

sysmex India-Pvt. Ltd.

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 Web: https://www.sysmex.co.in
 GST Reg. No: 27AADCS1551J1ZC Co. Reg. No: ABC



CSR No.: WO-100210433
 Revision No.:

Customer Service Report

Customer Name	Pravara Institute of Medical Sciences		
Contact Person	Dr. Nikhil Deshpande		
Installation Date	17/07/2020	Login Date/Time	29/12/2021 04:47:00 PM
Equipment ID	10117579	FSR Name	Amol Hole
Model	XN-10	From Date/Time	29/12/2021 07:51:40 PM
Serial No.	39934	To Date/Time	29/12/2021 10:29:00 PM
Total Cycle Count	63,816	Case No.	CAS-113795-D3P4R5

Defect Analysis	
Issue Code	Cause Code
Described in additional info [XN series]	Described in add info [XN series - Mainunit]
Issue	Cause
Perform Calibration	Perform Calibration

Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
Test Calibration Task	Completed		
Check Blank	Completed	0	0
Perform RBC Clog	Completed	99	100
Perform HGB Blank	Completed	5563	4969
Perform Aspiration Blank	Completed	5501	5063
Check Aspiration Span with Control L2, Lot No.-13291102, Exp-13-02-2022	Completed	6884	6884
Perform Sensitivity Adjustment with calibrator lot No.-13332101, Exp-2022-01-02.	Completed		
Perform Calibrator Calibration and PD Mode Calibration with calibrator XN-CAL, lot No.-13332101, Exp-2022-01-02.	Completed		
Perform QC L1(Lot No. QC-13281101, Exp-13-02-2022), L2(Lot No. QC-13291102, Exp-13-02-2022), L3(Lot No. QC-13261103, Exp-13-02-2022).	Completed		

Approved by

S. P. J. Joshi

Incharge
 CCL- Biochemistry
 PMT, RMC, Loni

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Contact Person	Dr. Nikhil Deshpande		
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Equipment ID	10117579	FSR Name	Amol Hole
Model	XN-10	From Date/Time	29/12/2021 07:51:40 PM
Serial No.	39934	To Date/Time	29/12/2021 10:29:00 PM
Total Cycle Count	63,816	Case No.	CAS-113795-D3P4R5

Remarks

Perform Calibration

Items Consumed

Product ID	VPN	Product Description	QTY	UOM
------------	-----	---------------------	-----	-----

Name:- Amol Hole

Acknowledged By : Dr. Nikhil Deshpande

Sign:

Sign :

Date: 30/12/2021 10:30:03 AM

Date: 30/12/2021 10:30:03 AM

Customer Confidential

Customer Service Report

Customer Name	Pravara Institute of Medical Sciences		
Contact Person	Dr. Nikhil Deshpande		
Installation Date		Login Date/Time	28/12/2021 10:24:00 AM
Equipment ID	10131182	FSR Name	Amol Hole
Model	SA-31	From Date/Time	29/12/2021 10:17:08 AM
Serial No.	11609	To Date/Time	29/12/2021 12:04:00 PM
Total Cycle Count	1	Case No.	CAS-113651-P4Y2H0

Defect Analysis

Issue Code	Cause Code
Issue	Cause
Preventative Maintenance	Preventative Maintenance


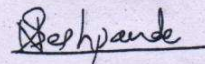
Action Taken	Action Code	Value Before Adjustment	Value After Adjustment
Done PM as per PM Checklist	Completed		

Remarks

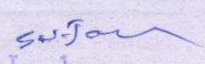
Done Preventative Maintenance as per standard procedure

Items Consumed

Product ID	VPN	Product Description	QTY	UOM
------------	-----	---------------------	-----	-----

Name:- Amol Hole	Acknowledged By : Dr. Nikhil Deshpande
Sign: 	Sign : 
Date: 30/12/2021 10:28:09 AM	Date: 30/12/2021 10:28:09 AM

Customer Confidential

Approved by 
 Incharge
 CCL- Biochemistry
 PMT, RMC, Loni

XN-3000/XN-3100(XR-3000) Preventive Maintenance Check List

Check item	When to perform	Check	Adjust / Clean	Replac ing	Remarks
XN(XR) front	Clean the inside of the instrument		<input checked="" type="checkbox"/>		
	Lubricate drive unit		<input checked="" type="checkbox"/>		
	Check position of rotation mechanical unit	<input checked="" type="checkbox"/>			
	Check and adjust blood detection sensor	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Check and adjust profile position	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Clean ID reader		<input checked="" type="checkbox"/>		
	Check and adjust barcode reading	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Check stand-alone operation	<input checked="" type="checkbox"/>			
	Clean instrument covers, table and belts		<input checked="" type="checkbox"/>		
SP front	Clean the inside of the instrument		<input checked="" type="checkbox"/>		
	Lubricate drive unit		<input checked="" type="checkbox"/>		
	Check position of rotation	<input checked="" type="checkbox"/>			
	Check and adjust blood detection sensor	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Check and adjust profile position	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Clean ID reader		<input checked="" type="checkbox"/>		
	Check and adjust barcode reading	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Check stand-alone operation	<input checked="" type="checkbox"/>			
	Clean instrument covers, table and belts		<input checked="" type="checkbox"/>		
Overall	Check program version	<input checked="" type="checkbox"/>			
	Back up setting values		<input checked="" type="checkbox"/>		
	Back up adjustment values		<input checked="" type="checkbox"/>		
	Check overall operation	<input checked="" type="checkbox"/>			

* The description in "When to perform" is just a rough indication, and differs depending on status of use.

