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ORIGINAL ARTICLE

Performance Validation and Evaluation of the Mindray BC-7900 Automated Hematology Analyzer

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SUMMARY

Background: **The performance of the Mindray BC-7900 automated hematology analyzer was evaluated to determine whether the instrument fulfills clinical requirements.**
Methods: **The BC-7900 hematology analyzer was evaluated based on the background count, carryover rate, precision, linear range, sample stability, comparability of results from different sample aspiration modes, comparability of results between instruments, erythrocyte sedimentation rate (ESR) for small blood volumes, and its ability to flag for abnormal leukocytes.**
Results: **The background count was consistently 0, and the maximum carryover rate was 0.54%. The coefficients of variation for the repeatability and the within-laboratory precision were within the allowable ranges. Verification of the linear range yielded $r^2 \geq 0.994$. The sample stability met the deviation requirements at both ambient and cryogenic temperatures. The results obtained from the two sample aspiration modes were comparable. The routine blood parameter values were highly correlated with those obtained using the BC-6800Plus analyzer. Specifically, the correlation coefficients for white blood cell count (WBC), neutrophil percentage (Neu%), lymphocyte percentage (Lym%), nucleated red blood cell percentage (NRBC%), RBC, hemoglobin (HGB), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and impedance (PLT-I) and hybrid platelet counts (PLT-H) were all greater than 0.99. The correlation coefficients for monocyte percentage (Mon%), eosinophil percentage (Eos%), and basophil percentage (Baso%) were all greater than 0.91, while the coefficient for the mean corpuscular hemoglobin concentration (MCHC) was greater than 0.89. Compared with the Westergren method, the results of ESR for both standard and trace blood sample volumes were well correlated, with correlation coefficients of 0.943 and 0.952, respectively. Additionally, the analyzer demonstrated excellent sensitivity and specificity for flagging for immature granulocytes (95.4% and 93.8%, respectively) and abnormal lymphocytes (86.9% and 90.7%). Finally, the hematological malignant cell (HMC) channel showed high sensitivity (98.4%) and moderate specificity for detecting blasts (including abnormal promyelocytes).**
Conclusions: **The BC-7900 automated hematology analyzer demonstrated strong performance, providing accurate and reliable results that meet clinical application requirements. This instrument provides excellent ESR detection methods for trace and standard blood sample volumes and an effective method for flagging blast cells.**
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INTRODUCTION

Routine blood examinations are a fundamental component of clinical laboratory work. Although their results may not be directly used for clinical diagnostics, they provide essential reference information for disease diagnosis and treatment [1]. Therefore, fast and accurate routine blood testing is highly desirable in all hematology laboratories. The BC-7900, the latest automated hematology analyzer developed by Mindray, is designed to meet these demands. In addition to providing routine blood cell analysis for clinical applications, it is also equipped with advanced functionalities. These include solutions for measuring the erythrocyte sedimentation rate (ESR) using trace amounts of blood samples and detecting abnormal blood cells.

Early and rapid screening is crucial, given the relatively high incidence of malignant tumors. When an individual presents with hematological malignancy, pathological changes are often observed in peripheral blood, including the presence of abnormal blood cells, such as blasts, and abnormal promyelocytes [2]. Existing hemocytometers typically rely on conventional blood cell analysis channels [3] to differentiate abnormal blood cells from normal ones. However, their screening specificity is often low, leading to a high rate of false-positive results and necessitating frequent clinical reexaminations [4]. To address these limitations, the hematological malignant cell (HMC) channel utilizes a novel approach. The double-stranded DNA in the nucleus undergoes a series of complex assembly processes, such as coiling and folding, and then is compressed and stored in the nucleus, thus forming a complex spatial structure. Primitive cells and abnormal promyelocytes are very active in gene expression regulation, and accordingly, the complexity of their DNA spatial structure is high. Moreover, the complexity of DNA spatial structure decreases during the process of cell differentiation from primitive to mature cells. The complexity of DNA spatial structure plays a key role in the process of malignant proliferation of abnormal lymphocytes because of the abnormal chromatin function in the process of malignant proliferation, resulting in the spatial structure of the originally tightly wound DNA becoming loose, so as to meet the needs of malignant proliferation of the cells. The HMC channel utilizes the special FM fluorescent dyes to bind with the double-stranded DNA in the cell nucleus by means of embedding, and during the process, the complexity of DNA spatial structure plays a key role. The more complex the spatial structure of DNA, the fewer sites the FM dye can bind to. Given the relatively complex spatial structure of DNA in primitive cells and abnormal promyelocytes, the number of sites where the FM dye can bind to them is limited, which results in a lower fluorescence than that in mature leukocytes, whereas abnormal lymphocytes, with their relatively loose spatial structure, present a higher fluorescence. By employing advanced hemolytic agents and fluorescent dyes, the HMC channel differentially processes various components of abnormal blood cells (such as the nucleus, plasma, and membrane), enabling it to more effectively distinguish abnormal cells from normal ones. This innovative technology demonstrates strong performance in detecting hematological malignancies, including acute promyelocytic leukemia (APL) and other hematological tumors.

The erythrocyte sedimentation rate (ESR) is a valuable diagnostic indicator, assessed under various conditions, for identifying disease activity, stability, and relapse and differentiating between benign and malignant tumors [5]. Currently, the clinically recognized gold standard for determining ESR is the Westergren method. However, this method is time-consuming, requires a substantial blood volume, relies on manual techniques, and exposes the blood sample to air. The BC-7900 addresses these challenges with its integrated ESR measurement functions, available in both whole blood mode and micro whole blood mode. This system employs Easy-Way ESR measurement technology, which rapidly evaluates the degree and speed of erythrocyte aggregation. Easy-W ESR technology, in order to quickly and accurately realize ESR measurement, obtains the degree and speed of aggregation through the process of erythrocyte aggregation in a short period of time, and obtains one-hour ESR value according to the erythrocyte aggregation and sedimentation model.

This technology utilizes high-speed laminar flow to depolymerize the red blood cells, rapid emergency stops to capture the peak aggregation rate, near-infrared light to measure the aggregation dynamics, and constant temperature throughout to eliminate temperature interference. It accurately calculates the one-hour ESR value, enabling rapid and precise ESR measurements that overcome the limitations of traditional methods.

In this study, the performance of BC-7900 was evaluated for the first time with respect to its core parameters. The device's ability to measure the ESR in both whole blood mode and micro whole blood mode was compared with that of the Westergren method. In addition, its performance in detecting abnormal leukocytes, such as immature granulocytes, reactive lymphocytes, and blasts (including abnormal promyelocytes), was analyzed.

