as it is only performed once per week turnaround time can be up to 10 days.

New Molecular Assay for Chlamydia trachomatis and Neisseria gonorrhoea: The laboratory has introduced a new molecular (PCR) test for the detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis and Neisseria gonorroeae to better aid in diagnosis of these diseases.

The new procedure may be performed on specimens from cervical or urethral swabs, urine and *ThinPreps*. Collection requirements for the new assay are as follows.

1. Cervical and uretheral specimens must be submitted in the **Aptima Swab Unisex Specimen Collection Kit**. Specimens submitted in other devices will be rejected.
2. Urine, not in Aptima device, must be submitted within 24 hours of collection.
3. *ThinPrep* vial submitted for Pap tests may be used. Results will no longer be reported with Cytology Pap results. Results will be under the individual test name (Chlamydia or GC RNA).

This is a qualitative procedure; results will be reported as **positive**, **negative** or **indeterminate** for Chlamydia and/or GC. Positive or negative indicates the presence or absence of the respective organism rRNA. Indeterminate indicates the specimen needs to be recollected for re-testing if clinically indicated.

CHEMISTRY

New Lipid Profile Calculated Component: The laboratory lipid profile report will include the calculated Non-HDL Cholesterol result (Non-HDL-C) starting in February. The new result is calculated as follows: Non-HDL-C = Total Cholesterol – HDL Cholesterol.

Interpretative guidelines are as follows:

Interpretation	Adult Reference Range
Desirable	<130 mg/dL (< 100 optional)
Borderline high	130 to 159 mg/dL
High	160 to 189 mg/dL
Very High	≥189 mg/dL

The TC/HDL C Ratio and the associated interpretative information from the Framingham Study are being deleted and are replaced by the new Non-HDL-C result.

Cystatin C with Estimated GFR: The laboratory will offer cystatin C analysis with estimated GFR starting February 25, 2014. The GFR will be estimated using the CKD-EPI Cystatin C (2012) equation. The test will be performed daily 24/7 with a TAT of less than 3 hours. It is not available stat at this time.

Cystatin C is useful for assessing renal function in patients especially where creatinine may be misleading (e.g. very obese, elderly and malnourished patients).

Cystatin C is a low molecular weight (13,250 kD) cysteine proteinase inhibitor that is produced by all nucleated cell and found in body fluids. Since it is formed at a constant rate and freely filtered by the kidneys, the serum concentration is inversely correlated with the glomerular filtration rate (GFR); that is, high values indicate low GFR while lower values indicate higher GFR, similar to creatinine.

The renal handling of cystatin C differs from creatinine. While both are freely filtered by the glomeruli, once filtered, cystatin C, unlike creatinine, is reabsorbed and metabolized by proximal renal tubules. Thus, under normal conditions, cystatin C does not enter the final excreted urine to any significant extent.

The serum concentration of cystatin C remains unchanged with infection, inflammatory or neoplastic states, and is not affected by body mass, diet, or drugs. Thus, cystatin C appears to be a more reliable marker of renal function (GFR) than creatinine.

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Test Information Guide – New Tests

Pancreatic Elastase – Stool:
Specimen: Random formed stool
Minimum Volume: 1 gram
Alternate test names: none
Stability: Ambient – 5 days, Refrigerated – 7 days, Frozen – 1 year
Availability: Performed once weekly
Turnaround Time: up to 10 days
Reference Range:
CPT: 82656
Limitations: 1. Discontinue pancreatic enzyme supplementation prior to sample collection.
2. Watery, diarreal stool is not recommended as it may give lowered E1 concentration than actually present.
Interpretative Information: This assay allows the diagnosis or exclusion of pancreatic exocrine insufficiency, which can be caused by chronic pancreatitis, cystic fibrosis, pancreatic tumor, cholelithiasis or diabetes mellitus.

Cystatin C with estimated GFR (eGFR):
Specimen: Serum (preferred) or Heparin plasma.
Minimum Volume: 0.5 mL
Alternate test names: none
Stability: Ambient – 1 day, Refrigerated – 14 days, Frozen – 1 year.
Availability: Monday – Sunday, 24/7, Not available Stat
Turnaround Time: 3 hr Routine
Reference Ranges:

Males:
- 0 – 22 years – no reference range available
- 23 – 29 years - 0.60 – 1.03 mg/L
- 30 – 39 years - 0.64 – 1.12 mg/L
- 40 – 49 years - 0.68 – 1.22 mg/L
- 50 – 59 years - 0.72 – 1.32 mg/L
- 60 – 69 years - 0.77 – 1.42 mg/L
- >70 years - 0.82 – 1.52 mg/L

Females:
- 0– 22 years - no reference range available
- 23– 29 years - 0.57 – 0.90 mg/L
- 30 – 39 years - 0.59 – 0.98 mg/L
- 40 - 49 years - 0.62 – 1.07 mg/L
- 50 - 59 years - 0.64 – 1.17 mg/L
- 60 – 69 years - 0.66 – 1.26 mg/L
- 70 – 80 years - 0.68 – 1.36 mg/
- >80 years - 0.70 – 1.45 mg/L

eGFR -
>60 mL/min/BSA
Not calculated for patients under 18 years.

eGFR (continued)
Interpretation per National Kidney Foundation Disease Outcome Quality Initiative:

Stage	Description	GFR(mL/min/BSA)
1	normal or high	>/= 90
2	mild decrease	60 – 89
3	moderate decrease	30 – 59
4	severe decrease	15 – 29
5	kidney failure	< 15

CPT: 82610
Limitations: Estimated GFR is not a precise measure of GFR and can be influenced by nonrenal factors.

Chlamydia trachomatis & Neisseria gonorrhea:
Specimen: 1.urine, 2.female endocervical or male urethral swab in Aptima GenProbe collection device, 3.Thin Prep Preservcyt sample
Minimum Volume: 2 ml urine, one female endocervical or one male urethral swab in Aptima GenProbe collection device, ThinPrep PreservCyt Sample
Stability: Urine, not in Aptima transfer tube: 24 hrs @ 2-30'C
Swab in Aptima GenProbe Collection Device: 30 days @ 2-30'C
ThinPrep PreservCyt: 30 days @ 2-30'C
Availability: Monday -Friday
Turnaround Time: 24-72 hrs
Reference Range: Negative
CPT: 87591 – Neisseria gonorrhoeae amplified RNA
CPT: 87491 – Chlamydia trachomatis amplified RNA

Lab Compliance Corner

Outpatient collection supplies are provided to Central Georgia Diagnostics (CGD) Laboratory clients to facilitate collection and transport of specimens from offsite facilities to CGD laboratory for testing.

Please note that the laboratory will only provide supplies for collection of specimens to be tested by CGD laboratory and cannot provide supplies for in office testing purposes. Supplies will be provided based on utilization and orders will be filled accordingly.

Please contact the laboratory client services desk at 478-633-1234 if you have any questions regarding collection supplies and availability.