

Validation of PSA by ELISA

Theresa Calicchio, Jennifer Hamill and Timothy D. Kupferschmid
Maine State Police Crime Laboratory, Augusta, ME 04330



Prostate-specific antigen (PSA or P30) is a single chain glycoprotein produced by the prostate. It is used as a forensic marker for the identification of primate semen and is particularly useful to identify semen from aspermatic males. Forensic laboratories typically identify semen by detecting the presence of sperm cells or by the detection of PSA. In the absence of sperm cells or when morphologically abnormal spermatozoa make sperm identification difficult, PSA analysis can provide an alternative solution. Traditionally, PSA analysis has been performed using crossover electrophoresis, rocket electrophoresis and radial-immunodiffusion. These methods are both laborious and time consuming. Detection of PSA by ELISA (Enzyme-linked Immunosorbent Assay) is a sensitive and efficient method for identifying semen. We present a detailed summary of the validation of Hybritech's Tandem® -E PSA ImmunoEnzymetric Assay for PSA detection.

The validation study evaluates method sensitivity, linearity, cross-reactivity, controls, casework samples and mixtures. The method detection limit (MDL) was determined to be 0.39ng/ml. The method was determined to yield a linear response from 0ng/ml to 75ng/ml PSA. A mixture study was performed to investigate the possibility of interference from other common matrices which may be encountered in casework samples. No interference was demonstrated in these samples. Representative samples of various body fluids were analyzed to assess the presence (or absence) of PSA. No significant levels of PSA were detected in these specimens. Although PSA was detected in neat male urine samples, the dilution of the sample in the extraction procedure will negate any effect that the endogenous PSA level could have on the result. All negative controls yielded results below sensitivity limits (BSL). All positive controls yielded positive PSA results. An analytical flow chart that follows biological evidence from receipt through DNA interpretation is presented as a guideline for "real-life" casework scenarios.