MATERIALS AND METHODS

Instruments and reagents

The instruments used in this study included BC-7900 and BC-6800 Plus [6] automated hematology analyzers with their original reagents and supporting quality control products, a Mindray SC-120 automated slide staining machine, an Olympus binocular microscope, Westergren erythrocyte sedimentation tubes and supporting erythrocyte sedimentation racks, and Sigma sodium citrate powder.

Sample source
This was a clinical evaluation study of in vitro diagnostic devices. The samples used were surplus specimens from hospital, ensuring no patient privacy or interests were compromised. As a result, the need to obtain signed informed consent from patients was waived. A total of 2,149 EDTA-K2 anticoagulant tubes of venous whole blood samples were collected from outpatient clinics, emergency departments, and inpatients at the Laboratory Department of the First Affiliated Hospital of Soochow University between May 2024 and July 2024. Out of the total, 525 random samples were selected to compare the performance of the BC-7900 with the BC-6800Plus and the Westergren methods. A total of 656 samples that violated the reexamination rules were used to assess the effectiveness of the immature granulocyte and reactive lymphocyte sensors. A total of 843 samples from suspected hematological disease cases or other reexamination rule violations were used to evaluate the effectiveness of the blast sensor. In accordance with Clinical and Laboratory Standards Institute (CLSI) H03-A6 [7,8], all samples had a volume of at least 1 mL and were free from hemolysis and coagulation. The samples were stored at room temperature (18 - 26°C). Except for the sample stability test, all analyses were completed within 4 hours after sample collection.

Blank count
The DS diluent provided with the instrument was used as the specimen for blank counts. Three consecutive tests were conducted in both automated whole blood and micro whole blood modes, and the maximum value of the three tests was selected for analysis.

Carryover rate
For each analyte, a fresh, high-concentration whole-blood sample was taken and mixed evenly for three consecutive measurements, which were denoted as H1, H2, and H3. Similarly, a low concentration sample was immediately taken for three consecutive measurements, denoted as L1, L2, and L3. The high and low concentration ranges of each parameter adhered to the requirements outlined in CLSI H26-A2 [7,8] and are shown in Table 1. The carryover rate was calculated using the following formula:

$$\text{Carryover} = \frac{\text{L1} - \text{L3}}{\text{H3} - \text{L3}} \text{ x } 100\%$$

Precision (reproducibility)
The precision of the instrument was assessed using commercial Quality Control (QC) material BC-6D (at low, medium, and high concentration levels) provided by Mindray Company. Testing was carried out over a period of at least 20 consecutive days. Each day, two tests were performed in the morning and two tests in the afternoon.

Precision (repeatability)
In accordance with the requirements outlined by International Council for Standardization in Hematology (ICSH) 2014 [9], fresh, whole-blood samples were obtained to cover the declared range of the instrument. Each sample was tested consecutively 10 times in both whole blood and micro whole blood modes of the BC-7900. The mean, standard deviation (SD), and coefficient of variation (CV%) were calculated for each group.

Linear range
Samples with high concentrations of analytes were taken and diluted to different proportions (100%, 50%, 25%, 12.5%, 6.25%, 0%) to cover the entire linear range. Each dilution was repeated three times, and the mean was calculated. This measured mean value was compared with the theoretical value, and regression analysis was performed on the data to calculate the corresponding absolute and relative deviations and correlation coefficients.

Sample stability
Ten healthy volunteers with no underlying diseases were recruited. Fresh venous whole blood samples were collected and stored at room (18 - 25°C) or low temperature (2 - 8°C). The room-temperature samples were tested at 0.5, 4, 6, 8, 12, and 24 hours, while the low-temperature samples were tested at 0.5, 4, 8, 12, 24, and 48 hours. The test result at 0.5 hours was used as the reference value to evaluate the relative and absolute deviations of the test results at the other time points.

Comparison of modes
Comparison of modes was conducted to evaluate the consistency of the results between the whole blood and micro whole blood analyses. No less than 40 random fresh whole blood samples were selected and tested once in the whole blood CD + ESR mode of the BC-7900 and in the micro whole blood CD + ESR mode, and the relative deviation between the means of the test results under the two modes was calculated.

Comparability
Using a calibrated BC-6800 Plus hematology analyzer as the reference instrument, no less than 100 fresh anticoagulated whole blood samples covering each medical decision level were tested on the BC-7900. Afterward, the ESR was measured in the samples with the Westergren method, all within 2 hours. Linear regression analysis was performed on the obtained data to calculate the correlation coefficient, absolute deviation, and relative deviation and to determine the linear regression equation.

Evaluation of the clinical applicability of ESR
At least 60 fresh whole blood samples from the departments of rheumatology, orthopedics, and hematology were selected. The ESR was determined simultaneously

Table 1. Requirements for high and low value sample range of blood sample carryover.

Parameters	Units	High value sample	Low Value sample
WBC	$\times 10^9$/L	> 90.0	> 0 - < 3.0
RBC	$\times 10^{12}$/L	> 6.20	> 0 - < 1.50
HGB	g/L	> 180	> 0 - < 50
PLT/PLT-I/PLT-O/PLT-H	$\times 10^9$/L	> 900	> 0 - < 30

Table 2. Results of blank counts.

Modes	Parameters	N	Minimum	Maximum
Whole blood mode	WBC	3	0.00	0.00
	RBC	3	0.00	0.00
	HGB	3	0.00	0.00
	PLT	3	0.00	0.00
	PLT-I	3	0.00	0.00
	PLT-H	3	0.00	0.00
Micro whole blood mode	WBC	3	0.00	0.00
	RBC	3	0.00	0.00
	HGB	3	0.00	0.00
	PLT	3	0.00	0.00
	PLT-I	3	0.00	0.00
	PLT-H	3	0.00	0.00

with the Westergren method and the BC-7900, and the correlation between the resulting values was assessed.

Capacity of abnormal leukocyte flagging

Capacity of immature granulocytes and reactive lymphocytes flagging

To evaluate the ability of the BC-7900 to warn for abnormal leukocytes, the samples of no less than 200 patients from the First Affiliated Hospital of Soochow University whose samples violated the reexamination rules were selected. The samples were tested with whole-blood CD mode on the BC-7900, and blood smears were prepared with an SC-120 slide maker. Then, experienced morphological microscopy examiners read the slides in accordance with the requirements outlined in CLSI H2O-A2 [7,8], recording the numbers of promyelocytes, myelocytes, metamyelocytes, and reactive lymphocytes. Using the established positive standard of the International Hematology Organization [10], the sensitivity and specificity of the BC-7900 in detecting immature granulocytes and atypical lymphocytes were calculated.

