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XN-L Series Calibration Report

Customer : Chittaranjan National Cancer Institute (2nd Unit)   Date: 13.01.2021

Model: XN-550   Serial No: 20191

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	0.00	$\leq 0.10 \times 10^*3/uL$	PASS
RBC	0.00	$\leq 0.02 \times 10^*6/uL$	PASS
HGB	0.0	≤ 0.1 g/dL	PASS
PLT-I	1	$\leq 10 \times 10^*3/\mu L$	PASS
RBC-O*	NA	$\leq 0.02 \times 10^*6/uL$	
PLT-O*	NA	$\leq 10 \times 10^*3/\mu L$	

* 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	
FSC (W) Rough	NA	Less than 0.15	

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	84	70 - 130	PASS
FSC (W) Fine	0.131	Less than 0.35	PASS

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

Parameters	Results	Acceptable Range	Status
SFL (X)	133.1	For Record Purpose	
SFL (W)	0.143	lower than 0.20	PASS
SSC (X)	79.2	50 - 90	PASS
SSC (W)	0.366	For Record Purpose	

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

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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	4989	5000 ± 200	PASS

6 ASPIRATION SENSOR BLANK ADJUSTMENT

Parameters	Results	Acceptable Range	Status
Aspiration Sensor	4989	5000 ± 200	PASS

7 ASPIRATION SENSOR SPAN ADJUSTMENT

7.1 *Material : ███████ / XN CAL
Lot : 03632101
Expiry : 2021-01-31
* Cross whichever not applicable

Parameters	Results	Acceptable Range	Status
Aspiration Sensor Span	12960	13000 ± 500	PASS

8 SENSITIVITY ADJUSTMENTS

8.1 Material :XN-CAL
Lot : 03632101
Expiry : 2021-01-31

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
WDF-X	160.5	161.0	± 2 ch	PASS	
WDF-Y	96.6	97.7	± 3 ch	PASS	Yes
WDF-Z / WDF-FSC	109	109.3	± 2 ch	PASS	

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
RBC-X	NA		± 1 ch	███	
RBC-Y	NA		± 3 ch		Yes
RBC-Z	NA		± 2 ch		

Parameters	Results	Assay Value	Acceptable Range	Status
MCV	79.5	79.6	± 2 ch	PASS
MPV	9.1	9.3	± 1 ch	PASS
HGB	12.1	12.09	± 0.2g/dl	PASS

NOTE: Please attach sensitivity adjustment screenshots.

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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 : 03632101
Expiry : 2021-01-31

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	4.43	4.38	4.50	4.47	4.47	4.45	4.383	1000	985	1.51	PASS
PLT_PD_CAL	265	257	263	259	257	260	252.5	939	911	2.96	PASS
HGB_PD_CAL	12.0	12.1	12.2	12.1	12.2	12.1	12.09	973	971	0.25	PASS
WBC_PD_CAL	8.05	7.87	7.74	7.68	7.79	7.83	7.502	1000	959	4.14	PASS
WBC-D/WDF_PI	7.55	7.40	7.21	7.22	7.27	7.33	7.077	1019	984	3.45	PASS
RET_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!			#DIV/0!	#DIV/0!	#DIV/0!
RBCO_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!			#DIV/0!	#DIV/0!	#DIV/0!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!			#DIV/0!	#DIV/0!	#DIV/0!

*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:
Expiry:

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	#DIV/0!			#DIV/0!	#DIV/0!	#DIV/0!
WBC_BF_CAL*	NA	NA	NA	NA	NA	#DIV/0!			#DIV/0!	#DIV/0!	#DIV/0!

*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-550**   Automated Hematology Analyzer S/N: **20191**   has been
successfully commissioned in accordance with the manufacturer's recommendations.

Report and Commissioning Performed By :

[signature]

Signature (Engineer 1)

Name: TANMOY DATTA
Date: 13-01-2021

Signature (Engineer 2)

Name:
Date:

Report Reviewed and Accepted By :

[signature]

Dr. SANKAR SENGUPTA
MBBS, MD (Microbiology), PGDHHM
Medical Superintendent / Head Laboratory Services
CNCI, 2nd Campus
Action Area I, New Town, Kolkata

Signature (Customer)

Name: Dr. Sankar Sengupta
Date: 13.01.2021

Date: 13th January 2021

Ref. No.: SIP/KOL/CNCI/Yearly/2021-22

Calibration Certificate for Automated Complete Blood Count Analyzer, Model XN-550

This is to certify that the Automated Complete Blood Count Analyzer, Model XN-550 vide S/N 20191 installed at **Chittaranjan National Cancer Institute (2nd Unit). Street No. 299, Plot No. DJ-1/1, A A-1, Newtown, Rajarhat, Kolkata - 700156** has been calibrated by Lot No.: 03632101, Exp.: 2021-01-31 on 13th January 2021.

This calibration is valid till 12th January 2022.

[signature]

For Sysmex India Pvt Ltd