

Category : **Sepsis: biomarkers**

**A483 - Clinical performance of a rapid sepsis test on a near-patient molecular testing platform**

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**Introduction:**

The purpose of this study was to clinically validate a new, rapid version of the SeptiCyte™ assay on a near patient testing platform (Biocartis Idylla™). SeptiCyte™ LAB is the first class sepsis diagnostic to gain FDA-clearance but has a complex workflow and a turnaround time (TaT) of ~ 6 hours. The assay in Idylla™ cartridge format is called SeptiCyte™ RAPID.

**Methods:**

SeptiCyte™ LAB was translated to the Biocartis Idylla™ patient testing platform and analytically validated. For this study, 0.9mL of peripheral blood PAXgene™ solution from previously collected patient samples was pipetted directly into the cartridge and inserted into the Idylla™ reader. Patients were part of an independent cohort (N=200) from Intensive Care Units located in the USA and Europe. SeptiCyte™ RAPID results were reported as a SeptiScore™ between 0 and 10 with higher scores representing higher probability of sepsis. Assay performance determined included technician hands-on-time (HoT), assay TaT, failure rates, and Area Under ROC Curve based on comparison to retrospective physician diagnosis.

**Results:**

Average HoT was 2 minutes, and average TaT was 65 minutes. Clinical samples could be processed immediately with SeptiCyte™ RAPID and did not require 2 hour preincubation of PAXgene blood, greatly improving TaT. Correlation of SeptiScore™ values between LAB and RAPID, based upon a subset of samples run on both platforms, was very high ( $R^2 > 0.97$ ). Estimated ROC AUC performance for discriminating sepsis from non-infectious systemic inflammation (NISI/SIRS) was similar to that previously reported for SeptiCyte™ LAB.

**Conclusion:**

This is the first demonstration of a validated, fully-integrated, rapid, reproducible, near-patient, immune-response sepsis diagnostic, providing actionable results ~ 1 hr, to differentiate sepsis from non-infectious systemic inflammation / SIRS.