Evaluation of Leukocyte-Depleted Blood Components from Citrate Phosphate Dextrose / Saline Adenine Glucose–Mannitol Quadruple Blood Bag with an Integrated Leukocyte Filter

Ubonwon Charoonruangrit, M.D.[1], Panwadee Tejawong, B.Sc.[2], Jutamas Sangsuemoon, B.Sc.[2], Phuping Pratchaya, B.Sc.[2]
[1]Department of Clinical Pathology, School of Medicine, Mae Fah Luang University, Chiang Rai, Thailand 57100
[2]Blood Bank Service, Division of Clinical Pathology, Medical Center Hospital, Mae Fah Luang University, Chiang Rai, Thailand 57100
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Abstract:

Background: Leukocyte-depleted blood components are widely used to reduce transfusion-related adverse reactions associated with residual leukocytes. When a new blood bag system is introduced into routine practice, evaluation of the quality of the resulting blood components is necessary to ensure compliance with the National Standards Criteria.

Objectives: This study aimed to evaluate leukocyte-depleted blood components, including leukocyte-depleted packed red cells in additive solution (LDPRC) and leukocyte-depleted fresh frozen plasma (LDFFP), prepared using a citrate phosphate dextrose/saline adenine glucose- mannitol (CPD/SAG-M) quadruple blood bag with an integrated leukocyte filter, and to evaluate the blood components quality according to the National Standards Criteria.

Materials and Method: This descriptive evaluation study was conducted at the Blood Bank, Division of Clinical Pathology Mae Fah Luang University Medical Center Hospital. Whole blood was collected using CPD/SAG-M quadruple blood bags with an integrated leukocyte filter and processed into LDPRC and LDFFP. Evaluation was done in accordance with the National Standards Criteria for approval of validation of blood component characteristic, including component volume, hemoglobin content, residual white blood cell (rWBC) count, and hemolysis during storage. Residual WBC enumeration was performed using an automated hematology analyzer in body fluid mode based on flow cytometric principles.

Results: All LDPRC units met the criteria for residual leukocyte content and other parameters throughout the storage period. Hemolysis remained within specified limits up to 42 days of storage. LDFFP units also complied with the criteria. Analysis of factor VIII activity is currently in progress.

Corresponding author: Ubonwon Charoonruangrit, M.D.
Department of Clinical Pathology, School of Medicine,
Mae Fah Luang University, Chiang Rai, Thailand 57100
E-mail: Ubonwon.cha@mfu.ac.th
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Conclusion: Leukocyte-depleted blood components prepared using the evaluated CPD/SAG-M quadruple blood bag with an integrated leukocyte filter met the National Standards Criteria, supporting the suitability of this system for routine blood component preparation in a hospital-based blood bank.

Keywords: Leukocyte-depleted blood components; Leukocyte-depleted packed red cells; Leukocyte-depleted fresh frozen plasma; Residual white blood cells; Quality control of blood components

Introduction

Leukocyte-depleted blood components are routinely used in transfusion practice to reduce febrile non-hemolytic transfusion reactions, HLA alloimmunization, and other adverse effects associated with residual leukocytes. These benefits result improvement of transfusion safety and clinical outcomes for patients who require repeated or high-risk transfusions, particularly those with chronic blood transfusions such as patients with thalassemia, as well as patients with hematologic malignancies or solid tumors undergoing intensive chemotherapy.[1-3] Various methods have been developed to reduce leukocyte content in blood components, including pre-storage whole blood leukocyte filtration.

In Thailand, the preparation and quality control of blood components must comply with National Standards for Blood Banks and Transfusion Services developed by the National Blood Centre, Thai Red Cross Society (NBC, TRCS)[1] and guidelines issued by relevant authorities. These standards specify acceptance criteria for residual leukocyte content, hemoglobin content, hemolysis during storage, and other key quality parameters. When a new blood bag system is introduced into routine use, evaluation of the resulting blood components is required to confirm compliance with these standards.

