

**MISSION
TO ZERO** 

**National Movement to a New Blood
Culture Contamination Benchmark of**

1%

Are you Ready?

Speakers



Gary Doern, PhD (ABMM)

Professor Emeritus, Dept. of Pathology
University of Iowa Carver School of Medicine
Former Editor in Chief Journal of Clinical Microbiology

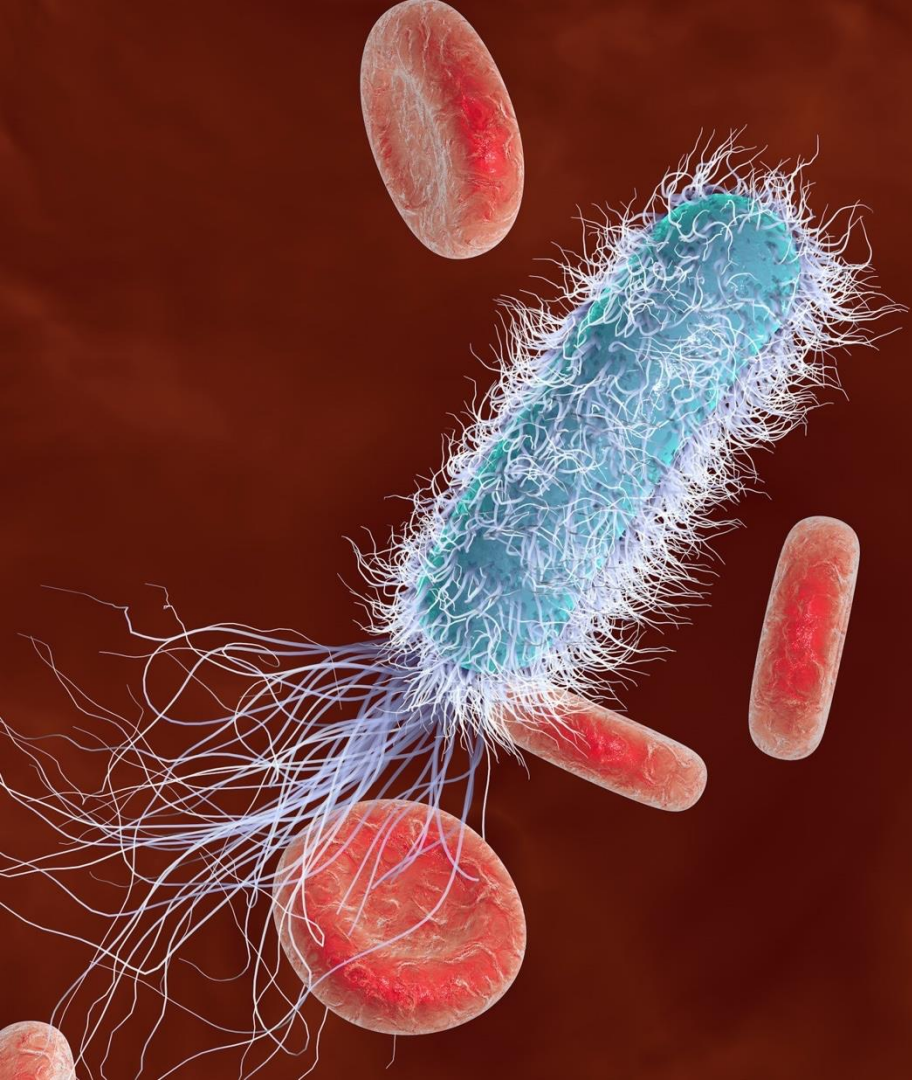


Barbara DeBaun, RN, MSN, CIC

Improvement Advisor for Cynosure Health
Former Director, Patient Safety and Infection Control
California Pacific Medical Center, San Francisco

Learning Objectives

- 1 Discuss the national movement towards a new blood culture contamination benchmark of less than 1.0% and when your hospital will be impacted
- 2 Describe the downstream patient, lab and economic impact of false-positive blood cultures with a focus on driving diagnostic and antibiotic stewardship to mitigate antibiotic resistance
- 3 Review traditional intervention methods to reduce blood culture contamination and their limited effectiveness
- 4 Describe best practices and an evidence-based Initial Specimen Diversion Device (ISDD) that can deliver sustained blood culture contamination rates of less than 1.0% in the ED and hospital-wide.
- 5 Discuss recent clinical studies that have demonstrated how hospitals achieved and sustained blood culture contamination rates as low as 0.0% utilizing the ISDD solution.



Sepsis is the #1 cause of death and readmissions in U.S. hospitals¹

... and blood cultures remain the gold standard for diagnosing this disease

¹ Finger K (Truven Health Analytics), Washington R (AHRO). Trends in Hospital Readmissions for Four High-Volume Conditions, 2009-2013. HCUP Statistical Brief #196. November 2015. Agency for Healthcare Research and Quality, Rockville, MD.

Statement of the Problem

Focal Infections leading to bacteremia



SEPSIS

- **1.7 million** cases of sepsis resulting in **270,000** deaths annually in the U.S.
- **30-50%** of hospital deaths due to sepsis

The Diagnosis of Sepsis



Phlebotomy



Inoculation of blood culture bottles



Processing in the laboratory

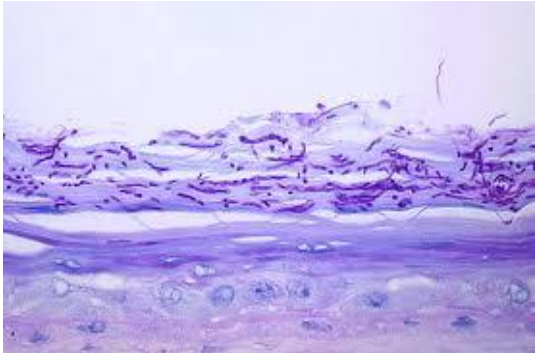


- 16-48 hours later blood culture becomes positive
- Then all treatment is optimized

But It Ain't That Simple...



3-5% of blood cultures are contaminated



Let's Do Some Arithmetic...

Approximately **40M** blood cultures performed annually in the U.S.



~ 3% contamination rate

At least **1.4M** contaminated blood culture events annually in the U.S.
\$6B in avoidable costs to U.S. healthcare system

What are the Consequences of Contaminated Blood Cultures?

