Technical Sheet for SeptiCyte™ RAPID in Europe

SeptiCyte™ RAPID 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 a PAXgene® Blood RNA Tube. SeptiCyte™ RAPID is used in conjunction with clinical assessments, vital signs and laboratory findings as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammation in patients suspected of sepsis. SeptiCyte™ RAPID generates a score (SeptiScore™) that falls within one of three discrete Interpretation Bands based on the increasing likelihood of infection-positive systemic inflammation. SeptiCyte™ RAPID is intended for *in vitro* diagnostic use.

For use on the Biocartis Idylla™ System.

Specimen requirements

Sample Type	The test is for processing a 0.9 ml sample of whole blood collected in PAXgene Blood RNA tubes per the manufacturer's instructions
Supported blood collection tubes	PAXgene Blood RNA tubes

Total turnaround time

Total time	65 minutes
Hands on time	Approx. 2 minutes (excluding sample collection/handing)

Result reporting

Test result	SeptiScore (0 – 15, increasing value indicates higher sepsis probability), Interpretation band (Band 1 -3, higher band indicates increased sepsis probability)
Quality status	Validity of test result, sample processing control status

Performance

Analytical sensitivity	LOD of 0.1 x 10^6 white blood cells per mL of blood
Reproducibility	The standard deviation was below 0.35 units 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 3 > 80%, based on unanimous diagnosis
Test sensitivity	92% - 95%, based on Band 1 threshold
Test specificity	86%, based on Band 3 threshold

SeptiCyte™ RAPID Publications

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