Medical Center, Navicent Health
MEDICAL LABORATORIES COMMUNIQUE'
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CHEMISTRY

New Cardiac Troponin (TpnI) Normal Range:

Effective November 17th a revised normal range is being implemented for cardiac TpnI that represents the manufacturer stated 99th percentile. This revision will provide direct application with the recommended criteria for MI from the Third Universal Definition of Myocardial Infarction.

	New	Previous
TpnI, ng/mL	- 0.000- 0.028	0.000 – 0.039

New CKMB Normal Ranges and Result Change:

Effective November 17th new normal ranges are being implemented that represent the manufacturer stated 99th percentile. This change will provide continuity with the normal range change to the primary cardiac biomarker TpnI.

	New	Previous
CKMB, ng/mL	0.0–7.2	0.0-6.6 Male
	0.0-3.4	0.0-6.6 Female

In addition on December 8th the total CPK and the relative index (RI) components of a CKMB order (previous components – MB (ng/mL), total CPK (u/L) and relative index (RI)) are being discontinued. Total CPK remains available as a standalone test. Reference/interpretative range data for these components dates back to the era of electrophoresis performance of CPK Isoenzymes and is not compatible with current generation (high sensitivity) TpnI, mass CKMB assays and the current recommendations for use per the Third Universal Definition of MI, etc.

Cardiac Biomarker Utilization:

The expert consensus recommendation from the Third Universal Definition of MI is that **Tpn is the preferred biomarker for ALL categories of MI.** TpnI and CKMB are both markers of myocardial injury with similar release kinetics post injury. TpnI is expressed exclusively in the heart while CKMB only has a relative specificity for heart tissue but is present in small amounts in other muscle types which may confound interpretation. The use of two markers (TpnI and CKMB) does not routinely provide additional information over TpnI alone.

Cardiac Profile Eliminated:

Effective the December 8th orderable profile combination of tests found in various "Powerplan", and "Careset" packages termed "cardiac profile" (TpnI, CKMB, Total CPK) is being discontinued and replaced by a list of available cardiac markers (TpnI & CKMB). The specific cardiac marker required must be selected individually (either one or both). Laboratory recommendation for AMI assessment is to routinely use TpnI as a single marker. Eliminating the local package cardiac profile will improve lab test utilization for assessment of AMI.

HEMATOLOGY

Functional Fibrinogen by TEG:

A new thromboelastograph (TEG) assay, Functional Fibrinogen (FF), will be available for addition to existing routine TEG orders on November 10th. FF assessment provides additional information on clot strength beyond that in the standard TEG analysis. FF combined with routine TEG results provides for an estimate of both fibrinogen and platelet contributions to clot strength. In addition LY30 will now be reported as part of routine TEG analysis (previously only part of a Trauma TEG order).

MICROBIOLOGY

New Molecular Panel for Upper Respiratory Pathogens:

A new multiplex molecular respiratory panel is now available for the qualitative detection and identification of multiple upper respiratory viral and bacterial pathogens. This test is performed from nasopharyngeal swabs placed in viral transport media.

The respiratory panel is designed to simultaneously detect and identify the following: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Influenza A (with subtyping for hemagglutinin genes H, 2009 H1and H3), Influenza B, Human Metapneumovirus (hMPV), Parainfluenza Virus 1 (PIV1), Parainfluenza Virus 2(PIV2), Parainfluenza Virus 3 (PIV3), Parainfluenza Virus 4 (PIV4), Respiratory Syncytial Virus (RSV), Rhinovirus/Enterovirus, Bordetella pertussis, Chlamydophila pneumonia and Mycoplasma pneumonia.

A viral collection kit may be obtained from the Microbiology Department of the Laboratory. The specimen in viral media can be held at room temperature for up to 4 hours and refrigerated for up to 3 days.

New Trichomonas Vaginalis Assay:

The new test is a qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA from Trichomonas vaginalis. The test may be performed on symptomatic or asymptomatic females from endocervical vaginal swabs, vaginal swabs, urine or specimens collected in PerservCyt Solutions (ThinPrep vials).

