



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued March 24, 2016

Product

- ARCHITECT Estradiol Reagent, list number (LN) 7K72
- All lot numbers
- UDI Number –Not applicable

Explanation Abbott has confirmed that the drug Fulvestrant (Faslodex®) may interfere with the ARCHITECT Estradiol assay (LN 7K72) leading to falsely elevated Estradiol results.

Patient Impact The potential risk to health applies only to patients being treated with the drug Fulvestrant which may lead to increased Estradiol results.

In worst case scenarios, falsely elevated Estradiol results may lead to incorrect menopausal state assessment and inappropriate therapy.

Investigational testing has yielded the following results per table 1 below:

Table 1: Investigation Results on the ARCHITECT i2000 System

| Population Estradiol Concentration Represents | Estradiol Result of Neat Sample pg/mL (pmol/L) | Estradiol Result of Spiked Sample, pg/mL (pmol/L) | % Recovery (Interference) | % Cross Reactivity |
|---|--|---|---------------------------|--------------------|
| Post-Menopausal Females | 29.14* (106.94) | 85.80 (314.89) | 294.44 | 0.23 |

- A sample was spiked with 25,100 pg/mL (92,117 pmol/L) Fulvestrant (25,100 pg/mL is a representative Cmax of Fulvestrant.)

- %Recovery = (spiked sample result/neat sample result) X 100.

- %Cross Reactivity = ((spike sample result in pg/mL – neat sample result in pg/mL)/concentration of Fulvestrant spiked in pg/mL) X 100.

*Unspiked human serum sample.

Necessary Actions We recommend that you follow the necessary actions below:

**Necessary
Actions (cont.)**

- Please review this letter with your Medical Director.
- Patients undergoing Fulvestrant therapy should not be tested with the ARCHITECT Estradiol assay.
- Complete the Customer Reply Form.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.
