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Research Article

Clinical Performance of the Erba H7100 Hematology Analyzer: Focus on Reticulocytes

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Abstract

This study comparatively evaluated the analytical performance of the Erba H7100 hematology analyzer against the Siemens Advia 2120i and Beckman Coulter DXH 900, using 243 patient samples. The study assessed the agreement and linear relationship across 14 key hematological parameters in whole blood, employing statistical methods that included mean bias, standard deviation of the difference, Pearson's correlation, and coefficient of determination. Additionally, reticulocyte counts were analyzed in 27 samples for Erba H7100 *vs.* Advia 2120i and 53 samples for Erba H7100 *vs.* DXH 900, revealing exceptional agreement with high Pearson's r and r-squared values. The performance of the Erba H7100 and DXH 900 in analyzing ascitic, cerebrospinal, and bronchial wash fluids was also evaluated. Notably, the Advia 2120i analyzer exhibited discrepancies in mean corpuscular volume (MCV) and monocyte counts (Mon#). Conversely, the Erba H7100 showed better agreement with the DXH 900 for MCV and Mon# in whole blood. In fluid samples, Erba H7100 and DXH 900 demonstrated a strong correlation with Microscopy in determining Neutrophil % and Lymphocyte % values. Strong linear correlations were observed for most parameters in whole blood, with reticulocyte counts showing near-perfect correlation. This study underscores the importance of rigorous validation and potential platform-specific reference intervals to ensure accurate and reliable hematological testing, emphasizing the need for standardized methodologies in clinical laboratories.

More Information

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Keywords: Hematology analyzer; Erba H7100; Siemens Advia 2120i; Beckman Coulter DXH 900; Correlation analysis; Bland-Altman analysis; Hematology standardization; Automated blood cell counters

Introduction

Automated hematology analyzers play a critical role in modern clinical laboratories by providing rapid and accurate blood cell counts. Hematology analyzers facilitate routine blood examinations for detecting anemia, infections, and hematologic malignancies. The Erba H7100 is a next-generation hematology analyzer designed to deliver precise results comparable to established systems such as Siemens Advia 2120i and Beckman Coulter DXH 900. As clinical decisions often rely on laboratory results, comparing new analyzers with widely used reference instruments is essential to validate performance. This study aims to evaluate the analytical performance of the Erba H7100 against these reference analyzers to determine its clinical reliability in various laboratory settings.

Materials and methods

This study was designed to evaluate and compare the performance of three automated hematology analyzers: DXH900 (Beckman Coulter), ADVIA 2120I (Siemens), and Erba H7100 (Erba Transasia). The study assessed the agreement and linear relationship between these instruments across 22 common hematological parameters. In this study, whole blood and body fluid analysis have been done. The fluid samples analyzed in this study included: Ascitic fluid, CSF (Cerebrospinal Fluid), and Bronchial wash.

Sample collection and preparation

Sample population: A total of 243 patient samples were included in this study. 54 samples were used for the comparison between DXH900 and Erba H7100 in whole blood analysis, and 31 samples were used for the comparison between DXH900 and Erba H7100 in body fluid analysis. 189 samples were used for the comparison between ADVIA 2120I and Erba H7100 in whole blood analysis. 27 samples were analyzed for reticulocyte count simultaneously with Erba H7100 and ADVIA 2120i, and 53 samples were analyzed for reticulocyte count simultaneously with Erba H7100 and DXH.

Samples were collected from patients presenting to Apollo Hospitals, Chennai, India, for routine hematological

analysis. Samples included a diverse patient population, encompassing a range of hematological abnormalities and normal results.

Sample type

- Peripheral venous blood samples were collected in standard K2-EDTA anticoagulant tubes.
- Fluid samples were collected, including 10 samples of Ascitic fluid, 1 sample of CSF (Cerebrospinal Fluid), 1 sample of Bronchial wash, and 2 samples of Pleural fluid.

Sample handling

- Whole blood samples were processed within 2 hours of collection to minimize pre-analytical variations. Samples were mixed thoroughly before analysis.
- Fluid samples were handled as per good laboratory practices.

