Impact of the Implementation of a Host-Response Sepsis Test on Blood Culture Utilization and Contamination Rates in the Emergency Department

Alyssa Hutto, MHA[1]; Dhruvangkumar Modi, MD, MPH[1]; Karla A. Guier, MSN, RN, CNL[1]; Benjamin Fragano, MSN, RN[1]; An Nguyen, MD[1]; Timothy Harris, MD[1]; Kelly Brown, MSN, RN, NE-BC[1]; Roya Sheybani, PhD[2]; Andrew Masica, MD, MSCI[1]; & Ferdinand Velasco, MD[1]

[1]Texas Health Resources Presbyterian Hospital, Denton, TX, USA; [2]Cytovale Inc., S. San Francisco, CA, USA

Introduction

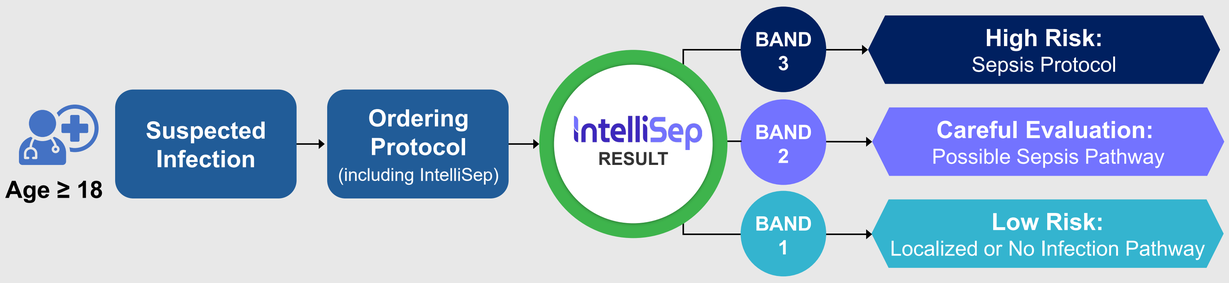
- Sepsis is a dysregulated host immune response to infection leading to organ dysfunction[1]
- There is substantial unmet need for rapid diagnosis to prevent morbidity and mortality[2]
- Guidelines stress quick intervention[3], yet undifferentiated patients present to the Emergency Department (ED) and physicians must diagnose before objective diagnostic data are available
- While blood cultures are the gold standard for pathogen identification, over-utilization leads to increased costs and potential false positives due to contamination

This study evaluated the impact of implementing a hospital laboratory-based host-response sepsis test (HRST) on blood culture ordering patterns and overall contamination rates in adult ED patients.

Methods

New Test Implementation:

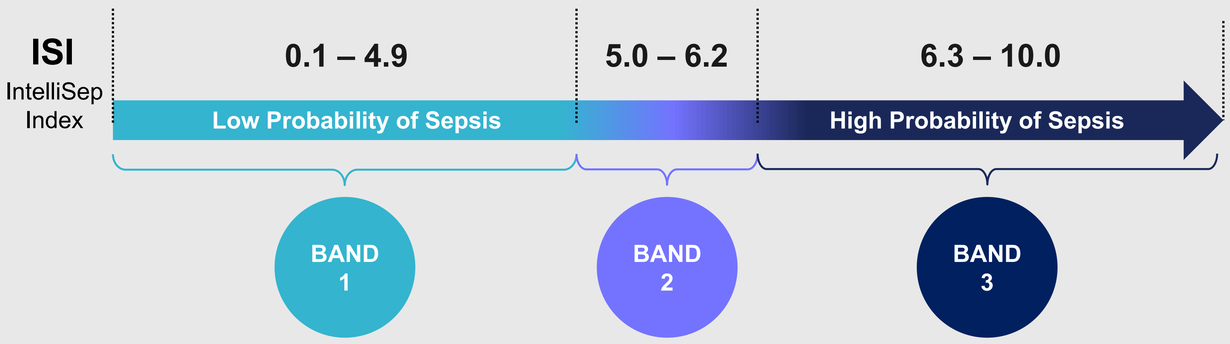
On June 17, 2025, the Texas Health Resources Denton Hospital laboratory (Denton, TX) implemented an HRST as part of a quality improvement initiative that included an ordering protocol, staff training, and evidence-based pathways aligned by test results.



Laboratory and clinical leaders guided implementation and continued to monitor sepsis alerts, blood culture practices, and antibiotic utilization to ensure consistent protocol application, support antimicrobial stewardship, and promote patient safety.

The Cytovale IntelliSep Test:

The IntelliSep test is an FDA cleared, semi-quantitative blood test that assesses the state of immune activation at the cellular level and is intended to aid in the early detection of sepsis with organ dysfunction manifesting within the first 3 days after testing for adults with signs and symptoms of infection presenting to the ED.



All results should be interpreted in the context of the other clinical observations and laboratory test results for the patient.

The test results in the IntelliSep Index (ISI), a single score between 0.1-10.0, in <10 minutes. Results are grouped into three interpretation bands reflecting increasing likelihood of sepsis, Band 1 (low) to Band 3 (high).

