



PROSTATE

For diagnostic triaging
of suspected prostate
cancer patients

trublood[®]
the no risk biopsy

trublood[®]

A new paradigm in prostate cancer diagnosis and management



- ▶ Individuals with elevated PSA or suspicious findings on DRE who have been advised an invasive prostate biopsy to check for prostate malignancy
- ▶ Individuals where a recent invasive biopsy has been inconclusive or inconsistent with clinical observations
- ▶ Known cases of prostate cancer with suspected metastatic relapse to rule out a new primary

Trublood[®] Prostate detects prostate-specific Circulating Ensembles of Tumor-Associated Cells (C-ETACs), which are present in the blood of individuals with prostate cancer and undetectable in healthy individuals or patients with benign prostate conditions.

Trublood[®] is the result of several years of research involving our team of more than 150 scientists and clinicians using the world's latest equipment and software. This technique has been clinically validated on more than 40,000 samples from patients and healthy individuals to whom we are ever grateful.

Executive summary



What?

Trublood® Prostate is a non-invasive, blood-based prostate cancer liquid biopsy for diagnostic triaging of symptomatic individuals such as those with difficulty in micturition or presenting with an enlarged prostate or elevated serum PSA levels



For whom?

- Every Individual who desires a risk-free triaging for prostate biopsy
- Individuals with urological suspicion of prostate cancer
- Patients with an enlarged prostate
- Patients with elevated PSA levels



Why?

Around 75% of all prostate conditions are benign. However, an invasive biopsy is required to differentiate between benign and malignant prostate conditions. Prostate biopsies may be unviable in some cases due to comorbidities. Invasive biopsies are risky, inconvenient, painful, and must be performed in a clinical setting. Blood samples for Trublood® can be collected from a patient's home or office.



How?

Circulating Ensembles of Tumor-Associated Cells (C-ETACs) and Circulating Tumor Cells (CTCs) are isolated from the patient's blood sample and extensively analysed to detect prostate malignancy.



Analytes

Circulating Ensembles of Tumor-Associated Cells (C-ETACs), Circulating Tumor Cells (CTCs)



Tests

Immunocytochemistry



Turnaround time

10 days



Sample type

15 ml venous blood



Prostate

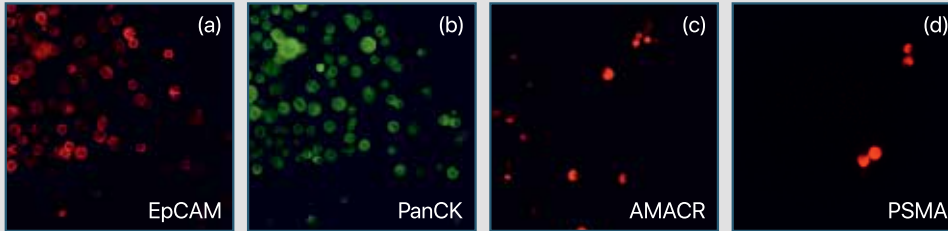
Advantages

- ▶ Large number of prostate biopsies are performed every year
- ▶ 75-80% of these biopsies eventually are diagnosed as benign
- ▶ Trublood® Prostate can identify individuals with prostate-specific C-ETACs who can then be prioritised for further clinical procedures such as biopsy. Individuals who test negative for prostate-specific C-ETACs can be considered for a later evaluation
- ▶ This technique can eliminate or significantly reduce the number of unnecessary prostate biopsies each year and alleviate the financial and infra-structural burden on cancer management infrastructure
- ▶ Trublood® Prostate is patient-friendly since it eliminates or significantly reduces the number of symptomatic individuals to be exposed to risks of pain and procedural complications

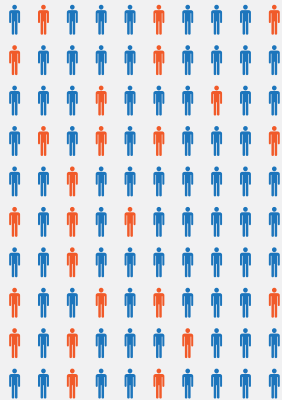
Limitations

- ▶ Trublood® Prostate cover the most common subtypes of prostate cancer, i.e., ductal and acinar adenocarcinoma, which make up ~96% of all prostate cancer cases
- ▶ Rare histopathological subtypes such as urothelial carcinoma, squamous cell carcinoma, neuroendocrine tumors, basal cell carcinoma, mesenchymal tumors, etc. are not within the scope of Trublood® Prostate analysis
- ▶ The limitation of the Trublood® Prostate is that it does not provide Gleason's score as obtained through the HPE and analysis of a tissue biopsy. And Trublood® Prostate does not distinguish ductal adenocarcinoma from acinar origin carcinoma.

