Abbott Ireland Diagnostics Division
Lisnamuck, Longford, Co.
Longford, Ireland

Abbott

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

cc Chairman Medical Board and relevant Head-of-Department

Date Issued February 05, 2019

Product

Product Description	List Number	Lot Number	UDI
ARCHITECT Estradiol Reagent Kit	7K72-20	All	N/A
ARCHITECT Estradiol Reagent Kit	7K72-25	All	N/A
ARCHITECT Estradiol Reagent Kit	7K72-35	All	N/A
Alinity i Estradiol Reagent Kit	07P5020	All	N/A
Alinity i Estradiol Reagent Kit	07P5030	All	N/A

Explanation

Abbott has confirmed that the drug Mifepristone may interfere/crossreact with the ARCHITECT Estradiol assay (LN 7K72) and Alinity i Estradiol assay (LN 07P50) leading to falsely elevated Estradiol results.

Please refer to Appendix 1 for additional information.

Patient Impact

Patient results may be falsely elevated. This patient impact only applies to patients currently being treated with or recently treated with the drug Mifepristone.

Refer to Appendix 1 for additional data.

Necessary Actions

We recommend that you follow the necessary actions below:

- Patients treated with Mifepristone should not be tested with the ARCHITECT or Alinity i Estradiol assay for up to two weeks based on information available regarding Mifepristone's bioavailability [1].
- Please review this letter with your Medical Director.
- If you have forwarded the products listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Complete the customer reply form.
- 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. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178). If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

[1] MIFEPREX (mifepristone) TABLETS label at https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm

Appendix 1

Investigational testing has yielded the following results (Table 1 and Table 2):

Table 1: Investigation results on the ARCHITECT i2000 System- Interference

Estradiol Result of Neat sample pg/ml (pmol/L)	Estradiol Result of Spiked sample pg/ml (pmol/L)	% Recovery	Difference pg/ml (pmol/L)	% Interference
70.58* (259.10)	777.92 (2855.74)	1102.13	707.33 (2596.61)	1002.13
185.92* (682.51)	860.00 (3157.06)	462.57	674.08 (2474.55)	362.57
494.00* (1813.47)	702.08 (2577.34)	142.12	208.08 (763.86)	42.12

These samples were spiked with 2.34 mg/L Mifepristone (identified as peak plasma concentration)
% recovery = mean Spike sample result /Mean Neat sample result*100
Difference= mean Spike sample result - Mean Neat sample result.
% Interference = difference/Mean unspiked sample result x 100

*Unspiked human serum sample.

Table 2: Investigation results on the ARCHITECT i2000 System- Cross-reactivity

Estradiol Result of Neat sample pg/ml (pmol/L)	Estradiol Result of Spiked sample pg/ml (pmol/L)	% Recovery	Difference pg/ml (pmol/L)	% Cross-reactivity
Zero	>1000 (>3671)	#	>1000 (>3671)	#

# Indicates that calculation cannot be performed due to a concentration value outside of the reportable range (10 – 1000 pg/mL) (36.71-3671 pmol/L).

Note: All testing was carried out on the ARCHITECT platform. As the formulation of the ARCHITECT and Alinity i Estradiol are identical this interference/cross-reactivity will also occur on Alinity i Estradiol.