

5/21/2013 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

TEST CHANGES				
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	Former Test Code	Test Name	Effective Date	Page #
<u>S49587</u>		Prostate Specific Antigen (PSA), Post Prostatectomy	5/28/2013	1

Due to the background information related to these changes, we are unable to use our normal method of communication. These changes listed in this document are effective in less than 30 days. Please note the individual effective dates below, as some of these changes require IMMEDIATE ACTION.

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the information that is changing appears in this update. Former test names and test codes have been italicized.

Prostate Specific Antigen (PSA), Post Prostatectomy	
Effective Date	5/28/2013
Test Code	<u>S49587</u>
Always Message	<p>REFERENCE RANGES for PSA:</p> <p>LESS THAN 0.10 ng/mL AFTER RADICAL PROSTATECTOMY.</p> <p>4.0 ng/mL OR LESS IN HEALTHY MALES WITHOUT PROSTATECTOMY.</p> <p>PSA values obtained with different assay methods or kits cannot be used interchangeably.</p> <p>This test was performed using the Beckman Coulter DxI method. PSA, ICMA is not to be used as a diagnostic procedure without confirmation of the diagnosis by another established product or procedure.</p> <p>The lower limit of accurate quantification for this assay is 0.02 ng/mL. PSA values less than 0.02 ng/mL cannot be accurately measured and will be reported as "less than 0.02 ng/mL." Specimens with PSA levels below the lower limit of accurate quantification should be considered as negative. In patients with a negative result for post prostatectomy PSA, serial monitoring of PSA levels at regular intervals, along with physical examinations and other tests, may help to detect recurrent prostate cancer.</p>
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano