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RESEARCH ARTICLE

Comparing the analytical performances of two Beckman Coulter BxU 850m Iris automates in the laboratory: Reliability and accuracy

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ABSTRACT

Cytobacteriological urine tests are necessary for diagnosing urinary tract infections, and there is a growing trend toward automated analytical methods that aim to shorten turnaround times as sample volumes increase. This study evaluated the analytical performance of two Beckman Coulter BxU 850m Iris automated urine analyzers, specifically examining reproducibility, repeatability, linearity, and sample contamination. The study, which lasted for one month, used thirty anonymized urine samples to check the accuracy of the tests and compare them to the standards set by the manufacturer. The results showed that the detection limits were satisfactory, the linearity was high with correlation coefficients of R-squared equal to 0.983 for white blood cells and R-squared equal to 0.999 for red blood cells, and the contamination rates were very low. The study found that both automated urine analyzers provide accurate results that meet analytical standards. This indicates that they can be used interchangeably in clinical laboratories if appropriate quality control procedures are in place.

Introduction

The cytobacteriological analysis of urine is among the most often requested tests in medical biology laboratories[1].This is crucial for detecting and monitoring issues related to the urinary tract and kidneys[1].Urinalysis, once merely the examination of urine, has evolved into a regulated laboratory discipline encompassing chemical, microscopic, and microbiological analyses[1,2].It remains a crucial component in contemporary clinical decision-making, aiding in the identification of urinary tract infections, inflammatory illnesses, glomerular diseases, and many urological or nephrological disorders[1,2]. The study of urinary cytology, particularly the identification and quantification of produced constituents such as leukocytes, erythrocytes, epithelial cells, casts, and bacteria, is essential for diagnosis[3,4]. Leukocyturia and bacteriuria are primary markers of urinary tract infection, while hematuria may signify underlying renal or urological illness[3,4]. The conventional reference method for manually evaluating urine sediment microscopically has existed for an extended period; nonetheless, it is labor intensive, time consuming, and susceptible to significant variability among observers[3,5]. The lack of comprehensive standardization in manual microscopy intensifies the difficulties of repeatability across laboratories[5].

The increasing demand for rapid turnaround times and the rising volume of samples in recent decades have resulted in the development of automated urine analysis systems[6,7]. Flow cytometry represented an initial advancement in automation[8,9]. It facilitated the rapid and reliable enumeration of particles in urine[8,9]. Subsequent technological breakthroughs resulted in the creation of digital imaging systems capable of capturing and classifying urine particles[10,11]. This enhanced the analysis and reduced its reliance on the operator[11]. These novel concepts have been extensively implemented in routine practice, enhancing workflow efficiency and ensuring more consistent analysis[7,12]. Numerous investigations have contrasted automated analyzers with manual microscopy[13,14]. Numerous studies indicate that leukocyte and erythrocyte counts exhibit significant similarity, and automated techniques provide high sensitivity for screening purposes[13,14]. Subsequent experiments have demonstrated that contemporary analyzers can reliably detect red and white blood cells; nevertheless, they have also identified issues in locating certain types of abnormal casts or dysmorphic erythrocytes[15,16]. Performance assessments of diverse platforms, including flow cytometry and image-based systems, have highlighted the discrepancies among devices and the imperative for local validation before standard application[10,17].

Automated urine analyzers provide commendable diagnostic efficacy in screening for urinary tract infections[18,19]. This may result in a reduction of superfluous urine cultures and an improved allocation of laboratory resources[18,19]. Recent advancements integrating machine learning algorithms with automated urinalysis platforms have enhanced analytical capabilities[20,21]. This has resulted in improved distinction of disease symptoms and assisted physicians in decision-making[20,21]. These modifications indicate that clinical microbiology and laboratory medicine are advancing towards more intelligent and interconnected diagnostic systems[22,23].

Despite technological advancements, manual microscopic examination of urine sediment remains essential in certain instances, particularly when automated results raise flags or when rare or atypical components are detected[7,24]. Consequently, current guidelines advocate for a hybrid methodology wherein automated methods facilitate rapid screening, while manual assessment is reserved for select cases[7,24].

The Beckman Coulter DxU 850m Iris system is among the latest analyzers[25,26]. It employs digital imaging and sophisticated classification algorithms to enhance accuracy and expedite the workflow[25,26]. Comparative analyses of automated urine cytometry systems, including the Beckman Coulter DxU 850m Iris system, indicate that while they are proficient in data analysis, ongoing quality assessments and collaborative efficacy studies are essential[27].

