

MEMORANDUM

To: All Regional Medical Laboratory (RML) Clients

From: Brent D. Hartsell, MD, Medical Director, RML St. John Medical Center
Caitlin Schein, MD, Director, RML Central Laboratory Chemistry Department

Date: February 28, 2018

Subject: New Troponin I Instrumentation and Reference Ranges

Regional Medical Laboratory (RML) has adopted a new instrument for immunoassay testing, the Architect by Abbott Corporation. This platform utilizes a sensitive Troponin I assay which does not demonstrate interference by high doses of Biotin. High doses of Biotin have been recently found to interfere in some immunoassay tests. Please refer to previous RML memo 12-15-2017 describing the FDA warning.

The Third Universal Definition of Myocardial Infarction defines an abnormal Troponin I value as above the 99th percentile of a normal reference control population. The overall upper limit of the 99th percentile for both adult men and women using the Architect immunoassay platform is **0.028 ng/mL** and is the new normal range adopted by RML. An increased value indicates evidence of myocardial injury or necrosis.

Myocardial infarction is defined by the Third Universal Definition of Myocardial Infarction as evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischemia accompanied by a detectable rise and/or fall of cardiac biomarkers such as Troponin I with at least one value above the 99th percentile of an upper reference control population. Elevated troponin may be seen outside of acute myocardial infarction, in settings including chronic renal failure, tachycardia, severe injury, burns, sepsis and demand ischemia.

Should you have any questions, please contact Dr. Brent Hartsell, Medical Director of the St. John Medical Center Laboratory, or Dr. Caitlin Schein, Director of the Clinical Chemistry Department at the Central Laboratory, at 918-744-2553.