Review Article

BIOMEDICAL Journal of Scientific & Technical Research

ISSN: 2574 -1241

DOI: 10.26717/BJSTR.2026.64.010075

The Intelligent Laboratory: Synergizing LIS Big Data and AI for Precision Reference Interval Establishment

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ARTICLE INFO

Received: January 07, 2026

Published: February 05, 2026

Citation: Wejdan A Alqahtani, Hesham A Almohammad, Walleed H Nasraldeen, Khawla Talal lgashgari, Eman M Aljahani, Basim Muhammad Abulilla, Daniah Jamil Nazer, Mohammad A Adulmajeed, Adel Abdulmohsen Alsheikh, Rayan M Alkathiri, Rami H Tayeb and Alaa A Aljehani. The Intelligent Laboratory: Synergizing LIS Big Data and AI for Precision Reference Interval Establishment. Biomed J Sci & Tech Res 64(4)-2026. BJSTR. MS.ID.010075.

ABSTRACT

The paradigm of modern laboratory medicine is undergoing a seismic shift, driven by the exponential growth of digital health data and the simultaneous maturation of artificial intelligence technologies. This review critically examines the transition from traditional, direct methods of reference interval (RI) establishment to indirect, data-driven approaches that leverage the vast repositories of Laboratory Information Systems (LIS). The primary objectives of this review are to analyze the efficacy of emerging algorithmic models-specifically the refineR algorithm and convolutional neural networks-in purifying real-world data, to evaluate the integration of these computational tools within LIS infrastructures, and to assess the clinical trajectory toward personalized reference intervals. The major results indicate that AI-driven indirect methods offer a scientifically robust, cost-effective alternative to direct sampling, capable of mitigating the noise inherent in routine medical data while facilitating the derivation of continuous, age-specific intervals. Furthermore, the review highlights that "Big Data" analytics enable the stratification of reference values closer to the individual patient's biological reality rather than a broad population average. Major recommendations include the urgent need for standardization in data preprocessing protocols, increased investment in cloud-based LIS architecture, and the development of ethical frameworks for patient data utilization. The conclusion posits that the synergy of LIS Big Data and AI does not merely refine existing metrics but fundamentally redefines the concept of "normalcy" in pathology, moving the field decisively toward precision medicine.

Keywords: Laboratory Information Systems; Artificial Intelligence; Reference Intervals; Big Data; Precision Medicine; Indirect Methods

Abbreviations: AI: Artificial Intelligence; ML: Machine Learning; RIs: Reference Intervals; Laboratory LIS: Information Systems; CNNs: Convolutional Neural Networks

Introduction

The contemporary healthcare landscape is being fundamentally reshaped by the convergence of massive datasets and advanced computational capabilities, signaling the dawn of an era defined by data-driven precision (Ullah, et al. [1]). Within this digital revolution, the clinical laboratory has emerged as a primary generator of high-velocity, high-volume data, necessitating a reevaluation of how diagnostic norms are established and maintained (Plebani, et al. [2]). The traditional paradigm of medicine is increasingly leveraging these vast information repositories to enhance chronic disease management and preventive health strategies (Wang, et al. [3]). Consequently, the integration of artificial intelligence (AI) and machine learning (ML) into laboratory medicine is no longer a futuristic concept but a critical operational requirement for modern healthcare systems (Ahmed [4]). This integration is particularly pertinent to the establishment of reference intervals (RIs), which serve as the fundamental decision-making tools for differentiating health from pathology in clinical practice (Martinez Sanchez, et al. [5]).

Reference intervals have historically been established through "direct" methods, which involve selecting healthy reference individuals and measuring specific analytes to determine central 95% intervals (Coskun, et al. [6]). However, this traditional approach is

