Nucleic Acid BCT™ 10 mL Equivalence Report

A 10 mL configuration of Nucleic Acid BCT has been developed to provide researchers with approximately twice the amount of plasma as the 5 mL configuration. Nucleic Acid BCT (10 mL) and Nucleic Acid BCT (5 mL) are made of the same glass material, stopper material and reagent and will provide the same blood-to-reagent ratio following draw.

This report demonstrates that both Nucleic Acid BCT (5 mL) and Nucleic Acid BCT (10 mL) limit hemolysis, maintain plasma cell-free DNA (cfDNA) and cell-free RNA (cfRNA) concentration and limit changes in plasma volume during whole blood sample handling and storage.

Nucleic Acid BCT (5 mL) and (10 mL) are For Research Use Only. Not for use in diagnostic procedures. Nucleic Acid BCT (5 mL) and Nucleic Acid BCT (10 mL) should only be used for research or in the development of new assays.

The following study and associated data analysis were performed by Streck R&D personnel:

Study:
Venous whole blood from 3 self-declared healthy donors was drawn into four Nucleic Acid BCT (5 mL) and two Nucleic Acid BCT (10 mL). Within four hours of blood draw, plasma was processed from two Nucleic Acid BCT (5 mL) and one Nucleic Acid BCT (10 mL) per donor according to the Nucleic Acid BCT Instructions For Use (IFU) and stored at -80 °C until needed. We chose this 2 x 5 mL and 1 x 10 mL design to ensure that the volume of plasma that was analyzed was the same for both configurations being compared. The remaining three BCTs (two Nucleic Acid BCT (5 mL) and one Nucleic Acid BCT (10 mL) per donor) were stored at room temperature. After 7 days, tubes were mixed end-over-end 10 times, and plasma was isolated and stored as described above. Nucleic acids were purified from 3 mL of plasma using the QIAamp Circulating Nucleic Acid Kit (QIAGEN®). Cell-Free DNA was analyzed with both the Qubit HS DNA Assay (Thermo Scientific™) and TapeStation cfDNA ScreenTape Assay (Agilent®) whereas concentration of cell-free RNA utilized the Qubit miRNA Assay (Thermo Scientific).

Results:
We began our analysis by determining that the recoverable plasma obtained from Nucleic Acid BCT (10 mL) was approximately the same as that of two samples collected into Nucleic Acid BCT (5 mL) and pooled (Figure 1).

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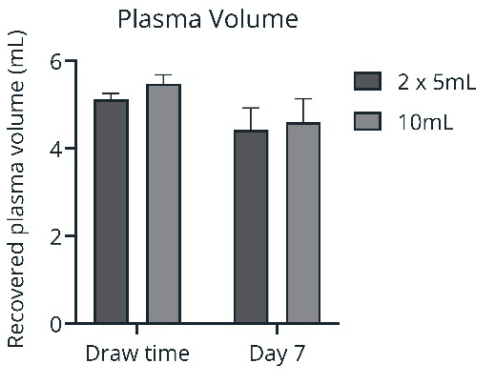

Figure 1. The volume of plasma isolated from Nucleic Acid BCT™ (10 mL) is approximately the same as that isolated from two Nucleic Acid BCT (5 mL) and pooled.

When hemolysis was monitored at draw and after seven days of ambient temperature storage, we observed that Nucleic Acid (10 mL) and Nucleic Acid BCT (5 mL) performed almost identically, with very little hemolysis following whole blood storage compared to what was seen for samples collected into EDTA and stored for the same amount of time (Figure 2).

