



**9 Calibration**

9.1 Please refer to Whole Blood Calibration Report Attached

9.2 PD Mode Calibration (NOTE: If Applicable)

Material: XN CAL (1:7 Dilution)

Lot:

Expiry:

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
PLT_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
HGB_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
WBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
WBC-D/WDF_PD	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
RET_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
RBCO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!

\*NOTE: Only Applicable when RET license has been activated

NOTE: Please attach PD Mode Calibration results screenshots

9.3 Body Fluid Calibration (NOTE: If Applicable)

Material: XN CAL

Lot: NA

Expiry:NA

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!

\*NOTE: Only Applicable when BF license has been activated

NOTE: Please attach BF Mode Calibration results screenshots

**10 QC Verification**

10.1 Please attach QC radar charts print outs for QC runs after the calibration.

11 Pipetors/Dilutors reproducibility and accuracy checked.





**9 Calibration**

9.1 Please refer to Whole Blood Calibration Report Attached

9.2 PD Mode Calibration (NOTE: If Applicable)

Material: XN CAL (1:7 Dilution)

Lot:

Expiry:

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
PLT_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
HGB_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
WBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
WBC-D/WDF_PD	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
RET_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
RBCO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA NA	NA NA	#VALUE!	#VALUE!	#VALUE!

\*NOTE: Only Applicable when RET license has been activated

NOTE: Please attach PD Mode Calibration results screenshots

9.3 Body Fluid Calibration (NOTE: If Applicable)

Material: XN CAL

Lot: NA

Expiry: NA

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!

\*NOTE: Only Applicable when BF license has been activated

NOTE: Please attach BF Mode Calibration results screenshots

**10 QC Verification**

10.1 Please attach QC radar charts print outs for QC runs after the calibration.

11 Pipetors/Dilutors reproducibility and accuracy checked.





12 Certification

We certify that the **XN-330** Automated Hematology Analyzer S/N: **14153** has been successfully commissioned in accordance with the manufacturer's recommendations.

Report and Commissioning Performed By :

\_\_\_\_\_  
Signature (Engineer 1)

Name: Rahul Thakur  
Date: 22-02-2023

\_\_\_\_\_  
Signature (Engineer 2)

Name: \_\_\_\_\_  
Date: \_\_\_\_\_

Report Reviewed and Accepted By :



\_\_\_\_\_  
Signature (Customer)

Name: Mr. Krishna Kumar  
Date: 22.2.23

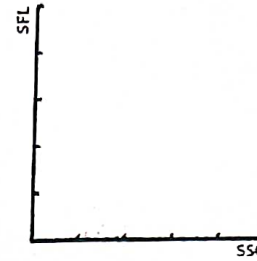
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 Name:  
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Adapter:  
 Ward:

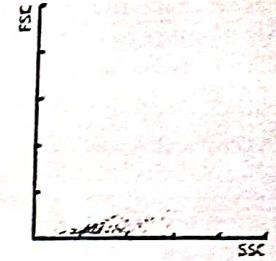
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 Doctor:  
 Birth:  
 Sex:  
 Nickname: XN-L

WBC	0.00	[10 <sup>3</sup> /uL]		
RBC	0.00	[10 <sup>6</sup> /uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	1	[10 <sup>3</sup> /uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10 <sup>3</sup> /uL]	----	[%]
LYMPH	----	[10 <sup>3</sup> /uL]	----	[%]
MONO	----	[10 <sup>3</sup> /uL]	----	[%]
EO	----	[10 <sup>3</sup> /uL]	----	[%]
BASO	----	[10 <sup>3</sup> /uL]	----	[%]
IG	----	[10 <sup>3</sup> /uL]	----	[%]

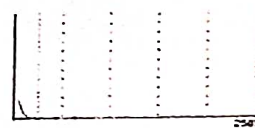
WDF



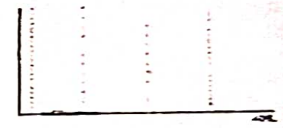
WDF - CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message





We Believe the Possibilities.

# Installation Qualification

## Automated Haematology Analyzer XN-L Series

Author: Chew Kui Jien


Last Edited: 07 Mar 2018

Version: 1.0

## 1. General Outline

### 1-1 Performer

The following person shall perform Installation Qualification (IQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

Name	:	Rahul Thakur
Company	:	Sysmex India Pvt. Ltd.
Date (Day/Month/ Year)	:	22-02-2023
Signature	:	

### 1-2 Reviewer

People in charge of reviewing installation procedures and being representatives of the customer shall fill out the following blanks:

Name	:	
Institution OR Company	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

Name	:	
Institution OR Company	:	
Title	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	


Remarks:

**Installation Qualification**

Model Number            XN – 330  
Serial Number            14153  
Software Version        00-24  
Installation Site         22/02/2023

By the subsequent signature it becomes evident that all validation procedures for Installation Qualification (IQ) of the above stated equipment are completed by the performer.

-Performer

Name : Rahul Thakur



Signature : \_\_\_\_\_

Date (day/month/year) : 22/02/2023

By the subsequent signature the reviewer witnesses that all validation procedures for Installation Qualification (IQ) of the above stated equipment are completed by the performer.