* If nothing is described in "When to perform" column, the item has to be performed every time.

[Check item details]

Check item	Check result
Program version	00-16

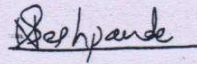
Facility name	Pravara Institute of Medical Sciences		
Instrument name	XN-3000 / XN-3100 / XR-3000	Serial NO.	11609
Service date	29 Dec 2021		
Name of service	Amol Hole		

Name:- Amol Hole

Sign: 

Date: 30/12/2021 10:28:09 AM

Acknowledged By : Dr. Nikhil Deshpande

Sign: 

Date: 30/12/2021 10:28:09 AM

Date: 6th Aug. 2021

Calibration Certificate

This is to certify that Automated Haematology Analyzer XN-10, Serial No: 39934 installed at "Pravara Institute of Medical Sciences, A/P: Loni Bk, Tal-Rahata, Dist-Ahmednagar, Pin: 413736" has been calibrated successfully.

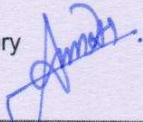
Calibration Done on: 5Aug2021
 Calibration Validity: 5 Aug 2021 to 4Aug 2022
 Calibration Due on: 4Aug 2022
 Material: XN-CAL (Lot No.-11932101, Expiry-2021-08-15)

Run	WBC-N	WBC-D	RBC	HGB	HCT	PLT
1	6.90	6.96	4.30	11.8	34.3	248
2	6.80	6.93	4.29	11.8	34.4	249
3	6.78	6.90	4.28	11.8	34.2	242
4	6.74	7.00	4.28	11.7	34.3	236
5	6.56	6.91	4.32	11.9	34.7	239
6	6.83	6.78	4.32	11.7	34.6	239
7	6.61	6.89	4.27	11.8	34.2	244
8	6.73	6.90	4.32	11.7	34.6	244
9	6.72	6.99	4.30	11.7	34.4	237
10	6.78	6.89	4.31	11.7	34.6	241
Mean	6.75	6.92	4.30	11.8	34.4	242
Target Value	6.833	6.997	4.353	11.9	34.78	243
CV%	1.5%	0.9%	0.4%	0.6%	0.5%	1.8%
Criteria	3.0%	3.0%	1.5%	1.0%	1.5%	4.0%

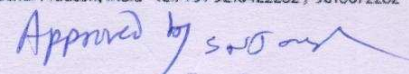
Calibration accepted for above mentioned values.

For Sysmex India Pvt. Ltd.

Authorized Signatory



Sysmex India Pvt Ltd (CIN: U33120MH1998PTC115943)
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 Factory Village Malpur, Pargana Dharampur, Nalagarh Road, Baddi - 173205, Dist. Solan, Himachal Pradesh, India Tel. +91-9218422282 / 9816672282
 www.sysmex.co.in

Approved by 

Incharge
 CCL- Biochemistry
 PMT, RMC, Loni

Approved by *[Signature]*
 Biochemistry
 RMG, Loni

05/08/2021 (Thu) 13:14
 Logon Name: PMT
 63.22 (Build 133)
 Data Browser
 Regist. Modify Validate
 Output Lower
 File Delete
 Menu QC File Work List Rule Explorer Browser
 Not Validated

05/08/2021 13:12:44
 BACKGROUNDCHECK
 Manual XN-3100-1-R

Item	Data	Unit	LL	UL
WBC	0.00	10 ³ /ul		
RBC	0.00	10 ⁶ /ul		
HGB	0.0	g/dL		
HCT	0.0	%		
MCV	---	fL		
MCH	---	pg		
MCHC	---	g/dL		
PLT	0	10 ³ /ul		
RDW-SD	---	fL		
RDW-CV	---	%		
PDW	---	fL		
MPV	---	fL		
P-LCR	---	%		
PCT	---	%		
NRBC#	---	10 ³ /ul		
NRBC%	---	%		

Item	Data	Unit	LL	UL
RET%		%		
RET#		10 ⁶ /ul		
IRF		%		
LFR		%		
MFR		%		
HFR		%		
RET-He		pg		

Item	Data	Unit	LL	UL
NEUT%		%		
LYMPH%		%		
MONO%		%		
EO%		%		
IG%		%		

Item	Data	Unit	LL	UL
IPF		%		

WB
 BACKGROUNDCHECK
 WB CBC DIFF RET PLT F
 XN-3100-1-L
 XN-3100-1-R
 WB
 Printer GROUP 0
 HOST

Approved by
S. J. O.
Incharge
Biochemistry
T, RMC, Loni

QC File	Work List	Patient List	Rule	Sample Explorer	Data Browser	Instructions for Use
LOGOFF	Exit IPU	History	Precision Check	Calibration	Analyzer Setting	IPU Setting
Version Information	GP Customize	RBC Clogs	RBC Clogs	Service Setting	NVRAM	

