

## **Neonatal Sepsis – Rapid Triage Test**

CARB	-X Diagnostics Target Product Pro	file*	
Variable	Minimal Requirement	Ideal Requirement	
1. Product Use Summary/Differentia	tion 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,	Regional/provincial	
	District hospital	hospital, District hospital,	
	District nospital	Health center	
Proposed target populations	Neonate (up to 90 days old) with a	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	≤ 500 uL	≤ 75 uL	
3. Performance		•	
Diagnostic/Clinical sensitivity	≥ 95%	≥ 98%	
Diagnostic/Clinical specificity	≥ 90%	≥ 90%	
Analytical sensitivity (only	≥ 90%	≥ 90%	
applicable for pathogen			
detection)			
Analytical specificity (only	≥ 90%	≥ 90%	
applicable for pathogen			
detection)			
Result output	Binary and in a simple readable for	Binary and in a simple readable format	
Time to result	≤ 30 min	≤ 15 min	
Operating Conditions	5-40°C, 40 - 98% relative humidity		
4. Manufacturing / Commercial Deta	nils		
Target Cost of Goods Sold for	≤ 5 USD	≤ 3 USD	
consumable			

<sup>\*</sup>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.