The objective of this study was to evaluate leukocyte-depleted blood components prepared using a CPD/SAG-M quadruple blood bag with an integrated whole blood leukocyte filter by assessing residual leukocyte counts and selected quality parameters of the final products in accordance with national standards and international guidelines.[4,5]

Materials and Method

Study Design and Blood Collection

This descriptive evaluation study was conducted at the Blood Bank, Department of Clinical Pathology Mae Fah Luang University Medical Center Hospital as a process-oriented evaluation. Whole blood was collected from voluntary non-remunerated donors in accordance with NBC, TRCS blood donation criteria1, using a CPD/SAG-M quadruple blood bag with an integrated whole blood leukocyte filter. The structure of the blood bag system is illustrated in Figure 1.

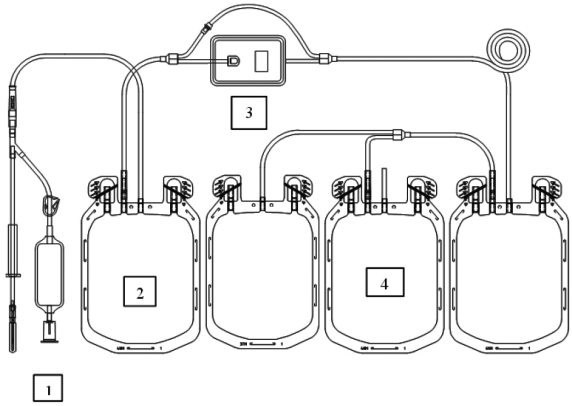

Figure 1 TRCS CPD/SAG-M quadruple blood bag 350 mL with whole blood leukocyte filter and sample diversion pouch
1 = Sample diversion pouch
2 = CPD blood bag
3 = Whole blood leukocyte filter
4 = SAG-M solution bag

Preparation of Leukocyte-Depleted Blood Components

A total of 17 whole blood units were collected from March 2025 to August 2025. During the initial implementation and process optimization phase, the first five units were excluded from analysis. The remaining 12 units were included for final evaluation. Whole blood units were filtered through the integrated leukocyte filter by gravity filtration to produce leukocyte-depleted whole blood according to the manufacturer's instructions. Following filtration, these units were centrifuged and separated into leukocyte-depleted packed red cells (LDPRC) and leukocyte-depleted fresh frozen plasma (LDFFP).

LDPRC units were supplemented with SAG-M additive solution and stored at 2–6 °C for up to 42 days and assessed for hemolysis, therefore they were not issued for clinical transfusions. LDFFP units were frozen within the specified time after collection and stored under appropriate freezing conditions. The overall study workflow is illustrated in Table 1.

Table 1 Study process

Step	Process	Method/Equipment	Out put
1	On Day 0: WB collection	CPD/SAG-M quadruple blood bag 350 mL with whole blood filter and sample pouch	WB
2	Measure WB weight, collection one sample segment.	Digital balance by OHAUS: RANGER2000	WB: weight(g), volume (mL)
3	Measure Hb and Hct of WB	Automatic blood cell counter by Mindray CAL6000: BC6200	WB: Hb (g/dL, g/unit), Hct (%)
4	Store WB at room temperature for at least 2 hours.		

Table 1 Study process (con.)

Step	Process	Method/Equipment	Output
5	Filter WB to obtain LDWB	As in step 1: Gravity filtration	LDWB
6	Measure LDWB weight, collection two sample segments.	As in step 2	LDWB: weight (g), volume (mL)
7	Measure Hb, Hct, cell count	As in step 3: Cell count use BF mode	LDWB: Hb (g/dL, g/unit), Hct (%), WBC (10^9/uL), residual leukocyte (10^9/unit)
8	Centrifuge LDWB Heavy spin at 5,102 g for 10 min.	Refrigerated centrifuge THERMO FISHER SCIENTIFIC: SORVALL LEGEND XTR	
9	Extract to separate red cell and plasma and store	Extractor, blood bank freezer	LDPRC in CPD and LDFFP keep -20°c
10	Add SAG-M to LDPRC	As in step 1	LDPRC in CPD/SAG-M
11	Measure LDPRC in CPD/SAG-M weight	As in step 2	LDPRC: weight (g), volume (mL)
12	Aseptic transfer LDPRC 15 mL into transfer bag	Transfer bag and sterile connecting device process*	15 mL LDPRC samples
13	Keep LDPRC at 4C (2 – 6 °C) to Day 14 and Day 42	Blood bank refrigerator 2-6 °C	
14	Transfer LDPRC sample to test tube 5 mL, 3 tubes	Polyethylene tube 12x75 mm.	
15	Tube 1: Measure Hb, Hct, cell count	As in step 7	LDPRC: Hb (g/dL, g/unit), Hct (%), WBC (10^9/uL), residual leukocyte (10^9/unit)
16	Tube 2 and 3 closes with parafilm centrifuge at 4200 rpm, 15 min at 4 °C	Centrifuge: THERMO FISHER SCIENTIFIC; HERAEUS CRYOFUGE 16 CENTRIFUGE	
17	Collect supernatant plasma and measure Hb	As in step 3	plasma Hb
18	Calculate % Hemolysis	%Hemolysis = [(100-Hct)/ Total Hb]x Plasma Hb	%Hemolysis on Day 0
19	On Day 14: Repeat step 12	As in step 18	%Hemolysis on Day 14
20	On Day 42: Repeat step 12	As in step 18	%Hemolysis on Day 42

