Trucheck™ Intelli

Patient Selection Criteria, Pre-Test Counselling and Care Flow Pathway

November, 2024

DATAR CANCER GENETICS

Trucheck™ Intelli - RECOMMENDED for

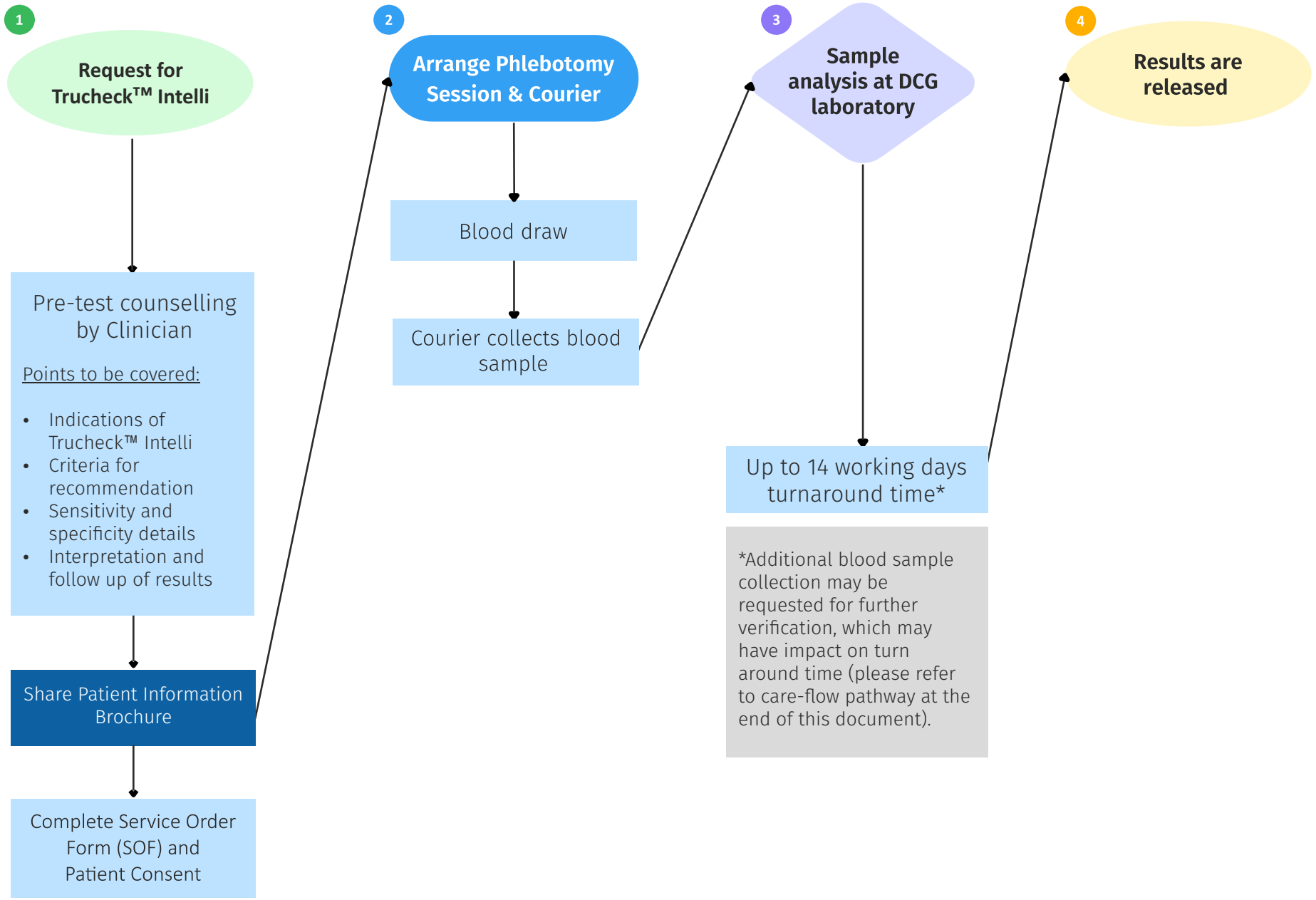
Trucheck™
Intelli

- Women and men age 40 years and older, who have never been diagnosed with any cancer
- Totally asymptomatic for cancer at present
- No clinical or radiological suspicion of cancer at present

Trucheck™ Intelli is NOT RECOMMENDED for

- Patients with any cancer at present or in past (solid organ or hematolymphoid).
- Patients in remission after completion of treatment.
- A patient in whom cancer is being monitored but patient/doctor wants to rule out other solid organ cancers.
- Patients with benign condition with intent to rule out cancer.
- Patients with suspicion of cancer- clinically or radiologically.
- Persons with blood transfusion in 72 hours prior to blood draw for Trucheck™-Intelli.
- Persons with history of Lymphoma, Leukemia, Polycythemia, Plasmacytoma, Multiple myeloma, Essential thrombocythemia.
- Persons with history of organ transplant, bone marrow transplants.
- Persons with physiological conditions like pregnancy.
- Persons with Immunocompromised status –Immunocompromised conditions like HIV, Immunomodulator therapy, Anti-immune therapy, Immunostimulant therapy.

