# XN-L Series Calibration Report

Customer : Unipath Specialty Laboratory (Gujarat) LLP
Model: XN-350
Date: 2/12/2023
Serial No: 17249

## 1 MECHANICAL ADJUSTMENTS

| Positions | Perform |
|---|---|
| Piercer/Pipette Position | Performed |
| Tube Holder Position | NA |
| Hand Position | NA |
| BCR Position | NA |

## 2 BACKGROUND VERIFICATION

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| *WBC* | 0.00 | ≤ 0.10 x 10*3/uL | PASS |
| *RBC* | 0.00 | ≤ 0.02 x 10*6/uL | PASS |
| *HGB* | 0.0 | ≤ 0.1 g/dL | PASS |
| *PLT-I* | 0 | ≤ 10 x 10*3/µL | PASS |
| *RBC-O** | NA | ≤ 0.02 x 10*6/uL | NA |
| *PLT-O** | NA | ≤ 10 x 10*3/µL | NA |

** Only applicable when RET license is activated*

## 3 OPTICAL AXIS VERIFICATION

**3.1 CELLPACK DFL 10ml + DUKE 4207A 5 Drops. The diluted latex was analyzed to determine the Optical Axis of the FSC (Rough). The results are as below :**

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| *FSC (X) Rough* | NA | 70 - 130 | NA |
| *FSC (W) Rough* | NA | Less than 0.15 | NA |

**3.2 CELLPACK DCL 10ml + DUKE 4207A 5 Drops. The diluted latex was analyzed to determine the Optical Axis of the FSC (Fine). The results are as below :**

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| *FSC (X) Fine* | 92.3 | 70 - 130 | PASS |
| *FSC (W) Fine* | 0.119 | Less than 0.35 | PASS |

**3.3 CELLPACK DCL 10ml + PS-FLUORED-L2830-4 2 Drops. The diluted latex was ana determine the Optical Axis of the SFL(Fine) & SSC(Fine). The results are as below :**

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| *SFL (X)* | 118.3 | For Record Purpose | |
| *SFL (W)* | 0.127 | lower than 0.20 | PASS |
| *SSC (X)* | 60.3 | 50 - 100 | PASS |
| *SSC (W)* | 0.166 | For Record Purpose | |

*NOTE: Please attach FSC(X) rough, FSC(X) fine, SFL(X) fine, SSC(X) fine peaks screenshots.*

## 4 RBC CLOG LEVEL ADJUSTMENT

**4.1** The RBC clog adjustment is monitored after the background check. The result is as below :

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| *RBC CLOG* | 100 | 100 ± 1 | PASS |

## 5 HGB BLANK ADJUSTMENT

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| HB Blank Gain | 5054 | 5000 ± 200 | PASS |

## 6 ASPIRATION SENSOR BLANK ADJUSTMENT

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| Aspiration Sensor | 5101 | 5000 ± 200 | PASS |

## 7 ASPIRATION SENSOR SPAN ADJUSTMENT

**7.1** ***Material : XN-CHECK / XN CAL**
**Lot :- 32381402**
**Expiry :- 05/12/2023**
* Cross whichever not applicable

| Parameters | Results | Acceptable Range | Status |
|---|---|---|---|
| Aspiration Sensor Span | 13064 | 13000 ± 500 | PASS |

## 8 SENSITIVITY ADJUSTMENTS

**8.1** **Material :XN-CAL**
**Lot :- 33032101**
**Expiry :- 03/12/2023**

| Parameters | Results | Assay Value | Acceptable Range | Status | Scattergram normal? |
|---|---|---|---|---|---|
| WDF-X | 163.5 | 163.5 | ± 3 ch | PASS | Yes |
| WDF-Y | 95.4 | 94.4 | ± 3 ch | PASS | |
| WDF-Z / WDF-FSC | 113.7 | 114.5 | ± 2.5 ch | PASS | |

| Parameters | Results | Assay Value | Acceptable Range | Status | Scattergram normal? |
|---|---|---|---|---|---|
| RBC-X | NA | NA | ± 1 ch | #VALUE! | NA |
| RBC-Y | NA | NA | ± 3 ch | #VALUE! | |
| RBC-Z | NA | NA | ± 2 ch | #VALUE! | |

| Parameters | Results | Assay Value | Acceptable Range | Status |
|---|---|---|---|---|
| MCV | 80.6 | 81.3 | ± 1 ch | PASS |
| MPV | 9.8 | 9.9 | ± 0.3 ch | PASS |
| HGB | 12.3 | 12.30 | ± 0.2g/dl | PASS |

*NOTE: Please attach sensitivity adjustment screenshots.*

## 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:- 33032101**
**Expiry:- 03/12/2023**

| Parameters | 1 | 2 | 3 | 4 | 5 | Average | Assay Value | Old Cal | New Cal | % Diff | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **RBC_PD_CAL** | 4.38 | 4.35 | 4.32 | 4.40 | 4.30 | 4.35 | 4.402 | 1030 | 1042 | -1.20 | PASS |
| **PLT_PD_CAL** | 252 | 239 | 242 | 248 | 246 | 245 | 247.9 | 980 | 990 | -1.02 | PASS |
| **HGB_PD_CAL** | 12.3 | 12.2 | 12.2 | 12.4 | 12.3 | 12.3 | 12.30 | 1010 | 1012 | -0.16 | PASS |
| **WBC_PD_CAL** | 7.27 | 7.32 | 7.41 | 7.50 | 7.59 | 7.42 | 7.593 | 970 | 993 | -2.36 | PASS |
| **WBC-D/WDF_PD** | 6.87 | 6.85 | 6.94 | 7.04 | 7.15 | 6.97 | 7.100 | 1005 | 1024 | -1.87 | PASS |
| **RET_PD_CAL*** | NA | NA | NA | NA | NA | #DIV/0! | NA | NA | #VALUE! | #VALUE! | #VALUE! |
| **RBCO_PD_CAL*** | NA | NA | NA | NA | NA | #DIV/0! | NA | NA | #VALUE! | #VALUE! | #VALUE! |
| **PLTO_PD_CAL*** | NA | NA | NA | NA | NA | #DIV/0! | 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:- 33032101**
**Expiry:- 03/12/2023**

| Parameters | 1 | 2 | 3 | 4 | 5 | Average | Assay Value | Old Cal | New Cal | % Diff | Status |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **RBC_BF_CAL*** | 4.292 | 4.36 | 4.36 | 4.29 | 4.23 | 4.307 | 4.402 | 1010 | 1032 | -2.20 | PASS |
| **WBC_BF_CAL*** | 7.093 | 7.04 | 7.06 | 7.12 | 7.04 | 7.070 | 7.100 | 978 | 982 | -0.43 | PASS |

**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-350** Automated Hematology Analyzer S/N: **17249** has been successfully calibrated in accordance with the manufacturer's recommendations.

**Report and Commissioning Performed By :**

**Signature (Engineer 1)**

**Name:** Mehul Ekavadiya
**Date:** 2/12/2023

**Signature (Engineer 2)**

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

**Report Reviewed and Accepted By :**

**Signature (Customer)**

**Name:** Ms. Pinkal Patel
**Date:** 2/12/2023