RBC Clogs

RBC Clogs Target	100	100	162
	Continue	Calc.	Close
		Send	

Normal Heater ON Auto Valid/Out ON

Service Menu X.m

Printer 0

HOST

WB

Append by
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 Biochemistry
 RMC, Loni

Sensitivity

Channel: HGB

HGB	Blank	5104	Blank Gain	158	x2
HGB	Target	0.0	Span Gain	174	
Calc.					
Aspiration Sensor	Blank	4941	Blank Gain	216	x2

Buttons: Send, Close

Grid of menu items:

- Sample Explorer
- Data Browser
- Instructions for Use
- Calibration
- Analyzer Setting
- IPU Setting
- Service Setting
- NVRAM

Grid of menu items:

- QC File
- Work List
- LOGOFF
- Exit IPU
- GP Customize
- Version Information

Bottom status bar:

Normal | Not ignore | Heater ON | Auto Valid/Out ON

XN-3100-1-L | X_m | WB | CBC | DIFF

XN-3100-1-R | X_m | WB | CBC | DIFF

Printer: 0 | HOST



Setting



Browser



Explorer



Rule



Work List



QC File



Menu

Menu icons: Menu, Setting, Browser, Explorer, Rule, Work List, QC File, Menu

Grid of main menu items:

- Instructions for Use (Question mark icon)
- Data Browser (Microscope icon)
- Sample Explorer (Magnifying glass icon)
- Rule (Table icon)
- Patient List (Person icon)
- Work List (Clipboard icon)
- QC File (Folder icon)
- Calibration (Target icon)
- Aspiration Sensor (Target icon)
- Exit IPU (Power icon)
- LOGOFF (Arrow icon)
- Analyzer Setting (Microscope icon)
- Version Information (Document icon)
- GP Customize (Scissors icon)
- Service Setting (Wrench icon)
- IPU Setting (Microscope icon)
- NVRAM (Chip icon)

Bottom status bar:

Normal | Not ignore | Heater ON | Auto Valid/Out ON

SERVICE MENU

Xm | >1 | WB | CBC | DIFF

Printer | GEMPL | 0

HOST

Aspiration Sensor

Please set Control(Level2). Then, push the start switch.

Value (Sample - blank)

Target Calc. Span(0-255)

Send Close

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Logon Name: systemx 05/08/2021 (Thu) 13:37

05/08/2021 12:31

- Menu
- QC File
- Work List
- Rule
- Explorer
- Browser
- Setting

Sensitivity

Channel: HGB

HGB	Blank	5108	Blank Gain	158	x2
HGB	Target	0.0	Span Gain	174	
Aspiration Sensor	Blank	4900	Blank Gain	216	x2

Buttons: Calc, Send, Close

- Sample Explorer
- Data Browser
- Instructions for Use
- Calibration
- Analyzer Setting
- IPU Setting
- Service Setting
- NVRAM

- QC File
- Work List
- LOGOFF
- Version Information
- GP Customize
- Exit IPU

Normal | Not Ignore | Heater ON | Auto Valid/Get ON

SERVICE MENU

Xm | Xn | Xp | Xq | Xr | Xs | Xt | Xu | Xv | Xw | Xx | Xy | Xz

WB | CBC | DIFF

Printer: 0

HOST

Menu of system functions:

- QC File
- Work List
- Rule
- Explorer
- Browser
- Menu
- Setting
- Instructions for Use
- Data Browser
- Sample Explorer
- Rule
- Patient List
- Work List
- Calibration
- Analyzer Setting
- IPU Setting
- Service Setting
- NVRAM
- LOGOFF
- Exit IPU
- GP Customize
- Version Information

Blood Sensor

Place two sample tubes on a rack as follows;
 Position 1: a empty tube
 Position 2: a tube containing 2mL of water.
 Then place the rack on the sampler, and press the Execute button.

Sensor gain1

Sensor gain2

Execute Close

Normal Not ignore Heater ON Auto Valid/Out ON

XN-3100-1-L
Xm

XN-3100-1-R
Xm

Printer 0

HOST

Sensitivity

Channel: WNR

WNR-X	182.2	Target	182.1	Calc.	SFL Gain	202	x4
WNR-Y	168.0	Target	167.7	Calc.	FSC Gain	117	x8
WNR-Z	113.9	Target	114.6	Calc.	SSC Gain	190	x4

