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:

Table:

<table>
<thead>
<tr>
<th># Datasets / Comparisons</th>
<th># Case / Controls</th>
<th>Patients</th>
<th>Location</th>
<th>Mean AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 / 35</td>
<td>1640 / 987</td>
<td>Adults</td>
<td>ICU, Ward, ED</td>
<td>0.88</td>
</tr>
<tr>
<td>2 / 4</td>
<td>177 / 513</td>
<td>Adults / Pediatric</td>
<td>Ward</td>
<td>0.85</td>
</tr>
<tr>
<td>7 / 16</td>
<td>417 / 589</td>
<td>Pediatric / Neonates</td>
<td>ICU, Ward, ED</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Totals

22 / 55                   | 2234 / 2089       |                      |                   | 0.87     |

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