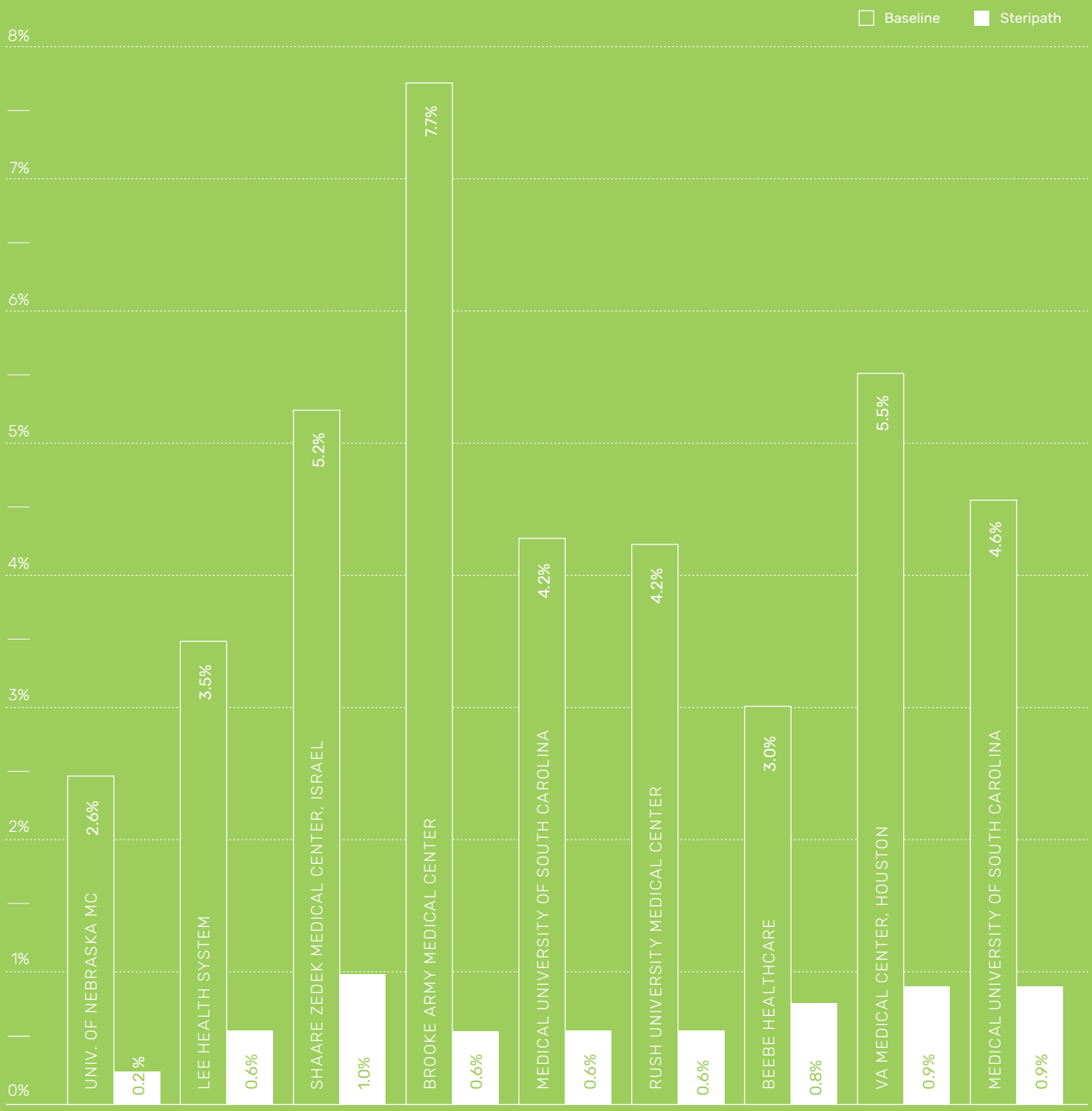
Steripath

CLINICAL & ECONOMIC **EVIDENCE REPORT**

Independent research defining the *new* standard of care for preventing blood culture contamination

The Initial Specimen Diversion Device®

CONTAMINATION REDUCTION RESULTS AT A GLANCE



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Steripath® (ISDD®) is supported by independent published clinical study results of 12-month sustained rates as low as 0.2% in the ED *(p.4)*. With improved test results, patients can benefit from reduced risk of sepsis misdiagnosis and unnecessary antibiotic treatment.