Laboratory Impacts

- Negatively impacts workflow
- Unnecessary tests
- Negatively impacts process, productivity, performance
- Major contributor to overtime
- Significantly increases avoidable costs

Doern *et al*, CMR 2020



Let's Do Some More Arithmetic at a 1% Benchmark...

Approximately **40M** blood cultures performed annually in the U.S.

~ **3%** contamination rate



~**1.4M** contaminated blood cultures annually in the U.S.

\$6B in avoidable costs to U.S. healthcare system

~ **1%** contamination rate

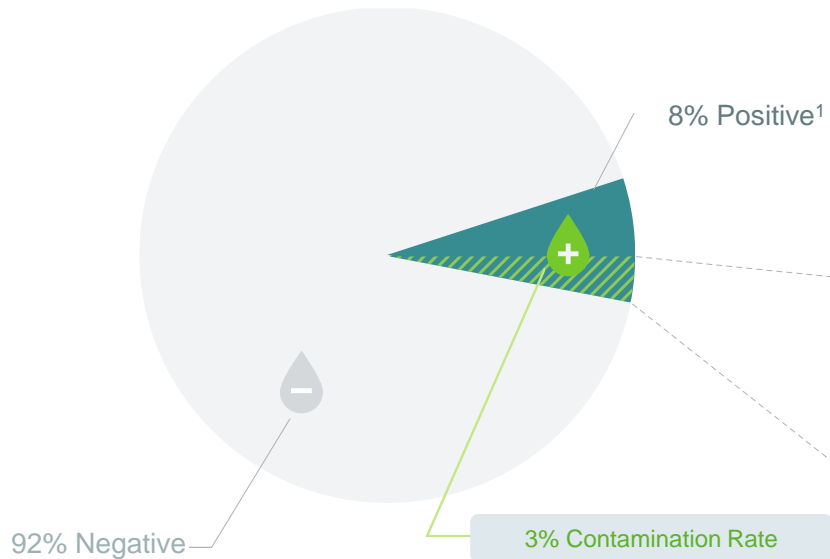


~**400K** contaminated blood cultures annually in the U.S.

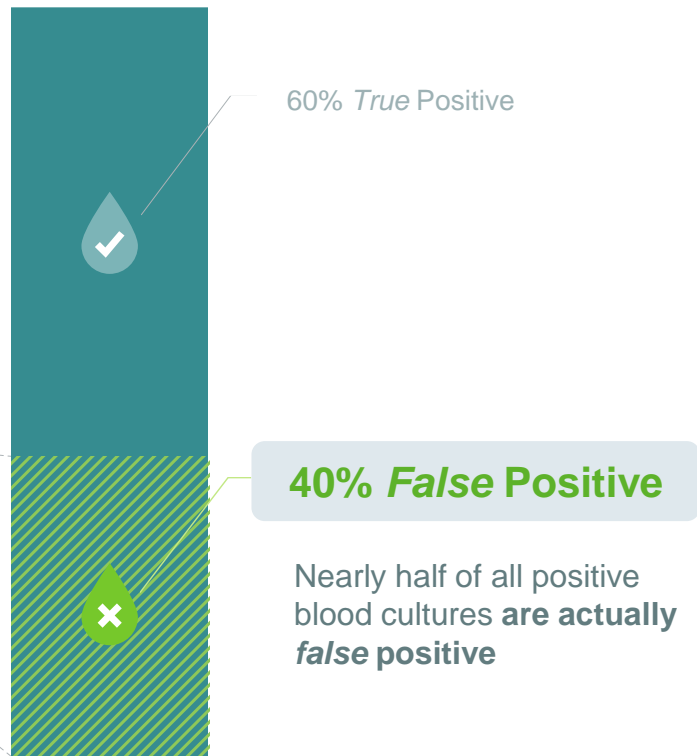
\$1.7B in avoidable costs to U.S. healthcare system

