Ms. A.B.C.

M221003073

Trucheck Intelli

Patient Information

Patient Details

Name : Ms. A.B.C.
Patient ID : 2399
Age : 60 Years
Gender : Female
Address : --

Specimen Details

Specimen Type : Blood
Draw Date : 21/12/2022 09:10 AM
Accession Date : 21/12/2022 02:15 PM
Report Date : 30/12/2022 07:36 AM
Referring Doctor : Dr. X.Y.Z.

Summary and Interpretation

Test result for Circulating Tumor Cells (CTCs)

☑ Negative ☐ Positive

Type of Malignancy

☐ Adenocarcinoma ☐ Squamous Cell Carcinoma ☐ Adenosquamous Carcinoma
☐ Neuroendocrine Tumor ☐ Sarcoma ☐ Gastrointestinal Stromal Tumor
☐ Glioma ☐ Mesothelioma ☐ Melanoma
☐ Transitional Cell Carcinoma ☑ Not Applicable ☐ Indeterminate

Probable Organ of Origin

☑ Not Applicable ☐ Indeterminate

Summary of Immunocytochemistry Analysis

EpCAM [-]	PanCK [-]	Melan A [-]	Synaptophysin [-]	Vimentin [-]	Desmin [-]
DOG1 [-]	Mesothelin [-]	GFAP [-]	Olig2 [-]	S100 [-]	*CD45 [+]

[+] Positive, [-] Negative, * CD45 is a marker expressed by leucocytes.

Test Interpretation and Advice

Circulating Tumor Cells (CTCs) indicative of Trucheck positivity as evaluated by immunocytochemistry analysis by quantitative fluorescence microscopy, were not detected in the given sample. It is suggestive of lower risk of detection of malignancy.

Trucheck Intelli may be repeated annually. Individual is advised to consult a physician if further guidance is required.

Guide to Interpretation of Test Results

Trucheck Intelli test detects Circulating Tumor Cells (CTCs) in peripheral blood of the individual and is intended to further analyze presence of malignant tumor cells belonging to any of the malignancies tested.

- Negative — Circulating Tumor Cells (CTCs) indicative of Trucheck positivity were not detected in the given sample as evaluated by immunocytochemistry analysis by quantitative fluorescence microscopy. Please be mindful that 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.
- Positive — CTCs indicative of Trucheck positivity were detected in the given blood sample which is suggestive of higher risk of detection of malignancy. The reflex analysis suggests likely organ of origin and malignancy type. Individuals with positive findings are advised consultation with their physician for appropriate guidance and additional standard of care work up as may be advised.
- Indeterminate — CTCs indicative of Trucheck positivity were detected in the given blood sample, however type of malignancy or organ of origin could not be determined.

Clinical Performance

The non-invasive Trucheck Intelli is a blood-based screening 'Laboratory Developed Test (LDT)' for detection of multiple malignancies listed below. This test has been validated by Datar Cancer Genetics through the 'RESOLUTE' and 'TRUEBLOOD' clinical trials (Registration No. CTRI/2019/01/017219 and CTRI/2019/03/017918 respectively).

The Test has an overall Sensitivity of 88.24% (detection +localization) as validated on samples from 5,342 cancer patients. The test has an overall Specificity of >99% as validated on 14,619 samples from asymptomatic individuals (n = 13,919) and individuals with non-malignant (benign) conditions (n = 700). For our publications pertaining to Trucheck Intelli test, please visit http://datarpgx.com/publications/.

