

Neonatal Sepsis – Pathogen ID Test

CARB-X Diagnostics Target Product Profile*		
Variable	Minimal Requirement	Ideal Requirement
1. Product Use Summary/Differentiation Strategy		
Intended Use(s)	Species-level identification of bacterial pathogens in the blood of septic neonates	
Pathogen Targets	<i>Staphylococcus aureus</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , and <i>Acinetobacter baumannii</i> .	<i>In addition to the Minimal Requirements and according to regional relevance:</i> <i>Burkholderia</i> spp <i>Citrobacter</i> spp., <i>Enterobacter</i> spp., <i>Klebsiella michiganensis</i> , <i>Ralstonia mannitolilytica</i> , <i>Pseudomonas aeruginosa</i> , <i>Serratia marcescens</i> , Coagulase-negative <i>Staphylococcus</i> spp., Group B <i>Streptococcus</i> , <i>E. meningoseptica</i> , <i>Enterococcus</i> spp, <i>L. monocytogenes</i> , <i>Salmonella</i> spp. (especially NTS)
Target level of health system	Regional/provincial hospital, district hospital	Regional/provincial hospital, district hospital, health center
Proposed target populations	Neonate (up to 90 days) with one or more signs of bacterial infection	
Lowest complexity level	Moderate	CLIA waived
2. Design		
Sample type/collection	Whole blood	
Sample volume	≤ 2 mL	≤ 1 mL
3. Performance		
Species differentiation	No cross-reactivity between species	
Polymicrobial infections	Able to detect polymicrobial infections	
Level of Detection	≤ 10 CFU/mL	≤ 5 CFU/mL
Analytic sensitivity	≥ 90%	≥ 95%
Analytical specificity	≥ 80%	≥ 90%
Clinical sensitivity	≥ 90%	≥ 95%
Clinical specificity	≥ 80%	≥ 90%
Result output	Provides pathogen identification at the species level	
Time to result	≤ 8 hours	≤ 4 hours
Operating Conditions	5-40° C, 40 - 98% relative humidity	
4. Manufacturing / Commercial Details		
Target Cost of Goods Sold for consumable	< \$12	< \$6

*Certain aspects of this TPP were guided by the following references:

- Sharma et al. 2023: Indian J Med Res 157:395-402.
- Milton et al. Neonatal sepsis and mortality in low-income and middle-income countries from a facility-based birth cohort: an international multisite prospective observational study. Lancet Glob Health. 2022;10(5):e661-e672.
- Nest 360. Use Cases: Sepsis Diagnostic – Infection Prevention and Control. 2020.