Introduction

Total Prostate Specific Antigen (PSA) testing is a useful test in the management of prostate cancer patients, and in particular is used to monitor the progress of patients post prostatic resection.

There is a high clinical interest in measuring PSA levels at very low concentrations, for the early detection of residual prostate tissue. Previously we reported PSA levels down to 0.10 mg/L, with the manufacturer established functional sensitivity 0.05 mg/L.

To determine if we could improve the limit of reporting to concentrations lower than 0.05 mg/L we needed to demonstrate linearity between 0.01 mg/L and 0.05 mg/L, with patient values lower than 0.05 mg/L reproducible with a CV of less than 20%. We also needed to obtain a reliable Quality Control material to routinely monitor assay performance.

Materials & Method

Currently we use the Abbott Architect Total PSA assay. This assay is a two-step Chemiluminescent Microparticle Immunoassay (CMIA) used for the quantitative determination of total PSA (both free and PSA complexed to alpha-1-antichymotrypsin) in human serum, used onboard an Architect ci16200 analyser.

The first step of our investigation was to assess the functional sensitivity of the assay (the concentration of Total PSA at which we can achieve a CV of less than 20%). We used patient samples of differing concentrations less than 0.10 mg/L, samples were analysed 5 times a day over 4 days using two different calibrations and two different reagent kits.

The next step was to obtain patient samples above the manufacturer’s functional sensitivity (0.05 mg/L) and perform manual dilutions in patient sera that contained no detectable PSA. The diluents used were a pool of female serum, as PSA is exclusively a male protease.

We also measured the precision of a low concentration quality control material over a period of two months, using Bio-Rad Tumor Marker Lyphochek Plus Control Level 1, we obtained a running mean value of 0.067 mg/L (+/- 0.004) with a CV of 5.9%.

Conclusion

We concluded that the Abbott Architect Total PSA reagent is fit for purpose at concentrations down to 0.01 mg/L, our laboratory has chosen to use 0.015 mg/L as our lower limit of reporting which is supported by routine use of a low level quality control material.