

## Confirmation of Equivalence of One-Spin and Two-Spin Protocols for Plasma Isolation from LBgard® Blood Tubes

This letter serves as confirmation that the High Speed One-Spin protocol described in Table 1 is equivalent or superior to the standard Two-Spin protocol found in the LBgard® Blood Tube Instructions for Use and also in Table 1. Performance attributes tested in validation of the High Speed One-Spin protocol were minimal hemolysis, plasma volume recovery, cfDNA recovery, and no change in plasma DNA concentration over time. For each performance attribute, results obtained using the High Speed One-Spin protocol were equivalent or superior<sup>1</sup> to results obtained using the Standard Two-Spin protocol<sup>2</sup>.

**Table 1. Comparison of Standard Two-Spin and High Speed One-Spin Protocols for Plasma Isolation from LBgard® Blood Tubes**

Step	Standard Two-Spin (IFU)	High Speed One-Spin
<b>Blood Phase Separation</b>	Spin whole blood in LBgard tube at 1900 x g for 10 minutes at room temperature or refrigerated.	Spin whole blood in LBgard tube at 3000 x g for 15 minutes at room temperature or refrigerated.
<b>Plasma Isolation</b>	Transfer the top plasma layer to an empty 15 mL conical tube, carefully avoiding the buffy coat and red blood cell layers.	Transfer the top plasma layer to an empty 15 mL conical tube, carefully avoiding the buffy coat and red blood cell layers.
<b>Plasma Clarification</b>	Spin the plasma at 4500 x g for 15 minutes.	Not necessary.
<b>Plasma Isolation</b>	Transfer the plasma to an empty 15 mL conical tube, carefully avoiding any remaining pelleted cells.	Not necessary.
<b>cfDNA Extraction</b>	Proceed with cfDNA extraction per extraction kit manufacturer instructions. (Optional: freeze plasma at -80 °C prior to DNA extraction.)	Proceed with cfDNA extraction per extraction kit manufacturer instructions. (Optional: freeze plasma at -80 °C prior to DNA extraction.)

If you have any question or concerns please contact Technical Support at [techsupport@biomatrica.com](mailto:techsupport@biomatrica.com).

<sup>1</sup> Plasma volume recovered using the High Speed One-Spin Protocol was higher than with the Standard Two-Spin Protocol.

<sup>2</sup> The user is responsible for establishing appropriate performance characteristics and validating use of the one spin protocol for their specific assay.