Process Overview



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Trucheck Pre-Test Counselling Sheet

Trucheck™ Intelli

Topic	Details
Test information	**Trucheck™ Intelli** is a blood test that can detect Circulating Tumor Cells, the presence of which could be suggestive of presence of solid organ cancers within the asymptomatic population. In the UK there are more than 1000 new cases of cancer diagnosed per day, with an average of around 45% of those cases being caught in the later stages (3/4), where interventions are more aggressive and patient outcomes are worse. When cancer is detected in early stage, the management of the disease is more effective and in many cases curative.
	Trucheck™-Intelli uses Circulating Tumor Cells (CTCs) to assess presence of cancer. As a biomarker, CTCs have been established as a hallmark of cancer through extensive clinical testing involving more than 40,000 participants.
Intended use	Trucheck™-Intelli is intended to be used in the asymptomatic general population age 40 years and older.
Unintended use	Trucheck™-Intelli should not be used for individuals who have previously had cancer, or who have symptoms of cancer. Trucheck™-Intelli is not recommended for any individual who had a cancerous lesion surgically removed in the past (e.g. Basal cell carcinoma, Melanoma etc). Trucheck™-Intelli should not be used as a cancer monitoring tool.
Can Trucheck™-Intelli be recommended for individuals under 40 years?	Trucheck™-Intelli, being a screening test, is advised for individuals age 40 years and older. However, it can be offered to individuals age 35-39 years if any of the following risk factors are applicable (Sample will be accepted only if this is clearly mentioned on the SOF). 1. A 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 and carcinogens

Disclaimer: This document is for discretionary use by clinicians and any recommendations made do not supersede the clinical decision-making process.

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Topic	Outcome	Details	Follow-up
Possible test outcomes	Circulating Tumor Cells (CTCs) detected, indicating higher risk of presence of cancer	CTCs indicative of Trucheck™-Intelli positivity have been detected in the given blood sample which is suggestive of higher risk of presence of cancer. The reflex analysis may be able to suggest likely organ of origin and malignancy type (subject to bio-technical feasibility and variability and sufficiency of CTCs). Individuals with positive findings are advised consultation with their physician for appropriate guidance and additional standard of care work up as may be advised. When the Trucheck™-Intelli test results indicate higher risk of presence of cancer, the finding must be confirmed by diagnostic tests in accordance with standard medical practice. These results should be interpreted in the context of the individual's clinical risk factors. Diagnostic decisions are the responsibility of the treating physician.	Please refer to the careflow pathway.
	Circulating Tumor Cells (CTCs) not detected, indicating lower risk of presence of cancer	Circulating Tumor Cells (CTCs), indicative of Trucheck™-Intelli positivity were not detected in the given sample. It is suggestive of lower risk of presence of cancer. A negative Trucheck report does not completely rule out the possibility of cancer as some cancers may not shed detectable tumor cells in the blood.	Follow-up as recommended by a clinician.

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Topic	Details	
Benefits	Psychosocial benefits	Negative results give peace of mind to the individual.
	Fast & effective follow up	Positive results allow for fast tracked and targeted follow up using imaging, biopsy, or other methods to confirm diagnosis and allows close surveillance in standard of care pathway.
Risks	Psychosocial implications	Anxiety may arise for individuals and their families as they await results. In a small number of cases, it is also possible that additional psychological and behavioural consequences may occur from receiving a false negative or false positive result.
Limitations	Blood /lymphatic cancers	Trucheck™ Intelli cannot detect blood or lymphatic system cancers because CTCs are associated with solid organ malignancies. Probable organ of origin may not be indicated if cells are insufficient for organ localization.
Test Performance	Sensitivity	This is the ability of the test to correctly identify patients with cancer. CTC-based tests performed using DCG's technology have shown sensitivity of 88.24%, while specificity of 96.3% was observed in asymptomatic individuals and specificity of 95% was observed in individuals with benign tumors. - **Trucheck™ Intelli** has an overall sensitivity of 88.24% - meaning that for every 100 patients tested who have cancer, it will correctly identify 88 of those patients, resulting in a 12% false negative rate.

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	Specificity	The ability of the test to correctly identify people without cancer. - **Trucheck™ Intelli** has specificity of 96.3% - meaning that for every 100 people tested, that do not have cancer, Trucheck™-Intelli will correctly identify 96 of these individuals, resulting in a 4% false positive rate. **It will be a clinician's responsibility to advise patients on all results including false negative or false positive results.**
Considerations	Cost	Trucheck™-Intelli may not be currently covered by healthcare insurance in the UK and the costs involved to access the test are privately funded by the individual. Following a positive result patients may need to self-pay for additional diagnostic procedures for confirmation of diagnosis.

