

Category :**Sepsis: biomarkers**

A205 - Comparison of a cellular host response test to common sepsis indicators in a suspected infection population presenting to the emergency department (ed)

H O'Neal¹; R Sheybani²; T Caffery³; H Tse²; A Shah²; C Thomas¹

¹LSU Health Sciences Center / Our Lady of the Lake Regional Medical Center, Pulmonary & Critical Care Medicine, Baton Rouge, LA, United States, ²Cytovale, LLC, Cytovale, San Francisco, CA, United States, ³LSU Health Sciences Center / Our Lady of the Lake Regional Medical Center, Emergency Medicine, Baton Rouge, LA, United States

Introduction:

Sepsis, a common and fast-moving condition, often arises in the community, and presents to the ED where providers must perform the initial diagnosis for patients with signs of infection. Currently, a rapid diagnostic with clinically actionable performance is needed to assist ED clinicians in this task. The objective of this study was to assess the potential of the IntelliSep test when compared to commonly-assessed indicators of sepsis.

Methods:

The IntelliSep test is an investigational in-vitro diagnostic that quantifies the state of immune activation by measuring the biophysical properties of leukocytes from a routine blood sample in under 10 minutes. The test provides a single score, the IntelliSep Index (ISI), between 0.1-10.0 (inclusive), stratified into three discrete interpretation bands of risk for disease severity: Green, Yellow, and Red.

Adult patients presenting to the ED with signs or suspicion of infection were prospectively enrolled at multiple sites in the USA (Feb. 2016 – Sept. 2019). EDTA-anticoagulated blood was assayed within 3 hours of draw, and patients were followed by retrospective chart review. Treating clinicians did not have access to assay results. All other measurements were taken per standard of care. Retrospective physician adjudication determined sepsis status (Sepsis-3).

Results:

For the 549 subjects (sepsis prevalence 20%) included in the final analysis, the ISI achieved an AUC of 0.88 (0.84 - 0.91, 95% CI) with a sensitivity of 87.4 (78.7 - 92.2, 95% CI) and specificity of 91.3 (84.1 - 95.6, 95% CI) in the Green and Red interpretation bands, respectively. Table 1 includes a comparison of the ISI with a selection of other commonly-assessed indicators of sepsis. Lactate values were available for 414 subjects.

Conclusion:

The ISI, a quantitative measure of immune activation, compared favorably to common indicators as an aid in the rapid assessment of sepsis risk for patients presenting to the ED with signs of infection.

Table:

	AUC (95% CI)	Negative Predictive Value (95% CI)	Positive Predictive Value (95% CI)	Diagnostic Odds Ratio (95% CI)
2+ SIRS	0.56 (0.53 - 0.58)	91.6 (84.1 - 95.6)	22.3 (14.4 - 30.4)	3.12 (0.6 - 7.7)
qSOFA (≥ 2)	0.63 (0.57 - 0.68)	82.8 (73.6 - 88.6)	41.8 (32.2 - 51.2)	3.45 (0.6 - 7.7)
WBC (< 4 or > 12 ×10 ³ cells/μL)	0.61 (0.57 - 0.65)	89.7 (81.9 - 94.3)	25.6 (17.5 - 34.4)	3.0 (0.6 - 7.7)
Lactate (low < 2; high ≥ 4)	0.72 (0.67 - 0.77)	84.5 (72.1 - 91.4)	52.8 (38.9 - 64.0)	6.1 (1.7 - 14.8)

APACHE II (≥ 15)	0.64 (0.59 - 0.69)	83.6 (74.6 - 89.4)	28.2 (19.8 - 37.2)	2.0 (0.2 - 6.4)
SOFA (≥ 2 up to 24 hours following presentation)	0.74 (0.69 - 0.78)	93.3 (86.3 - 96.8)	28.5 (19.8 - 37.2)	5.56 (2.0 - 11.4)
IntelliSep Index (low Green band; high Red band)	0.88 (0.84 - 0.91)	95.7 (88.1 - 98.7)	64.5 (52.6 - 74.1)	40.2 (29.2 - 51.1)

Comparison of the ISI to common biomarkers and scoring systems for sepsis