

# Biocept's Sample Collection for Tumor Cell Analysis Demonstrates Superior Performance.

Veena M. Singh<sup>1</sup>, Edgar Sales<sup>1</sup>, Lan Huynh<sup>1</sup>, Cecile Rose T. Vibat<sup>1</sup>, Anna E Barón<sup>2</sup>, William Feser<sup>2</sup>  
Heather Malinowski<sup>3</sup>, Daniel Merrick<sup>3</sup>, Adrie van Bokhoven<sup>3</sup>, Stephen Malkoski<sup>4</sup>, York E Miller<sup>4</sup>  
Holly J Wolf<sup>5</sup>, and Marileila V. Garcia<sup>6</sup>

<sup>1</sup>Biocept, San Diego, CA • <sup>2</sup>Department of Biostatistics and Informatics, Colorado School of Public Health, Aurora, CO

<sup>3</sup>Department of Pathology, University of Colorado School of Medicine, Aurora, CO

<sup>4</sup>Department of Pulmonary and Critical Care Medicine, University of Colorado School of Medicine, Denver, CO

<sup>5</sup>Department of Community and Behavioral Health, Colorado School of Public Health, Aurora, CO • <sup>6</sup>University of Colorado School of Medicine, Aurora, CO

## Background:

Liquid biopsy is a minimally invasive and cost effective way to assess cancer biomarkers without the risk of surgical biopsy complications. Circulating tumor cell (CTC) analysis from body fluids can provide critical information towards early detection, prognosis and treatment decisions. Accurate CTC evaluations require optimal cell preservation. Cell lysis, DNA degradation, or membrane alterations compromise CTC analyses and accurate diagnoses. This work compares Biocept's proprietary CEE-Sure™ BCT and Saccomanno's Cytology Fixative largely used for sputum collection.

## Methods:

One million BT474 (HER2 amplified) or H3112 (ALK re-arranged) cells were spiked into 500 µl medium; 500 µl of CEE-Sure or Saccomanno fixative was added. Tubes were stored at 4°C for 1 day, 1 week, or 1 month. Cells were centrifuged, resuspended, and counted (Celigo). Around 150 cells in 15 µl of RPMI medium were flowed into Biocept's microfluidic system for cell capture; recovery (%) was calculated. Captured cells were subjected to fluorescent *in situ* hybridization (FISH) analyses for qualitative signal evaluation.

## Results:

As similar results were observed for both cell lines and all time points, combined data will be shown. Median cell recovery after CEE-Sure™ incubation was 14.1% (range 1.7–44%, n = 12) vs 5.4% (range 0.07–26.9%, n = 12) in Saccomanno's fixative. Median cell capture of ~150 cells fed into Biocept's microchannel was 96% (range 72–98%) for CEE-Sure™ vs 82% (range 21–96%) for Saccomanno. Paired t-tests showed significant differences for both recovery and capture. FISH signals from CEE-Sure samples were qualitatively rated Fair to Good, while Saccomanno samples had Poor to Fair, grainy, non-specific signals.

## Conclusions:

This preliminary work shows consistently higher cell recovery, better cell membrane maintenance, and higher quality FISH signals for samples stored in Biocept's CEE-Sure™ vs Saccomano's fixative. With liquid biopsy testing gaining rapid traction, maximal cell stability during the transport and storage are crucial. Additional fixative comparison is ongoing in various patient specimen types. These results support expansion of molecular analyses in sputum samples enriched for lung epithelial cells.