Neonatal Sepsis – Rapid Triage Test

CARB-X

Combating Antibiotic Resistant Bacteria

CARB-X Diagnostics Target Product Profile*		
Variable	**Minimal Requirement**	**Ideal Requirement**
1. Product Use Summary/Differentiation Strategy		
Intended Use(s)	Rapid triage test to aid diagnosis of sepsis	
Detection method	Detection of validated host immune response markers indicating sepsis and/or detection of pathogen-specific markers indicating the presence of active bacteremia	
Target analytes	Relevant multiple host immune response markers must be used and/or bacterial pathogen markers	
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 old) with at least one sign of serious bacterial infection	
Lowest complexity level	Moderate	CLIA waived
2. Design		
Sample type/collection	Direct from specimen (e.g. blood).	
Sample volume	$\leq$ 500 uL	$\leq$ 75 uL
3. Performance		
Diagnostic/Clinical sensitivity	$\geq$ 95%	$\geq$ 98%
Diagnostic/Clinical specificity	$\geq$ 90%	$\geq$ 90%
Analytical sensitivity (only applicable for pathogen detection)	$\geq$ 90%	$\geq$ 90%
Analytical specificity (only applicable for pathogen detection)	$\geq$ 90%	$\geq$ 90%
Result output	Binary and in a simple readable format	
Time to result	$\leq$ 30 min	$\leq$ 15 min
Operating Conditions	5-40°C, 40 - 98% relative humidity	
4. Manufacturing / Commercial Details		
Target Cost of Goods Sold for consumable	$\leq$ 5 USD	$\leq$ 3 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.