DIAGNOSTIC LABORATORY SERVICES, INC.

Technical Memorandum

TO: Physicians, Clinical Staff and Clients

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Subject: Update to Coagulation reference ranges

Beginning January 19, 2026 for QMC-West Oahu and January 26, 2026 for QMC-Manamana DLS will change its current method for Troponin testing from the ROCHE TnT to the Beckman Coulter TnI assay.

Both TnT and TnI are subunits that are components of the contractile apparatus of muscle cells and both assays detect cardio-specific isoforms that are specific to myocardial cells and are different from the isoforms seen in skeletal muscle.

Both methods are based on an immunoassay methodologic principle where monoclonal antibodies to specific epitopes on the Tn molecule bind to it and generate a signal that can be measured. The amount of signal correlates to the concentration of Tn in the sample. As with all immunoassays, both are subject to general interferences that may include heterophile antibodies, hook effect, and clots in the sample. Unlike ROCHE, the Beckman Coulter assay does NOT have an issue with Biotin interference.

Both assays report out values in ng/L (whole numbers) and both have similar cutoffs, with the Beckman TnI 99th% universal cutoff being 18 ng/L while the ROCHE TnT 99th% universal cutoff being 19 ng/L. The coefficient of variation (CV) for both assays at these cutoffs are <10%, as recommended by The Fourth Universal Definition of MI.

While both are specific for cardiac myocytes, a single abnormal Tn result is not necessarily specific for the etiology of the myocyte damage. Current recommendations stress the importance of correlating results with clinical and ECG findings as well as serial testing and calculating the delta or change in successive troponin values, usually either 1 and/or 2 hours after the first Tn measurement, when evaluating patients.

DLS has performed an extensive method comparison between the two assays. Using the stated 99th% cutoffs by the manufacturer, greater than 90% of samples tested on both methods would be qualitatively flagged similarly. Of the discrepant samples, the majority were in patients whose Tn values were close to the cutoffs. The actual quantitative values did show numerical differences which are likely related to the differences between measuring the T vs I subunit, differences between manufacturer methodology, and interindividual variation between patients

themselves. There is a quantitative positive proportional bias between the two assays with the Beckman TnI showing increasingly higher values, compared to ROCHE TnT, as Tn levels increase. This difference starts to be seen as Tn values get above 50 ng/L, and become particularly evident as you approach Tn values of 100 ng/L and above. However around the respective 99th% cutoffs, the assay perform similarly.

If you have any questions, please call DLS client services at (808) 589-5131 or Dr. Wesley Kim at (808) 589-5131.