Vascular Integrity™ Microbial Diversion study

Introduction

Blood Culture contamination (BCC) increases length of stay (LOS) and leads to unnecessary antimicrobial therapy and/or hospital-acquired conditions (HACs) on a national level. The estimated burden in the USA for incremental unnecessary and avoidable healthcare costs related to false-positive blood cultures is a staggering 8.6 billion. Nationwide statistics estimate 30 million cultures are drawn annually of which 2-8% results are false positive. Each false positive BC resulted in incremental costs totaling $6463 per patient event.[1] The process of initial sample specimen diversion has shown to be successful in reducing False Positive Blood Cultures, however products may be highly specific, cumbersome to use, and difficult for nurses to adopt. In recent years, efforts to reduce patient venipunctures have exposed a need for improved blood collection technology at the time of line insertion and through indwelling lines. Reduction in blood culture false positives is multi-factorial. 10% of Blood Cultures are positive, a cost effective, intuitive, and user-friendly device offers a solution helping hospitals to achieve important economic and clinical outcome initiatives.

Purpose

The Vascular Integrity™ technology uniquely separates the VI ByPass Syringe Chamber™ clearance volume from the collection channel fluid path with a VI Sliding fluid Seal™. The purpose of the study is to validate the effectiveness of the VI ByPass Syringe™ device to effectively isolate contaminates in a worst-case scenario.

Study

Method Several test pilots were performed, and the following study proved to be the best study to demonstrate the ByPass Blood Collection Technology: Vitro-Skin covering a parafilm wrapped petri dish containing pooled whole human blood was contaminated with Staphylococcus aureus (ATCC-6538) and allowed to incubate under ambient conditions for a minimum of ten (10) minutes.

The inoculated Vitro Skin was placed atop the blood source containing approximately 150 mL blood. All testing was carried out in a biological laminar flow hood under ambient conditions.

For a baseline control, a standard 20 mL BD syringe fitted with a 23-gauge butterfly needle served as the device, one (1) red-top vacuum tube was collected. This simulates a routine blood draw with no waste of initial specimen (blood should go from the butterfly needle directly into the vacuum tube).

Next, three groups of samples were subjected to the same simulated draw using the Sponsors device(s) and butterfly needles for drawing 0.5, 1.0 and 2.0 mL to waste. Then to collect the waste draw, while grasping both vacuum holder and Sponsor device insert a new tube for collection of blood to be submitted for bacterial counts.

Each test group was collected in triplicate. Nine (9) BPS test article devices were divided into three groups: 0.5 mL waste draw, 1.0 mL waste draw and 2.0 mL waste draw.

Culture Preparation: Broth cultures were established and used to contaminate the simulated skin. The microbial challenge volume and application method were determined by three pilot studies, methods developed and refined with each trial. . Concentrations were 108 –109 estimated cfu's per milliliter.

Microbial Recovery: Microorganism recovery was performed by a sampling technique in which each "clean" blood draw was sampled and immediately transferred to fifteen (15) mL of sterile TSA and onto appropriate agar plates. Enumeration was performed in duplicate, with all cultures incubated under appropriate atmospheric conditions for a minimum of forty-eight hours. The TSA tubes were monitored for bacterial growth only.

Microbial Enumeration: After completion of the agar plate incubation period, the number of colonies on each plate was determined, values converted to colony forming units (CFU) per site and Log10 CFU reductions per test group were

calculated compared to the BD syringe draw without a waste. Appropriate comparisons were performed between the numbers of microorganisms recovered from each test and control devices.

The method used in this study was the analysis of the blood collected via the VI ByPass syringe Chamber™ and the VI Velocity Reduction System™ into a vacuum tube and comparing it to the blood collected straight into the standard syringe after the inoculation protocol (as outlined) using standard mathematical calculations.

ByPass Syringe Priming volume	
Volume of inner-cannula	0.0030 ml
Volume of inner cannula and channel	0.2309 ml
Study Organism	
Staphlococcus aureas	$>10^9$ cfu/ml

RESULTS: Percentage reduction of bacterial contamination with range of waste volumes as follows:

	Waste volume	Waste cfu	Whole blood	Diversion of bacterial contaminates
In-Vito skin inoculated with $>10^9$ CFU/ml on a blood source bag	0.5ml	1000 cfu	60 cfu	94.0% of contaminates were diverted
	1.0ml	1000 cfu	28 cfu	97.2% diversion
	2.0ml	1000 cfu	14 cfu	98.6% diversion

Conclusion

A study was designed to challenge the VI ByPass Syringe™ blood collection and line maintenance device. Direct veni-punctures were performed through vitro skin contaminated with heavy inoculants of Staphylococcus Aurous (MRSA). Without disinfection of the surface, under worst case scenario, a 2ml waste collection diverted 99% of contaminates.[2]

1. Geisler BP et al., Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes, Journal of Hospital Infection, https://doi.org/10.1016/j.jhin.2019.03.012
2. Contamination Challenge Study Data on File Vascular Integrity

[i]Vascular Logics is a fully owned brand name of Vascular Integrity™
[ii]Patent Pending

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