CLINICAL EFFECTIVENESS: REDUCTION OF BLOOD CULTURE CONTAMINATION

Steripath Clinical and Economic Evidence Report

Peer Reviewed Publication

UNIVERSITY OF NEBRASKA MEDICAL CENTER

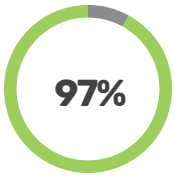
TITLE:	Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device® [Steripath®]
PUBLICATION:	***Clinical Infectious Diseases*** - 2017:65 (15 July)
AUTHORS:	Mark E. Rupp, MD, et al.
AFFILIATIONS:	Division of Infectious Disease, Department of Clinical Pathology, Department of Epidemiology, Emergency Department
DESIGN:	Single center, prospective, controlled, matched-pair, open label trial over a 12-month period – 904 patients (1,808 cultures)
METHOD:	Phlebotomists collected two cultures from each subject. (1) One using phlebotomy best practices (2) One using Steripath
RESULTS:	92% reduction in contamination compared to pre-intervention rate of 2.6%. 88% reduction during 12-month study period, 0.2% ISDD vs 1.8% standard practice. Sensitivity was not compromised.
SUMMARY:	Use of the ISDD was associated with a significant decrease in blood culture contamination. Annual cost savings were calculated to be $1.8M.

CONTAMINATION REDUCTION:

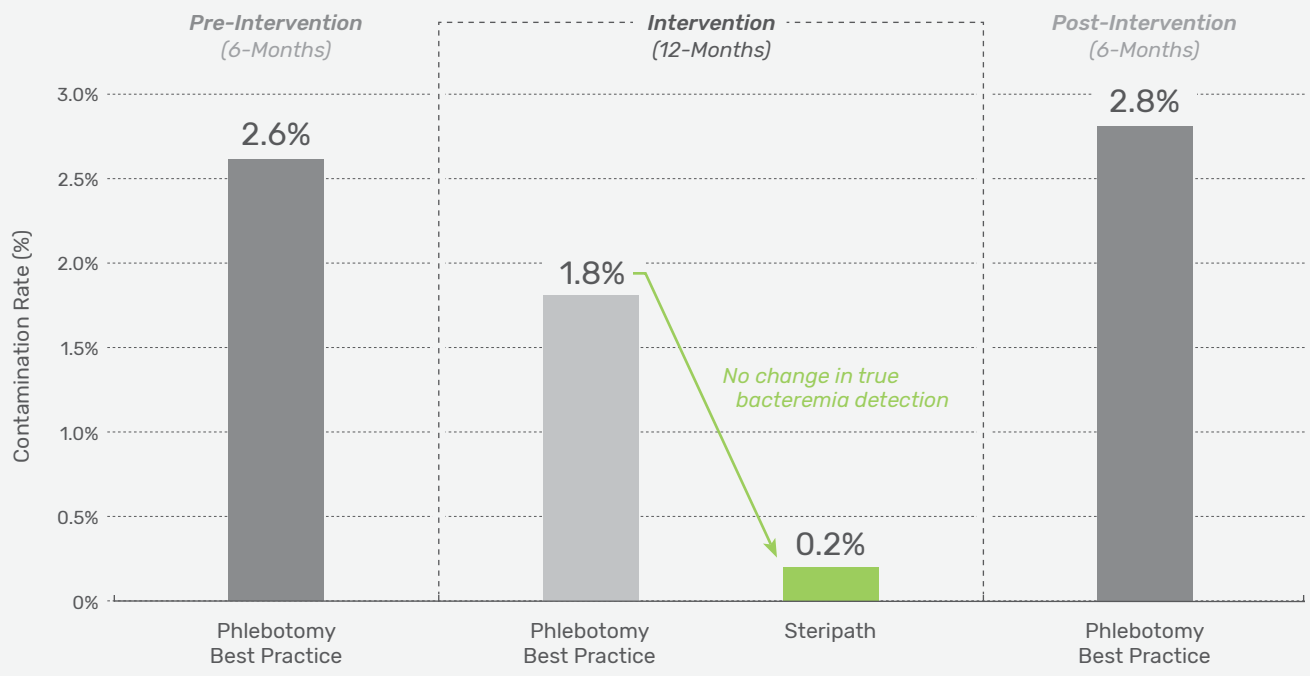
ANNUAL COST SAVINGS:

