PSA Standardization Questions

Prostate-specific antigen (PSA) testing continues to play an important role in the detection and monitoring of prostate cancer but several controversial aspects related to PSA measurement persist. In the 2009 K-B survey, we queried subscribers regarding PSA testing practices. Here are the results.

Question 1

As far as you know, does the total PSA assay used in your laboratory provide comparable results regardless of the ratio of free to complexed PSA?

Response

Commercially available assays have changed over the years in an attempt to make them "equimolar", i.e. responsive to the level of PSA present whether it was free or complexed with plasma protein. The overwhelming majority of the respondents (1677, or 90%) believe that this degree of standardization has been obtained.

Question 2

If the total PSA assay used in your laboratory is calibrated to the WHO 90:10 (National Institute for Biological Standards and Control 96/670) reference preparation, do you still use 4.0 ng/mL as the cut-off for an elevated total PSA?

Response

Several manufacturers have tried to standardize their assays using a reference material prepared by the World Health Organization. Results using assays calibrated against this standard may be significantly lower than those using the traditional calibration. Over a thousand laboratories reported using such an assay and a significant majority (80%) are still using 4.0 ng/mL as the cut-off for an elevated total PSA.

Question 3

If your laboratory reports the ratio of free and/or complexed PSA to total PSA, do you use the same manufacturer for both total and either free or complexed PSA?

Response

Almost 900 laboratories answered this question and the majority (72%) said that they did use the same manufacturer for both assays.

For a recent review of some of the issues surrounding PSA testing, see the October 2009 issue of *CAP Today*.

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