Performance evaluation of routine blood and C-reactive protein analysis using Mindray BC-7500 CRP auto hematology analyzer

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Background: Mindray's newly developed BC-7500 CRP auto hematology analyzers can simultaneously measure the routine blood and C-reactive protein (CRP) results, thereby significantly improving the efficiency and quality of clinical examination. This study was designed to evaluate the basic performance of the BC-7500 CRP as well as the performance characteristics of the new measurement mode combines routine blood and CRP.

Methods: Venous whole blood samples with the anticoagulant ethylene diamine tetraacetic acid K2 (EDTA-K2) were collected at the Fujian Medical University Union Hospital according to the guidelines of the American Clinical Laboratory Standards Institute (CLSI) and International Standards Committee for Hematology (ISCH). We analyzed and evaluated the performance of blank counts, carryover contamination rate, precision, comparability, flagging capability, sample stability, and automatic micro-whole blood (MWB) mode analysis in the BC-7500 CRP hematology analyzer.

Results: All parameters measured by the BC-7500 CRP showed good blank counts (CRP, 0.008–0.02 mg/L). The carryover contamination rates for each mode combination did not exceed 1%, it indicates a low carryover effect. The CRP showed high precision while the within-laboratory precision is 6.91% and 4.38% in two different levels. Relatively good correlation was found for the routine blood results between the BC-7500 CRP and Sysmex-XN (r=0.99), and CRP result between the BC-7500 CRP and IMMAGE 800 (r=0.99). The sensitivities of abnormal cell flagging for Blast, Immature Gran, and nucleated red blood cell (NRBC) were 93.9%, 91.6%, and 86.7%, while their specificities were 83.9%, 62.7%, and 97.5%. The test results of CRP at room temperature for 24 hours and refrigerated for 48 hours were –0.04% and –2.94%, which showed very stable changes. Also, the automatic micro-whole blood mode performed well (P=0.2014), which was very close to the test results of the automatic mixing test of peripheral blood and the manual mixing of open sampling.

Conclusions: The BC-7500 CRP analyzer provided reliable results on routine blood and CRP, which can meet the testing requirements of routine blood and CRP items in clinical whole blood samples and provide a guarantee for rapid and accurate laboratory diagnosis.

Keywords: Auto hematology analyzer; C-reactive protein (CRP); peripheral blood autoloader; clinical performance evaluation

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Introduction

The hematology analyzer is one of the most widely used clinical testing and diagnostic instruments in hospitals. It has the advantages of high precision, fast speed, easy operation, and strong function, which can replace the labor of laboratory workers and achieve efficient and accurate testing (1,2). With the development of medical level, the daily outpatient volume of hospitals has increased significantly, especially since blood analysis is a mandatory item of clinical testing. The efficiency and quality of these test items have become a cornerstone of the comprehensive strength of the laboratory department (3).

The normal range of leukocyte and its classification parameters is wide, and the results change slowly. The numerical changes of leukocyte cannot well reflect the dynamic changes of diseases and are subject to many factors (such as underlying diseases, physiology and medication, etc.). C-reactive protein (CRP) can make up for the deficiency of white blood cell count and neutrophil count in the observation of disease conditions, so it can be used as one of the differential diagnosis indicators of bacterial infection or viral infection, and can also be used as an application indicator of antibacterial treatment effect monitoring and postoperative infection control. Therefore, the combined detection of blood routine and CRP is of great significance in clinical practice. The results of the same blood routine and CRP test are complementary, and different secondary results are compared. Comprehensive analysis can further improve the accuracy of diagnosis.

The BC-7500 CRP analyzer, launched by Mindray (Shenzhen, China) in 2020, is a high-end hematology product that combines routine blood, CRP, and body fluid testing, along with the application of the Mindray hematology platform SF-Cube 2.0 (4) and the whole blood CRP testing platform M-100. In addition, it allows for integrated testing of high-end blood cells and high-end whole blood CRP testing, which is optimized to meet the multifaceted testing needs of users. The cells are classified and counted using sheath flow impedance, the laser scattering method, and flow cytometry combined with fluorescent staining; hemoglobin is determined using a colorimetric method; and the CRP concentration is measured using a latex-enhanced immunoscattering turbidimetric method. Normally, it is able to perform 110 routine blood tests alone per hour and 100 CRP tests alone per hour; however, BC-7500 CRP is an all-in-one machine for routine blood and CRP analysis, and can carry out a brand-new benefit revolution and process improvement for blood analysis. Furthermore, there are also flexible expansion functions for BC-7500 CRP; two BC-7500 CRP can form a cascade of CAL 7000, two BC-7500 CRP and one SC-120 (5,6) can form a pipeline CAL 7000, and one BC-7500 CRP and one SC-120 (5,6) can form a pipeline of CAL 7000. Therefore, BC-7500 CRP can be used in outpatient and emergency testing scenarios with continuous demand for both routine blood and CRP testing, as well as in inpatient testing scenarios with huge workload and complicated disease types.

This study was designed to evaluate the basic performance of the BC-7500 CRP as well as the performance characteristics of CRP analysis. We present the following article in accordance with the STARD reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1642/rc).

Methods

Specimen sources

This study is an *in vitro* diagnostic clinical evaluation. The remaining samples reported by the hospital on the evaluation instrument were examined to obtain the study data, which did not involve the privacy and interests of patients. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of the Fujian Medical University Union Hospital, Fuzhou (No. 2020KY077). Due to the study's retrospective nature, the requirement to obtain signed informed consent from the patients was waived. A total of 1,910 EDTA-K2 anti-coagulated venous whole blood samples were collected from outpatients and hospitalized patients at the Fujian Medical University Union Hospital from May to September 2020, including 266 samples of repeatability, 1,584 samples of comparability, 20 samples of CRP stability, and 40 automated micro-whole blood pattern control samples. All samples had a volume of at least 1 mL, and visible hemolysis and coagulation according to the CLSI H04-A6 (7,8) criteria were excluded from the evaluation. The samples were placed at room temperature between 18 and 26 ℃ and tested within 8 h of collection, except for stability tests.

Instruments and reagents

The BC-7500 CRP analyzer and supporting calibrators,

control materials, and reagents (Shenzhen Mindray Corporation, Shenzhen, China), and the SC-120 automatic blood smear preparation instrument and supporting reagents were obtained from the Shenzhen Mindray Corporation (Shenzhen, China). In addition, the fully automated hematology analyzer, XN-1000 (9), and supporting reagents were obtained from the Sysmex Corporation (Japan), and the fully automated specific protein analyzer, IMMAGE 800 (10), was obtained from Beckman Coulter (USA). Both the blood routine and CRP analyzers are commercially available and widely used in clinics. All instruments were effectively calibrated and well monitored by daily quality control, and all reagents were within their validity period.

Study methods

The clinical performance evaluation procedures were conducted according to the technical documents and standard guidelines of the ICSH (11) and CLSI (7,8). All instruments were calibrated according to the manufacturer's operating manual before the start of the test, and the calibration stability of the routine blood and CRP modules was monitored daily by BC-6D, BC-RET, and CRP control during the test, so that the test results of quality controls were confirmed to be in line with the deviation limits of the target values. In addition, the instruments and samples were operated in strict accordance with the operating manual and clinical testing protocols.

Blank counts

Blank counts were used to assess whether the assay system was contaminated or disturbed by electrical noise. After the instrument was normally turned on everyday, samples without components to be measured were tested once in whole blood mode, micro-whole blood mode, and prediluted mode, with the BC-7500 CRP matching diluent as blank counts. The results of blank count tests for white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), platelet (PLT) and C-reactive protein (CRP) parameters in each mode were counted at least 30 days.

Carryover contamination rate

The carryover contamination rate of the test protocol was designed according to the guidelines of the CLSI H26-A2 (8). Fresh whole blood samples with high test value (HTV) were selected for three consecutive tests, followed immediately by fresh whole blood samples with a low test value (LTV) for three consecutive tests. The HTV and LTV were required to meet the sample concentration requirements recommended in the CLSI H26-A2 (8). The carryover contamination rate could cover a combination of multiple testing modes of the instrument to evaluate the performance in different real clinical scenarios. The carryover contamination rate was calculated as:

$$\%Carryover = \frac{LTV1 - LTV3}{HTV3 - LTV3} \times 100\% \quad [1]$$

The carryover contamination rate of the WBC/RBC/HGB/PLT/CRP parameters was assessed and their 95% confidence intervals (CIs) were calculated.

