

## University of Nebraska Infectious Disease Researchers Study New Device That Could Help Clinical Laboratories and Phlebotomists Avoid Blood Culture Contamination and False Positive Results for Sepsis

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*Additionally, the device also could help reduce antibiotic-resistant infections and other HAIs and HACs, though this result was not part of the study*

Research findings indicate how a new system-in-a-box device that **phlebotomists** and **clinical laboratories** would use when drawing blood could reduce contamination of blood cultures and lower patients' use of antibiotics. In a study involving 1,800 blood cultures done on 904 patients at the **University of Nebraska Medical Center** (UNMC), use of the device was attributed to an 88% reduction in the blood culture contamination rate.

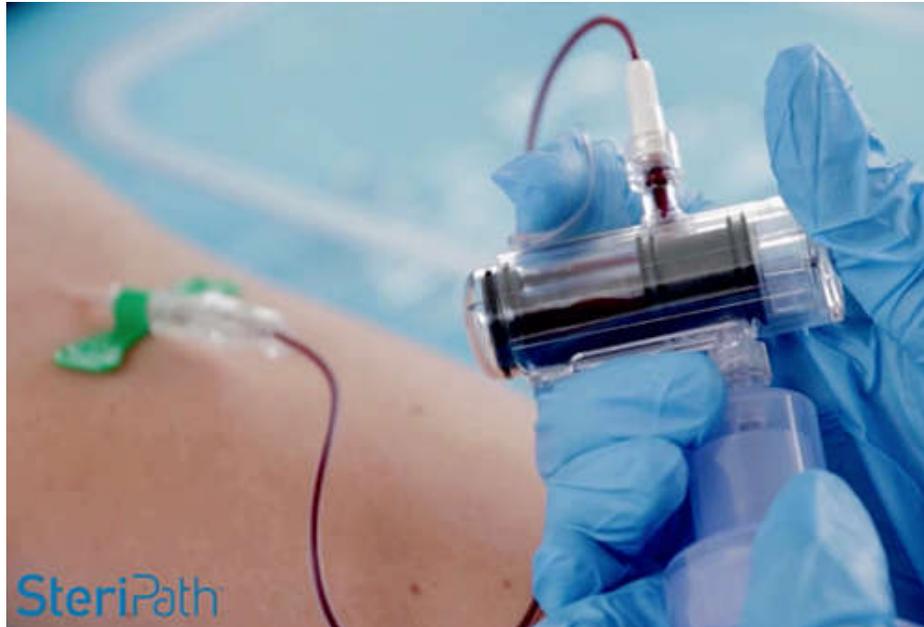
Developed by **Magnolia Medical Technologies**, the **SteriPath Initial Specimen Diversion Device** (ISDD) is compatible with standard **BD** and **bioMérieux** blood collection tubes and culture bottles, and has been approved by the **US Food and Drug Administration** (FDA) for marketing in the United States.

According to **a press release** by researchers at UNMC who studied the device, "With traditional blood draws, about 30% to 40% of patients with contaminated blood cultures are prescribed antibiotics unnecessarily. This contributes to antibiotic resistance and undermines nationwide efforts to improve antimicrobial stewardship." The researchers reported their findings in **an article published in the Oxford Academic journal *Clinical Infectious Diseases* (CID)**.

### Blood Culture Contamination Harms Patients and Increases Cost of Care

The UNMC researchers noted that, during a blood draw, a significant percentage of blood cultures become contaminated when skin fragments containing bacteria are dislodged and mix with the patient's blood. For the thousands of patients each day who have their blood drawn, contaminated blood cultures, which lead to false positive results for sepsis, often result in unnecessary antibiotic treatment. This in turn can lead to serious and deadly antibiotic-resistant infections with various multi-drug-resistant organisms such as ***Clostridium difficile* infection** (*C. diff*), as well as, other hospital-acquired infections and conditions (HAIs & HACs) due to unnecessary extended length of stay, according to **Mark Rupp, MD**, Professor, Department of Internal Medicine, Section of Infectious Diseases, and Medical Director, Department of Healthcare Epidemiology-Infection Control at **UNMC**.

In the *CID* article, Rupp and colleagues reported on a prospective, controlled trial conducted in the emergency department (ED) at UNMC's partner hospital **Nebraska Medicine**. Results of the trial showed that the SteriPath ISDD diverts and sequesters the first 1.5 to 2 mL portion of blood. The researchers presumed that these initial drops of blood would contain the contaminating skin cells and microbes.



SteriPath is a self-contained, preassembled, sterile blood collection system. It provides proprietary vein-to-bottle technology that significantly reduces blood culture contamination, according to [Magnolia Medical Technologies](#). This could be useful for helping phlebotomists and clinical laboratories improve the quality of specimens collected for use in blood culture testing. Click on the image above to view videos on the SteriPath ISDD. (Photo copyright: Magnolia Medical Technologies.)

The researchers tested the SteriPath ISDD during standard phlebotomy procedures in patients requiring blood cultures. After drawing 1,808 blood cultures from 904 study subjects, the researchers concluded that the ISDD significantly reduced blood culture contamination compared with standard phlebotomy procedures. The blood culture contamination among phlebotomists who used the ISDD decreased by nearly 90%, compared to phlebotomy procedures conducted by nurses who did not use the ISDD.

“We were able to decrease the false positive rate significantly through use of this device—from 1.78% down to 0.2%, which represents an 88% reduction,” Rupp noted in the UNMC press release. “The 1.78% baseline rate of contamination may seem small, but we should strive to decrease **adverse events** to the lowest possible level, because of the impact to the patient and the burden to our healthcare system.

“The device is innovative in that it diverts the first couple of milliliters of blood into the sequestration chamber,” Rupp explained. “That’s where we think the contaminants are. The remaining blood being drawn is then diverted into the sterile pathway into the blood culture vial, thereby preventing the contamination.”

### **Billions of Healthcare Dollars Could Be Saved with SteriPath’s ISDD**

During a conference call with reporters, Rupp admitted that cynics might scoff at such a low rate of improvement. “Many of those folks don’t understand that we do tens of millions of blood cultures in this country every year,” he explained. “Every year, we do about 30 million or so blood cultures. That many cultures means a 2% contamination rate equates to somewhere in the neighborhood of about 600,000 contamination events. And 2% is a very respectable level. Usually clinicians are satisfied anywhere below about 3%, which is about 900,000 events each year.”

For about 40% to 50% of patients whose blood is contaminated, physicians will prescribe antibiotics, order another blood test, and require patients to stay several days in the hospital, he added. “All of this results in thousands of extra dollars being spent,” he declared. If each blood contamination case costs about \$4,000, then reducing such contamination in potentially 600,000 cases each year could save more than \$1 billion healthcare dollars.

According to the researchers, costs associated with blood culture contamination ranged from \$1,000 per patient in 1998 to \$8,700 per patient in 2009. “If a midpoint cost estimate of \$4,850 is used, and the added cost of the device is not taken into account, it equates to a cost avoidance of \$1.8 million per year at our institution alone,” Rupp stated. “If the low rate of contamination that we observed in the study, 0.22%, was applied to all blood cultures throughout the country, billions of dollars of excess costs could be avoided.”

This clinical study offers strong evidence that the SteriPath ISDD might prove to be a useful tool that clinical laboratories could use to help prevent unnecessary exposure to antibiotics and hospital stays, lower healthcare costs, and improve patient test outcomes. If the UNMC clinical study outcomes are replicated in future studies, then it is a technology and a solution that has the potential to be adopted by phlebotomists in medical laboratories and hospitals.

*—Joseph Burns*