$1.8M

POSITIVE PREDICTIVE VALUE:



REDUCTION IN BLOOD CULTURE CONTAMINATION (MATCHED PAIR) STUDY

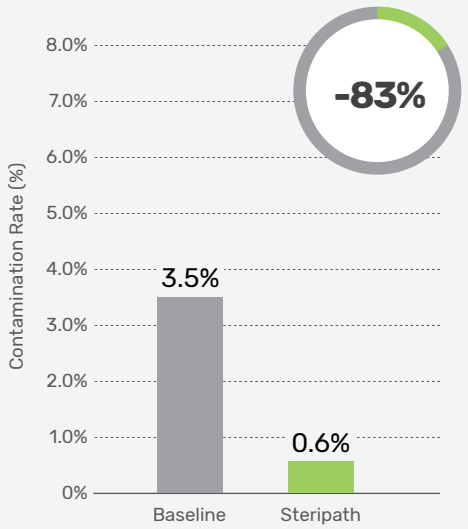


Peer Reviewed Publication

LEE HEALTH SYSTEM

TITLE:	Effectiveness of a Novel Blood Culture Collection System in Reducing Blood Culture Contamination Rates
PUBLICATION:	***Journal of Emergency Nursing*** (2018)
AUTHORS:	Mary Bell, MSN, RN, CEN, et al.
AFFILIATIONS:	Department of Emergency Medicine at Lee Health acute care centers (multicenter trial n=4)
DESIGN:	Multi-center, prospective, open label trial
METHOD:	7-month trial in four Lee Health ED's. BCC rates obtained during intervention with Steripath were compared to historical standard method BCC rates.
RESULTS:	83% reduction in contamination with Steripath by both venipuntcture and new peripheral IV line. Standard procedure: 3.5% rate for 35,392 cultures. Steripath: 0.6% (P=0.0001) rate for 6,293 cultures.
SUMMARY:	Steripath use prevented 1,008 false positives annualized basis. Cost savings of $641,792 during a 7-month period. Annual potential cost avoidance: $4,351,444 - $10,818,492

REDUCTION IN BLOOD CULTURE CONTAMINATION

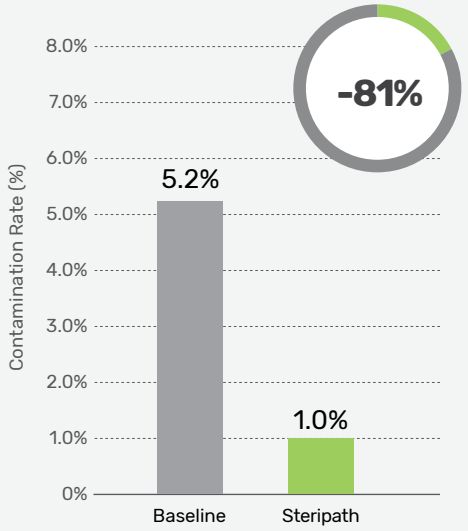


Peer Reviewed Publication

SHAARE ZEDEK MEDICAL CENTER, ISRAEL

TITLE:	Reducing Blood Culture Contamination Using an Initial Specimen Diversion Device
PUBLICATION:	***American Journal of Infection Control*** (2019)
AUTHORS:	Frederic S. Zimmerman, MD, et al.
AFFILIATIONS:	Department of Intensive Care, Laboratory of Clinical Microbiology, Department of Internal Medicine, Infectious Disease Unit
DESIGN:	Single center, prospective, controlled pragmatic study
METHOD:	Blood cultures were obtained using the initial specimen diversion device, either via integrated needle or attachment to a newly placed intravenous catheter. Cultures taken using standard methods served as the control (n = 671 blood cultures).
RESULTS:	81% reduction in blood culture contamination using Steripath. Standard procedure: 5.2% rate, Steripath: 1.0% (P=0.008) rate.
SUMMARY:	The use of the ISDD was associated with reduced culture contamination in hospitalized patients over a 6-month period, without concomitant reduction in true-positive cultures.

