

Evaluation of the XN-1000 Hematology Analyzer Equipped with the Blood Bank mode Software for Hematological Examination of Blood Components

Fuminori ARISAWA^{*1}, Shinobu WAKAMOTO^{*1}, Wataru OHASHI^{*1}, Yuichi TONE^{*1, 3}, Kaori SHIBAGAKI^{*2}, Hidekazu KOMAKI^{*2}, Hideo KITAGAWA^{*2}, Kiichiro NAMURA^{*2}, Mitsuaki AKINO^{*1} and Shuichi KINO^{*1, 4}

^{*1} Japanese Red Cross Hokkaido Block Blood Center, 1-1-20, Nijuyonken 2-Jo, Nishi-ku, Sapporo, Hokkaido, 063-0802, Japan

^{*2} Japanese Red Cross Kinki Block Blood Center

^{*3} (Japanese Red Cross Kyushu Block Blood Center)

^{*4} (Japanese Red Cross Blood Service Headquarters)

The residual white blood cell count (rWBC) in blood products, the platelet count (PLT) and residual red blood cell count (rRBC) in platelet concentrate (PC), and the hemoglobin concentration (HGB) in frozen-thawed red blood cell (FTRC) solutions are each measured by different methods.

The XN-Series Automated Hematology Analyzer (Sysmex Corporation, Kobe, Japan; hereinafter XN-1000), introduced in September 2022 as a testing system for rWBCs, is equipped with a measurement mode for quality testing of blood products, Blood Bank mode (BB), which may allow multiple tests to be performed at once. The XN-1000's BB (XN-1000/BB) can be used for quality tests other than rWBC assays. The PLT assay in PC showed good linearity at concentrations of 600 to $4,000 \times 10^3/\mu\text{L}$, eliminating the need to reassay high-concentration PLT samples, which is required in the conventional method. When excessive rRBC contamination is suspected in PC, specimens are examined using a blood cell counting chamber. The XN-1000/BB showed good correlation with the visual method in the rRBC range of 50 to 5,000/uL, thus eliminating the need for further specimen examination. The HGB of FTRC showed linearity over a range of 7 to 23 g/dL which correlated well with the conventional method. It was confirmed that multiple quality tests can be performed with a single XN-1000/BB. The introduction of this system is expected to reduce reagent inventory, manual testing steps, and lab costs.

Key Words

XN-1000, Blood Bank mode, Hematological Examination, Blood Components

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INTRODUCTION

The Japanese Red Cross Society (JRCS) conducts various tests to confirm the quality of blood products for transfusions. For each test, the authors have always used the latest testing equipment. In recent years, medical equipment and laboratory analyzers have made significant progress. Automatic hematology analyzers have been developed that are highly functional and can process multiple items at one time. The XN-Series Automated Hematology Analyzer (Sysmex Corporation, Kobe, Japan; hereinafter XN-1000, Sysmex) has an automatic retest function. This feature is essential for routine testing at medical facilities because it can simultaneously measure blood counts for multiple items. The small footprint device is ideal for saving space in the laboratory.^{1, 2)} Recently, a dedicated measurement mode, Blood Bank mode (BB), was developed that can be installed on the XN-1000 for measuring transfusion blood product samples, rather than using blood from healthy individuals or patients.³⁻⁷⁾

Beginning September 2022, the JRCS decided to conduct residual white blood cell count (rWBC) tests at each regional block blood center, previously carried out at the Central Blood Research Institute in Tokyo. They simultaneously replaced the conventional flow cytometer (FCM) with the XN-1000. We oversaw testing evaluations related to changes in the rWBC test method and found that the XN-1000's BB (XN-1000/BB) is an effective alternative to the FCM method.

The XN-1000/BB was initially developed to perform quality testing of blood products for transfusions. It was also used to test platelet counts (PLTs) and residual red blood cell counts (rRBCs) of platelet concentrates (PC) and hemoglobin concentrations (HGB) in frozen-thawed red blood cells (FTRC). However, these testing methods have not been fully evaluated.

Currently, an automated hematology analyzer XS-1000i (hereinafter XS-1000i, Sysmex) is used to measure PLT and rRBC counts in PC, but the measurement mode of this device is intended for healthy patients and/or healthy human blood. When the PLT count is $\geq 2,000 \times 10^3/\mu\text{L}$, the reliability of the measured value is low, necessitating a complicated

re-testing procedure in which the sample must be diluted and measured twice. The lower limit of the red blood cell count display is $10 \times 10^3/\mu\text{L}$ in the XS-1000i, making it difficult to accurately measure the rRBCs in the PC. Currently, reassay may be performed by visual method using a counting chamber and a microscope. A HGB level must be obtained on all FTRCs prior to shipment and the XS-1000i provides that measurement.

The authors posited that if multiple quality tests could be performed simultaneously using the XN-1000/BB, deployed at block centers nationwide as an inspection device for rWBCs, it would improve work efficiency by eliminating unnecessary reagent testing and documentation. Therefore, the authors investigated the possibility of using the XN-1000/BB for additional quality tests besides just the rWBC measurement.

METHODS

1. Specifications of the XN-1000/BB

Table 1 shows the specifications of the XN-1000/BB used in this study.