Test Results for Sepsis are Frequently Wrong

ALL BLOOD CULTURES



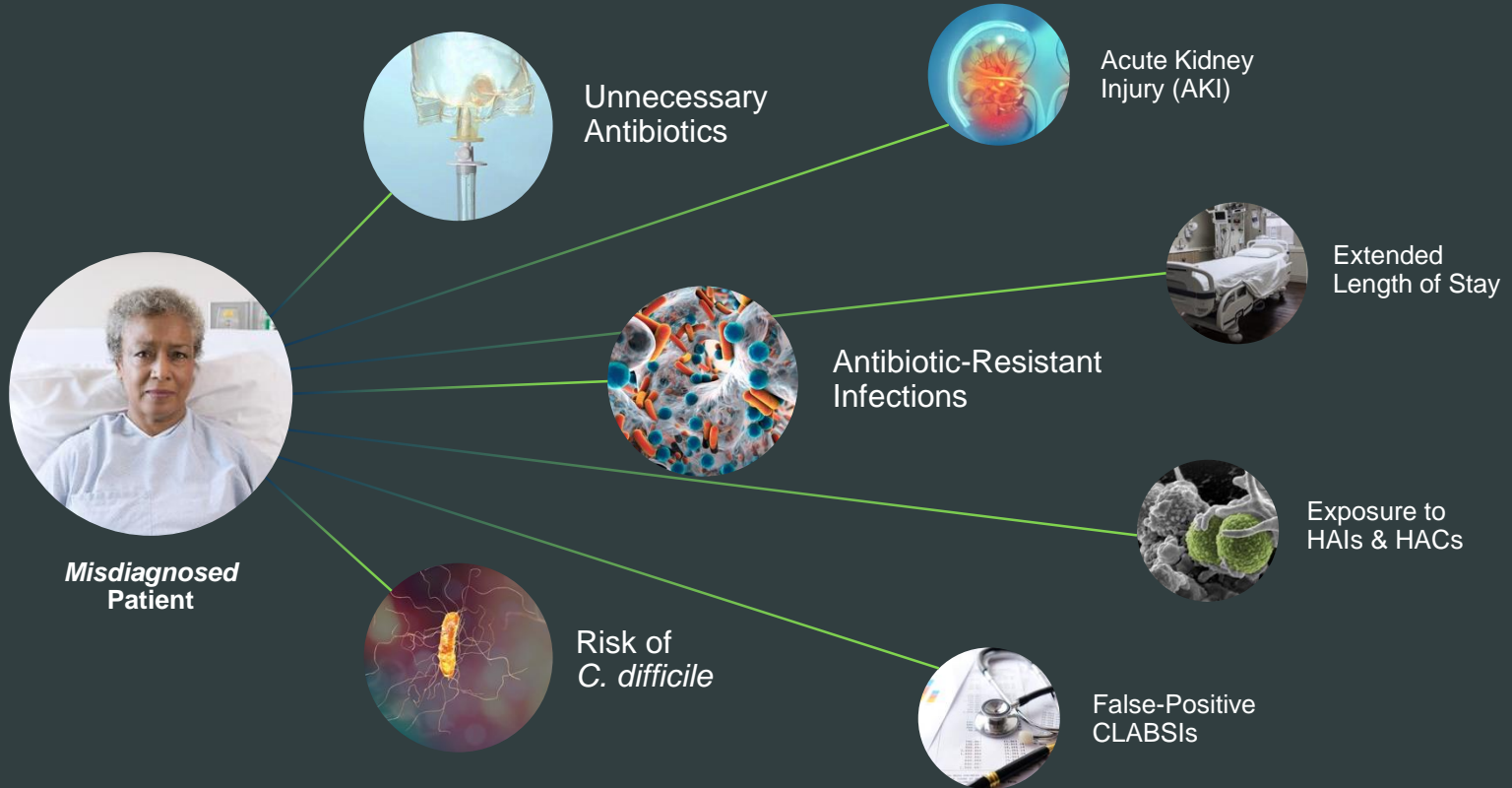
POSITIVE BLOOD CULTURES



False positives are a *preventable error* and can lead to a misdiagnosis of sepsis

¹Zwang O, Albert RK. Analysis of Strategies to Improve Cost Effectiveness of Blood Cultures. J Hosp Med. 2006 Sep;1(5):272-6.

False-positive blood cultures increase *many* harmful patient safety risks





- **Hospitals report HACs to NHSN**

1. CAUTI
2. SSI
3. *C. difficile*
4. MRSA
5. CLABSI

Significantly impacted by BC contamination

- **National SIR for CLABSIs increased 28% during COVID**

(Q2 '20 vs. Q2 '19)¹

- Critical Care Units increased most at **39%**¹

- **NHSN reports HACs to CMS**

- Impacts hospital's CMS reimbursement and penalties
- **Up to 7%** CMS revenue loss plus cost of initial care

Current National 'Standard'

for blood culture contamination



**Current benchmark
for blood culture
contamination rates
in the U.S.¹**

BUT IS THIS 'STANDARD' GOOD FOR PATIENTS?

¹Clinical and Laboratory Standards Institute (CLSI). Principles and procedures for blood cultures: approved guideline, Vol. 46, No. 31. Wayne (PA): Clinical and Laboratory Standards Institute; 2007. CLSI document M47-A.

What this means at a typical hospital

3% blood culture contamination rate in an **Emergency Department**



Patient Safety

Cultures / month: **833**

Contamination Rate: **X** **3.0%**

Patients impacted by
false positives / month: **=** **25**



Hospital Economics

Patients impacted / year: **300**

Average cost per
incident^{1,2} **X** **\$3,997**

Avoidable costs: **=** **\$1,199,100**

¹Skoglund, E., et al (2018). "Estimated Clinical and Economic Impact Through Use of a Novel Blood Collection Device [Steripath] to Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis." [J Clin Microbiol.](#)
²Geisler, B., et al (2018). "Potential Cost Savings and Decreased Clinical Burden Associated with Reducing Blood Culture Contamination." Submitted for publication

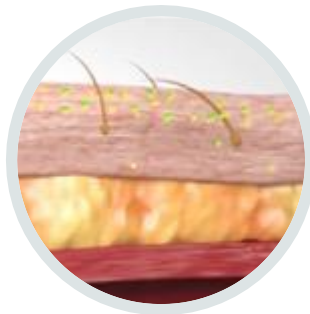
Training and Education on Best Practices Alone Will Not Solve the Problem

Contamination, It's Not Anyone's Fault



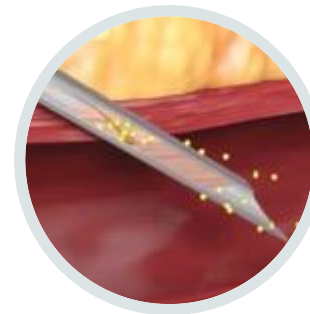
Human Factor(s)

Risk of contamination during assembly, preparation of supplies and skin prep



Skin Flora

You can disinfect but not sterilize the skin. Up to 20% of skin flora remains viable in the keratin layer of the skin even after skin prep¹



Skin Plug and Fragments

will enter the culture specimen bottle and commonly will contain viable microorganisms (when present)

Active diversion of the **initial 1.5-2.0 mL of blood** using a closed system (Steripath) has been clinically proven to reduce blood culture contamination^{2,3}

¹Anjanappa T. et al; Preparative Skin Preparation and Surgical Wound Infection. *Journal of Evidence based Medicine and Healthcare*. (January 2015)

²M. Rupp, et al; Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases* (August 2017)

³Bell, et al. *Journal of Emergency Nursing* (2018)

Manual Diversion (waste tube) Will Not Solve The Problem



Manual diversion of the initial volume of blood

- Peer-reviewed published data has shown only **modest unsustainable** reductions in contamination
- **Lowest published contamination rate achieved is 2.0%¹** (best case controlled clinical study scenario)

Active diversion of the **initial 1.5-2.0 mL of blood** using a closed system (Steripath) has been clinically proven to deliver up to **10 times greater reduction** in blood culture contamination^{2,3,4,5}