Trucheck Intelli has been validated only for detection of following types of malignancies:

Adenocarcinoma (AD): Bile Duct, Breast, Colon, Duodenum, EG Junction, Esophagus, Gall Bladder, Ileum, Jejunum, Liver, Lung, Ovary, Pancreas, Prostate, Rectum, Stomach, Thyroid, Uterus, Salivary Duct; **Adenosquamous Carcinoma:** Esophagus, Gall Bladder, Lung; **CNS Malignancies:** Astrocytoma, Ependymoma, Glioblastoma, Glioma, Neuroblastoma, Oligodendroglioma; **Gastro-Intestinal Stromal tumors (GIST):** Colon, Duodenum, Ileum, Jejunum, Rectum, Stomach; **Melanomas:** Cutaneous, Mucosal; **Mesothelioma:** Pleural, Peritoneal; **Neuroendocrine Tumors (NET):** Adrenal, Colon, Duodenum, Esophagus, Ileum, Jejunum, Lung, Pancreas, Prostate, Rectum, Thymus; **Renal Cell Carcinoma (RCC):** Kidney; **Sarcomas:** Carcinosarcoma, Chondrosarcoma, Leiomyosarcoma, Liposarcoma; **Small Cell Lung Cancer (SCLC):** Lung; **Squamous Cell Carcinoma (SCC):** Anorectum, Buccal Mucosa, Cervix, Esophagus, Hard Palate, Larynx, Lip, Lung, Oral Cavity, Paranasal Sinuses, Penis, Pharynx, Pyriform Fossa, Retromolar Trigone, Skin, Soft palate, Tongue, Tonsil, Vulva, Vagina; **Transitional Cell Carcinoma (TCC):** Bladder, Renal Pelvis, Ureter.

*Specificity is derived from screening of asymptomatic individuals, however specificity is likely to get impacted in patients with metasynchronous, metastatic conditions or by extremely rare biological processes

Methods and Qualifications

Peripheral Blood Mononuclear Cells (PBMCs) are isolated from the blood sample and are treated with a proprietary CTC enrichment medium (CEM), which is selectively toxic towards nonmalignant (epithelial, endothelial and hematolymphoid) cells and permits malignant cells (CTCs) to survive. Surviving apoptosis reluctant cells and clusters are characterized by fluorescent immunocytochemistry (fICC) profiling to determine the status of various markers (see following sections); these markers help identify CTCs as well as to determine the type of malignancy and the likely organ of origin.Quantitative fluorescence imaging is performed on Cell Insight CX7 High-Content Screening Platform (ThermoFisher Scientific).

Immunocytochemistry Markers (Internally Validated)

Marker (Clone)	Marker (Clone)	Marker (Clone)	Marker (Clone)
AFP (Polyclonal)	CK HMW (34BE12)	Hep par-1 (OCH1E5)	PAX8 (MD-50)
AMACR (13H4)	CK LMW (CAM 5.2)	HMB45 (HMB45)	Podoplanin (D2-40)
Arginase 1 (EP261)	CK19 (KS19.1)	Maspin (BSB-92)	PSMA (3E6)
CA IX (EP161)	CK20 (KS20.8)	Melan A (A103)	RCC (PN-15)
CA125 (OC125)	CK5/6 (CK5/6.007)	Mesothelin (5B2)	S100 (15E2E2)
CA19.9 (121SLE)	CK7 (OV-TL 12/30)	MUC2 (CCP58)	SATB2 (SATBA4B10)
Calcitonin (Polyclonal)	Desmin (D33)	Napsin A (TMU-Ad 02)	SMA (IA4)
Calretinin (Polyclonal)	DOG1 (1.1)	Nestin (EP287)	SOX10 (BC34)
CD10 (56C6)	EMA (E29)	NSE (BBS/NC/VI-H14)	Synaptophysin (27G12)
CD45 (REA747)	EpCAM (REA764)	OLIG 2 (211F1.1)	Thyroglobulin (2H11)
CD56 (123C3)	GATA3 (L50-823)	p16 (BC42)	TTF1 (8G7G3/1)
CDX2 (CDX2-88)	GCDFP15 (23A3)	p40 (BC28)	Uroplakin II (BC21)
CEA (COL-1)	GFAP (GA-5)	p63 (4A4)	Vimentin (V9)
Chromogranin A (LK2H10+PHE5)	Glypican-3 (1G12)	PanCK (REA831)	WT1 (6F-h2)

