

## **Liquid Biopsy Of Intact Ctcs Detects Early Changes In Breast Cancer Tumor Biology To Guide Therapeutic Intervention**

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### **Abstract**

#### **Background**

Early-stage and small tumors release circulating tumor cells (CTCs) into the bloodstream, potentially carrying tumor signatures that indicate therapeutically actionable targets. QCDx developed QCDx-br™ an enrichment-free, liquid biopsy to detect CTC among the WBCs, with high sensitivity. It profiles CTC heterogeneity with an immunofluorescent (IF) panel for CTC phenotypes and another panel that assesses response to anti-Her2, endocrine, and triple-negative targeted treatments. Intact, IF-stained WBC preparations (>1 million cells) are immobilized in hydrogel and imaged automatically to detect CTCs.

#### **Objective**

A clinical study aims to demonstrate the effectiveness of the QCDx-br enrichment-free method to detect and profile therapeutically important targets on CTCs and inform on timely intervention both in early and metastatic breast cancer.

#### **Methods**

In an observational, prospective and blinded study with the University of Connecticut Cancer Center, 11 neoadjuvant (Stage I & II) and 22 metastatic (Stage IV) breast cancer patients were recruited under an IRB approved protocol. Blood was drawn at 8-10 timepoints over the 24-month period and processed with QCD-br, including white blood cell isolation, staining and imaging on the RareScope™ fluorescence microscope which utilizes AI to optimize 3D-microscopy conditions, image analysis, cell segmentation and classification.

#### **Results**

Processing of all 250 blood samples will be completed by April 2025 and CTCs were detected in >90% of 160 blood samples analyzed to date. In neoadjuvant patients, CTCs expressing actionable markers were seen to gradually decline in response to treatment. In the metastatic cohort, changes in CTC profiles and burden provided intelligence on the patient's response to treatment. Two patients in ongoing therapy after metastatic disease diagnosis, had negative imaging for several years and through the time of study enrollment. They are being monitored for CTCs expressing treatment targets, as an indicator for disease relapse.

#### **Conclusion**

The ongoing, observational breast cancer study indicates that using QCDx' RareScope and QCDx-br allows for sensitive identification of CTCs expressing actionable therapeutic targets to determine the best treatments in real-time. It indicates evidence for real-time evaluation of treatment responses in both early and advanced disease, and may have the potential to improve disease detection, including of minimal residual disease.

### **Do you have any conflicts of interest?**

Yes, I have a conflict of interest.

Industry liaison