Precision

According to the requirements of the ICSH 2014 (11), the precision test was divided into With-run precision and Between-batch precision, which were used to assess the consistency of the repeated test results of samples, respectively. The fresh whole blood samples covering the detection range of the instrument and the medical decision level point of fresh whole blood samples were selected for With-run precision, including normal samples and clinical samples beyond the reference interval of HTV and LTV, which were mixed thoroughly and then repeated 10 times on the BC-7500 CRP, and for which the results of mean, standard deviation (SD) and coefficient of variation (CV%) were calculated for each set. According to the requirements of evaluation performance 05 (EP05), the Between-batch precision performance was evaluated by the commercial Quality Control (QC) BC-6D, BC-RET, and CRP QCs that accompanied the instrument, and QC was conducted twice each day in the morning and afternoon at different concentration levels (lasting for at least 20 days).

Comparability

We also assessed the proximity between the instrument to be tested and a marketed control instrument or reference method. The assay of the instrument to be tested, BC-7500 CRP, was divided into three parts, including complete blood count parameters, leukocyte sorting parameters, and specific protein CRP parameters, which were compared with three control instruments: XN-9000 (Sysmex, Japan), manual microscopic sorting, and IMMAGE 800 (Beckman Coulter, USA), respectively. Fresh whole blood samples with different value ranges were collected and tested on the instrument to be tested and the control instrument, respectively, according to the requirements of

the CLSI H26-A2. Samples for comparison with manual microscopic classification were prepared and stained with blood smear specimens by the automated blood smear preparation instrument SC-120. Next, 400 leukocytes and nucleated red blood cells in the corresponding areas were analyzed by two experienced microscopic technicians according to the CLSI H20-A2 (7,8), and the results of leukocyte classification parameters were compared with the microscopic counts. Statistical comparison data were analyzed by Passing-Bablok regression analysis, and Bland-Altman deviation plots were made.

Flagging capability

The abnormal cell flagging capability of the BC-7500 CRP analyzer was also assessed, of which hematology samples accounted for 50%. All samples were counted and confirmed by BC-7500 CRP, and manual microscopic classification. Taking the manual microscopic classification as the reference standard for determining the negative or positive abnormal cells, the flagging sensitivity, specificity, and effectiveness of the blast, immature gran (IG), and nucleated red blood cell (NRBC) were analyzed by the blood analyzer.

Sample stability

Referring to the method of stability evaluation in the ICSH 2014 (11), the fresh venous whole blood samples from 10 healthy volunteers without cardiovascular disease or inflammatory infection were recruited and divided into two groups: the room temperature (18–25 ℃) group and the refrigerated (2–8 ℃) group. The blood samples were divided into several aliquots placed in the designated temperature environment and tested on the machine at 0.5, 4, 8, 12, 24, and 48 h time points (recorded as H0.5, H4, H8, H12, H24, and H48 respectively), with testing twice at each time point. In addition, the test result of H0.5 was taken as the reference value, the difference between the test results and the reference value at other time points were assessed. In addition, the stability of CRP test values above the reference ranges were assessed using the 10 remaining fresh whole blood samples from each of the room temperature and refrigerated groups, with the HTV of CRP selected from the hospital sample bank.

Automated micro-whole blood mode

Forty fresh whole blood samples were collected and tested in the BC-7500 CRP opened micro-whole blood and automated micro-whole blood modes, respectively.

Statistical analysis

Statistical methods are based on generally accepted techniques according to the technical documents and standard guidelines of the CLSI H26-A2 and ICSH 2014, and statistical analyses were performed with the Analyse-it (https://analyse-it.com/) and Microsoft Excel 2019 software (Microsoft Corp., Redmond, WA, USA).

Results

Blank counts

The BC-7500 CRP test results in whole blood (WB) mode, micro-whole blood (MWB) mode, and prediluted (PD) mode are shown in *Table 1*. There were 50 tests in the WB and PD modes, respectively, and 53 tests in the MWB mode, among which all blank counts for RBC, HGB, and PLT parameters were 0. The blank counts for WBC parameters in the WB and MWB modes had a 95% CI of 0–0.001, and the PD mode had a 95% CI of 0–0.004. Also, the 95% CIs for the blank counts of CRP parameters were 0.008–0.02 in the WB mode, 0.010–0.021 in the MWB mode, and 0.004–0.01 in the PD mode.

Carryover contamination rates

The carryover contamination rates of WBC, RBC, HGB, HCT, PLT, and CRP parameters were 0.02–0.04%, 0.05–0.14%, 0.01–0.17%, 0.08–0.19%, 0.05–0.13%, and 0.16–0.37%, respectively. The results of all parameters did not exceed 1%, which suggested that there was no significant carrying contamination rate for each assessed parameter (refer to *Table 2* and *Figure 1*).

Precision

With-run precision

For the performance of With-run precision, a total of 266 fresh whole blood samples were collected and evaluated in the WB or MWB modes of the BC-7500 CRP analyzer. The CV% of samples with WBC parameters over 4.0×10^9 did not exceed 2%, and the SD of samples with low WBC values (from 0 to 2×10^9) was less than 0.1. Also, the CV% of samples with PLT parameters over 250×10^9 did not exceed 4%, and the SD of samples with low values of PLT from 0 to 50×10^9 did not exceed 5. Two samples with a CRP >10 mg/L exceeded 4%, and the rest were less than 4%. For samples with CRP <10 mg/L, the SD did not exceed

Table 1 Results of the evaluation of the main counting parameters of blank counts in the WB, MWB, and PD modes

Parameters	Modes	N	Mean	Minimum	Maximum	95% CI
WBC	WB mode	50	0	0	0.01	0–0.001
	MWB mode	53	0	0	0.01	0–0.001
	PD mode	50	0.002	0	0.04	0–0.004
RBC	WB mode	50	0	0	0	0–0
	MWB mode	53	0	0	0	0–0
	PD mode	50	0	0	0	0–0
HGB	WB mode	50	0	0	0	0–0
	MWB mode	53	0	0	0	0–0
	PD mode	50	0	0	0	0–0
PLT	WB mode	50	0	0	0	0–0
	MWB mode	53	0	0	0	0–0
	PD mode	50	0	0	0	0–0
CRP	WB mode	50	0.014	0	0.07	0.008–0.020
	MWB mode	53	0.016	0	0.07	0.010–0.021
	PD mode	50	0.007	0	0.04	0.004–0.010

WB, whole blood; MWB, micro whole blood; PD, prediluted; WBC, white blood cell; RBC, red blood cell; HGB, hemoglobin; PLT, platelet; CRP, C-reactive protein; 95% CI, 95% confidential interval.

Table 2 Assessment results of the carrying rate of contamination

Parameters	N	Mean (%)	Minimum (%)	Maximum (%)	95% CI (%)
WBC	28	0.03	0	0.10	0.02–0.04
RBC	28	0.09	0	0.45	0.05–0.14
HGB	28	0.09	0	0.56	0.01–0.17
HCT	28	0.13	0	0.54	0.08–0.19
PLT	28	0.09	0	0.46	0.05–0.13
CRP	28	0.26	0.02	1.00	0.16–0.37

WBC, white blood cell; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; PLT, platelet; CRP, C-reactive protein; 95% CI, 95% confidential interval.

0.5. Furthermore, RBC, HGB, HCT, and RET% exhibited excellent With-run precision performance, and CV% of MCV parameters in the WB mode did not exceed 0.6%. However, the MCV performance in the MWB mode was lower than that in WB mode, and the CV% was distributed between 0.4% and 1%. Overall, the imprecision of CV% decreased with increasing parameter values, while the SD showed a positive correlation with the parameter values (refer to *Figure 2*).

Within-laboratory precision

The routine blood parameters were evaluated with BC-6D and BC-RET for 31 days, and the CRP parameters were evaluated with the three rheumatic tests for 20 days. The with-run, between-run, between-day, and within-laboratory precision results of each parameter were calculated using Analyse-it software, as shown in *Table 3*.

