

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	☐ OncoDiscover® CTC with AR/AR-V7

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)		

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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 patients⁶. 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
- **AR/AR-V7** expression on CTCs is a clinically validated predictive and prognostic biomarker in metastatic castration-resistant prostate cancer (mCRPC), providing valuable guidance for treatment selection and therapeutic response monitoring.^{8,9,10}

REFERENCES

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3. Khandare J, *et al. Cancer Res* **2023**; 83(7_Supplement); 6684 (AACR 2023).
4. Pantel K, *et al. Nat Rev Clin Oncol.* **2019**; 16(7); 409-424.
5. Aceto N, *et al. Cell* **2014**; 158(5); 1110-1122.
6. Catherine Alix-Panabières *et al. Clinical Chemistry* **2021**; 67(11); 1503-1512
7. J Khandare, *et al. Cancer Res.* **2024**; 84(6_Supplement); 7509 (AACR 2024).
8. Scher H I, *et al. JAMA Oncol.* **2018**; 4(9); 1179-1186.
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10. A J Armstrong, *et al. J Clin Oncol* **2019**; 37; 1120-1129.

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.