

Clean Collect®

Blood Culture Diversion System

- Reduces contamination
- Improves patient outcomes
- Saves hospital resources



Stone Medical Corporation



Fisher
HealthCare

Blood Culture Contamination

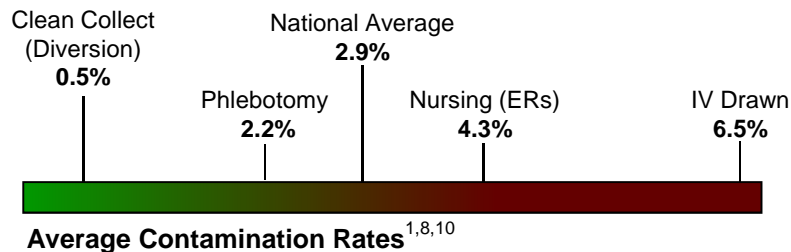


Overview

- **Sources:** Primary source of contamination is the ER where blood cultures are often drawn through IVs by nurses.¹
- **Patient Impact:** Contaminated blood cultures result in or prolong unnecessary treatment with broad spectrum IV antibiotics.²
- **Hospital Impact:** Average cost per contaminant has been measured at \$6,283 in published clinical trials.^{3,4,5,6} These costs are not typically reimbursed.⁷
- **Solutions:** Clean Collect provides a means to permanently control contamination rates.^{8,9}



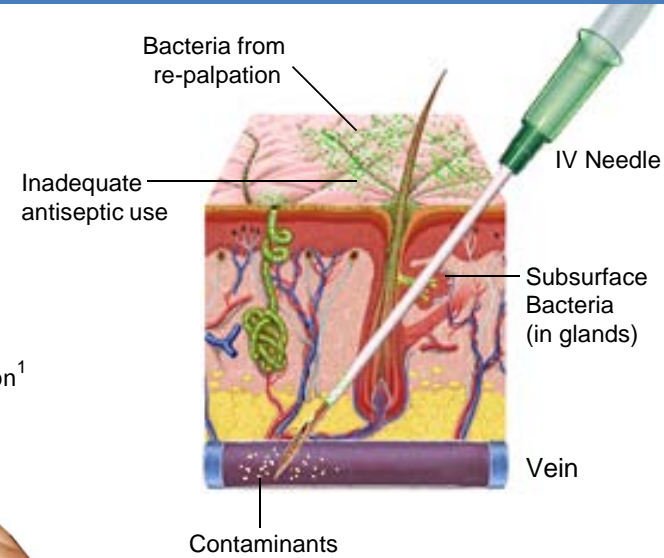
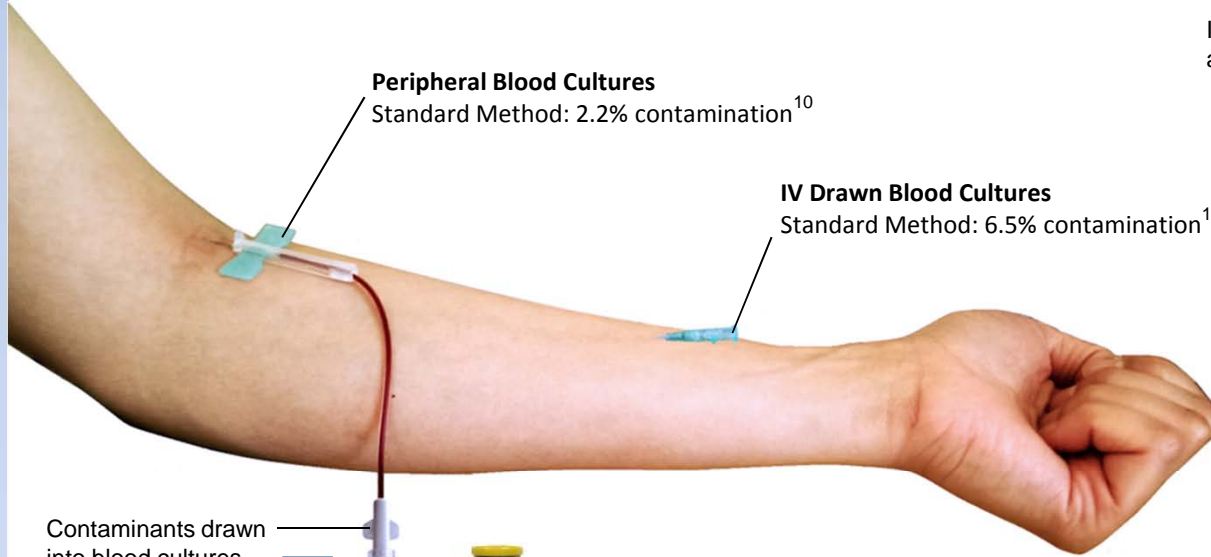
Blood Culture Systems
(Bactec®, BacT/Alert®, and VersaTREK®)



