trublood

Cancer Hope
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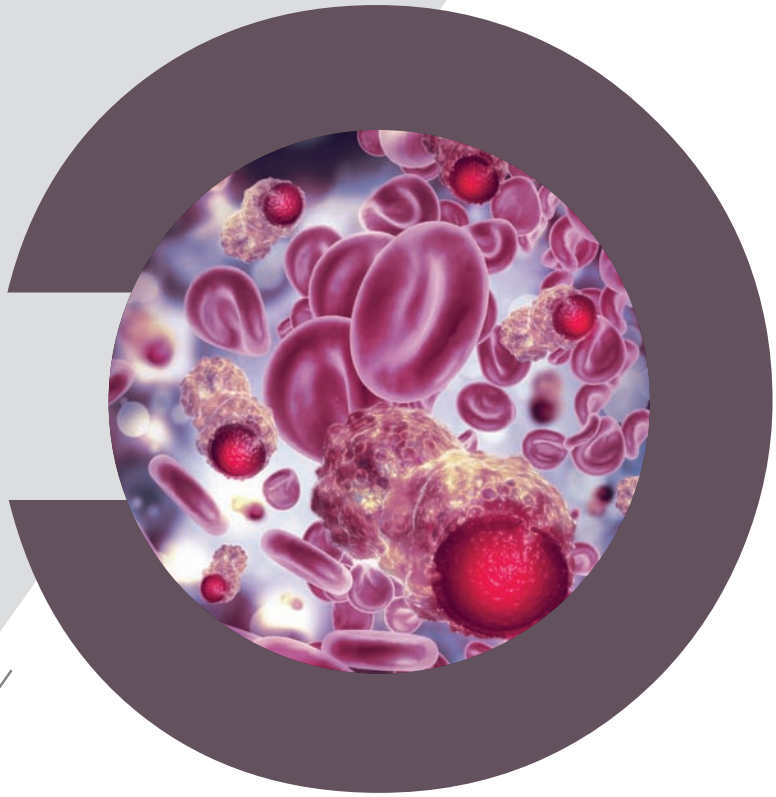
Risk stratification for symptomatic patients

trublood

the no risk biopsy

DATAR CANCER GENETICS
UNITED KINGDOM | GERMANY | INDIA



trublood can complement tissue biopsies.

About trublood

trublood is a minimally invasive diagnostic test for risk stratification of symptomatic patients, suspicious for a solid tumour.

trublood was developed by Datar Cancer Genetics based on the results of several clinical studies[1,2,3] and validated on more than 40,000 samples. The basis for trublood are circulating tumour cells/ clusters, which can be released into the blood by a tumour in a very early stage, sometimes even in pre-malignant situations.
These cells usually carry characteristics derived from their tissue of origin and can thus be assigned to a specific organ. trublood is a complement to standard of care, such as imaging, tissue biopsies or palpation examinations, in order to provide additional information, especially in uncertain clinical cases. If necessary, the test can be performed at short intervals to detect a malignant tumour at an early stage.

Basics of trublood

- Tumours release thousands of cells into the blood circulation, which are called circulating tumour cells (CTCs). They can survive for about 1 - 2.5 hours in the blood.
- So-called circulating tumour cell clusters, consisting of CTCs, immune cells and fibroblasts, have a survival advantage over individual CTCs and a significantly increased metastatic potential. These cell clusters (C-ETACs) can be detected in over 90% of solid tumours and are rare in asymptomatic individuals (< 3.7%).
- Healthy cells in the peripheral blood have a functional apoptotic mechanism that is not present in C-ETACs.
- A specially developed method based on a short-term culture enables the enrichment of viable, apoptosis-resistant C-ETACs from peripheral blood.
- The short-term culture medium enriched with apoptosis-inducing factors eliminates healthy cells, whereas CTCs and C-ETACs survive this procedure. As a result, a distinction between benign and malignant cells is possible.
- The initial organ or tissue of origin of C-ETACs can be determined in many cases on the basis of surface proteins present. Likewise, in certain cases, the histopathological subtype of the disease can be diagnosed.

trublood is particulary recommended ...

