

MEMORANDUM #

TO: UNC Hospitals Housestaff, Attendings, Department Heads and Supervisors

FROM: John F. Chapman, Dr. P.H., Director, Core Laboratory
Connie Bishop, Assistant Administrative Director, Core Laboratory
Mark Brecher, M.D., Director, McLendon Clinical Laboratories

SUBJECT: Upcoming Change in Reactivity for PSA Test

DATE: March 16, 2007

The laboratories were notified this February that the manufacturer of our current PSA test, Ortho Clinical Diagnostics (OCD), has made modifications in the reactivity of this test that would affect all future lots of reagent. OCD has taken this action because PSA values using their assay have been shown to run somewhat higher than those of some other commercial products. According to the company, this was found to be due to the assay's preferential reactivity to complexed versus free PSA in patient's samples. The new PSA product will demonstrate equimolar reactivity for complexed and free PSA and produce values consistent with WHO standards.

The effective date of the change to the new reagent formulation will be Friday, March 23 at 8:00 am. All PSA tests ordered after that date/time will be analyzed using the new formulation.

We have obtained new product and conducted internal comparison studies between the current and new formulations. Our regression data (n=109; PSA range 0-20 ng/mL) demonstrate that the new reagent will result in an *average PSA decrease* of approximately 17% for most patients. Patients with the lowest free PSA percentage would be expected to exhibit the greatest difference between the current and new formulations.

Conversion factors to approximate the expected differences are:

New PSA values $\times 1.205 \cong$ Previous PSA values
Previous PSA values $\times 0.83 \cong$ New PSA values

We anticipate that some physicians may wish to re-baseline certain patients via comparative PSA analysis of a sample by both current and new product. This can be accomplished free of charge via the test add-on system by free texting "PSA re-baseline" as the add-on request for the original PSA specimen. Re-baselining will be offered from March 23 until May 28 (the latest expiration date available for the limited amount of current reagent the company plans to manufacture). Re-baselining must be requested within five (5) days of the initial PSA request to ensure availability of the original sample. Re-baselining results will appear as a comment to the initial PSA result in WebCIS.

We hope the above actions will help facilitate a smooth transition. Please contact Core Laboratory Customer Service (6-2361) or Dr. John Chapman (6-3725) with questions.