WB = Whole blood, Hb = Hemoglobin, Hct = Hematocrit, LD = Leukocyte depleted, PRC = Packed red cell, FFP = Fresh frozen plasma, BF= Body fluid, * Transfer bag (JMS Transfer Pack; Sterile nonpyrogenic non-toxic 300 mL capacity), Automatic benchtop tube sealer blood bag tube welder; TSCD®-II Terumo

Table 2 Criteria for approval of blood component quality and characteristics[1]

Criteria for Blood Component Quality and Characteristics

Blood components	Test items	Specification	% Passed criteria
Whole blood (WB)	Volume	364 – 434 mL	100%
	Hemoglobin	≥ 35 g/unit	100%
	Hematocrit*	-	-
Leukocyte depleted whole blood (LDWB)	Volume*	-	-
	Hemoglobin*	-	-
	Hematocrit*	-	-
	Residual leukocytes	< 1 x 10^6 /unit by count	90%
Leukocyte depleted packed red cell (LDPRC)	Volume	180 – 270 mL	100%
	Hemoglobin	≥ 32 g/unit	100%
	Hematocrit	50 -70 % (in additive solution)	100%
	Residual leukocytes	< 1 x 10^6 /unit by count	90%
	Hemolysis (day 0, 42)	< 0.8 % (at initial, end)	100%
Leukocyte depleted fresh frozen plasma (LDFFP)	Volume	≥ 150 mL	100%
	Factor VIII	≥ 0.7 IU/mL	100%
	Appearance	No abnormal color, No visible clots	100%
	Leakage	No leakage in any part of container	100%

*Measured for information only.

According to the National Standards[1], the criteria for blood component quality and characteristics are presented in Table 2.

Evaluation of leukocyte-depleted blood components included component volume, hemoglobin content, hematocrit, residual white blood cell count (rWBC), and percentage hemolysis during storage. Component volume was determined by weight measurement. Hemoglobin content and hematocrit were measured using Mindray BC-6200 automated hematology analyzer. Residual white blood cell counts (rWBC) was determined using the mentioned automated hematology analyzer in body fluid (BF) mode, which utilizes flow cytometric principles for cell detection and counting.[6] Hemolysis was assessed on Day 0, Day 14, and Day 42 of storage. The percentage hemolysis was calculated using the standard formula.[7,8] :

$$\%\text{Hemolysis} = [(100 - \text{Hct}) / \text{Total Hb}] \times \text{Plasma Hb}$$

LDFFP characteristics were preliminarily evaluated based on volume, visual appearance, and evidence of leakage. Factor VIII activity analysis is currently ongoing.

Results

A total of 17 whole blood units were collected during the study period. Of these,

12 units proceeded to final quality evaluation after exclusion of 5 units used during the initial implementation and process optimization phase.

Evaluation results of WB: All 12 units of WB prior to filtration met the criteria at 100% pass in both volume and hemoglobin content. The mean volume was 394.31 mL (range: 387.24–400.38 mL) and the mean hemoglobin content was 46.16 g/unit (range: 41.42–50.73 g/unit). The results are summarized in Table 3.