Capacity of the blast (including abnormal promyelocyte) flagging

To evaluate the ability of BC-7900 to detect blasts, no fewer than 200 samples of patients with suspected hematological diseases and no fewer than 200 samples that violated the reexamination rules were selected. Detection was performed in whole blood CD + HMC mode, and blood smears were prepared with an SC-120 slide maker. Then, experienced morphological microscopy examiners read the slides according to the requirements outlined in CLSI H2O-A2 [7,8], recording the number of blasts and abnormal promyelocytes in the slides. The positive standards developed by the International Hematology Organization were used to compare the sensitivity and specificity of the BC-7900 in CD mode and CD + HMC mode in identifying blasts (including abnormal promyelocytes).

Data analysis

Analyse-it (https://analyse-it.com/) and Microsoft Excel 2019 software (Microsoft Corp., Redmond, WA, USA) were used to collate and analyze the test data of the above mentioned items, and the SD and CV% were calculated to evaluate the within-laboratory precision and repeatability of the parameters. Linear regression analy-

Table 3. Result of the within-laboratory precision of routine blood and body fluid parameters.

Parameter	Level	N	Mean	Between-run		Between-day		Within-laboratory	
				SD	CV %	SD	CV %	SD	CV %
WBC ($\times 10^9$/L)	level 1	80	3.85	0.00	0.00%	0.08	2.09%	0.11	2.91%
	level 1	80	7.72	0.05	0.64%	0.18	2.27%	0.24	3.14%
	level 1	80	20.97	0.00	0.00%	0.24	1.12%	0.44	2.11%
Neu%	level 1	80	54.50	0.25	0.46%	0.26	0.48%	0.99	1.82%
	level 1	80	47.80	0.00	0.00%	0.46	0.96%	0.78	1.63%
	level 1	80	54.30	0.19	0.36%	0.00	0.00%	0.39	0.71%
Lym%	level 1	80	25.40	0.18	0.70%	0.16	0.63%	0.69	2.73%
	level 1	80	36.30	0.31	0.85%	0.00	0.00%	0.63	1.75%
	level 1	80	32.10	0.07	0.20%	0.06	0.18%	0.38	1.17%
Mon%	level 1	80	3.60	0.00	0.00%	0.03	0.80%	0.19	5.37%
	level 1	80	5.00	0.00	0.00%	0.00	0.00%	0.18	3.55%
	level 1	80	4.50	0.00	0.00%	0.04	0.88%	0.15	3.29%
Eos%	level 1	80	15.00	0.00	0.00%	0.32	2.16%	0.78	5.16%
	level 1	80	9.50	0.18	1.91%	0.22	2.27%	0.47	4.93%
	level 1	80	7.80	0.10	1.25%	0.00	0.00%	0.26	3.30%
Baso%	level 1	80	1.50	0.00	0.00%	0.01	0.97%	0.04	2.57%
	level 1	80	1.40	0.00	0.00%	0.00	0.00%	0.01	0.80%
	level 1	80	1.40	0.00	0.00%	0.00	0.23%	0.07	5.43%
NRBC%	level 1	80	8.20	0.30	3.61%	0.00	0.00%	0.68	8.23%
	level 1	80	4.20	0.13	3.12%	0.00	0.00%	0.29	6.88%
	level 1	80	2.30	0.00	0.00%	0.07	2.88%	0.15	6.63%
RBC ($\times 10^{12}$/L)	level 1	80	2.22	0.01	0.52%	0.00	0.00%	0.02	0.98%
	level 1	80	4.19	0.02	0.55%	0.00	0.00%	0.03	0.76%
	level 1	80	5.05	0.02	0.32%	0.01	0.23%	0.03	0.67%
HGB (g/L)	level 1	80	58.00	0.19	0.33%	0.38	0.66%	0.63	1.08%
	level 1	80	121.00	0.34	0.28%	0.68	0.56%	0.90	0.74%
	level 1	80	155.00	0.57	0.37%	0.68	0.44%	1.07	0.69%
MCV (fL)	level 1	80	82.00	0.17	0.21%	0.19	0.23%	0.40	0.49%
	level 1	80	92.00	0.25	0.27%	0.25	0.27%	0.45	0.49%
	level 1	80	99.00	0.28	0.29%	0.29	0.29%	0.50	0.50%
MCH (pg)	level 1	80	26.10	0.16	0.62%	0.17	0.66%	0.32	1.22%
	level 1	80	29.00	0.10	0.36%	0.17	0.59%	0.27	0.95%
	level 1	80	30.80	0.07	0.22%	0.13	0.43%	0.22	0.71%
MCHC (g/L)	level 1	80	319.30	0.97	0.31%	3.45	1.08%	4.76	1.49%
	level 1	80	314.70	0.88	0.28%	2.74	0.87%	3.50	1.11%
	level 1	80	311.40	0.66	0.21%	2.19	0.70%	2.89	0.93%
PLT ($\times 10^9$/L)	level 1	80	54.00	0.37	0.69%	1.36	2.51%	2.67	4.95%
	level 1	80	209.00	1.98	0.95%	1.13	0.54%	5.58	2.67%
	level 1	80	398.00	2.96	0.74%	1.05	0.26%	6.71	1.68%
PLT-I ($\times 10^9$/L)	level 1	80	54.00	0.37	0.69%	1.36	2.51%	2.67	4.95%
	level 1	80	209.00	1.98	0.95%	1.13	0.54%	5.58	2.67%
	level 1	80	398.00	2.96	0.74%	1.05	0.26%	6.71	1.68%
PLT-H ($\times 10^9$/L)	level 1	80	54.00	0.37	0.69%	1.36	2.51%	2.67	4.95%
	level 1	80	209.00	1.98	0.95%	1.13	0.54%	5.58	2.67%
	level 1	80	398.00	2.96	0.74%	1.05	0.26%	6.71	1.68%
ESR (mm/hour)	level 1	80	36.07	0.13	0.35%	0.12	0.34%	0.22	0.60%
	level 1	80	14.53	0.05	0.35%	0.13	0.92%	0.15	1.02%
	level 1	80	10.86	0.03	0.32%	0.03	0.27%	0.05	0.48%

Table 4. Result of linearity.

Parameters	Range	r	Slope	Intercept
WBC (× 10^9/L)	0 - 103.53	0.9999	1.0498	0.048
	96.62 - 353.25	0.9998	2.579	96.161
	349.66 - 507.21	0.9990	1.618	345.590
RBC (× 10^{12}/L)	0 - 8.71	1.0000	0.088	0.022
HGB (g/L)	0 - 257	1.0000	2.570	0.997
HCT (%)	0 - 77.8	1.0000	0.777	0.031
PLT (× 10^9/L)	0 - 1,027	0.9999	10.279	3.695
	992 - 5,155	0.9981	43.701	1,039.612
PLT-I (× 10^9/L)	0 - 1,027	0.9999	10.279	3.695
	992 - 5,155	0.9981	43.701	1,039.612
PLT-H (× 10^9/L)	0 - 1,151	0.9997	11.522	-9.344
	992 - 5,155	0.9981	43.701	1,039.612
Nrbc% (/100WBC)	0 - 670.58	0.9999	6.862	0.288
Nrbc# (× 10^9/L)	0 - 23.034	0.9999	0.231	0.012

Table 5. Result of comparison of modes.

