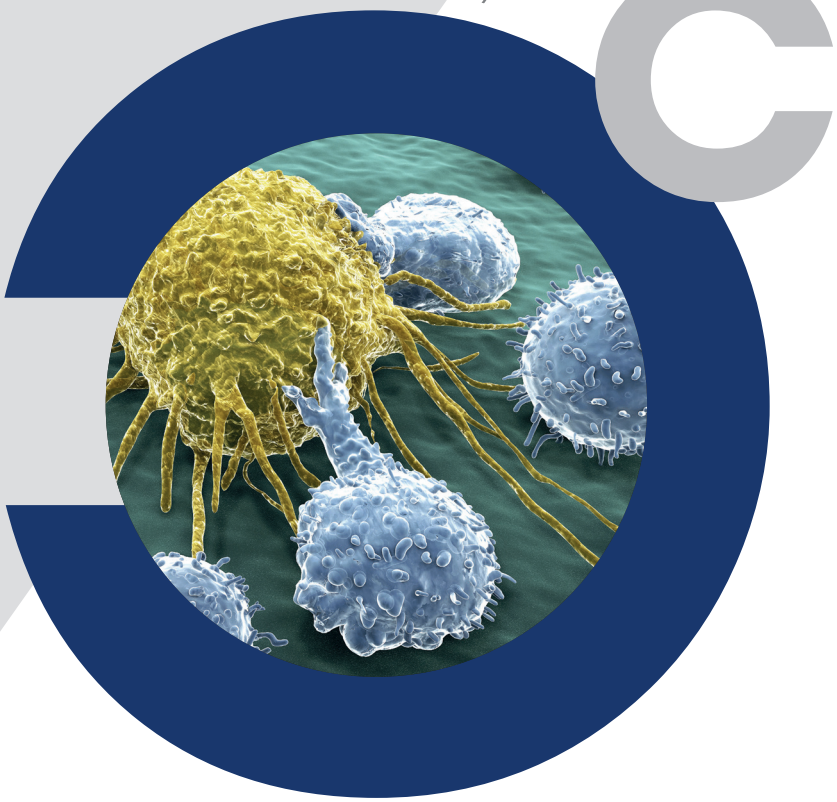
Trucheck™

Early Cancer Screening

DATAR CANCER GENETICS

UNITED KINGDOM | UNITED STATES | GERMANY | INDIA



About Trucheck™

Trucheck™ is a blood based screening test for solid tumours.

About 4.4 million new cases of cancer are detected in Europe every year and there are about 2 million cancer-related deaths. Unfortunately, some cancers are first diagnosed in advanced stages which demand more intensive and expensive treatments with a greater risk of side effects. Detection of cancers at early / local stages is vital for successful treatments, fewer treatment costs, lower toxicities and improved survival rates.

Trucheck™ is the culmination of years of collaborative international research on circulating tumour cells and innovation and has been **developed**, **tested and validated on > 57.000 individuals.**

Trucheck™ is a non-invasive blood-based test to detect solid tumours in asymptomatic individuals.

Trucheck™ is particulary recommended for ...

... asymptomatic individuals who have a family history of cancer.

... individuals who want to include this test in their yearly check-up.

... asymptomatic individuals who have a high risk for cancer.

... individuals between the ages of 40 and 70 who have never been diagnosed with any cancer.

... individuals with no clinical or radiological suspicion of cancer at present.

Trucheck™ is NOT recommended for ...

- Patients with any cancer disease at present or in the past (solid organ or hematolymphoid)
- History of lymphoma, leukemia, polycythemia, plasmacytoma, multiple myeloma, essential thrombocythemia
- Any suspected cancer, clinically or radiologically ➡ please ask for Trublood analysis
- Benign condition with intent to rule out cancer ➡ please ask for Trublood analysis
- Blood transfusion in the last 10 days prior to collection of sample
- History of organ transplant, bone marrow transplants
- Pregnancies
- Immunocompromised conditions like HIV, immunomodulator therapy, anti-immune therapy, immunostimulant therapy

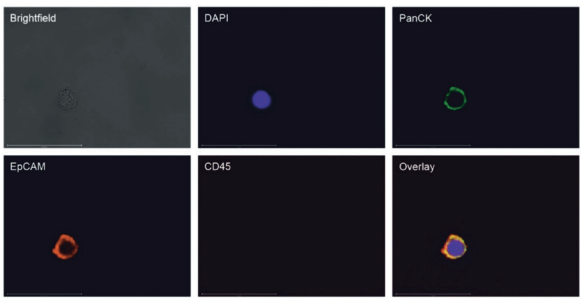
Available solutions

Trucheck™ intelli (70+ Tumours)	Trucheck™ FemmeSafe (Breast, Ovarian, Endometrium, Cervix)

Trucheck™ technology

Trucheck™ detects circulating tumour cells (CTCs) which are released by malignant tumours, but not from non-cancerous (normal / benign tumour) tissue.