Table 3 Evaluation results of whole blood (WB) prior to leukocyte filtration (n = 12 units)

		WB				
		Weight (g)	**Volume (mL)**	**Hb (g/dL)**	**Hb (g/unit)**	**Hct (%)**
Specification			**364-434 mL**		**=>35 g/unit**	
Criteria pass			**100%**		**100%**	
		Results				
No. unit	397	449.5	392.86	12.6	49.5	38.6
No. unit	398	449.5	392.86	10.6	41.6	33.2
No. unit	417	447.3	390.76	10.6	41.4	33.4
No. unit	418	445.1	388.67	11.2	43.5	34.1
No. unit	419	443.6	387.24	12.4	48.0	38.5
No. unit	420	457.4	400.38	10.6	42.4	32.6
No. unit	421	455.6	398.67	11.6	46.2	37.2
No. unit	768	456.5	399.52	11.6	46.3	36.0
No. unit	769	449.9	393.24	12.9	50.7	38.9
No. unit	770	449.2	392.57	12.8	50.2	39.6
No. unit	771	454.5	397.62	12.2	48.5	38.3
No. unit	772	454.2	397.33	11.4	45.3	36.3
			100%		100%	
			pass		pass	

Evaluation results of LDWB: Fifty percent of LDWB met the specification; therefore, the acceptance criteria were not fully achieved. The mean rWBC was 1.144×10^6 cells/unit (range: 0–3.200×10^6 cells/unit). Detailed results are presented in Table 4.

Table 4 Evaluation results of leukocyte-depleted whole blood (LDWB) after filtration (n = 12 units)

LDWB								
		Weight (g)	Volume (mL)	Hb (g/dL)	Hb (g/Unit)	Hct (%)	WBC BF mode (10^3/uL)	rWBC BF mode (10^6/unit)
Specification								**<1x10^6 /unit**
Criteria pass								**90%**
Results								
No. unit	397	406.8	352.19	13.0	45.8	40.4	0.004	1.4088
No. unit	398	399.9	345.62	11.1	38.4	35.1	0.001	0.3456
No. unit	417	403.1	348.67	12.1	42.2	37.5	0.008	2.7893
No. unit	418	408.4	353.71	11.6	41.0	35.4	0.000	0.0000
No. unit	419	403.8	349.33	13.0	45.4	40.4	0.006	2.0960
No. unit	420	409.2	354.48	11.3	40.1	35.0	0.006	2.1269
No. unit	421	410.3	355.52	12.4	44.1	40.0	0.009	3.1997
No. unit	768	407.7	353.05	11.2	39.5	35.3	0.002	0.7061
No. unit	769	407.9	353.24	12.6	44.5	38.2	0.003	1.0597
No. unit	770	411.4	356.57	12.4	44.2	38.3	0.000	0.0000
No. unit	771	414.2	359.24	10.9	39.2	34.2	0.000	0.0000
No. unit	772	414.9	359.90	11.2	40.3	35.9	0.000	0.0000
								50%
								not pass

Evaluation results of LDPRC: All 12 units of LDPRC, which was added SAG-M to each unit, met the criteria at 100% pass in volume, hemoglobin content and rWBC. The mean volume was 210.53 mL (range: 197.81–224.76 mL). The mean hemoglobin content was 41.46 g/unit (range: 38.2–46.1 g/unit). The mean rWBC count was 0.00 × 10^6 cells/unit (range: 0.00–0.00 × 10^6 cells/unit). Component characteristics are shown in Table 5

Table 5 Evaluation results of Leukocyte-depleted packed red cell in SAG-M (LDPRC) (n = 12 units)