-Reviewer



# Operational Qualification

## Automated Haematology Analyzer XN-L Series


Author: Chew Kui Jien

Last Edited: 08 Mar 2018

Version: 1.0



The following person shall perform Operational Qualification (OQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

Name	:	Rahul Thakur
Company	:	Sysmex India Pvt. Ltd.
Date (Day/Month/ Year)	:	22/02/2023
Signature / Initial	:	

### 1-2 Reviewer

People in charge of reviewing installation procedures and being representatives of the customer shall fill out the following blanks:

Name	:	
Institution OR Company	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

Name	:	
Institution OR Company	:	
Title	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

### 3-1 Equipment

-

Model Number	XN-330
Serial Number	14153
Software Version Number	00-24
Installation Site	22-02-2023

By the subsequent signature it becomes evident that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Performer

Name: Rahul Thakur

Signature: 

Date (day/month/year): 22-02-2023

By the subsequent signature the reviewer witnesses that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Reviewer

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date (day/month/year): \_\_\_\_\_

-Reviewer

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date (day/month/year): \_\_\_\_\_

End of Document



## PERFORMANCE QUALIFICATION

**Instrument** : XNL-330 Hematology Analyzer  
Sr. No: 14153

**Laboratory** : Rajasthan Vikas Sansthan,  
Kudi Hud, City Circle  
Jodhpur- 342005

**Manufacturer** : Sysmex Corporation

**Supported by** : 1002, Damji Shamji Business Galleria,  
10th Floor, LBS Marg  
Kanjurmarg (West), Mumbai 400 078, India  
Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790



Sysmex India Pvt Ltd  
HO. 1002, Damji Shamji Business Galleria, 10<sup>th</sup> Floor, LBS Marg, Kanjurmarg ( West ), Mumbai 400078, India  
Tel. +91-22-6112-6666 Fax. +91-22-2577-6790  
Factory. Village Malpur, Nalagarh Road, Baddi 173205, H. P. Tel. +91-9218422282/9816672282

[www.sysmex.co.in](http://www.sysmex.co.in)

CIN : U33120MH1998PT115943

### PERFORMANCE QUALIFICATION PROTOCOL

This Performance Qualification protocol will be performed on the installation located at

Rajasthan Vikas Sansthan,  
Kudi Hud, City Circle  
Jodhpur- 342005

This protocol will define the documentation that will be used to evaluate the instrument and documented in accordance with the user specification requirements. Successful completion of this protocol will verify that the instrument performance consistently meets pre-determined specifications under normal conditions.

Performance checks will be carried out by repeatedly running the system on its intended schedule and record the information/data to demonstrate that it consistently meets the required performance, as expected.

Department personnel along with the trained personnel from Sysmex will perform qualification studies as mentioned in this protocol. Department personnel will record the information and write the report. The technical person from Sysmex will verify the records. The reports will be reviewed by head of the department and approved by QA person. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated, and appropriate course of action will be determined.





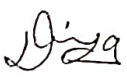
Sysmex India Pvt Ltd  
HO. 1002, Damji Shamji Business Galleria, 10<sup>th</sup> Floor, LBS Marg, Kanjurmarg ( West ), Mumbai 400073, India  
Tel. +91-22-6112-6666 Fax. +91-22-2577-6790  
Factory. Village Malpur, Nalagarh Road, Baddi 173205, H. P. Tel. +91-9218422282/9816672282

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CIN:U33120MH1998PT115943



Report Sign Off:

Prepared by:	Mr. Ravi Kumar Sah	
Title: Application Specialist	Sign: 	Date: 23.05.2023
Checked By: Mr. Vikas Dagar (Manager-North)	Sign: 	Date: 23.05.2023
Approved by:	Rajasthan Vikas Sansthan, Jodhpur	
Name:	Mr. Krishna Kumar	
Title: CTO	Sign: 	Date: 23.05.2023
<b>VYAS MEDICITY : CITY CENTRE</b> Plot No. F-320-21, MIA Phase-II, AIIMS Road, JODHPUR (Raj.)		



## PQ SCHEDULE

The following activities mentioned below must be performed to complete the performance qualification.

### Contents

#### Evaluation met Lab Managers for Whole Blood Mode

1. Precision
2. Accuracy
3. Linearity
4. Carryover
5. Limit of Blank
6. Limit of Detection and Limit of Quantitation

### PERFORMANCE QUALIFICATION PROCEDURE

#### Performance Qualification

##### 1. Precision Check

###### Procedure for Precision Testing

###### Requirements: - 1 Peripheral Blood sample

1. Set the analyser to WB Mode, analyse Peripheral Blood for 11 consecutive times. The coefficient of variation of counting for each analysing parameter should meet the following condition.
2. Input the data into the provided table. Calculate Mean, SD and CV%.
3. Compare these values with the performance criteria for Within-run Precision Table.
4. Acceptable Variation are as follows:



Sysmex India Pvt Ltd  
HO. 1002, Damji Shamji Business Galleria, 10<sup>th</sup> Floor, LBS Marg, Kanjurmarg ( West ), Mumbai 400078, India  
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Factory. Village Malpur, Nalagarh Road, Baddi 173205, H. P. Tel. +91-9218422282/9816672282

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