Compatibility and Efficacy of Ceres NEAT Liquid Biopsy Kit – Streck BCT with Blood Collected in Streck Cell-Free DNA BCT®

James Erickson, Dalton Bunde, Chamodya Ruhunusiri and Stephanie Barksdale,
Application Scientists, Ceres Nanosciences

Introduction

Cell-free DNA (cfDNA) is extracellular fragmented genetic material released by cells found in many body fluids, including blood, cerebrospinal fluid and urine. While all cells shed cfDNA, conditions such as cancer and pregnancy can elevate the presence of cfDNA in body fluids due to increased cellular turnover. Notably, cfDNA derived from cancer cells may carry specific mutations that can be detected through minimally invasive fluid collections in what is referred to as liquid biopsy (1, 2). FDA approval has been granted for cfDNA tests for specific cancer types, such as non-small cell lung cancer, however, challenges for these types of tests persist (3). One challenge is that actionable mutations are frequently present at very low concentrations, potentially below the detectability thresholds set by the employed assays. Another challenge is that large amounts of genomic DNA (gDNA) can be present in these samples, which may affect the limits of detection in the assay (4, 5). This becomes a larger issue for samples that need to be transported or stored prior to analysis, as blood samples that are not stabilized begin to release additional gDNA that can further dominate the plasma nucleic acid population. Addressing these challenges is crucial for improving the reliability and applicability of liquid biopsy in cancer diagnostics and monitoring.

Streck's stabilizing blood collection tube, Cell-Free DNA BCT, maintains draw-time cfDNA concentrations and minimizes release of gDNA during room temperature whole blood storage. While this addresses part of the gDNA challenges faced by liquid biopsy assay developers, it cannot enrich for the low concentration biomarkers of interest. Ceres Nanosciences' Nanotrap® Extraction Advanced Technology (NEAT) Liquid Biopsy Kit uses the Nanotrap hydrogel particle technology to capture and concentrate cfDNA from plasma samples while further reducing gDNA contamination. The result is a purer, more concentrated cfDNA product for downstream analysis. The NEAT Liquid Biopsy Kit is compatible with automated and manual methods available for a range of plasma volumes.

Here, we demonstrate that the NEAT Liquid Biopsy Kit – Streck BCT is suitable for use with the Streck Cell-Free DNA BCT.

Methods

Blood samples from three donors were drawn into Streck Cell-Free DNA BCT and stored at room temperature (19 °C to 23 °C). After two and seven days of storage, plasma was collected per tube manufacturer's instructions and cfDNA was isolated from 4 mL of plasma sample using competitor Kit 2 (automated, magnetic silica bead-based method) and the NEAT Liquid Biopsy Kit – Streck BCT. Samples were processed using the KingFisher™ Apex System and cfDNA was analyzed using the Agilent Cell-Free DNA ScreenTape on the 4200 TapeStation.

Results

NEAT Liquid Biopsy Kit – Streck BCT extracts higher concentrations of cfDNA from samples collected into Cell-Free DNA BCT.

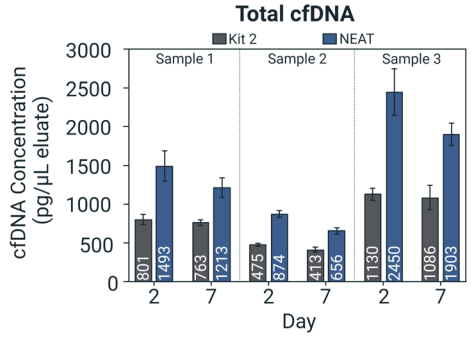

Figure 1. Concentration of cfDNA extracted from samples collected into Cell-Free DNA BCT using NEAT Liquid Biopsy Kit – Streck BCT or a competitor kit (Kit 2). Bars represent the concentrations of the average of three technical replicates and error bars indicate one standard deviation.

Performance characteristics of Cell-Free DNA BCT have only been established on the Guardant360® CDx and Guardant Shield™ assay. NEAT Liquid Biopsy Kit – Streck BCT is for Research Use Only. Not for use in diagnostic procedures.

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Conclusions

These data confirm that the NEAT Liquid Biopsy Kit – Streck BCT is a dependable and efficient method for cfDNA capture and concentration for samples collected into Streck Cell-Free DNA BCT®. Use of the NEAT Liquid Biopsy Kit – Streck BCT in combination with Cell-Free DNA BCT provides laboratories with purer, higher concentrations of cfDNA and greater flexibility in sample storage, shipping and handling.

References

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