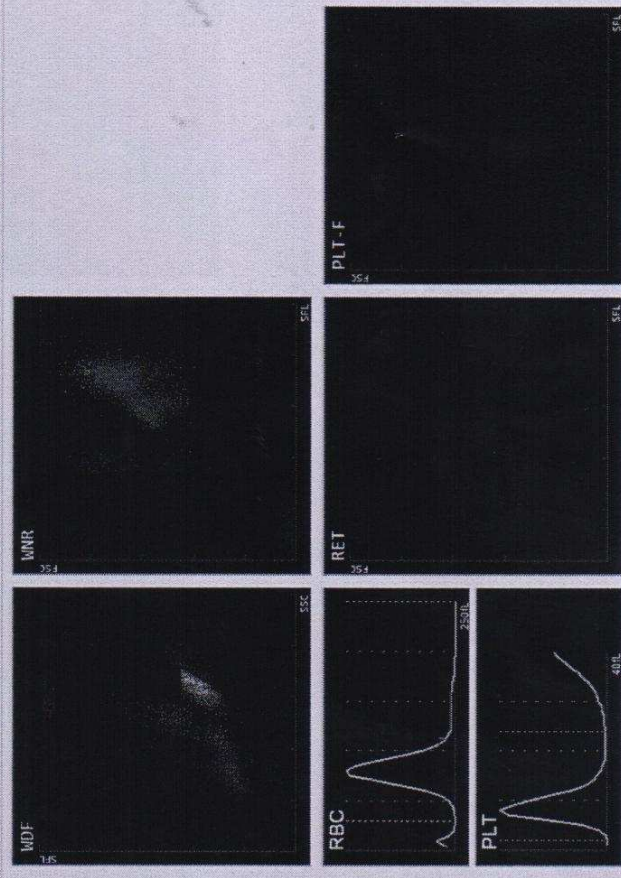
Send Close

CBC

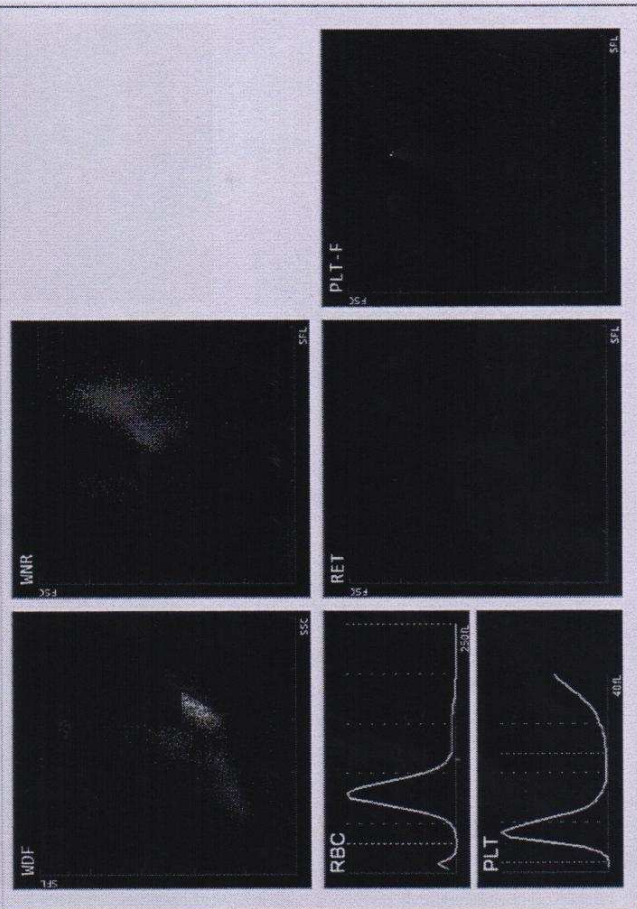
Item	Data	Unit	DIFF	Item	Data
WBC	6.59	10 ³ /uL	2.8	NEUT#	2.8
RBC	4.32	10 ⁶ /uL	1.9	LYMPH#	1.9
HGB	11.9	g/dL	0.8	MONO#	0.8
HCT	34.7	%	0.6	EO#	0.6
MCV	80.3	fL	42.1	BASO#	0.3
MCH	27.5	pg	29.1	NEUT%	42.1
MCHC	34.3	g/dL	12.1	LYMPH%	29.1
PLT	231	10 ³ /uL	10.1	MONO%	12.1
RDW-SD	46.4	fL	4.1	EO%	10.1
RDW-CV	16.1	%	0.7	BASO%	4.1
PDW	8.3	fL	10.1	IG#	0.7
MPV	9.2	fL	10.1	IG%	10.1
P-LCR	14.2	%			
PCT	0.21	%			
NRBC#	0.46	10 ³ /uL			
NRBC%	7.0	%			