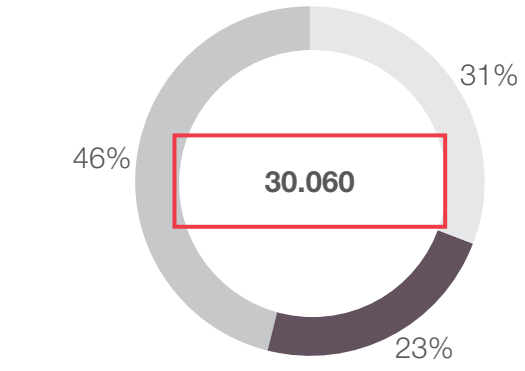
... for symptomatic individuals, in whom a tissue biopsy is difficult to perform.

... for patients in whom standard procedures (imaging, biopsy) have failed to provide a result or do not match the clinical observations.

Advantages of trublood

trublood advantages
Minimally invasive; simple blood draw
No risk of injury to any organ / bleeding
Provides real-time data and covers all active sites
Can be performed as often as necessary

Clinical studies



Patients with known cancer diseases

Symptomatic individuals with suspected cancers

Asymptomatic individuals without previous cancer diagnosis

C-ETACs were found in **91,8%** of cancer cases[2]

C-ETACs provided diagnostically relevant information in **>93%** of cases[1]

CTC-based diagnosis comparable with histopathology

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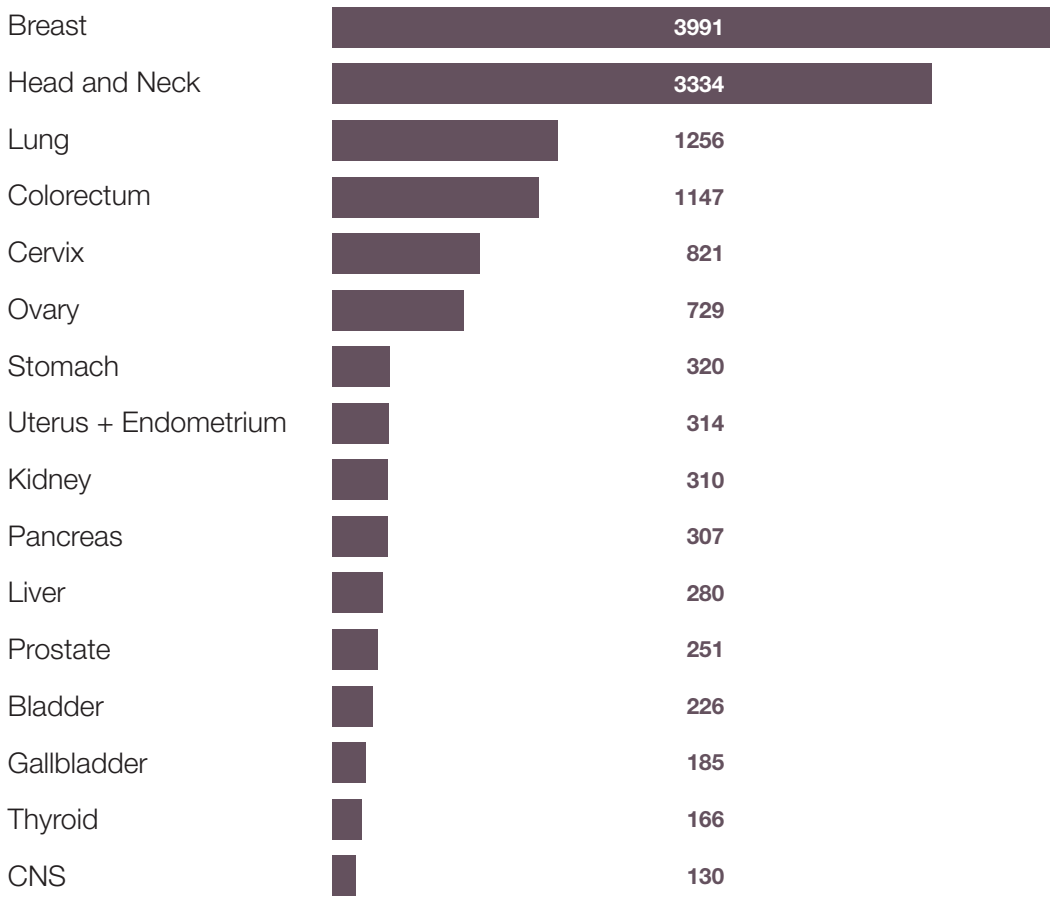
trublood in detail

