

Technical Sheet for SeptiCyte® RAPID CE-IVD

The SeptiCyte® RAPID (SB3020C) test is a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes isolated from whole blood collected in either the PAXgene® Blood RNA Tube or an EDTA blood tube. The SeptiCyte® RAPID test is used in conjunction with clinical assessments and other laboratory findings as an aid to differentiate infection-positive (sepsis) from infection negative systemic inflammation in patients suspected of sepsis. The SeptiCyte® RAPID test generates a score (SeptiScore®) that falls within one of four discrete Interpretation Bands based on the increasing likelihood of infection-positive systemic inflammation. SeptiCyte® RAPID is intended for in-vitro diagnostic use on the Biocartis Idylla™ System.

Specimen requirements

Sample Type	The test is for processing a 0.9 ml whole blood collected in PAXgene® blood RNA tubes or 0.24 ml whole blood collected in K2/K3 EDTA blood collection tubes
Supported blood collection tubes	PAXgene® blood RNA tubes or K2/K3 EDTA blood collection tubes

Total turnaround time

Total time	60-65 minutes
Hands-on time	Approx. 2 minutes (excluding sample collection/handling)

Result reporting

Test result	SeptiScore® (0 – 15, increasing value indicates higher sepsis probability), Interpretation band (Band 1 - 4, higher band indicates increased sepsis probability)
Quality status	Validity of test result, sample processing control status

Performance

Analytical sensitivity	LOD of 25 white blood cells per µL of whole blood
Reproducibility	The standard deviation of the SeptiScore® was below 0.35 for all sample pools for all sources of variation (operator, lot, instrument).
Accuracy	High correlation between SeptiCyte® RAPID and FDA-cleared comparator test ($r^2 = 0.94$).
Sepsis probability	Band 1 < 10%; Band 4 > 80%, based on consensus diagnosis
Test sensitivity	94%, based on Band 1 threshold
Test specificity	90%, based on Band 4 threshold

SeptiCyte® RAPID Publications

Check our website: <https://www.septicyte.com/septicyte-technology/> for complete bibliography including latest publications.