For the XS-1000i, PLT and rRBC counts in PC were measured using the direct current detection method. For the XN-1000/BB, the FCM method is used. The XN-1000/BB is capable of measuring PLT counts of $\geq 2,000 \times 10^3/\mu\text{L}$ and RBCs around $50/\mu\text{L}$ which is not possible using the XS-1000i. The XN-1000/BB's PLT measurement technology selectively stains platelets with a dedicated solution. Each sample is diluted to a predetermined magnification using a specific diluent and then measured by FCM which generates a scatter plot (**Fig. 1**) using side fluorescence and forward scattered light information.

The rRBCs are measured by FCM after nucleic acids in the blood cells are stained with a dedicated solution. Scatter plots, derived from side fluorescence and forward scattered light, serve to distinguish nucleic acid-stained leukocytes and platelets from not stained residual red blood cells. The SLS-hemoglobin method is used to measure the HGB which is consistent with the XS-1000i technology.

Table 1 Basic Specifications of XN-1000/BB

Item			XS-1000i	XN-1000/BB*1
Blood Cell Count in Blood Products*2	rWBC	Measurement Principle	FCM method	FCM method *4
		Measurement Range	not available *3	≥3 /μL *5
	rRBC	Measurement Principle	Impedance method	FCM method *6
		Measurement Range	not available *3	≥50 /μL *5
	PLT	Measurement Principle	Impedance method	FCM method *7
		Measurement Range	≤2,000 (×10 ³ /μL)	≤4,000 (×10 ³ /μL) *5
	HGB	Measurement Principle	SLS-Hemoglobin method	SLS-Hemoglobin method
		Measurement Range	0.0–26.0 g/dL	0.0–26.0 g/dL
Aspiration Volume			20 μL	150 μL (RBC Pack) 205 μL (PLT Pack)
Throughput (samples/hour)			52 samples	without residual cells 79 samples (RBC Pack) 62 samples (PLT Pack) with residual cells 33 samples (RBC Pack) 19 samples (PLT Pack)

*1 Blood Bank mode (software version 22.15 was referred)

*3 Residual cell count is not available.

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*7 XN-1000/BB performs about 4 times-multiplied cell count than XS-1000i.

*2 Concurrent Measurement is available on XN-1000/BB.

*4 XN-1000/BB performs about 4 times-multiplied cell count than XS-1000i.

*6 XN-1000/BB performs about 134 times-multiplied cell count than XS-1000i.

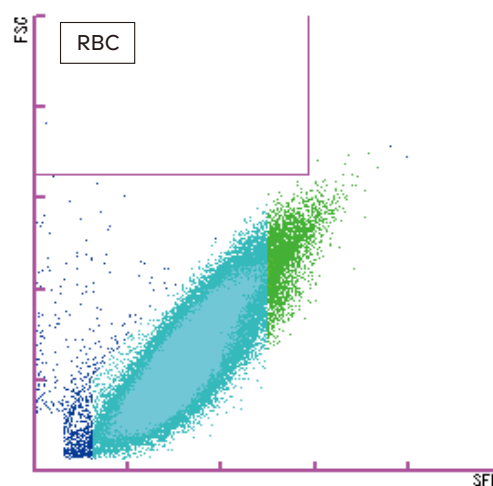


Fig. 1 Representative PLT-F Scattergram of XN-1000/BB

A representative PLT-F scattergram of routine PC samples used for Correlation Study with the Conventional Method (3.1 under METHODS) (SFL: Side Fluorescence, FSC: Forward Scatter)

2. Evaluation of Basic Functions

The basic functions of the XN-1000/BB were examined by preparing diluted samples containing a known number of cells. The linearity, reproducibility, and carry-over tests (only for PLT measurement in PC) were used to evaluate basic analyzer functions. The test tubes were polypropylene auto tubes with round bottoms (13 φ x 74.5 mm, ASIAKIZAI Inc.) in compliance with the SOP. The PLT measurements were not multiplied by a correction factor, instead, the values indicated by each measuring device were used. The following studies were conducted at two facilities (Centers A and B) from December 2021 to January 2022.

2.1 Preparation of Diluted Samples

The following linearity and reproducibility tests were conducted using artificially prepared diluted samples at Center A. The supernatant was removed by centrifuging (3,000 rpm, 10 min, 22°C) Ir-PC-LR 20 that failed the liver function test to prepare a concentrated solution with a PLT count of 3,000 to $4,000 \times 10^3/\mu\text{L}$ (the PLT count was confirmed by measuring a 2-fold diluted sample with the XS-1000i). The supernatant of platelet-poor plasma (PPP) after centrifugation was further centrifuged twice under the same conditions, and the PLT-free supernatant (0/ μL measured by the XS-1000i) was separated and used as diluent. The concentrated and diluted solutions were mixed to prepare five types of samples with different concentrations [(1) 600 to 800, (2) 1,000 to 1,330, (3) 1,500 to 2,000, (4) 2,000 to 2,670, and (5) 2,500 to $3,330 \times 10^3/\mu\text{L}$] and used as diluted PC samples for various tests. The diluted samples used for the rRBC evaluation in PC were prepared by mixing the expired Ir-PC-LR 15 with insufficient whole blood. The mixtures obtained were residual RBCs in PC at counts of 50, 100, 500, 1,000, and $5,000/\mu\text{L}$. Ir-RBC-LR2 that failed the liver function test was used as the HGB diluted sample. Five types of diluted samples [(1) 7 to 9, (2) 10 to 13, (3) 14 to 16, (4) 17 to 19, and (5) 20 to 23 g/dL] were prepared by mixing Ir-RBC-LR2 and MAP solutions. The empty weight (a), weight after addition of specimen (b), and weight after addition of diluent (c) of each test tube were measured so that errors in the preparation of each diluted specimen would not

affect the results. The expected value of each concentration was obtained from the following formula:

$$\text{Expected value} = \text{PLT} (x 10^3/\mu\text{L}), \text{RBC} (/ \mu\text{L}) \text{ or HGB (g}/\mu\text{L}) \times (b - a)/(c - a)$$

