AN ANNUAL BLOOD TEST TO DETECT WOMEN'S CANCERS

Rx Only

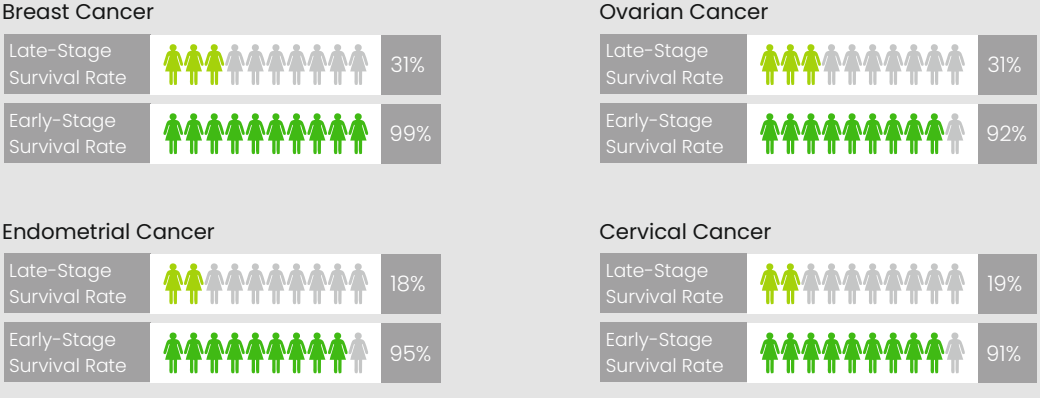
Trucheck™

FemmeSafe

Why should I consider Cancer Screening?

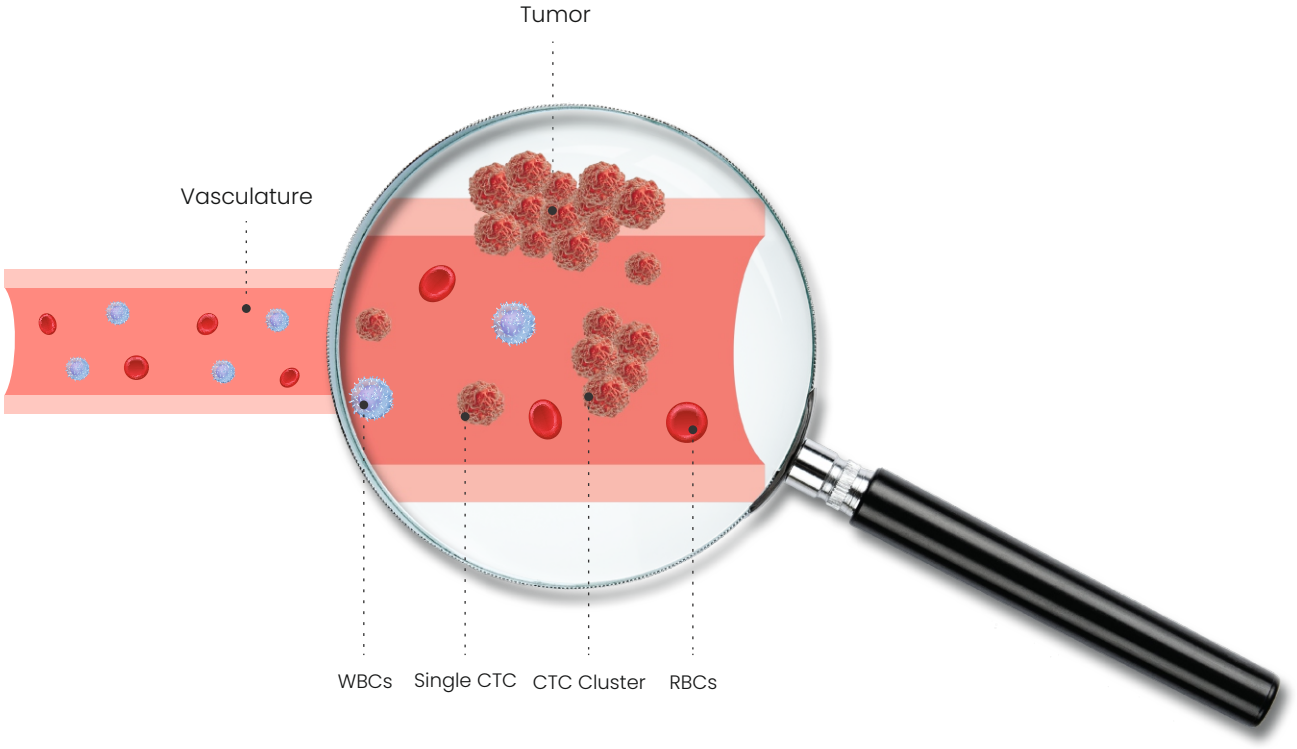
Cancers of the breast, ovary, cervix and uterus account for about 3.6 million diagnosed cases and 1.3 million deaths in women annually worldwide (Globocan, 2020). Early detection of these cancers leads to more effective treatments and improved survival prospects. Screening is available for breast and cervical cancers as individual tests but is unavailable for ovarian and uterine cancers.

