RML
REGIONAL MEDICAL LABORATORY

MEMORANDUM

To: All RML Clients

From: Brittany Vaughn, MHA, MLS(ASCP) SM, Director of Clinical Operations
Caitlin Schein, MD, Chief of Clinical Chemistry

Date: December 15, 2017

Subject: Biotin Interference with Certain Laboratory Tests

The U.S. Food & Drug Administration (FDA) issued a warning on November 28, 2017, of potentially inaccurate laboratory results due to high concentrations of biotin in blood or other samples.

Biotin may cause either falsely elevated or falsely decreased immunoassay laboratory results in testing platforms that utilize the biotin-streptavidin method. This has been most widely documented in thyroid function tests but also has the potential to affect cardiac markers, including troponin. Biotin is widely used as a dietary supplement with touted benefits for hair and nails, and is sometimes prescribed at high doses for treatment of multiple sclerosis.

Regional Medical Laboratory is committed to providing accurate and high quality results to our patients and clients, and we are taking this warning very seriously. We are in the process of converting the immunoassay testing at our laboratories to a new vendor whose tests are not susceptible to biotin interference. This transition is expected to be complete in Spring 2018. In the meantime, due to the large number of laboratory tests affected by this supplement, biotin use should be discontinued for at least 12 hours prior to any laboratory testing. If biotin interference is suspected, consultation with the laboratory is recommended.

For more information, please reference the FDA communication at the following web address.

https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm586505.htm

Please contact Brittany Vaughn or Dr. Caitlin Schein at 918-744-2553 with questions regarding this update.