2.2 Linearity Test (for PLT in PC, rRBC in PC, and HGB in FTRC)

To evaluate the PLT count in PC, diluted samples prepared in 2.1 concentrations were measured with the XN-1000/BB or the XS-1000i. The correlation with the expected value and the correlation between the two instruments were examined. Measurements were performed twice per sample. When the PLT count was $\geq 2,000 \times 10^3/\mu\text{L}$ on the XS-1000i, samples were measured using diluted 2-fold with the device diluent (CELLPACK™, Sysmex).

For the evaluation of rRBCs in PC, the results of the visual method using an Improved Neubauer's Counting Chamber (Erma Inc.) were used as a control. Average results from the two chambers of the calculation board were compared with the measured values of the XN-1000/BB. For the evaluation of HGB in FTRC, diluted specimens prepared in 2.1 were measured by the XN-1000/BB or the XS-1000i, and the correlation between the two was examined.

2.3 Reproducibility Test (for PLT in PC and HGB in FTRC)

For the evaluation of PLTs in PC, diluted samples for PC prepared in 2.1 were used ($n = 1$). For HGB levels in FTRC, FTRC was prepared with Ir-RBC-LR2, which failed liver function tests ($n = 3$) was used. Ten test tubes were prepared from each sample and measured continuously with the XN-1000/BB or the XS-1000i. The coefficient of variation (CV value) was calculated from the mean and standard deviations (SD).

2.4 Carry-over Test (for PLT in PC)

The carry-over test was performed to confirm that the measured blood components did not affect subsequently assayed samples. Since automated

hematology analyzers continuously aspirate samples from the same probe, it is recognized that the measured value of the previously aspirated sample may affect the result of the next sample.⁸⁾ To test this concept, the authors measured a low-concentration sample (diluent: B) containing no PLTs after running a high-concentration sample (stock solution: A) containing approximately $3,800 \times 10^3/\mu\text{L}$ of PLTs. Three test tubes (A1, A2, A3, B1, B2, B3) containing (stock solution: A) and (diluent: B), respectively, were prepared at Center A. Three consecutive measurements of stock solution: A were run with the XN-1000/BB followed by three consecutive measurements of diluent: B. The carry-over ratio⁹⁾ was calculated using the formula below. A carry-over ratio of $\leq 1.0\%$, which is the specification of the XN-1000/BB, was considered acceptable.

$$\text{Carry-over ratio (\%)} = (B1 - B3) / (A3 - B3) \times 100$$

3. Comparison Study with the Conventional Method Using Routine Specimens (for PLT in PC)

Residual specimen measurements from the XS-1000i were used to determine the number of units of PC. These samples were used as routine specimens and then measurements were correlated with the XN-1000/BB at Center B. PC was evaluated for each blood component collection device for both Trima Accel-derived and CCS-derived samples. For consistency, sample measurements were performed on the same day of the blood collection.

3.1 Correlation Study with the Conventional Method

XS-1000i samples were immediately measured using the XN-1000/BB to examine the correlation between the two analyzers ($n = 130$). Polypropylene auto tubes as specified in the SOP, and an autosampler were used for the XN-1000/BB measurement.

3.2 Stability Test Over Time

The stability over time of routine samples was examined using the XN-1000/BB ($n = 5$). Test tubes measured by the XS-1000i were immediately tested

using the XN-1000/BB. The value obtained was used as the zero time (initial value). “Initial value” samples were kept at room temperature and measured after 3, 5, and 24 hours, respectively. The “initial value” was set as the base point (100%), and the sample “rate of change over time” was calculated.

4. Statistical Processing

For both the linearity test using diluted samples and the correlation test using routine samples, regression analysis was performed. A correlation coefficient (r) of ≥ 0.95 was considered good correlation. For the reproducibility test, a CV value of $\leq 2.5\%$ was considered good for the PLT test, and a CV value of $\leq 1.0\%$ was considered good for the HGB test.

RESULTS

1. Measurement of PLT in PC by the XN-1000/BB

1) Linearity Test

A good linear relationship ($y = 1.0617x - 32.906$, $r = 0.9996$) was obtained between the expected value from diluting a known PLT sample and the measured value of the XN-1000/BB in the range of 600 to $4,000 \times 10^3/\mu\text{L}$ (**Fig. 2A**). **Fig. 2B** shows the correlation between the XN-1000/BB and the XS-1000i using PLT diluted samples. For these samples, a very high correlation ($y = 1.0081x - 20.842$, $r = 0.9999$) was observed between the XN-1000/BB and the XS-1000i.

