The ability to accurately diagnose sepsis at admission is key to effective clinical management and efficient resource utilization. Most tests used for sepsis diagnosis are either insensitive, such as blood culture, or non-specific such as general inflammatory markers, and thus most patients suspected of sepsis are treated with antimicrobials and admitted to hospital or the ICU as a precaution, leading to overtreatment. SeptiCyte LAB™ is the only FDA-cleared test that analyzes the patient’s own genetic response to discriminate infection from non-infection in systemically inflamed patients.

**MATERIALS AND METHODS**

In a trial enrolling suspected sepsis patients at ICU admission over 6 sites, clinical and laboratory results were recorded and blood samples were banked for later SeptiCyte™ LAB testing.

Initial Diagnoses: Standard of care diagnosis was defined as negative if the attending physician classified the patient as “no-infection” and no non-prophylactic antimicrobials were administered in the first 3 days. The remaining patients were classified as positive. SeptiCyte™ diagnosis was defined as negative if the sample taken at admission returned a SeptiScore of less than 3.1.

Reference Standard: At the conclusion of each patient stay, an independent panel of three expert physicians reviewed all available clinical and microbiological data while blinded to SeptiCyte results and assigned patients into the following categories: sepsis at admission, no sepsis at admission, or indeterminate. A majority consensus was used to classify all patients into one of these three categories as the reference standard.

Models were produced by Precision Health Economics, Boston, a firm specializing in quantifying health economic impacts for new technologies and interventions. The per hospital annual national average for ICU admissions suspected of sepsis was used as the basecase (N=265). Patients were allocated based on proportions of initial diagnosis against the reference diagnosis observed in the trial (Table 1). The associated costs/savings for each classification captured mortality, antibiotic usage, and costs of patient of stay based on aggregate national averages. Overall savings were calculated by applying SeptiCyte™ LAB diagnosis proportions from the same trial (matched) to reallocate patients from baseline. Patients that were indeterminate in the reference diagnosis were excluded.

**RESULTS**

<table>
<thead>
<tr>
<th>Initial Diagnosis</th>
<th>Length of Stay (median days)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>True Positive (TP)</td>
<td>ICU: 5.167</td>
<td>6.773</td>
</tr>
<tr>
<td></td>
<td>Ward: 2.407</td>
<td>3.627</td>
</tr>
<tr>
<td>False Positive (FP)</td>
<td>3.203</td>
<td>3.413</td>
</tr>
<tr>
<td>False Negative (FN)</td>
<td>3.923</td>
<td>3.627</td>
</tr>
<tr>
<td>Treated as sepsis (Indet Gold Std)</td>
<td>5.901</td>
<td>9.770</td>
</tr>
<tr>
<td>Not treated as sepsis (Indet Gold Std)</td>
<td>3.403</td>
<td>7.690</td>
</tr>
</tbody>
</table>

Figure 1: Numbers and proportions of patients diagnosed differently by SeptiCyte™ LAB compared to the standard of care at ICU admission in a representative sample of 265 patients. A panel of experts blinded to SeptiCyte™ LAB scores and to each other adjudicated the gold standard which was based on a majority consensus.

**KEY FINDINGS**

Compared to Standard of Care:
- SeptiCyte™ LAB was significantly more accurate against the retrospectively adjudicated reference standard.
- SeptiCyte™ LAB nearly doubled the rate of identification of sepsis-negative patients (TNs) without an increase in missed diagnoses (FNs).
- Identification of sepsis-negative patients is associated with reduced length of stay in both ICU and post-ICU.
- SeptiCyte™ LAB reduced False Positives identifications by 4.5% of the total trial population.
- False Positives are associated with futile antimicrobial administrations and increased costs due to extended patient stays of 2-3 days for monitoring.
- The average ICU with 265 suspected sepsis admissions per year is expected to save at least $5m per year with the adoption of SeptiCyte™ LAB.
- 27/265 (10.2%) of all patients in the trial could not be classified by an expert panel. SeptiCyte™ LAB made a determination of Positive in the majority (25) these cases.
- Changes in reimbursement resulting from diagnostically supported ICD10 and DRG codes were not modeled, but would be in addition to these figures.

**CONCLUSIONS**

SeptiCyte™ LAB provides diagnostic information at the time of ICU admission that may provide significant opportunity for better patient management and more efficient health resource utilization.

**ACKNOWLEDGEMENTS**

Joanne Hathaway and Phil Cyr of Precision Health Economics designed and developed the econometric models.


2022 | Modeling Improved Patient Management and Hospital Savings with SeptiCyte™ LAB in the Diagnosis of Sepsis at ICU Admission

L.C. McHugh, Immunexpress, Seattle, WA, USA
Notes

- Using PHE model. SeptiCyte threshold of 3.1
- 100% market share for SoC at baseline. No change until yr 3, then with 100% share for SeptiCyte so that the 3 year cumulative models reflect the full change.