Parameters (n = 69)	Mean of WB CD + ESR	Mean of MWB CD + ESR	d	d %
WBC (× 10^9/L)	6.14	6.12	-0.03	-0.41%
Neu%	60.73	61.00	0.27	0.44%
Lym%	30.08	29.85	-0.23	-0.77%
Mon%	6.90	6.74	-0.15	-2.22%
Eos%	1.93	1.91	-0.02	-1.28%
Baso%	0.44	0.37	-0.07	-15.84%
Nrbc%	0.71	0.71	0.00	0.04%
RBC (× 10^{12}/L)	4.05	4.02	-0.03	-0.71%
HGB (g/L)	116.30	115	-1.30	-1.12%
MCV (fL)	88.35	89.81	1.46	1.65%
HCT (%)	35.41	35.76	0.35	0.98%
PLT (× 10^9/L)	223.91	221.80	-2.12	-0.94%
PLT-I (× 10^9/L)	225.36	224.01	-1.35	-0.60%
PLTH (× 10^9/L)	223.91	221.80	-2.12	-0.94%
ESR (mm/hour)	15.08	14.48	-0.60	-4.01%

sis was performed to assess the linearity of the data. Sample stability was determined by calculating the relative and absolute deviations. The consistency between the modes was analyzed and evaluated, and $p < 0.05$ was considered to indicate statistical significance.

Passing-Bablok regression analysis and Bland-Altman consistency analysis were conducted to evaluate the correlation between the BC-7900 and both the BC-6800Plus and the Westergren method and to evaluate the clinical applicability of the measured ESRs.

Table 6. Result of immature granulocyte and atypical lymphocyte.

Items (n = 565)	Immature granulocyte	Atypical lymphocyte
TP	249	53
TN	285	457
FP	19	47
FN	12	8
Sensitivity %	95.4%	86.9%
Specificity %	93.8%	90.7%
PPV%	92.9%	53.0%
NPV%	96.0%	98.3%
FP%	6.3%	9.3%
FN%	4.6%	13.1%
Agreement (overall efficiency) %	94.5%	90.3%

Table 7. Result of CD and HMC flag.

Items (n = 843)	Mindray BC-7900 CD Flag	Mindray BC-7900 HMC Flag
TP	181	181
TN	376	505
FP	283	154
FN	3	3
Sensitivity %	98.4%	98.4%
Specificity %	57.1%	76.6%
PPV%	39.0%	54.0%
NPV%	99.2%	99.4%
FP%	42.9%	23.4%
FN%	1.6%	1.6%
Agreement (overall efficiency) %	66.1%	81.4%

RESULTS

Blank count

The white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), and normal (PLT), intensity (PLT-I), and hybrid platelet (PLT-H) background counts for three tests were all 0. The results are summarized in Table 2. Each parameter had very low blank values.

Carryover rate

The carryover rates for WBC, RBC, HGB, hematocrit (HCT), PLT-I, and PLT-H are shown in Figure 1. The maximum carryover rate for each routine blood parameter in each mode was 0.54%, which was less than 1.0%.

Precision (reproducibility)

For 20 consecutive days, the BC-6D of three concentration levels was tested twice a day in the morning and afternoon. The between-run, between-site, and within-laboratory values were calculated according to CLSI EP05-A3. The between-run, between-site, and within-laboratory CV% values for WBC, neutrophil percentage (Neu%), lymphocyte percentage (Lym%), RBC, HGB, mean corpuscular volume (MCV), and ESR were all less than 3.2%, those of the monocyte percentage (Mon%), eosinophil percentage (Eos%), basophil percentage (Baso%), PLT, PLT-I, and PLT-H were less than 5.5%, and the CV% of the nucleated RBC percentage (NRBC%) was less than 8.3%. All results were considered acceptable (Table 3).

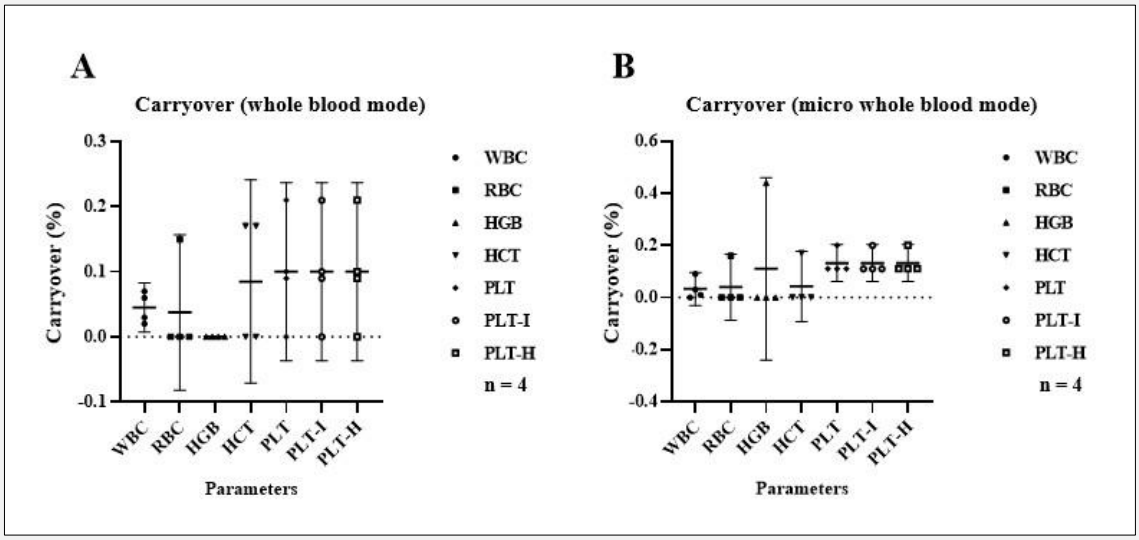

Figure 1. BC-7900 carryover rate.

A in whole blood mode and B in micro whole blood mode.