Parameters

This study evaluated the agreement and relationship between hematology measurements obtained from three different analyzers: DXH900, ADVIA 2120I, and Erba H7100. The following 22 hematological parameters were recorded for each sample: White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Neutrophil Percentage (Neu%), Lymphocyte Percentage (Lym%), Monocyte Percentage (Mon%), Eosinophil Percentage (Eos%), Basophil Percentage (Bas%), Absolute Neutrophil count (Neu#), Absolute Lymphocyte count (Lym#), Absolute Monocyte count (Mon#), Absolute Eosinophil count (Eos#), Absolute Basophil Count (Bas#), Platelet count (PLT), Mean Platelet Volume (MPV), and Plateletcrit (PCT), Reticulocyte count.

Analytical procedure

Sample analysis: Each sample was analyzed on all three hematology analyzers according to the manufacturer's instructions. Quality control procedures were performed daily to ensure the accuracy and precision of the instruments.

Data collection: The results for all 22 parameters were recorded for each sample from each analyzer.

The performance of the DXH900 and Erba H7100 analyzers was also evaluated on 25 body fluid samples (e.g., pleural, ascitic, CSF, bronchial wash). Parameters measured included Total WBC Count, Neutrophil %, and Lymphocyte %.

Statistical analysis

Measures of agreement:

1. Mean bias (average difference) between the two compared analyzers was calculated for each parameter.
2. Standard deviation of the difference was calculated to assess the variability of the differences.

Measures of relationship:

1. Pearson's correlation coefficient (r) was calculated to assess the linear relationship between the analyzers.
2. Coefficient of determination (R^2) was calculated to assess the predictability of one analyzer's results from the other.

Data analysis tools: Statistical analysis was performed using SPSS version 20.0.

Results

This study evaluated the agreement and relationship between hematology measurements obtained from three different analyzers: DXH900, ADVIA 2120i, and Erba H7100. The results are summarized in Table 1, presenting the Coefficient of Correlation (R), Coefficient of Determination (R^2), Mean Bias, and Standard Deviation of the Difference for each parameter (Table 1).

DXH900 vs. Erba H7100 ($n = 54$)

The DXH900 demonstrated strong agreement with the Erba H7100. R values ranged from 0.99 to 1.00, indicating a very strong linear relationship between the measurements from the two analyzers. R^2 values were also high (0.98 - 1.00), signifying that the DXH900's measurements closely explain the variance in the Erba H7100's measurements. Mean bias was generally low, suggesting minimal systematic differences between the two analyzers. Similarly, the standard deviation of the difference was small, indicating low variability in the paired measurements.

Erba H7100 v/s DXH 900- Reticulocyte count: ($n = 53$)

The mean bias of approximately -0.01 reveals an even smaller average difference, confirming excellent agreement between the DXH 900 and Erba H7100. The SD bias of approximately 0.04 further emphasizes the low variability. The Pearson's r of approximately 0.995 and r-squared of around 0.99 indicate an extremely strong positive correlation, showing that the DXH 900 results are nearly identical to the Erba H7100 results, with 99% of the variance accounted for.

ADVIA 2120i v/s Erba H7100 ($n = 189$)

The ADVIA 2120i showed a moderate to strong correlation

Table 1: Measurement of Agreement and Relationship.

