OncoDiscover®

Liquid Biopsy Technology for Detecting Circulating Tumor Cells.

Actorius™ Innovations & Research

TEST REQUISITION FORM

FOR PATIENT	PHYSICIAN AND HOSPITAL DETAILS/ REFERRED BY
Name:	Physician Name:
Contact Number:	Contact Number:
Email ID:	Email ID:
DOB/Age:	CC Report to:
Gender: ☐ Male ☐ Female ☐ Others	Hospital (Name & Address):
Address:	

MEDICAL HISTORY

Previously diagnosed with cancer: ☐ Yes ☐ No	If yes, cancer type:
If tested earlier at Actorius Innovations and Research Laboratory: ☐ Yes ☐ No	Date of chemotherapy/ radiotherapy received: dd/mm/yyyy

SELECT THE TEST

☐ OncoDiscover® CTC ☐ OncoDiscover® CTC with PD-L1 ☐ OncoDiscover® CTC with HER-2

BLOOD COLLECTION	REPORT GENERATION
Date: dd/mm/yyyy Time: hh/mm/ss	**7 working days** from the date of receipt of sample.
Is blood infectious ☐ Yes ☐ No If yes, please specify:	

CONSENT OF PATIENT (रोगी की सहमति)

- I have read and understood the information and voluntarily consent to provide my blood sample for the OncoDiscover® test.
  मैंने दी गई जानकारी को समझ लिया है और ऑन्कोडिस्कवर परीक्षण हेतु स्वेच्छा से अपना रक्त नमूना देने की सहमति देता/देती हूँ।
- I consent to storage and use of my sample for clinical research and related applications.
  मैं अपने नमूने के भंडारण एवं नैदानिक अनुसंधान तथा संबंधित उपयोग हेतु सहमति देता/देती हूँ।
- I understand that test results depend on sample quality and methodology and must be interpreted with clinical findings.
  मैं समझता/समझती हूँ कि परीक्षण परिणाम नमूने की गुणवत्ता एवं विधि पर निर्भर करते हैं तथा उनका मूल्यांकन नैदानिक निष्कर्षों के साथ किया जाना चाहिए।
- I confirm that Actorius Innovations and Research Pvt. Ltd. has provided all necessary information regarding the test and sample collection.
  मैं पुष्टि करता/करती हूँ कि एक्टोरियस इनोवेशन्स एंड रिसर्च प्राइवेट लिमिटेड ने परीक्षण एवं नमूना संग्रहण से संबंधित सभी आवश्यक जानकारी प्रदान की है।

Date	Place	Signature
(dd/mm/yyyy)		

Laboratory: 208, B Wing, GO Square, Aundh-Hinjewadi Road, Wakad, Pune - 411057, Maharashtra, India.

TEST REQUISITION FORM

INSTRUCTIONS

- **Washout Period**: Blood sample should be collected at least 7 days after last chemotherapy/radiation therapy.
- **Container**: K2.EDTA Blood coated vacutainer tube (purple capped tube).
- **Volume**: 10 mL.
- **Blood Source**: Peripheral whole blood.
- **Collection**: Blood collection lab phlebotomist must be trained and have expertise in blood collection.
- **Mixing**: Gently invert EDTA tubes 180° and back 8-10 times.
- **Storage**: After collection and during transport, it is recommended to store tube at 2- 8°C.
- **Transportation**: Within 1-3 days of collection, shipment under recommended conditions.
- **Stability**: Stable for 15 days.
- **Rejection**: Short draws, clot/aggregation in blood, frozen blood, labeling error, incorrect, Leaked or broken container, improper transport.

CLINICAL SIGNIFICANCE

- The **OncoDiscover® Circulating Tumor Cell (CTC) Test** is intended for enumeration of Circulating Tumor Cells (CD45-, EpCAM+, and CK8, 18 and 19+) in peripheral blood of epithelial origin cancer patients. [1,2,3] CTC detection at primary diagnosis of cancer predicts an unfavorable prognosis. Presence of CTC post treatment indicates minimal residual disease.[4]
- **CTC clusters** are defined as a group of two or more aggregated CTCs. Presence of CTC Clusters may be an early indicator of an aggressive metastatic disease.[5] Patient should do a follow-up test upon clinical correlation by the physician.
- **PD-L1 expression** on CTC is an up- regulated dynamic protein biomarker, whereas PD-L1 expression on tissue is a static snapshot and often not available or adequate. Presence of PD-L1 on CTCs is correlated with a poor prognosis in cancer patients[6]. CPS score of tissue-based PD-L1 is not well co-related with CTC and its PD-L1 expression. However, PD-L1 on CTC is not a standardized diagnostic measure and clinical correlation is advised when interpreting the data.
- **HER-2** is the most valid tumor marker, used as a diagnostics and prognostic biomarker in metastatic breast cancer (MBC). However, HER-2 on CTC is not a standardized diagnostic measure and clinical correlation is advised when interpreting the data.[7]

REFERENCES

1. CDSCO India License No. MFG/IVD/**2019**/000031.
2. American Society of Clinical Oncology (ASCO) - Khandare *et. al. Journal of Clinical Oncology* **2019**; *37*; e14516.
3. American Association of Cancer Research (AACR) - Khandare *et al. Cancer Res* **2023**; *83*; 6684.
4. Pantel, Klaus, and Catherine Alix-Panabières. *Nature Reviews Clinical Oncology* **2019**; *16*(7); 409-424.
5. Aceto Nicola *et. al. Cell* **2014**; *158*(5): 1110-1122.
6. Catherine Alix-Panabières *et. al. Clinical Chemistry* **2021**; *67*(11); 1503-1512.
7. American Association of Cancer Research (AACR) - Khandare *et al. Cancer Res* **2024**; *84*; 7509.

DISCLAIMER

a. The test result alone shall not be used as a definitive diagnosis.
b. A negative result does not completely rule out disease, and a positive result may require further clinical confirmation.