LDPRC Residual leukocyte (rWBC)								
		Weight (g)	**Volume (mL)**	**Hb (g/dL)**	**Hb (g/Unit)**	**Hct (%)**	**WBC BF mode (10^3/uL)**	**rWBC BF mode (10^6/unit)**
Specification			**180-270 mL**		**=>32 g/unit**			**<1x10^6/unit**
Criteria pass			**100%**		**100%**			**100%**
Results								
No. unit	397	273.0	224.76	20.5	46.1	63.7	0.000	0.0000
No. unit	398	249.4	202.29	18.9	38.2	59.5	0.000	0.0000
No. unit	417	256.6	209.14	19.3	40.4	60.0	0.000	0.0000
No. unit	418	251.7	204.48	19.8	40.5	60.9	0.000	0.0000
No. unit	419	268.9	220.86	20.8	45.9	65.3	0.000	0.0000
No. unit	420	244.7	197.81	20.4	40.4	63.5	0.000	0.0000
No. unit	421	271.6	223.43	19.1	42.7	61.5	0.000	0.0000
No. unit	768	251.3	204.10	19.0	38.8	60.6	0.000	0.0000
No. unit	769	258.2	210.67	20.6	43.4	62.5	0.000	0.0000
No. unit	770	262.3	214.57	20.2	43.3	63.1	0.000	0.0000
No. unit	771	252.0	204.76	18.7	38.3	59.1	0.000	0.0000
No. unit	772	257.0	209.52	18.9	39.6	60.7	0.000	0.0000
			100%		100%			100%
			pass		pass			pass

Percentage of hemolysis: LDPRC units were evaluated for %hemolysis on Day 0, 14 and 42 after blood collection. On Day 0, there was an error occurred on measuring process, therefore 10 units were evaluated and showed 0% hemolysis in all units. On Day 14, twelve LDPRC units showed mean percentage hemolysis at 0.08% (range: 0.00–0.31%) then on Day 42 showed slightly increasing of mean percentage hemolysis at 0.15% (range: 0.00–0.35%). The results are presented in Table 6,7, and 8

Table 6 Percentage hemolysis in LDPRC on Day 0 (n = 10 units)

LDPRC % Hemolysis Day 0					
		Total Hb (g/dL)	**Hct (%)**	**Plasma Hb (g/dL)**	**day 0**
Specification					**<0.8%**
Criteria					**100%**
Result					
No. unit	397	20.5	63.7	Error	Error
No. unit	398	18.9	59.5	Error	Error
No. unit	417	19.3	60.0	0.0	0.00
No. unit	418	19.8	60.9	0.0	0.00
No. unit	419	20.8	65.3	0.0	0.00
No. unit	420	20.4	63.5	0.0	0.00
No. unit	421	19.1	61.5	0.0	0.00
No. unit	768	19.0	60.6	0.0	0.00
No. unit	769	20.6	62.5	0.0	0.00
No. unit	770	20.2	63.1	0.0	0.00
No. unit	771	18.7	59.1	0.0	0.00
No. unit	772	18.9	60.7	0.0	0.00
					100%
					pass

Table 7 Percentage hemolysis in LDPRC on Day 14 (n = 12 units)

LDPRC % Hemolysis Day14					
		Total Hb (g/dL)	**Hct (%)**	**Plasma Hb (g/dL)**	**day 14**
Specification					**<0.8%**
Criteria					**100%**
Result					
No. unit	397	20.3	64.4	0.0	0.00
No. unit	398	19.1	60.9	0.1	0.20
No. unit	417	19.4	62.3	0.0	0.00
No. unit	418	19.9	62.3	0.0	0.00
No. unit	419	20.8	67.7	0.2	0.31
No. unit	420	20.3	64.1	0.1	0.18
No. unit	421	19.1	63.1	0.1	0.19
No. unit	768	19.1	61.8	0.0	0.00
No. unit	769	20.7	63.5	0.1	0.18
No. unit	770	20.2	64.4	0.0	0.00
No. unit	771	18.7	60.1	0.0	0.00
No. unit	772	18.9	62.0	0.0	0.00
					100%
					pass

Table 8 Percentage hemolysis in LDPRC on Day 42 (n = 12 units)

LDPRC % Hemolysis Day42					
		Total Hb (g/dL)	**Hct (%)**	**Plasma Hb (g/dL)**	**day 42 (end)**
Specification					**<0.8%**
Criteria					**100%**
Result					
No. unit	397	20.5	69.0	0.1	0.15
No. unit	398	19.0	63.9	0.0	0.00
No. unit	417	19.5	65.0	0.0	0.00
No. unit	418	19.9	64.7	0.0	0.00
No. unit	419	20.7	70.1	0.2	0.29
No. unit	420	20.5	66.4	0.0	0.00
No. unit	421	19.2	66.6	0.2	0.35

Table 8 Percentage hemolysis in LDPRC on Day 42 (n = 12 units) (con.)

