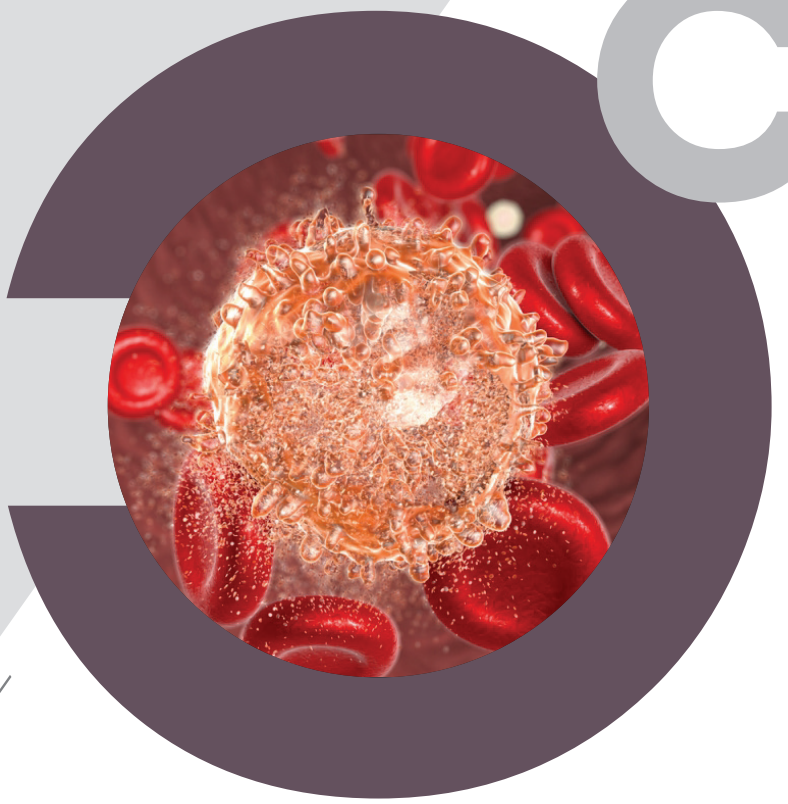
trublood®

The alternative biopsy

Nordic Laboratories®

For professional use only



About trublood®

trublood® is a minimally invasive, diagnostic test that can clearly identify cancer in symptomatic patients. trublood® provides diagnostic information similar to that of a tissue biopsy when it is inconclusive or not possible. Based on the test result, therapy can be aligned.

trublood® was developed by Datar Cancer Genetics based on the results of several clinical studies and validated on more than 40,000 samples. These included samples from asymptomatic subjects undergoing screening tests such as mammograms, colonoscopies, PAP smears, serum CA markers and other clinical examinations, as well as more than 17,000 samples from patients with various cancers and patients with benign diseases.

trublood® can complement, or if necessary, replace invasive biopsies.

OVERALL SENSITIVITY	OVERALL SPECIFICITY
89.8 %	97.0 %

trublood® is particulary recommended for ...

... symptomatic individuals who have been advised an invasive tissue biopsy to check for mailgnancy.

... patients where an invasive biopsy has been inconclusive or inconsistent with clinical observations.

... suspected metastatic relapse to rule out new primary.

