



# BacDetect: Development of a rapid, ultra-sensitive platform for bacterial detection from blood

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## Background

Blood stream infection (BSIs) are associated with high mortality rates and increasing healthcare costs. The current gold-standard approach for species identification (ID) is a culture-based method, which suffers from slow turnaround time (TAT), often requiring days to provide conclusive results. Unfortunately, mortality with BSIs increase significantly when correct therapy is delayed by only hours. To enable faster TATs for detection of BSIs, Day Zero Diagnostics has developed BacDetect, a rapid DNA amplification-based detection method that determines the presence of gram-positive or gram-negative bacteria in a sample in 30 minutes. When paired with Blood2Bac™, a process for ultra-high enrichment of bacterial DNA from blood, BacDetect can determine the presence of bacterial pathogens in a blood sample within 10 hours of blood draw.

## Methods

We employed BacDetect to assess the presence of bacterial DNA in 27 blood samples containing bacteria spiked-in at single-digit CFU/mL loads and processed with Blood2Bac. We tested 11 clinically relevant bacterial pathogens (5 gram-negative and 6 gram-positive) commonly causing BSIs. In addition to test samples, we also assessed BacDetect performance on blood samples drawn from 13 hospitalized patients with suspected BSI.

## Results

BacDetect confirmed the presence of highly enriched bacterial DNA in all 27 test samples with correct determination of gram-positive or gram-negative status. When evaluated on 13 patient samples, BacDetect provided a positive result in 4 of 4 cases where bacteremia was confirmed with blood culture drawn on the same day. In all 4 cases, gram-type called by BacDetect matched the isolate obtained by culture. In 2 cases, BacDetect was positive with gram-type agreement when culture was negative on the day of the draw, but positive on the day prior. BacDetect was negative on all samples where cultures were negative both the day of blood draw and the day prior.

## Conclusion

BacDetect, when paired with Blood2Bac, can determine the presence of bacterial DNA from a blood sample at single-digit CFU/mL loads across 11 bacteria species within 10 hours. This will reduce TAT to enabling more rapid informed clinical decisions for patients with suspected BSIs.