Trucheck™-FemmeSafe is a prescription only test for early detection of breast, ovarian, cervical and uterine (endometrial) cancers in asymptomatic women, generally aged 40 years and above, who do not have prior cancer history and who currently do not have any clinical or radiological suspicion of cancer. Trucheck™-FemmeSafe addresses the current void for meaningful and inclusive cancer screening in asymptomatic women by facilitating accurate early detection of these cancers.



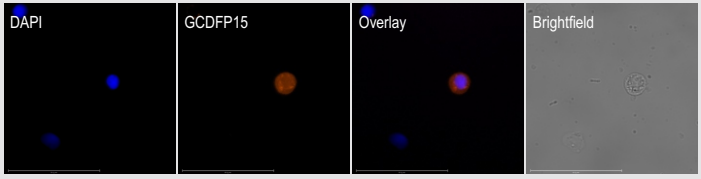
Why should I consider Trucheck™?

- Circulating Tumor Cells (CTCs) and their clusters are present in the blood of almost all cancer patients and are undetectable in healthy individuals.
- Trucheck™ technology to detect and characterise CTCs has been proven through extensive clinical validations involving more than 40,000 participants.
- The test is a paradigm shift in cancer screening, as it does not involve radiation or invasive procedures. The test is performed at our accredited laboratory facility.

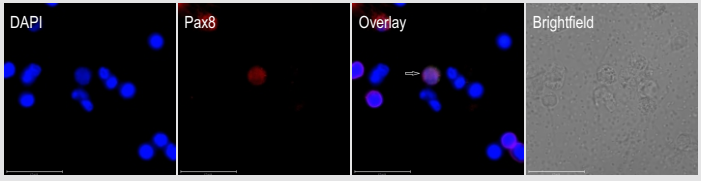


Illustrative images of circulating tumor cells

Breast
GCDFP-15, GATA3



Ovary
Pax8, WT1, CA125



Trucheck™ - FemmSafe

Trucheck™-FemmeSafe detects adenocarcinoma involving Breast, Ovary and Uterus and squamous cell carcinoma involving Cervix.

Advantages of Trucheck™?

Advantages of Trucheck™-FemmeSafe

Trucheck™-FemmeSafe may be beneficial for all women aged 40 years and over who do not have prior cancer history and who are not experiencing any symptoms or clinical suspicion of any cancer at the time of testing.

Trucheck™-FemmeSafe analyzes blood samples for presence of CTCs and if present, indicates higher risk of presence of women's cancers.

When CTCs are detected, the patients can be advised clinical follow-up for determining the appropriate clinical management pathway. When CTCs are not detected, the patients can consider repeat testing after one year while continuing their participation in standard cancer screening programs.

Precautions

Trucheck™-FemmeSafe is a 'Prescription Use Only' test and it must be prescribed by a licensed physician. The test findings must be interpreted and used by a licensed physician along with other relevant clinical evidence and investigations. This test is not intended for diagnosis of cancer. It is also not intended for follow-up or surveillance in women who have past history of cancer. This test is not intended to replace existing standard of care cancer screening tests.

FAQs

1. **What is the turnaround time of the Trucheck™-FemmeSafe test?**

✓ The test result will be communicated within 12 working days from receipt of the sample at Laboratory.

2. **How often can the test be performed?**

✓ Trucheck™-FemmeSafe can be performed annually as a screening test.

