PROGENSA® PCA3 Assay Media Backgrounder

The PROGENSA® PCA3 Assay is the first FDA approved molecular test that detects the over-expression of the PCA3 gene[1]. The specific information provided by the urine-based test -- the PCA3 Score – can be used in conjunction with other patient history to decide whether a repeat biopsy is necessary in men with one or more previous negative biopsies and for whom a repeat biopsy would be recommended by a urologist. Data on the PCA3 marker has been cited in over 80 publications and more than 200,000 tests have been used in clinical practice throughout the world[2].

Clarity for Solving the PSA Dilemma

Current practices for detecting prostate cancer rely on the PSA test and result in approximately 1,000,000[3,4] patients referred for prostate biopsy in the U.S. each year. Approximately 25% of these biopsies are positive for prostate cancer[3]. Unfortunately, this means that 75% of first biopsies are negative. The fear that cancer was missed often leads to repeat biopsies, many of which may have been needless and put patients at risk of complications of unnecessary invasive procedures, such as infection, bleeding and hospitalization[6]. Men with an elevated PSA and a negative biopsy present a clinical dilemma -- the PSA Dilemma. This creates a medical need for additional tests to help physicians and patients make more informed repeat biopsy decisions.

PCA3 is a gene that is highly over-expressed in more than 95% of prostate cancers. Prostate cancer cells express 60 to 100 times more PCA3 RNA than normal cells[1]. The PROGENSA PCA3 Assay provides much needed information to help decide whether a repeat biopsy is necessary.

How does the test work?

Specimen for the test are collected from urine following a digital rectal examination (DRE) conducted by an urologist or other physician. The sample of urine is then sent to a specialist laboratory to obtain the PCA3 Score[2].

What is a PCA3 Score?

The PCA3 Score describes the amount of PCA3 gene detected in urine, and is associated with a repeat biopsy outcome. As the PCA3 Score increases, the likelihood of a positive biopsy result increases. As the PCA3 Score decreases, the likelihood of a positive biopsy result decreases. By using the PCA3 Score, combined with existing clinical information, physicians can more accurately predict a repeat biopsy outcome.

Availability

The Gen-Probe PROGENSA PCA3 test is approved in the United States and Canada, and is CE-marked in Europe. For additional information about the PROGENSA PCA3 assay, access www.gen-probe.com/PCA3.

BLACK BOX WARNING: The PROGENSA PCA3 Assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy. Men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.

WARNING: The Clinical Study of the PROGENSA PCA3 assay only included men who were recommended for a repeat biopsy. Therefore, the performance of the assay has not been established in men for whom a repeat biopsy was not already recommended.

REFERENCE LIST

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