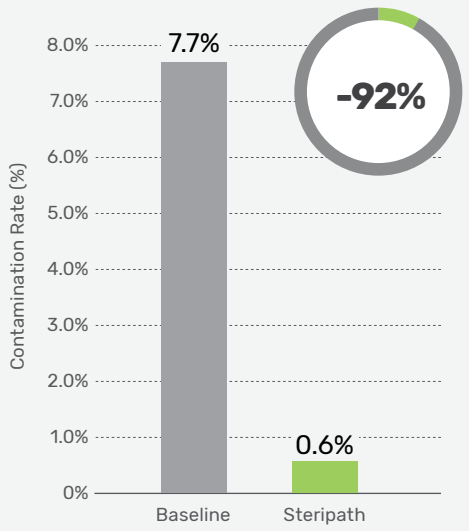
REDUCTION IN BLOOD CULTURE CONTAMINATION



BROOKE ARMY MEDICAL CENTER

TITLE:	Reduction of Blood Culture Contaminations in the Emergency Department
PRESENTED AT:	***Department of Defense Healthcare Quality and Safety Award Winner*** (2016)
AUTHORS:	LTC Charlotte Lanteri Ph.D., et al.
AFFILIATIONS:	Department of Emergency Medicine
DESIGN:	Single center, prospective, open label trial
METHOD:	Blood cultures were collected via venipuncture or peripheral IV starts in the Emergency Department. Patients randomized to either standard method or use of Steripath.
RESULTS:	92% reduction in contamination with Steripath. Standard procedure: 7.7% (52/672) contamination rate, Steripath: 0.6% (5/784) contamination rate.
SUMMARY:	Hospital savings over $235,000 during 5-month trial period.

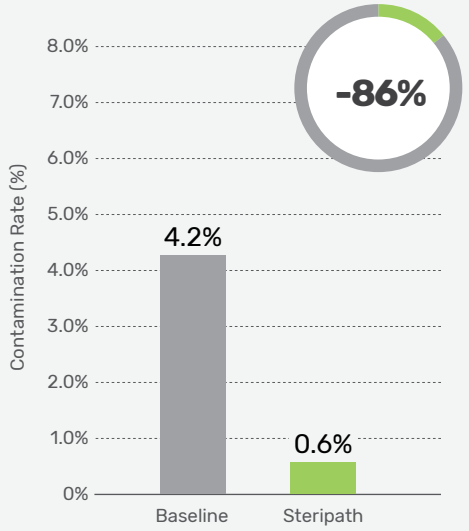
REDUCTION IN BLOOD CULTURE CONTAMINATION



MEDICAL UNIVERSITY OF SOUTH CAROLINA

TITLE:	Reducing the Laboratory Cost of False Positive Blood Cultures in the Adult Emergency Department
PRESENTED AT:	***Institute for Healthcare Improvement National Forum*** (2016)
AUTHORS:	Lori Gauld, MT, SM, et al.
AFFILIATIONS:	Department of Pathology & Laboratory Medicine, Adult Emergency Department
DESIGN:	Single center, prospective, open label trial
METHOD:	ED nursing personnel were trained on the use of Steripath via venipuncture and peripheral IV starts. Floating nursing personnel were not trained and therefore utilized standard blood collection procedures that served as internal control.
RESULTS:	86% reduction in blood culture contamination using Steripath. Standard procedure: 4.2% rate, Steripath: 0.6% rate.
SUMMARY:	Steripath was adopted in the adult ED and was expanded to a second, separate adult ED, and the ICU.

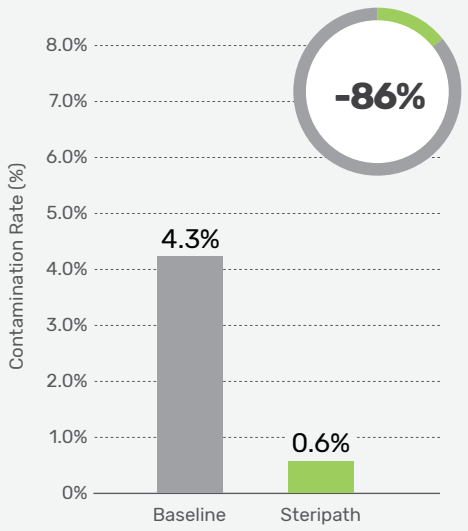
REDUCTION IN BLOOD CULTURE CONTAMINATION



RUSH UNIVERSITY MEDICAL CENTER

TITLE:	Significant Reduction of Blood Culture Contamination in the Emergency Department (ED) Using the Steripath® Blood Diversion Device
PRESENTED AT:	***IDSA IDWeek Conference*** (2017)
AUTHORS:	Chawat Tongma, MD, et al.
AFFILIATIONS:	Emergency Department, Department of Pathology
DESIGN:	Single center, prospective, open label trial
METHOD:	3 month pre-post intervention study. Pre-intervention blood cultures were collected using standard aseptic technique by nurses in the ED. During intervention, blood cultures were collected using the Steripath device.
RESULTS:	86% reduction in blood culture contamination using Steripath. Standard procedure: 4.3% contamination rate, Steripath: 0.6% contamination rate.
SUMMARY:	The Steripath device represents a simple and effective method for reducing blood culture contamination.