2) Reproducibility Test

CV value of $< 2\%$ was obtained by consecutively measuring 10 identical diluted PLT samples at different concentrations using the XN-1000/BB (**Table 2**).

3) Carry-over Test

Table 3 shows carry-over test results to confirm the absence of carry-over with low-concentration samples after the measurement of high-concentration samples. The carry-over ratio of the XN-1000/BB was 0.026%, which met expected criterion (1.0% or less).

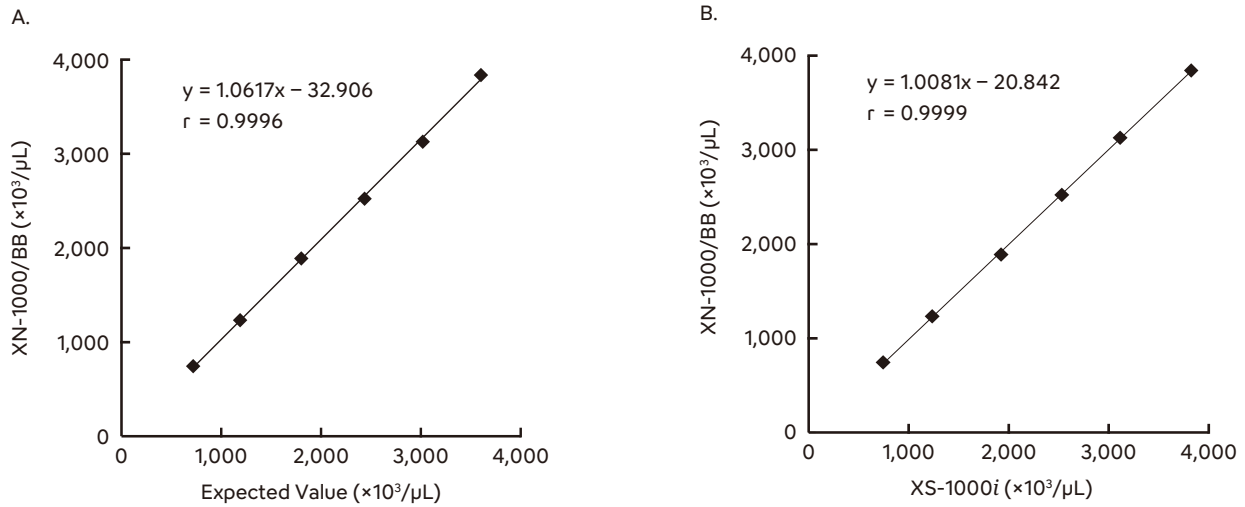


Fig. 2 Linearity Results and Correlation Results Using PLT Dilution Samples

A. Linearity between expected values of dilution samples and XN-1000/BB results
B. Correlation between XS-1000i and XN-1000/BB results

Table 2 Repeatability Study Results for PLT Measurements

Diluted Sample ($\times 10^3/\mu\text{L}$)	Expected Value ($\times 10^3/\mu\text{L}$)	XN-1000/BB		XS-1000i	
		Results ($\times 10^3/\mu\text{L}$)	CV *1 (%)	Results ($\times 10^3/\mu\text{L}$)	CV *1 (%)
Original	3,601.5	3,783.6 $\pm$ 10.2	0.27	3,985.3 $\pm$ 33.6 *2	0.84
1,500–2,000	1,801.4	1,851.4 $\pm$ 8.5	0.46	1,900.7 $\pm$ 27.0	1.42
1,000–1,330	1,187.3	1,204.8 $\pm$ 6.4	0.53	1,239.9 $\pm$ 14.9	1.20
600– 800	718.5	718.2 $\pm$ 4.2	0.58	736.4 $\pm$ 6.8	0.93

Mean $\pm$ SD *1 CV was calculated by standard deviation/mean value $\times$ 100.

*2 Measured by 2-fold dilution.

Ten consecutive measurements were performed ($n = 1$) on ten test tubes prepared from the PC diluted samples.

Table 3 Carry-over Study Results for PLT Measurement

Sample ($\times 10^3/\mu\text{L}$)	Tube	XN-1000/BB PLT-F ($\times 10^3/\mu\text{L}$)
Original Sample	A1	3,846
	A2	3,824
	A3	3,844
Diluent	B1	2
	B2	2
	B3	1
Carry-over Ratio (%) *		0.026

*Carry-over Ratio (%) = (B1-B3) / (A3-B3) $\times$ 100

4) Correlation Test with the XS-1000i Using Routine Samples

Fig. 3 shows a comparison test with the conventional method using actual samples. The PLT measurement of PC derived from Trima Accel® (Terumo BCT, Inc.) using the XN-1000/BB showed $y = 1.0029x - 12.576$, $r = 0.9985$ ($n = 70$), and the measurement of PC derived from Component Collection System (Haemonetics Corporation; hereinafter CCS) showed $y = 1.0011x - 10.424$, $r = 0.9957$ ($n = 60$), both were in agreement with the XS-1000i.

