Vascular Integrity™ Hemolysis Study 2020

Introduction

An independent laboratory study was conducted on the Vascular Integrity VI ByPass syringe™ technology to determine the amount of Hemolysis created when utilized during a simulated blood draw.

Hemolysis of blood samples can lead to inaccurate results and repeat draws, causing additional pain, delaying treatment decisions, and increasing length of stay (Tanabe, Kyriacou, & Garland, 2003). Hemolysis accounts for 40% to 60% of blood specimen rejections by the laboratory (Söderberg, Jonsson, Wallin, Grankvist, & Hultdin, 2009). Hemolysis rates from 3.3% to 77% have been reported and vary depending on the method of blood sample collection (Halm & Gleaves, 2009). Reliability of laboratory results affects treatment decisions, and blood draws that must be repeated because of hemolysis increase length of stay and workload and can affect clinical outcome. A variety of factors have been studied for their association with hemolysis, including anatomic site, tourniquet time, equipment, technique, transport, personnel, education, monitoring feedback, phlebotomy, and nursing workloads.

Purpose

The purpose of the study was to determine the potential hemolytic activity, via the induction of increased levels of free plasma hemoglobin in rabbit blood, in response to the Vascular Integrity™ Technology, the devices are designed to consistently achieve quality blood samples while providing needlestick protection for the health care worker in various clinical applications.

Methods

Blood Collection: Fresh whole rabbit blood was collected from 3 donors on each test day into tubes containing an anticoagulant (citrate). Approximately 5 mL of blood was drawn from each animal then pooled together. The blood was used within 4 hours of collection.

Evaluation criteria

Determination of the Hemolytic Activity: The absorbance values were used to determine the concentration of hemoglobin in the supernatant. The percent (%) hemolysis of the test article was calculated after subtraction of the blank and evaluated based on the following grades:

Hemolytic Index Above the Negative Control Article (%) Hemolytic Grade

Value	Description	Appearance
<2	Non-Hemolytic	Colorless
≥2 and <5	Slightly hemolytic	Colorless
≤5	Hemolytic	Reddish

Results

Hemolysis Results

Sample	Sample 1	Sample 2	Sample 3	Average	Blank corrected Hemolysis %	Blank corrected Hemolysis %	Blank corrected Hemolysis %	Mean	STD Dev	Hemolysis above Neg %
Blank	0.0037	0.0040	0.0048	0.0042	-0.09	-0.03	0.13	0.00	0.12	
Neg	0.0047	0.0050	0.0049	0.0049	0.11	0.17	0.15	0.14	0.03	
Pos	0.4012	0.4233	0.4505	0.4250	80.58	85.06	90.58	85.41	5.01	85.27
Test	0.0111	0.0112	0.0125	0.0116	1.40	1.42	1.68	1.5	0.16	1.36

Blank corrected Hemolysis % = $[(A^s-A^b)/(A^t-A^b)] \times 100\%$ details on fie

Conclusion

Based on the criteria of the protocol and the ASTM F756 guidelines, the Vascular Integrity Bypass Syringe™ meets the requirements of the test and is considered **non-Hemolytic.**

Reference: Independent Laboratory, Toxikon. 15 Wiggins Avenue, Bedford MA 01730