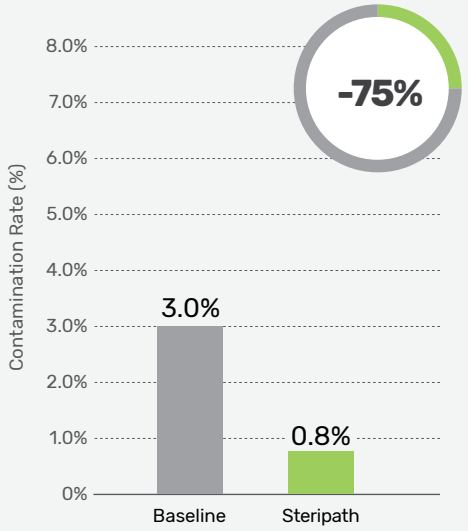
REDUCTION IN BLOOD CULTURE CONTAMINATION



BEEBE HEALTHCARE

TITLE:	Reduction of Blood Culture Contamination Using Initial Specimen Diversion Device®
PRESENTED AT:	***ASM Microbe Conference*** (2018)
AUTHORS:	Jennifer Blakeney, MT(ASCP)SM, et al.
AFFILIATIONS:	Laboratory, Adult Emergency Department and ICU
DESIGN:	Single center, prospective, non-randomized trial
METHOD:	Blood cultures were collected in the Emergency Department over a 4-month period. Patients non-randomized to either standard procedure or Steripath for blood culture collection.
RESULTS:	75% reduction in blood culture contamination using Steripath vs. Standard procedure: 3.0% rate (24/802), Steripath: 0.8% rate (14/1837).
SUMMARY:	Hospital-wide adoption of Steripath as the new standard practice.

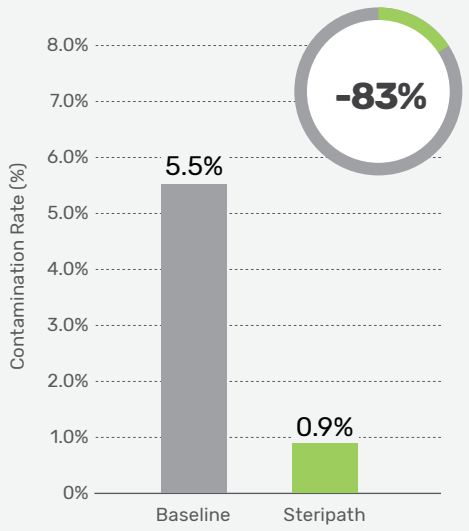
REDUCTION IN BLOOD CULTURE CONTAMINATION



VA MEDICAL CENTER, HOUSTON

TITLE:	ER Pilot Leads to Hospital-Wide Implementation of Blood Culture Device
PRESENTED AT:	***Emergency Nursing Conference*** (2018)
AUTHORS:	Karen Stonecypher, PhD, MSN, RN, et al.
AFFILIATIONS:	Emergency Department, ER Quality Improvement Committee
DESIGN:	Single center, prospective, non-randomized trial
METHOD:	Blood cultures were collected via venipuncture and new peripheral IV lines in the Emergency Department over a 2-month period. Patients non-randomized to either usual care or Steripath for blood culture collection.
RESULTS:	83% reduction in blood culture contamination using Steripath Standard procedure: 5.5% rate (13/237), Steripath: 0.9% rate (3/321)
SUMMARY:	Hospital-wide adoption of Steripath as the new standard practice

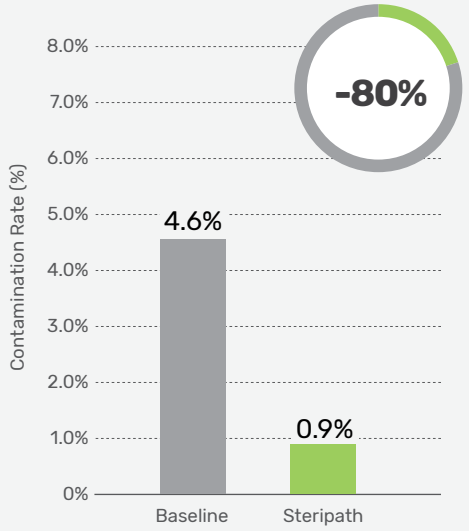
REDUCTION IN BLOOD CULTURE CONTAMINATION



