

May 8, 2019

## Biotech Clinical Laboratories Technical Bulletin

Effective May 13, 2019 Biotech Clinical Laboratory will change methodologies and reference ranges for the following tests:

- Creatinine Kinase MB isoenzyme (CK-MB)
- Troponin I
- Total T3

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### CK-MB

Current Methodology: Chemiluminescent Microparticle Immunoassay by Abbott Diagnostics on Architect Analyzer.

Current Reference Range: 0.0 - 10 ng/mL

**New Methodology:** CK-MB is a two-site immunoenzymatic (“sandwich”) CK-MB assay by BeckmanCoulter on UniCelDxI immunoassay analyzer.

**New Reference Range: 0.6 – 6.3 ng/mL**

*Notice a change in reference ranges*

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### Troponin I

Current Methodology: Chemiluminescent Microparticle Immunoassay by Abbott Diagnostics on Architect Analyzer.

Current Reference Range: 0 – 0.4 ng/mL

**New Methodology:** High Sensitivity Troponin Assays is a two-site immunoenzymatic (“sandwich”) assay by BeckmanCoulter on UniCelDxI immunoassay analyzer using monoclonal antibody.

**New Reference Range: 14.3 – 25.6 pg/mL**

*Notice a change in reference ranges*

*Troponin results differ between methods due to selection of standardization or traceability. Do not use results between troponin methods interchangeably.*

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### Total T3

Current Methodology: Chemiluminescent Microparticle Immunoassay by Abbott Diagnostics on Architect Analyzer.

Current Reference Ranges: 0.58 – 1.59 ng/mL

**New Methodology:** BeckmanCoulter Access Total T3 assay is a competitive binding immunoenzymatic assay. Sample is added to a reaction vessel with a stripping agent to dissociate T3 from the binding proteins. 912-17Assay is performed on UniCelDxI Analyzer.

**New Reference Ranges: 0.87 – 1.78 ng/mL**

*Notice a change in reference ranges*

For additional information or any questions about this change please contact Technical Director Dr. E.Dvorin at 248-912-1700 or by e-mail [edvorin@biotechclinical.com](mailto:edvorin@biotechclinical.com).