Total number of patients according to cancer type (and in total) where C-ETACs could be detected[1,3]:



Type of cancer	Prospective cohort			Retrospective cohort		
	Male	Female	Total	Male	Female	Total
Bladder	46	21	67	130	29	159
Breast	31	1198	1229	48	2714	2762
CNS	48	82	130	-	-	-
Cervix	0	324	324	0	497	497
Colorectum	191	124	315	511	321	832
Gallbladder	30	44	74	49	62	111
Head and Neck	1089	294	1383	1621	330	1951
Kidney	86	43	129	140	41	181
Liver	149	58	207	54	19	73
Lung	423	151	574	404	278	682
Ovary	0	167	167	0	562	562
Pancreas	92	56	148	113	46	159
Prostate	111	0	111	140	0	140
Stomach	98	51	149	101	70	171
Thyroid	24	51	75	31	60	91
Uterus + Endometrium	0	95	95	0	219	219

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Sample collection

REQUIREMENTS

Basic diagnostics (trublood)
(total 3 tubes containing 26 ml whole blood)

Blood draw	3 EDTA tubes (purple cap): 2 x 10 ml and 1 x 6 ml - total 26 ml

Basic diagnostics + ctDNA (trublood Comprehensive)
(total 3 tubes containing 36 ml whole blood)

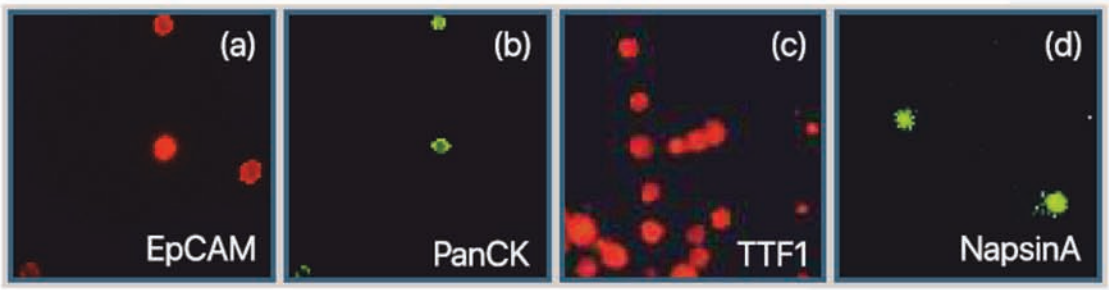
1. Blood draw	10 ml DCG tubes (camouflage cap)
2. Blood draw	3 EDTA tubes (purple cap): 2 x 10 ml and 1 x 6 ml - total 26 ml

NOTE
Blood tubes must be shipped at + 2 °C to + 6 °C in a container provided by DCG.

PRECAUTIONS

1. Suspicion of cancer in the patient due to:
   - Imaging
   - Colonoscopy
   - Palpation examination
   - Clinical Values
2. Patient must not have a history of cancer.
3. A detailed report on the patient's current situation.

Sample images



Microscopic images of stained cells from a patient with lung cancer

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FAQs

Which clinical relevance does trublood have?
To date, 6 clinical studies with over 40,000 individuals have been published regarding trublood and early cancer detection.

How is the analysis performed and which analytes are included?
Circulating tumour cells (CTCs / C-ETACs) and, if required, nucleic acids (ctDNA) are isolated and comprehensively analysed.

trublood is available for the following organs:
Bladder, Breast, Cervix, CNS, Colorectum, Esophagus, Gallbladder, Head and Neck, Kidney, Liver, Lung, Ovary, Pancreas, Prostate, Stomach, Thyroid, Uterus

Is trublood able to distinguish between adeno- and squamous cell carcinomas? YES.

Can trublood determine the grade of tumour? NO.

Can trublood be used for haematological malignancies? NO.

Can CTCs be found in the blood of in situ carcinomas?
In the case of in situ carcinoma, up to 3 million CTCs can be found in the blood.

Sample collection:
- 26 ml - 36 ml peripheral blood drawn in provided DCG and EDTA blood tubes

Turn-Around-Time:
- approx. 10 working days from receipt of sample in laboratory

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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