PLT-F

Item	Data	Unit
RET%		%
RET#		10 ⁶ /uL
IRF		%
LFR		%
MFR		%
HFR		%
RET-He		pg



Manual (Open)
 XN-3100-1-R



Printer
 GPNP 0

HOST

Sensitivity

Channel: RBC/PLT

MCV: 80.3
 Target: 79.9
 Calc. 144
 RBC Gain

MPV: 9.2
 Target: 9.1
 Calc. 160
 PLT Gain

Send

Close

Item	Data	Unit	DIFF	Item	Data	Unit
WBC	6.59	10 ³ /uL	NEUT#	2.8		
RBC	4.32	10 ⁶ /uL	LYMPH#	1.9		
HGB	11.9	g/dL	MONO#	0.8		
HCT	34.7	%	EO#	0.6		
MCV	80.3	fL	BASO#	0.3		
MCH	27.5	pg	NEUT%	42.9		
MCHC	34.3	g/dL	LYMPH%	29.1		
PLT	231	10 ³ /uL	MONO%	12.2		
RDW-SD	46.4	fL	EO%	10.4		
RDW-CV	16.1	%	IG#	4.7		
PDW	8.3	fL	BASO%	0.7		
MPV	9.2	fL	IG%	10.1		
P-LCR	14.2	%				
PCT	0.21	%				
NRBC#	0.46	10 ³ /uL				
NRBC%	7.0	%				

Item	Data	Unit	DIFF	Item	Data	Unit
RET%		%	IPF			
RET#		10 ⁶ /uL				
IRF		%				
LFR		%				
MFR		%				
HFR		%				
RET-He		pg				

Service Menu
 X m

WB CBC DIFF

Normal Not ignore Heater ON Auto Valid/Out ON

XN-3100-1-L
 X m

WB

CBC

Item	Data	Unit
WBC	6.64	10 ³ /uL
RBC	4.36	10 ⁶ /uL
HGB	12.0	g/dL
HCT	34.8	%
MCV	79.8	fL
MCH	27.5	pg
MCHC	34.5	g/dL
PLT	239	10 ³ /uL
RDW-SD	46.0	fL
RDW-CV	16.0	%
PDW	8.7	fL
MPV	9.1	fL
P-LCR	14.0	%
PCT	0.22	%
NRBC#	0.42	10 ³ /uL
NRBC%	6.3	%

DIFF

Item	Data	Unit
NEUT#	2.91	10 ³ /uL
LYMPH#	1.91	10 ³ /uL
MONO#	0.81	10 ³ /uL
EO#	0.69	10 ³ /uL
BASO#	0.32	10 ³ /uL
NEUT%	43.8	%
LYMPH%	28.8	%
MONO%	12.2	%
EO%	10.4	%
BASO%	4.8	%
IG#	0.77	10 ³ /uL
IG%	11.6	%

PLT-F

Item	Data	Unit
RET%		%
RET#		10 ⁶ /uL
IRF		%
LFR		%
MFR		%
HFR		%
RET-He		pg

WBC Flag(s)

RBC Flag(s)

PLT Flag(s)

WNR

RET

RBC

PLT

Service Menu [Xm] [F] [P] [I] [R] [L] [B] [C] [B] [C] [B] [D] [I] [F]

Printer GP/PP 0

HOST

Approved by
S. S. S. S. S.
Incharge
Biochemistry
T.R.M.C, Loni

1/2

Calibrator Calibration

No.	WBC-N	WBC-D
1	6.76	6.95
2	6.90	6.96
3	6.80	6.93
4	6.78	6.90
5	6.74	7.00
6	6.56	6.91
7	6.83	6.78
8	6.61	6.89
9	6.73	6.90
10	6.72	6.99
11	6.78	6.89
Mean Value	6.75	6.92
SD	0.100	0.062
CV (%)	1.5	0.9
Limit (%)	3.0	3.0

Calibration Cancel

Instructions for Use

Data Browser

Sample Explorer

Calibration

Analyzer Setting

Service Setting

IPU Setting

NVRAM

HOST

Printer GROUP 0

Work List

Exit IPU

GP Customize

QC File

LOGOFF

Version Information

Normal Not ignore Heater ON Auto Valid/Out ON

SERVICE MENU X m

CAL-CAL-11 WB CBC DJFE

Approved by *S. Wilson*
 Charge
 Biochemistry
 RMC, Loui

- Menu
- QC File
- Work List
- Rule
- Explorer
- Browser
- Setting

2/2

Calibrator Calibration

1 1 2

No.	RBC	HGB	HCT	PLT
1	4.30	11.8	34.3	248
2	4.30	11.8	34.3	248
3	4.29	11.8	34.4	249
4	4.28	11.8	34.2	242
5	4.28	11.7	34.3	236
6	4.32	11.9	34.7	239
7	4.32	11.7	34.6	239
8	4.27	11.8	34.2	244
9	4.32	11.7	34.6	244
10	4.30	11.7	34.4	237
11	4.31	11.7	34.6	241
Mean Value	4.30	11.8	34.4	242
SD	0.019	0.07	0.18	4.4
CV (%)	0.4	0.6	0.5	1.8
Limit (%)	1.5	1.0	1.5	4.0