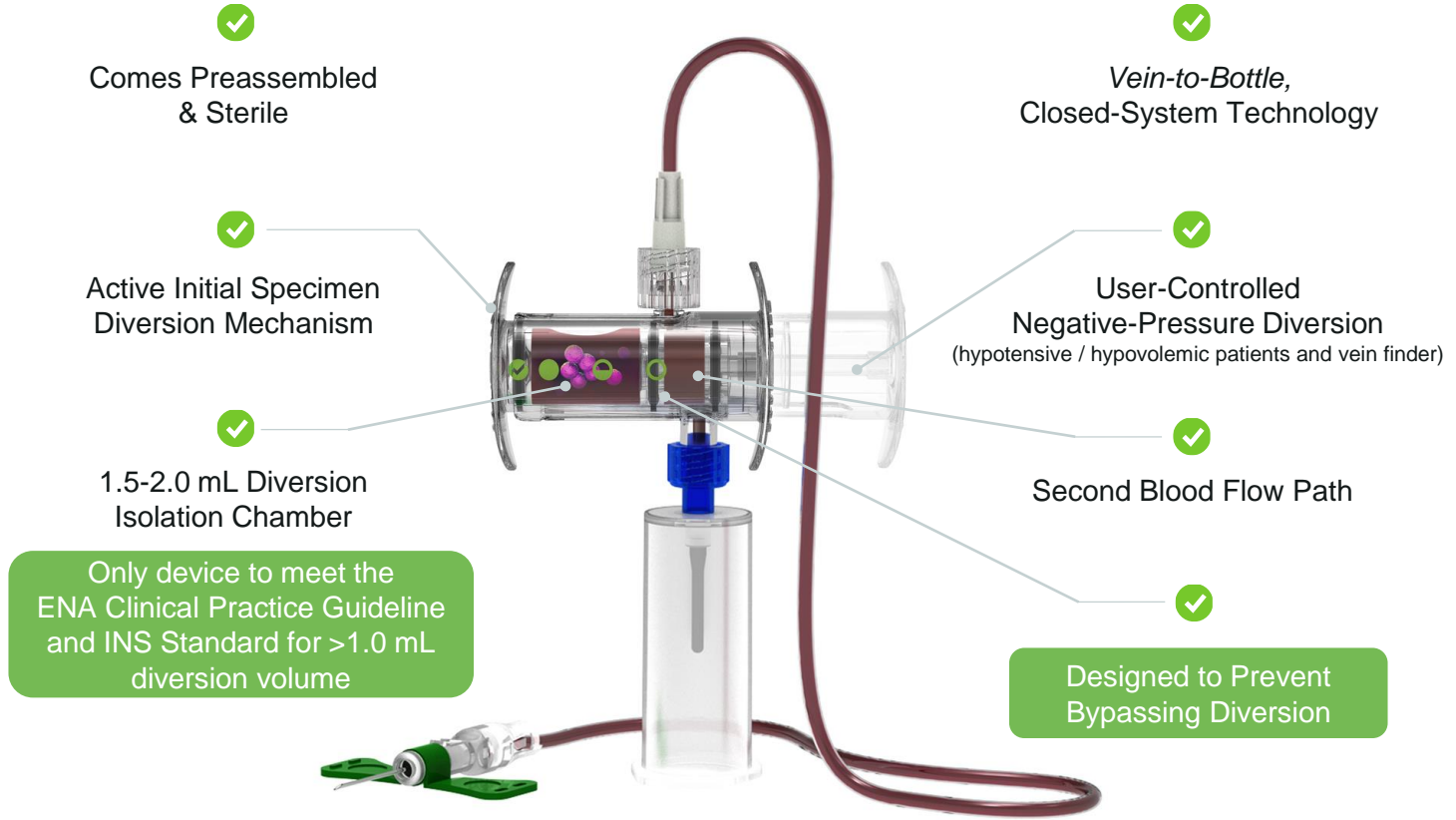
Prevention Strategies To-Date: They're Not Enough!

- Training and Education
- Appropriate skin disinfection
- Dedicated Phlebotomy Teams
- Manual Diversion
- Avoiding central line draws



Engineering Out Human Factors

Only FDA 510(k)-cleared device indicated to reduce blood culture contamination



Enables Peripheral IV (PIV) Start Blood Culture Draws

Steripath via PIV and butterfly deliver equivalent near-zero sustained contamination rates

Clinically Proven Effective



The only device clinically proven to reduce blood culture contamination via PIV starts¹

11 studies including 3 peer-reviewed publications

Effective Diversion Volume



1.5-2.0 mL diversion volume is clinically proven effective for draws from PIV starts¹



9" Luer Extension

CT Compatible
(400 PSI rated)



Nursing Efficiency

Enables nurses to leverage PIV starts for blood culture draws

Eliminates up to 2 venipunctures per patient



+ Patient Experience

Prevents patients from enduring unnecessary venipunctures



The ***only*** FDA 510(k)-cleared
device ***indicated*** to reduce blood
culture contamination¹

Clinical Infectious Diseases

MAJOR ARTICLE



Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device

Mark E. Rupp,¹ R. Jennifer Cavaleri,¹ Cole Marshall,¹ and Elizabeth Lyden²¹Division of Infectious Diseases, and ²Department of Epidemiology, University of Nebraska Medical Center, Omaha

(See the Editorial Commentary by McAdam on pages 206–7.)

Background. Blood culture contamination is a clinically significant problem that results in patient harm and excess cost. **Methods.** In a prospective, controlled trial at an academic center Emergency Department, a device that diverts and sequesters the initial 1.5–2 mL portion of blood (which presumably carries contaminating skin cells and microbes) was tested against standard phlebotomy procedures in patients requiring blood cultures due to clinical suspicion of serious infection.

Results. In sum, 971 subjects granted informed consent and were enrolled resulting in 904 nonduplicative subjects with 1808 blood cultures. Blood culture contamination was significantly reduced through use of the initial specimen diversion device[®] (ISDD) compared to standard procedure: (2/904 [0.22%] ISDD vs 16/904 [1.78%] standard practice, $P = .001$). Sensitivity was not compromised: true bacteremia was noted in 65/904 (7.2%) ISDD vs 69/904 (7.6%) standard procedure, $P = .41$. No needlestick injuries or potential bloodborne pathogen exposures were reported. The monthly rate of blood culture contamination for all nurse-drawn and phlebotomist-drawn blood cultures was modeled using Poisson regression to compare the 12-month intervention period to the 6 months before and after periods. Phlebotomists (used the ISDD) experienced a significant decrease in blood culture contamination while the nurses (did not use the ISDD) did not. In sum, 73% of phlebotomists completed a post-study anonymous survey and widespread user satisfaction was noted.

Conclusions. Use of the ISDD was associated with a significant decrease in blood culture contamination in patients undergoing blood cultures in an Emergency Department setting.

