

Laboratory Bulletin

Important News from DCL Medical Laboratories



June 23, 2009

Reference range changes for DCL's Prostate Specific Antigen (PSA) assay

A recent review of vendor information, clinical guidelines and medical literature has prompted DCL decision to change our PSA reference values

The reference range for DCL's Prostate Specific Antigen (PSA) assay will be changing to 0.000 - 3.200 ng/ml.

DCL Medical Laboratories uses the Immulite 2000 third generation PSA solid phase chemiluminescent immunometric assay for the quantitative measurement of prostate specific antigen (PSA). The assay's intended use is as an aid in the detection of prostate cancer when used in conjunction with digital rectal examination (DRE). The assay is further indicated as an adjunctive test to aid in the management of prostate cancer patients.

The Immulite 2000 calibrates the third generation PSA assay using National Institute for Biological Standards and Control (NIBSC) / World Health Organization (WHO) International Standard PSA calibration material. This calibration material produces a result that is 20% lower than original PSA assays that use Hybritech calibration material. Due to this difference in calibration standard used on this testing platform, the PSA reference range cut off for the Immulite 2000 has been adjusted to 3.2 ng/mL from the traditional 4.0 ng/mL value that is used with other testing platforms.

The concentration of PSA in a given specimen determined with different assays can vary due to differences in assay methods and reagent specificity. Results obtained with different assay methods or kits cannot be used interchangeably. Prediction of malignant prostatic disease recurrence should be based on a complete clinical evaluation of the patient, which may also include serial serum PSA determinations.

If you have any questions regarding this testing, we are happy to help, please contact DCL Client Services at (317) 874-1334 or toll free at (866) 874-1334.

Reference:

1. Immulite 2000 Third Generation PSA. Package Insert. Siemens 2009
2. Immulite 2000 PSA. Package Insert. Siemens 2006
3. McDermed J. DPC's Third Generation PSA Assay: The Clinician's Choice for PSA Testing. DPC technical report
4. Henry's Clinical Diagnosis and Management by Laboratory Methods. 21st ed. Saunders 2007
5. Cook B. PSA Testing. Clinical Laboratory News:vol 34,number 6, June 2008

PSA, Total	
PSAT	DCL #: 3027
Also known as:	Prostate-Specific Antigen, Total; tPSA
Collection Container:	SST - Serum
Storage/Stability:	2 days refrigerated
Turnaround Time:	Within 24 Hours
Days Run:	Mon - Fri
Preferred amount:	1.0 mL Serum
Minimum amount:	0.5 mL Serum
Centrifuge required?:	Yes
Fasting required?:	No
Method:	Chemiluminescent immunometric Assay
Reference Range:	0.00 - 3.2 ng/ml
Clinical Utility:	As an aid in the detection of prostate cancer in men aged 50 years or older and serial measurements are used to aid in the management of cancer patients
CPT: 84153	Medicare Reimbursement: \$26.85

* Per Jan. 2009 Clinical Diagnostic Laboratory Fee Schedule for Indiana.