

PATIENT	
JOHN DOE	90 M
5000 University Drive	02/05/402

5000 University Drive 03/05/1922 Coral Gables, FL 33146 **COLLECTED** 08/19/2012

**CASE NUMBER** 

**RECV'D** 08/19/2012

MICRO 08/22/2012

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PHYSICIAN

Alfredo Gomez, M.D. 5000 University Drive Miami, FL 33146

TR12-62002

FS		

## **POSITIVE**

## RESULT FOR PCA 3 ProfileR<sup>TM</sup> TEST

PCA3/PSA ratio is 28 (POSITIVE)

INTERPRETATION:

POSITIVE RESULT: PCA/PSA result of 25 or greater

NEGATIVE RESULT: PCA/PSA result below 25

INCONCLUSIVE RESULT: Inadequate amount of PSA mRNA

PCA3 is a prostate-specific gene that is highly upregulated in prostate cancer cells. PCA3 ProfileR<sup>TM</sup> uses transcription-mediated amplification (TMA) technology to measure the quantity of PCA3 mRNA from a urine specimen. In studies, PCA3 ProfileR<sup>TM</sup> had specifity for detecting prostate carcinoma of 74% and a sensitivity of 58%, as determined by subsequent biopsy.

PSA mRNA levels are used to normalize PCA3 signals and verify recovery of prostate mRNA. The PCA3/PSA mRNA ratio is the prognostic indicator.

An inadequate amount of PSA mRNA suggests that not enough prostate cells were collected in the sample procured and thus the result would be inconclusive.

The test was performed at the University of Michigan Health System, Department of Pathology, CLIA #23D1088637.

The PCA3 ProfileR<sup>TM</sup> test must not be used alone to diagnose prostate cancer. This test must be used in conjunction with additional pathologic data.

\* Higher ratios correlate with higher probability of a positive biopsy.

\* Ratio may also be elevated in cases of highgrade PIN or atypical glands.

\* Unlike serum PSA levels, the PCA/PSA mRNA levels are independent of prostate gland volume.

References:

Marks, LS, et.al.

Specificity of the PCA mRNA molecular urine test for prostate cancer.

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Ana L. Viciana, M.D. Electronically Signed: 08/22/2012