Clinical Trials Registration. NCT02102087.**Keywords.** blood culture; contamination; initial specimen diversion device.

Blood cultures are frequently obtained in the care of patients with serious infections to detect bacteremia and fungemia and guide specific antimicrobial therapy. Unfortunately, contamination rates routinely range from 0.6% to 6%, resulting not infrequently in unnecessary antibiotic treatment and added laboratory expense [1]. False-positive blood cultures increase laboratory costs by approximately 20%, are associated with a nearly 40% increase in antibiotic charges, are treated with antimicrobials up to one half of the time, extend the length of hospital stay by up to 5 days, and subject patients to the real harms associated with antibiotic exposure such as toxicity, adverse effects, interactions, and emergence of resistance [2–7]. Because of their clinical significance, great efforts have been expended to limit false-positive blood cultures including the use of various skin disinfectants, trained phlebotomy teams, blood culture kits, needle exchange

systems, culture bottle disinfection protocols, use of sterile gloves, and other programmatic attempts to limit contamination [1, 2, 8, 9]. Contamination of blood cultures is thought to be due in part to skin fragments colonized with bacteria that are dislodged with venipuncture [10]. The purpose of this study was to test a device that diverts and sequesters the first 1.5–2 mL portion of blood, which presumably carries the contaminating skin fragments, from the culture specimens to determine whether blood culture contamination is diminished [11].

METHODS**Study Design**

Single center, prospective, controlled, open label trial. This study was reviewed and approved by the UNMC Institutional Review Board. This trial was registered at clinicaltrials.gov (NCT 02102087).

Setting

Emergency department and trauma center in an urban 689-bed university hospital.

Test Device

Initial specimen diversion device (ISDD) (SteriPath[®], Magnolia Medical Technologies), a pre-assembled, sterile blood culture

TITLE:

Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device[®] [SteriPath[®]]

PUBLICATION:

Clinical Infectious Diseases - 2017;65 (15 July)

INSTITUTE:

University of Nebraska Medical Center

AUTHORS:

Mark E. Rupp, MD, et al

AFFILIATIONS:

Division of Infectious Disease, 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.

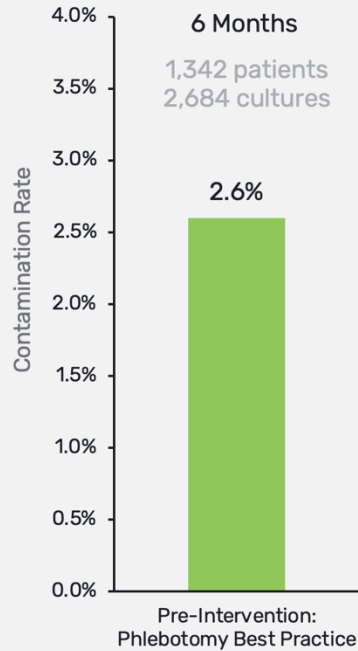
- 1) One using Phlebotomy best practices
- 2) One using SteriPath

Received 21 December 2016; editorial decision 1 March 2017; accepted 29 March 2017; published online May 17, 2017.
Correspondence: M. E. Rupp, 965400 Nebraska Medical Center, Omaha, NE 68198 (rupp@unmc.edu).

Clinical Infectious Diseases © 2017, 65(15):201–6
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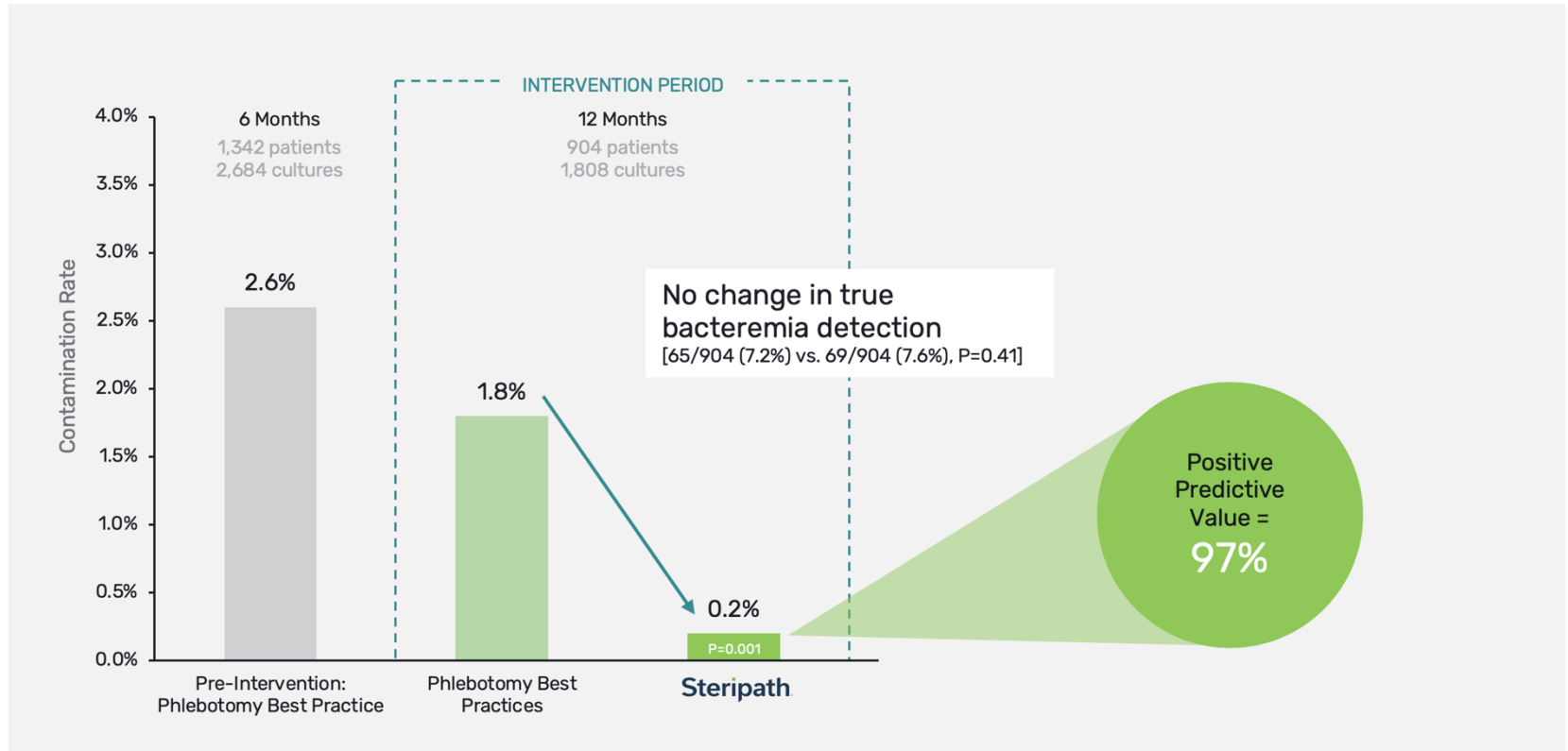
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device[®] [Steripath[®]]