MEDICAL UNIVERSITY OF SOUTH CAROLINA

TITLE:	Novel Blood Culture Collection Device Reduces False-Positive Blood Cultures, Saves Costs, and Increases Accuracy of Bloodstream Infection Diagnosis
PRESENTED AT:	***Institute for Healthcare Improvement National Forum*** (2017)
AUTHORS:	Lisa L Steed, PhD, D(ABMM), et al.
AFFILIATIONS:	Department of Pathology & Laboratory Medicine, Adult Emergency Department
DESIGN:	Single center, prospective, open label trial
METHOD:	ED nurses were trained on the use of the Steripath ISDD for blood culture collection via venipuncture and peripheral IV starts. Once trained, ED nurses used their judgment when to use ISDD.
RESULTS:	81% reduction in blood culture contamination for 20-months using Steripath. Baseline: 4.6% rate, Steripath: 0.9% rate.
SUMMARY:	Steripath ISDD use decreased false-positive blood cultures below 1% in a busy adult ED, well below the national benchmark of 3%. This reduction has been sustained for 20 months.

REDUCTION IN BLOOD CULTURE CONTAMINATION



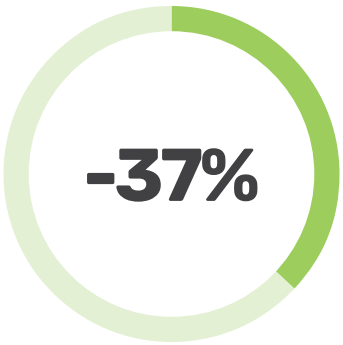
THE IMPACT:
ANTIBIOTIC USAGE, LENGTH OF STAY & COST EFFECTIVENESS

Steripath Clinical and Economic Evidence Report

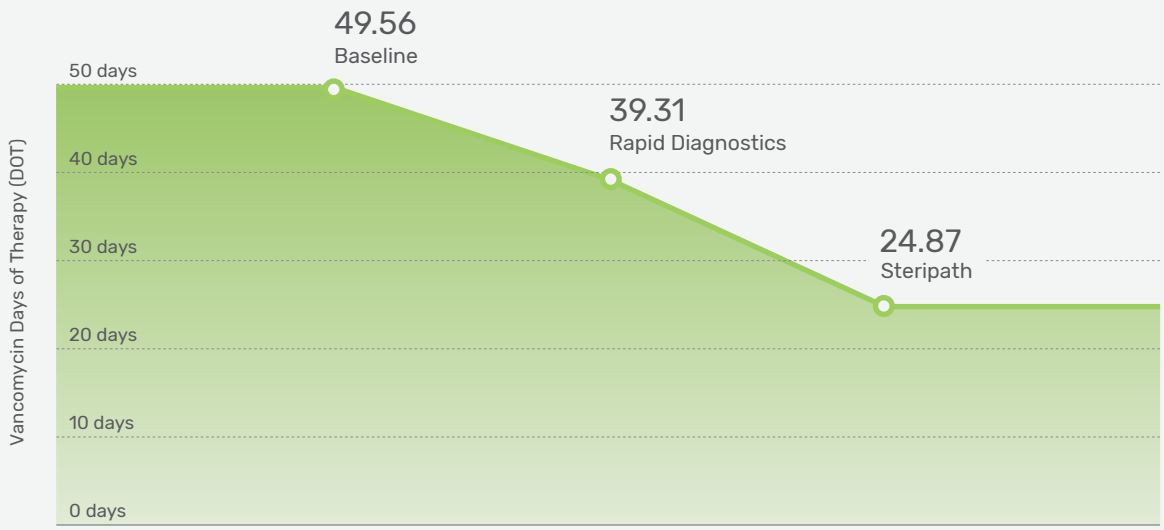
BROOKE ARMY MEDICAL CENTER

TITLE:	Impact of Blood Culture Diversion Device and Molecular Pathogen Identification on Vancomycin Use
PRESENTED AT:	***SHEA Conference*** (2017)
AUTHORS:	David Chang, MD, et al.
AFFILIATIONS:	Infectious Diseases, Clinical Microbiology, Antimicrobial Stewardship Program
DESIGN:	Single center, retrospective, non-randomized trial
METHOD:	Comparison of vancomycin DOT before and after interventions to reduce pathogen detection time (RDT) and blood culture contamination (Steripath) in ED. Hospital wide vancomycin DOT was collected through EMR.
