

PARAMETER CALIBRATION CERTIFICATE OF BC6000 HEMATOLOGY ANALYZER

NAME OF THE INSTITUTE	ESI HOSPITAL
MANUFACTURER	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
NAME OF THE EQUIPMENT	BC-6000(AUTO HEMATOLOGY ANALYZER)
EQUIPMENT SR.NO	TU-14001804
CALIBRATION DATE	20.07.2023
NEXT DUE DATE	19.07.2024

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE PERFORMANCE QUALIFICATION HAS BEEN SUCESSFULLY COMPLETED FOR THE ABOVE STATED INSTRUMENT.

ENGINEER :



Signature :

Name :Gokulnath Ramadoss

Designation : Area Service Manager

PERFORMANCE ANALYSIS

Calibration:

The aforesaid analyzer has been calibrated as per the protocol mentioned in the Operator's Manual using the 6-part haematology calibrator SC-CAL PLUS bearing the LOT number 0823, Expiry- 05.09.2023 for the measured parameters including White Blood Cells (WBC), Red Blood Cells (RBC), Haemoglobin (HGB) & Platelets (PLT)

5 replicates of background check have been carried out & verified for the acceptable limits of background before the use of the calibrator.

Background Verification

	Select	Operator	WBC	RBC	HGB	PLT	WBC-D
10	Yes	service	0	0	0	0	0
9	Yes	service	0	0	0	0	0
8	Yes	service	0	0	0	0	0
7	Yes	service	0	0	0	0	0
6	Yes	service	0	0	0	0	0
5	Yes	service	0	0	0	0	0
4	Yes	service	0	0	0	0	0
3	Yes	service	0	0	0	0	0
2	Yes	service	0	0	0	0	0
1	Yes	service	0	0	0	1	0
Limit			0.1	0.02	0.1	5	0.2
Result			Pass	Pass	Pass	Pass	Pass

Before Calibration:

The aforesaid analyzer has been verified before calibration.

S.NO	PARAMETER	RESULT
1	WBC	9.14
2	NEU #	8.91
3	LYM #	0.21
4	MON #	0
5	EOS #	0.01
6	BAS #	0.01
7	IMG #	0.02
8	NEU #	97.5
9	LYM #	2.3
10	MON #	0
11	EOS #	0.1
12	BAS #	0.1
13	IMG #	0.2
14	RBC	4.63
15	HGB	13.6
16	HCT	42.6
17	MCV	92.1
18	MCH	29.3
19	MCHC	31.8
20	RDW-CV	15
21	RDW-SD	51.8
22	PLT	253
23	MPV	11.3
24	PDW	16.7
25	PCT	0.287
26	P-LCC	91
27	P-LCR	36
28	NRBC #	0
29	NRBC %	0

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	Select	WBC	RBC	HGB	MCV	PLT
Target		9.23	4.6	13.5	92.6	249
WB 1#	Yes	9.37	4.6	13.5	92.2	248
WB 2#	Yes	9.47	4.68	13.7	92.2	245
WB 3#	Yes	9.48	4.61	13.7	92.3	245
WB 4#	Yes	9.42	4.67	13.7	92.1	246
WB 5#	Yes	9.52	4.62	13.7	92.5	249
WB 6#	Yes	9.45	4.62	13.7	92	248
WB 7#	Yes	9.37	4.65	13.7	92.1	252
WB 8#	Yes	9.53	4.7	13.7	92.4	248
WB 9#	Yes	9.52	4.55	13.6	92.1	230
WB 10#	Yes	9.53	4.56	13.7	92.5	243
Mean		9.47	4.63	13.7	92.3	245
CV%		0.659	1.066	0.53	0.19	2.4
Old Factor (%)		100	99	100	100	100
New Factor (%)		99.83	93.65	99.88	101.13	99.15

After Calibration:

The aforesaid analyzer has been verified after calibration using the same patient sample.