LDPRC % Hemolysis Day42					
		Total Hb (g/dL)	**Hct (%)**	**Plasma Hb (g/dL)**	**day 42 (end)**
Result					
No. unit	768	19.4	67.4	0.2	0.34
No. unit	769	20.9	68.7	0.1	0.15
No. unit	770	20.3	70.3	0.1	0.15
No. unit	771	18.8	64.1	0.1	0.19
No. unit	772	19.0	66.7	0.1	0.18
					100%
					pass

Table 9 Evaluation results of leukocyte-depleted fresh frozen plasma (LDFFP) (n = 12 units)

LDFFP					
		Volume (mL)	**Factor VIII (IU/mL)**	**Appearance**	**Leakage**
Specification		=> 150 mL	=>0.7 IU/mL	no abnormal color, no visible clot	no
Criteria pass		100%	100%	100%	100%
Result					
No. unit	397	182.32	NA	PASS	PASS
No. unit	398	207.77	NA	PASS	PASS
No. unit	417	201.00	NA	PASS	PASS
No. unit	418	208.00	NA	PASS	PASS
No. unit	419	200.00	NA	PASS	PASS
No. unit	420	218.00	NA	PASS	PASS
No. unit	421	191.00	NA	PASS	PASS
No. unit	768	222.00	NA	PASS	PASS
No. unit	769	216.00	NA	PASS	PASS
No. unit	770	214.00	NA	PASS	PASS
No. unit	771	225.00	NA	PASS	PASS
No. unit	772	220.00	NA	PASS	PASS
		100%	On going	100%	100%
		pass		pass	pass

Evaluation results of LDFFP: All 12 LDFFP units met the criteria preliminary at 100% pass in volume, appearance and leakage observation. The mean volume of LDFFP was 208.76 mL/unit (range: 182.32–225.00 mL). No abnormal color or visible clots observed, and no leakage detected. Analysis of factor VIII activity is ongoing process. Detailed results are presented in Table 9.

Discussion

The present study demonstrated that leukocyte-depleted blood components prepared using a CPD/SAG-M quadruple blood bag with an integrated leukocyte filter consistently met National Quality Standards, particularly for leukocyte-depleted packed red cells (LDPRC), which achieved full compliance in terms of volume, hemoglobin content, and residual white blood cell (rWBC) levels. These findings indicate that the overall blood component production process is robust and effective under routine operational conditions.

This study was designed as a process-oriented evaluation rather than a formal blood bag system validation, which is typically conducted by manufacturers or reference institutions in accordance with international guidelines. According to the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC), data supporting the evaluation of blood pack systems may be derived from the manufacturer, and blood establishments are not required to repeat full validation but are expected to perform local installation and process validation under routine operational conditions to confirm that blood components produced using this system meet established quality standards within our institution.

In addition, the blood bag system evaluated in this study is produced by the National Blood Centre, Thai Red Cross Society and has been approved as a medical device by the Thai Food and Drug Administration (approval date: 29 July 2025; valid until 31 December 2029). This indicates that its safety and performance, including the intrinsic characteristics and leukocyte filter, have been previously assessed through regulatory processes. The sample size decided in this study is consistent with routine quality control practices in blood banks, where representative sampling is performed to ensure compliance with quality specifications, as recommended by international standards such as AABB and EDQM.4,5 The recommended number is about 1% of blood component production or not less than 10 units. Therefore, the number of units in this study is appropriate for its intended purpose as a process-oriented quality assessment under routine operational conditions.

All whole blood prior to filtration (WB) met acceptance criteria, reflecting the effectiveness of donor selection, blood collection procedures, and process control during blood donation and collection. However, 50% of leukocyte-depleted whole blood (LDWB), met acceptance criteria on residual white blood cell (rWBC). This observation suggests variability in leukocyte removal efficiency during the whole blood filtration step. Potential contributing factors include leukocyte filter performance, filtration technique, time interval between collection and filtration, and environmental conditions during processing. These findings indicate the need for ongoing monitoring and process review at the LDWB filtration stage to improve consistency in routine practice.