RESULTS:	Vancomycin DOT per 1,000 patient days decreased 20%, 49.56 to 39.31 (P=0.001) after implementation RDT. Steripath resulted in an incremental decrease in vancomycin DOT by 37%, 39.31 to 24.87 (P=0.007).
SUMMARY:	De-escalation of vancomycin DOT was best achieved through a combination of a molecular detection assay (RDT) and use of Steripath for both venipuncture and new peripheral IV line blood culture draws.

INCREMENTAL REDUCTION IN VANCOMYCIN DOT:



REDUCTION IN VANCOMYCIN DAYS OF THERAPY (DOT) STUDY



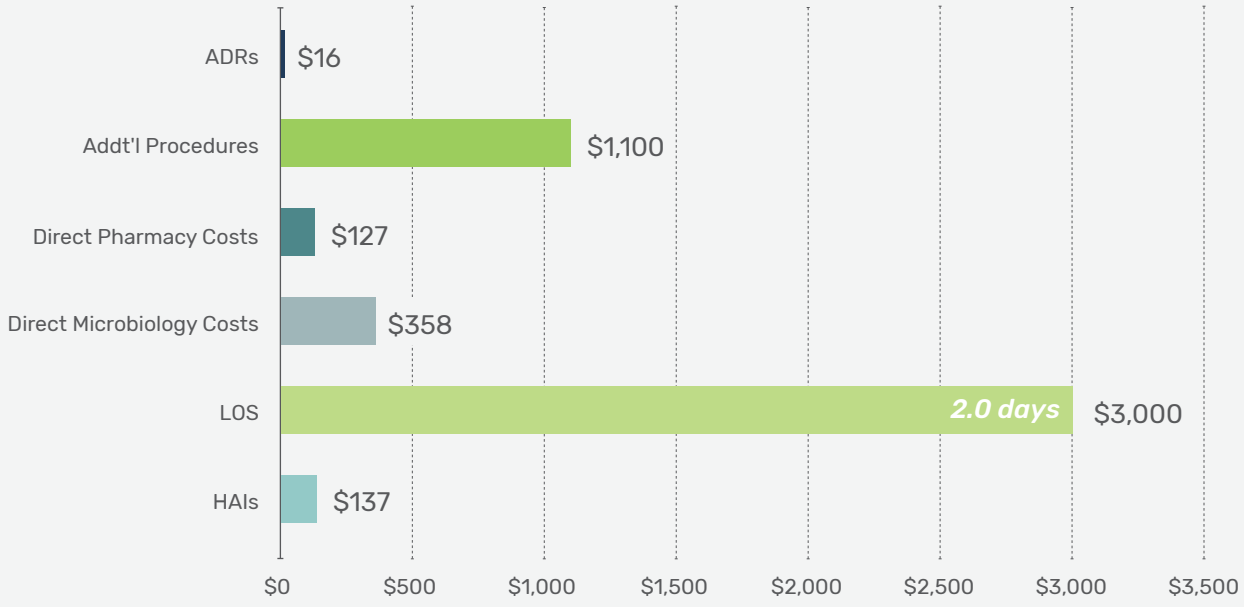
Peer Reviewed Publication

UNIVERSITY OF HOUSTON (COLLEGE OF PHARMACY)

TITLE:	Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: a Cost-Benefit Analysis
PUBLICATION:	***Journal of Clinical Microbiology*** (2019)
AUTHORS:	Erik Skoglund, et al.
AFFILIATIONS:	Pharmacy Practice and Translational Research, Pharmaceutical Health Outcomes and Policy, College of Pharmacy
DESIGN:	Decision tree analysis model
METHOD:	Decision tree health care economic model to assess the cost benefit of routine use of Steripath ISDD in a health system ED and to evaluate the downstream clinical and economic impacts of routine ISDD.
RESULTS:	Total costs of $4,739 per contamination event with a length of stay increase of 2.0 days. Estimated costs savings of $79-$367 per blood culture after adoption of Steripath.
SUMMARY:	These findings support the routine use of the Steripath ISDD for the collection of blood cultures in the ED as a cost-beneficial strategy to reduce the clinical and economic effect of blood culture contamination.