5) Stability Test Over Time When Stored in Test Tubes

The stability over time of routine specimens after storage in test tubes was examined using the XN-1000/BB. Although PLT counts decreased with time after specimen collection, the rate of change was $\leq 3\%$ at all measurement points. Regardless of the blood collection method, no significant change over time was observed (**Fig. 4**)

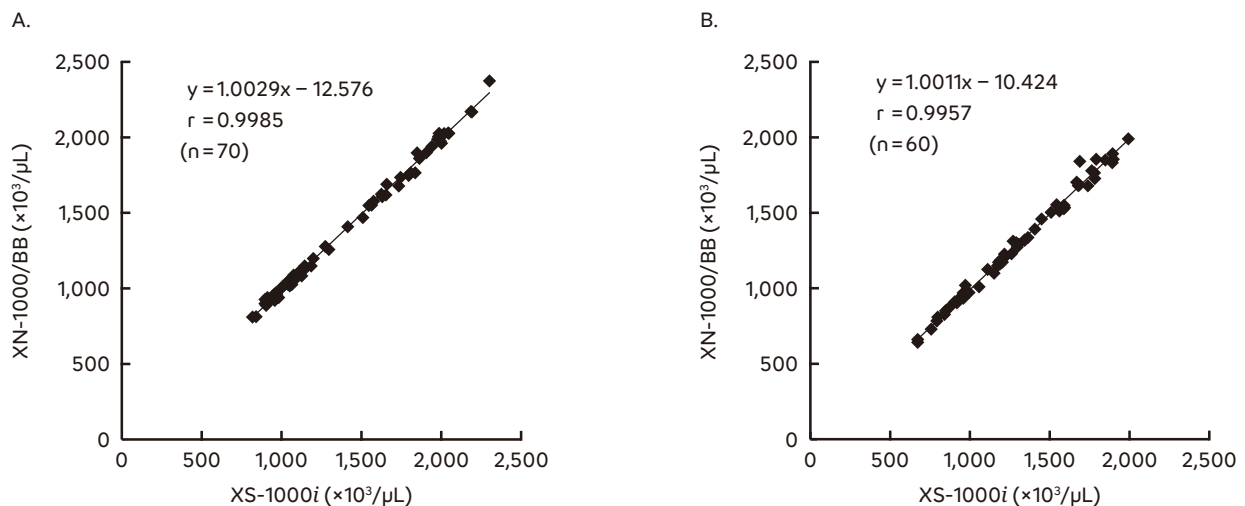


Fig. 3 Correlation Study Results between XS-1000i and XN-1000/BB Using Routine Samples

A. Results collected from PC samples using Trima Accel

B. Results collected from PC samples using CCS

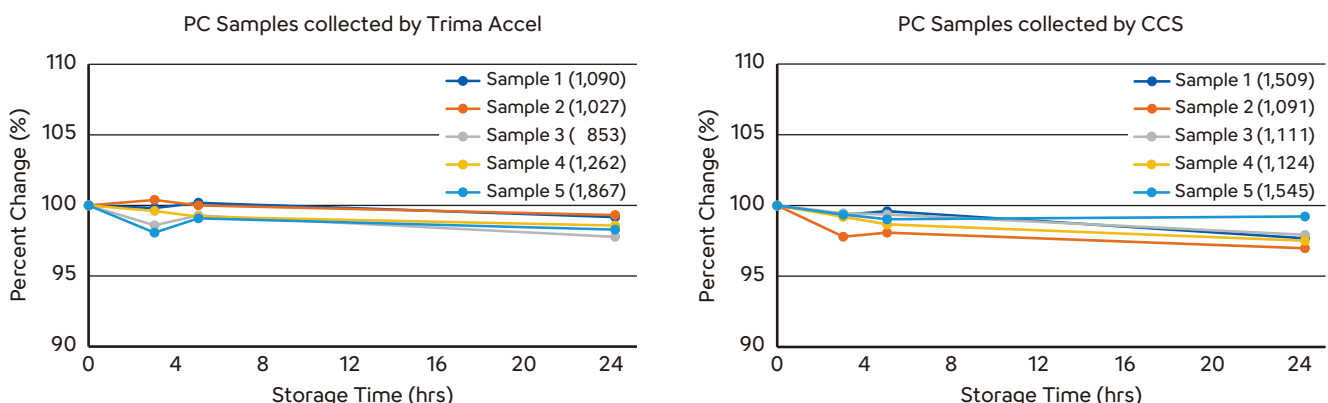


Fig. 4 PLT-F Sample Stability Study Results (stored in tubes)

Each plot represents percent change (%) when the initial results are regarded as 100%. Numerical value in parentheses represents PLT count of each PC sample ($\times 10^3/\mu\text{L}$).

2. RBC Measurement in PC by the XN-1000/BB

The measurement results of samples containing known RBCs using the XN-1000/BB and the correlation with the visual method are shown in **Fig. 5**. Good linearity ($y = 0.8821x + 5.8528$, $r = 1.0000$) was observed between expected and measured values by the XN-1000/BB in the RBC range of 50 to 5,000/ μL . A high correlation ($r = 1.0000$) was obtained between the XN-1000/BB and the visual method.

3. HGB Measurement of FTFC by the XN-1000/BB

1) Linearity Test

A correlation of $y = 1.0109x - 0.6047$, $r = 0.9997$ was obtained between expected and measured values for diluted samples of 7 to 23 g/dL (**Fig. 6A**), which verified the accuracy of HGB measurements on the XN-1000/BB. It also showed a good correlation ($y = 0.9727x + 0.1552$, $r = 1.0000$) with the XS-1000i (**Fig. 6B**).

