CAMBRIDGE CLINICAL LABORATORIES

Proclarix Prostate Cancer Test Report

Patient and Specimen Information

ID 1	Example	CCL ID	Example
ID 2	Example	Collection Date	Example
Patient Name	Example	Date Received	Example
Date of Birth	Example	Sample Comments	Example

Physician Information

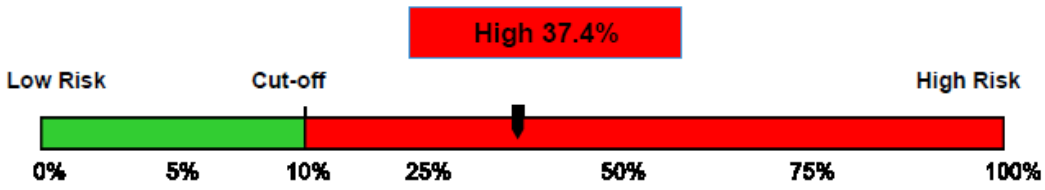
CCL Account No	Example	Requesting Physician	Example
Clinic/Hospital Name	Example		

Patient Results

Clinical Information

Patient ID:	example report		
CTSD:	172 µg/L		
THBS1:	32881 µg/L	Software Version:	2.1.1
Total PSA:	4.51 µg/L	Configuration Version:	3
Free PSA:	1.00 µg/L	PSA Test Manufacturer:	BioMérieux Systems
Calculated %fPSA:	22%	Report ID:	1147
Age:	74 years	Report Date:	28.11.2022 12:21:59

Risk of High-Grade Prostate Cancer (Proclarix Risk Score)



Result Interpretation

PSA levels rise in prostatic pathologies such as benign prostatic hyperplasia (BPH) or prostate cancer. Testing for PSA and its evolution is useful for monitoring and controlling the efficacy of prostatic carcinoma therapy.
Determination of PSA levels enables the detection of the onset of metastases or the persistence of disease following prostate cancer therapy.
An elevated PSA level after therapy or a persistently high level during therapy indicates residual or recurrent disease.
PSA is present in blood with three main forms. The most important immunoreactive form is PSA bound to alpha-1-antichymotrypsin (PSA-ACT). Free PSA is the other immunoreactive form present in serum. Calculation of the percentage of free PSA, determined by dividing the free PSA (FPSA) concentration by that of total PSA (TPSA), has been suggested as a way of improving the differentiation of BPH and prostate cancer Interpretation of test results should be made taking into consideration the patient's clinical history, and the results of any other tests performed.

Proclarix returns a Risk Score corresponding to the probability of detecting high-grade prostate cancer (defined as Gleason score 7 or higher, i.e. ISUP grade group 2 or above based on a prostate biopsy). The risk for high-grade prostate cancer is low in men with a Proclarix Risk Score below the cut-off value of 10% and high with a Proclarix Risk Score above the cut-off value. Given the high negative predictive value of 95%, the risk of missing high grade cancer below the Proclarix Risk Score cut-off is less than 5% [1].
Due to systemic and assay variability, test results between 6.7% and 12.3% should be interpreted with caution. Test results should be interpreted in conjunction with other laboratory and clinical data and consultation of the relevant guidelines on the decision for biopsy. Prostate biopsy is required for diagnosis of prostate cancer. Use outside of the indication has not been validated.

Proclarix Test Description

Prostate cancer is the second most frequent cancer diagnosis made in men [2]. Proclarix is an aid in prostate cancer diagnosis for patients with elevated PSA values. The Proclarix Risk Score provides physicians and patients with actionable information to confidently take decisions when considering a prostate biopsy that is required for final diagnosis. Proclarix is comprised of two quantitative immunoassays that measure the concentration of thrombospondin 1 (THBS1) and cathepsin D (CTSD) in human serum [3, 4]. The Proclarix Risk Calculator integrates the values for THBS1 and CTSD, age, total and free PSA (normalized values from third party instruments) to calculate a Risk Score.
The Proclarix cut-off value has been established in a multicenter study with two European clinical centers including 955 men matching the intended use.
The cut-off value was set to 10%, referring to a sensitivity of 90% (95% CI: 84-94%) and a negative predictive value of 95% (95% CI: 92-97%) for high grade prostate cancer using transrectal prostate biopsy. The specificity is 43% (95% CI: 39-46%) [1]. Proclarix was further evaluated in multiple clinical studies [5-8].
Proclarix is indicated in men with elevated total PSA (2.0 to 10.0 µg/L), a digital rectal examination finding consistent with elevated prostate volume (35 mL or higher) and not suspicious for cancer. Proclarix is intended for professional use only.

References

[1] Klocker et al. BJUI Compass. 2020;1:15-20; [2] Bray et al. CA Cancer J Clin. 2018;68(6):394-424; [3] Steuber et al. BJU Int. 2019. 123(5):826-833; [4] Macagno et al. PLoS One. 2020;15(5):e0233442
[5] Steuber et al. European Urology Oncol. 2021; [6] Morote et al. World J Men's Heal. 2021;40: 0; [7] Morote et al. Urology Open Sci. 2022;37: 38-44; [8] Morote et al. Int J Biological Markers. 2022.

Approved By: X

Report prepared by: Example