Medical Device Correction Alert

St. Luke's Laboratory Services

St. Luke's Laboratory PSA Testing

St. Luke's Laboratory received an Urgent Medical Device Correction notification from the manufacturer of our Siemens ADVIA Centaur XP PSA reagent.

The manufacturer has confirmed that certain lot numbers of ADVIA Centaur XP PSA reagent are not meeting the current High-Dose Hook Effect expectation that the manufacturer has established and could lead to falsely decreased results. Based on manufacturers internal testing, samples with a PSA result between 4200 ng/mL and 8400 ng/mL, do not assay >100 ng/mL but instead result in falsely decreased concentrations of approximately 50 ng/mL to 94 ng/mL.

St Luke's Laboratory started using the affected PSA reagent 05/18/2015.

Measurements of PSA should always be used in conjunction with other diagnostic procedures, including information from the patient's clinical evaluation.

Required Action:
If you feel that a patient's PSA result is not fitting the clinical picture and could possibly be affected by the High-Dose Hook Effect, a new specimen should be tested.

If you have questions, please contact Kristin Baer, M.D. 218-249-5751, Chemistry Medical Director, Jennifer Viergutz, MT(ASCP), Laboratory Operations Manager, 249-5724, or Amber LaMourea, MT (ASCP) 218-249-5024, Immunology Technical Specialist.

St. Luke's Laboratory Services has developed a Web page which contains New Test Announcements.
http://www.slhduluth.com/hospital/laboratory-services/