			DXH900 *vs.* TBM H7100 (*n* = 54)				ADVIA *vs.* TBM H7100 (*n* = 189)			
			Measures of Agreement		Measures of Relationship		Measures of Agreement		Measures of Relationship	
Parameter	**Abbreviation**	**Abbreviation**	Mean Bias	Standard Deviation of the Difference	Coefficient of the Correlation	Coefficient of the Determination	Mean Bias	Standard Deviation of the Difference.	Coefficient of the Correlation	Coefficient of the Determination
White Blood Cell Count	WBC	$x10^3/\mu L$	-1.66	9.08	0.99	0.98	-0.47	1.84	1.00	1.00
Red Blood Cell Count	RBC	$x10^6/\mu L$	0.18	0.12	0.99	0.99	0.19	0.12	0.99	0.99
Hemoglobin	HGB	g/dL	0.08	0.26	1.00	0.99	0.41	0.20	1.00	1.00
Hematocrit	HCT	%	0.36	0.83	0.99	0.99	2.05	1.42	0.99	0.97
Mean Corpuscular Volume	MCV	fL	-2.90	1.22	1.00	0.99	0.81	9.99	0.68	0.47
Neutrophil Percentage	Neu%	%	0.47	4.21	0.98	0.96	0.50	2.07	0.99	0.99
Lymphocyte Percentage	Lym%	%	-0.47	2.08	0.99	0.99	-0.33	2.64	0.99	0.97
Monocyte Percentage	Mon%	%	0.26	1.30	0.96	0.93	-1.81	1.37	0.94	0.88
Eosinophil Percentage	Eos%	%	0.07	0.35	1.00	0.99	-0.24	0.74	1.00	0.99
Absolute Neutrophil Count	Neu#	$x10^3/\mu L$	-1.32	3.70	1.00	1.00	-0.26	1.22	1.00	1.00
Absolute Lymphocyte Count	Lym#	$x10^3/\mu L$	-0.02	1.16	1.00	1.00	-0.07	0.51	0.98	0.96
Absolute Monocyte Count	Mon#	$x10^3/\mu L$	-0.51	2.28	0.95	0.90	-0.46	2.65	0.57	0.33
Absolute Eosinophil Count	Eos#	$x10^3/\mu L$	-0.03	0.26	0.98	0.95	-0.03	0.14	0.99	0.98
Platelet Count	PLT	$x10^3/\mu L$	-11.63	24.17	0.98	0.96	-14.26	27.39	0.99	0.98
Basophil Percentage of Total Blood Monocytes	Bas%	%	0.10	0.30	0.95	0.93	0.10	0.95	0.96	0.92
Basophil Number of Total Blood Monocytes	Bas#		0.09	0.39	0.98	0.96	0.15	1.69	0.98	0.97
Mean Corpuscular Hemoglobin	MCH	pg	-1.19	0.38	0.96	0.93	-0.51	6.37	0.95	0.97
Mean Corpuscular Hemoglobin Concentration	MCHC	g/dL	-0.29	1.31	0.93	0.94	-1.02	1.16	0.98	0.97
Red Cell Distribution Width - CV	RDW-CV	%	0.11	2.30	0.95	0.91	-0.92	1.81	0.98	0.96
Mean Platelet Volume	MPV	fL	-0.63	2.47	0.96	0.96	-1.31	2.22	0.96	0.98
Plateletcrit	PCT	%	-0.16	0.79	0.98	0.98	-0.12	0.79	0.96	0.97

with the Erba H7100 for most parameters. R values ranged from 0.95 to 0.99. However, the R^2 values exhibited more variability compared to the DXH900 comparison. For some parameters, such as MCV (R^2 = 0.47) and Absolute Monocyte Count (R^2 = 0.33), the R^2 values were notably lower, indicating that the ADVIA 2120I's measurements explained a smaller proportion of the variance in the Erba H7100's measurements. The standard deviation of the difference was also generally higher, indicating greater variability in the discrepancies between the ADVIA 2120I and Erba H7100 measurements.

Erba H7100 vs. Advia 2120i for reticulocyte count: (n = 27)

The mean bias of approximately -0.02 suggests a very small average difference, indicating close agreement between Advia 2120i and Erba H7100 results. The low SD bias of approximately 0.05 signifies minimal variability in these differences. The exceptionally high Pearson's r of approximately 0.99 and an r-squared of around 0.98 demonstrate a nearly perfect positive correlation, meaning the Advia 2120i results are almost entirely predictable from the ERBA H7100 results, with 98% of the variance explained (Figures 1-8).

Body fluid results

This study compared the performance of Microscopy and two instruments—Erba H7100 and DXH 900—in analyzing fluid samples, focusing on Total White Blood Cell (WBC) count and differential counts. Overall, Erba H7100 and DXH 900 demonstrated a strong correlation with Microscopy in measuring Total WBC. Specifically, both instruments accurately reflected the trends established by Microscopy, with only minor variations observed across the samples. For WBC, Erba H7100 and DXH 900 showed a high degree of agreement with Microscopy, confirming their reliability in this measurement.

Reticulocyte count

27 samples were analyzed for reticulocyte count

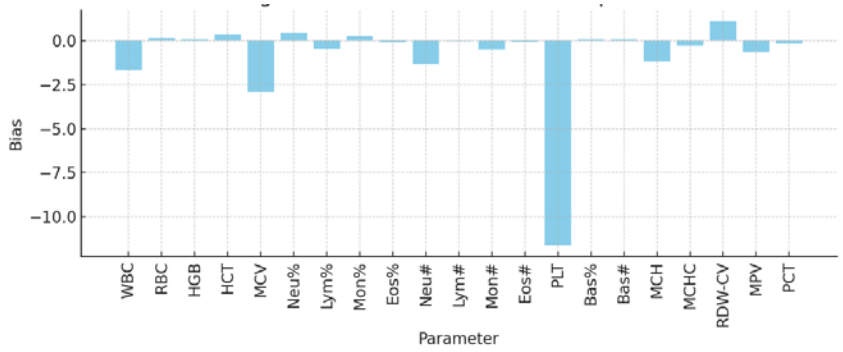

Figure 1: DXH900 Mean Bias Comparison.