Calibration

Cancel

Version Information

GP Customize

Exit IPU

LOGOFF

Work List

QC File

QC File

Work List

Rule

Explorer

Browser

Setting

Sample Explorer

Data Browser

Instructions for Use

Calibration

Analyzer Setting

IPU Setting

Service Setting

NVRAM

Normal

Hot Ignore

Heater ON

Auto Valid/Out OK

XN-3100-1-L

Xm

WB

XN-3100-1-R

Xm

WB

CAL - CAL - 11

WB

CBC


DIFF

Printer


05/08/21

HOST


- Menu
- QC File
- Work List
- Rule
- Explorer
- Browser
- Setting



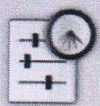
Sample Explorer




Data Browser




Instructions for Use




Calibration




Analyzer Setting



IPU Setting



Service Setting



NVRAM

1/2

Calibrator Calibration

Analysis Result


Read Target

Lot No. : CL- 11932101


Read

	WBC-N	WBC-D
	10 ³ /uL	10 ³ /uL
Target	6.883	6.997
Range Value	0.34	0.22
Max Range	0.53	0.54
Mean Value	6.745	6.915
Delta Percent (%)	2.05	1.19
Acceptable Limit (%)	2.87	2.27
Service Limit (%)	14.00	14.00
Current Rate (%)	104.7	101.8
New Rate (%)	106.8	103.0


OK
Cancel




QC File




Work List




LOGOFF



Exit IPU



GP Customize



Version Information

Normal Not ignore Heater ON Auto Valid/Out ON

XN-3100-1-L

WB

XN-3100-1-R

CAL-CAL-11

WB CBC DIFF

Approved by
5/25/21
Incharge
Biochemistry
T, RMC, Loni

2/2

Calibrator Calibration

Analysis Result

Read Target

Lot No.: CL- 11932101

1 2.4

	RBC	HGB	HCT	PLT
	10 ⁶ /uL	g/dL	%	10 ³ /uL
Target	4.353	11.90	34.78	243.0
Range Value	0.05	0.2	0.5	13
Max Range	0.12	0.2	1.0	26
Mean Value	4.299	11.76	34.43	241.9
Delta Percent (%)	1.26	1.19	1.02	0.45
Acceptable Limit (%)	1.25	0.78	2.64	4.16
Service Limit (%)	4.00	5.00	5.00	10.00
Current Rate (%)	101.0	101.3	99.6	98.2
New Rate (%)	102.3	102.5	99.3	98.6

