Medical Device Correction Alert

St. Luke's Laboratory Services

St. Luke's Laboratory Estradiol Testing

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

The manufacturer has confirmed the drug fulvestrant (Faslodex®) may cause cross reactivity in our estradiol assay. The cross reactivity could lead to falsely elevated estradiol results leading to an inappropriate clinical assessment of estrogen status.

Fulvestrant (Faslodex®) is used in post-menopausal women treated for estrogen receptor positive recurrent stage IV breast cancer. If St. Luke's Laboratories estradiol assay was used to assess the menopausal status of such a patient population, falsely elevated estradiol levels could lead the clinician to misinterpret the patient as pre-menopausal possibly leading to altered or discontinued use of the potential beneficial drug fulvestrant. If this situation has occurred, reassessing the menopausal status of the patient by other means or using an alternate estradiol measurement should be considered.

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

Required Action:
If you have a fulvestrant-treated patient requiring estradiol testing, please order Miscellaneous. Provide Mayo Laboratories test code ESST (Estradiol, Serum) in the description along with a comment stating that this patient is a fulvestrant-treated patient requiring estradiol testing.

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/