Comparability

The comparability assessment of the BC-7500 CRP analyzer was performed in three parts, with a total of 1,584 fresh whole blood samples (of which only 139 samples were collected and tested simultaneously on the reticulocyte (RET) channel of both instruments) collected for comparison of routine blood parameters except leukocyte classification with the Sysmex-XN (12). Also, 100 samples were collected to compare their CRP parameters with IMMAGE 800 results, and 809 samples were collected to compare the leukocyte classification parameters with the manual microscopic

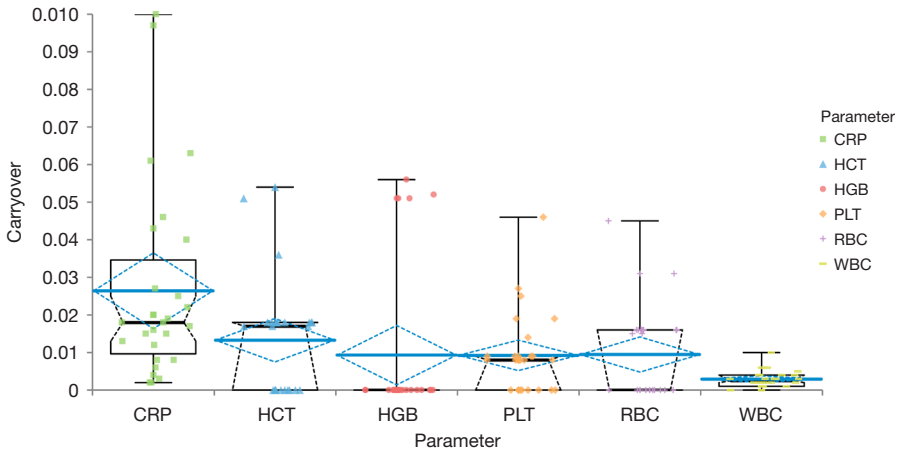

Figure 1 Distribution of the data on the carriage rate. The horizontal axis indicates the different evaluation parameters, and the vertical axis indicates the results of the carriage rate test for each group. CRP, C-reactive protein; HCT, hematocrit; HGB, hemoglobin; PLT, platelet; RBC, red blood cell; WBC, white blood cell.

classification results. All comparisons were performed by Passing-Bablok regression (13) and Bland-Altman bias (14) analyses. The routine blood parameters compared using Sysmex-XN (12) showed extremely high correlation (r>0.95), except for MPV. Bland-Altman deviation plots suggested that the variable coefficient of red cell volume distribution width (RDW-CV) and mean platelet volume (MPV) parameters were 20–30% lower in a small proportion of BC-7500 CRP samples compared with Sysmex-XN (12), while the remaining parameters showed no significant deviation. The CRP parameters were well correlated with the results of IMMAGE 800, whose deviations were within the clinically acceptable range. The leukocyte classification parameter comparison with manual microscopic classification suggested that the Pearson's correlation coefficients r of Neu%, Lym%, Mon%, Eos%, and IMG% parameters were larger than 0.9, and the correlation of Bas% was relatively poor (r=0.6950). Furthermore, the Bland-Altman deviation plots suggested that the deviation of Bas% parameters with manual microscopy was –0.08, without a significant impact on clinical diagnosis and treatment (refer to *Table 4*, *Figures 3*,*4*).

Flagging capacity

According to the CLSI H20-A2 (7,8) guidelines, manual microscopic classification was taken as the reference standard for negative-positive evaluation of abnormal cells and the flagging capacity of blast, immature granulocyte, and NRBC for BC-7500 CRP was evaluated. 795 clinical samples were collected, and blast% ≥1% by manual microscopy was used as a positive criterion for blast flagging. 31 of the 33 blast-positive samples confirmed by microscopy were flagged by BC-7500 CRP, with a sensitivity of 93.9%. There were two samples of blast false negatives of report flagged with IG by BC-7500 CRP, and no abnormal samples were missed, confirmed by clinical retesting. The specificity of blast flagging was 83.9%, which indicated that the poor consistency of the results was mainly due to the high false-positive samples, which would only increase the workload of retesting without any clinical risk. Metamyelocyte ≥2%, promyelocyte/myelocyte ≥1%, or the sum of immature granulocyte ≥2% were the positive criteria for IG. Among the 310 positive samples of IG confirmed by microscopy, BC-7500 CRP flagged 284 cases, with a sensitivity of 91.6%. Among the 26 samples with false-negative IG reported by BC-7500 CRP, 13 cases were flagged with other abnormal cells, while in the remaining 13 cases, three cases triggered the rule of retesting, there was one case of insufficient aspiration, and nine cases of missing detection among the actual 310 positive samples, accounting for 2.90%. IG was within 2%, other counting parameters were normal, and the specificities of IG were 62.7%.

For the evaluation of NRBC, 120 positive samples were confirmed by microscopic examination according to the criterion of nucleated erythrocytes ≥1%, and a total of 104 samples were identified by BC-7500 CRP, with a sensitivity of 86.7%. There were 8 samples with no detectable nucleated red blood cells, 12 with other abnormal cell flagging, and 4 samples with a series of abnormal red blood system flagging such as red blood cell fragmentation,

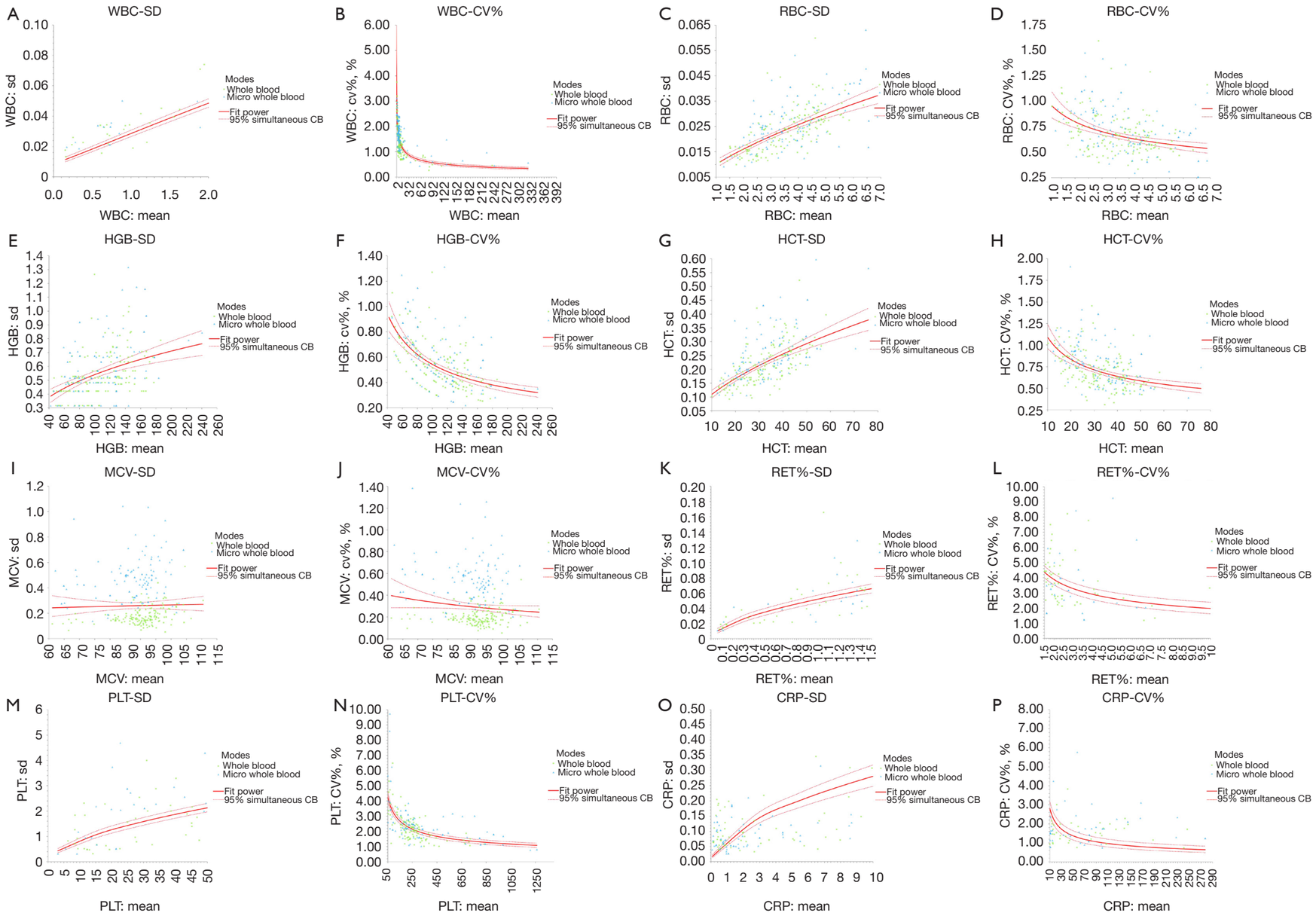

Figure 2 Distribution of the With-run precision assessment results for the main blood routine and CRP parameters. The horizontal axis represents the mean value of the 10 repeatability test results per group of each parameter, and the vertical axis is the SD or CV% of the 10 test results, where the points of the green squares represent the test results of the WB mode, while the points of the blue triangles represent the test results of the MWB mode (A-P). WBC, white blood cell; SD, standard deviation; CV, coefficient of variation; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; RET%, reticulocyte; PLT, platelet; CRP, C-reactive protein.

