Rapid molecular detection directly from whole blood for the early diagnosis of paediatric bloodstream infections using the CUBE DX system

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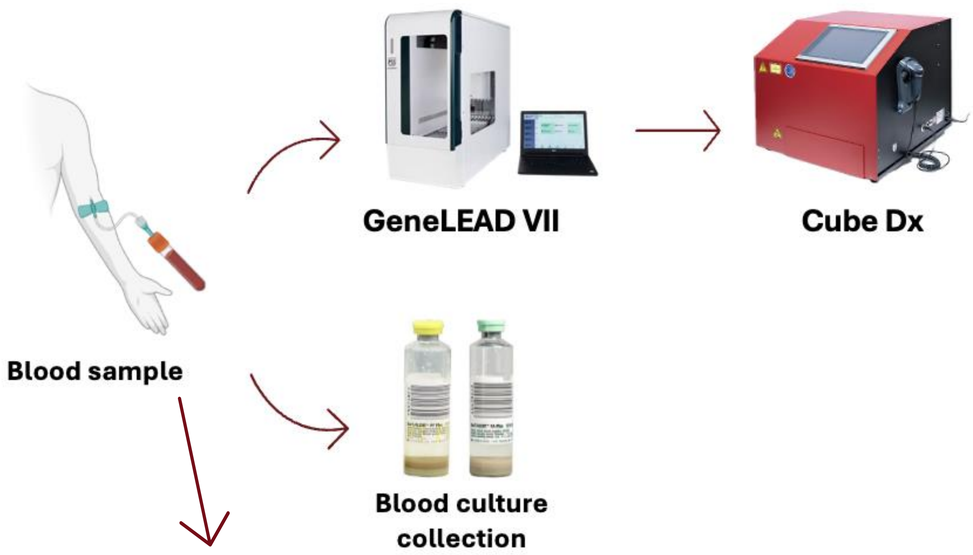
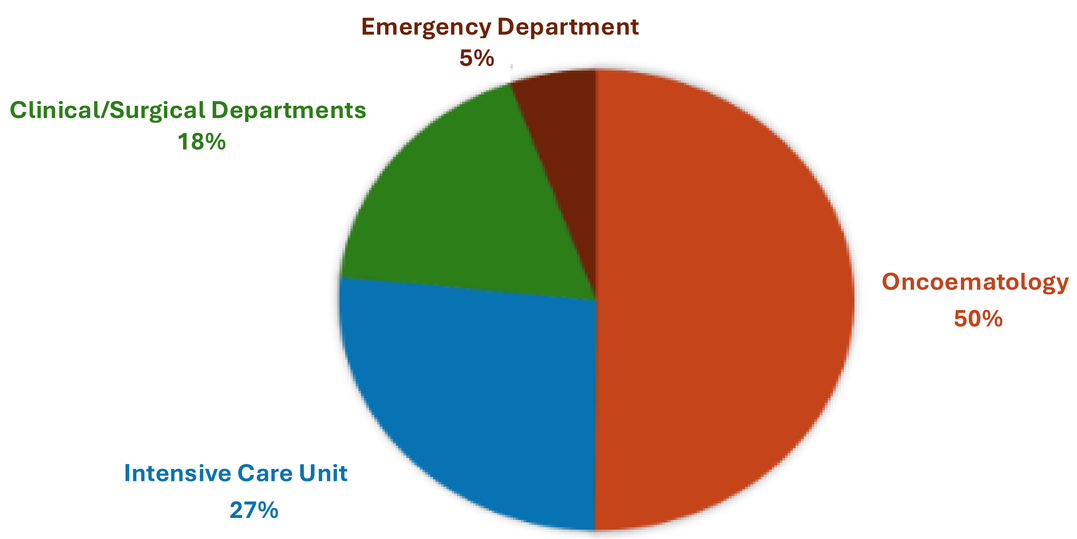
BACKGROUND

Bloodstream infections (BSI) especially in pediatric patients require rapid and accurate pathogen identification to guide early antimicrobial therapy. While blood culture (BC) remains the gold standard, its long incubation times and substantial blood volume requirements limit diagnostic yield in neonates and young children. The CUBE DX system provides a direct-from-whole-blood molecular approach, enabling pathogen detection without prior culture and potentially accelerating diagnosis.



MATERIALS AND METHODS

A prospective study was conducted at Bambino Gesù Children's Hospital (Rome, Italy) between July 2025 and February 2026. A total of 109 whole-blood samples (≥1 mL) from pediatric patients aged <18 years with suspected bloodstream infection/sepsis were analyzed using the CUBE DX system. In parallel, conventional blood cultures were collected using BACT/ALERT® Culture Media Bottles (bioMérieux, France). Agreement between CUBE DX and blood culture, diagnostic performance, and the clinical-microbiological significance of discrepant results were evaluated.



RESULTS

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GINA PROTOCOL		BLOOD CULTURE		
		POSITIVE	NEGATIVE	TOT
CUBE DX	POSITIVE	13*	3**	19
	NEGATIVE	9***	84	90
	TOT	24	85	109

* **1/13 are concordant in positivity but discordant in ID -** CUBE DX - *Streptococcus sp.* / BC - *Microbacterium laevaniformans*;

** **Cases of negative Blood Cultures but positive for analysis in other samples or previous BC** (*Serratia marcescens*, *Haemophilus influenzae, Staphylococcus epidermidis)*

*** **Negative CUBE DX due to the absence of the microorganism in the test panel** (*Campylobacter jejuni*), **contamination of the BC, or to discrepancies in collection date and in the vascular access site.**

Sensitivity	**59.09%**
Specificity	**96.55%**
Positive predictive value	**81.25%**
Negative predictive value	**90.32%**
Accuracy	**88.99%**

A total of 109 whole-blood samples were analysed. Most samples originated from Oncohematology (50%), followed by the Intensive Care Unit (27%), Clinical/Surgical Departments (18%), and the Emergency Department (5%). Blood culture was positive in 24/109 samples, whereas CUBE DX was positive in 19/109. When blood culture was used as the reference method, CUBE DX yielded 13 true-positive, 84 true-negative, 3 false-positive, and 9 false-negative results, corresponding to a sensitivity of 59.1%, specificity of 96.6%, positive predictive value of 81.3%, negative predictive value of 90.3%, and an overall accuracy of 89.0%. Among the 13 samples positive by both methods, organism identification was concordant in 12 cases, while one showed discordant species-level identification (CUBE DX: *Streptococcus* spp.; blood culture: *Microbacterium laevaniformans*). Notably, all three CUBE DX-positive/blood culture-negative cases were supported by positivity in other clinical specimens or previous blood cultures (*Serratia marcescens*, *Haemophilus influenzae*, and *Staphylococcus epidermidis*). Conversely, several blood culture-positive/CUBE DX-negative discrepancies were associated with organisms not included in the CUBE DX panel, possible blood culture contamination, or differences in sampling time and vascular access site.

CONCLUSIONS

CUBE DX showed good specificity and a high negative predictive value for the direct-from-whole-blood detection of paediatric bloodstream pathogens, providing clinically relevant microbiological information within hours. Although sensitivity was moderate when blood culture was used as the comparator, some discrepant CUBE DX-positive results were supported by additional microbiological evidence, suggesting potential added value in selected clinical settings. Larger studies are warranted to better define the role of CUBE DX alongside standard culture-based diagnostics.

REFERENCES

SMARTDIAGNOS – next generation molecular sepsis diagnosis technology for whole blood samples
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