Non-invasive Diagnosis of Sepsis in Neonates Using Saliva

True Class \ Predicted Class	Correctly Identified as Non-infected	Misclassified as Infected
	227 (77%)	69 (23%)
Misclassified as Non-infected	**Correctly Identified as Infected**	
17 (25%)	52 (75%)	

Clinical Need

"Rule-out sepsis" is the most ordered test in the Neonatal Intensive Care Unit (NICU) but currently requires a harmful blood collection to diagnose. The gold standard blood culture test is inaccurate and slow, leading to unnecessary antibiotic exposure.

Our Innovative Approach

In the largest salivary study to date of 1,215 neonates, we identified a panel of 11 protein biomarkers and total protein in saliva to quickly and non-invasively identify sepsis.

Results

Our biomarker panel enabled non-invasive sepsis diagnosis from only 10 µL of saliva collected at a single timepoint with 77% sensitivity and 75% specificity (AUC 0.83)—a two-fold improvement over standard of care. This assay enhances infection-screening accuracy to minimize unnecessary antibiotic exposure in newborns and offers a pain-free and safe alternative for detecting sepsis.

Commercial Potential

Limited competition exists for neonatal sepsis detection (e.g., NAATs and blood culture), while a clear reimbursement pathway enables market entry. We seek partners for point-of-care device development, manufacturing at scale, regulatory approval, and distribution to bring this innovative solution to NICUs worldwide.

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