Version Information

GP Customize

Exit IPU

LOGOFF

Work List

QC File

Version Information

GP Customize

Exit IPU

LOGOFF

Work List

QC File

Sample Explorer

Calibration

Analyzer Setting

Service Setting

Data Browser

IPU Setting

NVRAM

Instructions for Use

Normal Heater ON

SERVICE MENU

Xm

WB

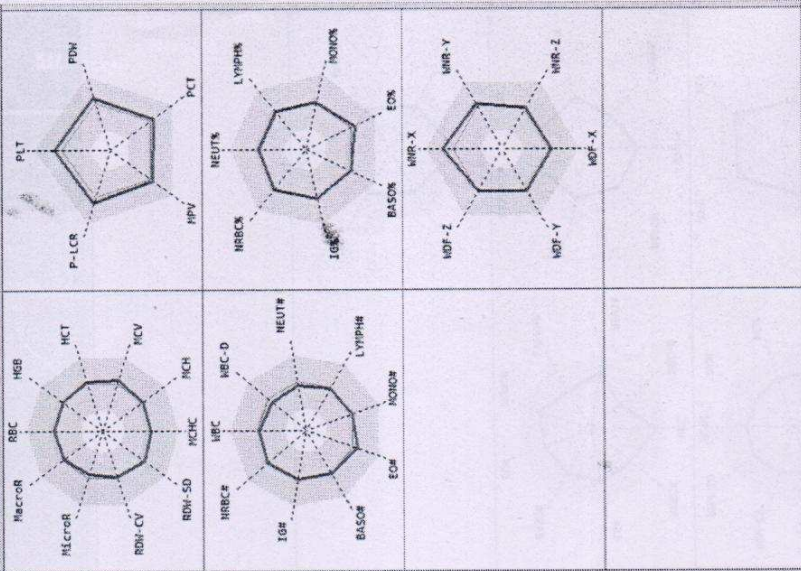
CAL-CAL-11

WB CBC DIFF

Printer GROUP 0

HOST

Approved by [Signature]
 Incharge Biochemist [Signature]
 P, RMC, Lom



Nickname	File No.	Material	Lot No.	Regist.	Analysis Date	Exp. Date
XN-3100-1-R	QC01	Control Level1	QC-02441101	20/11/2020	22/11/2020 15:38:19	22/11/2020
XN-3100-1-R	QC02	Control Level2	QC-02441102	20/11/2020	22/11/2020 15:39:30	22/11/2020
XN-3100-1-R	QC03	Control Level3	QC-02441103	20/11/2020	22/11/2020 15:38:55	22/11/2020
ERROR	XN-3100-1-R	Control Level1	QC-03001101	23/11/2020	08/12/2020 10:22:19	17/01/2021
ERROR	XN-3100-1-R	Control Level2	QC-03021102	23/11/2020	15/01/2021 10:06:59	17/01/2021
ERROR	XN-3100-1-R	Control Level3	QC-03001103	23/11/2020	15/01/2021 10:07:45	17/01/2021
ERROR	XN-3100-1-R	Control Level1	QC-03561101	18/02/2021	13/03/2021 10:24:12	14/03/2021
ERROR	XN-3100-1-R	Control Level2	QC-03581102	18/02/2021	13/03/2021 10:08:55	14/03/2021
ERROR	XN-3100-1-R	Control Level3	QC-03561103	18/02/2021	13/03/2021 10:09:40	14/03/2021
ERROR	XN-3100-1-R	Control Level1	QC-11041101	19/06/2021	04/07/2021 09:38:47	04/07/2021
ERROR	XN-3100-1-R	Control Level2	QC-11041102	19/06/2021	04/07/2021 09:39:59	04/07/2021
ERROR	XN-3100-1-R	Control Level3	QC-11021103	19/06/2021	04/07/2021 09:39:23	04/07/2021
XN-3100-1-R	QC13	Control Level3	QC-11581103	30/07/2021	05/08/2021 15:02:55	29/08/2021
XN-3100-1-R	QC14	Control Level1	QC-11601101	30/07/2021	05/08/2021 15:04:07	29/08/2021
XN-3100-1-R	QC15	Control Level2	QC-11611102	30/07/2021	05/08/2021 15:03:31	29/08/2021
XN-3100-1-R	QC16					
XN-3100-1-R	QC17					
XN-3100-1-R	QC18					
XN-3100-1-R	QC19					
XN-3100-1-R	QC20					
XN-3100-1-R	QC21					
XN-3100-1-R	QC22					
XN-3100-1-R	QC23					
XN-3100-1-L	XN-3100-1-R					

Service Menu Xm [Icons] WB

Service Menu Xm [Icons] WB

Printer Group 0

HOST

Approved by *ENJ*
 Incharge
 Biochemist
 T.R.M.C, Loni

Menu QC File Work List Rule Explorer Browser QC File QC Chart Modify QC Chart Filter Sort

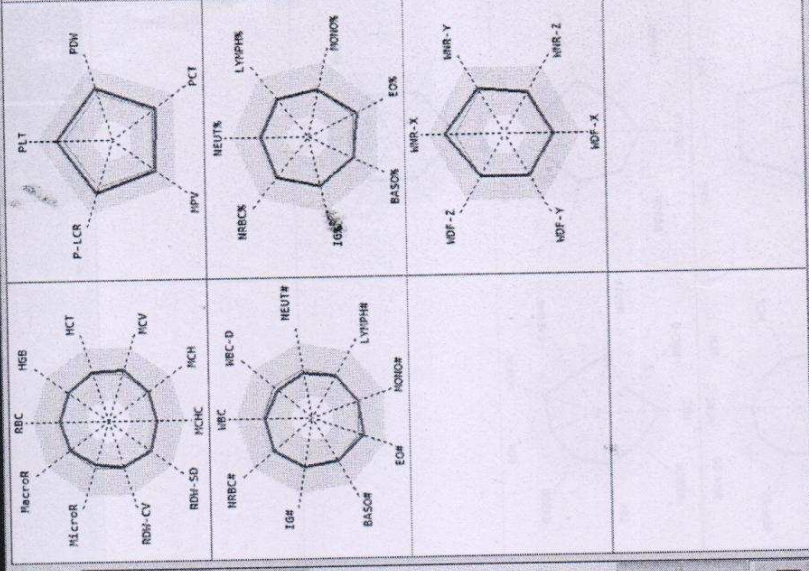
Upper Lower

File Delete Close

A A A A

Filter: All Files
 Sort: File No. (Asc.)

Nickname	File No.	Material	Lot No.	Regist.	Analysis Date	Exp. Date
XN-3100-1-R	QC01	Control Level1	QC-02441101	20/11/2020	22/11/2020 15:38:19	22/11/2020
XN-3100-1-R	QC02	Control Level2	QC-02461102	20/11/2020	22/11/2020 15:39:30	22/11/2020
XN-3100-1-R	QC03	Control Level3	QC-02441103	20/11/2020	22/11/2020 15:38:55	22/11/2020
ERROR	XN-3100-1-R	Control Level1	QC-03001101	23/11/2020	08/12/2020 10:22:19	17/01/2021
ERROR	XN-3100-1-R	Control Level2	QC-03021102	23/11/2020	15/01/2021 10:06:59	17/01/2021
ERROR	XN-3100-1-R	Control Level3	QC-03001103	23/11/2020	15/01/2021 10:07:45	17/01/2021
ERROR	XN-3100-1-R	Control Level1	QC-03561101	18/02/2021	13/03/2021 10:24:12	14/03/2021
ERROR	XN-3100-1-R	Control Level2	QC-03581102	18/02/2021	13/03/2021 10:08:55	14/03/2021
ERROR	XN-3100-1-R	Control Level3	QC-03561103	18/02/2021	13/03/2021 10:09:40	14/03/2021
ERROR	XN-3100-1-R	Control Level1	QC-11041101	19/06/2021	04/07/2021 09:38:47	04/07/2021
ERROR	XN-3100-1-R	Control Level2	QC-11041102	19/06/2021	04/07/2021 09:39:59	04/07/2021
ERROR	XN-3100-1-R	Control Level3	QC-11021103	19/06/2021	04/07/2021 09:39:23	04/07/2021
XN-3100-1-R	QC13	Control Level3	QC-11581103	30/07/2021	05/08/2021 15:02:55	29/08/2021
XN-3100-1-R	QC14	Control Level1	QC-11601101	30/07/2021	05/08/2021 15:04:07	29/08/2021
XN-3100-1-R	QC15	Control Level2	QC-11611102	30/07/2021	05/08/2021 15:03:31	29/08/2021