Precision (repeatability)

To verify the repeatability, a total of 11 fresh whole blood samples were collected and evaluated in the whole blood mode as well as 12 samples in the micro whole blood mode of the BC-7900. The repeatability of all the parameters in each mode, including WBC, Neu%, Lym%, Mon%, Eos%, Baso%, RBC, HGB, MCV, MCH, MCHC, and PLT, was excellent. The repeatability of PLT-I, PLT-H, and ESR is shown in Figure 2. In the whole blood mode, the maximum CV% was less than 7% for Mon% and high ESR values (above 15). The CV% of the other parameters were less than 4%, and the standard deviations (SD) of Eos%, Bas%, and low ESR values (below 15) were less than 1.2. In the micro whole blood mode, the CV% of Mon% was less than 11% and the CV% of the other parameters except ESR was less than 5%. The SDs of Eos% and Bas% were less than 1. When the ESR values were above 15, the maximum value of the CV% was 6.28%, and when the ESR values were below 15, the maximum value of the standard deviation was 1.32, indicating that the performance of BC-7900 for trace amounts of blood samples of blood ESR was stable.

Linear range

The linear ranges of the low, middle, and high WBC counts were (0 - 103.53) × 10^9/L, (96.62 - 353.25) × 10^9/L, and (349.48 - 530.15) × 10^9/L, respectively; therefore, (0 - 530.15) × 10^9/L can be used as the linear range for the WBC count. Similarly, (0 - 5155) × 10^9/L can be used as the linear range for the PLT, PLT-I, and PLT-H counts. The linear correlation, slope, and intercept of each parameter and the corrected concentrations are shown in Table 4.

The correlation coefficients of all the parameters in each range were greater than 0.998, indicating excellent linear relationships.

Sample stability

A total of 10 fresh whole blood samples were collected from volunteers to verify sample stability. The results for each parameter at room temperature (RT) and low temperature (LT) are shown in Figure 3. At RT, the relative deviation of each parameter within 24 hours was less than 3%. At RT, the relative deviations in the WBC, RBC, HGB, PLT, PLT-I, and PLT-H counts were all less than 2.5% within 48 hours. The absolute deviation of the ESR at both RT and LT within 48 hours was less than 2.2.

Comparison of modes

A total of 69 fresh whole blood samples were collected to verify the consistency of the CD + ESR mode between whole blood mode and micro whole blood mode. The results are shown in Table 5. The absolute and relative deviations for the ESR between whole blood and micro whole blood modes were -0.6 and -4.01%. The absolute deviation for Baso% was -0.07; excluding Baso%, the maximum relative deviation of other parameters between the modes was less than 4.1%, and the ab-

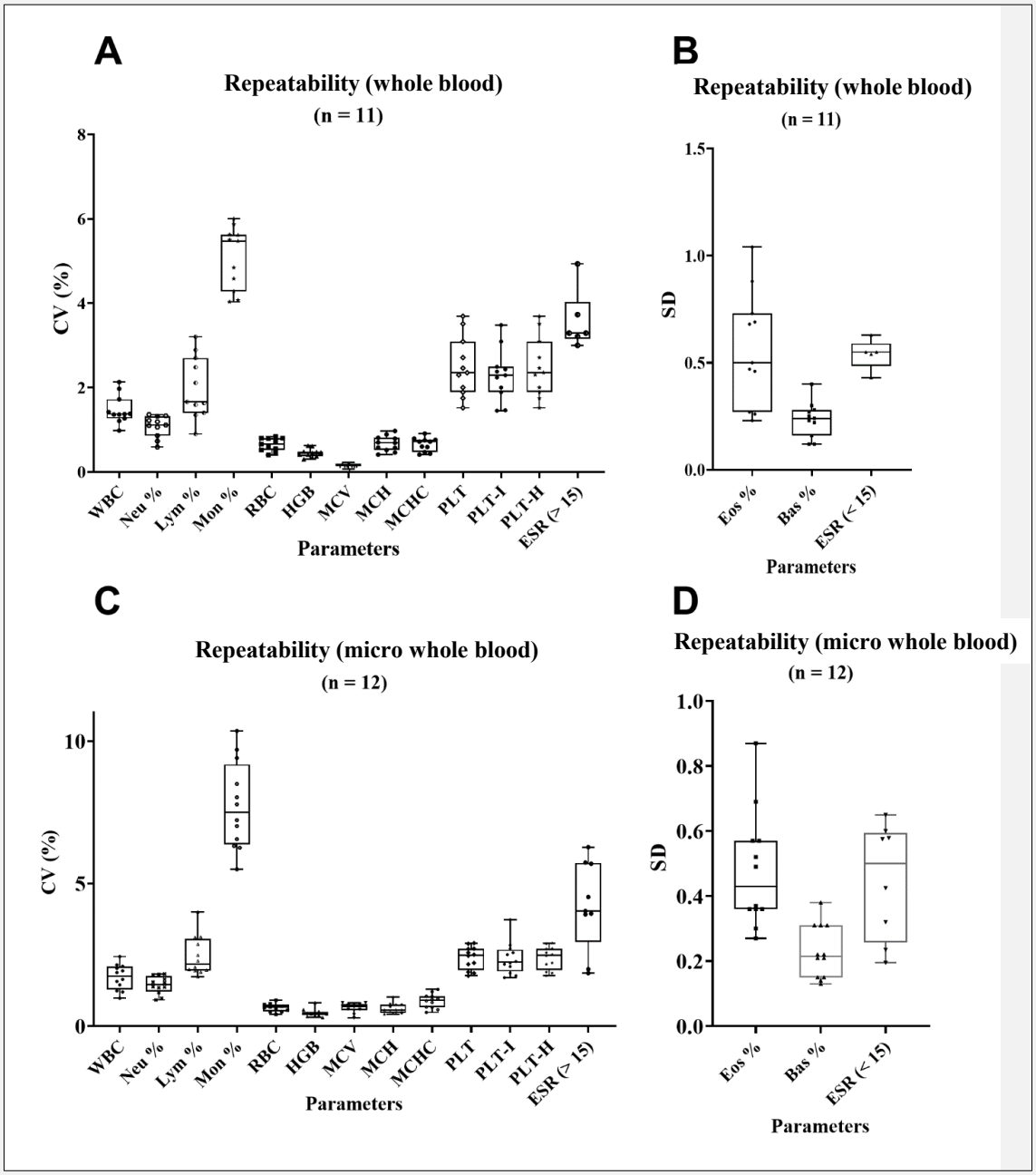

Figure 2. BC-7900 repeatability.

A Whole blood mode repeatability CV%. B Whole blood mode repeatability SD. C Micro whole blood mode repeatability CV%. D Micro whole blood mode repeatability SD.

solute deviation was less than 2.2, indicating that there was no difference in the performance of the two BC-7900 modes. Analysis of variance (ANOVA) revealed that there was no significant difference between the ESR obtained in the whole blood and that obtained in micro whole blood mode ($p < 0.01$).

