Metamark™
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PROGENSA® PCA3

Performing Site: Clinical Lab
Metamark, Inc

Metamark, Inc. • 100 Kestrel Drive, Collegeville, PA 19426 • Phone 877-743-3338 • www.metamark.us

PATIENT INFORMATION

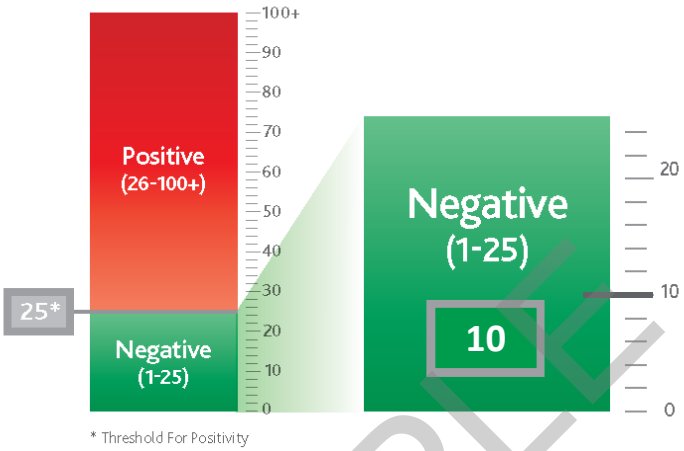
Name: Patient Name
DOB: XX/XX/XXXX
Patient #: XXXXXXXXX

SPECIMEN ID #: XXXXXXXXX

Date Collected: 4/28/2015
Date Received: 4/29/2015
Date Reported: 4/30/2015

PHYSICIAN

Primary Physician: Physician Name
Client: XXXXXXXXXX
Client #: XXXXXX



PROGENSA PCA3 DIAGNOSIS

1. A negative score is associated with a decreased likelihood of a positive biopsy for prostate cancer.
2. An adequate amount of PSA RNA was detected in the urine sample.

The Progensa PCA3 test was developed and its performance characteristics determined by Hologic, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Metamark is certified under Clinical Laboratory Improvements Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

REFERENCES

Progensa PCA3 Assay Package Insert 502083 Rev. B. Hologic Inc.

TEST CHARACTERISTICS

Due to normal assay variability, specimens with PCA3 scores near the cut-off of 25 (i.e. 18-31) could yield a different overall interpretation of positive or negative upon repeat testing. PCA3 scores in the range from 18 to 31 should, therefore, be interpreted with caution. The testing method is target capture, transcriptionmediated amplification (TMA) and hybrid protection assay (HPA), manufactured by Hologic, Inc and performed using the Hologic, Inc Progensa assay kit.

Dwight Mirmow, MD
Final Report Electronically Signed on 4/30/2015 at 2:56 PM
CPT Codes: 81313

CLIA #: 39D1089277

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