



April 21, 2017

--IMPORTANT NOTICE--
SHBG Assay

Contacts:

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Effective Date: Immediately

Effectuated Tests:

Test Name	Testosterone, Free	Testosterone, Free (Only)	Testosterone, Total	Testosterone, Free and Total
PDM Number	1750080	1750094	1750075	1750074

Summary:

CPAL has received a Product Correction notification from the manufacturer of the SHBG assay used in our laboratory. The SHBG assay is not an orderable test, however the SHBG result is used in the calculation for free and % free testosterone. Abbott Diagnostics 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.

Patient Impact:

There is a potential for falsely decreased Architect SHBG results to be generated when using the assay with the Potassium EDTA specimen tube type. Internal studies have determined the use of this specimen 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. As a result, an increase in Free Testosterone Index calculations of up to 30% may also be observed when using Potassium EDTA specimen tubes.

Necessary actions:

Please discontinue the use of Potassium EDTA tubes for collection of specimens with testosterone orders. Please refer to www.cpallab.com for the appropriate specimen type(s).

References:

1. Product Correction: ARCHITECT ® SHBG Reagent. Abbott Germany Diagnostics Division; April 2017
2. Fillmore CM, Fear TR, Hoover RN et al. Biomarkers: Biochemical Indicators Of Exposure, Response, And Susceptibility To Chemicals. *Biomarkers* 2000;5(5): 395-398.