Comparability

A total of 391 fresh whole blood samples were collected and tested to compare the performance of the BC-7900 with BC-6800Plus and the Westergren method in detecting the different parameters, while 134 fresh whole blood samples were collected and used to compare the

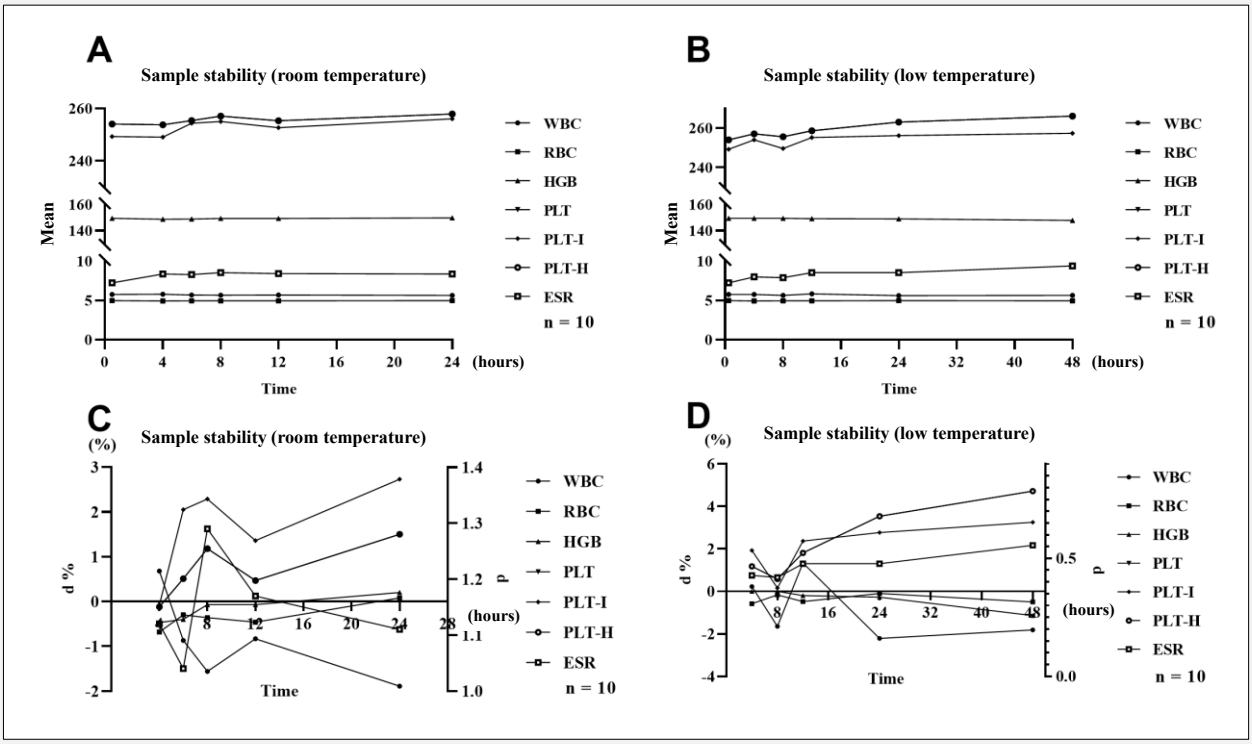

Figure 3. BC-7900 sample stability.

A Mean value of the sample stability at room temperature. B Mean value of the sample stability at low temperature. C Sample stability at room temperature d% and D Sample stability at low temperature d%.

ESR obtained with micro whole blood mode and the ESR obtained with the Westergren method. Passing-Bablok regression analysis was used for methodological comparisons. The results are shown in Figure 4.

The correlation coefficients for WBC, Neu%, Lym%, NRBC%, RBC, HGB, MCV, MCH, PLT-I, and PLT-H between the BC-7900 and BC-6800Plus were all greater than 0.99, whereas the correlation coefficients for Mon%, Eos%, and Baso% were greater than 0.91, and the correlation coefficient for MCHC was greater than 0.89. The relative deviations of WBC, Neu%, Lym%, Mon%, Baso%, RBC, HGB, MCV, MCH, and MCHC were smaller than 1%, and those of Eos%, PLT-I, and PLT-H were smaller than 4%, while the absolute deviation of NRBC% was -0.02. The correlation coefficients between the ESR obtained in whole blood mode and micro whole blood mode and the ESR obtained with the Westergren test were greater than 0.94. The values of all the parameters strongly correlated with those obtained with the control method.

Clinical applicability of the ESR

A total of 110 samples from rheumatology, orthopedics, and hematology departments were collected to evaluate the applicability of the ESR in clinical practice. Passing-Bablok regression analysis and Bland-Altman consistency analysis were performed, and the results are shown in Figure 5. The correlation coefficient between the ESR measured with the BC-7900 and that measured with the Westergren method was 0.963, and the result of the consistency analysis was 5.031 (95% CI: -10.746 - 20.808). The two methods yielded a good correlation and deviation, and both meet clinical requirements.

Capacity of abnormal leukocyte flagging

Capacity of immature granulocytes and reactive lymphocytes flagging

A total of 565 samples that violated the reexamination rules were collected and tested to evaluate the ability of the BC-7900 to warn for immature granulocytes and reactive lymphocytes. With reference to the positive microscopy examination criteria developed by the International Hematology Organization, the expression “Metamyelocyte%>2% or Myelocyte%≥1% or Promyelo-

