

PATIENT: **Nasr Al Jafari**TEST REF: *********

TEST NUMBER: *****

COLLECTED: *****

GENDER: Male

RECEIVED: *****

AGE: ***

TESTED: *****

PRACTITIONER:

Dr. Nasr Al-JafariDNA Health Medical Center , Villa 899
Al Wasl Road corner Al Manara,
Opposite of Costa Cafe, Dubai, UAE**TEST NAME: Trucheck™ Intelli****Summary and Interpretation**

Trucheck Report Summary and Interpretation

Test result for Circulating Tumor Cells (CTCs) for Epithelial Malignancy Negative Positive**Type of Malignancy**

<input type="checkbox"/> Adenocarcinoma	<input type="checkbox"/> Squamous Cell Carcinoma	<input type="checkbox"/> Adenosquamous Carcinoma
<input type="checkbox"/> Neuroendocrine Tumor	<input type="checkbox"/> Sarcoma	<input type="checkbox"/> Gastrointestinal Stromal Tumor
<input type="checkbox"/> Glioma	<input type="checkbox"/> Mesothelioma	<input type="checkbox"/> Melanoma
<input type="checkbox"/> Transitional Cell Carcinoma	<input checked="" type="checkbox"/> Not Applicable	<input type="checkbox"/> Indeterminate

Probable Organ of Origin Not Applicable Indeterminate**Summary of Immunocytochemistry Analysis**

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

[+] 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 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** No CTCs are detected in the given blood sample. Such individuals can repeat Trucheck Intelli test annually.
- **Positive** CTCs are detected in the given blood sample which is suggestive 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 are 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'



PATIENT: **Elisa Custodio Fausto**

TEST REF: **TST-DL-35300**

TEST NUMBER: T-DL-1126572 (1694)

COLLECTED: 22/08/2022 08:50 AM

PRACTITIONER:

GENDER: Female

RECEIVED: 25/08/2022 08:36 AM

Dr. Nasr Al-Jafari

AGE: 49

TESTED: 06/09/2022 09:33 AM

DNA Health Medical Center , Villa 899
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TEST NAME: Trucheck™ Intelli

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 metachronous, 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 hemolymphoid) 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)	Maspain (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

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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****



Dr. Kiran Bendale
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Consultant Pathologist

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,

EC REP Advena Ltd.,
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013,
Malta
CE IVD



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Important Note

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- 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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