

Category : **Sepsis: biomarkers**

**A484 - Accuracy of Septicyte™ for diagnosis of sepsis across a broad range of patients.**

**R Brandon<sup>1</sup> ; K Navalkar<sup>2</sup> ; D Sampson<sup>2</sup> ; R Davis<sup>2</sup> ; T Yager<sup>2</sup>**

<sup>1</sup>Immunexpress, Seattle, United States, <sup>2</sup>Immunexpress, Immunexpress, Seattle, United States

### **Introduction:**

The purpose of the study was to demonstrate sepsis diagnostic performance of the biomarkers of SeptiCyte™ in subjects other than critically ill adults, and in hospital locations other than ICU. SeptiCyte™ LAB was the first immune-response sepsis diagnostic assay to gain FDA-clearance (K163260) and, as part of gaining this clearance, clinical validation was performed on adult patients admitted to intensive care (ICU) only [1]. We therefore performed an *in silico* analysis across a broad range of patients using the SeptiCyte™ host immune response biomarkers and algorithm.

### **Methods:**

Peripheral blood gene expression data, including public and private datasets, were chosen based on quality, annotation, and clinical context for the intended use of SeptiCyte™. Multiple comparisons were performed with datasets to better understand the diagnostic performance in certain cohorts including healthy subjects. Diagnostic performance was determined using Area Under Curve (AUC).

### **Results:**

The Table shows some characteristics of the selected datasets and patients, including number of datasets (N=22) and comparisons (N=55), number of cases (N=2234) and controls (N=2089) used in comparisons, patient category and hospital location. SeptiCyte™ AUCs for the three groups of adults, adult / pediatric and pediatric neonates were 0.88, 0.85, and 0.87 respectively, which is similar to that previously reported (0.82 – 0.89) [1].

### **Conclusion:**

These results suggest that the SeptiCyte™ signature has diagnostic utility beyond adults suspected of sepsis and admitted to ICU. This signature has now been translated to the near-patient testing platform Biocartis Idylla™ (as SeptiCyte™ RAPID) which promises rapid (~1 hour) diagnosis of sepsis in a broad patient population following further validation.

### **References:**

Miller III, R. R. et al. AJRCCM 198: 903–913, 2018.

### **Table:**

# Datasets / Comparisons	# Case / Controls	Patients	Location	Mean AUC
13 / 35	1640 / 987	Adults	ICU, Ward, ED	0.88
2 / 4	177 / 513	Adults / Pediatric	Ward	0.85
7 / 16	417 / 589	Pediatric / Neonates	ICU, Ward, ED	0.87
Totals				
22 / 55	2234 / 2089			0.87

*Numbers of datasets and comparisons, and patient types used in the analysis*