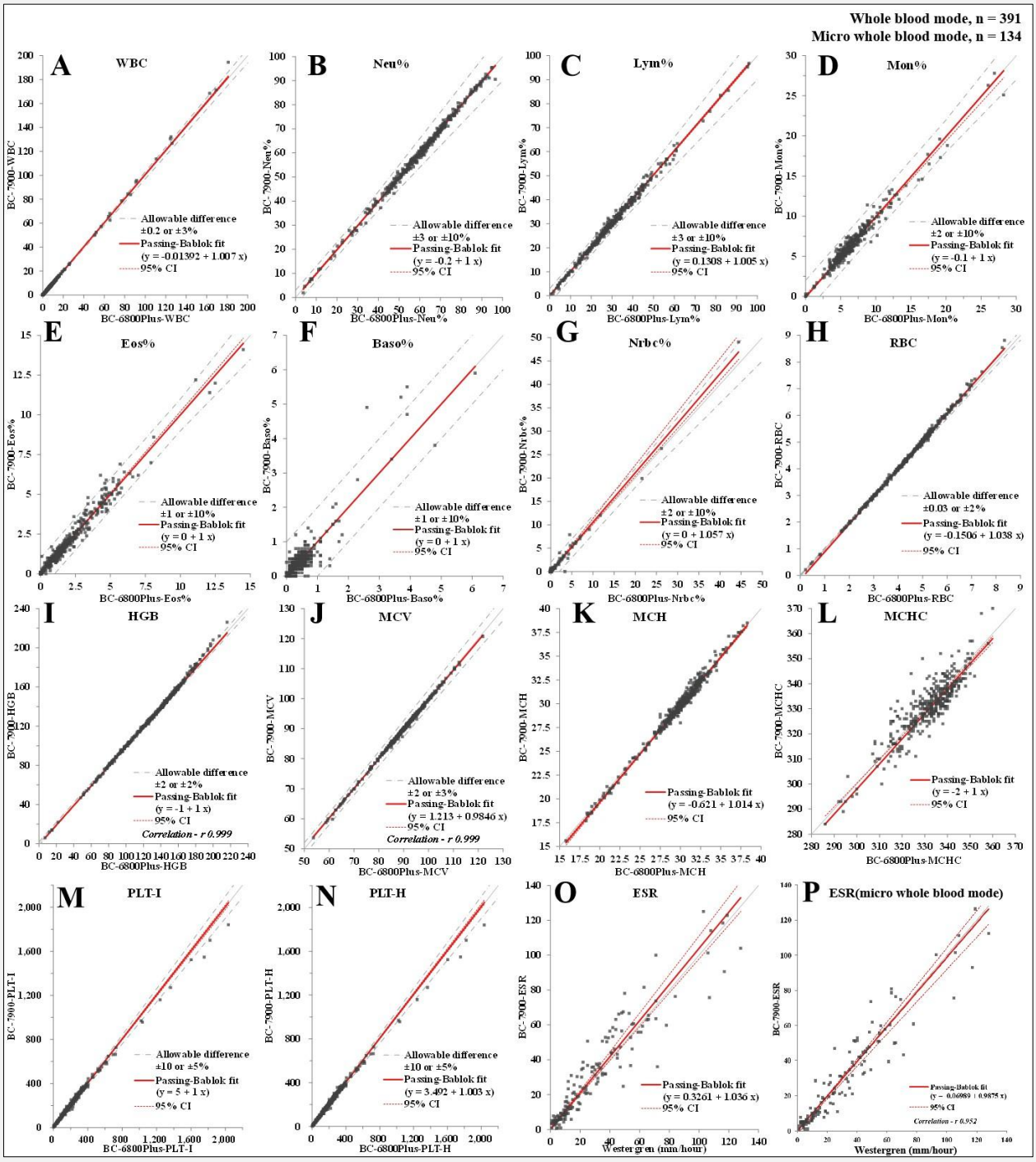

Figure 4. Comparison of the BC-7900 and the BC-6800Plus and the Westergren method.

The horizontal axis represents the results from the BC-6800Plus or the Westergren method, and the vertical axis represents the test results from the BC-7900. The solid line is the Passing-Bablok regression line, and the dotted line represents the 95% confidence interval (A - P). WBC; Neu%; Lym%; Mon%; Eos%; Baso%; NRBC%; RBC; HGB; MCV; MCH; MCHC; PLT-I; PLT-H; ESR (whole blood); ESR (micro whole blood).

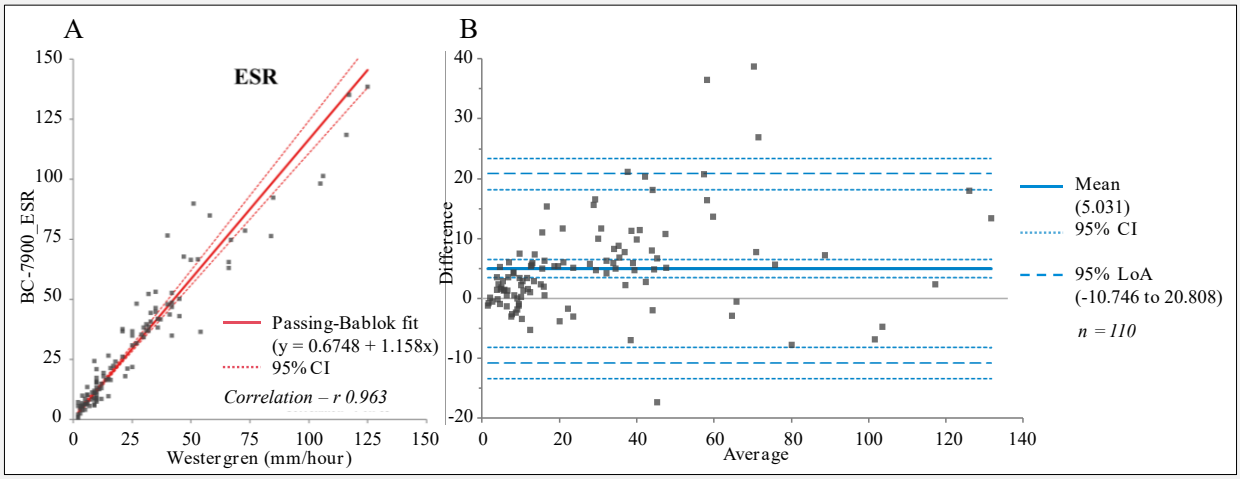

Figure 5. Clinical applicability of the ESR measured from samples from the rheumatology, orthopedics, and hematology departments.

A Passing-Bablok regression analysis. The horizontal axis represents the results of the Westergren method, and the vertical axis represents the results of the BC-7900. B Bland-Altman deviation diagram. The horizontal axis represents the mean of the results of the BC-7900 and the Westergren method, and the vertical axis represents the difference between the BC-7900 results and the Westergren method results.

cyte%≥1% or Myelocyte% +Promyelocyte%≥1% or Metamyelocyte% +Myelocyte% +Promyelocyte%>2%" was regarded as a positive warning for immature granulocytes, and "Reactive lymphocyte%>5%" was regarded as a positive warning for reactive lymphocytes. The results are shown in Table 6. According to manual microscopy, among the 565 samples, 261 were immature granulocyte alarm-positive samples, 304 were negative samples, 61 were atypical lymphocyte alarm-positive samples, and 304 were negative samples. The alarm sensitivity, specificity, and effectiveness for immature granulocytes were 95.4%, 93.8%, and 94.5%, respectively, and those for atypical lymphocytes were 86.9%, 90.7%, and 90.3%, respectively.

Capacity of the blast (including abnormal promyelocyte) flagging

At least 200 samples from patients with suspected hematological diseases (hematology outpatients or inpatients) and no fewer than 200 samples that violated the reexamination rules were selected for this analysis. The sensitivity and specificity of the alarm for blast cells (including abnormal promyelocytes) of the BC-7900 in CD mode and CD + HMC mode were compared, and the results are shown in Table 7. With reference to the results from manual microscopy, among the 843 samples, there were 184 positive samples and 659 negative samples; the sensitivity, specificity, and effectiveness of the alarm in CD + HMC mode were 98.4%, 76.6%, and 81.4%, respectively; the specificity was significantly better than that of the original alarm in CD mode. Microscopy results for the false-positive samples in CD mode showed that there were 42 samples containing promyelocytes and 146 samples containing reactive lymphocytes. And the microscopy results for the false-positive samples in CD + HMC mode showed that there were 25 samples containing promyelocytes and 66 samples containing reactive lymphocytes. The false-positive samples that triggered an alarm mainly contained reactive lymphocytes and promyelocytes.

