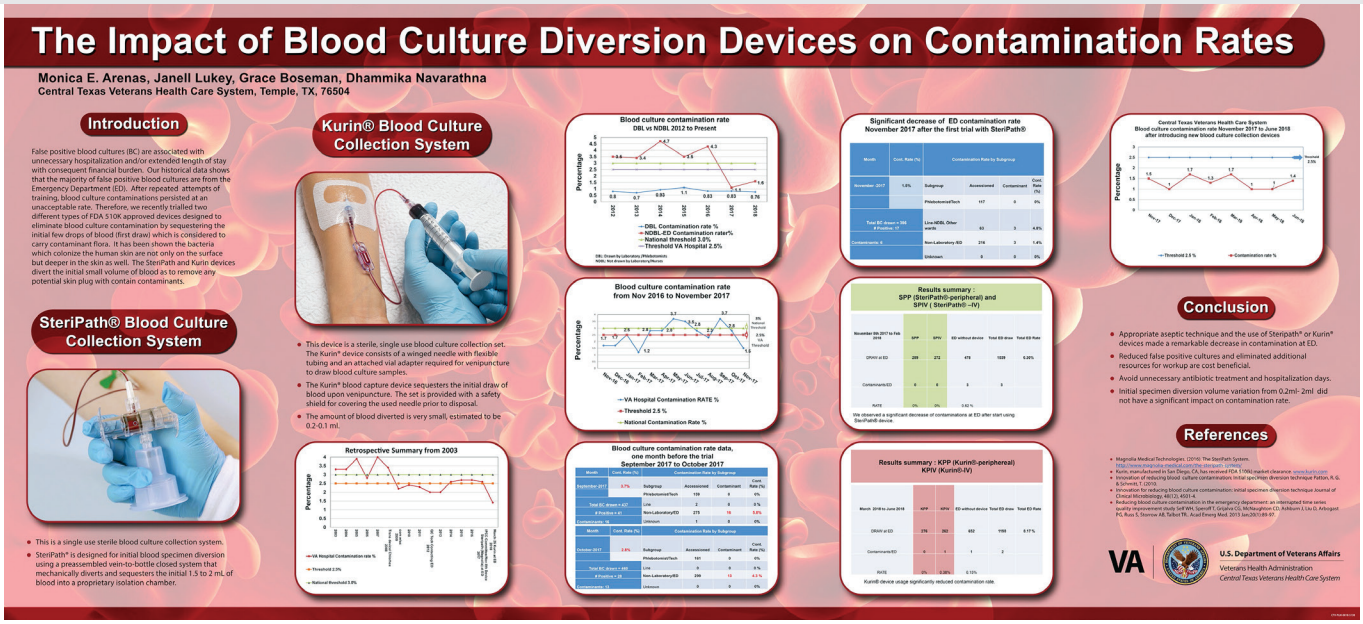
Kurin® CLINICAL RESULTS

Presented at SWACM Conference, September 2018, San Antonio, TX



The impact of Blood Culture Diversion Devices on Contamination Rates

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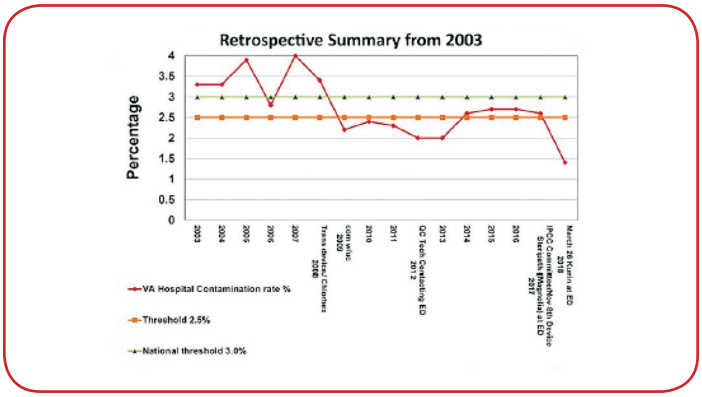
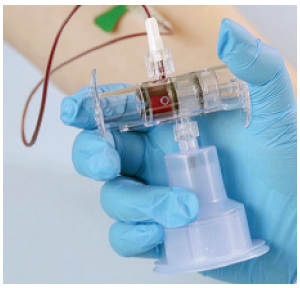
Introduction

False positive blood cultures (BC) are associated with unnecessary hospitalization and/or extended length of stay with consequent financial burden. Our historical data shows that the majority of the false positive blood cultures are from the Emergency Department (ED). After repeated attempts of training, blood culture contaminations persisted at an unacceptable rate. Therefore, we recently [trialed] two different types of FDA 510(k)-approved devices* designed to eliminate blood culture contamination by sequestering the initial few drops of blood (first draw) which is considered to carry contaminant flora. It has been shown [that] the bacteria which colonize the human skin are not only on the surface but deeper in the skin as well. The Steripath® and Kurin® devices divert the initial small volume of blood to remove any potential skin plug [which may] contain contaminants.



*Correction: as of September 2018, the Steripath device had not received 510(k) clearance.

