



## TECHNICAL BULLETIN

## □ NEW TEST ⊠TEST CHANGE

NOTIFICATION DATE: JULY 26, 2021 EFFECTIVE DATE: JULY 26, 2021

## Total and Free Prostatic Specific Antigen (PSA) (PSAF)

On the effective date Northwell Health Laboratories will implement the Roche Elecsys assays for Total PSA and Free PSA testing with increased biotin tolerance (up to 1,200 ng/mL) on the Cobas e801 module.

Trends in biotin use as an over-the-counter supplement for hair, skin, and nail health in doses up to 125 times the suggested intake have raised concerns of potential biotin interference in immunoassays. Successful strategies to mitigate this risk include asking questions and encouraging patients to report if they are taking biotin.

Also, certain medical conditions such as Multiple Sclerosis are being treated experimentally with very high doses of biotin. Some studies have shown that serum concentrations of biotin can reach up to 355 ng/mL within the first hour after biotin ingestion for subjects consuming supplements of 20 mg biotin per day and up to 1160 ng/mL for subjects after a single dose of 300 mg biotin. With the new Total and Free PSA assays, patients will have no biotin interference in serum concentrations up to 1200 ng/mL.

The new Total PSA and Free PSA assays have no biotin interference in serum concentrations up to 1200 ng/mL, which was made possible by using a specific protein scavenger in the buffer that binds to free biotin, but does not bind to the biotin attached to the immunologically active components of the assay. Consequently, assay performance, reference ranges, cutoffs, and medical decision points are not impacted by this update.

	PSA Prostatic Specific Antigen	PSA Free and Total
Computer Interface Code	5302500	5302504
Test Order	PSA	PSAF

## If you have any questions, please contact Client Services at (516) 719-1100.