TOTAL ATTRIBUTABLE COSTS PER CONTAMINATION EVENT:

ATTRIBUTABLE COSTS OF BLOOD CULTURE CONTAMINATION



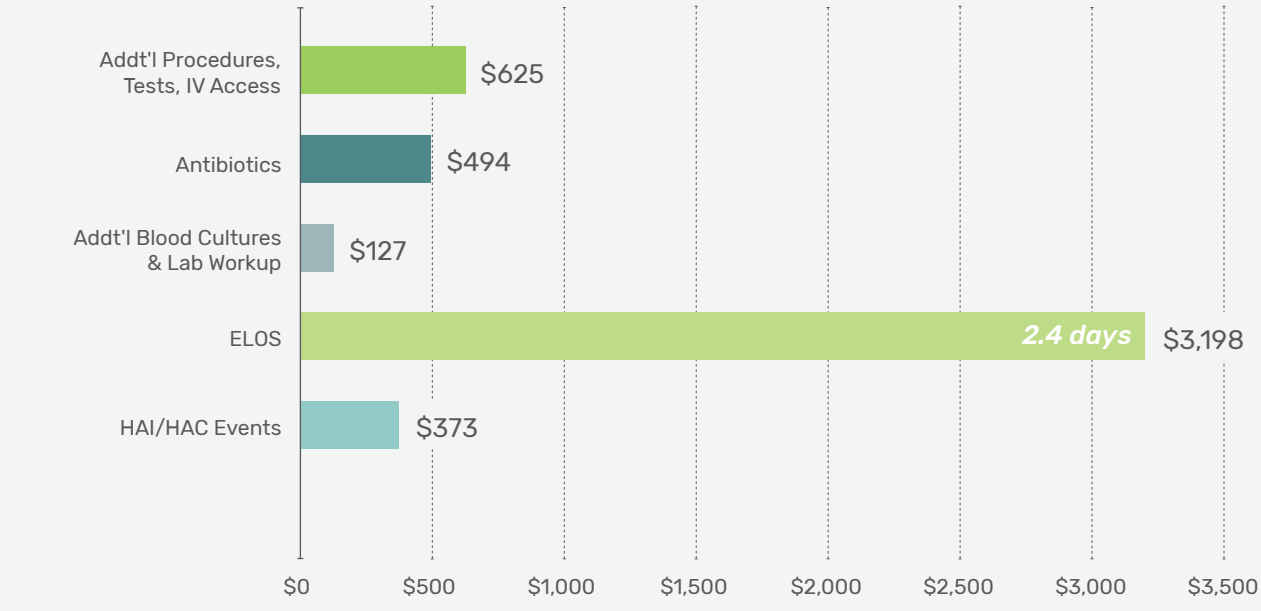
Peer Reviewed Publication

MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL, WING TECH INC

TITLE:	Model to Evaluate the Impact of Hospital-Based Interventions Targeting False-Positive Blood Cultures on Economic and Clinical Outcomes
PUBLICATION:	***Journal of Hospital Infection*** (2019)
AUTHORS:	B.P. Geisler, et al.
AFFILIATIONS:	General Medicine and Infectious Diseases, Mass General Infectious Diseases, Harvard Medical School
DESIGN:	Retrospective matched survival analysis
METHOD:	Based on hospitalized patients with septicaemia-compatible symptoms. BCC costs, HACs and potential savings were calculated based on the primary LOS data, a modified Delphi process and published sources.
RESULTS:	Total costs of $4,817 per contamination event with a length of stay increase of 2.4 days. Estimated costs savings of $186 per blood culture after adoption of Steripath.
SUMMARY:	The use of Steripath ISDD is the single most effective intervention so far explored for reducing costs related to false-positive blood cultures, saving the typical 250- to 400-bed hospital $1.9M or $186 per blood culture, and preventing 34 HACs (including three *C. difficile* cases)

TOTAL ATTRIBUTABLE COSTS PER CONTAMINATION EVENT

ATTRIBUTABLE COSTS OF BLOOD CULTURE CONTAMINATION



Steripath®

PHONE	1-888-617-3420
EMAIL	info@magnolia-medical.com
WEB	magnolia-medical.com

MAGNOLIA®
MEDICAL TECHNOLOGIES

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