



XN-L Series Commissioning Report

Customer : Arpan Diagnostics Centre, Rajkot
Model : XN-550

Date: 28-02-2020
Serial No: 17581

1 MECHANICAL ADJUSTMENTS

Positions	Perform
Piercer/Pipette Position	OK
Tube Holder Position	OK
Hand Position	OK
BCR Position	OK

2 BACKGROUND VERIFICATION

Parameters	Results	Acceptable Range	Status
WBC	0	$\leq 0.10 \times 10^3/\mu\text{L}$	PASS
RBC	0	$\leq 0.02 \times 10^6/\mu\text{L}$	PASS
HGB	0	$\leq 0.1 \text{ g/dL}$	PASS
PLT-I	0	$\leq 10 \times 10^3/\mu\text{L}$	PASS
RBC-O*	NA	$\leq 0.02 \times 10^6/\mu\text{L}$	NA
PLT-O*	NA	$\leq 10 \times 10^3/\mu\text{L}$	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	89	70 - 130	NA
FSC (W) Rough	0.135	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	91.6	70 - 130	PASS
FSC (W) Fine	0.175	Less than 0.35	PASS

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

Parameters	Results	Acceptable Range	Status
SFL (X)	126.1	For Record Purpose	
SFL (W)	0.143	lower than 0.20	PASS
SSC (X)	73.8	50 - 90	PASS
SSC (W)	0.217	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	5040	5000 ± 200	PASS

6 **ASPIRATION SENSOR BLANK ADJUSTMENT**

Parameters	Results	Acceptable Range	Status
Aspiration Sensor	5036	5000 ± 200	PASS

7 **ASPIRATION SENSOR SPAN ADJUSTMENT**

7.1 *Material : XN-CHECK / XN CAL

Lot :00221102

Expiry : 12/04/2020

* Cross whichever not applicable

Parameters	Results	Acceptable Range	Status
Aspiration Sensor Span	12911	13000 ± 500	PASS

8 **SENSITIVITY ADJUSTMENTS**

8.1 Material :XN-CAL

552101

Expiry : 29/03/2020

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
WDF-X	160	161	± 2 ch	PASS	NA
WDF-Y	102.6	102.9	± 3 ch	PASS	
WDF-Z / WDF-FSC	114.3	113.4	± 2 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	80.7	80.5	± 2 ch	PASS
MPV	9.9	9.9	± 1 ch	PASS
HGB	12.4	12.42	± 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: Not Applicable)

Material: XN CAL (1:7 Dilution)

Lot: NA

Expiry: NA

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

*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	NA	NA
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

*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.

XN-L Series Commissioning Report

Date: 28-02-2020
Sample No: 17581



12 Certification

We certify that the **XN-550** Automated Hematology Analyzer S/N: **17581** has been successfully commissioned in accordance with the manufacturer's recommendations.

Report and Commissioning Performed By :

Signature (Engineer 1)

Name: Satish Rajak
Date: 28-02-2020



Signature (Engineer 2)

Name: _____
Date: _____

Report Reviewed and Accepted By :



Signature (Customer)

Name: _____