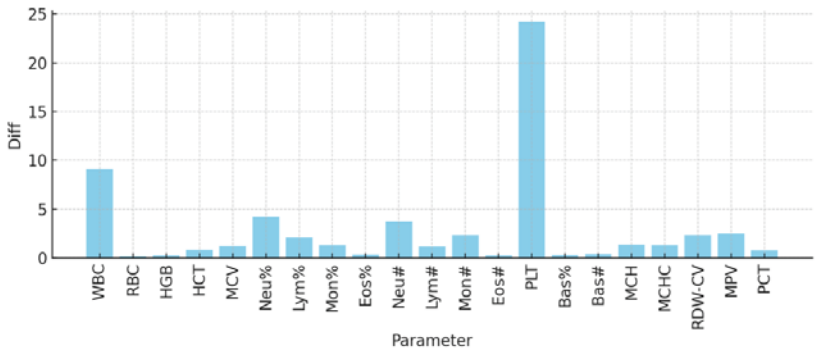

Figure 2: DXH900 Standard Deviation of Difference.

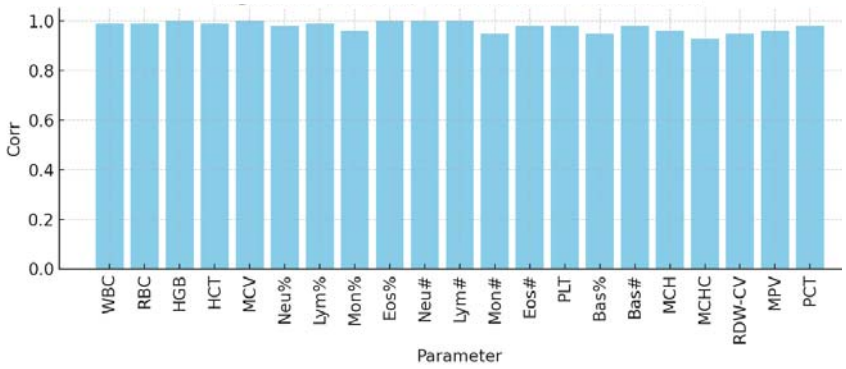

Figure 3: DXH900 Coefficient of Correlation.

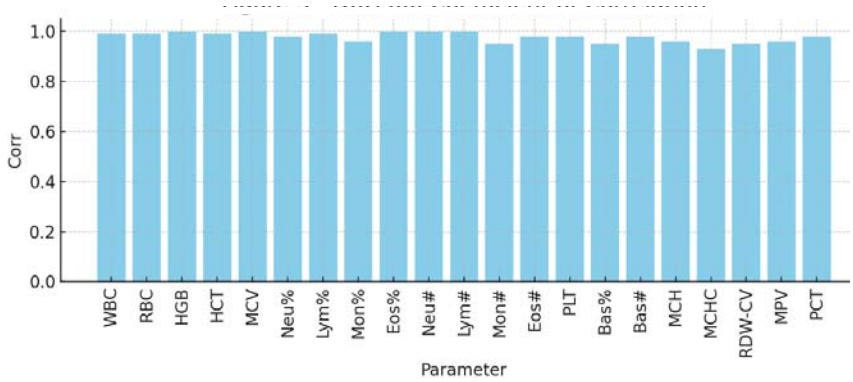

Figure 4: DXH900 Coefficient of Determination.

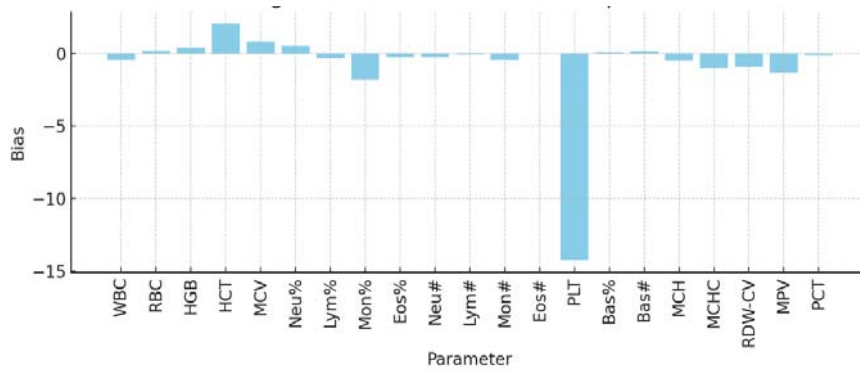

Figure 5: ADVIA Mean Bias Comparison.