This study sought to assess the analytical performance of two Beckman Coulter DxU 850m Iris analyzers located in our laboratory. The objective was to evaluate the reliability, accuracy, and interchangeability of the results obtained under standard operating conditions. The examination focused on analytical reproducibility, repeatability,

linearity, and the assessment of potential inter-sample cross contamination to ensure high quality and consistency in normal practice.

Materials and methods:

The present prospective study was conducted over a period of 30 days. All analyses were conducted under ambient temperature and relative humidity conditions that comply with the manufacturer's recommendations. The study began with a calibration phase of the automaton, followed by an evaluation of its performance in accordance with the specifications stated by the manufacturer. The experimental protocol was implemented in accordance with the recommendations from the guide for verification and validation of methods in medical biology, ensuring conformity with accepted quality and performance standards[22]. The equipment used includes two BxU 850m Iris analyzers and thirty urine samples from anonymized patients. Result management software used for data analysis, such as Excel and Jamovi. To evaluate reproducibility, each sample was analyzed twice on each device. A comparison of the results from the two analyzers was conducted to evaluate inter-device concordance. The measured parameters include white blood cells (WBC), red blood cells (RBC), epithelial cells, urinary crystals, and urinary casts. Data analysis: The coefficient of variation (CV) is calculated for each parameter, with the aim of evaluating the reproducibility of the measurements. A comparison of the results obtained by the two devices was conducted using the Pearson correlation coefficient. An analysis of average deviations and systematic disparities is conducted. Analysis of inter-sample contamination, commonly referred to as "carryover" was assessed according to standardized procedures recommended for automated urine analyzers[10,22].

Results:

The validation outcomes on the performance of the two analyzers, concerning repeatability, reproducibility, detection limit, linearity, and cross-contamination for leukocytes, erythrocytes, cylinders, and epithelial cells, were deemed adequate.

The detection limits were assessed, establishing thresholds at zero per microliter for leukocytes, erythrocytes, and other particles. The reproducibility, assessed via internal quality controls, demonstrates successive coefficients of variation (CV) of 7.05% and 5.6% for Iris 1 and Iris 2, with corresponding averages of 957 ± 67.5 and 1023 ± 57.6 for Iris 2.

The repeatability of leukocyte and erythrocyte measurements is outlined in Table 1 below, which gives the coefficient of variation for each instrument and parameter.

Table 1: The repeatability study of leukocytes and erythrocytes positive samples

	GB iris 1	GR iris 1	GB iris 2	GR iris 2
Moyenne	3.90	7.83	5.27	7.90
Ecart-type	1.67	1.78	1.55	2.44
CV%	42,8	22,7	29,4	30,8

As shown, the measured coefficients of variation (CV) are lower in positive samples, which suggests increased repeatability and analytical reliability in those cases. We evaluated the connection between the analyzers' measurements for leukocytes and erythrocytes concerning linearity. The linear correlation coefficient for leukocytes, illustrated in Figure 1, was determined to be 0.983.