Clinical Infectious Diseases - 2017:65 (15 July)



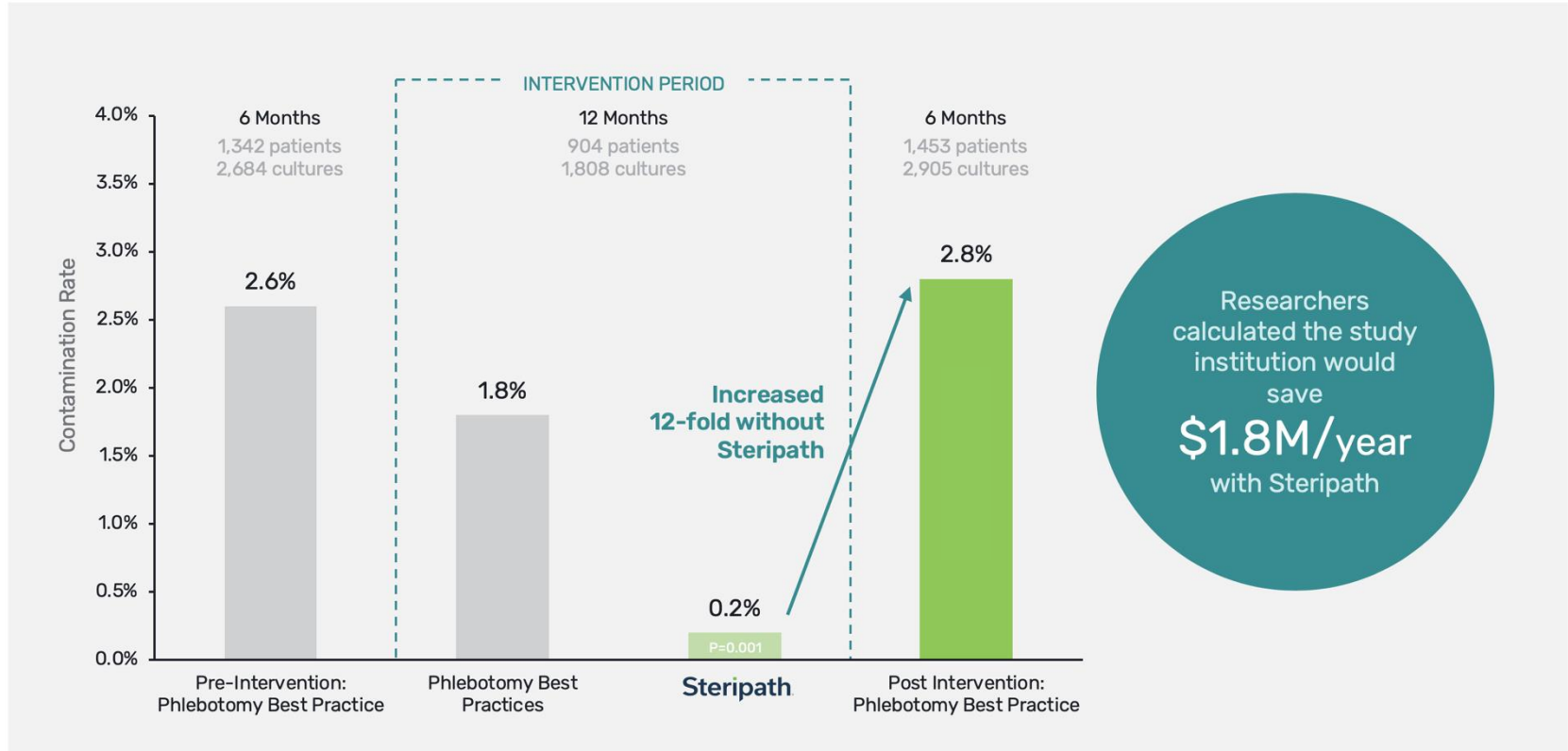
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device® [Steripath®]

Clinical Infectious Diseases - 2017:65 (15 July)



Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device[®] [Steripath[®]]

Clinical Infectious Diseases - 2017;65 (15 July)



TITLE: Effectiveness of a Novel Blood Culture Collection System in Reducing Blood Culture Contamination Rates in the ED

PUBLICATION: *Journal of Emergency Nursing – 2018*

INSTITUTE: Lee Health (multicenter trial n=4)

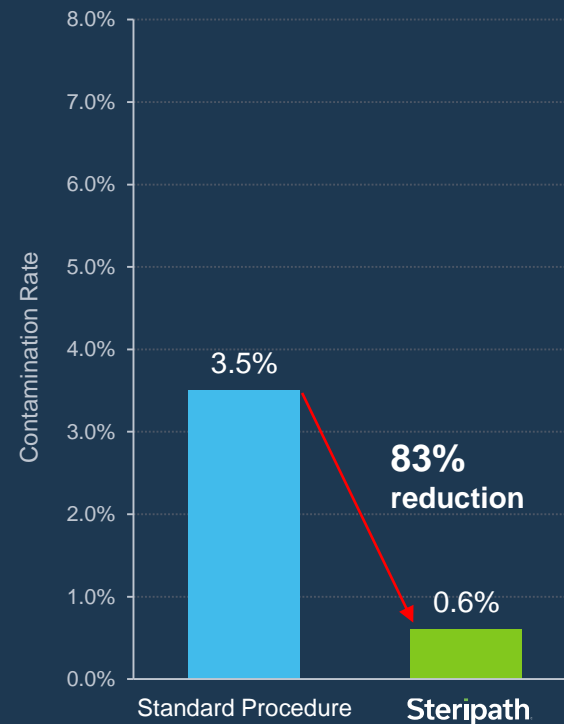
AUTHORS: Bell, M. MSN, RN, CEN, et al

AFFILIATIONS: Department of Emergency Medicine

METHOD: Blood cultures contamination rates with Steripath collected via **venipuncture & peripheral IV starts** were compared historical rates via standard method