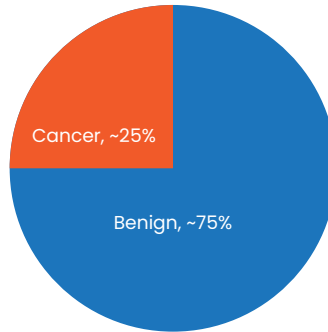
Illustrative immunocytochemistry images



Conventional Approach

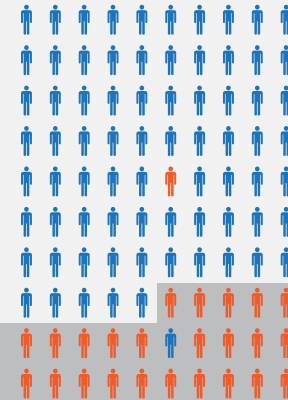


Millions of prostate biopsies are performed each year



~75% of all prostate biopsies are negative, indicating the high proportion of individuals who undergo an invasive procedure that is retrospectively deemed unnecessary.

Trublood® Approach



With Trublood® diagnostic triaging, ~75% of all potentially unnecessary biopsies could be avoided

Alternative Diagnosis / Wait and Watch
(Subject to Clinical Judgment)

Priority for Biopsy

Trublood® Prostate identifies individuals who can be prioritized for Prostate Biopsies

Validation



trublood[®]

Trublood[®] non-invasive diagnostic biopsy for solid organ cancers has been developed by Datar Cancer Genetics based on the findings of two clinical trials registered with the CTRI (Registration Nos. CTRI/2019/01/017219 and CTRI/2019/03/017918).

Trublood[®] has been extensively validated with data from more than 22,000 samples from asymptomatic individual donors as well as more than 18,000 samples from patients with various cancers/patients with benign conditions, totalling more than 40,000 evaluable samples till December 2019.

Comparison with other Methods

Method	Sensitivity	Specificity	NPV	PPV
Trublood [®]	92.2%	92.2%	97.4%	100.0%
ExoDx*##	90.0%	90.0%	89.3%	40.1%
SOC*	90.0%	90.0%	80.5%	33.7%
PCPT*	90.0%	90.0%	82.2%	34.4%
ERSPC*	90.0%	90.0%	80.2%	33.6%
PSA	90.0%	90.0%	81.0%	33.9%

SOC: Standard of Care model; **PCPT:** Prostate Cancer Prevention Trial; **ERSPC:** European Randomized Study of Screening for Prostate Cancer; **PSA:** Prostate-Specific Antigen; **NPV:** Negative Predictive Value; **PPV:** Positive Predictive Value.

*McKiernan J, et al. Eur Urol. 2018;74(6):731-738. #Granted Breakthrough Device Designation by the FDA

Parameter	Analytical	Clinical
Sensitivity	96.30%	92.20%
Specificity	100.00%	100.00%
PPV	-	100.00%
NPV	-	97.50%
Accuracy	98.15%	98.10%

Publications



IJC

International Journal of Cancer

- ✓ Circulating Ensembles Of Tumor Associated Cells: A Redoubtable New Systemic Hallmark Of Cancer.

AACR
Cancer Research

- ✓ Viable Circulating Ensembles of Tumor Associated Cells Persist in Pre-treated Patients with Solid Organ Cancers showing No Radiologically Detectable Disease.
- ✓ Encyclopedic Non-invasive Liquid Biopsies for Differential Diagnosis in Prostate Cancer.
- ✓ Circulating Tumor Cells Express Tissue Specific Antigens In Multiple Cancers.

Intellectual Property

- Trublood® comprises processes, technologies, and trademarks/copyrights, which are proprietary to Datar Cancer Genetics and could be the subject matter of Intellectual Property Rights under various jurisdictions.

DATAR CANCER GENETICS

UNITED KINGDOM | GERMANY | INDIA



Advena Ltd.,
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013, Malta

Contact us:

✉ **UK** - enquiries@datarpgx.com • **Germany** - info-eu@datarpgx.com • **India** - info@datarpgx.org

🌐 datarpgx.com

Proprietary Technology, All Intellectual Property Rights Protected under relevant laws.