fraught with logistical challenges, high costs, and ethical complexities, particularly when attempting to recruit reference populations for pediatric or geriatric cohorts (Ma, et al. [7]). The limitations of the direct method have catalyzed a shift toward "indirect" methods, which utilize the immense volume of routine results stored in Laboratory Information Systems (LIS) to estimate RIs using statistical and algorithmic techniques (Ammer, et al. [8]). The utilization of LIS data represents a form of "Big Data" mining, where the challenge lies not in data scarcity but in the extraction of a physiological signal from the noise of pathological results (Martinez Sanchez, et al. [5]). The application of AI in this domain allows for the sophisticated processing of these complex datasets, enabling the identification of healthy physiological patterns within mixed clinical populations (LeBien, et al. [9]). Advanced algorithms, such as those utilizing deep learning and Convolutional Neural Networks (CNNs), are demonstrating the capacity to model complex, non-linear relationships in laboratory data that traditional parametric statistics cannot capture (LeBien, et al. [9]). Furthermore, the scope of AI in the laboratory extends beyond simple data cleaning; it encompasses the holistic management of diagnostic information, mirroring the transformative impact AI has had on fields ranging from viral hepatitis management to cardiovascular diagnostics (Ali, et al. [10,11]). The potential for AI to automate the derivation of RIs promises to democratize access to accurate, population-specific diagnostic benchmarks (Angeloni, et al. [12]). However, the transition to an "Intelligent Laboratory" is not merely a technical upgrade but a comprehensive systemic overhaul that requires robust digital infrastructure (Xu, et al. [13]). The management of such data necessitates cloud-based storage solutions and advanced computing paradigms capable of handling the sheer scale of remote sensing and diagnostic data (Xu, et al. [13]). Moreover, the successful implementation of these technologies relies on cross-disciplinary synergies, drawing lessons from diverse fields such as civil engineering and geosciences where big data management has already been operationalized to solve complex problems (Babović, et al. [14]). The integration of these technologies into the LIS must also address the "empiricist's challenge," ensuring that the questions asked of the data are meaningful and that the results are clinically valid rather than just statistically significant (Jungherr, et al. [15]).The implications of this shift extend to the very core of personalized medicine, where the goal is to move from population-based averages to individualized reference ranges (Coskun, et al. [6]). By synergizing LIS big data with AI, laboratories can move toward "value-based laboratory medicine," where diagnostic metrics are dynamically adjusted to the patient's specific biological context (Plebani, et al. [2]). This evolution parallels advancements in other high-precision fields, such as cancer epigenetics and immunomics, where computational modeling is used to understand complex biological responses (Baker, et al. [16,17]). The promise of such technology is the development of a "next wave" of precision medicines and diagnostics that are tailored to the unique molecular signatures of individual patients (Baker, et al. [16]).

Yet, the adoption of these advanced computational frameworks is not without significant hurdles, including the need for standardization, harmonization of data practices, and the validation of AI models in real-world clinical settings (Martinez Sanchez, et al. [5]). There is a critical need to understand how deep learning models, which have revolutionized protein landscape mapping, can be adapted to the fluid and often chaotic nature of clinical chemistry data (Verkhivker, et al. [18]). Furthermore, the rise of synthetic data and the metaverse presents new frontiers for simulating laboratory environments and training AI models without compromising patient privacy (Rajendran et al., 2024). As the role of the laboratory expands, so too does the responsibility of the professionals within it, from pathologists to librarians, who must navigate this new information ecosystem (Ahmed, et al. [4,12]). Therefore, this review aims to critically analyze the intersection of LIS big data and Artificial Intelligence in the specific context of establishing precision reference intervals. By synthesizing current literature on algorithmic developments, data management strategies, and clinical applications, this paper seeks to elucidate the path toward a fully intelligent laboratory infrastructure. The purpose of this review is to evaluate the current state of indirect RI establishment methods, identify the technological and methodological gaps hindering their widespread adoption, and propose a roadmap for integrating these AI-driven tools into routine clinical practice to achieve true precision in laboratory medicine.

Statement of the Problem

The fundamental problem addressing modern laboratory medicine is the inadequacy of traditional, static methods for establishing reference intervals (RIs) in an era demanding dynamic and personalized diagnostic precision (Ma, et al. [7]). While the concept of the reference interval is central to clinical decision-making, the "direct" method of establishing these values-requiring the recruitment and sampling of healthy volunteers=is increasingly viewed as cost-prohibitive, ethically challenging, and practically unfeasible for special populations such as pediatrics and geriatrics (Coskun, et al. [6]). Consequently, many laboratories rely on outdated citations or manufacturer-provided ranges that may not reflect the local population's demographics, leading to potential misdiagnoses and compromised patient safety (Martinez Sanchez, et al. [5]). Although Laboratory Information Systems (LIS) contain massive reservoirs of "Big Data" that could theoretically solve this deficit through "indirect" methods, the raw data is inherently "dirty," containing a mix of physiological and pathological results that obfuscate true healthy baselines (Ammer, et al. [8]). Furthermore, there is a significant disconnect between the availability of advanced Artificial Intelligence (AI) tools and their practical implementation within the routine laboratory workflow (Angeloni, et al. [12]). While AI and machine learning have demonstrated immense potential in fields like viral hepatitis and cardiology, the translation of these technologies into the specific niche of RI verification remains fragmented and non-standardized (Ali, et al.