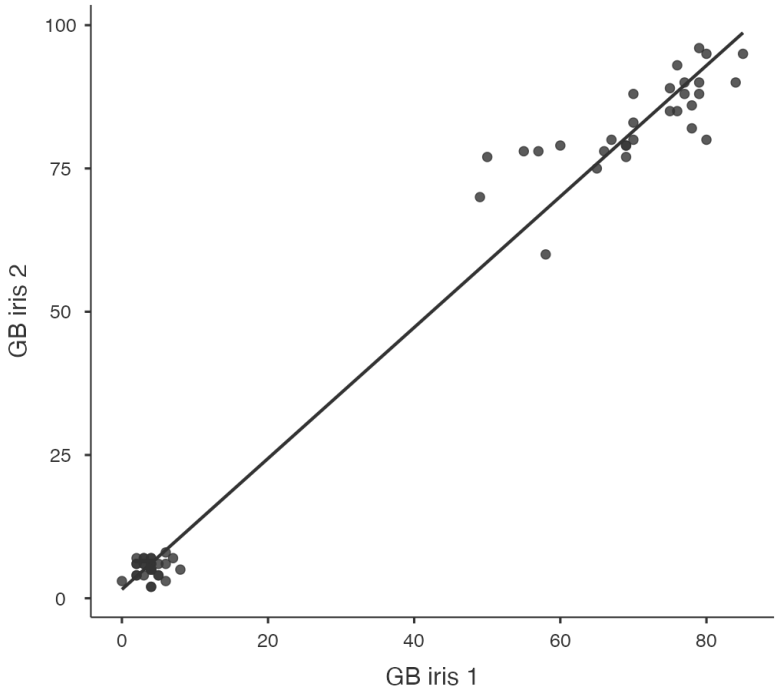

Figure 1: linearity study of leukocytes

This figure demonstrates the robust linear correlation between leukocyte counts from the two analyzers, affirming their high level of concordance and reliability in measurements. The elevated linearity exhibited by leukocytes indicates the analyzers' strong efficacy for this critical parameter. Concurrently, Figure 2 illustrates a comparably elevated correlation for erythrocyte counts.

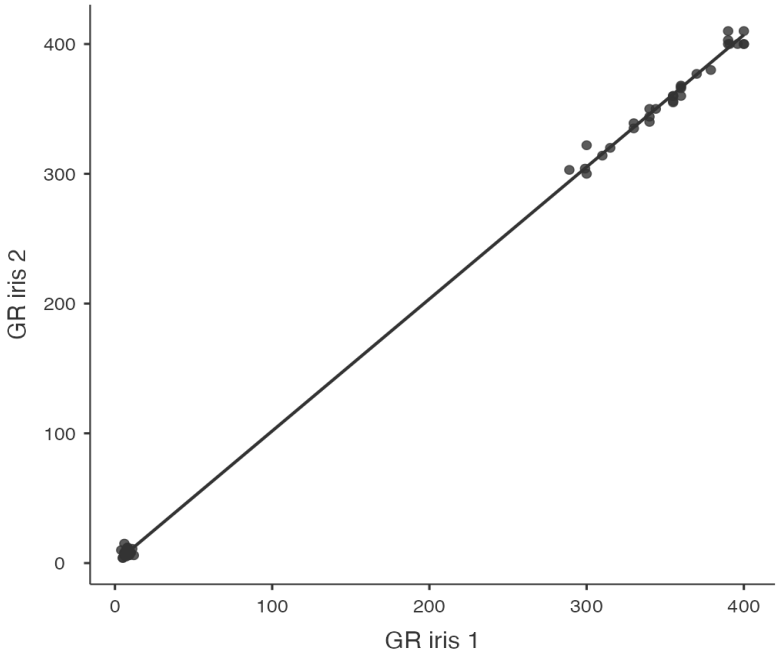

Figure 2: linearity study of erythrocytes

The graphical analysis in Figure 2 demonstrates that the erythrocyte measurements had a nearly perfect linear correlation ($R^2 = 0.999$), underscoring the analytical robustness of the system. The practically flawless correlation for erythrocyte measurements is further substantiated by the comprehensive statistical study of the correlation coefficients. The values, in conjunction with those for leukocytes, are encapsulated in Table 2.

Table 2: the Pearson correlation coefficient for leukocytes and erythrocytes

		GB iris 1	GB iris 2	GR iris 1	GR iris 2
GB iris 1	r de Pearson	—			
	ddl	—			
	valeur p	—			
GB iris 2	r de Pearson	1.000	—		
	ddl	28	—		
	valeur p	<.001	—		
GR iris 1	r de Pearson	0.657	0.657	—	
	ddl	28	28	—	
	valeur p	<.001	<.001	—	
GR iris 2	r de Pearson	0.530	0.530	0.987	—
	ddl	28	28	28	—
	valeur p	0.003	0.003	<.001	—

The correlation coefficients for the parameters recorded by both devices were examined numerically and visually using a correlation heatmap, offering an easy picture of the degree of agreement between the various analyzer results. Figure 3 below illustrates this depiction.