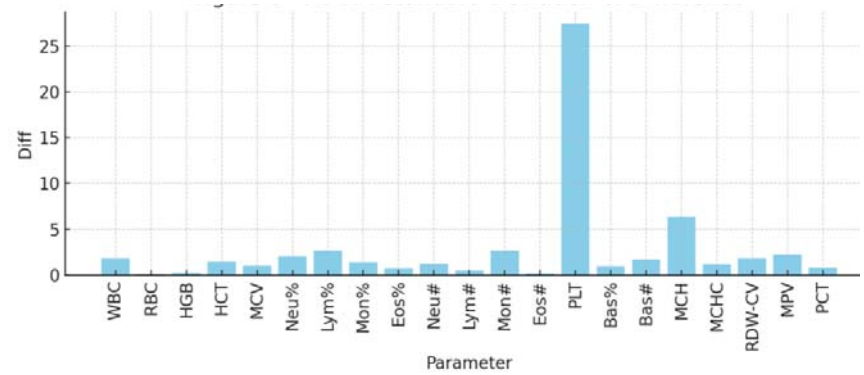

Figure 6: ADVIA Standard Deviation of Difference.

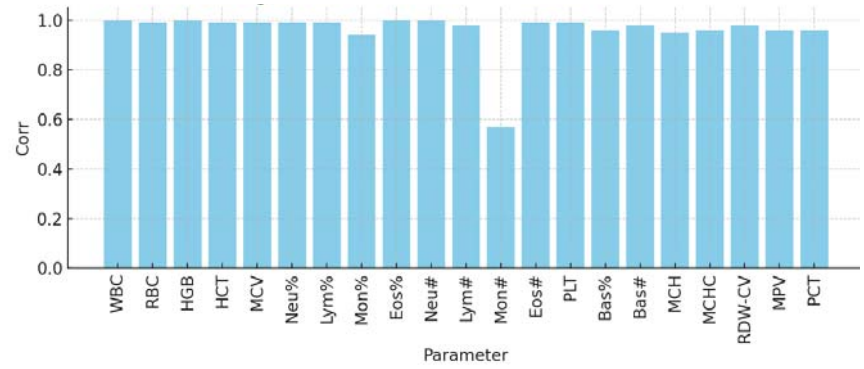

Figure 7: ADVIA Coefficient of Correlation.

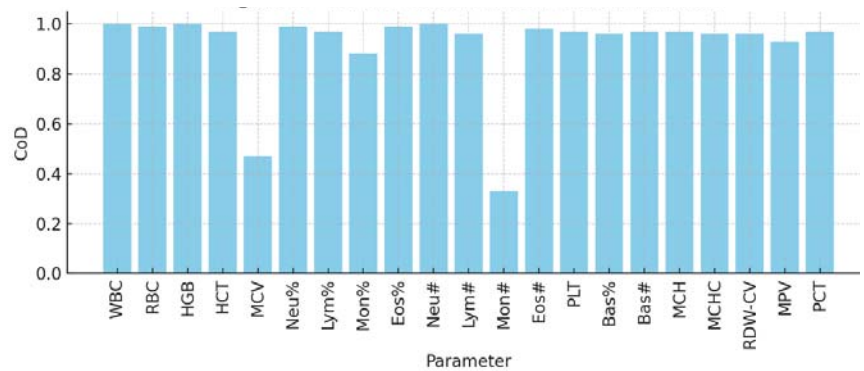

Figure 8: ADVIA Coefficient of Determination.

simultaneously with Erba H7100 and Advia 2120i, and 53 samples were analyzed for reticulocyte count simultaneously with Erba H7100 and DXH 900.

Discussion

This study aimed to evaluate the performance of the Erba H7100 hematology analyzer by comparing it with the Beckman Coulter DXH 900 and Siemens Advia 2120i platforms. Conversely, reticulocyte count analysis demonstrated exceptional agreement between the Erba H7100 and both Advia 2120i and DXH 900 platforms. Automation was also found to be superior in detecting low reticulocyte counts, with the automated method often providing a value when the corresponding manual method yielded zero [1,2]. The results for reticulocyte counts revealed near-perfect correlation and minimal bias, with Pearson's r values exceeding 0.99 and r-squared values above 0.98.