RESULTS: **83%** reduction in contamination with Steripath.
Steripath: **0.6% (P=0.0001)** contamination rate (38/6,293)
Standard procedure: **3.5%** contaminate rate for (1,238/35,392)

SUMMARY: Prevented **182** false positive events
86% of Steripath draws are via PIV starts
Cost savings of **\$641,792** during a 7-month trial period



TITLE: Getting to Zero: Eliminating Blood Culture Contamination Using the Initial Specimen Diversion Device (Steripath Gen2 ISDD)

CONFERENCE: *IDWeek 2020 and PACCARB 2021*

INSTITUTE: **Stanford Health Care**

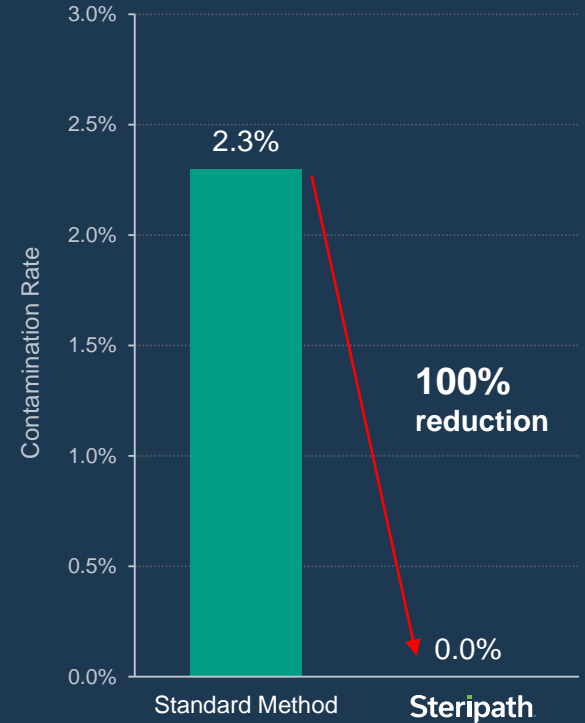
AUTHORS: Lucy Tompkins, MD, PhD et al

DESIGN: Single center, prospective, controlled study
March 2019–January 2020 (10-months)








METHOD: Blood cultures were obtained **hospital-wide** by **Phlebotomy team** using the Steripath Gen2 compared to standard method

RESULTS: **100%** reduction in blood culture contamination using Steripath
Steripath Gen2: **0.0% (0/11,202)** contamination rate
Standard procedure: **2.3% (111/4,759)** contamination rate

NHSN/CMS Reportable False-Positive CLABSIs
1 with Steripath
12 with standard method
 SIR fell by **30-50%** when contaminants were removed



Steripath. Peer-Reviewed Published Studies and Clinical Study Presentations at Major Medical Conferences

#	Institution	Publication or Conference Presentation	Date	Duration	Baseline or Control Rate	Steripath® Rate	BCC Reduction	Ann. Savings
1	Stanford Health Care	IDSA – IDWeek / PACCARB	2020	11 months	3.9%	0.0%	100%	NR
2	Central Texas VA Medical Center	Journal of Emergency Nursing 	2021	5 months	2.2%	0.0%	100%	NR
3	Univ. of Nebraska Medical Center	Clinical Infectious Diseases 	2017	12 months	1.8%	0.2%	88%	\$1,800,000
4	Baylor Scott & White Med Ctr.	Emergency Nurses Association (ENA)	2021	4 months	3.2%	0.2%	93%	NR
5	Kern Medical Center	Association for Professionals in Infection Prevention (APIC)	2021	18 months	2.4%	0.4%	83%	NR
6	Lee Health System (4 sites)	Journal of Emergency Nursing 	2018	7 months	3.5%	0.6%	83%	\$1,100,000
7	Brooke Army Medical Center	DOD Healthcare Quality Safety Award	2016	5 months	7.7%	0.6%	92%	\$564,000
8	Medical Univ. of South Carolina	Institute for Healthcare Improvement (IHI)	2016	8 months	4.2%	0.6%	86%	NR
9	Rush University Medical Center	IDSA - IDWeek	2017	3 months	4.3%	0.6%	86%	NR
10	Inova Fairfax Hospital	Emergency Nurses Association (ENA) 	2019	12 months	4.4%	0.8%	82%	\$932,000
11	SCL St. Mary's Medical Center	American Organization for Nursing Leadership (AONL)	2020	6 months	3.3%	0.8%	76%	NR
12	Beebe Healthcare	American Society for Microbiology (ASM)	2018	4 months	3.0%	0.8%	75%	NR
13	Medical Univ. of South Carolina	Institute for Healthcare Improvement (IHI)	2017	20 months	4.6%	0.9%	80%	\$447,000
14	Ascension Via Christi (3 sites)	Society of Hospital Epidemiology of America (SHEA)	2021	3 months	4.3%	0.9%	80%	NR
15	VA Houston	Emergency Nurses Association (ENA)	2018	7 months	5.5%	0.9%	83%	NR
16	Shaare Zedek Medical Center	American Journal of Infection Control 	2019	6 months	5.2%	1.0%	81%	NR
17	Brooke Army Medical Center	Society for Healthcare Epidemiology of America (SHEA)	2017	14 months	37% reduction in vancomycin DOT (P=0.007)			
18	University of Houston	Journal of Clinical Microbiology 	2019	Steripath ISDD can save the hospital 2.0 bed days and \$4,739 per false positive blood culture event				
19	Mass General/ Harvard/ WingTech	Journal of Hospital Infection 	2019	Steripath ISDD can save the hospital 2.4 bed days , \$4,817 per false positive blood culture event and \$1.9M annually & prevent 34 HACs including 3 C.diff				



