Early diagnosis and screening of

prostate cancer





PerkinElmer Life and Analytical Sciences

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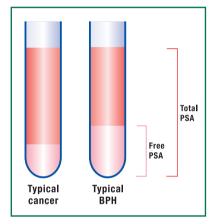
Prostate cancer is the most common cause of cancer and one of the leading causes of cancer-related deaths among men in the western countries. Several cancer organisations world wide, among them the American Cancer Society and the European Group on Tumour Markers recommend an annual PSA test together with DRE (digital rectal examination) for men.

PerkinElmer is committed to the improvement of the laboratory blood tests as the most convenient and economic way of improving the differential diagnosis of prostate cancer and BPH (benign prostatic hyperplasia) and thus paving the way for prostate cancer screening.

Measure free and total PSA for better distinction between cancer and benign growth

PSA is a typical protease enzyme. It exists as free form and also complexed to various inhibitors. It has been shown that these different forms of PSA exist in different relative amounts in subjects with BPH and prostate cancer. Patients having only benign growth of the prostate have more free PSA in relation to total PSA in their blood than patients with prostatic cancer. This has made it possible to design a new diagnostic tool to find early prostate cancer: measurement of the ratio of free PSA to total PSA (F/T PSA). The F/T PSA ratio is particularly useful in the diagnostic grey zone where levels of total PSA are $4 - 10 \mu g/L$. Improved diagnostic specificity means that less biopsies are needed.

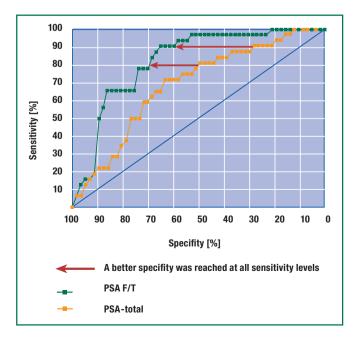
Prostate Cancer or BPH? Different forms of PSA exist in different relative amounts



The relative proportions of the free and the bound forms of PSA in blood provide a basis for distinction between prostatic cancer and benign prostatic hyperplasia.

First clinical tests show a clear improvement in diagnostic specifity when using PerkinElmer's DELFIA PSA Free/Total kit.

(Björk, T. et al. Urology 48 [6] 1996)



he tools

needed for prostate cancer screening



DELFIA® PSA Free/Total Kit Three results from one measurement

PerkinElmer's PSA Free/Total kit provides clinically and technically unique features. It measures simultaneously, from one microtitration well two analytes: Free PSA and Total PSA, giving separate results for both of them, and also the ratio of Free/Total PSA. Obtaining three results from a single measurement is made possible by utilizing the DELFIA® technology and time-resolved fluorometry.

The only assay giving an exact value for the PSA Free/Total ratio

By measuring both the Free PSA and Total PSA and thereby also the ratio of Free/Total from the same well the DELFIA PSA Free/Total immunoassay is the only commercially available assay that is consistent over time, giving an exact ratio.

Calibrated against the WHO 1st IRP for PSA

Assay variability has created substantial problems with the interpretation of PSA concentrations. The DELFIA PSA Free/Total kit is calibrated against the WHO 1st IRP for PSA. By using our assays your laboratory can be confident about giving out the right result and the clinician interpreting the PSA results can be confident in diagnosing the patient correctly.

Wide dynamic range

PSA Free/Total PSA Free 0.04 – 250 ug/L PSA Total 0.05 – 250 ug/L

Why screen for prostate cancer?

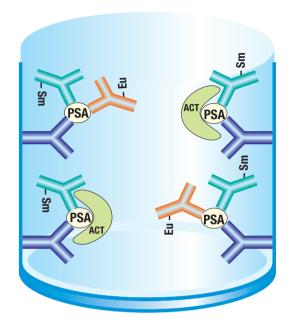
The amount of men being diagnosed with prostate cancer world-wide is increasing and it is estimated that about 550 000 men are diagnosed and more than 200 000 men die from the disease each year. The incidence is highest in North America, with 92/100 000 cases per year, followed by Australia and New

Zealand, and Western European

countries.

Prostate cancer is a cancer of elderly males. With increasing age the likelihood of developing prostate cancer increases from 1 in 10 000 in men under age 39, to 1 in 103 in the range of 40 to 59 years, to 1 in 8 between the ages 60 - 79.

For men in their 50's and 60's, early diagnosis of prostate cancer is vital. Patients in this age range are more likely to develop cancers with an aggressive growth pattern and metastatic potential. If untreated they will ultimately be the cause of death. Identified in time, a localized prostatic cancer can be cured



Principle of the DELFIA® PSA Free/Total assay

Microtitration wells are coated with a monoclonal antibody which is equally specific for free PSA and PSA-ACT complex in a serum sample. Two tracing antibodies are used: the europium labelled one binds only to free PSA molecules attached to the solid phase. From the europium signal we get the result for free PSA in the patient sample. The other, samarium labelled monoclonal antibody, binds equally to both of the PSA forms, thus giving an equimolar result for total PSA in the sample.

Chelates of europium and samarium have mutually exclusive light emission spectra, allowing their measurement with great sensitivity using time-resolved fluorometry.

DELFIA® PSA EQM Kit

For follow-up of patients already being diagnosed with prostate cancer PerkinElmer Life and Analytical Sciences offers a DELFIA, PSA EQM kit. Like the PSA Free/Total kit it is calibrated against the WHO 1st IRP for PSA.

All PerkinElmer diagnostic products may not be available in all countries. For information on availability please contact your local representative. DELFIA® tumor marker kits are not available for sale in the USA.



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