UNC HEALTH CARE

MEMORANDUM #131

TO: UNC Hospitals Attending Physicians, Housestaff, Nursing Coordinators, Department Heads and Supervisors

FROM: Nichole Korpi-Steiner, PhD, Interim Director, Core Laboratory
Christian Cristobal, Assistant Administrative Director, Core Laboratory
Connie Bishop, Director, McLendon Clinical Laboratories
Herbert Whinna, MD, PhD, Medical Director, McLendon Clinical Laboratories

DATE: July 22, 2016

SUBJECT: Estradiol Testing in Patients Receiving Fulvestrant

An urgent product notification was recently issued by Ortho Clinical Diagnostics (OCD) indicating fulvestrant interference with estradiol testing using OCD immunoassay methodology which is used here in UNCH Core Laboratory.

Patients receiving fulvestrant therapy could have falsely elevated estradiol results. The manufacturer's investigation confirmed the positive bias interference:

Sample ID	Results for Samples with 0 ng/mL Fulvestrant	Results for Samples Containing 30* ng/mL Fulvestrant
Sample 1	35 pmol/L (9.534 pg/mL)	1295 pmol/L (352.8 pg/mL)
Sample 2	43 pmol/L (11.71 pg/mL)	1366 pmol/L (372.1 pg/mL)
Sample 3	128 pmol/L (34.87 pg/mL)	1687 pmol/L (459.5 pg/mL)
Sample 4	138 pmol/L (37.59 pg/mL)	1758 pmol/L (478.9 pg/mL)
*30 ng/mL of Fulvestrant is the peak serum concentration of this therapeutic drug (Cmax concentration)		
Measuring (Reportable) Range for Estradiol: 23.347–14,000 pmol/L (6.360–3813.6 pg/mL)		

Ref. CL2016-141

For patients NOT receiving fulvestrant therapy, estradiol testing will continue to be performed in the UNCH Core Laboratory.

For patients receiving fulvestrant therapy, estradiol testing by mass spectrometry (send-out test) is recommended to minimize any analytical interference.

- Order Estradiol, Ultrasensitive in EPIC and include a comment that patient is receiving fulvestrant therapy.

For questions or more information, please contact Dr. Korpi-Steiner or Marsha Owens at 984-974-1412.