Table 3 Assessment results of the within-laboratory precision of routine blood and CRP parameters

Parameters	Level	N	Mean	Within-run		Between-run		Between-day		Within-laboratory	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	BC-6D H	124	20.19	0.192	0.95%	0.103	0.51%	0.095	0.47%	0.238	1.18%
	BC-6D N	124	7.48	0.117	1.56%	0.040	0.54%	0.036	0.48%	0.128	1.71%
	BC-6D L	124	3.74	0.072	1.92%	0.011	0.29%	0.060	1.60%	0.094	2.51%
Neu%	BC-6D H	124	53.59	0.479	0.89%	0.000	0.00%	0.333	0.62%	0.559	1.04%
	BC-6D N	124	49.53	0.675	1.36%	0.308	0.62%	0.000	0.00%	0.724	1.46%
	BC-6D L	124	55.52	0.994	1.79%	0.000	0.00%	0.687	1.24%	1.195	2.15%
Lym%	BC-6D H	124	29.40	0.517	1.76%	0.000	0.00%	0.554	1.88%	0.732	2.49%
	BC-6D N	124	33.81	0.676	2.00%	0.203	0.60%	0.315	0.93%	0.773	2.29%
	BC-6D L	124	24.38	0.733	3.01%	0.321	1.32%	0.331	1.36%	0.866	3.55%
Mon%	BC-6D H	124	6.89	0.316	4.58%	0.000	0.00%	0.087	1.26%	0.325	4.72%
	BC-6D N	124	6.38	0.418	6.56%	0.099	1.55%	0.159	2.49%	0.458	7.18%
	BC-6D L	124	2.77	0.407	14.68%	0.000	0.00%	0.092	3.33%	0.388	14.02%
Eos%	BC-6D H	124	9.67	0.301	3.12%	0.085	0.88%	0.197	2.04%	0.370	3.83%
	BC-6D N	124	9.96	0.442	4.44%	0.149	1.50%	0.388	3.90%	0.607	6.09%
	BC-6D L	124	17.12	0.867	5.06%	0.219	1.28%	0.907	5.30%	1.274	7.44%
Bas%	BC-6D H	124	0.45	0.074	16.52%	0.000	0.00%	0.019	4.22%	0.069	15.44%
	BC-6D N	124	0.32	0.068	21.18%	0.048	14.84%	0.012	3.90%	0.084	26.15%
	BC-6D L	124	0.21	0.082	39.56%	0.018	8.63%	0.022	10.69%	0.087	41.88%
IMG%	BC-6D H	124	0.33	0.077	23.48%	0.000	0.00%	0.024	7.31%	0.074	22.53%
	BC-6D N	124	0.38	0.111	29.65%	0.000	0.00%	0.027	7.09%	0.104	27.64%
	BC-6D L	124	0.38	0.125	33.16%	0.000	0.00%	0.000	0.00%	0.123	32.60%
NRBC%	BC-6D H	124	2.50	0.179	7.15%	0.000	0.00%	0.053	2.11%	0.174	6.96%
	BC-6D N	124	4.24	0.466	10.97%	0.000	0.00%	0.000	0.00%	0.424	10.00%
	BC-6D L	124	8.24	0.786	9.53%	0.000	0.00%	0.133	1.61%	0.760	9.23%
RBC	BC-6D H	124	5.66	0.037	0.66%	0.012	0.22%	0.054	0.96%	0.067	1.18%
	BC-6D N	124	4.69	0.027	0.57%	0.017	0.37%	0.032	0.69%	0.045	0.97%
	BC-6D L	124	2.35	0.020	0.86%	0.007	0.32%	0.014	0.58%	0.025	1.08%
HGB	BC-6D H	124	175.06	0.813	0.46%	0.707	0.40%	1.021	0.58%	1.485	0.85%
	BC-6D N	124	132.06	0.622	0.47%	0.475	0.36%	0.565	0.43%	0.966	0.73%
	BC-6D L	124	56.58	0.524	0.93%	0.238	0.42%	0.173	0.31%	0.600	1.06%
HCT	BC-6D H	124	57.29	0.371	0.65%	0.282	0.49%	0.430	0.75%	0.634	1.11%
	BC-6D N	124	42.50	0.283	0.66%	0.230	0.54%	0.232	0.55%	0.432	1.02%
	BC-6D L	124	18.39	0.159	0.87%	0.095	0.52%	0.187	1.02%	0.263	1.43%

Table 3 *(continued)*

Table 3 *(continued)*

Parameters	Level	N	Mean	Within-run		Between-run		Between-day		Within-laboratory	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%
MCV	BC-6D H	124	101.31	0.230	0.23%	0.370	0.36%	0.585	0.58%	0.729	0.72%
	BC-6D N	124	90.68	0.222	0.24%	0.355	0.39%	0.585	0.64%	0.719	0.79%
	BC-6D L	124	78.40	0.210	0.27%	0.395	0.50%	0.779	0.99%	0.898	1.15%
MCH	BC-6D H	124	30.96	0.207	0.67%	0.000	0.00%	0.135	0.44%	0.241	0.78%
	BC-6D N	124	28.19	0.175	0.62%	0.084	0.30%	0.076	0.27%	0.209	0.74%
	BC-6D L	124	24.12	0.207	0.86%	0.103	0.43%	0.039	0.16%	0.234	0.97%
MCHC	BC-6D H	124	305.56	1.980	0.65%	0.000	0.00%	1.632	0.53%	2.502	0.82%
	BC-6D N	124	310.89	2.012	0.65%	0.421	0.14%	1.630	0.52%	2.623	0.84%
	BC-6D L	124	307.73	2.559	0.83%	0.808	0.26%	2.462	0.80%	3.642	1.18%
RDW-CV	BC-6D H	124	13.95	0.070	0.50%	0.061	0.44%	0.020	0.15%	0.095	0.68%
	BC-6D N	124	15.15	0.087	0.57%	0.039	0.26%	0.061	0.40%	0.113	0.74%
	BC-6D L	124	17.57	0.144	0.82%	0.070	0.40%	0.054	0.31%	0.169	0.96%
RDW-SD	BC-6D H	124	51.16	0.291	0.57%	0.253	0.49%	0.312	0.61%	0.496	0.97%
	BC-6D N	124	50.10	0.310	0.62%	0.000	0.00%	0.245	0.49%	0.392	0.78%
	BC-6D L	124	50.05	0.397	0.79%	0.278	0.56%	0.205	0.41%	0.526	1.05%
PLT (PLT-I)	BC-6D H	124	418.65	7.117	1.70%	2.590	0.62%	2.993	0.71%	8.144	1.95%
	BC-6D N	124	211.71	5.760	2.72%	0.000	0.00%	0.497	0.23%	5.734	2.71%
	BC-6D L	124	59.89	3.367	5.62%	1.467	2.45%	2.092	3.49%	4.227	7.06%
MPV	BC-6D H	124	10.16	0.087	0.86%	0.038	0.38%	0.047	0.47%	0.106	1.05%
	BC-6D N	124	11.80	0.212	1.80%	0.000	0.00%	0.052	0.44%	0.217	1.84%
	BC-6D L	124	10.60	0.544	5.13%	0.000	0.00%	0.166	1.57%	0.507	4.78%
PDW	BC-6D H	124	16.92	0.092	0.54%	0.009	0.05%	0.006	0.03%	0.092	0.54%
	BC-6D N	124	17.35	0.164	0.95%	0.080	0.46%	0.000	0.00%	0.177	1.02%
	BC-6D L	124	17.07	0.397	2.32%	0.000	0.00%	0.121	0.71%	0.362	2.12%
PCT	BC-6D H	124	0.43	0.008	1.88%	0.004	0.99%	0.002	0.58%	0.009	2.20%
	BC-6D N	124	0.25	0.009	3.70%	0.002	0.96%	0.000	0.00%	0.009	3.71%
	BC-6D L	124	0.06	0.006	9.48%	0.001	0.97%	0.003	3.96%	0.007	10.32%
P-LCR	BC-6D H	124	28.06	0.680	2.42%	0.235	0.84%	0.125	0.44%	0.730	2.60%
	BC-6D N	124	38.95	1.213	3.11%	0.363	0.93%	0.000	0.00%	1.244	3.19%
	BC-6D L	124	35.08	3.170	9.04%	0.000	0.00%	1.120	3.19%	2.897	8.26%
RET%	RET H	124	7.63	0.120	1.58%	0.029	0.38%	0.047	0.61%	0.132	1.73%
	RET N	124	4.46	0.063	1.42%	0.012	0.28%	0.020	0.45%	0.068	1.52%
	RET L	124	1.16	0.034	2.91%	0.004	0.39%	0.020	1.71%	0.039	3.40%

