Exploring the gains: potential economic impact of a rapid, direct from whole-blood-to-report NGS-based diagnostic platform (LiDia-SEQ™) for BSI detection

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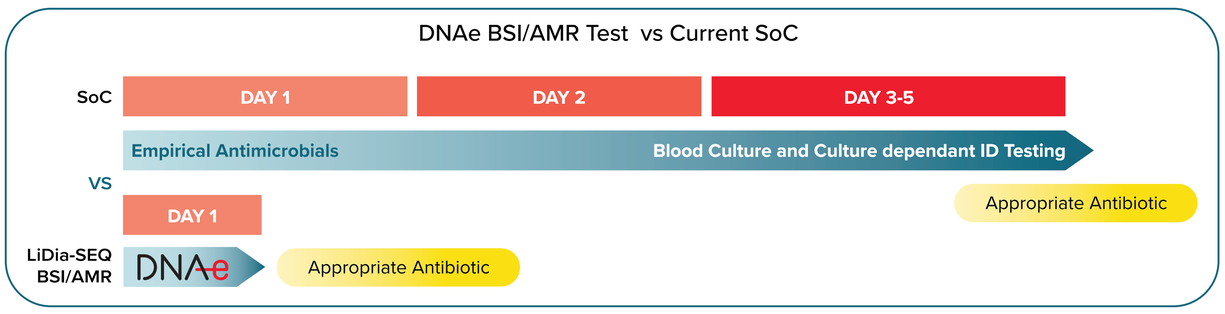
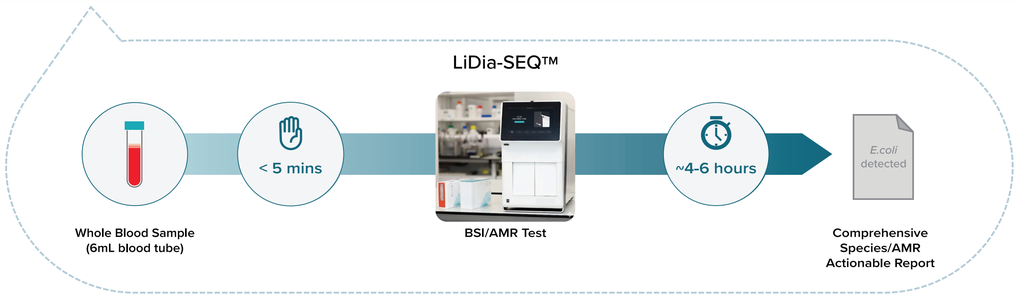
BACKGROUND

Bloodstream infections (BSIs) – leading to sepsis – are one of the deadliest and most costly challenges in modern healthcare[1]. This life threating condition is caused by a wide range of pathogens, with an estimated 49 millions cases globally per year[2]. For every hour in delay of appropriate therapy, risk of mortality is increased by 4-9%[3]. The average cost per hospital stay for sepsis patients is double the average cost per stay across all other conditions[4]. In the USA alone, the annual financical impact on the healthcare system is ~$62 billion[5]. Current standard of care (SoC) approaches like blood culture take a long time (days), cannot detect many pathogens and require additional testing for antimicrobial resistance (AMR) profiling resulting in poorer patient outcomes, extended hospital stays, and escalation in healthcare costs.

DNAe's BSI/AMR Test on its breakthrough LiDia-SEQ™ platform will offer clinicians and patients a transformative solution: a true sample-to-report NGS-based diagnostic platform that delivers comprehensive results within hours – dramatically faster than the current blood culture dependent SoC.





The LiDia-SEQ platform workflow

Time to Results

- Whole blood to pathogen ID + AMR report in less than a work shift
- Direct from a single < 6mL whole blood sample, without the need for culture

Comprehensive Test Panel

- Designed to detect:
  - ~7400 bacterial + ~26 most common AMRs
  - ~800 fungal species
- Low LOD of ~1-3 CFU/mL anticipated

Ease of use

- Fully-integrated automated workflow, true sample-to-report
- < 5 mins hands-on time
- Fully automated onboard bioinformatics analysis are reporting

METHODS AND MATERIALS

Two economic value frameworks were developed to evaluate the potential cost impact of adopting the LiDia-SEQ BSI/AMR Test compared with the current SoC pathways for suspected BSI/sepsis patients. Inputs were obtained from published material including peer-reviwed literature, policy institutions, healthcare bodies, and internal data.

Impact of test performance and offerings

The first framework assessed the potential economic impact of LiDia-SEQ BSI/AMR Test was evaluated by comparing to an existing blood-culture-dependent molecular rapid diagnostic test (mRDT). The framework assessed the cost impact on several key components: time to organism identification, time to effective therapy, antimicrobial therapies, and impact of effective and timely treatment on length of stay (LOS). A derived adult patient population of 1,000 individuals hospitalised with suspected BSI/sepsis was generated for this study. Framework inputs are described in Table 1.