Sources of Contaminants



Standard Methods



Contaminants drawn into blood cultures



1



Blood Culture Bottles*

2



Other Non-Sterile Tubes

Sources of Contamination:

1. Re-palpation
2. Inadequate Antiseptic Use
3. Subsurface Bacteria
4. Equipment (luers, syringes)

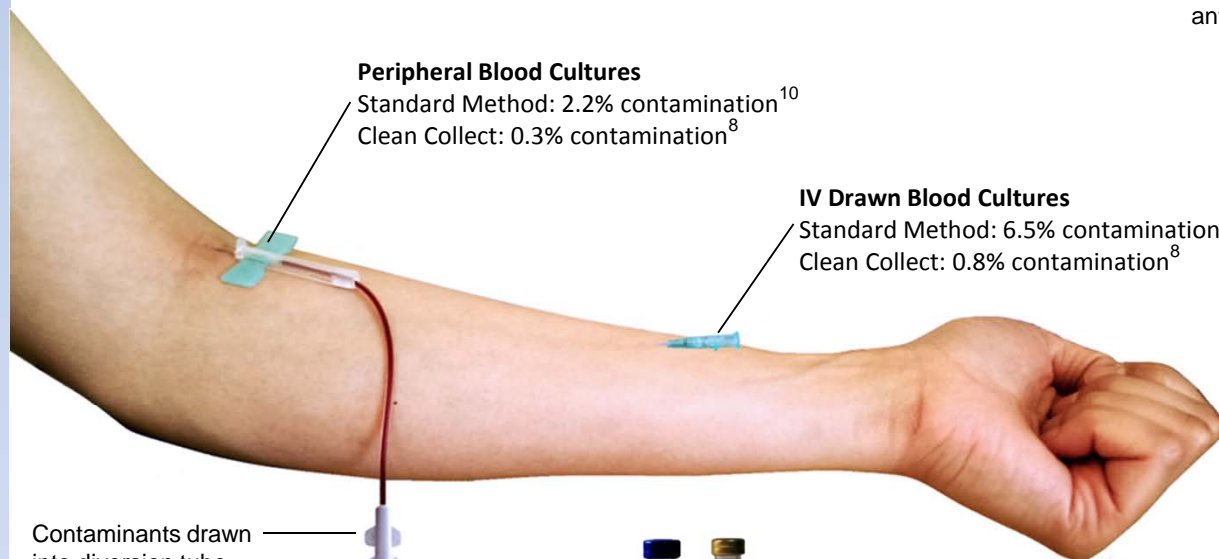


*Current standard method requires that blood cultures be drawn first in the order of draw