Table 3 *(continued)*

Table 3 *(continued)*

Parameters	Level	N	Mean	Within-run		Between-run		Between-day		Within-laboratory	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%
RHE	RET H	124	23.85	0.089	0.37%	0.083	0.35%	0.295	1.24%	0.319	1.34%
	RET N	124	30.96	0.116	0.38%	0.071	0.23%	0.215	0.70%	0.255	0.82%
	RET L	124	29.42	0.195	0.66%	0.335	1.14%	0.470	1.60%	0.609	2.07%
PLT(PLT-O)	RET H	124	531.00	7.773	1.46%	3.193	0.60%	7.778	1.46%	11.450	2.16%
	RET N	124	288.98	0.117	1.56%	0.000	0.00%	2.631	0.91%	5.705	1.97%
	RET L	124	124.18	0.072	1.65%	0.000	0.00%	1.570	1.26%	3.386	2.73%
IPF	RET H	124	4.50	0.499	11.09%	0.247	5.49%	0.108	2.40%	0.568	12.61%
	RET N	124	4.28	0.526	12.30%	0.104	2.44%	0.056	1.32%	0.539	12.61%
	RET L	124	4.54	0.483	10.64%	0.171	3.76%	0.000	0.00%	0.508	11.18%
CRP	CRP 1	80	2.584	0.124	4.79%	0.129	4.98%	0.000	0.00%	0.179	6.91%
	CRP 2	80	40.631	1.286	3.16%	1.230	3.03%	0.000	0.00%	1.779	4.38%

WBC, white blood cell; Neu%, neutrophil percentage; Lym%, lymphocyte percentage; Mon%, monocyte percentage; Eos%, eosinophil percentage; Bas%, basophil percentage; IMG%, immature granulocyte percentage; NRBC%, nucleated red cells percentage; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin; MCHC, mean corpuscular hemoglobin concentration; RDW-CV, the variable coefficient of red cell volume distribution width; RDW-SD, the standard deviation of red cell volume distribution width; PLT (PLT-I), platelet (impedance); MPV, mean platelet volume; PDW, platelet distribution width; PCT, plateletcrit; P-LCR, platelet-large cell rate; RET%, reticulocyte; RHE, reticulocyte hemoglobin content; PLT (PLT-O), platelet (optical); IPF, immature platelet fraction; CRP, C-reactive protein; BC-6D H/N/L, BC-6D control high/normal/low level; RET H/N/L, RET control high/normal/low level; CRP 1/2, CRP control 1/2 level.

bimodal, and abnormal red blood cell size, 1 sample with insufficient aspiration, and 2 cases with missing detection in the actual 120 positive samples accounting for 1.67%. The NRBC microscopy results of the two missed NRBC false-negative samples were both 1%, which met the criteria for positive erythrocytes. The NRBC specificity of BC-7500 CRP was 97.5%, which were highly consistent with the microscopic results (*Table 5*).

According to the 41 retesting rules recommended by international hematology (7,8), the presence of blast, IG, and NRBC in the first test result of a sample requires a smear microscopy review, and the three flags were combined into one WBC total flags to assess the screening and identification ability of the instrument for abnormal cells in leukocyte classification. The sensitivities of BC-7500 CRP was 95.8%, with good recognition ability for abnormal cells, which could assist the laboratory technician in screening abnormal cell samples. The specificity was 55.9%, which may be caused by more false-positive samples of blast and IG, and may increase the retesting workload of laboratories.

Sample stability

The BC-7500 CRP samples at room temperature and refrigerated environment were stable (refer to *Tables 6*,*7*). The CRP parameters showed a slight increasing trend in the room temperature environment, which was more obvious after 12 hours. The average relative deviation of CRP at 24 and 48 hours were 6.10% and 8.69%, respectively, compared to the 4-hour test results. The CRP test results in the refrigerated environment showed little fluctuation with time, and its average relative CRP deviation at 24 and 48 hours were 1.00% and 3.30%, respectively (refer to *Figure 5*).

Automatic MWB mode

The accuracy of the automatic MWB mode of BC-7500 was good, and the main counting parameters WBC, RBC, HGB, PLT, RET%, and CRP were not statistically different compared to the opened MWB mode. Meanwhile, the HCT and MCV parameters were improved by 0.36 and 1.07, respectively, but this difference did not affect the

Table 4 Assessment results of comparability between BC-7500 CRP, Sysmex-XN, IMMAGE 800, and manual microscopic classification

Parameters	Method	N	r	Slope (95% CI)	Intercept (95% CI)	Difference (95% CI)	95% lower LoA (95% CI)	95% upper LoA (95% CI)
WBC	Sysmex-XN	1,584	0.9996	1.003 (1.001 to 1.005)	−0.017 (−0.028 to −0.005)	−0.01% (−0.207% to 0.194%)	−7.99% (−8.333% to −7.647%)	7.98% (7.634% to 8.320%)
RBC	Sysmex-XN	1,583	0.9986	0.994 (0.991 to 1.000)	0.0314 (0.020 to 0.039)	0.55% (0.459% to 0.633%)	−2.92% (−3.070% to −2.772%)	4.01% (3.864% to 4.162%)
HGB	Sysmex-XN	1,584	0.9985	1.000 (1.000 to 1.000)	−1.000 (−1.000 to −1.000)	−0.80% (−0.889% to −0.715%)	−4.25% (−4.400% to −4.104%)	2.65% (2.500% to 2.797%)
HCT	Sysmex-XN	1,584	0.9973	1.008 (1.000 to 1.012)	−0.369 (−0.466 to −0.200)	−0.77% (−0.879% to −0.653%)	−5.27% (−5.459% to −5.072%)	3.73% (3.540% to 3.927%)
MCV	Sysmex-XN	1,584	0.9842	0.947 (0.938 to 0.957)	3.653 (2.730 to 4.588)	−1.32% (−1.412% to −1.234%)	−4.86% (−5.010% to −4.706%)	2.21% (2.059% to 2.363%)
RDW-CV	Sysmex-XN	1,549	0.9659	1.000 (0.9726 to 1.000)	0.300 (0.300 to 0.7342)	−1.53% (1.246% to 1.815%)	−9.65% (−10.132% to −9.160%)	12.71% (12.221% to 13.193%)
RET%	Sysmex-XN	139	0.9928	1.014 (0.992 to 1.048)	−0.007 (−0.048 to 0.021)	2.31% (−3.136% to 7.752%)	−61.31% (−70.638% to −51.986%)	65.93% (56.603% to 75.255%)
PLT	Sysmex-XN	1,584	0.9962	1.011 (1.006 to 1.016)	−1.109 (−1.411 to −0.629)	−2.41% (−3.490% to −1.339%)	−45.19% (−47.030% to −43.352%)	40.36% (38.524% to 42.201%)
MPV	Sysmex-XN	1,191	0.8762	1.143 (1.114 to 1.174)	−2.443 (−2.783 to −2.154)	−9.61% (−10.006% to −9.218%)	−23.19% (−23.865% to −22.519%)	3.97% (3.294% to 4.641%)
CRP	IMMAGE 800	100	0.9962	1.008 (0.9843 to 1.027)	−0.578 (−0.841 to −0.108)	−3.50% (−5.927% to −1.070%)	−27.49% (−31.650% to −23.322%)	20.49% (16.325% to 24.653%)
Neu%	Manual	809	0.9815	0.993 (0.979 to 1.005)	−1.354 (−2.405 to −0.351)	−2.13 (−2.381 to −1.888)	−9.15 (−9.570 to −8.726)	4.88 (4.457 to 5.301)
Lym%	Manual	809	0.9811	1.000 (0.985 to 1.014)	1.100 (0.900 to 1.352)	1.24 (1.027 to 1.454)	−4.82 (−5.180 to −−4.451)	7.30 (6.932 to 7.661)
Mon%	Manual	809	0.9218	1.039 (1.000 to 1.075)	0.549 (0.370 to 0.800)	0.80 (0.691 to 0.915)	−2.37 (−2.561 to −2.179)	3.98 (3.785 to 4.167)
Eos%	Manual	809	0.9702	1.014 (1.000 to 1.050)	0.096 (0.060 to 0.100)	0.14 (0.060 to 0.212)	−2.03 (−2.160 to −1.899)	2.30 (2.171 to 2.432)
Bas%	Manual	809	0.6950	0.667 (0.600 to 0.667)	0.000 (0.000 to 0.020)	−0.08 (−0.107 to −0.059)	−0.76 (−0.803 to −0.721)	0.60 (0.555 to 0.637)
IMG%	Manual	809	0.9057	1.350 (1.281 to 1.417)	0.195 (0.100 to 0.200)	0.63 (0.530 to 0.727)	−2.18 (−2.345 to −2.007)	3.43 (3.264 to 3.602)