Trucheck™ intelli can distinguish **up to 70 types of solid tumours** which account for ~81 % of all cancer cases and ~84 % of all cancer-related deaths in Europe.



Illustrative immunochemistry images of a cancer patient

Advantages of Trucheck™

- In contrast to screening for only a single cancer type at a time, Trucheck™ can identify multiple cancer types via a simple blood draw that may be undetectable by present standard methods.
- Trucheck™ examines CTCs for the molecular imprint of the tumour mass from where the CTCs originated, i.e., Trucheck™ reveals diagnostically relevant information about the tissue / organ of origin of the tumour with high accuracy.
- CTC-based tests can be used in conjunction with traditional imaging studies. Combining different screening modalities may enhance the overall sensitivity and specificity of cancer detection, providing a more comprehensive assessment.

Trucheck™

Details

SENSITIVITY

65 % - 89 %

For detection and localisation of solid organ malignancies across stage 0 to IV

Sensitivity is the ability of a test to correctly identify individuals who have the disease.

SPECIFICITY

96 % - 99 %

Asymptomatic individuals

Specificity is the ability of a test to correctly identify individuals who do not have the disease.

Why is a range given?

- It provides a more realistic reflection of how the test might perform in different populations in real-world scenarios. Data from case control studies / blinded studies is often limited to a few centers and ethnics or age cohorts introducing unintended bias.
- Providing a range allows clinicians and researchers to understand the pros and cons between sensitivity and specifictiy and choose a balance that aligns with the clinical objectives and context.
- It helps account for variability in disease presentation, ensuring that the test's performance is understood in a broader context and emphasises the need for cautious interpretation.

What to expect	What not to expect
Comprehensive screening Trucheck™ aims to screen for a variety of cancers simultaneously. Trucheck™ analyses blood for circulating tumour cells indiciating a higher risk for having a solid tumour.	**Perfect accuracy** False positives and false negatives can occur. Follow-up diagnostic tests are necessary to confirm results and rule out false positives.
Potential early detection The primary goal is to identify cancers at an early stage when they may be more treatable. Detecting cancers early can increase the chances of successful treatment and improve overall outcomes.	**Replacement for traditional screenings** Multi-cancer tests are not intended to replace traditional cancer screenings, such as mammograms, colonoscopies, or PAP smears. Rather, they may complement existing screening methods.
Minimally invasive Trucheck™ is minimally invasive and involves a simple blood draw.	**Diagnosis without confirmation** Positive results from a multi-cancer test do not provide a definitive diagnosis. Further diagnostic procedures, such as imaging studies or biopsies, are required.
Convenience Compared to separate screening tests for different types of cancer, a screening test such as Trucheck™ offers the convenience of testing for several types of cancer at the same time.	**Elimination of other risk factors** Trucheck™ does not eliminate the importance of managing other risk factors for cancer, such as lifestyle factors (e.g., smoking).

Trucheck™

Sample collection

REQUIREMENTS

Total 3 tubes containing 30 ml whole blood

Blood draw: 3 × 10 ml whole blood in EDTA tubes (purple colour cap)

PRECAUTIONS

Patient should be fasting when blood sample is taken (drinking is permitted) and should not have received a blood transfusion for at least 10 days prior to the collection.

NOTE

Blood draw must only be carried out by a qualified therapist.
Ship at 2 °C - 6 °C in the container provided by DCG.

FAQs

Are there any age limits for the Trucheck™ analysis? If so, are exceptions possible?

Trucheck™ is advised for individuals between the ages of 40 and 70, as aging is an important risk factor for cancer. However, it can be offered to individuals aged 35-40 years if any of the following risk factors are applicable:

1. Family history of cancer and / or known carrier status
2. Presence of risk associated hereditary germline mutation/s
3. Obesity
4. Type 2 diabetes
5. Hx infectious diseases (HPV, hepatitis B or hepatitis C viruses)
6. Documented / significant exposure to specific chemicals or carcinogens

What are the benefits of a Trucheck™ analysis?

