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## 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.

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## 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.

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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 :**

Thakur

**Signature (Engineer 1)**

**Name:** Rahul Thakur
**Date:** 22-02-2023

**Signature (Engineer 2)**

**Name:**
**Date:**

**Report Reviewed and Accepted By :**

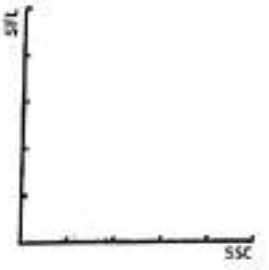
**Signature (Customer)**

**Name:** Mr. Krishna Kumal
**Date:** 22.2.23

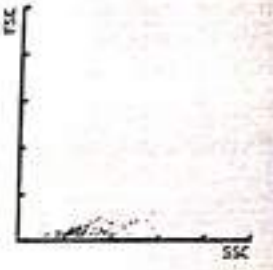
Sample No.: BACKGROUNDCHECK Adapter: Pos.: 2023/02/22 14:59:49 WE
Patient ID: Ward: Doctor:
Name: Birth: Sex:
Sample Comment: Nickname: XN-L

| | | | | |
|---|---|---|---|---|
| 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 | 1 | [10^3/uL] | | |
| RDW-SD | ---- | [fL] | | |
| RDW-CV | ---- | [%] | | |
| PDW | ---- | [fL] | | |
| MPV | ---- | [fL] | | |
| P-LCR | ---- | [%] | | |
| PCT | ---- | [%] | | |
| NEUT | ---- | [10^3/uL] | ---- | [%] |
| LYMPH | ---- | [10^3/uL] | ---- | [%] |
| MONO | ---- | [10^3/uL] | ---- | [%] |
| EO | ---- | [10^3/uL] | ---- | [%] |
| BASO | ---- | [10^3/uL] | ---- | [%] |
| IG | ---- | [10^3/uL] | ---- | [%] |

WDF




WDF-CBC




RBC

PLT

WBC IP Message

RBC IP Message

PLT IP Message

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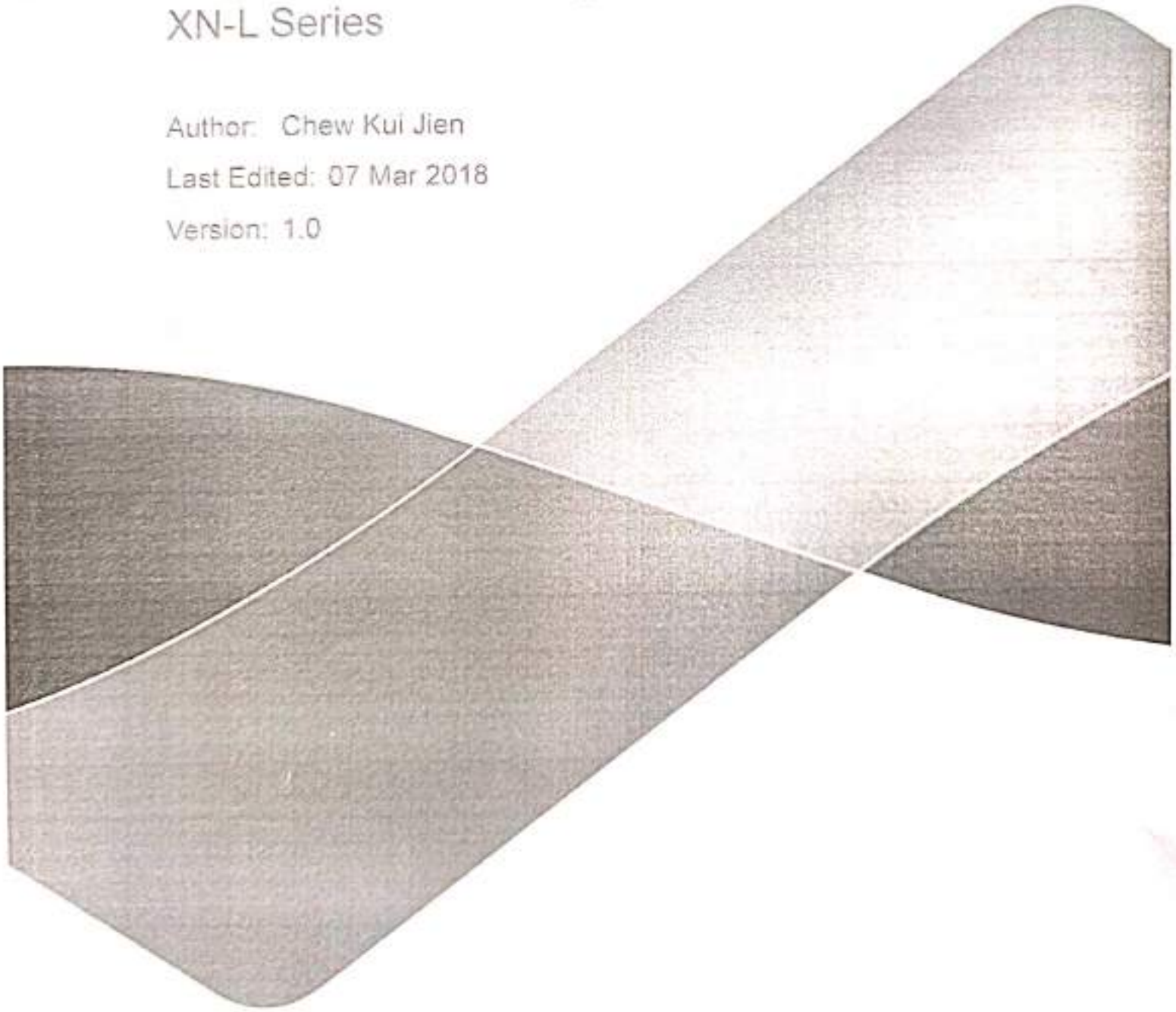
# Installation Qualification

## Automated Haematology Analyzer
## XN-L Series

Author: Chew Kui Jien

Last Edited: 07 Mar 2018

Version: 1.0



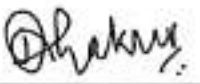


Sysmex Asia Pacific Pte Ltd

# 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

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# Operational Qualification

## Automated Haematology Analyzer
## XN-L Series

Author: Chew Kui Jien

Last Edited: 08 Mar 2018

Version: 1.0



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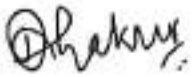
The following person shall perform Operational Qualification (OQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

| | | |
|---|---|---|
| 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: Thakur

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

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# PERFORMANCE QUALIFICATION

| | | |
|---|---|---|
| Instrument | : | XNL-330 Hematology Analyzer<br>Sr. No: 14153 |
| Laboratory | : | Rajasthan Vikas Sansthan,<br>Kudi Hud, City Circle<br>Jodhpur- 342005 |
| Manufacturer | : | Sysmex Corporation |
| Supported by | : | 1002, Damji Shamji Business Galleria,<br>10th Floor, LBS Marg<br>Kanjurmarg (West), Mumbai 400 078, India<br>Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790 |

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## 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.

Report Sign Off:

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

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# 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: