Product fact sheet

Blood Bank mode

Version 1.0

Manufacturer information

Sysmex Corporation
www.sysmex-europe.com

Summary

Blood component safety is key in transfusion medicine and blood product manufacturing. Therefore, high standards during the whole process from donor qualification to quality monitoring of the products are required. Especially residual cell enumeration is important for process quality control. Until now, haematology analysers could not reach the lower limit of quantification required for this.

The Blood Bank mode[1] is an exclusive analysis mode of XN-Series analysers to analyse blood products such as red blood cell concentrates and platelet concentrates for blood transfusion. The advanced technology used in this mode enables counting of RBC and PLT in dense blood packs as well as the determination of reliable residual WBC and RBC counts.

The Blood Bank mode is an optional application and software licence registration is required for its activation on applicable XN-Series configurations.

[1] Note Blood Bank mode is not CE-IVD marked and thereby it is not to be used for diagnostic purposes.

Productivity

- Decreased workload by using one single analyser for multiple parameters
- Fully automated and standardised measurement
  - Automated background check analysis to avoid carryover
  - Specific profiles tailored for different blood products
- Sampler analysis capability ensures high throughput for blood banks/transfusion laboratories
- Easy mode switching function between Whole Blood[2] and Blood Bank mode

[2] This is a dedicated mode for human whole blood analysis.

Ordering information

Item code	Item	Qty
ZE004088	Blood Bank Mode Licence	1

Available configurations for Blood Bank mode

Blood Bank mode is applicable to XN-1000 and XN-2000 configurations. The basic prerequisites of the XN analysis module are described in the table below. Please note that

- in case of an XN-2000, Blood Bank mode licence activation on each analyser is mandatory.
- SA-10 sampler unit is the only supported sampler for an XN-1000 configuration.

XN-1000   XN-2000

Analysis module	Default applications				Required applications	
XN-10	XN-CBC	XN-DIFF			RET	PLT-F
XN-20	XN-CBC	XN-DIFF	RET	WPC	PLT-F	

Profile overview

Profile	Description
RBC Pack	Enumerating RBC and measuring HGB and HCT in red blood cell packs
RBC Pack + Res. Cell[3]	Enumerating RBC and measuring HGB and HCT, additionally counting residual WBC in red blood cell packs
PLT Pack	Enumerating PLT in platelet packs
PLT Pack + Res. Cell[3]	Enumerating PLT, additionally counting residual WBC and RBC in platelet packs

[3] 'Res. Cell' indicates 'residual cells' in blood packs.

Product specifications

Feature	Description
Analysis mode	Blood Bank mode
Sampling mode	• Sampler analysis • Manual analysis
Analysis time	
RBC Pack RBC Pack + Res. Cell PLT Pack PLT Pack + Res. Cell	• 45 sec (< 1 min) • 109 sec (< 2 min) • 58 sec (≈ 1 min) • 186 sec (≈ 3 min)
Technologies	• Fluorescence flow cytometry • Hydrodynamically focused DC detection method • Cyanide-free SLS haemoglobin method
Analysis parameters	
RBC Pack & RBC Pack + Res. Cell	• RBC – Red blood cell count • HGB – Haemoglobin concentration • HCT – Haematocrit • WBC[4] – White blood cell count
PLT Pack & PLT Pack + Res. Cell	• PLT – Platelet count • WBC[4] – White blood cell count
Research parameters	
RBC Pack & RBC Pack + Res. Cell	• MCV – Mean corpuscular volume • MCH – Mean corpuscular haemoglobin • MCHC – Mean corpuscular haemoglobin concentration • RDW-SD – Red blood cell distribution width (standard deviation) • RDW-CV – Red blood cell distribution width (coefficient variation)
PLT Pack & PLT Pack + Res. Cell	• IPF% - Immature platelet fraction ratio • IPF# - Immature platelet fraction count • PDW – Platelet distribution width • MPV – Mean platelet volume • RBC-O[4] – Red blood cell count from the RET channel • RBC-I[5] – Red blood cell count from the RBC/PLT channel • HGB – Haemoglobin concentration
Sampler unit capacity	• 10 racks (100 samples)

External output functionalities[6]	• Output to the printer (GP/LP) • Output in CSV format

Quality control and calibrator materials

XN Check Level 1 XN Check Level 2 XN Check Level 3	• QC material for monitoring the Whole Blood mode in three concentration levels
XN Cal	• Calibrator material
XN Cal PF	• Calibrator material for PLT-F channel

[4] Analysed when residual cell count analysis is performed.

[5] Reporting this parameter depends on one Service Setting.

[6] SUIT XN and *Extended* IPU integration are under development.