WBC, white blood cell; Neu%, neutrophil percentage; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; RDW-CV, the variable coefficient of red cell volume distribution width; RET%, reticulocyte; PLT, platelet; MPV, mean platelet volume; CRP, C-reactive protein; Neu%, neutrophil percentage; Lym%, lymphocyte percentage; Mon%, monocyte percentage; Eos%, eosinophil percentage; Bas%, basophil percentage; IMG%, immature granulocyte percentage; r, correlation coefficient; LoA, limits of agreement; 95% CI, 95% confidential interval.

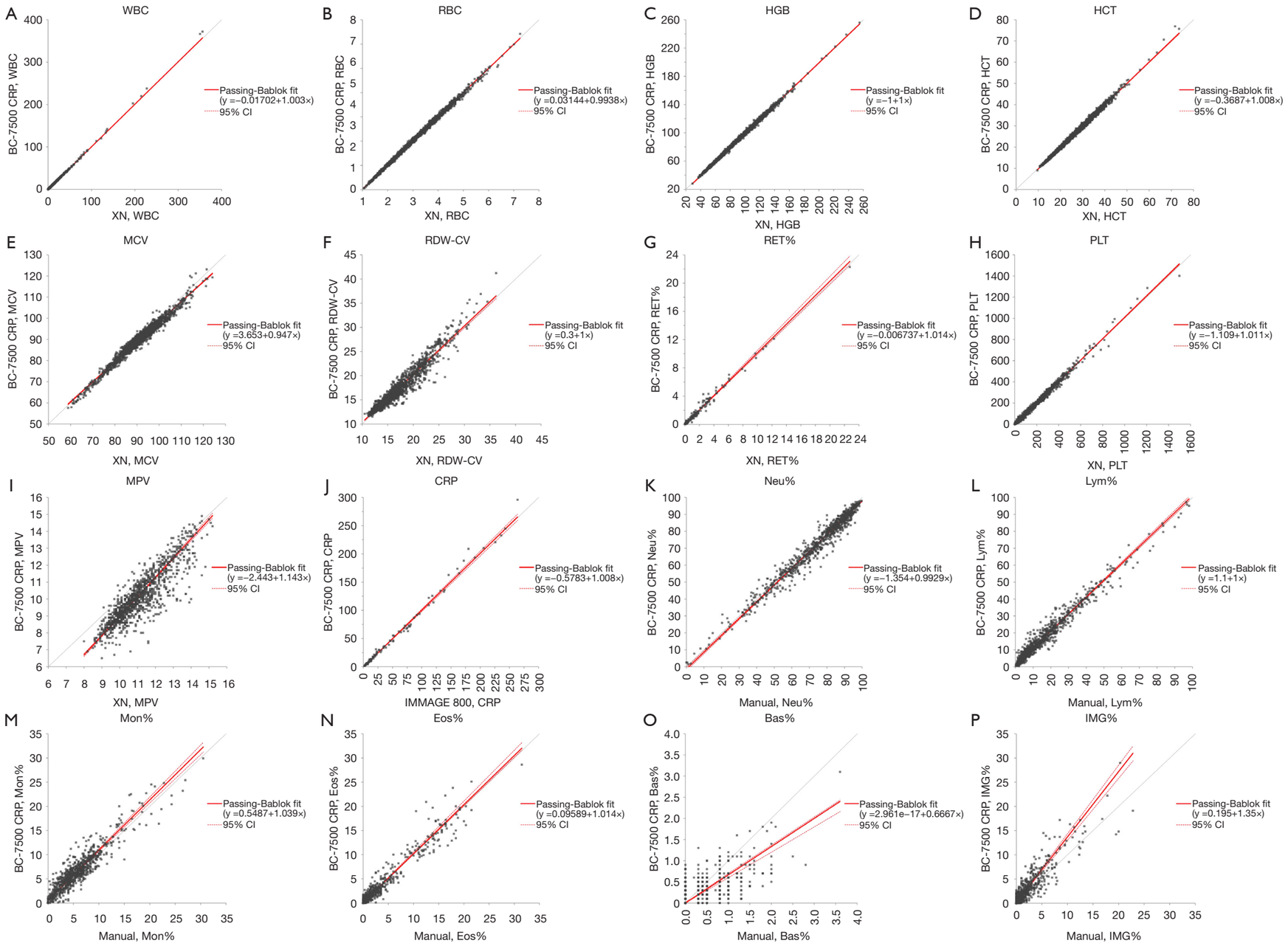

Figure 3 Graphical representation of Passing-Bablok regression analysis of BC-7500 CRP with Sysmex-XN, IMMAGE 800, and manual microscopic classification. The horizontal axis represents the test results of comparable control methods and the vertical axis indicates the test results of BC-7500 CRP. The red solid lines indicate the Passing-Bablok fit regression lines, and the red dashed lines indicate 95% confidence intervals (CIs) (A-P). WBC, white blood cell; XN, Sysmex-XN automated hematology analyzer; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; CV, coefficient of variation; RET%, reticulocyte; PLT, platelet; CRP, C-reactive protein.