For Trucheck™, only a simple blood test is necessary. Cancers may be detected that are undetectable by present standard methods. An earlier detection of cancer is associated with greater rates of successful treatment and improved survival.

What are the risks of a Trucheck™ analysis?

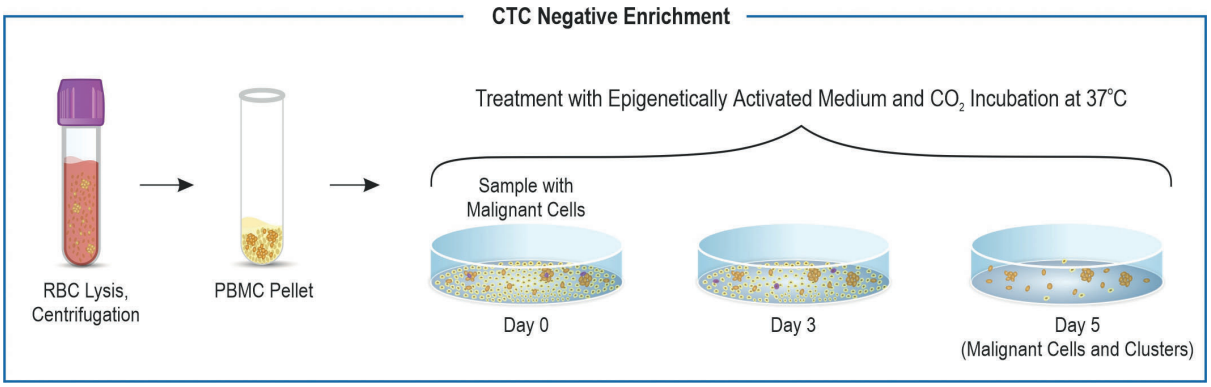
The knowledge of being at risk or having cancer, even it is at an early stage, may have significant psychological impact on patients.
Patients should be aware that they may still need to undergo regular screenings based on established guidelines as Trucheck™ is not intended to replace standard cancer screenings.

Trucheck™

Method

CTC enrichment:

Trucheck™ employs an epigenetically activating medium (EAM) which negatively enriches CTCs via the cancer hallmark of evading apoptosis. When isolated peripheral blood mononuclear cells (PBMCs) are treated with the EAM, all non-malignant cells are killed by their functional apoptosis machinery, whereas all cancer derived malignant cells (CTCs) survive.



Tissue and organ of origin specific markers:

Conventional CTC based technologies infer the presence of CTC based on detection of EpCAM positive, PanCK positive and CD45 negative cells. These technologies overlook cancers in which the cells have been shown to have other characteristics. Trucheck™ includes markers that cover various subtypes of carcinomas as well as markers that are specific for other cancer types such as gliomas.

Publications

1. O'Neill, K. et al. Profiling of circulating glial cells for accurate blood-based diagnosis of glial malignancies. International Journal of Cancer 2023; 154(7): 1298-1308. doi: 10.1002/ijc.34827.
2. Limaye, S. et al. Accurate prostate cancer detection based on enrichment and characterization of prostate cancer specific circulating tumor cells. Cancer Med. 2023 Jan 30. doi: 10.1002/cam4.5649.
3. Crook, T. et al. Accurate Screening for Early-Stage Breast Cancer by Detection and Profiling of Circulating Tumor Cells. Cancers. 2022 Jul; 14(14):3341. doi: 10.3390/cancers14143341.
4. Gaya, A. et al. Evaluation of circulating tumor cell clusters for pan-cancer noninvasive diagnostic triaging. Cancer Cytopathol. 2021 Mar; 129(3): 226-238. doi: 10.1002/cncy.22366.
5. Ranade, A. et al. Hallmark Circulating Tumor-Associated Cell Clusters Signify 230 Times Higher One-Year Cancer Risk. Cancer Prev Res (Phila). 2020 Sep 21. doi: 10.1158/1940-6207.CAPR-20-0322. Epub ahead of print.
6. Akolkar, D. et al. Circulating ensembles of tumor-associated cells: A redoubtable new systemic hallmark of cancer. International Journal of Cancer. 2020; 146(12): 3485-3494. doi: 10.1002/ijc.32815.

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