Prostate Specific Antigen (PSA) Test Harmonisation

Outcomes Agreed at the National Cancer Control Program PSA Harmonisation Board Workshop

Authors

Developed by the NCCP PSA Harmonisation Board:
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The following is a summary of the PSA harmonisation outcomes and the full report can be accessed by clicking on this link:

The full report *PSA Test Harmonisation Outcomes Agreed at the NCCP PSA Harmonisation Board Workshop 3rd of December 2014.*

The following PSA test harmonisation outcomes were agreed by the laboratories of the NCCP-designated cancer centres:

1. The unit of measurement of PSA concentration in serum or plasma shall be µg/L and at least one decimal point is required.

2. Assay details (calibration followed by manufacturer) shall be specified with the test name on PSA reports.

3. Whole blood specimens for PSA measurement shall be drawn, transported, logged-in, and serum / plasma separated and ready for analysis in less than 24 hours. Requesting doctors shall be advised of this requirement. A warning shall accompany results on specimens exceeding this agreed time limit.

   PSA testing shall not be performed on an un-centrifuged blood specimen received more than 48 hours after it was drawn, unless conclusive evidence indicates that longer contact times do not contribute to result error.

4. Only PSA assays calibrated to the WHO International Standard for Prostate-Specific Antigen (NIBSC Code 96/670) shall be used.

5. All NCCP-designated cancer centres shall participate in an ongoing external quality assessment (EQA) scheme for PSA operated by IEQAS. The types of EQA samples used in the scheme will include pooled residual serum and occasionally donor serum samples. EQA results shall be returned for each analytical system from which patient PSA results are generated.

6. Each NCCP-designated cancer centre shall:
   a) Set internal quality control (IQC) limits for PSA using existing IQC material so as to achieve realistic concordance with coefficients of variation currently attained.
   b) Run a common IQC two-level product for the intensive quality management of PSA measurement. The common IQC material is not intended to replace or displace a centre's existing IQC material.
   c) Set agreed common acceptance / rejection criteria for this material with the aim of improving the quality of results reported across all the centres.

See the full report for more information on approaches to achieving harmonisation of clinical laboratory results.