The ADVIA 2120I analyzer exhibited notable discrepancies in MCV and monocyte counts (Mon#), as evidenced by lower correlation coefficients (r) and coefficients of determination (R^2) compared to the Erba H7100. This highlights potential analytical differences in these parameters. Erba H7100 showed a better agreement with the DXH 900 analyzer than the ADVIA 2120i analyzer, over the MCV and Mon# parameters. This suggests that the Erba H7100 and DXH 900 are more aligned in their methodologies for those parameters.

The consistently strong linear correlations ($r > 0.94$) and high coefficients of determination ($R^2 > 0.96$) observed for most parameters across all comparisons indicate a robust linear relationship. However, the discrepancies in mean biases and standard deviations of differences highlight the importance of evaluating both measures of agreement and relationship to fully understand the comparability of hematology analyzers.

Erba H7100 demonstrated a high level of agreement and a high level of correlation with the DXH 900. This shows a high level of comparability between these two analyzers.

The findings of this study underscore the importance of comprehensive validation and comparison studies to ensure the reliability and comparability of hematology analyzers. As previously noted, spurious counts and results, especially for platelets, can occur, emphasizing the need for thorough analyses [1-3]. Pre-analytical factors, which can influence CBC results, should also be considered [6]. The evaluation of new parameters and platelet measurement channels, as highlighted in previous research, is crucial for improving diagnostic accuracy [1,10,11].

The observation of significant mean biases, particularly for PLT, necessitates careful consideration when interpreting results and potentially implementing platform-specific reference intervals. The ADVIA 2120i's discrepancies in MCV and Mon# may be attributed to differences in methodologies, as seen in other comparative studies [5,14]. Erba H7100's better agreement with the DXH 900 for MCV and Mon# suggests a closer alignment in their analytical approaches for these parameters.

In conclusion, this study underscores the importance of comprehensive validation and comparison studies to ensure the reliability and comparability of hematology analyzers. Further emphasizing the clinical relevance of reticulocyte analysis, a study highlighted the nuanced interpretation required for reticulocyte counts, considering various physiological and pathological conditions [16]. Moreover, a large-scale study identified a high reticulocyte count as a potential risk factor for the development of metabolic dysfunction-associated steatotic liver disease, suggesting a broader systemic implication of erythropoiesis [17]. In the context of hematology analyzer performance, a comparison study evaluated reticulocyte counts and extended parameters obtained from different platforms, providing valuable insights into inter-analyzer variability and the establishment of reference intervals [18].

Clinical implications

The significant platelet count biases observed necessitate careful inter-platform result comparisons, potentially requiring platform-specific reference ranges. Clinicians must exercise caution when interpreting results from different analyzers, especially for critical parameters like platelets and white blood cells. The ADVIA 2120i analyzer's MCV and monocyte count discrepancies highlight the importance of understanding platform-specific methodologies. ERBA H7100 has better agreement with the DXH 900 for MCV and monocyte counts, suggesting a potential preference for these parameters in some settings. Ultimately, this study emphasizes the need for thorough validation before adopting new hematology analyzers to maintain patient safety.

Conclusion

This study revealed significant platelet count biases and variability among the Erba H7100, DXH 900, and ADVIA 2120i analyzers. The ADVIA 2120i analyzer showed notable discrepancies in MCV and monocyte counts compared to the Erba H7100. While the Erba H7100 demonstrated better agreement with the DXH 900 for MCV and monocyte counts, it exhibited significant biases for PLT and WBC. Conversely, reticulocyte count analysis demonstrated exceptional agreement between Erba H7100 and both Advia 2120i and DXH 900, with Pearson's r values exceeding 0.99 and r-squared values above 0.98, indicating near-perfect correlation and minimal bias. In hematological fluid analysis, both Erba H7100 and DXH 900 were closely aligned with Microscopy in determining Neutrophil % and Lymphocyte % values, demonstrating comparable performance.

Laboratories should consider platform-specific reference ranges or correction factors to mitigate inter-platform result discrepancies in other parameters. Further research with larger sample sizes and diverse clinical populations is needed to refine our understanding of these analyzers and optimize their clinical use in various hematological parameters.

Ethical consideration

The study adhered to institutional ethical standards, with anonymized patient data used solely for analytical validation.

Conflict of interest: The authors declare no conflict of interest in relation to this study.

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