

11/20/2012 - TSO Update, Quest Diagnostics Nichols Institute, Valencia

SEND OUTS				
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 #
S52276		Prostate Cancer Gene 3 (PCA3)	11/20/2012	1

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION**.

Prostate Cancer Gene 3 (PCA3)													
Effective Date	11/20/2012												
Test Code	S52276												
Always Message	<p>Interpretation: BACKGROUND: PCA3 is a non-coding prostate-specific mRNA that is highly over-expressed in some prostate cancer cells (median 66-fold over adjacent benign tissue); in contrast, PSA gene expression is similar in benign and malignant prostate cells. Both PCA3 and PSA mRNA can be quantitated from urine samples. The PCA3 assay utilizes voided urine collected following a digital rectal examination and processed by addition into a urine transport medium (UTM) which lyses cells and stabilizes RNA. The PSA mRNA level serves to confirm that there is sufficient prostate RNA for analysis present in the sample and to normalize the PCA3 mRNA signal. In a study of 466 patients with a previous negative prostate biopsy, 102 of whom had a positive follow-up biopsy, utilizing the PCA3 score cutoff value of 25 was shown to have 77.5% sensitivity and 57.1% specificity for prostate cancer. This assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on current standard of care before consideration of PCA3 assay results. This assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy; men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.</p> <p>METHODOLOGY: The PCA3 assay is performed utilizing the PROGENSA assay kit from Gen-Probe, comprised of two quantitative nucleic acid amplification tests, one for PCA3 RNA, one for PSA RNA. In both, the target RNA molecules are isolated from urine specimens utilizing complementary RNA oligonucleotides and a magnetic separation system to capture the target sequences. A reverse transcriptase is utilized to make DNA copies (template) of the target RNA and an RNA polymerase is utilized to produce multiple RNA copies (amplicon) of the template (transcription-mediated amplification or TMA). Chemiluminescence-labeled complementary probes are utilized to detect the amounts of amplicon present. PCA3 and PSA mRNA are quantitated by comparison with standard curves generated with every assay. The PCA3 score is calculated as 1000 times the ratio of the concentration of PCA3 RNA to the concentration of PSA RNA ($\frac{[PCA3\ mRNA]}{[PSA\ mRNA]} \times 1000$).</p> <p>REFERENCES: Aubin SM et al. 2010. PCA3 molecular urine test for predicting repeat prostate biopsy outcome in populations at risk: validation in the placebo arm of the dutasteride REDUCE trial. <i>Urology</i>. 184:1947-1952. Marks LS et al. 2007. PCA3 molecular urine assay for prostate cancer in men undergoing repeat biopsy. <i>Urology</i>. 44:8-16. PROGENSA PCA3 Assay Package Insert 502083 Rev. A. Gen-Probe Incorporated.</p>												
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>13363</td> <td>AOE</td> <td>Specimen Type:</td> </tr> <tr> <td>31382</td> <td></td> <td>Result (PCA3 Score):</td> </tr> <tr> <td>31366</td> <td></td> <td>Interpretation:</td> </tr> </tbody> </table>	Result Code	Type	Result Name	13363	AOE	Specimen Type:	31382		Result (PCA3 Score):	31366		Interpretation:
Result Code	Type	Result Name											
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Additional Information	The referral lab has updated the report format.												

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