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Be-SQuISH-ED Study

Assessment of a Cellular Host Response Test as a Sepsis Diagnostic for Those With Suspected Infection in the Emergency Department

Study Objective

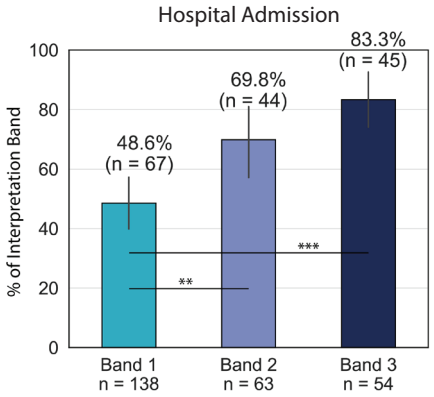
Sepsis is a common cause of morbidity and mortality. A reliable, rapid, and early indicator can help improve efficiency of care and outcomes. The study objective was to assess the IntelliSep test, a novel in vitro diagnostic that quantifies the state of immune activation by measuring the biophysical properties of leukocytes, as a rapid diagnostic for sepsis and a measure of severity of illness, as defined by Sequential Organ Failure Assessment and Acute Physiology and Chronic Health Evaluation-II scores and the need for hospitalization.

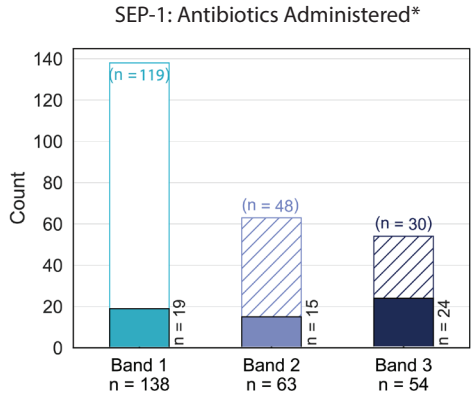
Study Population

Adult patients presenting to two emergency departments with signs of infection (two of four systemic inflammatory response syndrome criteria, with at least one being aberration of temperature or WBC count) or suspicion of infection (a clinician order for culture of a body fluid), were prospectively enrolled. Sepsis status, per Sepsis-3 criteria, was determined through a 3-tiered retrospective and blinded adjudication process consisting of objective review, site-level clinician review, and final determination by independent physician adjudicators.

IntelliSep Observations

- n = 255, 18.0% sepsis in population
- 90.7% Sensitivity, 86.3% Specificity
- 97.1% NPV (Band 1), 44.2% PPV (Band 3)





* Observed trends in the administration of antibiotics within the 3-hour SEP-1 bundle window across ISI Interpretation Bands. Solid bars denote the number of subjects in each Band that received the care metric, outlined (for Band 1) and hashed bars (for Bands 2 and 3) denote the remainder of the subjects in each Band that did not receive the care metric.

Study Conclusions

In patients presenting to the emergency department with signs or suspicion of infection, the IntelliSep Index is a promising tool for the **Rapid Diagnosis and Risk Stratification for sepsis**.†

† Subsequently, Cytovale completed a clinical validation study and IntelliSep was FDA cleared to aid in the early detection of sepsis for adults presenting to the Emergency Department. See IFU for cleared intended use.

O'Neal HR, Jr., et. al., Assessment of a Cellular Host Response Test as a Sepsis Diagnostic for Those With Suspected Infection in the Emergency Department. *Crit Care Explor* 2021; 371 3: e0460.

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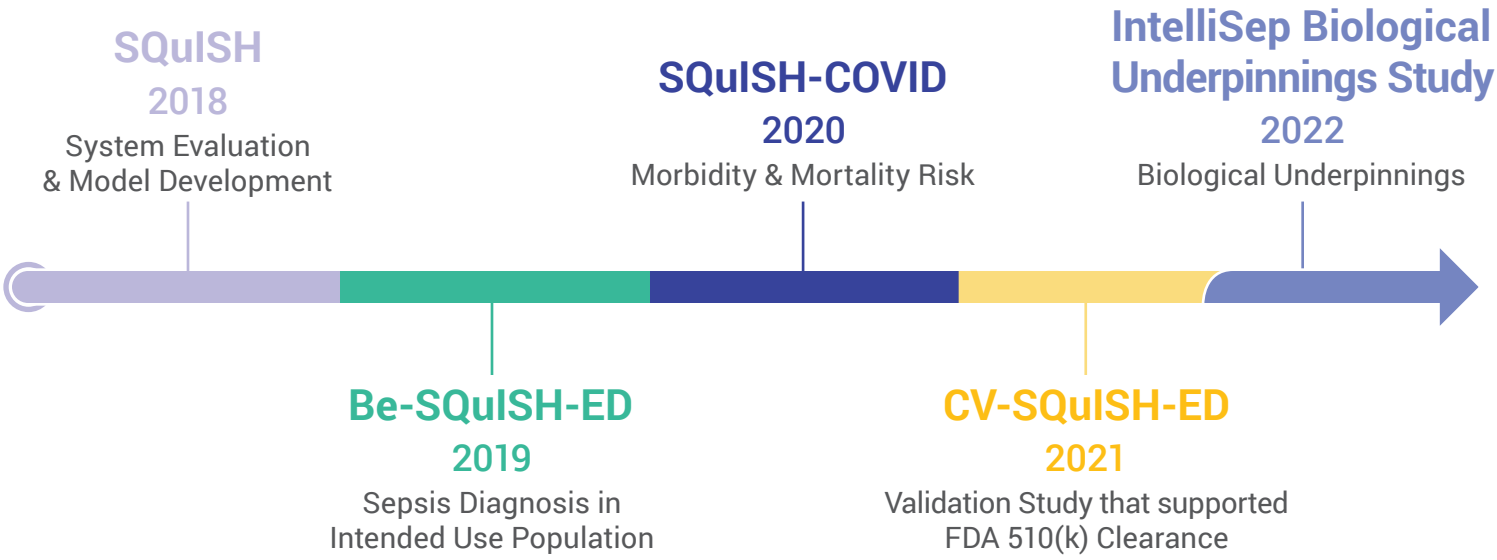
IntelliSep Clinical Data

Supported by clinical studies* of over 2000 subjects, the FDA-cleared IntelliSep test is a first-of-its-kind host immune response diagnostic helping clinicians identify sepsis and get the right care to the right patients at the right time.



*Key Publications

Crawford K, et. al., Rapid Biophysical Analysis of Host Immune Cell Variations Associated with Sepsis. *Am J Respir Crit Care Med* 2018; 198: 280-282.

Guillou L, et al., Development and validation of a cellular host response test as an early diagnostic for sepsis. *PLoS One* 2021; 16: e0246980.

O'Neal HR, Jr., et. al., Assessment of a Cellular Host Response Test as a Sepsis Diagnostic for Those With Suspected Infection in the Emergency Department. *Crit Care Explor* 2021; 371 3: e0460.

O'Neal HR, Jr., et. al., Assessment of a cellular host response test to risk-stratify suspected COVID-19 patients in the Emergency Department setting. *PLoS One* 2022; 17(3): e0264220.

Sorrells M, Seo Y, Magnen M, et al., Biophysical Changes of Leukocyte Activation (and NETosis) in the Cellular Host Response to Sepsis. *Diagnostics* 2023; 13(8):1435.

U.S. Food and Drug Administration. IntelliSep test decision summary, 510(k) number K220991, December 20, 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220991.pdf.

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