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Test Information Guide – New Tests

Creatine Kinase (CK) MB Isoenzyme (CKMB)
Alternate name: CKMB
Specimen: Serum, gel tube, centrifuge within 2 hours
Minimum Volume: 0.5 ml
Stability: 12 hr Room Temp
7 days at 2 – 8° C
Available: Monday – Sunday 24 hr daily
Turnaround Time: < 3 hr, < 1 hr stat
CPT: 82553
Normal Range: Manufacturer stated 99th percentile
0.0 – 7.2 ng/mL Male
0.0 – 3.4 ng/mL Female
Interpretative guide: CKMB has been replaced by troponin for the assessment of most patients with acute chest pain; however, MB may be helpful in assessing reinfarction or troponin results which are inconsistent with other patient assessment or persistent elevated troponin results that do not show a rise or fall pattern consistent with myocardial damage.
Note: Total CK Enzymatic Activity is no longer performed as part of a CKMB order and consequently a Relative Index (RI = CKMB/Total CK Activity x 100) is no longer calculated. If total CK Activity is required it must be ordered as a separate test.

Troponin Powerplans
Previously named: Cardiac Profile (TpnI and CKMB)
New Name: Troponin Serial Studies
Available Time Deltas: Q3 hr X 3 recommended
Q8 hr X 2
Q8 hr X 3
STAT (timed) – single order

CK-MB Powerplans
Previously named: Cardiac Profile (TpnI and CKMB)
New Name: CKMB Serial Studies
Available Time Deltas: Q3 hr X 3
Q8 hr X 2
Q8 hr X 3
STAT (timed) – single order
Note: TpnI is the recommended cardiac biomarker for AMI assessment. Routine use of both CKMB and TpnI is discouraged. MB maybe helpful in assessing re-infarction and in rare instances of interferences in the TpnI assay.

Troponin I
Specimen: Serum, Heparin (Na or Li) gel tube. Use the same sample type for each sample of a serial TpnI assessment on a patient.
Minimum Volume: 0.5 mL serum or plasma
Alternate test names: TpnI, Cardiac Troponin
Stability: 2 hr room temp, 1 day if refrigerated, 6 months if frozen at < -20' C. Centrifuge within 2 hours of collection.
Availability: Monday – Sunday, 24/7, Stat
Turnaround Time: 40 minutes STAT; 2 hr Routine
Reference Ranges: 0.000 – 0.028 ng/mL - 99th %
Critical Value = > 0.300 ng/mL
Manufacturer 99th percentile: 0.000 -.028 ng/mL based on a population of healthy adults with no know diseases of the cardiovascular system (including elevated BP or treatment for elevated BP) or other serious diseases.
Interpretative Information:
Evaluation of weak positive TpnI results (0.029 to 0.08) can be facilitated by looking at the change in serial TpnI results (delta value) with in the 6 – 9 hour after presentation window typically used for MI assessment with biomarkers. **A change of > = 30% in these weak positive values represents an analytically statistically significant change in TpnI concentration**
CPT: 84484
Limitations: Assays using antibodies have the possibility of interference due to heterophile antibodies in the patient sample. Patients who have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies (e.g. HAMA) that interfere. Such interfering antibodies typically produce a false positive result that is markedly elevated and does not change over the time period used for MI assessment. Testing using an alternate TpnI method (e.g. iSTAT) or alternate cardiac biomarker (e.g. CK-MB) is recommended as these will not normally show the same interference.

Functional Fibrinogen
Alternate name: TEG FF
Specimen: Citrated whole blood within 1 hr of collection
Minimum Volume: 2.7 mL
Test Code: TEGFF
Stability: 1 ½ hr at room temp
Availability: 24/7
Turnaround Time: < 1/2 hr.
Normal Range: see report
CPT: 85576 X2
Note: Specimens **must** be transported to the laboratory immediately after collection so that testing is performed within two (2) hours after collection. Transport of specimens to the laboratory must be by courier except from the OR and EC Trauma Bay where a specimen securely wrapped in "memory" foam and sent via the hospital pneumatic tube system is acceptable.