Important Note :

- The performance characteristics of the test are based on the case-control clinical studies performed by the Company under strict protocols.
- Performance of the test in the real-world setting has not yet been established and the Company makes no claims/representation that the real-world performance of the test will be similar to that of the case-control clinical studies.
- 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.
- Test specifications are periodically upgraded without notice as part of continual improvement.

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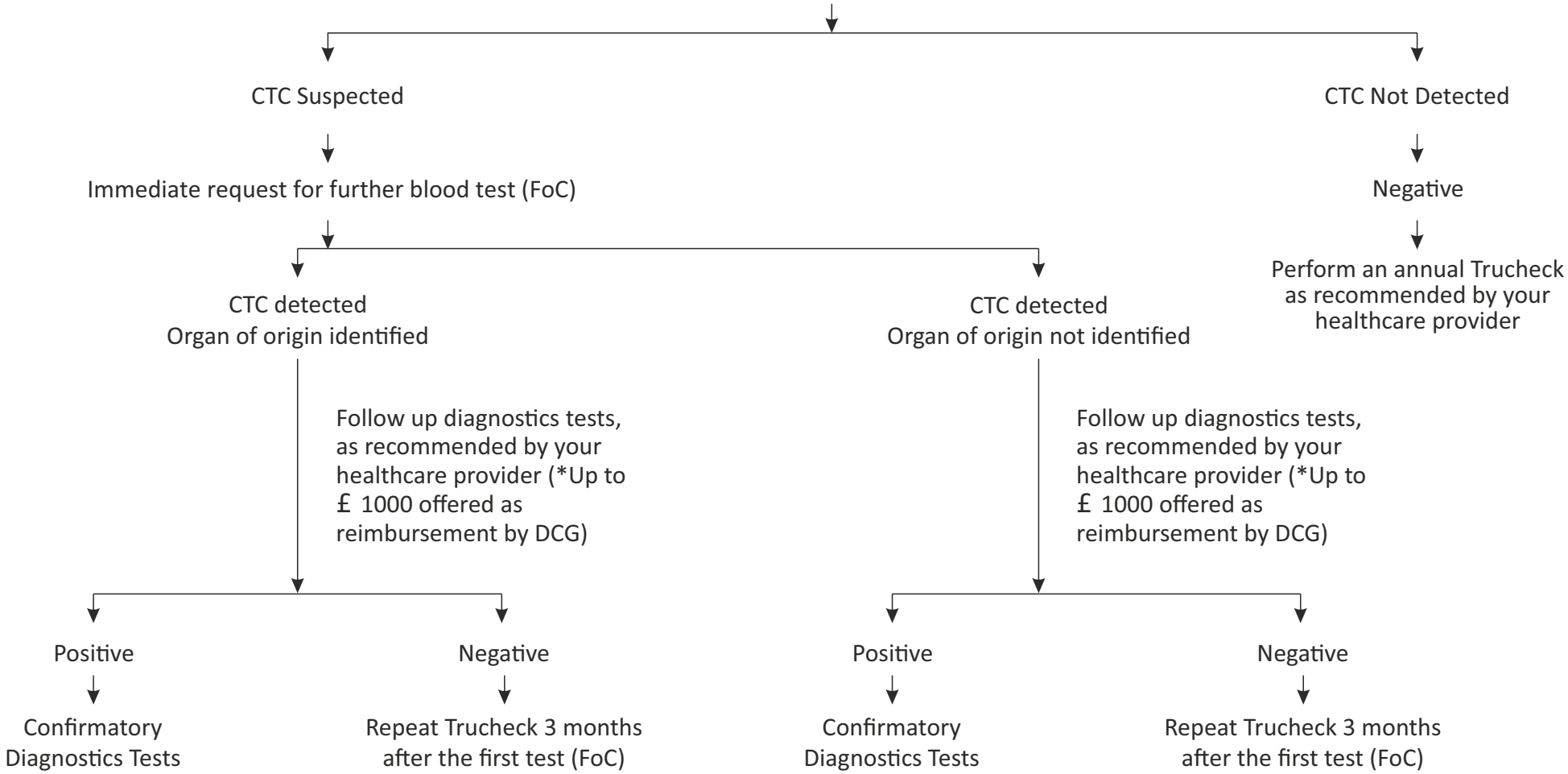
Care Flow Pathway



** Subject to receipt of medical reports and bills*

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Accreditations and Certifications

Accredited by Clinical Laboratory Improvement Amendments (CLIA) – USA
Registered with Care Quality Commission

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

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