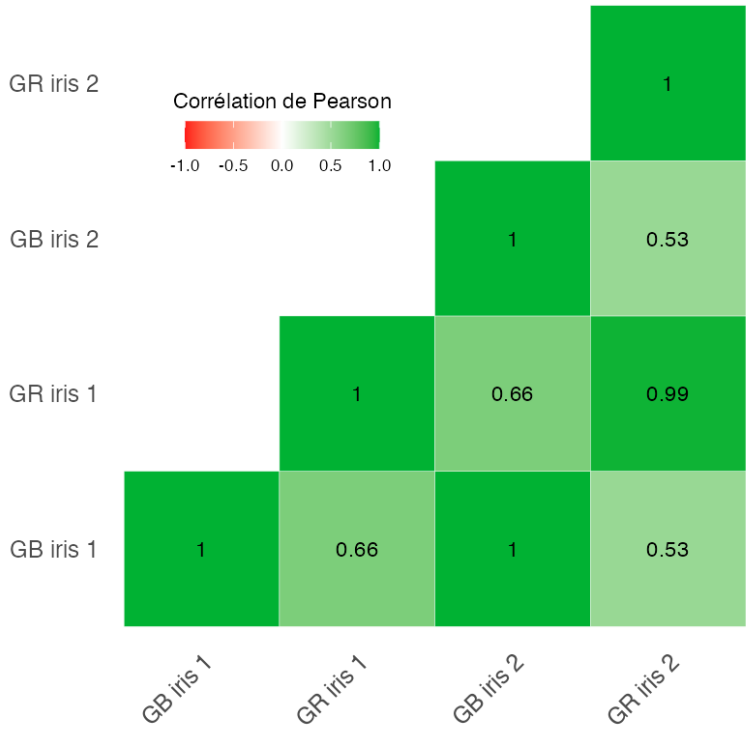

Figure 3: Pearson Correlation Heatmap for Leukocyte and Erythrocyte Measurements Across Both Analyzers

The heatmap displays the Pearson correlation coefficients between leukocyte (GB) and erythrocyte (GR) values acquired from both Iris 1 and Iris 2 analyzers. Darker green squares signify stronger positive connections, whilst lighter hues denote weaker correlations. This graphic depiction verifies the substantial agreement between the devices for both cell types.

This graphical overview enhances the numerical results presented earlier in Table 2, further validating the analytical consistency between the two Beckman Coulter BxU 850m Iris analyzers. The robust correlations discovered substantiate the conclusion that findings from both devices can be reliably compared and, when necessary, utilized interchangeably in clinical practice.

Regarding contamination, following the rinsing of the device, three samples exhibiting turbidity as well as a high concentration of various measured parameters were analyzed consecutively, followed by three clear samples, showing low, even undetectable concentrations, and were analyzed three times. The contamination of leukocytes and particles (epithelial cells, cylinders, and urinary crystals), proved to be almost negligible (0.02 to 0.04%) on the Beckman Coulter BxU and 850m Iris automated analyzers. Regarding erythrocytes, the contamination rates were 0.5% and 0.4%, respectively.

Bland-Altman analyses were conducted to offer further insight into the concordance between the two analyzers. Figure 4 illustrates the Bland-Altman plot for leukocytes, indicating a modest negative bias (-185), which implies a marginal average underestimate between the devices.

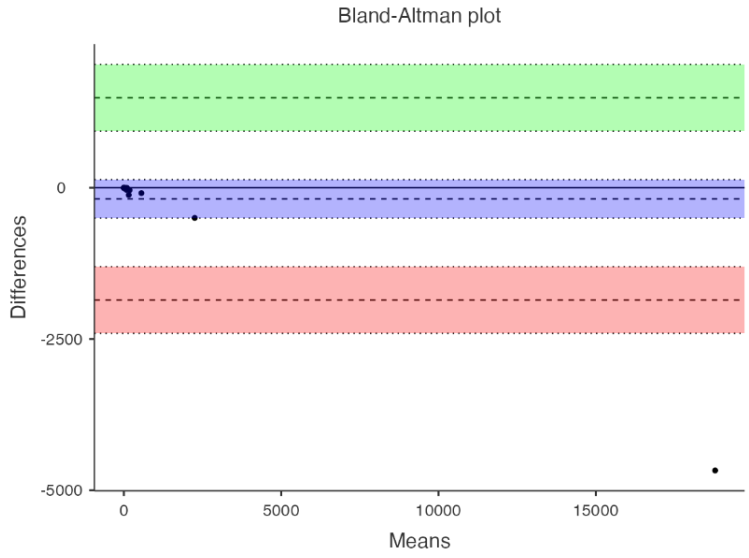

Figure 4: Bland Altman analyses for leukocytes

The leukocyte count plot illustrates the disparity between the two analyzers throughout the measurement range, with the majority of data points residing within the boundaries of agreement, but significant interindividual variability is apparent. The observed diversity in the concordance intervals (–1857 to +1486) may bear clinical significance for specific threshold values. Erythrocyte measures were similarly assessed utilizing the Bland-Altman method, as illustrated in Figure 5.

