Nordic Laboratories

PATIENT: XXXXXXXXXXXXXX			TEST REF: GNL-NL-XXXXX
TEST NUMBER: G-NL-XXXXX	COLLECTED: 00-XXX-2024		PRACTITIONER: XXXXXXXXXXXXX
GENDER: XXXXXX	RECEIVED: 00-XXX-2024		
AGE: XX	TESTED: 00-XXX-2024		XXXXXXXXXXXXXXXXXXXXX

TEST: TC_ Femmesafe Positive Sample report_15.01.2024

Summary and Interpretation

Test Results

Circulating Tumor Cells (CTCs) not detected, indicating lower risk of presence of carcinoma

Circulating Tumor Cells (CTCs) detected, indicating higher risk of presence of carcinoma

Carcinoma Type

Probability of carcinoma (Adenocarcinoma)	Not Applicable	Indeterminate

Probable Organ of Origin

Breast	Not Applicable	Indeterminate

Immunocytochemistry Analysis

EpCAM [+]	PanCK [+]	GCDFP15 [+]	GATA3 [+]	CK7 [+]	*CD45 [-]	CA125 [-]
CEA [-]	CK19 [-]	PAX8 [-]	P16 [-]	P63 [-]	WT1 [-]	

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

Test Interpretation and Advice

Please note that the results of this test are not to be used as the sole means of diagnosis and are not intended to substitute standard of care procedures. Please also be mindful of the limitations of the test which include the possibilities of 'false positives' and 'false negatives' for detection of CTCs due to biological variations beyond the performance spectrum of the test.

Circulating Tumor Cells (CTCs), indicative of Trucheck positivity were detected in the submitted sample. Reflex analysis for type of carcinoma and probable organ of origin by immunocytochemistry markers is suggestive of higher risk of presence of Breast adenocarcinoma.

Individual is advised to consult a physician for further guidance to undertake follow-up investigations.

When the Trucheck test results indicate higher risk of presence of a particular 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. When Circulating Tumor Cells are detected, even after a negative diagnostic evaluation of a particular cancer, the risk of presence of cancer remains elevated and may warrant further evaluation.

This test has been conducted based on the information provided in the service order form, which includes declaration that there is no past history of cancer. Please note that the results will not be valid in case of incorrect / insufficient information provided in the service order form.

Nordic Laboratories Aps
Nygade 6, 3.sal • 1164 Copenhagen K • Denmark
Tlf. +45 33 75 10 00

UK Office:
11 Old Factory Buildings • Stonegate • E. Sussex TN5 7DU • UK
Tel: +44 (0)1580 201 687

www.nordic-labs.com
info@nordic-labs.com

© Copyright **2024** Nordic Laboratories. Reproduction may be made for personal use only. Systematic electronic or print reproduction and distribution including duplication of any material in this paper for a fee or for commercial purposes, or modification of the content of the paper are prohibited.

TEST: TC_ Femmesafe Positive Sample report_15.01.2024

Guide to Interpretation of Test Results

Trucheck Femmesafe test detects Circulating Tumor Cells (CTCs) in peripheral blood of the individual and is intended to further analyse presence of adenocarcinoma of Breast, Ovary, Uterus and squamous cell carcinoma of Cervix.

- Circulating Tumor Cells (CTCs) not detected, indicating lower risk of presence of carcinoma
  Circulating Tumor Cells (CTCs) were not detected in the given sample as evaluated by immunocytochemistry analysis by quantitative fluorescence microscopy. Please be mindful that this Trucheck FemmeSafe report does not completely rule out the presence of carcinoma as some carcinomas may not shed detectable tumor cells in the blood.

- Circulating Tumor Cells (CTCs) detected, indicating higher risk of presence of carcinoma
  CTCs were detected in the given blood sample which is suggestive of higher risk of presence of carcinoma. The reflex analysis suggests likely organ of origin and carcinoma type. Individuals with such findings are advised consultation with their physician for appropriate guidance and additional standard of care workup as may be advised.

- Indeterminate
  CTCs were detected in the given blood sample, however type of carcinoma or organ of origin could not be determined.

Clinical Performance

Trucheck FemmeSafe test is a blood-based 'Laboratory Developed Test (LDT)' for detection of group of carcinomas 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).

CTC-based tests performed using DCG's technology have shown sensitivity of 88.24% for detection and localization of solid organ malignancies with specificity of 96.3% in asymptomatic individuals and specificity of 95% in individuals with benign tumors[6].

For our publications pertaining to Trucheck, please visit https://trucheck360.com/publications/

Trucheck FemmeSafe has been validated only for evaluation of risk of presence of following types of cancers:
Adenocarcinoma of Breast, Ovary, Uterus and squamous cell carcinoma of Cervix.

Important Note

The performance characteristics of the test are given 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 freely 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.