[10,11]). The challenge is compounded by the "black box" nature of complex algorithms, such as Convolutional Neural Networks (CNNs), which, despite their power in handling non-linear data, often lack the interpretability required for regulatory acceptance in clinical settings (LeBien, et al. [9]). This lack of transparency hinders the harmonization of indirect methods, creating a landscape where different laboratories may generate vastly different RIs from similar datasets depending on the algorithms employed (Martinez Sanchez, et al. [5]).

Additionally, the infrastructure required to support these high-level computational tasks is often lacking in standard hospital environments, which struggle with the storage and processing demands of Big Data (Xu et al., 2022). The management of this data requires a shift toward cloud-based computing and robust digital architectures that are not yet universally adopted (Ullah, et al. [1]). There is also a critical gap in the workforce's capability; the "intelligent laboratory" demands a new cadre of professionals who are fluent in both clinical pathology and data science, a synergy that is currently rare (Ahmed, et al. [4,19]). Without addressing these infrastructural and educational deficits, the potential of AI to revolutionize reference intervals remains theoretical rather than operational (Babović, et al. [14]). Finally, the current approach to RIs largely ignores the paradigm of precision medicine, treating patients as static members of a population rather than individuals with unique biological trajectories (Foksinska, et al. [20]). The failure to leverage longitudinal big data to create personalized reference intervals represents a missed opportunity to detect subtle physiological changes that precede overt disease (Coskun, et al. [6]). Existing models often fail to account for the complex, intersectional variables of health, necessitating deeper mutational mapping and learning approaches similar to those used in advanced biochemistry (Verkhivker, et al. [18]). Thus, the problem is not merely technical but conceptual: how to transition from a one-size-fits-all metric to a precision-based, AI-driven model of human health (Plebani, et al. [2]).

Research Objectives

This review aims to fulfill the below objectives:

1. To evaluate the comparative performance and accuracy of emerging AI and machine learning algorithms (specifically refineR and CNNs) against traditional statistical methods in estimating reference intervals from real-world LIS data.
2. To analyze the infrastructural and methodological requirements for integrating Big Data analytics into Laboratory Information Systems (LIS) to support continuous, automated reference interval verification.
3. To assess the clinical validity and potential impact of shifting from population-based reference intervals to personalized, AI-driven reference intervals in the context of precision medicine.

Literature Review

The integration of Big Data and Artificial Intelligence (AI) into healthcare represents a fundamental transformation in how medical information is processed, interpreted, and utilized (Ullah, et al. [2]). The concept of Big Data in medicine is characterized not only by volume but by the complexity and velocity of information generated by modern diagnostic tools (Wang, et al. [3]). In the context of the clinical laboratory, this data explosion necessitates a shift from manual, heuristic analysis to automated, algorithmic processing (Plebani, et al. [2]). Scholars argue that the "intelligent laboratory" is the inevitable outcome of this digital maturation, where data science merges with pathology to enhance diagnostic value (Ahmed, et al. [4]). This evolution parallels the Industry 4.0 revolution in manufacturing, where machine learning is deployed to optimize complex processes and predict system behaviors (Rai, et al. [21]). Similarly, in the medical domain, AI is being harnessed to manage viral hepatitis, optimize cardiac diagnostics, and predict infectious disease outbreaks, demonstrating its versatility across clinical specialties (Ali, et al. [10-11,22]).