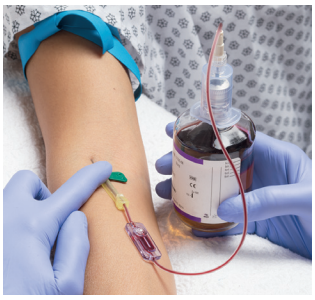
Steripath® Blood Culture Collection System

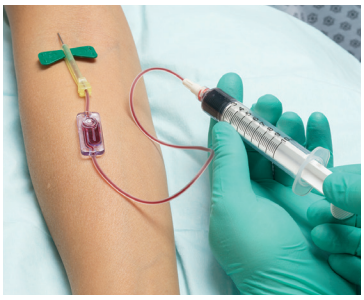


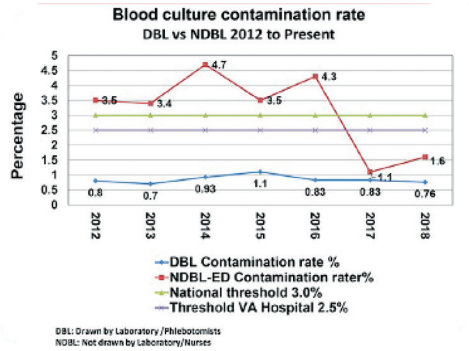
- This is a single-use sterile blood culture collection system.
- SteriPath is designed for initial blood specimen diversion using a preassembled vein-to-bottle closed system that mechanically diverts and sequesters the initial 1.5 to 2 mL of blood into a proprietary isolation chamber.

Kurin® Blood Culture Collection System

- This device is a sterile, single-use blood culture collection set. The Kurin device consists of a winged needle with flexible tubing and an attached vial adapter required for venipuncture to draw blood culture samples.
- The Kurin blood capture device sequesters the initial draw of blood upon venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal.
- The amount of blood diverted is very small, estimated to be 0.2-0.1 mL.



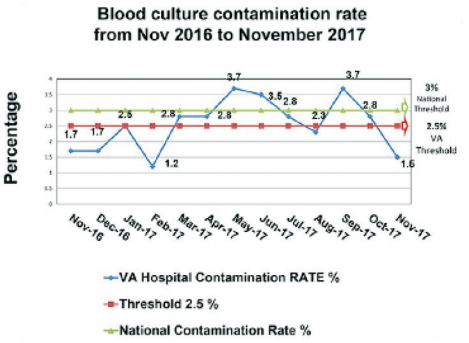




Results summary : SPP (SteriPath®-peripheral) and SPIV (SteriPath® –IV)

November 8th 2017 to Feb 2018	SPP	SPIV	ED without device	Total ED draw	Total ED Rate
DRAW at ED	289	272	478	1039	0.30%
Contaminants/ED	0	0	3	3	
RATE	0%	0%	0.62 %		

We observed a significant decrease of contaminations at ED after start using SteriPath® device.



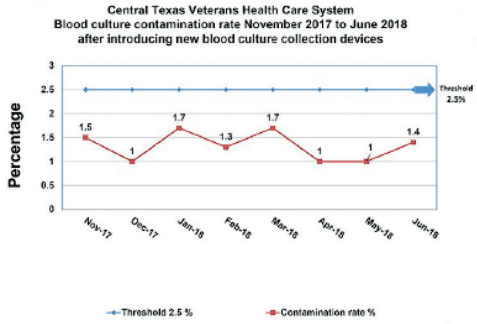
Results summary : KPP (Kurin®-peripheral) KPIV (Kurin®-IV)

March 2018 to June 2018	KPP	KPIV	ED without device	Total ED draw	Total ED Rate
DRAW at ED	276	262	652	1190	0.17 %
Contaminants/ED	0	1	1	2	
RATE	0%	0.38%	0.15%		

Kurin® device usage significantly reduced contamination rate.

Blood culture contamination rate data, one month before the trial September 2017 to October 2017

Month	Cont. Rate (%)	Contamination Rate by Subgroup			
September-2017	3.7%	Subgroup	Accessioned	Contaminant	Cont. Rate (%)
		Phlebotomist/Tech	159	0	0%
Total BC drawn = 437		Line	2	0	0 %
# Positive = 41		Non-Laboratory/ED	275	16	5.8%
Contaminants: 16		Unknown	1	0	0%
Month	Cont. Rate (%)	Contamination Rate by Subgroup			
October-2017	2.8%	Subgroup	Accessioned	Contaminant	Cont. Rate (%)
		Phlebotomist/Tech	161	0	0%
Total BC drawn = 460		Line	9	0	0 %
# Positive = 28		Non-Laboratory/ED	299	13	4.3 %
Contaminants: 13		Unknown	0	0	0%



Significant decrease of ED contamination rate November 2017 after the first trial with SteriPath®

Month	Cont. Rate (%)	Contamination Rate by Subgroup			
November -2017	1.5%	Subgroup	Accessioned	Contaminant	Cont. Rate (%)
		Phlebotomist/Tech	117	0	0%
Total BC drawn = 396 # Positive: 17		Line-NDBL Other wards	63	3	4.8%
Contaminants: 6		Non-Laboratory /ED	216	3	1.4%
		Unknown	0	0	0%

Conclusion

- Appropriate aseptic technique and the use of Steripath® or Kurin® devices made a remarkable decrease in contamination [in the] ED.
- Reduced false positive cultures and eliminated additional resources for workup are cost beneficial.
- Avoid unnecessary antibiotic treatment and hospitalization days.
- Initial specimen diversion volume variation from 0.2ml–2ml did not have a significant impact on contamination rate.

References:

- Magnolia Medical Technologies. (2015) The SteriPath System. http://www.magnolia-medical.com/the -steripath-system/
- Kurin, manufactured in San Diego, CA has received FDA 510(k) market clearance. www.kurin.com
- Innovation for reducing blood culture contamination: Initial Specimen diversion technique. Patton RG, Schmitt T. J Clin Microbiol. 2010 Dec;48(12):4501-3.
- Reducing blood culture contamination in the emergency department: an interrupted time series quality improvement study. Self WH, Speroff T, Grijalva CG, McNaughton CD, Ashburn J, Liu D, Arbogast PG, Russ S, Storrow AB, Talbot TR. Acad Emerg Med. 2013 Jan;20(1):89-97.