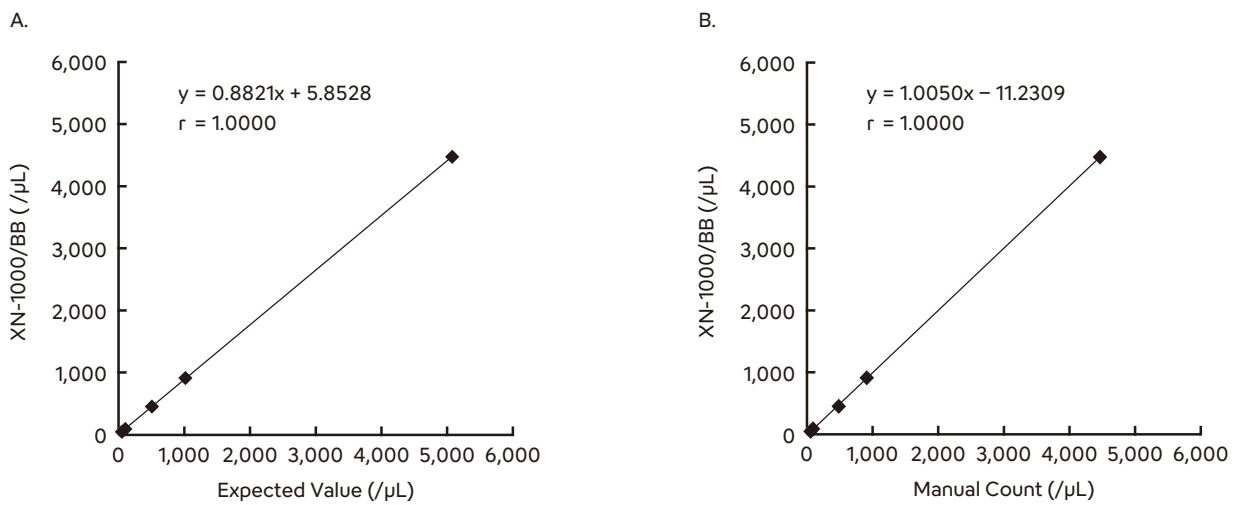


Fig. 5 rRBC Linearity and Correlation Study Results

A. Linearity between expected values of dilution samples and XN-1000/BB results

B. Correlation between manual count and XN-1000/BB results

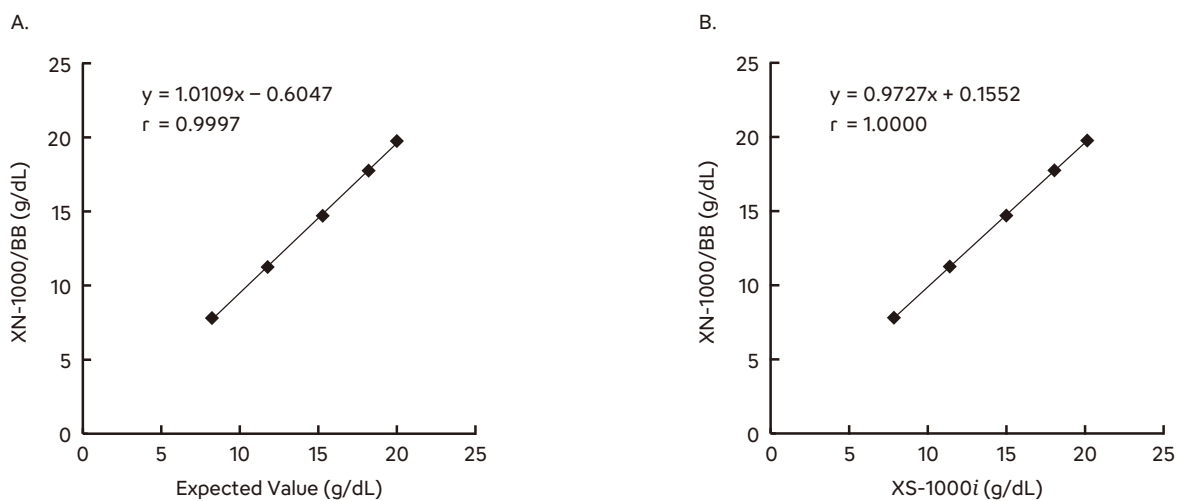


Fig. 6 HGB Linearity and Correlation Study Results

A. Linearity between expected values of dilution samples and XN-1000/BB results

B. Correlation between XS-1000i and XN-1000/BB results

Table 4 Repeatability Study Results for HGB Measurements

Sample	XN-1000/BB		XS-1000i	
	Results (g/dL)	CV * (%)	Results (g/dL)	CV * (%)
Exp. 1	16.15 ± 0.05	0.31	16.41 ± 0.05	0.33
Exp. 2	16.38 ± 0.06	0.37	16.58 ± 0.06	0.36
Exp. 3	16.70 ± 0.04	0.27	16.96 ± 0.05	0.29

Mean ± SD *CV was calculated by standard deviation/mean value × 100.