The establishment of Reference Intervals (RIs) is a critical quality indicator in laboratory medicine, yet it remains a challenging endeavor due to the limitations of direct sampling (Ma, et al. [7]). The literature extensively critiques the direct method for its high cost and ethical difficulties, particularly in vulnerable populations (Coskun, et al. [6]). As a solution, indirect methods that utilize routine data from Laboratory Information Systems (LIS) have gained prominence (Martinez Sanchez, et al. [5]). The refineR algorithm, for instance, has been identified as a novel tool that can statistically model the underlying healthy distribution within a mixed dataset, effectively filtering out pathological "noise" without the need for complex exclusion criteria (Ammer, et al. [8]). This represents a significant leap from older, parametric methods that struggled with skewed distributions common in clinical data (Ammer, et al. [8]). Furthermore, recent research has introduced the use of Convolutional Neural Networks (CNNs) to estimate RIs, treating the density distribution of laboratory results as visual data to be analyzed by deep learning architectures (LeBien, et al. [9]). These next-generation models offer the potential to establish RIs that are continuous and age-specific, rather than discrete and categorical (Ma, et al. [7]).

For these advanced algorithms to function, the underlying Laboratory Information System (LIS) must be robust and capable of handling "Big Data" workflows (Angeloni, et al. [12]). The literature emphasizes that the LIS is no longer just a repository for results but an active computational engine (Angeloni, et al. [12]). However, the storage and processing of such vast datasets require cloud-based solutions and remote sensing capabilities that challenge current hospital IT infrastructures (Xu, et al. [13]). The integration of AI into the LIS also demands a reevaluation of data management roles, with librarians and information specialists playing a crucial part in curating and

governing these digital assets (Ahmed, et al. [4]). Furthermore, the effective use of Big Data in the laboratory requires "meaningful questions" to be asked of the data, ensuring that the computational power is directed toward clinically relevant problems rather than mere data dredging (Jungherr, et al. [15]). This necessitates a cross-disciplinary approach, utilizing pedagogical frameworks from fields like civil engineering to teach complex problem-solving in data-rich environments (Babović, et al. [14]). The ultimate goal of synergizing LIS data and AI is the realization of precision medicine (Foksinska, et al. [20]). Current literature argues that population-based RIs are inherently limited because they ignore inter-individual biological variation (Coskun, et al. [6]). By leveraging longitudinal data stored in the LIS, AI models can establish "personalized" reference intervals that track an individual's deviation from their own homeostasis rather than a population average (Coskun, et al. [6]). This approach is supported by advancements in cancer epigenetics and immunomics, where big data and computational modeling are used to understand the unique molecular landscapes of diseases (Baker, et al. [16,17]). The TITAN-X platform, for example, illustrates how AI can integrate diverse data streams to model immune responses, serving as a template for how laboratories might model reference intervals in the future (Baker, et al. [16]). Additionally, deep learning techniques used to map allosteric protein landscapes demonstrate the power of AI to uncover hidden patterns in biochemical data, which could be translated to detecting subtle shifts in clinical chemistry analytes (Verkhivker, et al. [18]).

Despite the promise of the intelligent laboratory, significant challenges remain regarding data privacy, standardization, and algorithmic transparency (Martinez Sanchez, et al. [5]). The literature points to the potential of synthetic data and the "Metaverse" to create training environments for AI that do not compromise patient confidentiality (Rajendran, et al. [23]). There is also the "empiricist's challenge" of ensuring that big data approaches do not supplant clinical reasoning but rather augment it (Jungherr, et al. [15]). Citizen science initiatives in neuroscience suggest that engaging a broader community in data analysis could help overcome some of the workforce limitations in processing large datasets (Roskams, et al. [19]). Ultimately, the vision for the future is a value-based laboratory where AI and big data are seamlessly integrated to provide precise, timely, and actionable diagnostic information (Plebani, et al. [2]). This requires a concerted effort to harmonize practices and develop open-source frameworks that allow deep-learning models to be universally adopted across different LIS platforms (Angeloni, et al. [12]).

Results

The review of the literature reveals that AI and machine learning algorithms demonstrate superior efficacy in handling the complexities of real-world laboratory data compared to traditional statistical methods (Ammer, et al. [8]). Specifically, the refineR algorithm has emerged as a potent tool for estimating reference intervals (RIs) from routine data, successfully identifying healthy distributions within contaminated datasets without the need for extensive clinical filtering (Ammer, et al. [8]). This algorithmic approach addresses the limitations of direct sampling by utilizing the vast statistical power of existing LIS databases (Ammer, et al. [8]). Furthermore, the application of Convolutional Neural Networks (CNNs) has shown a remarkable ability to process density estimates of laboratory values, as demonstrated in the estimation of RIs for cancer antigen 125 (LeBien, et al. [9]). These deep learning models can capture non-linear relationships and subtle demographic variations that conventional parametric methods often miss (LeBien, et al. [9]). The results indicate that these "next-generation" models provide a more accurate reflection of physiological reality by generating continuous RIs that adjust fluidly for age and sex, rather than relying on arbitrary age bins (Ma, et al. [7]).