Clean Collect Diversion Method



Diversion Method



Peripheral Blood Cultures

Standard Method: 2.2% contamination¹⁰
Clean Collect: 0.3% contamination⁸

IV Drawn Blood Cultures

Standard Method: 6.5% contamination¹
Clean Collect: 0.8% contamination⁸

Contaminants drawn into diversion tube



1



Sterile Diversion Tube*

2

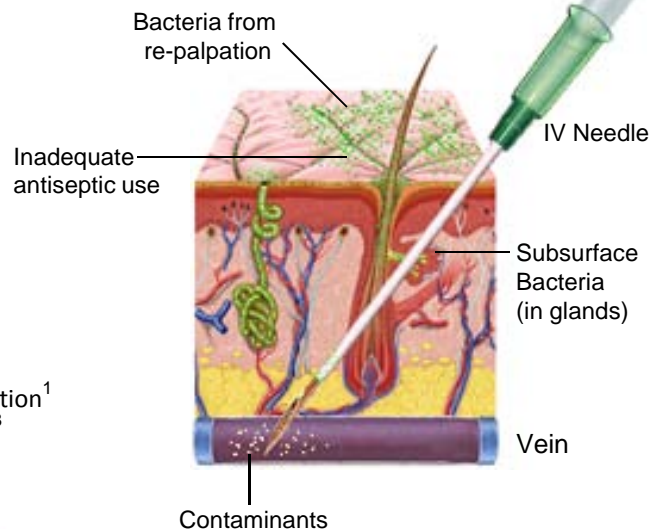


Blood Culture Bottles

3



Non-Sterile Tubes



Sources Eliminated by Diversion:

1. Re-palpation
2. Inadequate Antiseptic Use
3. Subsurface Bacteria
4. Equipment (luers, syringes)

0.5%

Average Rate of Contamination⁸

*Diversion tube must be sterile. Non-sterile tubes can increase contamination rates up to 17%¹¹

US Patent 6,913,580



Impact of Blood Culture Contamination

- Contamination results in unnecessary treatment of patients with broad spectrum IV antibiotics.^{2,3,4,5,6}
- Antibiotic treatment results in *C. difficile* infections, anaphylactic shock, kidney and liver failure, and other side effects.
- Wasted resources include IV antibiotics, repeat testing, isolation for *C. diff* patients, dialysis, and personnel costs. These costs average \$6,283 per incident.^{3,4,5,6}
- Medicare and insurers using DRG and other fixed payment systems typically do not reimburse the costs of contamination.⁷
- Additional penalties for *C. diff* infection rates start in 2016 and can total millions annually.^{12,13}

Cost of Contamination Research (Published Data – Inflation Adjusted to 2016)

| Investigator | Journal | Cost per Contaminant |
|----------------------|-----------------------------------|--------------------------------|
| Dr. Rita Gander | Journal of Clinical Microbiology | \$9,563 per contaminant |
| Dr. Oren Zwang | Journal of Hospital Medicine | \$10,370 per contaminant |
| Dr. Sever Surdulescu | Clinical Perf. Quality Healthcare | \$9,146 per contaminant |
| Dr. David Bates | JAMA | \$7,670 per contaminant |
| Dr. William Dunagan | American Journal of Medicine | \$10,240 per contaminant |
| | Average (in charges) | \$9,377 per contaminant |
| | Average (resource costs) | \$6,283 per contaminant |

Resource Savings at a Mid-Sized US Hospital

| ER Blood Culture Data | | Total Blood Culture Data | |
|------------------------------|--------------------|------------------------------|--------------------|
| Blood Cultures (per month) | 406 | Blood Cultures (per month) | 1,218 |
| Contamination Rate | 4.6% | Contamination Rate | 2.7% |
| Rate with Clean Collect | 1.2% | Rate with Clean Collect | 0.8% |
| ER Cost Reduction | | Total Cost Reduction | |
| Current Cost (\$6,283/cont.) | \$1,408,096 | Current Cost (\$6,283/cont.) | \$2,479,473 |
| Resources Saved | \$1,163,209 | Resource Saved | \$1,744,814 |
| Added Cost (Annual) | \$5,613 | Added Cost (Annual) | \$18,708 |
| Net Savings | \$1,157,597 | Net Savings | \$1,726,106 |



