Elevated PSA?

Clear answers on unclear PSA results with Proclarix.
Did you know, that more than 50 percent of biopsies in men with elevated PSA are negative or clinically insignificant leading to overdiagnosis and overtreatment?
Whenever PSA results are confusing.

Today, the initial step to diagnose prostate cancer is by testing the PSA and do a digital rectal examination (DRE) at the GP. The PSA test is a well-established prostate specific marker that measures the concentration of PSA molecules (Prostate-Specific Antigen) in a patient’s blood sample. A high level of PSA can be a sign of prostate cancer. Therefore European guidelines recommend prostate biopsy, if the PSA > 3 ng/ml. But high levels of PSA can also be raised for lots of other reasons including infections, prostate stimulation, vigorous exercise or even certain medications. For many patients and also physicians, the PSA results can be confusing. Patients are sent to further examinations which is time consuming. And anxiety grows, when a biopsy is taken into consideration.
Patients with a PSA level between 2 and 10 are considered to be in a grey zone. In such a situation, the doctor faces an inconclusive situation, where he does not have sufficient information to decide, whether to further investigate or discharge the patient. For the patient, unclear results can lead to anxiety, additional time in health care process and eventually unnecessary biopsies. Proclarix is a breakthrough in identification of those patients with elevated PSA that really require further medical investigation. The Proclarix risk score provides clear and immediate diagnostic support for further treatment decisions.

Proclarix gives clear answers.

PROCLARIX REDUCES UNCERTAINTY BY GIVING CLEAR RESULTS ON THE RISK OF PROSTATE CANCER.
With a simple reflex test

Proclarix is a simple protein based blood test. It can be done as a reflex test with the same sample as the PSA test. As a patient you don’t have to undergo any additional intervention and results are available after a short time. Moreover, it is available as an affordable immunoassay test, which can be offered on existing infrastructure by any local diagnostic laboratory.
clarity is just one blood sample away.

Proclarix is a breakthrough in identification of those patients with elevated PSA that really require further medical investigation. These are values between 2 and 10ng/ml where by now it was unclear whether further medical investigation was helpful. Proclarix gives clarity from the beginning so patients don’t have to waste time worrying without reason. Chances are high, that there are other reasons for the elevated results than prostate cancer.
Proclarix (CE, IVD) is a breakthrough in identification of those patients with elevated PSA that really require further medical investigation with an NPV of 95%. Proclarix is indicated in men with elevated total PSA (2.0 to 10.0 ng/mL), a digital rectal examination finding consistent with elevated prostate volume (≥35 mL) and not suspicious for cancer. Just two specific biomarkers in combination with an decision support software gives clear diagnostic answers in the form of a risk score. The risk score identifies patients with Gleason Score ≥ 7 who have the probability of detecting high-grade prostate cancer based on a prostate biopsy. Proclarix is comprised of two quantitative Enzyme-linked Immunosorbent Assays (ELISA) that measure the concentration of thrombospondin 1 (THBS1) and cathepsin D (CTSD) in human serum. The software integrates the values for THBS1 and CTSD, age, total and free PSA to calculate a risk score. The risk for high-grade prostate cancer is low in men with a Proclarix result below the cut-off of 9.42% and high with Proclarix result above. The cut-off refers to a 90% sensitivity of the test for detecting high-grade cancer.
and make an informed decision.

«Prostate biopsy is a very anxiety provoking procedure. Men are very fearful about one specific question: Do I have prostate cancer? The Proclarix test helps Urologists decide when a prostate biopsy is an appropriate next plan of action.»

PROF. DR. MAX MUSTER
UNIVERSITÄTSSPITAL ZÜRICH
This is how you benefit from Proclarix

PATIENT
- Immediate clarity after first doctor-visit: relief if no or non-significant cancer vs. immediate referral
- Less anxiety and time spent about potential prostate cancer diagnosis

PHYSICIANS
- Clear decision support in patients with elevated PSA: relief or immediate referral
- Works as a reflex test with the same blood sample as PSA
- Improve patient management and patient satisfaction

HEALTHCARE SYSTEM
- Strong health economic benefits thanks to early rule out of patients with no or non-significant cancer
- Fewer complications (e.g. bleeding, infections)
Proclarix
Next generation blood test

PRECISE
Proclarix reliably identifies aggressive prostate cancer

NON-INVASIVE
Diagnosis without the risk, pain and costs of tissue biopsies

ACCESSIBLE
Proclarix is compatible with open platforms at most laboratories.

FAST
Saves time by doing a reflex test with same bloodsample as PSA

CONTACT
Eperum quatet hil mossimp orenim illor moluptur, que pererruptur ratium, quia