Printer 0
 HOST

SERVICE MENU
 Xm |> |<|

WB



Traceability and Uncertainty

XN CAL/XN CAL PF Sysmex Calibrator System

XN Series Automated Hematology Analyzer

LOT NO: 1193 2101/1193 2102
 EXP. DATE: 15-Aug-2021

Paramter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-N	*1	-	6.833	0.22	10 ⁹ /L
WBC-D	*1	-	6.997	0.22	10 ⁹ /L
WBC-P	*1	-	7.127	0.27	10 ⁹ /L
RBC	*1	-	4.353	0.070	10 ¹² /L
RBC-O	*1	-	4.291	0.12	10 ¹² /L
PLT	*2	-	243.0	12	10 ⁹ /L
PLT-O	*2	-	244.3	15	10 ⁹ /L
PLT-F	*2	-	227.6	11	10 ⁹ /L
HGB	*3, *4	-	11.90	0.23	g / dL
HCT	*5	-	34.78	0.80	%

* : This uncertainty (expanded uncertainty: k=2) was calculated in accordance with the "Guide to the expression of uncertainty in measurement" (GUM: 1995).

*1: ICSH Expert Panel on Cytometry, Clinical Laboratory Haematology, 16, 131-138, 1994

"Reference method for the enumeration of erythrocytes and leucocytes"

*2: ICSH Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting, American Journal of Clinical Pathology, 115, 460-464, 2001

"Platelet Counting by the RBC/Platelet Ratio method - A reference Method"

*3: CLSI, H15-A3

"Reference and selected procedures for the quantitative determination of hemoglobin in blood - 3rd edition; Approved

*4: Journal of Clinical Pathology, 49, 271-274, 1996

"Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemoglobinocyanide reference preparation (4th ed.)"

*5: CLSI H7-A3

"Procedure for Determining Packed Cell Volume by the Microhematcrit Method - 3rd edition; Approved Standard"

Approved by
 S. H. S. au
 Incharge
 CCL- Biochemistry
 PMT, RMC, Loni

Confidential

< XN CAL™ ASSAY SHEET for service staff >

For XN-10 and XN-20

Lot No. **11932101**

Valid until * **2021-08-08**

Exp. Date **2021-08-15**

	RBC 10 ⁶ /μL	HGB		HCT %	PLT 10 ³ /μL	MPV fL
		g/dL	m mol/L			
TARGET	4.353	11.90	7.39	34.78	243.0	9.1

	WBC 10 ³ /μL	WBC-D 10 ³ /μL	WBC-P 10 ³ /μL	RET% %	RBC-O 10 ⁶ /μL	PLT-O 10 ³ /μL
TARGET	6.833	6.997	7.127	2.261	4.291	244.3

	MCV fL	MCH **		MCHC **		RBC-He		RET-He	
		pg	f mol	g/dL	m mol/L	pg	f mol	pg	f mol
TARGET	79.9	27.3	1.697	34.2	21.2	28.3	1.756	23.9	1.483

	RET# ** 10 ⁶ /μL	HFR ** %	MFR ** %	LFR ** %	IRF ** %
TARGET	0.098	3.7	23.5	72.8	27.2

	WNR-X (SFL) ch	WNR-Y (FSL) ch	WNR-Z (SSC) ch	WDF-X (SSC) ch	WDF-Y (SFL) ch	WDF-Z (FSL) ch	WPC-X (SSC) ch	WPC-Y (SFL) ch	WPC-Z (FSL) ch
TARGET	182.1	167.7	114.6	167.9	100.7	118.7	209.0	195.7	134.9

	RET-RBC-X (SFL) ch	RET-RBC-Y (FSL) ch	RET-RBC-Z (SSC) ch	PLT-F-RBC-X (SFL) ch	PLT-F-RBC-Y (FSL) ch	PLT-F-Z (SSC) ch
TARGET	23.5	159.6	23.9	82.8	231.7	35.0

There are some parameters which is not displayed on IPU according to the instrument.

Please refer to the package insert for the handling of the XN CAL.

Do not leave calibrator in the room temperature over an hour.

Please store it in a refrigerator (2-8°C) immediately after use.

*: This refers to the validity of the assay values for service parameters.

** : Don't calibrate ** marked parameter.

Approved by
S. S. S.

Incharge
CCL- Biochemistry
PMT, RMC, Loni