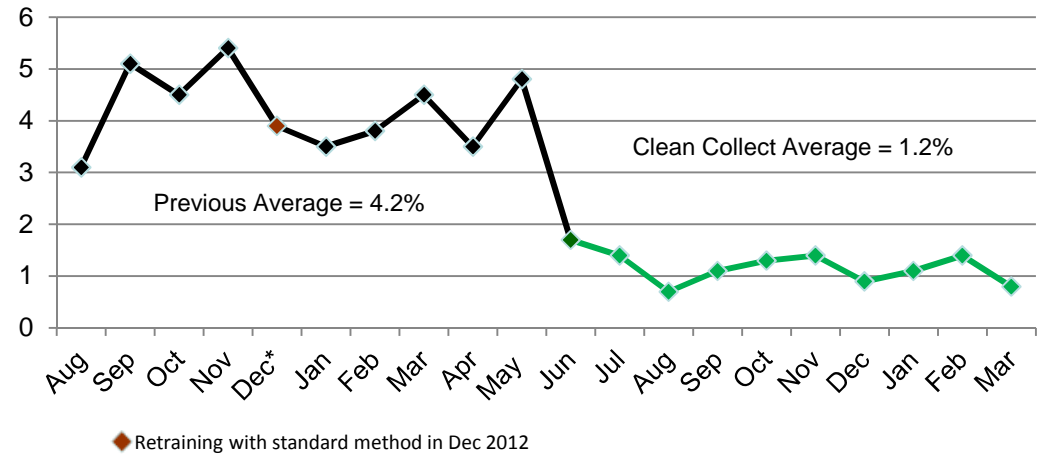
Clean Collect Results

- **Effective** – Clean Collect has reduced contamination rates by an average of 74% in practice.⁸
- **Standardized** – Promotes consistent use of a highly effective method to achieve long term reduction of contamination rates.⁸
- **Long Term Improvement** – Continually eliminates contaminants from re-palpation, inadequate antisepsis, and mishandling of equipment.
- **Cost Reduction** – Saves considerable resources that would have been wasted on unnecessary treatment and side effects (*C. diff* infections, etc.)

“Our contamination rate is the lowest it has ever been”

- ER Director at a mid-sized hospital

Long Term Improvement with Clean Collect®



Results with Clean Collect®

| Start Date | Department | Previous Rate | Clean Collect |
|-----------------|---------------|---------------|---------------|
| 1 - (3/01/13) | ER and floors | 3.8% | 0.0% |
| 2 - (3/12/13) | Emergency | 4.6% | 0.8% |
| 3 - (5/01/13) | Emergency | 6.3% | 0.7% |
| 4 - (07/01/13) | Emergency | 4.2% | 0.9% |
| 5 - (1/22/14) | Emergency | 4.0% | 0% |
| 6 - (4/15/14) | ER and floors | 3.6% | 0.4% |
| 7 - (7/18/14) | ER and floors | 4.1% | 0.7% |
| Averages | | 4.4% | 0.5% |

Clean Collect Peripheral Kits



Clean Collect® CC-220 & CC-225

Peripheral Blood Culture Kits

Contains:

- Sterile Diversion Tube
- Prevantics® Swabstick
- Alcohol Pads (for bottle tops)
- Latex Free Tourniquet
- Tracking Decal Set
- Sterile Gloves
- Bandage



Butterfly Needle Options



BD Push Button: CC-220R / 225R
 No Butterfly: CC-220B / 220B
 K-Shield Butterfly: CC-220 / 225



CC-220



CC-225

| SMC Number | Fisher Catalog # | Notes |
|------------|------------------|--------------------------|
| CC-220 | 23200100 | K-Shield Butterfly |
| CC-220B | 23200101 | No butterfly |
| CC-220R | 23200102 | BD Push Button Butterfly |

| SMC Number | Fisher Catalog # | Notes |
|------------|------------------|--------------------------|
| CC-225 | 23200104 | K-Shield Butterfly |
| CC-225B | 23200105 | No butterfly |
| CC-225R | 23200106 | BD Push Button Butterfly |

