B BRAUN
SHARING EXPERTISE

CARESITE MICRO™ LUER ACCESS DEVICE (LAD):

Mechanical Hemolysis Test of the Needleless Connector

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Abstract

Blood frequently flows through needleless connectors. Aspiration for assessment of catheter patency, transfusion of blood components, and obtaining blood samples are often performed through needleless connectors. This study on the hemolysis associated with the mechanical use of the CARESITE Micro Luer Access Device (LAD) demonstrates that blood samples can be obtained through this LAD without risk of hemolysis at amounts that would affect clinical decisions.[1]

Background

Many patients require the transfusion of blood, blood sampling, and blood withdrawals through needleless connectors. Hemolysis, which is defined as a rupture of red blood cells with the release of hemoglobin into the plasma, can cause inaccurate values for some laboratory tests including potassium and other electrolytes, kidney and liver function tests and cardiac enzymes.[2,3] Hemolyzed blood samples require obtaining a second sample from the patient, causing a potential delay in critical treatment decisions and increasing the costs of care.[4] Numerous factors including the design of some needleless connectors have been identified as contributing to the problem of hemolysis.[5] The CARESITE Micro LAD was tested by an independent laboratory to determine the percent of hemolysis produced when aspirating blood through the valve.

Methods

The test system consisted of citrated rabbit blood, obtained from New Zealand White rabbit donors. Equal volumes of rabbit blood from five donors were drawn into 3.2% sodium citrate collection tubes, stored at 2-8°C, and used within 48 hours of collection. The blood was tested and verified for hematocrit levels within the acceptable range of 30-50% for each donor prior to use for the test samples and controls.

Five CARESITE Micro LAD valves were tested for aspiration or drawing of blood through the device. Each LAD was attached to a sterile 5 mL syringe with 2 mL of blood aspirated through the LAD and into the syringe. Average rate of draw was approximately 1 mL/sec. The LAD was then removed from the syringe and the blood slowly dispensed from the syringe into a sterile vessel. Blood aspiration was then repeated without an LAD (syringe only) in triplicate using fresh blood, to serve as a procedural control and to measure any hemolysis attributed to use of the syringe.

The blood aspirated through test articles and procedural controls was then diluted with saline. Unaspirated rabbit blood was also added to sterile saline and sterile WFI for the negative and positive controls, respectively. All test and control solutions were incubated under static conditions for 60 ± 2 minutes at 37° ± 1°C.

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[1] B. Braun Data on File

[2] Dugan L, Leech L, Gabel Speroni K, Corriher J. (2005). Factors Affecting Hemolysis Rates in Blood Samples Drawn From Newly Placed IV Sites in the Emergency Department. Journal of Emergency Nursing, 31(4), 339-340.

[3] Grant, MS (2003). The Effect of Blood Drawing Techniques and Equipment on the Hemolysis of ED Laboratory Blood Samples. Journal of Emergency Nursing, 29(2), 116.

[4] Wan Azman WN, Omar J, Koon TS. Tuan Ismail TS. Hemolyzed specimens: Major challenge for identifying and rejecting specimens in clinical laboratories. Oman Medical Journal. 2019;34(2):94-98. doi:10.5001/omj.2019.19

After the 60-minute incubation, the vessels were gently mixed and the contents decanted into new vessels and centrifuged. The supernatant was carefully removed and inspected for color change and the presence of particles, and the absorbance of the supernatant was measured using a spectrophotometer.

Results

Statistical analysis was performed to calculate the average and standard deviations of the absorbance readings. The average % hemolysis was calculated for the test articles and procedural controls. Under the conditions of this study, the procedure-control corrected % hemolysis of the test articles was 0.28%.

The results indicate that the material and the design of the device are considered non-hemolytic.

Conclusion

This study on mechanical hemolysis associated with the CARESITE Micro™ LAD demonstrates that blood samples can be obtained through this LAD without risk for hemolysis at amounts that would affect clinical decisions.

Discussion

The hemolysis value of 0.28% was well below the 5% hemolysis limit, indicating that the material used in and the design of the device do not produce hemolysis.

Please note that other variables that are not considered within this study may contribute to the production of hemolysis, including the use of a vacuum tube system, the length of tourniquet time and the lumen size of the catheter or needle used for venipuncture.[4] Variations in clinical practice can have an impact on specimen hemolysis and could affect clinical decisions about patient treatment.[5]

[5] Sharp M.K, Mohammad S.F. (2003) Hemolysis in Needleless Connectors for Phlebotomy. ASAIO Journal