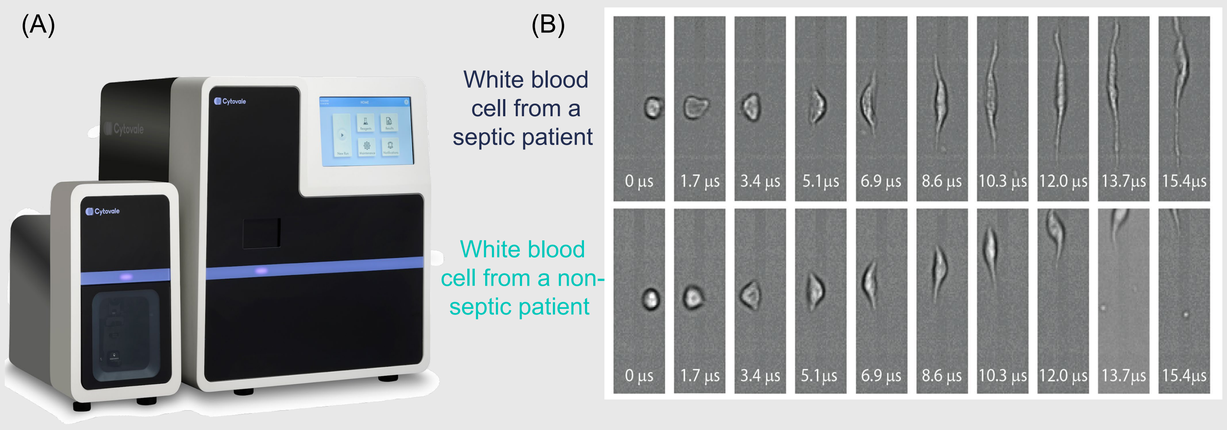


Figure 1: (A) Photograph of the Cytovale system, a benchtop instrument on which the IntelliSep test is performed; (B) Time series of cell deformation for a representative leukocyte of a septic Band 3 patient (top) and a non-septic Band 1 patient (bottom).

Methods (continued)

Study Design & Setting

- Retrospective cohort study comparing 1 year of pre-implementation data (July 2024–June 2025) to 6 months of post-implementation data (July 2025–December 2025)
- Outcomes included:

Blood Culture Utilization Rate = Blood Cultures Ordered / ED Encounters

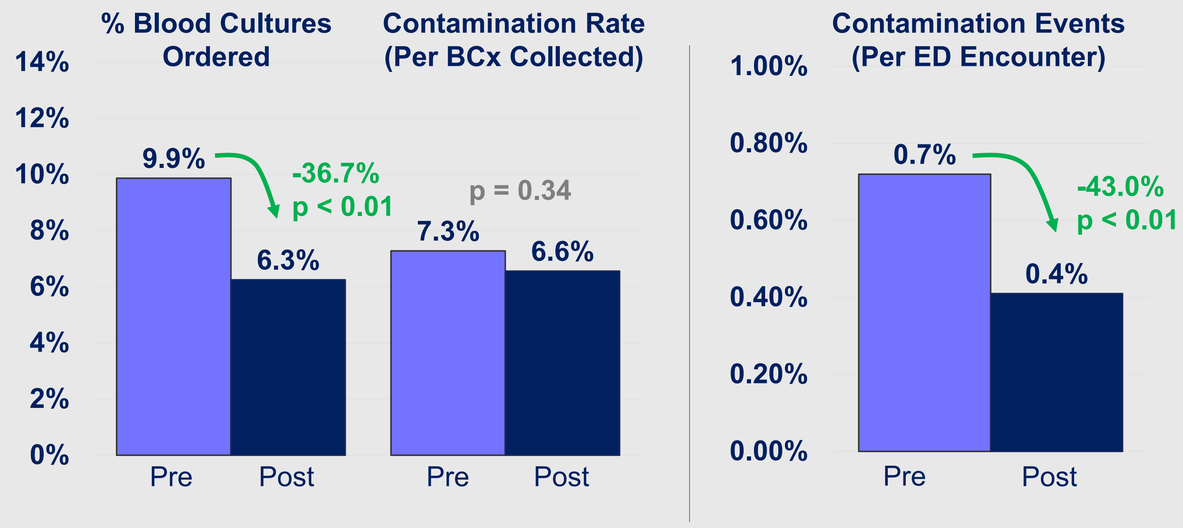
Contamination Rate = Contaminated Cultures / Blood Cultures Ordered

Contaminations per Patient Seen = Contaminated Cultures / ED Encounters

- Contamination savings were calculated by subtracting the contaminations observed "post" from the expected value (contaminations per patient seen "pre" multiplied by "post" ED encounters)
- Between-period comparisons were performed using Pearson chi-square tests for equality of proportions (two-sided, α = 0.05)

Results & Discussion

- 46,931 ED encounters were included in the pre-implementation period and 24,910 in the post-implementation period
- Following implementation of HRST, the blood culture utilization rate decreased significantly from 9.87% to 6.25% (36.70% relative reduction; p < 0.01)
- The contamination rate showed a non-significant downward trend (7.28% to 6.56%; p = 0.34)
- Reduction in total culture volume led to a significant decrease in contaminations per patient seen, from 337 pre (0.72%) to 102 post (0.41%), a 42.98% relative reduction (p < 0.01)
- An estimated 77 contaminations were saved in the 6-month post-implementation period



Conclusions

Implementation of a host-response test in the hospital laboratory significantly improved diagnostic stewardship by reducing unnecessary blood culture orders. Although the inherent contamination rate of the collection process remained stable, the overall frequency of contaminated results per ED encounter was nearly halved. **These findings suggest that using HRST can streamline sepsis evaluations, lessen laboratory workload, and potentially reduce the downstream clinical costs associated with false-positive blood cultures.**

Acknowledgements

We would like to thank the providers and nursing staff of the Texas Health Resources Denton Hospital Emergency Department for their tireless efforts in adopting new process and technology to improve the care of our patients who present with signs or suspicion of infection. We also thank the clinical laboratory staff who have worked with us over the last year to implement this test. Finally, we thank the THR Denton Quality and Safety team that works to ensure we are providing the best possible care to our patients.

References

[1] Singer, *JAMA*, 2016
[2] Wang, *Crit Care Med* 2017.
[3] Surviving Sepsis Campaign Declarations. 'Barcelona Declaration' [cited 2020].