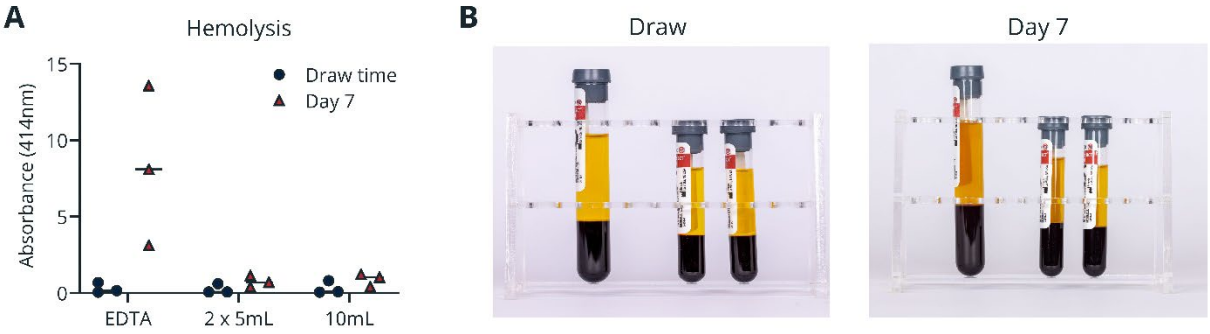

Figure 2. Nucleic Acid BCT has similar stabilization performance as it relates to limitation of hemolysis during whole blood sample handling and storage regardless of configuration (5 mL or 10 mL). Absorbance at 414nm is used to measure the amount of free hemoglobin in the sample.

As expected, both configurations of Nucleic Acid BCT maintained draw-time cell-free DNA (cfDNA) and cell-free RNA (cfRNA) concentrations for up to seven days of ambient temperature storage (Figures 3 and 4).

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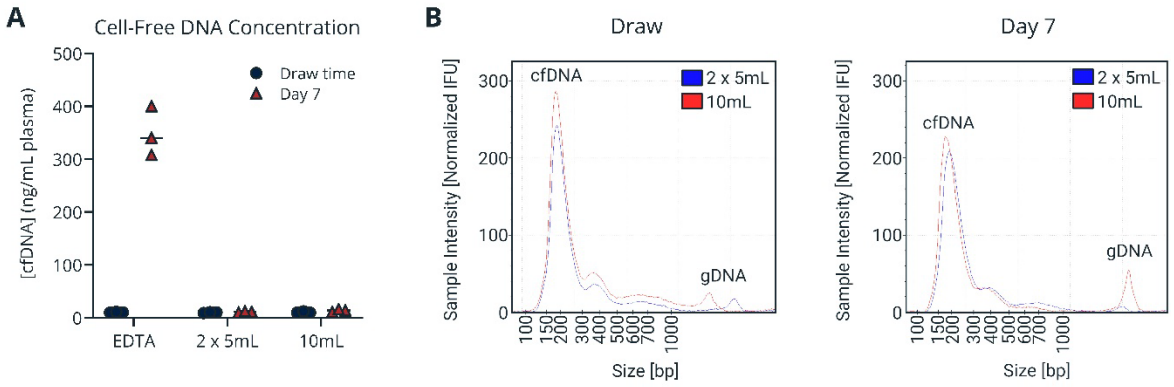

Figure 3. Nucleic Acid BCT™ has similar stabilization performance as it relates to preservation of draw-time cfDNA concentration and reduction of gDNA release during whole blood sample handling and storage regardless of configuration (5 mL or 10 mL). Blue peaks, 2 x 5 mL; red peaks, 10 mL.

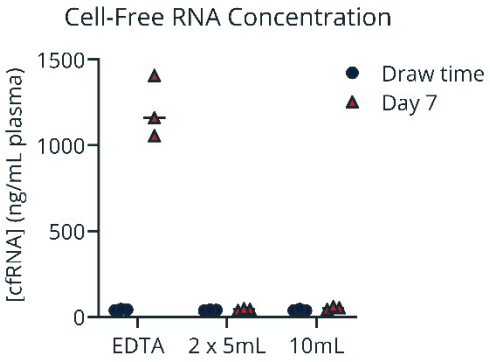

Figure 4. Nucleic Acid BCT has similar stabilization performance as it relates to preservation of draw-time cfRNA concentration during whole blood sample handling and storage regardless of configuration (5 mL or 10 mL).

Conclusion:
Overall, the results of this analysis suggest that Nucleic Acid BCT (10 mL) and Nucleic Acid BCT (5 mL) have the same stabilization performance as it relates to maintenance of draw-time plasma volume and preservation of draw-time cfDNA and cfRNA concentration during whole blood sample handling and storage.

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