



Quarterly HOTLINE: Effective November 12, 2018

New Test **3000134** **Prostate Health Index** **PROST INDX**
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Methodology: Quantitative Chemiluminescent Immunoassay
Performed: Mon
Reported: 1-7 days

Specimen Required: Patient Prep: Specimens for testing must be drawn prior to prostate manipulations such as digital rectal examination (DRE), prostatic massage, transrectal ultrasound (TRUS), and prostatic biopsy.
Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Allow specimen to clot completely at room temperature. Separate from cells within 3 hours of collection. Transfer 1.5 mL serum to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Ship patient and control specimens together.
Unacceptable Conditions: Plasma.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: Unacceptable; Frozen: 5 months

Reference Interval: By report

Interpretive Data: The Prostate Health Index (P Score) is indicated for use as an aid in distinguishing prostate cancer from benign prostatic conditions, for prostate cancer detection in men aged 50 years and older with total PSA between 4 and 10 ng/mL, and with digital rectal examination findings that are not suspicious for cancer. The P Score may also be used to determine the probability of prostate cancer on biopsy for an individual patient. Higher P Scores are associated with higher probability of prostate cancer. Prostatic biopsy is required for diagnosis of cancer.

Testing is performed with Beckman Coulter UniCel DxI 800 Access PSA, free PSA, and p2PSA assays using Hybritech calibration. Results obtained with different assay methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

Probability of prostate cancer on biopsy based on P Score in patients with PSA between 4 and 10 ng/mL

Prostate Health Index (P Score)	Probability of Cancer (percent)	95 percent Confidence Interval
0-26.9	9.8	5.2-15.4
27.0-35.9	16.8	11.3-22.2
36.0-54.9	33.3	26.8-39.9
55.0 and greater	50.1	39.8-61.0
When total PSA is <4 ng/mL or >10 ng/mL, free PSA and p2PSA assays are not performed. P Scores are therefore not available in that scenario.		

When PSA is between 4 and 10 ng/mL, percent free PSA is also calculated.

The probability of prostate cancer for men with non-suspicious digital rectal exam (DRE) results and PSA between 4 and 10 ng/ml by patient age based on percent free PSA

Percent free PSA	Probability of Cancer for Ages 50-64 years	Probability of Cancer for Ages 65-75 years
0-10	56	55
11-15	24	35
16-20	17	23
21-25	10	20
25 or greater	5	9

Note: If the Total PSA result is in the range of 4 to 10 ng/mL, then free PSA and p2PSA along with calculation of the free PSA percent and a P Score will be added. Additional charges will apply.

CPT Code(s): 84153; if reflexed add 84154, 86316

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.