Trucheck™ Intelli

Patient Information

Patient Details

Name : Mr. A. B. C.
Patient ID : --
Age : 42 Years
Gender : Male
Address : --

Specimen Details

Specimen Type : Blood
Draw Date : 22/03/2022 09:41 AM
Accession Date : 22/03/2022 05:20 PM
Report Date : 06/04/2022 03:44 PM
Referring Doctor : Dr. X. Y. Z.

Summary and Interpretation

Test Results

☑ Negative ☐ Positive ☐ Equivocal

Malignancy Type

☐ 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

Immunocytochemistry Analysis

EpCAM [-]	PanCK [-]	p63 [-]	p40 [-]	Melan A [-]	Chromogranin A [-]
Synaptophysin [-]	Vimentin [-]	SMA [-]	Desmin [-]	DOG1 [-]	Mesothelin [-]
Podoplanin [-]	GFAP [-]	S100 [-]	Calretinin [-]	*CD45 [+]	

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

Test Interpretation and Advice

No Circulating Tumor Cells (CTCs) are detected above threshold in the given sample as evaluated by immunocytochemistry analysis by quantitative fluorescence microscopy.

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

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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 — No CTCs are detected in the given sample. Such individuals can repeat Trucheck™ Intelli test annually.
- Positive — CTCs are detected in the blood specimen tested which is suggestive of malignancy. The reflex analysis suggests likely organ of origin and malignancy type. Individuals with positive findings are hence advised consultation with their doctor for appropriate guidance and additional Standard of Care work up as may be advised.
- Equivocal — Number of CTCs are detected below threshold, which neither confirms nor rules out the malignancy completely. Individuals with equivocal result are advised to repeat Trucheck™ Intelli test in 8 to 12 weeks.
- Indeterminate — CTCs are detected, however type of malignancy or organ of origin could not be determined. This may be due to presence of squamous cell carcinoma or any other malignancy in which markers may be inadequately expressed.

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 a detection rate of 88.24% as validated on samples from 18700 Cancer patients. The test has an overall specificity of >99% (CI:98.92 to 99.27%) and localization marker specificity of 99%* (CI: 99.97% to 100.00%) as determined by the screening of 12009 asymptomatic individuals.

Circulating Tumor Cells (CTCs) which are defined as cells in the peripheral blood that are EpCAM and PanCK positive and CD45 negative as accepted by the US FDA (ref: CellSearch CTC Test) are harvested using a proprietary medium. CTCs are thereafter characterized for various organ specific markers. AFP, AMACR, Arginase 1, CA IX, CA125, CA19.9, Calcitonin, Calretinin, CD10, CD56, CDX2, CEA, Chromogranin A, CK HMW, CK LMW, CK19, CK20, CK5/6, CK7, Desmin, DOG1, EMA, GATA3, GCDFP15, GFAP, Glypican-3, Hep par-1, HMB45, Maspin, Melan A, Mesothelin, MUC2, Napsin A, Nestin, NSE, OLIG 2, p16, p40, p63, PAX8, Podoplanin, PSMA, RCC, S100, SATB2, SMA, SOX10, Synaptophysin, Thyroglobulin, TTF1, Uroplakin II, Vimentin, WT1. For our publications pertaining to Trucheck™ Intelli, 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; Urachal Carcinoma (URC): Bladder.

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

Methods and Qualifications

Trucheck™ Intelli test analyzes Circulating Tumor Cells (CTCs) and their clusters in peripheral blood collected in EDTA vacutainers. Isolated Peripheral Blood Mononuclear Cells (PBMCs) undergo cell stabilization with epigenetically activated medium under laboratory conditions. The medium provokes differential apoptosis in cells of different lineages. This approach selectively kills hematolymphoid cells with proficient apoptotic mechanisms in response to intense pro-growth stimuli. Processed samples are thereafter observed by phase contrast microscopy and cell clusters, if any, are harvested by aspiration for further characterization with fluorophore conjugated

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antibodies against multiple immunocytochemistry markers. 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
URC: Urachal carcinoma

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 malignancy. 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 and medical imaging and histopathology. A 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.

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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.

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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CE IVD

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