Proposed *New National Standard*

for blood culture contamination

Standard of Care Initiative



**benchmark for
blood culture
contamination rates
in the U.S.**

*achieved by using Mechanical Initial
Specimen Diversion Device*

THE RIGHT 'STANDARD' FOR PATIENTS



Gary Doern, PhD
Professor Emeritus, Dept of Pathology
University of Iowa
Former Editor-in-Chief, J Clin Micro



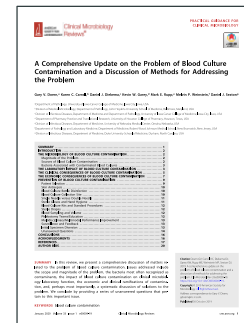
Dan Sexton, MD
Professor, Infectious Diseases
Duke University
Chair, Duke IC and AMS Outreach Network



Clinical Microbiology
Reviews

Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem

Call-to-action: New National Blood Culture
Contamination Benchmark of $\leq 1.0\%$



Melvin Weinstein, MD
Professor, Chief Infectious Diseases
RWJ University Hospital



Dan Diekema, MD
Professor, Director Infectious Diseases
University of Iowa Med Ctr.



Karen Carroll, MD
Professor, Director Div. Microbiology
Johns Hopkins



Kevin Garey, PharmD
Professor, Chair Pharmacy and Research
University of Houston College Pharmacy



Mark Rupp, MD
Professor, Chief Infectious Diseases
University of Nebraska Med Ctr.

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria



Lucy Tompkins, MD, PhD

*Professor, Infectious Diseases and Microbiology
Hospital Epidemiologist
Medical Director, Infection Prevention & Control
Stanford University Hospital*

“As a human-factor engineered device, Steripath can dramatically reduce blood culture contamination and has clearly demonstrated that getting to **0.0% is achievable**,” added Dr. Tompkins.”

“As a result of our experience with the Steripath Gen2 platform, we join others in the national movement to establish a goal of 0.0% blood culture contamination starting with a **new standard benchmark of less than 1.0%** as the new standard of care.”

CLSI M47 ED2-2021 (Proposed Draft) *Principles and Procedures for Blood Cultures*

Published for public comment on May 11, 2021



National Movement to

1%

“It should be possible to achieve blood culture contamination rates substantially lower than **3%** even if **0%** is not reached; when best practices are followed, a target contamination rate of **1%** is achievable.”

Quality Indicator:

“The benchmark for blood culture contamination rate is less than **3%**, with a benchmark of **1%** with best practices.”



U.S. Department of Veterans Affairs

117TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
1st Session } { 117-81

MILITARY CONSTRUCTION, VETERANS AFFAIRS, AND
RELATED AGENCIES APPROPRIATIONS BILL, 2022

JULY 2, 2021.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Ms. WASSERMAN SCHULTZ of Florida, from the Committee on
Appropriations, submitted the following

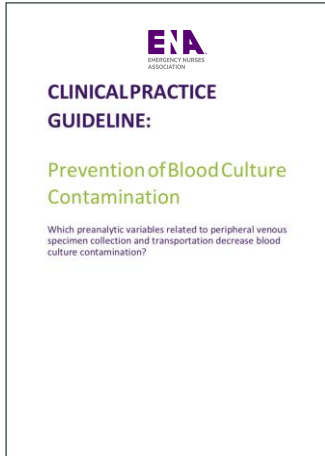
R E P O R T

House of Representatives passage of
H.R. 4355, Military Construction, Veterans Affairs,
and Related Agencies Appropriations Act, 2022
("MILCON-VA")
July 2021

“Reducing Blood Culture Contamination – The Committee is aware that blood culture contamination leads to **enormous clinical implications, laboratory ramifications, and economic costs.**

The Committee directs VA to prioritize the development of a **specific quality measure** for blood contamination based on the recommendation of **less than 1%** blood culture contamination rate within 6 months of enactment.

VA is directed to report to the Committees on Appropriations of both Houses of Congress **within 180 days of enactment** of this Act detailing the implementation of this standard of care across the VA medical system.”

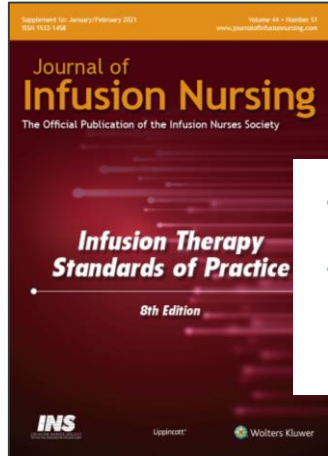
ENA
EMERGENCY NURSES ASSOCIATION

CLINICAL PRACTICE GUIDELINE:

Prevention of Blood Culture Contamination

Which preanalytic variables related to peripheral venous specimen collection and transportation decrease blood culture contamination?

1.0–2.0 mL
diversion
volume



ISSN 1525-4066

Volume 44 • Number 11
November 2021

Journal of Infusion Nursing
The Official Publication of the Infusion Nurses Society

Infusion Therapy Standards of Practice
8th Edition

INS
Lippincott® Wolters Kluwer

1.5 mL or greater
diversion
volume



CLINICAL AND LABORATORY STANDARDS INSTITUTE

DRAFT - 2021

M47-A
Principles and Procedures for Blood Cultures;

1.0 mL
diversion
volume

The **only** device that meets the evidence-based guidelines and standards for diversion

(M47 ED2 Proposed Draft - 2021)



National Movement to 1% Benchmark



Achieve zero or near-zero blood culture contamination and false positive CLABSIs





Your Role in Achieving $\leq 1\%$

- ✓ Implement and monitor blood culture best practices
- ✓ Adopt an engineered technology solution: Steripath

Improve *Sepsis Testing Accuracy* Improve *Patient Outcomes*

- ✓ Reduce unnecessary and inappropriate antibiotic treatment
- ✓ Drive antibiotic stewardship
- ✓ Lessen risk of *C. difficile*, MDROs, kidney injury and other antibiotic-related complications
- ✓ Reduce unnecessary length of stay and associated HAIs/HACs
- ✓ Prevent risk of false-positive CLABSIs
- ✓ Drive significant hospital hospital cost savings

**MISSION
TO ZERO** 

More Information.

- ✓ info@magnolia-medical.com
- ✓ 888.617.3420
- ✓ www.magnolia-medical.com