Abbreviations

AD: Adenocarcinoma
CNS: Central Nervous System
CTC: Circulating Tumor Cell
GIST: Gastro-Intestinal Stromal Tumors
ICC: Immunocytochemistry
NET: Neuroendocrine Tumors
RCC: Renal Cell Carcinoma
SCLC: Small Cell Lung Cancer
SCC: Squamous Cell Carcinoma
TCC: Transitional Cell Carcinoma

Information to Patients

The Trucheck Intelli test is a Laboratory Developed Test, and its performance characteristics were determined by Datar Cancer Genetics UK Private Limited, United Kingdom. It has not been cleared or approved by the U.S. Food and Drug Administration.
The processing of samples is carried out in Datar Cancer Genetics UK Private Limited, United Kingdom. This laboratory is registered under the Clinical Laboratory Improvement Amendments (CLIA)-USA to perform high complexity clinical laboratory testing.
The data analysis and interpretation as well as the preparation of Reports, is carried out by our partner laboratory - Datar Cancer Genetics Private Limited, Nasik, India. This laboratory is certified to be compliant with ISO 15189:2012, ISO 27001:2013 and ISO 9001:2015 and is also accredited by the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA).

Disclaimer

Results of ICC (antigen expression on CTCs) may vary from that of primary tumor tissue and over time due to tumor heterogeneity and other biological processes. Further, certain conditions such as steroid use, active inflammatory diseases, medications, exposure to radiation, UV induced sunburn etc. may interfere with accuracy of assay results. Other potential sources of error include, but are not limited to, sample contamination / degradation or pre-analytical deviations.

The Trucheck Intelli test is performed on blood samples from asymptomatic individuals as a part of screening for the above listed malignancies only. This test is not designed for detection of any other malignancy including hemato-lymphoid malignancies. This test may not be able to differentiate between breast and salivary duct carcinoma in positive cases as both the carcinomas share the same ICC markers. Decisions on patient care and treatment must be based on the independent medical judgement of the treating physicians taking into consideration all available and relevant information concerning the patient's condition, such as personal and family history, physician's examination as well as information from other pertinent diagnostic tests, medical imaging and histopathology. The treating physician's decisions should not be based on a single test or solely on the information contained in this report

This report should be read as a whole and used and acted upon only by a registered / licensed medical practitioner under the relevant law who is duly qualified to practise medicine. This is not a prescription.

References

1. Akolkar et al. B15: Circulating tumor cells express tissue specific antigens in multiple cancers. Clin Cancer Res.2020; 26(11_Suppl). DOI: 10.1158/1557-3265.LiqBiop20-B15.
2. Akolkar et al. Circulating ensembles of tumor-associated cells: A redoubtable new systemic hallmark of cancer. Int. J. Cancer:2019; 146, 3485-3494. DOI: 10.1002/ijc.32815.
3. Gaya A et al. Evaluation of circulating tumor cell clusters for pan-cancer noninvasive diagnostic triaging. Cancer Cytopathol. 2020; 129 (3) 226-238 doi: 10.1002/cncy.22366.
4. Ranade A et al. Hallmark Circulating Tumor-Associated Cell Clusters Signify 230 Times Higher One-Year Cancer Risk. Cancer Prev Res. 2021;14:11-6 DOI:10.1158/1940-6207.CAPR-20-0322.
5. Crook T et al. Accurate Screening for Early-Stage Breast Cancer by Detection and Profiling of Circulating Tumor Cells. Cancers (Basel). 2022 Jul; 14(14): 3341. DOI: 10.3390/cancers14143341.

End of Report

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Trucheck Intelli fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices and is registered as a CE-IVD by Datar Cancer Genetics EU Authorized Representative,

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Malta

CE IVD

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- This report should be interpreted and acted upon only by a duly qualified medical professional who is registered / licensed to practice medicine under the relevant law.
- This report should always be read as a whole and reproduced if necessary, in its entirety.
- Please read the Disclaimer section carefully.

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