The results highlight that the successful implementation of AI-driven RI establishment is inextricably linked to the modernization of Laboratory Information Systems (LIS) (Angeloni, et al. [12]). Current research indicates that integrating computational pathology and deep learning models directly into the LIS workflow significantly enhances diagnostic precision (Angeloni, et al. [12]). However, this integration requires a shift from on-premise servers to cloud-based storage and computing architectures to handle the volume and velocity of Big Data (Xu, et al. [13]). The review finds that the "intelligent laboratory" operates on a framework where data is not merely stored but actively managed and interrogated (Ahmed, et al. [4]). This necessitates the involvement of information specialists and librarians to oversee data governance and ensure the integrity of the datasets used for algorithmic training (Ahmed, et al. [4]). Additionally, the use of synthetic data and metaverse technologies has been identified as a viable strategy to augment training datasets, allowing for robust model development even when real-world data is scarce or protected by privacy concerns (Rajendran, et al. [23]).

A major finding of this review is the demonstrable shift from population-based RIs to personalized reference intervals enabled by AI (Coskun, et al. [6]). The literature confirms that comparing a patient's results to their own previous values (individual biological variation) is far more sensitive for detecting early pathology than comparison to a broad population range (Coskun, et al. [6]). Advanced computational modeling platforms, such as TITAN-X, validate this approach by integrating bioinformatics and big data to understand individual immune responses (Baker, et al. [16]). Similarly, the application of AI tools like mediKanren in rare disease cases illustrates the power of precision medicine to tailor diagnostics to the specific genetic and biochemical profile of the patient (Foksinska, et al. [20]). The results suggest that the synergy of LIS Big Data and AI facilitates a "value-based" approach to laboratory medicine, where the definition of "normal" is dynamically customized (Plebani, et al. [2]). This transition is supported by broader trends in chronic disease management, where the integration of medical and preventive data leads to more proactive health outcomes (Wang, et al. [3]).

The review also uncovers that the methodologies required for this transformation are not unique to medicine but share significant overlap with other data-intensive fields (Babović, et al. [14]). The successful management of laboratory big data mirrors strategies used in civil engineering and geosciences to solve complex, multi-variable problems (Babović, et al. [14]). Furthermore, the application of deep learning to map protein landscapes in biochemistry provides a template for how laboratory medicine can zoom in on "allosteric intersections" of data to find hidden diagnostic meaning (Verkhivker, et al. [18]). The results indicate that harnessing these cross-disciplinary insights allows for a more robust interrogation of clinical data (Jungherr, et al. [15]). This implies that the future of RI establishment relies on a "citizen scientist" approach where data accessibility and collaborative analysis drive innovation (Roskams, et al. [19]). Ultimately, the results confirm that AI is not just a tool for automation but a transformative agent for managing the complexity of modern viral and infectious disease diagnostics (Ali, et al. [10,22]).

Discussion

The results of this review underscore a pivotal transformation in laboratory medicine, driven by the synergy of Laboratory Information Systems (LIS) Big Data and Artificial Intelligence (AI) (Plebani, et al. [2]). The demonstrated efficacy of algorithms like refineR and Convolutional Neural Networks (CNNs) implies that the traditional "direct" method of reference interval (RI) establishment is becoming increasingly obsolete for many routine analytes (Ammer, et al. [8,9]). This shift is not merely methodological but represents a fundamental change in how "normality" is defined; by utilizing vast datasets of real-world data, laboratories can generate RIs that are more representative of the actual population they serve, rather than a theoretical cohort of "perfectly healthy" individuals (Ma, et al. [7]). The ability of these AI models to filter out pathological noise aligns with the broader industry trend toward "Industry 4.0," where machine learning optimizes production quality by identifying and removing anomalies in real-time (Rai, et al. [21]).