DISCUSSION

Hematology analyzers play a critical role in clinical work by rapidly processing large volumes of samples and delivering accurate routine blood test results. However, certain clinical scenarios present unique challenges, including situations where the remaining blood sample is insufficient for performing complete blood counts (CBC). In particular, for neonates or elderly individuals, blood collection is often difficult, and the blood volume obtained is typically small. In pediatrics, blood is commonly acquired from the fingertip [11], but again, the volume of blood is often small, making it difficult to obtain an accurate complete blood count. These scenarios necessitate the development of hematology analyzers capable of producing accurate results from trace amounts of blood. At present, the warnings generated by analyzers, such as the detection of blast cells, are of-

ten used as screening criteria [12] to determine whether a sample requires morphological reexamination. This process aids in the timely screening of diseases and helps avoid missing potential hematological diseases. However, existing signals have high false-positive rates, resulting in an excessive number of samples requiring clinical reexamination, placing a burden on laboratory resources and increasing diagnostic inefficiencies. To address these challenges, Mindray developed the BC-7900 automated hematology analyzer in 2024, which is capable of producing results for both standard and trace amounts of blood sample accurately and rapidly. Furthermore, for the first time, the HMC module has been integrated into the analyzer, enabling more precise detection of blasts and abnormal promyelocytes.

This study evaluated several properties of the Mindray BC-7900 automated hematology analyzer. The performance verification test revealed that the background counts under different modes was 0, and the carryover rate for each parameter reached 0.54%. The linear correlation coefficients, r, were all greater than 0.998. The between-run, between-day, and within-laboratory CVs for WBC, Neu%, Lym%, RBC, HGB, MCV, and ESR were all under 3.2%, while those of Mon%, Eos%, Baso%, PLT, PLT-I, and PLT-H CV% were all under 5.5%, and the CV% of NRBC% was less than 8.3%. The reproducibility CV% and SD for each parameter was good. The analyzer also demonstrated good adaptability to different storage conditions; the absolute deviation of the ESR within 24 hours at room temperature and within 48 hours at low temperature was less than 2.2; the relative deviation of all parameters within 24 hours at room temperature was less than 2.5%, while the relative deviations of WBC, RBC and HGB within 48 hours at low temperature were less than 2.5%, and the relative deviations of PLT-I and PLT-H were less than 5%. With reference to the existing BC-6800Plus, the BC-7900 exhibited good linear relationships for all parameters, in which the correlation coefficients for WBC, Neu%, Lym%, NRBC%, RBC, HGB, MCV, PLT, PLT-I, and PLT-H were above 0.99, and those for Mon%, Eos% and Baso% were above 0.91, meeting the claim of comparability between the instruments and indicating that the test results of BC-7900 are accurate and reliable. According to ICSH EP09-A3, the accuracy of an analyzer should be verified by comparison with a standard method. If direct comparison with a standard method is not feasible, results may be compared to those from control instruments in other laboratories. In this study, results from the BC-7900 were compared to the Westergren method for ESR, and the results showed a strong correlation (r = 0.943). Evaluation of the clinical applicability of the samples selected from the rheumatology, orthopedics, and hematology departments also revealed that the results of BC-7900 and Westergren methods strongly correlated. Accurate ESR results serve as important references for identifying rheumatic diseases and evaluating treatment responses [13]. The results of this study revealed that the BC-7900 can be applied to detect diseases in patients in related departments, which is consistent with the results of Shen et al. [14].

The ESR measured using the micro whole blood mode was evaluated for reproducibility and comparability with those of the whole blood ESR and the Westergren method-derived ESR. The CV% and SD of the repeatability were far lower than those of the declared standards. The two sampling methods for whole blood and micro whole blood mode were compared. The correlation coefficient for the ESR was 0.98, and the deviation was -4.01%. ANOVA revealed that there was no significant difference between the ESR measured with micro whole blood and whole blood modes, suggesting that both methods could accurately measure the ESR of the samples. The repeatability of the micro whole blood ESR was also good, as the CV%, when the ESR was above 15, and the SD, when the ESR was under 15, were both far lower than the declared standards. The correlation coefficient between the ESR measured in micro whole blood mode and the ESR from the Westergren method was r = 0.952, indicating that a small amount of blood can be used to measure the ESR with the BC-7900, addressing existing problems in measuring the ESR with small blood volumes and providing additional information for early clinical diagnosis and the formulation of treatment plans. The instrument performed excellently and stably in micro whole blood mode, indicating that it is suitable for addressing clinical detection difficulties associated with trace amounts of blood, including peripheral blood.

The alarm performance of the BC-7900 for abnormal leukocytes was evaluated. The results showed that the alarms for immature granulocytes and atypical lymphocytes had high sensitivity, specificity, and effectiveness. Furthermore, evaluation of the alarm for blast cells (including abnormal promyelocytes) showed that the sensitivity of the alarm in CD mode and CD + HMC mode was equivalent, and the false-negative rate was low; however, the CD + HMC mode effectively yielded fewer false-positive alarms (23.4% versus 42.9%), increasing the total alarm effectiveness from 66.1% to 81.4%. Among the 136 samples that were negative for the original CD + HMC alarm and positive for the CD alarm, 83 had reactive lymphocytosis, 17 had promyelocytosis, and 47 had normal microscopic examination results, indicating that the CD + HMC mode can differentiate reactive lymphocytes and promyelocytes from blasts and effectively avoid interference by these two types of cells. Moreover, the CD + HMC mode can effectively reduce the workload for microscopic re-examination, efficiently and accurately screen abnormal blood cells in the peripheral blood, and thus, improve the probability of early diagnosis for hematological tumors. This could, in turn, result in better cure rates and outcomes for the patients.

CONCLUSION

The Mindray BC-7900 is a fully automated hematology analyzer with good performance. The instrument can simultaneously deliver the results of routine hematology analysis and ESR measurement and can work with not only standard amounts but also trace amounts of peripheral blood. Moreover, the BC-7900 offers a clinical blast cell alarm scheme with excellent performance, improves and optimizes the sample reexamination process, and meets the clinical needs of routine blood tests and ESR measurement.

Ethical Approval Statement:

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the ethical principle outlined in the Declaration of Helsinki and was approved by the Ethics Committee at The First Affiliated Hospital of Soochow University (2022216). Due to the study's retrospective nature, the requirement to obtain signed informed consent from patients was waived.

Declaration of Interest:

The authors declare that there is no conflict of interest regarding the publication of this article.

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