	Date/Time	WBC	RBC	HGB	MCV	PLT	Neu#	Lym#	Mon#
20	05-09-23 17:00	6.42	4.67	13.8	89.3	210	4.42	1.41	0.48
19	05-09-23 16:59	6.2	4.7	13.8	89	207	4.35	1.3	0.46
18	05-09-23 16:59	6.42	4.77	13.9	89.8	210	4.58	1.32	0.43
17	05-09-23 16:58	6.39	4.76	13.9	90	202	4.5	1.4	0.42
16	05-09-23 16:57	6.25	4.69	13.8	89.9	204	4.33	1.35	0.47
15	05-09-23 16:57	6.35	4.71	13.8	90.1	206	4.44	1.3	0.5
14	05-09-23 16:56	6.51	4.68	13.8	89.9	203	4.52	1.46	0.47
13	05-09-23 16:56	6.23	4.77	13.8	89.9	197	4.39	1.33	0.44
12	05-09-23 16:55	6.28	4.69	13.9	89.3	220	4.38	1.41	0.43
11	05-09-23 16:54	6.16	4.64	13.9	90	210	4.31	1.34	0.45
10	05-09-23 16:06	6.25	4.76	13.8	87.8	220	4.43	1.34	0.42
Mean		6.32	4.71	13.8	89.7	207	4.42	1.36	0.46
SD		0.114	0.045	0.03	0.38	6.2	0.088	0.055	0.025
Min		6.16	4.64	13.8	89	197	4.31	1.3	0.42
Max		6.51	4.77	13.9	90.1	220	4.58	1.46	0.5
R		0.35	0.13	0.1	1.1	23	0.27	0.16	0.08
d(Min)		0.03	0	0	0.1	0	0	0.01	0
d(Max)		0.19	0.07	0.1	0.7	13	0.16	0.1	0.04
CV%		1.8	0.9	0.2	0.4	3	2	4	5.6
Limit(%)		2.5	1.5	1	1	4	6	6	16
Result		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Eos#	Bas#	IMG#	Neu%	Lym%	Mon%	Eos%	Bas%	IMG%	HCT	MCH
0.07	0.04	0.02	68.9	21.9	7.4	1.1	0.7	0.3	41.7	29.6
0.06	0.03	0.02	70	21	7.5	1	0.5	0.4	41.8	29.4
0.06	0.03	0.03	71.4	20.6	6.7	0.9	0.4	0.5	42.8	29.2
0.03	0.04	0.03	70.3	21.9	6.6	0.5	0.7	0.5	42.8	29.1
0.06	0.04	0.03	69.2	21.6	7.6	0.9	0.7	0.5	42.2	29.5
0.07	0.04	0.05	69.9	20.4	7.9	1.1	0.7	0.8	42.4	29.4
0.03	0.03	0.03	69.5	22.4	7.2	0.5	0.4	0.5	42.1	29.5
0.03	0.04	0.02	70.4	21.4	7	0.5	0.7	0.4	42.9	28.9
0.03	0.03	0.03	69.9	22.4	6.9	0.4	0.4	0.4	41.9	29.5
0.03	0.03	0.04	70	21.7	7.3	0.5	0.5	0.7	41.8	29.9
0.03	0.03	0.02	71.1	21.4	6.7	0.4	0.4	0.3	41.8	28.9
0.05	0.03	0.03	70	21.5	7.2	0.7	0.6	0.5	42.2	29.4
0.018	0.005	0.009	0.69	0.69	0.41	0.28	0.14	0.15	0.46	0.28
0.03	0.03	0.02	68.9	20.4	6.6	0.4	0.4	0.3	41.7	28.9
0.07	0.04	0.05	71.4	22.4	7.9	1.1	0.7	0.8	42.9	29.9
0.04	0.01	0.03	2.5	2	1.3	0.7	0.3	0.5	1.2	1
0.01	0	0	0	0.1	0	0.2	0.1	0	0	0
0.02	0.01	0.02	1.5	1.1	0.7	0.4	0.2	0.3	0.7	0.5
38.9	15.1	31.4	1	3.2	5.7	38.3	24.9	29.8	1.1	0.9
20	30	25	6	6	16	20	30	25	1.5	1.5
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

MCHC	RDW-CV	RDW-SD	MPV	PDW	PCT	P-LCC	P-LCR
33.1	13.7	46.4	10.8	16.3	0.227	66	31.3
33	13.3	44.9	10.6	16.3	0.22	60	28.8
32.5	13.6	46.1	10.6	16.2	0.222	62	29.5
32.5	13.1	44.6	10.6	16.1	0.215	59	29
32.7	13.6	46.2	10.8	16.3	0.221	64	31.2
32.5	13.4	45.5	10.7	16	0.221	61	29.5
32.8	13.6	46	10.6	16.3	0.216	60	29.4
32.2	13.2	44.8	10.9	16.3	0.215	62	31.7
33.2	13.5	45.3	10.9	16.3	0.239	68	31.1
33.3	13.2	44.9	10.6	16.1	0.224	63	30.2
33	13.2	44.6	10.9	16.3	0.24	66	30.1
32.8	13.4	45.5	10.7	16.2	0.222	63	30.2
0.35	0.21	0.66	0.13	0.11	0.0071	2.8	1.07
32.2	13.1	44.6	10.6	16	0.215	59	28.8
33.3	13.7	46.4	10.9	16.3	0.239	68	31.7
1.1	0.6	1.8	0.3	0.3	0.024	9	2.9
0	0	0	0	0	0	1	0
0.6	0.3	0.9	0.2	0.2	0.017	6	1.5
1.1	1.6	1.5	1.2	0.7	3.2	4.5	3.5
1.5	2	2	3	10	5	15	15
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Conclusion:

The Calibration for BC6000 has been carried out successfully & the results obtained were inacceptable limits.

For Avantor Performance Materials India Private Limited



Gokulnath Ramadoss

Area Service Manager - Tamilnadu