

# IN SILICO PERFORMANCE OF A RAPID SEPSIS TEST IN PATIENTS WITH CANDIDEMIA

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## INTRODUCTION

The purpose of the study was to determine the performance of SeptiCyte® RAPID biomarkers in patients with candidemia using *in silico* data. SeptiCyte® LAB is the first-in-class sepsis diagnostic to gain FDA-clearance for differentiating infection

negative systemic inflammation INSI/SIRS from sepsis. The assay in Biocartis Idylla™ cartridge format is called SeptiCyte® RAPID. We have previously demonstrated that SeptiCyte® RAPID biomarkers can differentiate both bacterial and viral

sepsis from INSI/SIRS. Here we highlight the performance of SeptiCyte® RAPID for differentiating patients with candidemia from clinical controls.

## METHODS

The two genes of SeptiCyte® RAPID were used in an *in silico* analysis of U219 microarray data. Patients with positive blood cultures for Candida (n=6) were compared to a Healthy cohort (n=42) along with patients who were initially suspected

of sepsis and treated with antibiotics but subsequently demonstrated not to have an infection ("not infected", n=26) and INSI/SIRS (43) patients. Patients and samples were selected from the MARS database and biobank based

on discharge diagnosis and/or clinical microbiology results. For candidemia, only those with a single organism isolated were used. Diagnostic performance was measured using Area under the Receiver Operating Characteristic Curve (AUROC).

## RESULTS

Using *in silico* data from an Affymetrix U219 microarray, the two biomarkers of SeptiCyte® RAPID had AUCs of 1.00, 0.942 and 0.942 for differentiating candidemia (n=6) from

healthy subjects (n=42) and patients suspected of sepsis but with a discharge diagnoses of INSI/SIRS (n=43) or not infected (n=26) (Figures 1, 2). Patients with candidemia had only a single

organism isolated, so these patients could be considered to have a "pure" fungal infection.

Figure 1: SeptiCyte® Performance – Box and Whisker Plot

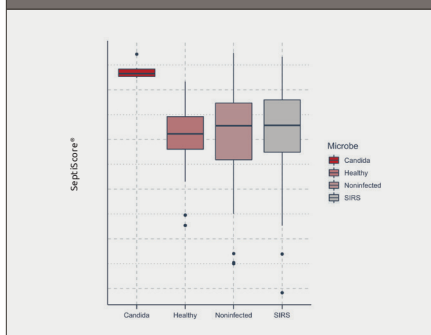


Figure 2: SeptiCyte® Performance – ROC Curves

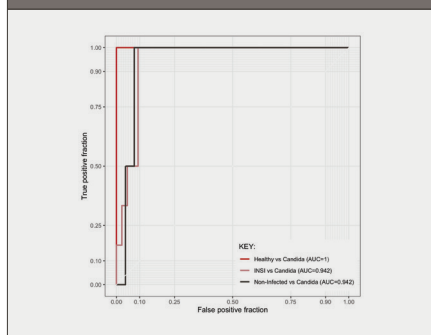


Figure 1: Box and whisker plot showing *in silico* performance of the biomarkers of SeptiCyte® RAPID for differentiating patients with candidemia, healthy subjects, not infected, and INSI/SIRS.

Figure 2: ROC curve demonstrating clinical performance of SeptiCyte® RAPID in candidemia patients vs other cohorts. Clinical evaluation was made between 6 candidemia patients and healthy (n= 42), not infected (n=26), INSI (n=43) and all clinical groups (n=111).

## CONCLUSIONS

• *In silico* analyses of microarray data has demonstrated that the two genes of SeptiCyte® RAPID differentiated patients with candidemia from those with INSI/SIRS, not infected and healthy subjects.

• In combination with prior work, we have now demonstrated that SeptiCyte® RAPID differentiates patients with bacterial, viral or candida sepsis from patients with INSI/SIRS or not infected.

Table 1: SeptiCyte® Performance - AUC

Case / Control	Patients	AUC
6 / 26	Candida / No Infection	0.942
6 / 43	Candida / INSI	0.942
6 / 42	Candida / Healthy	1.000