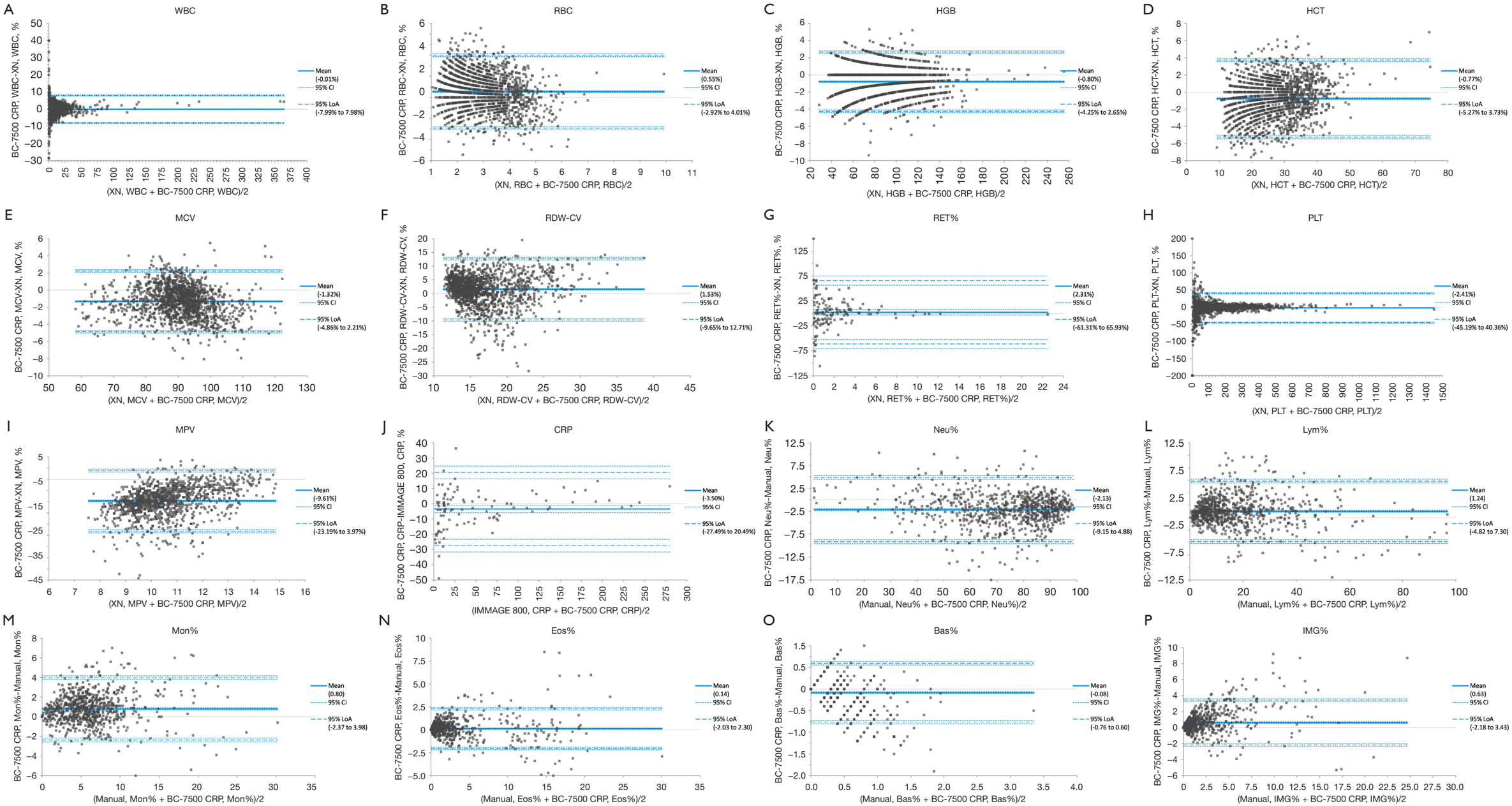

Figure 4 Graphical representation of the Bland-Altman deviation analysis of BC-7500 CRP with Sysmex-XN, IMMAGE 800, and manual microscopic classification. The horizontal axis represents the mean value of test results of two methods, the vertical axis represents the test result differences between BC-7500 CRP and the control method, the blue solid lines represent the mean differences, and the blue dashed lines represent 95% LoA (limits of agreements band) (A-P). WBC, white blood cell; XN, Sysmex-XN automated hematology analyzer; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; RDW-CV, the variable coefficient of red cell volume distribution width; RET%, reticulocyte; PLT, platelet; MPV, mean platelet volume; CRP, C-reactive protein; Neu%, neutrophil percentage; Lym%, lymphocyte percentage; Mon%, monocyte percentage; Eos%, eosinophil percentage; Bas%, basophil percentage; IMG%, immature granulocyte percentage.

Table 5 Assessment results for the flagging ability of abnormal cells in BC-7500 CRP

Flagging	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)	Efficiency (95% CI)
Blast	31	123	639	2	93.9% (80.4–98.3%)	83.9% (81.1–86.3%)	84.3% (81.6–86.6%)
Immature Gran	284	181	304	26	91.6% (88.0–94.2%)	62.7% (58.3–66.9%)	74.0% (70.8–76.9%)
NRBC	104	17	658	16	86.7% (79.4–91.6%)	97.5% (96.0–98.4%)	95.8% (94.2–97.0%)
WBC total	362	184	233	16	95.8% (93.2–97.4%)	55.9% (51.1–60.6%)	74.8% (71.7–77.7%)

CRP, C-reactive protein; NRBC%, nucleated red cells percentage; WBC, white blood cell; 95% CI, 95% confidential interval; TP, true positive; FP, false positive; TN, true negative; FN, false negative.

Table 6 Results of sample stability assessment in a room temperature environment

Time point	WBC	RBC	HGB	HCT	MCV	PLT	RET%	CRP
Mean								
0.5 h	6.190	5.285	151.9	45.32	86.33	227.1	2.123	0.867
4 h	6.283	5.330	152.5	45.83	86.59	225.9	2.013	0.951
8 h	6.275	5.325	153.2	45.93	86.83	222.0	2.001	0.964
12 h	6.228	5.308	152.3	45.88	87.00	222.4	1.988	0.876
24 h	6.200	5.347	152.3	46.58	87.69	219.2	2.199	0.865
d%								
4 *vs.* 0.5 h	1.51%	0.84%	0.43%	1.14%	0.30%	–0.51%	–5.16%	1.34%
8 *vs.* 0.5 h	1.37%	0.76%	0.86%	1.36%	0.58%	–2.22%	–5.72%	1.54%
12 *vs.* 0.5 h	0.62%	0.43%	0.30%	1.25%	0.78%	–2.05%	–6.34%	0.14%
24 *vs.* 0.5 h	0.16%	1.16%	0.30%	2.79%	1.58%	–3.48%	3.58%	–0.04%

WBC, white blood cell; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; PLT, platelet; RET%, reticulocyte; CRP, C-reactive protein; d%, relative deviation.

clinical judgment (*Table 8*).

Discussion

Blood cell analyzers have been upgraded due to the expansion of testing needs, from the earliest simple blood cell count to three subgroups and five classifications, which meet the testing needs of test workers for routine blood cell count and leukocyte classification. Five classifications have been added on the basis of nucleated red blood cells (NRBC), reticulocytes (RET), immature granulocyte (IG), body fluids, and other tests, in order to meet the testing demand for more blood cell types and specimen types. In addition, technological advances in hematology analyzers are reflected in increased detection speed, reduced aspiration volume, improved performance, as well as convenient and user-friendly operation (1-3).

Developed by Mindray in 2020, the BC-7500 CRP analyzer is the latest hematology analyzer, combining the three technologies of fluorescence 3D analysis, routine blood and CRP co-testing, and fully automated peripheral blood testing, which can simplify the testing operation process and improve the efficiency and quality of testing. The BC-7500 CRP analyzer adopts the SF-Cube 2.0 fluorescence platform (4) for white blood cell, red blood cell, and platelet detection, especially for abnormal specimens, such as low-value and abnormal platelets. The instrument accurately outputs the full parameters of blood analysis and accurately alerts for abnormal cells (such as progenitor cells and heterogeneous lymphocytes). Moreover, it can simultaneously output two test reports of routine blood and CRP with one injection. CRP detection adopts latex-enhanced immunoscattering turbidimetry, and the volume interference of white blood cells, red blood

Table 7 Results of sample stability assessment under refrigerated environment

Time point	WBC	RBC	HGB	HCT	MCV	PLT	RET%	CRP
Mean								
0.5 h	6.190	5.285	151.9	45.32	86.33	227.1	2.123	0.867
4 h	6.255	5.338	153.0	45.70	86.19	227.8	2.069	0.927
8 h	6.290	5.355	153.5	45.89	86.24	224.7	2.091	0.990
12 h	6.275	5.341	152.8	45.81	86.32	225.4	2.034	0.869
24 h	6.261	5.351	152.8	45.89	86.32	222.9	1.980	0.757
48 h	6.241	5.310	152.4	45.51	86.25	218.0	1.833	0.684
d%								
4 *vs.* 0.5 h	1.06%	0.99%	0.76%	0.85%	−0.16%	0.31%	−2.52%	0.95%
8 *vs.* 0.5 h	1.62%	1.32%	1.05%	1.26%	−0.10%	−1.04%	−1.48%	1.95%
12 *vs.* 0.5 h	1.37%	1.05%	0.63%	1.08%	−0.01%	−0.73%	−4.19%	0.03%
24 *vs.* 0.5 h	1.16%	1.24%	0.63%	1.27%	−0.01%	−1.85%	−6.74%	−1.76%
48 *vs.* 0.5 h	0.82%	0.46%	0.36%	0.42%	−0.09%	−4.01%	−13.66%	−2.94%

WBC, white blood cell; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; PLT, platelet; RET%, reticulocyte; CRP, C-reactive protein; d%, relative deviation.

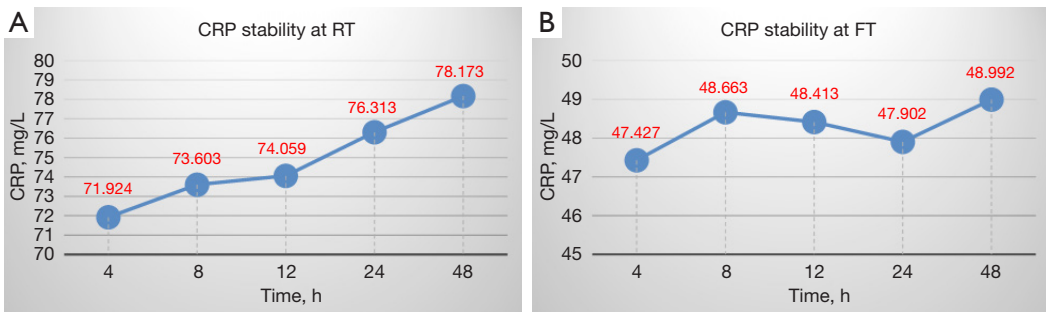

Figure 5 Stability of high-value CRP samples in room temperature and refrigerated environments. (A) CRP showed a small tendency to increase under RT (18–25 ℃) environment, which was more obvious increments after 12 hours; (B) CRP showed very stable results over time under FT (refrigerated, 2–8 ℃) environment. CRP, C-reactive protein; RT, room temperature; FT, refrigerated temperature.

