Clin Chim Acta. 2018 Jul 29;486:185-191. doi: 10.1016/j.cca.2018.07.043. [Epub ahead of print]

Biological variation estimates for prostate specific antigen from the European Biological Variation Study; consequences for diagnosis and monitoring of prostate cancer.

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Abstract

BACKGROUND: Prostate-specific antigen (PSA) is central in the diagnosis of prostate cancer. However, high-quality biological variation (BV) estimates for PSA are scarce. Here BV estimates from the European Biological Variation Study (EuBIVAS) for total (tPSA), free (fPSA), conjugated PSA (cPSA), and percent free PSA (%fPSA) are provided.

METHOD: EuBIVAS samples were collected weekly from thirty-seven healthy males (22-59 years) for 10 weeks. All samples, stored at -80 °C, were measured in duplicate with a Roche Cobas e801. Outlier and homogeneity analysis were performed followed by CV-ANOVA to determine BV, analytical variation, analytical performance specifications (APS), reference change values (RCV) and the number of samples required to estimate the homeostatic set points.

RESULTS: Within-subject BV estimates were for tPSA 6.8% (6.1-7.4); fPSA 7.1% (6.5-7.7) cPSA: 8.8% (8.0-9.7) and %fPSA 5.3% (4.8-5.8), delivering RCV for increase of 15-20% and indicating that one sample is sufficient to estimate the homeostatic set points within ±15%. BV estimates for tPSA were lower than previously published estimates. Estimates for fPSA, cPSA and %fPSA have not previously been reported in healthy subjects.

CONCLUSIONS: Highly powered EuBIVAS BV estimates of tPSA, fPSA, cPSA and %fPSA provide updated APS and RCV for monitoring for prostate cancer.