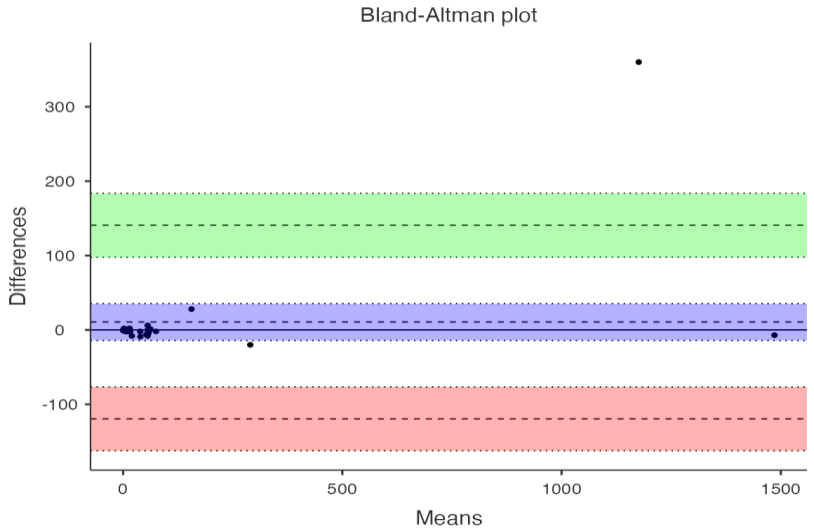

Figure 5: Bland Altman analyses for erythrocytes

The Bland-Altman plot for erythrocytes illustrates a low-amplitude bias (10.6), signifying a satisfactory general concordance between the analyzers; yet, the limits of agreement indicate significant variability among individual samples. These findings emphasize the necessity of stringent quality controls and statistical oversight to guarantee consistency and precision, especially when analyzers are utilized interchangeably in the clinical laboratory.

Discussion:

The assessment of the Beckman Coulter DxU 850m Iris 1 and Iris 2 automated systems reveals strong analytical efficacy for urine sediment analysis, validating their appropriateness for regular clinical use. Both devices demonstrated satisfactory repeatability, reproducibility, linearity, detection capabilities, and little carryover for essential urine constituents, including leukocytes (WBCs), erythrocytes (RBCs), casts, and epithelial cells. These findings corroborate previous research highlighting the dependability of contemporary automated urinalysis systems and their capacity to replace manual microscopy[1,2,11,15]. An especially significant observation is the elevated sensitivity of both analyzers. The absence of measurable detection thresholds for RBCs, WBCs, and other cellular components underscores their capacity to identify minor cellular quantities, supporting the assertion that automated analyzers employing digital imaging or flow cytometry demonstrate enhanced sensitivity relative to manual methods. Internal quality control assessments revealed coefficients of variation (CVs) of 7.05% for Iris 1 and 5.6% for Iris 2, signifying negligible inter-device variability and affirming precision under standard laboratory circumstances. This precision guarantee's reliability in high-throughput clinical environments, where accuracy and efficiency are paramount. Repeatability evaluations in positive patient samples further validated measurement stability. The elevated linear correlation values (R^2 = 0.983 for WBCs and R^2 = 0.999 for RBCs) demonstrate reliable analytical performance throughout the test spectrum. These results align with prior research on the Sysmex UF-1000i, UriSed®, Cobas 6500, and Sysmex UN-3000 analyzers, demonstrating a robust correlation with manual microscopy for primary urine constituents. Automated systems diminish operator-dependent variability, hence enhancing inter-laboratory reproducibility. Carryover analysis indicated negligible contamination between successive samples, underscoring the effectiveness of rinse techniques and the dependability of ensuing measurements[10,17]. This is especially crucial in laboratories managing substantial quantities of specimens, where even slight cross-contamination may jeopardize diagnostic precision. Previous study highlighted that stringent pre-analytical and cleansing protocols are crucial for precise automated urinalysis. Comparative analyses of various automated systems offer further perspective. Assessments of UriSed® and UX 2000 analyzers revealed reliable quantification of leukocytes and erythrocytes, but variability was noted for more morphologically intricate constituents, underscoring platform-dependent discrepancies[5,21,26]. The DxU 850m Iris analyzers demonstrated performance comparable to the Sysmex UF-1000i, hence validating both flow cytometry and digital morphology-based methodologies. This underscores the function of automated analyzers in delivering swift, consistent, and reproducible measurements[1,12,15,17]. Although generally reliable, automated analyzers demonstrate inconsistent concordance with manual microscopy for specific elements such as epithelial cells, casts, and crystals. Lekfif et al. emphasized that while the DxU 850m Iris system effectively quantifies standard urinary components, atypical cytological findings require microscopic verification. This is a hybrid methodology wherein technology manages regular assessments, while focused manual examination guarantees precise identification of intricate specimens. Mejuto et al. highlighted that automated analysis via flow cytometry can efficiently screen samples in microbiology laboratories, but culture confirmation may be required in certain instances. Bland–Altman analysis revealed negligible systematic bias between Iris 1 and Iris 2 for WBC and RBC assays, signifying strong concordance between the devices. The broader bounds of agreement at the extremities indicate the variability documented for automated analyzers. This underscores the imperative for continuous statistical monitoring and rigorous quality control to identify drift or bias over time. Automated solutions provide workflow and clinical benefits that extend beyond analytical performance. Contemporary analyzers diminish turnaround time, augment laboratory throughput, and facilitate more

