

LAB ALERT: REPORTING CHANGE

NOTIFICATION DATE: 6/27/2013

EFFECTIVE DATE: 6/27/2013

PSA URGENT MEDICAL DEVICE RECALL

PROSTATE-SPECIFIC ANTIGEN (PSA), PSA, FREE AND TOTAL

EXPLANATION: Due to a product recall of PSA reagents from the vendor, our laboratory will no longer be able to offer the test after June 27, 2013.

Since Siemens requires discontinuation of the use of the kit, ClearPoint will be sending these specimens out to ARUP Laboratories until we revalidate this test on an alternate analyzer.

Siemens Healthcare Diagnostics has confirmed an overall average **Positive Bias** of approximately 20% to 23% across the assay range relative to WHO 96/670 with the IMMULITE Systems PSA assays. This Positive Bias also affects patient values.

Since a positive bias in PSA results could impact clinical interpretation of test results, especially with regards to scheduling a biopsy for the patient, our laboratory offers to Re-Test the patients' specimens that were reported to be abnormal in the past **Two-Month** period at **No Charge**.

When ordering Re-Testing please include the phrase "**Look-back PSA No Charge**" as a comment on the requisition.

TEST CODES: New interface order code: 1000752 (no change)
New result interface code: 1003977

ACCEPTABLE SPECIMEN TYPE(S): **PSA:** Collect Serum separator tube or Plain Red tube.
Allow specimen to clot completely at room temperature.
Separate serum or plasma from cells ASAP (as soon as possible) or within 2 hours of collection.

Transfer 1.0 mL serum or plasma to a Standard Transport Tube (Minimum: 0.5 mL).

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STORAGE/TRANSPORT	Frozen/Refrigerated
UNACCEPTABLE CONDITIONS	Grossly hemolyzed specimens
TURN-AROUND TIME:	2 – 4 days.
CPT CODE(s)	PSA 84153; PSA Free 84154

ORDER/CONTACT INFORMATION: **ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799**