2) Reproducibility Test

Ten samples taken from three packs of Ir-FTRC-LR2 were measured continuously using the XN-1000/BB and compared with the results from the XS-1000i (**Table 4**). The CV value of the XN-1000/BB was good, ≤1.0% in all cases.

DISCUSSION

We evaluated the feasibility of using the XN-1000/BB, which was developed for quality testing of transfusion blood products, for measuring PLTs and rRBCs in PC and HGB levels in FTRC.

Currently, PLT measurements, which are essential for determining the number of units of PC, are performed using the XS-1000i automated hematology analyzer. However, the XS-1000i was not developed to measure the properties and quality of transfusion blood products. Therefore, if the PLT count in the PC is $\geq 2,000 \times 10^3/\mu\text{L}$, the measured analyzer value may be inaccurate. The sample must be diluted twice, and the re-measured value is multiplied by the dilution factor to correct the result. The current blood services information system does not have a function to check that the measured value is the result of re-measurement or that the dilution factor is appropriate. Since the work is checked visually, the likelihood that the unit numbers may be wrong due to human error cannot be ruled out. There has been a long-awaited alternative method to avoid such risky re-measurement operations from inspection and manufacturing sites. The XS-1000i determines platelet volume using the direct current detection method and displays the PLT count. The XN-1000/BB, examined in this study, uses the FCM method which specifically stains platelets with a fluorescent dye to

discriminate the cell from other blood components and then displays the value. The volume of the sample to be measured in the XN-1000/BB was increased 4-fold compared to the XS-1000i to improve the sensitivity. Based upon our review, the XN-1000/BB can measure PLTs more accurately and with a higher sensitivity. The XN-1000/BB can measure a PLT count of $\geq 2,000 \times 10^3/\mu\text{L}$ without dilution, which is difficult using the XS-1000i. The PLT count exhibited good linearity in the range of 600 to $4,000 \times 10^3/\mu\text{L}$. High reproducibility was obtained even for samples with high-concentration PLT of approximately $3,600 \times 10^3/\mu\text{L}$. In addition, a good correlation was observed between the XS-1000i and the conventional method using routine samples. Therefore, the XN-1000/BB is a useful successor to the XS-1000i and can measure PLT samples of $\geq 2,000 \times 10^3/\mu\text{L}$ without the need for dilution. The measurement of PLTs in washed platelets is currently under investigation.

It is known that rRBCs contained in PC may cause antigen sensitization in ABO or RhD heterotypic transfusions. Therefore, some countries examine rRBCs in PC as a quality test and set an upper limit. Germany measures rRBC by the FCM method and sets the upper limit at $3,000/\mu\text{L}$, while the United Kingdom and the Netherlands both set the upper limit at $4,000/\mu\text{L}$ and $6,000/\mu\text{L}$ by appearance tests using color samples.^{10,11)} It has also been reported that a primary immune response to RhD may be induced at $800/\mu\text{L}$.¹²⁾ In Japan, when supplying HLA-matched platelets, it is sometimes necessary to supply PC with different ABO types.¹³⁾ Minimum Requirements for Biological Products¹⁴⁾ states that “PC shall not contain excessive red blood cells,” and when PC are produced, a visual examination is conducted. Any PC suspected of containing $\geq 2,500/\mu\text{L}$ of red blood cells

can be identified using the naked eye due to their reddish appearance.¹⁵⁾ In addition to such visual confirmation at the manufacturing site, rRBC measurements using the XS-1000i are performed as a product sampling test. In this sampling test, the authors infrequently found samples with red blood cell counts of $\geq 100,000/\mu\text{L}$, and these samples were re-measured visually using a microscope. However, since rRBCs are rarely measured, the XS-1000i is considered incapable of accurately measuring rRBCs in the PC. The XS-1000i has a lower limit of $10,000/\mu\text{L}$ for red blood cells, but the XN-1000/BB can display even lower minimum concentrations. While the XS-1000i discriminates RBCs by the direct current detection method, the XN-1000/BB separates blood cell components based on FCM principles. Therefore, the XN-1000/BB increases the number of measured blood cells by approximately 134 times that of the XS-1000i, thus enabling the measurement of minute numbers of RBCs. Based upon this study, the authors confirmed the accuracy of the rRBC measurement of 50 to $5,000/\mu\text{L}$ in PC with the XN-1000/BB. They found that the results were consistent with those obtained using the visual method. Therefore, the XN-1000/BB can accurately measure low RBC concentrations in PC, which are known to induce antigen sensitization according to global rRBC and RhD standards. The ability of an automated analyzer to obtain this measurement may eliminate the need for the current specimen inspection process.

The total HGB content of FTRC must be at least 12 g per 200 mL whole blood draw according to the Minimum Requirements for Biological Products.¹⁴⁾ Therefore, it is necessary to measure the HGB contained in FTRC at the time of delivery. Based on the average volume of one unit of FTRC (117.0 mL), the HGB that meets the Minimum Requirements for Biological Products is 10.3 g/dL. We investigated the measurement accuracy of the XN-1000/BB in a HGB range of 7 to 23 g/dL and found that it was consistent with the expected value of diluted samples on the XS-1000i. This indicates that the XN-1000/BB can be used to determine HGB levels in FTRC prior to shipment.

