ZENTRUM FÜR LABORMEDIZIN

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Analytical validation of the Proclarix Risk Score for the diagnosis of prostate cancer

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Background: Controversy continues to roil around the role of PSA testing for prostate cancer detection. Elevated PSA can be caused by multiple factors other than cancer leading to unnecessary biopsies, overtreatment, patient anxiety and unnecessary healthcare spending. Better tools to select patients for prostate biopsy, particularly in the diagnostic grayzone between 2 and 10 ng/ml PSA, are needed. Proclarix® is a novel multianalyte assay with algorithmic analysis (MAAA) that combines serum concentrations of thrombospondin-1 (THBS1), cathepsin D (CTSD), total PSA (tPSA), free PSA (fPSA), and patient age to calculate a risk score for clinically significant prostate cancer. The objective of this study was to evaluate the feasibility of implementing Proclarix in the routine workflow of a clinical laboratory.

Methods: Proclarix (Proteomedix, Zurich, Switzerland) was established and conducted at the Center for Laboratory Medicine (St. Gallen, Switzerland) according to manufacturer instructions. tPSA and fPSA were measured on a UniCel® DxI800 instrument using Access® Hybritech reagents (Beckman Coulter Inc, USA). THBS1 and CTSD were measured on a DSX® workstation (Dynex Technologies, USA) using Proclarix reagents. The Proclarix Risk Calculator software (Proteomedix, Zurich, Switzerland) was used to calculate risk scores. Reproducibilities were determined by measuring eight serum samples over six days.

Results: A total of 48 risk scores were generated based on 192 analyte measurements. Risk scores of all measurements and coefficients of variation (CV) per sample are shown in Figure 1. Mean total CV were 2.7%, 5.6%, 3.1%, 5.9% and 5.0% for tPSA, fPSA, THBS1, CTSD and the risk score respectively. Linear regression analysis between manufacturer assigned risk scores and measured average risk scores showed high linear relationship (Figure 2).

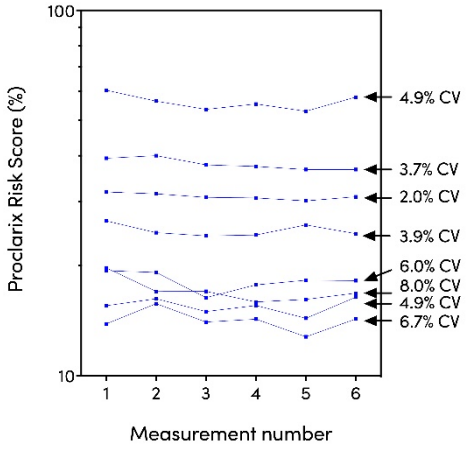

Figure 1: Eight samples measured over six days. CVs of samples are indicated on the right.

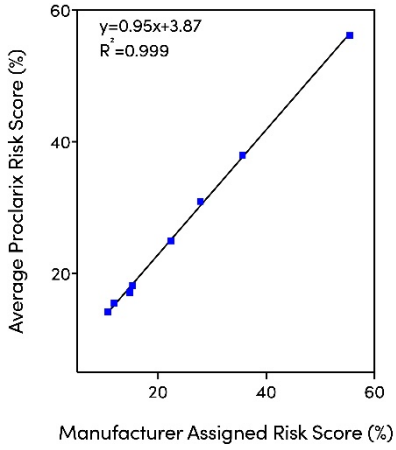

Figure 2: Linear regression analysis between manufacturer assigned risk scores and average risk scores measured at the Center for Laboratory Medicine.

Conclusion: Precision of the risk score was high and the risk score correlated well with target values. The implementation of Proclarix in the clinical laboratory workflow was efficient and successful.