Methods and Qualifications

Trucheck FemmeSafe test analyzes Circulating Tumor Cells (CTCs) in peripheral blood collected in EDTA vacutainers. Isolated Peripheral Blood Mononuclear Cells (PBMCs) undergo cell stabilization with epigenetically activated medium under laboratory conditions. Processed samples undergo further characterization with fluorophore conjugated antibodies against multiple immunocytochemistry markers. Quantitative fluorescence imaging is performed on High-Content Screening Platform.

Nordic Laboratories Aps
Nygade 6, 3.sal • 1164 Copenhagen K • Denmark
Tlf. +45 33 75 10 00

UK Office:
11 Old Factory Buildings • Stonegate • E. Sussex TN5 7DU • UK
Tel: +44 (0)1580 201 687

www.nordic-labs.com
info@nordic-labs.com

© Copyright **2024** Nordic Laboratories. Reproduction may be made for personal use only. Systematic electronic or print reproduction and distribution including duplication of any material in this paper for a fee or for commercial purposes, or modification of the content of the paper are prohibited.

Nordic Laboratories

PATIENT: XXXXXXXXXXXXXX
TEST NUMBER: G-NL-XXXXX
GENDER: XXXXXX
AGE: XX

COLLECTED: 00-XXX-2024
RECEIVED: 00-XXX-2024
TESTED: 00-XXX-2024

TEST REF: GNL-NL-XXXXX
PRACTITIONER:
XXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXX

TEST: TC_ Femmesafe Positive Sample report_15.01.2024

Immunocytochemistry Reflex Markers (performed only if EpCam and PanCk positive CTCs are detected)

Marker (Clone)	Marker (Clone)	Marker (Clone)	Marker (Clone)
EpCAM (REA764)	PanCK (REA831)	CD45 (REA747)	GCDFP15 (23A3)
GATA3 (L50-823)	CK7 (OV-TL 12/30)	PAX8 (MD-50)	CEA (REA1158)
CA125 (REAL909)	p16 (REA973)	CK19 (REAL822)	WT1 (REA925)
p63 (4A4)			

Abbreviations

CTC: Circulating Tumor Cell
ICC: Immunocytochemistry

Important Information for Patients

The Trucheck Femmesafe 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.
This facility is certified by the College of American Pathologists (CAP) and under the Clinical Laboratory Improvement Amendments (CLIA)-USA as qualified to perform high complexity clinical laboratory testing.

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, active inflammatory diseases, medications, exposure to radiation 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 Femmesafe test is performed on blood samples from asymptomatic individuals as a part of screening for the above listed carcinomas only. This test is not designed for screening of any other malignancy including hematolymphoid malignancy.

Specificity is derived from screening of asymptomatic individuals, however sensitivity and specificity are likely to be impacted in patients with metasynchronous, metastatic conditions or by rare poorly understood biological processes.

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 practice medicine.

This is not a prescription.

References

1. Akolkar D et al. Noninvasive liquid biopsies for guideline-compliant diagnostic assessment in ovarian cancers DOI: 10.1158/1557-3265.LiqBiop20-B16 Published June 2020
2. 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.
3. 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.
4. Crook T et al. Accurate Screening for Early-Stage Breast Cancer by Detection and Profiling of Circulating Tumor Cells DOI: 10.3390/cancers14143341
5. Datta V et al. Circulating microtumors: A functional hallmark for cancer detection and management. DOI: 10.1200/JCO.2020.38.15_suppl.3544.

Nordic Laboratories Aps
Nygade 6, 3.sal • 1164 Copenhagen K • Denmark
Tlf. +45 33 75 10 00

UK Office:
11 Old Factory Buildings • Stonegate • E. Sussex TN5 7DU • UK
Tel: +44 (0)1580 201 687

www.nordic-labs.com
info@nordic-labs.com

© Copyright **2024** Nordic Laboratories. Reproduction may be made for personal use only. Systematic electronic or print reproduction and distribution including duplication of any material in this paper for a fee or for commercial purposes, or modification of the content of the paper are prohibited.

6. 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.
7. Limaye S et al. Viable circulating ensembles of tumor-associated cells persist in pretreated patients with solid organ cancers showing no radiologically detectable disease. D OI: 10.1158/15573265.LiqBiop20-A49.
8. 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.
9. Srinivasan A et al. Viable circulating ensembles of tumor associated cells persist in patients with no radiologically detectable disease after treatment in breast cancer. D OI: 10.1158/1538-7445.SABCS19-P4-01-17

End of Report

Authorised Signatory

Authorised Signatory

Accreditations and Certifications

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS | CLIA Accredited Laboratory No. 99D2270399 | Regulated by CareQuality Commission

Nordic Laboratories Aps
Nygade 6, 3.sal • 1164 Copenhagen K • Denmark
Tlf. +45 33 75 10 00

UK Office:
11 Old Factory Buildings • Stonegate • E. Sussex TN5 7DU • UK
Tel: +44 (0)1580 201 687

www.nordic-labs.com
info@nordic-labs.com

© Copyright **2024** Nordic Laboratories. Reproduction may be made for personal use only. Systematic electronic or print reproduction and distribution including duplication of any material in this paper for a fee or for commercial purposes, or modification of the content of the paper are prohibited.