	LiDia-SEQ BSI/AMR Test	Blood culture-dependant mRDT
Incidence of BSI	8.5%[9]	
Time to organism ID	7.2 h	28.2 h
BSI cases missed by method	4%	40%[10]
Sensitivity	96%	98.9%[11]
Specificity	99%	99.6%[11]
Patients treated based on clinical symptoms after a negative test	5%	95%
LOS costs per day (adjusted for 2025 $)	$3,304[12]	

Typical LOS for an individual receiving appropriate antimicrobial therapy is 7 days and inappropriate antimicrobial therapy is 10 days[9, 13]

Table 1: Value framework inputs

Impact of time to actionable results on LOS

The second framework assessed the impact of time to actionable diagnosis on patients' LOS when comparing LiDia-SEQ BSI/AMR test to the SoC. The study employed a derived adult patient cohort hospitalised with a BSI, who when receiving uninformed empiric antimicrobial therapy had an average LOS of 7.8 days[6,7].

The time to a positive blood culture was set at 24 hours and is defined as T0. The number of hours between T0 and the point when an actionable result is available was calculated (Table 2). For every hour increase beyond T0 to an actionable result a penalty of 1.004 per hour was incurred[8].

	LiDia-SEQ BSI/AMR Test	Blood culture-dependant mRDT	Blood culture + MALDI-TOF
Time to actionable result	T0 - 17 h	T0 + 4 h	T0 +18 h

Table 2: Calculated time to actionable result

Assumptions and limitations

Targeted therapy begins immediately after infectious organism identification. Individuals do not develop significant complications or reoccurrence of disease once treated. All LiDia-SEQ BSI/AMR test input information, while informed, is hypothetical.

RESULTS

Impact of test performance and offerings

The cost analysis framework identified an estimated saving of $3,147 per patient tested ($3,942 vs $7,088) with adoption of the LiDia-SEQ BSI/AMR Test compared with an existing culture-dependent mRDT (Table 3). The culture-independent design, comprehensive panel coverage, and expected analytical performance metrics of the LiDia-SEQ BSI/AMR Test, enables a greater proportion of patients to receive guided therapy (Table 3). LiDia-SEQ BSI/AMR Test has the ability to process a raw whole blood sample and may deliver substantial time and cost efficiencies by shortening the time to pathogen identification, even when accounting for a potentially higher diagnostic work-up cost (Table 3).

	LiDia-SEQ BSI/AMR Test	Blood culture-dependant mRDT
Patients receiving guided therapy	101	70
Patients receiving unguided therapy	4	35
Cost of hospitalization - unguided therapy patients	$5,617	$1,070,394
Cost of hospitalization - guided therapy patients	$2,327,816	$1,614,522
Hospitalisation diagnostic wait and work-up costs	$1,591,200	$4,387,200
Cost of therapy	$17,431	$16,678
Total cost – per patient tested	$3,942	$7,089
Total cost – per 1,000 patients tested	$3,942,064	$7,088,793
Budget impact DNAe vs SoC per tested patient	**$3,147**	

Table 3: Output of a cost-analysis framework comparing LiDia-SEQ BSI/AMR Test with an existing culture-dependent mRDT

Impact of time to actionable results on LOS

The unique ability of the LiDia-SEQ BSI/AMR to pair direct from whole blood sample input (culture-independent) with a comprehensive sequencing panel enables an earlier time to diagnostic result of approximately 7 hours, compared with 28 hours with a current SoC mRDT method. Consequently, adoption of the LiDia-SEQ BSI/AMR Test could offer cost savings of ~$5,100 per tested patient ($24,033 vs $29,164) when compared to the existing SoC + Maldi-TOF or a saving of $2,929 ($24,033 vs $26,962) when compared to a culture-dependant mRDT (Table 4).

	LiDia-SEQ BSI/AMR Test	Blood culture-dependant mRDT	Blood culture + MALDI-TOF
LOS Cost	$23,433	$26,457	$28,738
Total (LOS costs + Diagnostics costs)	$24,033	$26,962	$29,164
Cost vs LiDia-SEQ BSI/AMR Test		+ $2,929	+ $5,131

Table 4: Estimated costs per patient tested for the LiDia-SEQ BSI/AMR Test, existing culture-dependant mRDT, and a blood culture followed by MALDI-TOF

CONCLUSION & DISCUSSION

This postulated study demonstrates that the LiDia-SEQ BSI/AMR Test can offer significant potential savings when compared to the current SoC, and with current established culture-dependent mRDTs. This highlights the potential benefits of a diagnostic test, like LiDia-SEQ BSI/AMR Test, capable of delivering truly comprehensive and actionable results in a rapid timeframe, thereby enabling informed decision making, better resource utilization, and outcomes.

The LiDia-SEQ BSI/AMR Test, a single culture-independent test offering a comprehensive testing panel direct from whole blood, is positioned to address the limitations of current SoC approaches. By reducing time to pathogen identification and associated AMR detection in patients hospitalized with suspected BSI or sepsis, it has the potential to deliver $2,929 - $3,147 savings per patient and meaningfully influence patient management. Earlier actionable identification of causative pathogens can lead to faster initiation or de-escalation of antimicrobials, thereby reducing associated costs of delayed time to actionable results, inappropriate antimicrobial therapy, and prolonged LOS.

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