Clean Collect IV Blood Culture Kits



Clean Collect® CC-310 & CC-315

IV Method Blood Culture Kits

Contains:

- Sterile Diversion Tube
- Chloraprep® Frepp
- Gauze Pads
- Alcohol Pads (for bottle tops)
- Latex Free Tourniquet
- SureSite® IV Dressing
- Curad® Tape Roll
- Tracking Decal Set
- Sterile Gloves



| SMC Number | Fisher Catalog # | Notes |
|------------|------------------|-------------------------------------|
| CC-310 | 23200103 | Compatible with Bactec or VersaTrek |
| CC-315 | 23200107 | Compatible with BacT/Alert |

© 2014 Thermo Fisher Scientific Inc. All rights reserved.
 Trademarks used are owned as indicated at www.fishersci.com/trademarks.

In the United States:

For customer service, call 1-800-640-0640
 To fax an order, use 1-800-290-0290
 To order online: www.fisherhealthcare.com



A Thermo Fisher Scientific Brand

Comparison of Solutions

- Many previous solutions to blood culture contamination do not effectively handle blood cultures drawn through IVs, which are the primary source of contamination in ERs with an average rate of 6.5%.¹
- Clean Collect is a diversion system that has demonstrated significant reductions in contamination rates for both peripheral and IV drawn blood cultures with long term improvement of the problem.⁸

| Solution | Peripheral | IV Drawn | Added Cost | Notes |
|-----------------------|-------------|-------------|------------------------|--|
| Procedure Trays | 2.0% | 6.5% | \$3.50 per test | Less effective, IV draws are not handled |
| Blood Culture Kits | 2.0% | 6.5% | \$1.50 per test | Less effective, IV draws are not handled |
| Retraining | 1.7% | 4.4% | \$1,200 per event | Less effective overall. Rates often rebound within 45 days |
| Phlebotomy in ED | 1.7% | N/A | \$6.53 per test | Requires 3 - 5 needle sticks per patient, disrupts workflow, increases missed draws, and can lower patient satisfaction scores |
| Clean Collect* | 0.3% | 0.8% | \$1.50 per test | Effective for significant, long term reduction of contamination rates |

Frequently Asked Questions

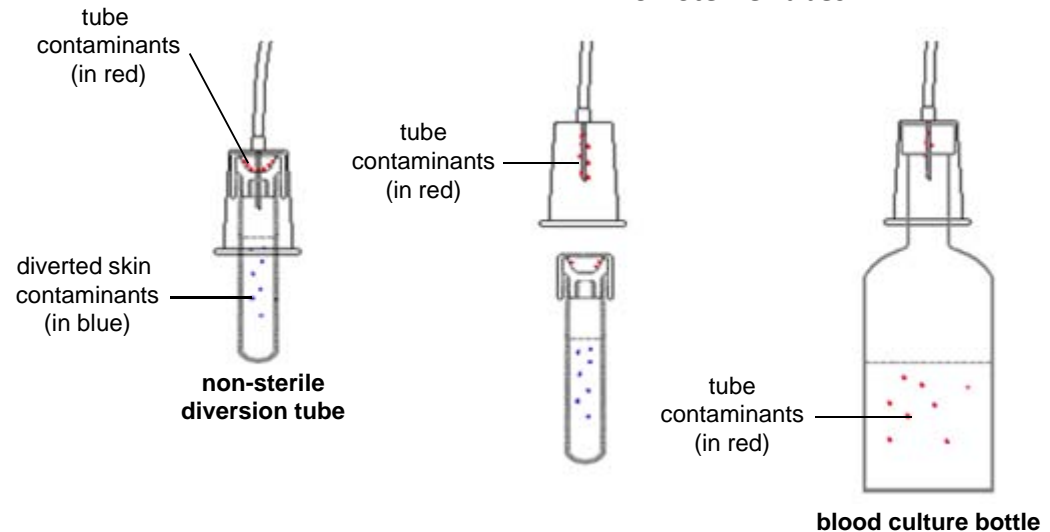


Q1. Could we use regular blood collection tubes to draw the first sample and get the same effect?

