

Patient Information Brochure- Trucheck™ Intelli

Trucheck™ Intelli is a sophisticated blood test that can detect Circulating Tumor Cells, the presence of which indicates a solid organ cancer. Trucheck™ -Intelli is intended to be used in people who are well with no symptoms as a multi cancer early detection tool in the general population age 40 years and above.

The Trucheck™ Intelli test results can be as follows:

1. Circulating Tumor Cells (CTCs) detected, indicating higher risk of presence of cancer: This result is NOT a cancer diagnosis. This result requires further evaluation for cancer. In this group the organ of origin of cancer may or may not be identified. Therefore, ALL individuals with CTCs positive findings are advised consultation with a qualified health care professional for appropriate guidance and additional standard of care diagnostic tests.
2. Circulating Tumor Cells (CTCs) not detected, indicating lower risk of presence of cancer: A negative Trucheck™ report does not completely rule out the possibility that cancer is present or will occur in the future. Please note that some cancers may not shed detectable tumor cells in the blood. The test is designed to ensure that there are minimal false positives and in order to achieve that the sensitivity of the test is about 88-90% so approximately 1 in 10 cancers may be missed, hence the recommendation to do this annually.

Please note that:

1. **Trucheck™ Intelli is a screening test and NOT a diagnostic test.**
2. A positive Trucheck™ Intelli is not a diagnosis of cancer
3. Diagnostic decisions are the responsibility of treating physicians

4. This test is **NOT** intended to replace any single organ screening tests like Mammography or Colonoscopy.
5. Trucheck™ Intelli cannot detect blood (leukemia) or lymphatic system (lymphoma) cancers because CTCs are associated with only solid organ cancers.
6. Trucheck™ Intelli should not be used for individuals who have previously had cancer (even if surgically removed), or who have symptoms of cancer.
7. The nature of the test, the disease, and the analyte are subject to biological dynamics which may not be fully understood and persons opting for the test must obtain sufficient advice from a qualified physician regarding the suitability of the test for a given individual before blood sample collection.
8. In the event of a positive test (approx. 1 in 200 chance in the general population) there is a chance that any subsequent tests and investigations will be negative and no evidence of cancer will be seen. In this situation your physician will keep you under close follow up with repeat blood tests to see if the levels of CTC or circulating tumour DNA (ctDNA) are rising or falling. This could indicate that the immune system is clearing any cancer cells, or that the cancer is just too small to be seen on imaging. Before taking the test you must be prepared to accept this possible uncertainty and requirement for close monitoring.