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trublood® basics

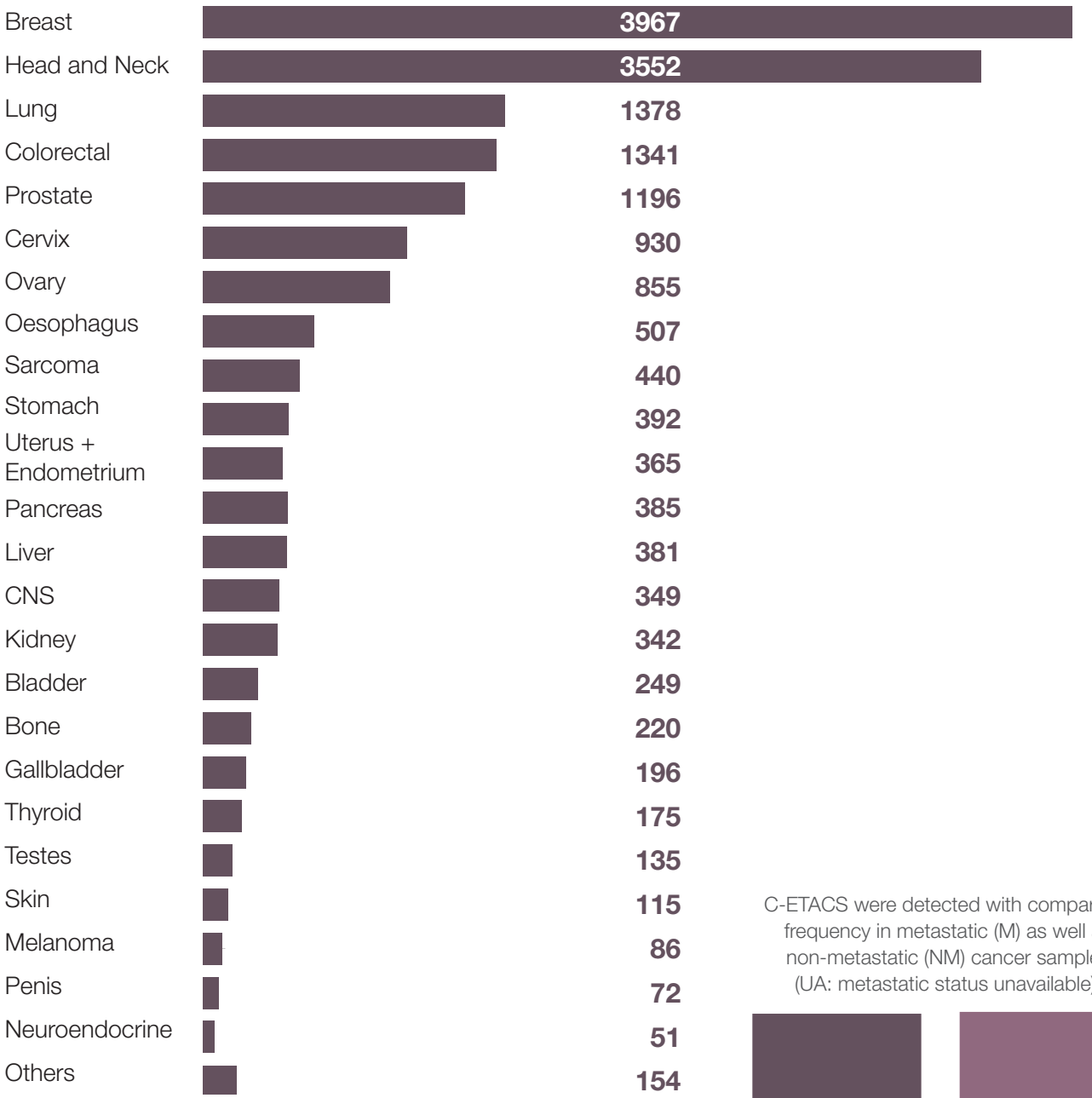
- Tumours release thousands of cells into the circulation, where circulating tumour cells (CTCs) survive for about 1 - 2.5 hours.
- In order to detach from the primary tumour and disseminate into the blood, cells must undergo a cellular process known as Epithelial Mesenchymal Transition (EMT).
- EMT enhances migratory capabilities of tumour cells, which allows cells to penetrate into the vasculature and circulate as single or clusters of circulating tumour cells.
- CTCs extravasate having undergone the reverse process known as Mesenchymal to Epithelial Transition (MET) and colonise at distant organs.
- CTCs are defined as EpCAM (+), PanCK (+), CD45 (-) cells. Circulating tumour associated cells (C-TACs) are EpCAM (+), PanCK (+), CD45 (+/-) cells of tumourigenic origin in peripheral blood.
- Non-tumourigenic cells in peripheral blood have functional apoptotic mechanism, but CTCs and C-TACs are resistant to apoptosis.
- An epigenetically active stabilising process can eliminate normal cells and confer survival privilege on apoptosis-resistant CTCs and C-TACs.
- Sufficient C-TACs can be enriched and harvested for immunocytochemistry (ICC) profiling with markers used in immunohisto-chemistry (IHC) which aid in determination of histopathological subtypes of tumour tissue.
- Antibody clones used in the trublood® assay for analysis of tumour antigens / markers are internationally approved for IVD use.

trublood® in comparison

Usual Tissue Biopsy / FNAC	trublood®
Invasive, need of tissue	Minimally-invasive
Usually painful, possible stitches and scars	No pain, no stitches, no scars; only one blood draw
Risk of tumour cell seeding	No risk
Risky procedure for organs like lung, liver, pancreas	No risk of injury to any organ / bleeding
Possibly misleading as it is site / time dependent	Provides real time data and covers all active sites
Serial / sequential biopsies are impossible	Can be performed as often as necessary
Not viable if primary tumor is not easily visualised	Viable even if primary / metastasis are undetectable

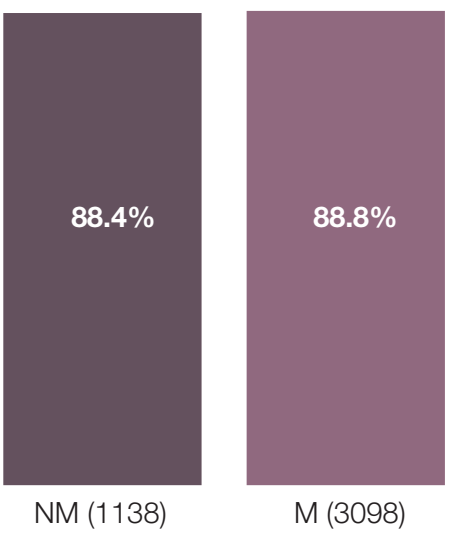
Comprehensive trublood®

Total number of patients in each cancer type (and overall) where Circulating Ensembles of Tumor-Associated Cells could be detected:



Particulars	Samples
All Cancers	17.833
Benign Conditions	488
Asymptomatic Individuals	22.030
Total	**40.351**

C-ETACS were detected with comparable frequency in metastatic (M) as well as non-metastatic (NM) cancer samples (UA: metastatic status unavailable).



