

PROSTATE SPECIFIC ANTIGEN (PSA), TOTAL, SERUM

EXPLANATION: Recently, Mayo Medical Laboratories identified an infrequent, but reproducible artifact which causes false positive prostate specific antigen (PSA) results. The interference is attributable to heterophile antibodies, which are antibodies induced by external antigens (heterophile antigens) that cross-react with self-antigens. Heterophile antibodies are a known problem in immunoassays and are a rare occurrence. However, we believe that the current lot of PSA Total reagent manufactured by Beckman Coulter for the Access Hybritech assay has an increased frequency of false positive PSA results due to heterophile antibody interference.

This issue was originally identified in a patient undergoing serial PSA testing where the results unexpectedly changed from an undetectable (<0.1 ng/mL) to a detectable result (0.3 ng/mL); further investigation traced the event to a new lot of PSA reagents. Given the potential impact of a false-positive PSA result, especially in those patients being followed after radical prostatectomy, we have instituted a protocol to retest PSA results in the low end of the measurable range (0.1 - 1.0 ng/mL) with another assay to proactively identify the false-positive samples. PSA results which are discrepant between the two methods will undergo further testing and be noted in the report.

PSA Total result values from June 9, 2010 to October 25, 2010 for the following tests may be impacted:

Unit Code	Test Name
800065	Prostate Specific Antigen, Serum
800066	Prostate-Specific Antigen (PSA), Total and Free, Serum

Please share this communication with your physicians and providers that have ordered PSA testing from one of our testing laboratories since 6/9/2010. If they have observed any PSA results in their patients which are inconsistent or unexpected, please call Mayo Medical Laboratories (800-533-1710) immediately and further investigation will be initiated.

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Greg Renkly, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710