3. **What will the report tell me?**

✓ The report will tell you if CTCs were detected (indicating higher risk of presence of women's cancer) or CTCs were not detected (indicating a lower risk of presence of women's cancer) in the submitted sample. When Circulating Tumor Cells are detected, it allows your healthcare practitioner to advise your next steps.

4. **What are the next steps for those with higher risk of presence of women's cancer?**

✓ Individuals with these findings are advised consultation with their physician for appropriate guidance and additional standard of care workup as may be advised.

5. **What are the next steps for those with a lower risk of presence of women's cancer?**

✓ Trucheck™-FemmeSafe test may be repeated annually and the individual is advised to consult a physician if further guidance is required.

6. **Is this a genetic predisposition test?**

✓ No. This test detects presence of intact Circulating Tumor Cells (CTCs) in peripheral blood of the individual.

7. **Does Trucheck™-FemmeSafe replace conventional cancer screening like pap smear or mammography?**

✓ Trucheck™-FemmeSafe is not intended to be and should not be considered as a replacement for any Standard of Care screening tests.

8. **What are CTCs?**

✓ These are the tumor cells which are circulating in blood when shed from the carcinoma.

Trucheck™ - Research

Circulating Ensembles of Tumor Associated Cells: A Redoubtable New Systemic Hallmark of Cancer.

International Journal of Cancer - IJC

https://doi.org/10.1002/ijc.32815

Hallmark Circulating Tumor Associated Cell Clusters Signify 230 Times Higher One-Year Cancer Risk.

American Association for Cancer Research - AACR

https://doi.org/10.1158/1940-6207.CAPR-20-0322

Evaluation of Circulating Tumor Cell Clusters for Pan-Cancer Noninvasive Diagnostic Triaging.

ACS Journals - Cancer Cytopathology

https://doi.org/10.1002/cncy.22366

Accurate Screening for Early-Stage Breast Cancer by Detection and Profiling of Circulating Tumor Cells.

Cancers

https://doi.org/10.3390/cancers14143341

Essential Safety Information

The Trucheck™-Femmesafe test is advised for use in adults with a higher risk of developing cancer, typically recommended for individuals above the age of 40 years and who do not have prior history of cancer. The Trucheck™-Femmesafe test should be used in addition to other cancer screening procedures advised by a healthcare professional. The objective of using Trucheck™-Femmesafe is to identify cancer footprints i.e. CTCs and identify the probable organ / location that may be affected. Trucheck™-Femmesafe should not be used by pregnant women. Trucheck™-Femmesafe should never be used as the sole means of diagnosis and the results must always be corroborated by Standard of Care methodologies undertaken through a duly qualified and authorized medical professional.

If additional testing does not confirm the presence of cancer, it may indicate that cancer is not currently present (the Trucheck™-Femmesafe test is 'false-positive'), and 'watchful waiting' is advised subject to the opinion of the individual's prescribing physician. It is clarified that owing to the diverse biological behavior of cancer and/or the technical limitations of the performance of the test, it is possible for the test findings to be both false-positive (a biological footprint suggestive of cancer is found when cancer is not present) and false-negative (a biological footprint suggestive of cancer is not identified when cancer is present). Prescription Required. A healthcare professional should interpret the results in light of the patient's medical history, physical symptoms, and clinical indicators. A "No Circulating Tumor Cells Detected" test result merely signifies a reduced risk of presence of cancer but it however does not definitively exclude the possibility of cancer. A "Circulating Tumor Cells Detected" test result must necessarily be confirmed by independent diagnostic evaluation using medically accepted Standard of Care techniques (like imaging, for example) and a positive result does not confirm the existence of cancer.

Information from the laboratory about the test

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) has certified Datar Cancer Genetics clinical laboratory in Guildford, UK, and the College of American Pathologists (CAP) has granted it accreditation. The Trucheck™-Femmesafe test was developed by Datar Cancer Genetics, and the laboratory has determined the performance parameters of the test. The Food and Drug Administration (US-FDA) has neither approved, endorsed, nor cleared the Trucheck™-Femmesafe test. High-complexity testing is regulated under the CLIA regime in the Company's clinical laboratory. The Trucheck™-Femmesafe test is designed to be used in a clinical setting only.

DATAR
CANCER GENETICS

Accreditations

Regulated by Care Quality Commission | CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS | CLIA Accredited Laboratory No.: 99D2270399

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