Quelle: Akolkar, D. et al. Circualting Ensembles of Tumor-Associated Cells: A Redoubtable New Systemic Hallmark of Cancer. Int. J. of Cancer 2019, p.38.

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Sample collection

REQUIREMENTS

Basic diagnostics
(total 3 tubes containing 22 ml whole blood)

- First draw 2 ml SST tube (yellow colour cap)
- Second draw 2 x EDTA tubes (purple colour cap) of 10 ml each - total 20 ml

Basic diagnostics + cfDNA
(total 4 tubes containing 25 - 30 ml whole blood)

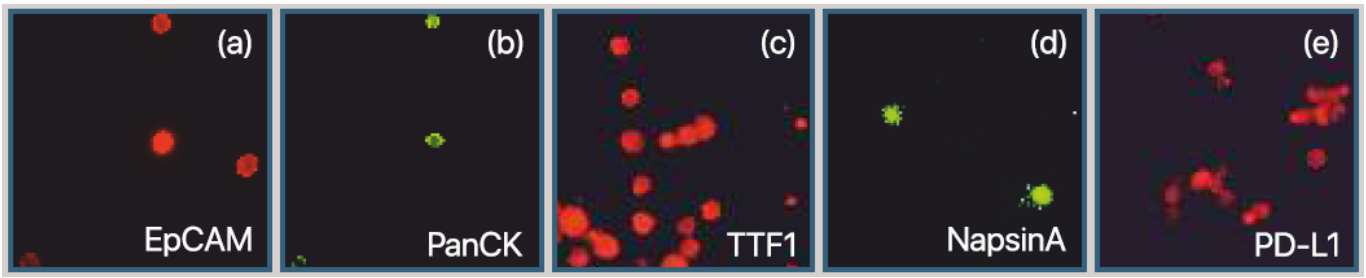
- First draw 2 ml SST tube (yellow colour cap)
- Second draw 8 ml DCG tube (camouflage colour cap)
- Third draw 2 x EDTA tubes (purple colour cap) - total 15 - 20 ml

NOTE
Sequence of draw should not be altered.
Blood should be drawn only and only as per above method.
Blood drawn should be performed only be qualified phlebotomist under medical supervision.
Ship at 2 - 8 °C in the container provided by DCG.

PRECAUTIONS

- The patient must not have received any form of cancer therapy (radiation / chemo-therapy / surgery / endocrine therapy etc.) at least 15 days prior to collection of sample.
- The patient must not have received oral or IV corticosteroids at least 15 days prior to collection of sample.
- Patient has no current febrile or any other acute inflammatory illness.
- Patient does not have acute exacerbation or flare-up of an inflammatory condition requiring escalation in medical therapy at least 5 days prior to collection of sample.
- Patient has not received blood transfusion / PET-CT / CT scan at least 5 days prior to collection of sample.
- Patient is not positive for HIV / HBV / HCV.

Illustrative Immuno-cytochemistry images



Illustrative immunochemistry images of patient with lung cancer

FAQ's

Whom is the test appropriate for?
trublood® is suitable for every individual who desires a risk free biopsy.

How is the test performed and which analytes are included?
Circulating tumour cells (CTCs) and Nucleic Acid are isolated from patient's blood sample and extensively analysed for diagnosis, prognosis and theranostics.
The analytes, which are examined, are CTCs, cell-free DNA + RNA as well as Germline DNA.

What are the most important facts regarding the sample collection?

- 22 ml - 30 ml peripheral blood as per protocol depending upon extent of test
- Turn-Around-Time: 10 days from receipt of the sample

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Publications

1. Gaya, A., Crook, T., Plowman, N. et al. Evaluation of Circulating Tumor Cell Clusters for Pan-Cancer Noninvasive Diagnostic Triaging. Cancer Cytopathol 2020. DOI: 10.1002/cncy.22366
2. Akolkar, D., Patil, D., Crook, T. et al. Circulating ensembles of tumor-associated cells: A redoubtable new systemic hallmark of cancer. Int. J. Cancer 2020. 146(12). S.3485-3494 DOI: 10.1002/ijc.32815
3. Ranade, A., Bhatt, A., Page, R. et al. Hallmark Circulating Tumour Associated Cell Clusters Signify 230 Times Higher One-Year Cancer Risk. Cancer Prev Res 10/2020. DOI: 10.1158/1940-6207.CAPR-20-0322

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