Table 8 Comparability validation results of the automated MWB mode

Parameter	WBC	RBC	HGB	HCT	MCV	PLT	RET%	CRP
Opened MWB mode, mean	9.340	4.373	112.0	35.84	83.06	223.7	2.687	12.730
Automatic MWB mode, mean	9.295	4.364	119.8	36.20	84.13	223.3	2.675	12.825
Mean difference	−0.045	−0.009	−0.2	0.36	1.07	−0.4	−0.012	0.096
95% CI	−0.096 to 0.006	−0.018 to 0.001	−0.4 to 0.1	0.25 to 0.46	0.91 to 1.23	−2.6 to 1.7	−0.044 to 0.020	−0.053 to 0.245
P value	0.0844	0.0732	0.1830	<0.0001	<0.0001	0.6906	0.4452	0.2014

MWB, micro whole blood; WBC, white blood cell; RBC, red blood cell; HGB, hemoglobin; HCT, hematocrit; MCV, mean corpuscular volume; PLT, platelet; RET%, reticulocyte; CRP, C-reactive protein.

cells, and platelets is corrected by BloodCell Volume (BCV) technology to ensure consistency with serum CRP. Also, combined routine blood and CRP inspection can improve the efficiency of outpatient and emergency detection and reduce turn-around time (TAT) time. The automatic peripheral blood sampling function breaks the traditional manual test operation habit of peripheral blood. It is equipped with a customized puncture peripheral blood test tube, which can be barcoded, without removing the cap and mixing. The sense of automation is equivalent to the venous blood test, which can improve the peripheral blood test experience, reduce biological safety hazards, and guarantee the TAT. In this study, the analytical performance of the BC-7500 CRP analyzer was evaluated in two parts—routine blood and CRP testing, which showed that the routine blood and CRP analysis modules of the BC-7500 CRP analyzer had an excellent clinical performance. Meanwhile, it can better meet the clinical testing of routine blood and CRP items in clinical whole blood samples, which can guarantee rapid and accurate laboratory diagnosis.

This study was performed in accordance with the technical documents and standard guidelines of the ICSH (11) and CLSI (7,8), and aimed to verify the main performance of BC-7500 CRP and determine whether it meets the requirements for clinical use. BC-7500 CRP exhibited good blank count results, which indicated that the assay system was less affected by electrical noise and the reagents and pipelines were not contaminated. Some of the CRP blank counts are not equal to 0, given that the CRP was detected by scattering immunoturbidimetric assay, which is more sensitive in the region of very low values, and the highest value of this blank count was 0.07, without any effect on the basic detection of CRP. The carryover contamination rate of the instrument did not exceed 1%, which was much smaller than that claimed in the instrument manual. Moreover, the distribution of the carryover contamination rate data also showed that the level of the carryover contamination rate did not differ significantly between different modes of the instrument, which suggested that the cleaning function of the instrument was good.

The stability of the BC-7500 CRP was evaluated by its precision indexes, including repeatability and reproducibility of both short- and long-term test results. Regarding the repeatability, the fresh whole blood samples of each range of different parameters were collected for continuous testing and analysis. Almost all samples performed well, except for very low value samples of some parameters, such as WBC, PLT, and CRP. As their own concentrations were too low, this resulted in a significantly larger CV% compared to normal or high value samples. In this study, the repeat performance of the whole blood and micro-whole blood modes were tested separately, and there was no significant difference between the repeat performances of the two modes, except for the MCV parameter. However, the CV% of most samples did not exceed 1%, which suggested that the BC-7500 CRP showed good reproducibility. For low-value platelet samples, the optical platelet counting function with nucleic acid fluorescence staining was adopted in the BC-7500 CRP analyzer, which could exclude the interference of other particulate components, increase the effective particle count, and ensure the accuracy of low-value platelet counting. Two QCs, BC-6D, and BC-RET of precision were tested, and the reproducibility of both the routine blood channel and reticulocyte channel was evaluated, which found that the total precision of the instrument in each parameter was small, which could meet the requirements of clinical use.

For the comparability evaluation of routine blood, 1,584 fresh whole blood samples with different parameter ranges and covering different medical decision level (MDL) were selected for comparison with Sysmex-XN (12), and the results suggested a strong correlation between blood count-related parameters and Sysmex-XN (12), and the Passing-Bablok regression (13) and Bland-Altman deviation (14) analyses showed a high level of agreement with Sysmex-XN (12). The comparison of categorical parameters with manual microscopy showed good correlations between Neu%, Lym%, Mon%, Eos%, and IMG% parameters, with Pearson's correlation coefficient (r) exceeding 0.9. Bas% had a relatively poor correlation due to its LTV, with a –0.08 deviation in manual microscopy; however, this value would not affect clinical use. The correlation coefficient of the specific protein analysis results of the CRP parameters (0.9962) was well correlated with IMMAGE 800, indicating that the BC-7500 CRP analyzer could accurately convert CRP results in plasma or serum by measuring whole blood samples based on the BCV correction technology.

Regarding the flagging capacity of leukocyte abnormal cells, we evaluated the three most common types of cells that require microscopic reexamination for confirmation in clinical practice (blast, IG, and NRBC), BC-7500 CRP showed good flagging capacities. In this study, based on the WBC total flagging combined the flagging for the above three categories of abnormal cells, the sensitivity, specificity, and total validity of the BC-7500 CRP analyzer were 95.8%, 55.9%, and 74.8%, respectively, which indicates that BC-7500 CRP analyzer had a strong ability to screen and

identify abnormal cells in leukocyte classification. However, it is important to be aware that the increased sensitivity may result in higher false positives, especially for samples at the boundary of positive microscopy. Moreover, the false positive results normally do not pose clinical risks and only increase the retesting workload of clinical staff.

Due to the restricted conditions, many samples are not immediately tested on the machine after collection, and may be stored at room temperature or refrigerated before centralized testing. Thus, it is necessary to determine whether the test results are stable after the samples are stored in different environments. The validation of fresh whole blood samples collected from healthy volunteers revealed that the BC-7500 CRP analyzer performed well in terms of sample stability in both room temperature and low temperature environments, with accurate test results for whole blood samples stored at room temperature for 24 hours and refrigerated storage for 48 hours. The evaluation of the high-value CRP samples also revealed that the CRP samples showed a gradual increase with time in the room temperature environment, with a significant phenomenon after 12 hours, and their results were higher (2.97%, 6.10%, and 8.69% at 12, 24, and 48 h of room temperature storage, respectively) compared to those at 4 hours. However, there was no significant difference at each time point in the refrigerated environment, and the deviations between 4 and 12, 24, and 48 h were 2.08%, 1.00%, and 3.30%, respectively. Considering that users usually complete the CRP assay within 12 hours in a room temperature environment, for which the relative deviation was within the clinically acceptable range, it was estimated that these results would not have an impact on clinical use.

Finally, in this study, the automatic micro-whole blood mode of the BC-7500 CRP was compared with the manual open mode, and the results of each parameter of the instrument were found to be in good agreement with the manual open mode. The P values of the paired *t*-test results of the main counting parameters with the control mode were greater than 0.05, except for the HCT and MCV parameters, which were not statistically different between the effects of automatic mixing of surface end blood and manual mixing. The HCT and MCV parameters (0.36 and 1.07, respectively) were higher, but these differences did not affect clinical judgment.

Conclusions

BC-7500 CRP is a fully automatic hematology analyzer with excellent performance and function. It can output both routine blood and CRP test results, with good correctness and precision for the common routine blood and CRP parameters. Moreover, the automatic sampling technology of terminal blood can better meet the needs of clinical testing workload as well as disease diagnosis and treatment. This instrument is especially suitable for scenarios where the CRP test and TAT time are in great demand in the outpatient and emergency departments of tertiary hospitals and special hospitals for women and children.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1642/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1642/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1642/coif). The authors have no conflicts of interest to declare.

Ethical 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of the Fujian Medical University Union Hospital, Fuzhou (No. 2020KY077). Due to the study's retrospective nature, the requirement to obtain signed informed consent from the patients was waived.

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