Answer: Regular tubes are not sterile on the exterior. If drawn first they can carry contaminants from the tube's stopper into the blood cultures drawn afterwards, increasing contamination rates up to 17%. Clean Collect uses a pre-sterilized diversion tube to eliminate contaminants from multiple sources without creating a new contamination problem. Manually treating tube stoppers with antiseptics has proven inconsistent in practice with hospitals reporting increased contamination rates instead of reductions.

Diversion Method
(Sterile vs Non-sterile Diversion Tubes)

| Diversion Tube for 1 st Sample | Volume | Standard Method | Diversion Method |
|---|--------|-----------------|------------------|
| Non-sterile tubes | 4mLs | N/A | 16.8% |
| Manually treated tubes | 4mLs | 4.2% | 4.7% |
| Clean Collect (Sterile Tube) | 4mLs | 4.4% | 0.5% |



Q2. What can the diverted sample be used for?

Answer: The diverted red top tube sample can be used for more than 50 diagnostic tests on serum and is accepted by Labcorp, Quest, and other reference labs. These tests include: Viral (hepatitis, West Nile, influenza) Acute Phase Reactants/Markers (procalcitonin, C-reactive protein), Hormonal (thyroid stimulating hormone, thyroxine), Immunology (allergen profiles, anti-nuclear antibodies), serum antibiotic levels, and other testing.



1. Self WH, Speroff T, McNaughton CD. Blood Culture Collection through Peripheral Intravenous Catheters Increases the Risk of Specimen Contamination among Adult Emergency Department Patients. *Infection Control and Hospital Epidemiology*, Vol. 33, No. 5 (May 2012), pp. 524-526
2. Alamadi, YM, Aldeyab, MA, McElhay, JC, Scott, MG, et al. Clinical and economic impact of contaminated blood cultures within the hospital setting. *Journal of Hospital Infection*, 77, 233-236
3. Gander RM, Byrd L, DeCrescenzo M, Hirany S, Bowen M, and Baughman J. Impact of Phlebotomy-Drawn Blood Cultures on Contamination Rates and Health Care Costs in a Hospital Emergency Department. *Journal of Clinical Microbiology* 2009 Apr; 47(4): p. 1021 -1024
4. Zwang O, Albert RK. Analysis of strategies to improve cost effectiveness of blood cultures. *Journal of Hosp Med*. 2006 Sep;1(5):272-6
5. Surdulescu, S., D. Utamsingh, and R. Shekar. Phlebotomy teams reduce blood-culture contamination rate and save money. *Clin. Perform. Qual. Health Care* 6:60-62. 1998
6. Bates DW, Goldman L, Lee TH. Contaminant blood cultures and resource utilization. The true consequences of false-positive results. *JAMA*. 1991 Jan 16;265(3):365-9
7. Center for Medicare and Medicaid Services (CMS). *Guidance for Coding Hospital Acquired Conditions 2014*
8. Stone Medical Corporation. *Clean Collect: Multi-Center Product Evaluations 2013-2014*
9. Patton RG and Schmitt T. Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique. *Journal of Clinical Microbiology*, December 2010, p. 4501-4503 Vol. 48, No. 12
10. Bekeris LG, Tworek JA, Walsh MK, Valenstein PN. Trends in blood culture contamination: a College of American Pathologists Q-Tracks study of 356 institutions. *Arch Pathol Lab Med*. 2005 Oct 129(10):1222-51
11. Stone Medical Corporation. *Importance of Discard Tube Sterility for Diversion Methods 2014*
12. Center for Medicare and Medicaid Services. *Hospital Acquired Condition (HAC) Reduction Program 2016*
13. Center for Medicare and Medicaid Services. *Value Based Purchasing Program 2016*