prompt reporting, thereby directly influencing patient management[2,5,7,25]. Walczak et al. indicated that the Sysmex UN-3000 could reliably replace manual microscopy for routine urinalysis, alleviating workload while preserving accuracy[25]. Bakan et al. demonstrated that the Cobas 6500 and Iris IQ200 systems produced results comparable to manual microscopy[26]. Staerk et al. illustrated that the DxU 850m Iris analyzer accurately identifies culture-negative urine samples, potentially decreasing unnecessary urine cultures[34]. Automated urinalysis enhances standardization across laboratories. Manual microscopy is susceptible to inter- and intra-observer variability[1,2,24]. Automation employs established methods and objective standards for cell classification, minimizing human error. Cho and Hur emphasized that the integration of flow cytometry with digital microscopy promotes sensitivity and specificity, especially for low-abundance or morphologically complex elements. Additionally, pre-analytical optimization, encompassing sample handling and processing, further improves reliability. Regulatory advice, including Moroccan laboratory standards, emphasizes the significance of technique validation and ongoing quality control[29,35]. Recent research reveal supplementary therapeutic and operational advantages of automation. Morita et al. assessed the UF-1500 analyzer, emphasizing enhancements in precision and workflow efficiency. Belgacem et al. indicated that UriSed® automation enhances diagnostic accuracy in the examination of urinary tract infections. Fan and Bai highlighted that automated urinalysis yields reproducible, clinically relevant data that supports routine integration. Lekfif et al. underscored the significance of DxU-850m Iris automation in routine cytology, demonstrating its reliability and concordance with manual microscopy. In high-volume laboratories, automated systems enable traceable, rapid, and standardized reporting, minimizing human error and improving data quality. The integration of automation with targeted manual inspection is optimal: automated analyzers manage regular assessments, whereas microscopy verifies atypical or difficult specimens[1,12,5,17]. This hybrid methodology guarantees elevated throughput and diagnostic precision.

In summary, the DxU 850m Iris 1 and Iris 2 analyzers deliver consistent, sensitive, and accurate urine sediment analysis. Minimal inter-device variance, exceptional linearity, low carryover, and high sensitivity facilitate interchangeable usage in clinical laboratories. Although infrequent or morphologically intricate cells may necessitate human validation, these methods are appropriate for standard urinalysis, integrating efficiency, dependability, and adherence to regulations. The results underscore the essential function of automated urinalysis in contemporary laboratory medicine, facilitating the shift from conventional microscopy to high-throughput, standardized, and clinically reliable systems.

Conclusion:

The present study aimed to evaluate the reliability and precision of two BxU 850 Iris analyzers in a routine laboratory environment. The results obtained highlight satisfactory reproducibility and high concordance between the two automated analyzers, despite the observation of minor variations regarding certain parameters. These discrepancies, although minimal, highlight the necessity of rigorous monitoring of calibration and quality controls, with the aim of ensuring the standardization of results. The analysis of inter-sample contamination justifies the establishment of rinsing protocols and additional controls to ensure the absence of influence between two successive analyzes. Therefore, the concomitant use of these analyzers can be considered with confidence, provided that meticulous performance monitoring and adequate cleaning between samples are ensured to prevent any potential contamination.

Conflict of Interest Statement:

The authors declare no conflicts of interest.

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