Medical Device Correction Alert

St. Luke's Laboratory Services

St. Luke's Laboratory Progesterone Testing

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

The risk to health is limited to patients taking DHEA supplements as part of their IVF treatment plan and who are being considered for fresh embryo transfer. The manufacturer has confirmed that the presence of DHEA-S (a metabolite of DHEA, a steroid hormone that may be used as part of *in vitro* fertilization (IVF) protocols to improve ovarian response and IVF treatment outcomes) causes falsely elevated progesterone results around the clinically important decision level of approximately 1 ng/mL.

For patients taking DHEA supplements, an alternate method should be used to measure progesterone concentrations. St. Luke's Laboratory will forward specimens to Mayo Medical Laboratories for testing upon specific physician request. Please call X5200 within 72 hours of specimen collection and request reference laboratory testing.

Measurements of progesterone should always be used in conjunction with the patient's medical history, clinical examination and/or other diagnostic procedures.

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.