Ishihara et al. stated that in order to produce safe, high-quality, and standardized transfusion blood products, it is important to define and verify the

work process.¹⁶⁾ In the PLT measurement process, which affects the number of units of PC, it is important to specify in the SOP the time from specimen preparation to measurement. We examined the stability of the XN-1000/BB and the test tubes (polypropylene auto tubes) specified in the SOP for storage in test tubes over time. We confirmed that stable assay values were maintained for up to 24 hours after transferring specimens to the test tubes, supporting the report by Ishihara et al. In this report, the authors used specimens collected from PC bags on the day of blood collection or the next day. Therefore, it should be noted that the timing of specimen collection for PLT measurements may be different for future planned bacterial screening. In addition, the PLT measurement results in this paper were not multiplied by the recommended correction factor. When the XN-1000/BB is introduced, a correction factor should be applied to maintain traceability with previous automated hematology analyzers.

Since September 2022, rWBC tests for transfusion blood products have been conducted at each block blood center using the XN-1000/BB, while the XS-1000i is used to measure PLTs and rRBCs in PC, and HGB levels in FTRC. Currently, two types of automated hematology analyzers are used in practice. This has increased the need for complicated work processes including maintenance of instruments, management of reagents, and creation/oversight of needed documents.

In this study, the authors demonstrated that the XN-1000/BB is a useful next-generation quality control device for transfusion blood products to measure PLTs and rRBCs in PC, and HGB levels in FTRC. The XN-1000/BB can measure rWBCs in blood products, PLTs and rRBCs in PC, and HGB levels in FTRC for a single unit. The XN-1000/BB is expected to improve workflow efficiency and simplify the measurement process for transfusion blood products. Furthermore, early introduction of this analyzer may reduce laboratory costs for equipment maintenance and reagent usage.

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References

- 1) Ochi Y, Maruki Y, Jia Y, et al. Overview of the XN-Series multiparameter automated hematology analyzer. *Sysmex Journal*. 2011; 34 Suppl.2: 31–46. (Japanese)
- 2) Abe T, Kobayashi S, Osaki A, et al. Basic study of the XN-Series multiparameter automated hematology analyzer and its clinical reference range. *Sysmex Journal*. 2011; 34 Suppl.2: 72–81. (Japanese)
- 3) Arisawa F, Wakamoto S, Akino M, et al. Evaluation of the Blood Bank mode software of Sysmex XN-1000 hematology analyzer for counting residual red blood cells and platelets in platelet concentrates, and residual white blood cells in leucocyte-reduced whole blood. *Sysmex Journal International*. 2021; 31 (2): 18–27.
- 4) Branco RA, Cavagnetto C, Willmott L, et al. The use of a hematology analyzer with a new generation of software as an alternative to flow cytometry for enumerating residual white blood cells in blood components. *Transfusion*. 2020; 60 (1): 155–164.
- 5) Cavagnetto C, Alejo Blanco R, McKenna H, et al. Residual red cells in blood components: A multisite study of fully automated enumeration using hematology analyzer. *Transfusion*. 2021; 61 (2): 568–578.
- 6) Mack S, Vassallo RR. Component residual white blood cell counting made easy? *Transfusion*. 2020; 60(1): 4–6.
- 7) Lagerber JW, de Korte D. Improved accuracy in counting residual white blood cells in red cell concentrates using new blood bank mode software of SYSMEX XN-1000 hematology analyzer. *Transfusion*. 2020; 60(10): 2456–2457.
- 8) Horii T. Question 11: What is carry-over in immunoserology and how can it be prevented? *Journal of Clinical Laboratory Medicine*. 2012; 56: 1172–1173. (Japanese)
- 9) International Council for Standardization in Haematology, Writing Group; Briggs C, et al. ICSH guidelines for the evaluation of blood cell analysers including those used for differential leucocyte and reticulocyte counting. *Int J Lab Hematol*. 2014; 36(6): 613–627.
- 10) Cardigan R, New HV, Estcourt L, et al. International Forum on Policies and Practice for Transfusion of ABO and RhD Non-Identical Platelets: Summary. *Vox Sang*. 2022; 117(1): 136–144.
- 11) Cardigan R, New HV, Estcourt L, et al. International Forum on Policies and Practice for Transfusion of ABO and RhD Non-Identical Platelets: Responses. *Vox Sang*. 2022; 117(1): e1–e20.
- 12) Klein HG, Anstee DJ. *Mollison's blood transfusion in clinical medicine: 11th Edition*. Blackwell Publishing. 2005; 187.
- 13) Fujiwara k, Lee E, Ishida A, et al. Guide to the use of HLA-matched platelets. *Japanese Journal of Transfusion and Cell Therapy*. 2021; 67: 573–588. (Japanese)
- 14) Ministry of Health, Labour and Welfare. Minimum Requirements for Biological Products. Ministry of Health, Labour and Welfare Notice No. 190, 2023; 200. (Japanese)
- 15) Akino M, Homma C, Kato T, et al. Appearance verification of blood products for transfusion. *Journal of the Society for Japanese Blood Programme*. 2013; 36(1): 9–22. (Japanese)
- 16) Ishihara T, Akino M, Homma C, et al. Verification of platelet concentration measurement process affecting concentrated platelet units. *Journal of the Society for Japanese Blood Programme*. 2012; 35(1): 57–63. (Japanese)