



MEMORANDUM

TO: All Regional Medical Laboratory Clients

FROM: William Fitter, MD, Chief of Clinical Chemistry and Toxicology
Mary Pille MT(ASCP)SBB, Manager of Chemistry Department

DATE: June 27, 2013

SUBJECT: PSA Positive Bias

We have received a recall notice on PSA reagent from Siemens (our vendor for Free PSA/PSA tests) performed on the Immulite analyzer. Siemens has confirmed an overall average positive bias of 20-23% across the assay range relative to WHO 961670 with PSA assays on the affected lot numbers. Regional Medical Laboratory had the affected lot in use June 12, 2013 through June 27, 2013.

Positive Bias in PSA results may impact clinical interpretation of test results. Physicians that had patients tested for PSA FREE during this period of time may request a new specimen drawn and testing repeated at no charge.

Effective immediately, all PSA FREE requests will be sent to an external reference lab using a methodology unaffected by the recall. Siemens expects replacement reagents to be released the week of July 8. This recall doesn't affect our Total PSA test and this will continue to be offered with no delays.

We apologize for any inconvenience this may cause. If you have questions or concerns, please contact Dr. William Fitter or Mary Pille at 918-744-2500.