Aspiration and required sample volume

Profile	Analysis type	Tube type	Aspiration volume	Required sample volume
RBC Pack & RBC Pack + Res. Cell[7]	Sampler analysis	Closed tube	150 µL	1 mL
	Manual analysis	Closed tube		1 mL
		Open tube		400 µL
		Micro collection tube		260 µL
PLT Pack & PLT Pack + Res. Cell[7]	Sampler analysis	Closed tube	205 µL	1 mL
	Manual analysis	Closed tube		1 mL
		Open tube		400 µL
		Micro collection tube		300 µL

[7] 'Res. Cell' indicates 'residual cells' in blood packs.

Performance specifications

Feature	Description
Throughput	
RBC Pack	• 79 samples/hour
RBC Pack + Res. Cell	• 33 samples/hour
PLT Pack	• 62 samples/hour
PLT Pack + Res. Cell	• 19 samples/hour
Analysis range	
WBC	• 0.0000 – 0.3500 x10³/µL
RBC[8]	• 0.00 – 8.60 x10⁶/µL
HGB	• 0.0 – 26.0 g/dL • 0.0 – 16.1 mmoL/L
HCT	• 0.0 – 75.0%
PLT[9]	• 0 – 5,000 x10³/µL

Limit of Blank (LoB) / Limit of Detection (LoD) / Limit of Quantitation (LoQ)		LoB	LoD	LoQ
WBC	(x10³/µL)	0.0000	0.0020	0.0020
RBC	(x10⁶/µL)	0.00	0.01	0.01
HGB	(g/dL)	0.0	0.1	0.1
HCT	(%)	0.0	0.1	0.1
PLT	(x10³/µL)	0	1	1

Precision (repeatability)	
WBC	• ≤ 40.0% (0.0020 – 0.0050 x10³/µL) • ≤ 20.0% (0.0051 – 0.0150 x10³/µL) • ≤ 10.0% (0.0151 – 0.0300 x10³/µL) • ≤ 7.0% (≥ 0.0301 x10³/µL)
RBC[8]	• ≤ 1.5% (≥ 4.00 x10⁶/µL)
HGB	• ≤ 1.0%
HCT	• ≤ 1.5%
PLT[9]	• ≤ 5.0% (20 – 99 x10³/µL) • ≤ 2.5% (≥ 100 x10³/µL)

Precision (intermediate precision / reproducibility)	
WBC	• ≤ 35% (XN Check BF Level 1) • ≤ 25% (XN Check BF Level 2)
RBC[8]	• ≤ 5% (XN Check Level 1) • ≤ 5% (XN Check Level 2) • ≤ 5% (XN Check Level 3)
HGB	• ≤ 4% (XN Check Level 1) • ≤ 3% (XN Check Level 2) • ≤ 3% (XN Check Level 3)
HCT	• ≤ 10% (XN Check Level 1) • ≤ 10% (XN Check Level 2) • ≤ 10% (XN Check Level 3)
PLT[9]	• ≤ 45% (XN Check Level 1) • ≤ 30% (XN Check Level 2) • ≤ 15% (XN Check Level 3)

Accuracy	
WBC	• Correlation coefficient r ≥ 0.95 Slope 0.9 – 1.1
RBC[8]	• within ± 2% or ± 0.03 x10⁶/µL
HGB	• within ± 2% or ± 0.2 g/dL
HCT	• within ± 3% or ± 1.0% HCT
PLT[9]	• within ± 5% or ± 10 x10³/µL

Linearity	
WBC	• R² ≥ 0.95 (0 – 0.350 x10³/µL)
RBC[8]	• within ± 2% or ± 0.03 x10⁶/µL (0 – 8.00 x10⁶/µL) • within ± 4% or ± 0.06 x10⁶/µL[10] (8.01 – 8.60 x10⁶/µL)
HGB	• within ± 2% or ± 0.2 g/dL (0 – 25.0 g/dL) (0 – 15.5 mmoL/L) • within ± 5% or ± 0.5 g/dL[10] (25.1 – 26.0 g/dL) (15.6 – 16.1 mmoL/L)
HCT	• within ± 3% or ± 1.0% HCT (0 – 75%)
PLT[9]	• within ± 5% or ± 10 x10³/µL (0 – 1,000 x10³/µL) • within ± 6%[10] (1,001 – 5,000 x10³/µL)

Carryover	
WBC	• ≤ 0.01%
RBC[8]	• ≤ 1.0%
HGB	• ≤ 1.0%
HCT	• ≤ 1.0%
PLT[9]	• ≤ 1.0%

[8] RBC count from the RBC/PLT channel.

[9] PLT count from the PLT-F channel.

[10] Verification using stabilized substances

For detailed information please always refer to 'Blood Bank mode Instructions for Use' document.

For detailed information about XN-10 and XN-20 analysis module please refer to the respective Product Fact Sheets.