Neonatal Sepsis – Antibiotic Susceptibility/Resistance Test

CARB-X Diagnostics Target Product Profile*		
Variable	Minimal Requirement	Ideal Requirement
1. Product Use Summary/Differentiation Strategy		
Intended Use(s)	Rapid test to determine the antibiotic susceptibility and resistance markers of bacterial pathogens found in the blood of septic neonates	
Detection method	Genotypic or Phenotypic	
Pathogen Targets	*Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae*, and *Acinetobacter baumannii.*	*In addition to the Minimal Requirements and according to regional relevance:* *Burkholderia* spp *Citrobacter* spp., *Enterobacter* spp., *Klebsiella michiganensis, Ralstonia mannitolilytica, Pseudomonas aeruginosa, Serratia marcescens,* Coagulase-negative *Staphylococcus* spp., Group B *Streptococcus, E. meningoseptica, Enterococcus spp, L. monocytogenes, Salmonella* spp. (especially NTS)
Antibiotics assessed and Resistance detection	Antibiotic susceptibility determination and detection of common resistant mechanisms to the current standard of care agents specific for each targeted pathogen	
Target level of health system	Regional/provincial hospital, district hospital	Regional/provincial hospital, district hospital, health center
Proposed target populations	Neonates (up to 90 days old) with possible signs and symptoms of sepsis	
Lowest complexity level	Moderate	CLIA waived
2. Design		
Sample type/collection	Whole blood	
Sample volume	$\leq$ 2 mL	$\leq$ 1 mL
3. Performance		
Concordance	$\geq$ 90%	$\geq$ 95%
Reference Method	Blood Culture	Blood Culture, with sequencing used for discrepancy analysis
Result output	Provides resistance categories as resistance and susceptible to the pathogen-specific antibiotics	
Time to result	$\leq$ 8 hours	$\leq$ 4 hours
4. Manufacturing / Commercial Details		
Target Cost of Goods Sold for consumable	$\leq$ $50 USD	$\leq$ $25 USD

*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.