The leukocyte reduction performance observed in this study is consistent with previous reports demonstrating that modern leukocyte filtration systems can achieve residual white blood cell levels of $\leq 1 \times 10^6$ cells/unit, which is widely

accepted as the international standard.[4,5] In the present study, all LDPRC units showed undetectable or extremely low rWBC levels, indicating effective leukocyte removal comparable to established leukocyte filtration technologies.

Similarly, the percentage hemolysis observed throughout storage remained well below the acceptable threshold (<0.8%), with a gradual increase over time, which is consistent with expected storage-related changes in red blood cells. These findings agree with previously published studies reporting low hemolysis levels during storage of packed red cells under appropriate conditions[7,8], supporting the adequacy of the additive solution, storage conditions, and product handling in this study.

For leukocyte-depleted fresh frozen plasma (LDFFP), all evaluated parameters met the specified criteria, indicating that the plasma component derived from this system is preliminary acceptable for routine use. The analysis of factor VIII activity is ongoing and will provide additional information regarding the functional quality of the plasma component.

Residual white blood cell enumeration is conventionally performed using a Nageotte chamber or flow cytometer, which are considered reference methods. In this study, rWBC measurements were performed using an automated blood cell counter (Mindray CAL-6000: BC-6200), routinely used in the central laboratory for hematology and body fluid cell analysis. This analyzer applies flow cytometric principles combined with fluorescence detection and includes a body fluid (BF) mode designed for low cell count analysis. According to manufacturer specifications[6], the background/blank count for WBC in BF mode is $\leq 0.001 \times 10^9$/L, approximately 100-fold lower than that of the complete blood count (CBC) mode ($\leq 0.1 \times 10^9$/L). Therefore, BF mode was selected for preliminary rWBC assessment in this evaluation.

Based on the manufacturer's Clinical Performance Evaluation Report (CE) for the Mindray BC-6000 series, the limit of detection (LoD) for WBC measurement in BF mode is 0.003×10^9/L. Using the allowable maximum LDPRC volume specified by national criteria (180–270 mL), a worst-case scenario calculation based on a volume of 270 mL (0.27 L) yields an LoD of 0.81×10^6 cells per unit. When compared with the criterion for LDPRC (rWBC $\leq 1 \times 10^6$ cells per unit), the calculated LoD remains below the specified threshold. These findings indicate that the BC-6200 analyzer operated in BF mode provides sufficient analytical sensitivity for preliminary confirmation of LDPRC quality and is suitable for use in routine quality control.

Nevertheless, to ensure full compliance with national and international standards[4,5], the blood bank plans to conduct a comparative evaluation of rWBC measurements obtained using the BC-6200 analyzer and a reference flow cytometry method in the future. This comparison will further validate the accuracy and reliability of automated cell counting for quality assessment of leukocyte-reduced blood components, including leukocyte-poor packed red cells, leukocyte-depleted packed red cells, and single-donor platelets, to support routine blood bank operations.

In addition to technical performance, the evaluated blood bag system offers practical advantages in routine blood donation settings, particularly its 350 mL collection volume, which is suitable for donors with lower body weight such as 45-50 kg. who constitute a significant proportion of the donor population in our setting. This feature may enhance donor safety and expand donor eligibility while maintaining product quality.

Overall, the findings of this study support the use of this system for routine blood collection and blood component

preparation, resulting in leukocyte-depleted blood components that meet established quality standards.

Conclusion

Leukocyte-depleted blood components prepared using a CPD/SAG-M quadruple blood bag with an integrated leukocyte filter met National Standards for residual leukocyte content and other key component parameters. The use of this system supports the provision of safer blood components for patients by minimizing leukocyte-related transfusion reactions while maintaining acceptable component quality. This is particularly relevant for patient groups who are vulnerable to transfusion-related complications, such as chronically transfused patients with thalassemia and patients with oncologic diseases, indicating the suitability of this system for routine preparation of leukocyte-depleted blood components in a hospital-based blood bank.

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Conflict of Interest

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