However, the interpretation of these results must be tempered by the infrastructural realities of modern healthcare systems (Xu, et al. [13]). While the theoretical potential of cloud-based LIS and deep learning integration is vast, the practical application is often hindered by legacy IT systems and fragmented data standards (Angeloni, et al. [12]). The discussion highlights that the "Intelligent Laboratory" cannot exist in a vacuum; it requires a robust digital ecosystem that mirrors the data management capabilities seen in remote sensing and global communication systems (Ullah, et al. [1,13]). Furthermore, the role of human oversight remains critical; as AI takes over the computational heavy lifting, the role of laboratory professionals and information specialists must evolve to focus on data governance and the clinical interpretation of algorithmic outputs (Ahmed, et al. [4]). This echoes the "empiricist's challenge," reminding us that Big Data is only as valuable as the meaningful clinical questions we ask of it (Jungherr, et al. [15]).

The move toward personalized reference intervals, as highlighted by the results, represents the most significant clinical implication of this review (Coskun, et al. [6]). The data suggests that the future of diagnostics lies in longitudinal monitoring-the "n-of-1" approach-where AI tracks a patient's individual trajectory rather than placing them in a static population bin (Coskun, et al. [6,20]). This aligns with advancements in precision oncology and immunomics, where the integration of multi-omics data allows for treatments tailored to specific molecular signatures (Baker, et al. [16,17]). The implication here is that laboratory medicine must move beyond being a provider of discrete test results to becoming a central hub of integrated diagnostic intelligence (Plebani, et al. [2]). This holistic view is supported by the successful application of AI in managing complex diseases like viral hepatitis and cardiovascular conditions, where data synthesis is key to patient management (Ali, et al. [10,11]). Finally, the discussion must address the harmonization and standardization prerequisites for this new era (Martinez Sanchez, et al. [5]). If different laboratories utilize different AI algorithms to clean their data, there is a risk of creating new inconsistencies in Reference Intervals (Martinez Sanchez, et al. [5]). Therefore, the community must look toward open-source frameworks and collaborative data validation methods, similar to "citizen science" models, to ensure transparency and reproducibility (Roskams, et al. [19]). The use of synthetic data and virtual realms (Metaverse) offers a promising avenue for testing these standards without risking patient privacy (Rajendran, et al. [23]). Ultimately, the integration of deep learning and Big Data allows us to "zoom in" on the hidden intersections of biochemical data, revealing diagnostic insights that were previously invisible (Verkhivker, et al. [18]).

Conclusion & Recommendations

This review has comprehensively examined the transformative potential of synergizing Laboratory Information Systems (LIS) Big Data with Artificial Intelligence (AI) for the establishment of precision Reference Intervals (RIs). The analysis confirms that indirect methods, powered by advanced algorithms such as refineR and Convolutional Neural Networks, offer a scientifically valid, cost-effective, and ethically superior alternative to traditional direct sampling. The findings indicate that the "Intelligent Laboratory" is not merely a technological upgrade but a paradigm shift toward value-based, personalized medicine. By leveraging the massive volume of routine clinical data, laboratories can move away from static, population-based averages toward dynamic, individualized benchmarks that better reflect true physiological health. However, the realization of this vision is currently constrained by infrastructural maturity, the need for specialized workforce training, and a lack of standardized algorithmic protocols.

Based on the review findings, the following recommendations are proposed:

1. International bodies of clinical chemistry should establish standardized guidelines for the validation and application of AI-based indirect methods (such as refineR) to ensure harmonization of reference intervals across different laboratories.
2. Healthcare institutions must prioritize the migration of Laboratory Information Systems to secure cloud-based architectures. This is essential to support the storage and computational demands of Big Data analytics and real-time AI processing.
3. Academic curricula for laboratory medicine and pathology programs should be updated to include data science, bioinformatics, and AI ethics. This will create a "hybrid" workforce capable of managing the intelligent laboratory.
4. Policymakers and hospital administrators must develop robust ethical frameworks and consent models that facilitate the secondary use of routine patient data for algorithm training while strictly protecting patient privacy.
5. Laboratories should begin piloting the reporting of "Personalized Reference Intervals" (based on longitudinal patient data) alongside traditional population-based intervals, particularly for chronic disease management, to facilitate a gradual clinical transition toward precision medicine.

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ISSN: 2574-1241

DOI: 10.26717/BJSTR.2026.64.010075

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Submission Link: https://biomedres.us/submit-manuscript.php