



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued April 18, 2017

Product

Product Name	List Number	Lot Number	UDI
ARCHITECT SHBG Reagents	8K26-20	01916E000	(01) 00380740017408 (17) 170425 (10) 01916E000 (240) 8K2620
		00316F000	(01) 00380740017408 (17) 170527 (10) 00316F000 (240) 8K2620
		01816G000	(01) 00380740017408 (17) 170712 (10) 01816G000 (240) 8K2620
		00916I000	(01) 00380740017408 (17) 170905 (10) 00916I000 (240) 8K2620
		07316I000	(01) 00380740017408 (17) 171021 (10) 07316I000 (240) 8K2620
		00916L000	(01) 00380740017408 (17) 171216 (10) 00916L000 (240) 8K2620
ARCHITECT SHBG Reagents	8K26-25	01816E000	(01) 00380740017415 (17) 170425 (10) 01816E000 (240) 8K2625
		00216F000	(01) 00380740017415 (17) 170527 (10) 00216F000 (240) 8K2625
		01716G000	(01) 00380740017415 (17) 170712 (10) 01716G000 (240) 8K2625
		00816I000	(01) 00380740017415 (17) 170905 (10) 00816I000 (240) 8K2625
		07216I000	(01) 00380740017415 (17) 171021 (10) 07216I000 (240) 8K2625

Explanation

The purpose of this letter is to inform you of a product correction for the ARCHITECT SHBG assay and to provide instructions on what actions your laboratory must take.

Abbott has identified that ARCHITECT SHBG results generated with the Potassium EDTA specimen tube type may demonstrate a negative shift relative to results generated with serum. SHBG dimer destabilization in EDTA could result in low SHBG measurements by immunoassay*. All in-date lots of current reagent inventory are impacted.

*Fillmore CM, Fear TR, Hoover RN et al. Biomarkers: Biochemical Indicators Of Exposure, Response, And Susceptibility To Chemicals. *Biomarkers* 2000;5(5): 395–398.

Patient Impact

There is a potential for falsely decreased ARCHITECT SHBG results to be generated when using the ARCHITECT SHBG assay with the Potassium EDTA specimen tube type. Internal studies have determined use of the Potassium EDTA specimen tube type may result in a decrease in SHBG concentration values of greater than 20% when compared with serum collected in serum tubes. The shift was observed across the full analytical range of the assay.

As a result, an increase in Free Androgen Index / Free Testosterone Index calculations of up to 30% may also be observed when using Potassium EDTA specimen tubes.

Necessary Actions

- 1) **Immediately** discontinue use of the Potassium EDTA specimen tube type with the ARCHITECT SHBG assay according to your laboratory procedures.
 - 2) Please review this letter with your Medical Director to ensure they are aware of the issue and determine if a review of results previously generated using the Potassium EDTA specimen tube type is necessary.
 - 3) 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.
 - 4) Please complete and return the Customer Reply Form.
 - 5) Please retain this letter for your laboratory records.
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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.
