ZENTRUM FÜR
LABORMEDIZIN

Analytical performance of automated thrombospondin-1 and cathepsin D immunoassays for prostate cancer risk assessment

Jana Jentsch[A], Carolin Thurnher[A], Regine Garcia Boy[A], Lukas Graf[A], <u>Wolfgang W. Korte</u>[A]
[A]Center for Laboratory Medicine, St. Gallen, Switzerland

Background: PSA-based prostate cancer testing is under debate in the medical community as it leads to overdiagnosis, negative biopsies and overtreatment of patients. Proclarix® is a novel diagnostic test that acts as a decision aid for patients with unclear PSA results. A risk calculator combines the test results of the serum-markers total PSA, free PSA, thrombospondin-1 (THBS1) and cathepsin D (CTSD) with the patient's age to calculate a prostate cancer risk score. As automation is a vital part of clinical laboratories to manage testing workload and maximize efficiency, we evaluated precision and recovery of the THBS1 and CTSD immunoassays on the automated Dynex DSX® immunoassay analyzer.

Methods: THBS1 and CTSD immunoassays (Proteomedix, Zurich, Switzerland) were implemented at the ZLM (Center for Laboratory Medicine, St. Gallen, Switzerland) on existing DSX instruments (Dynex Technologies Inc, Chantilly, VA, USA) using assay files provided by the manufacturer. Automated measurements of 16 serum samples were performed over six days and compared to manual measurements of the same samples over six days. Recoveries were calculated using the median concentrations of the manual measurements as references. Within-run, between-run and total precision were calculated according to CLSI guideline EP5-A2.

Results: Both assays showed within-run (THBS1: 3.5%, CTSD: 3.9%), between-run (THBS1: 3.0%, CTSD: 1.5%) and total precision (THBS1: 4.7%, CTSD: 4.2%) coefficients of variation (CV) below 5%. Recoveries for all measurements are shown in Figure 1. The mean biases of automated compared to manual measurements were -4.0% for THBS1 and -1.8% for CTSD.
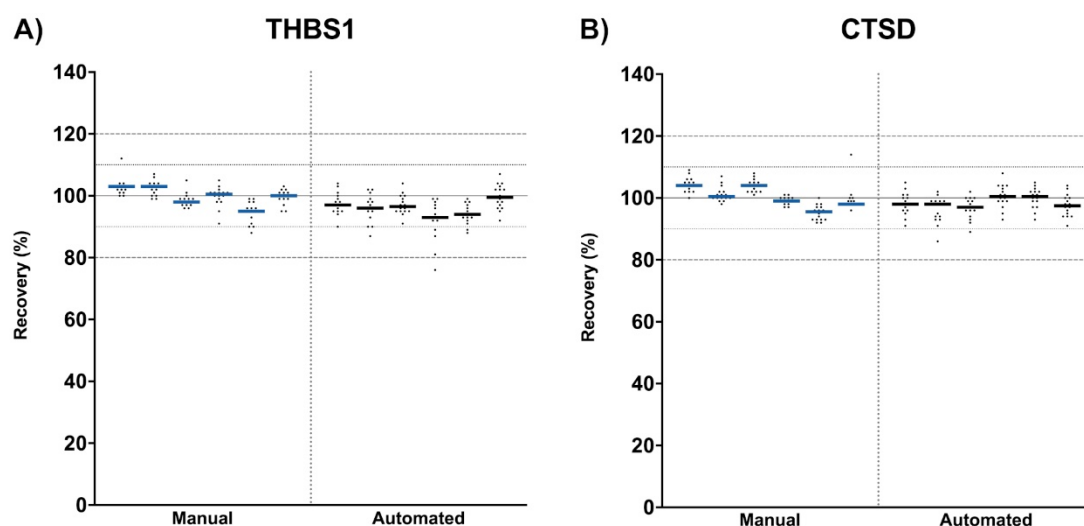
Figure 1: Recoveries of 16 samples measured six times manually and six times on an automated ELISA analyzer. A) THBS1 and B) CTSD. 100% = median concentrations of the manual measurements.

Conclusion: Automated processing of the THBS1 and CTSD immunoassays suits the requirements posed by the workflow of clinical laboratories and increases workflow efficiency. Concentrations determined on the Dynex DSX were comparable to values obtained by manual processing of the immunoassays and the precision was similar.