

Date: 02/12/2021
Effective Date: 02/12/2021

Certificate of Calibration

Customer Name: Rapid Laboratories

Model : Automated Hematology Analyzer H560

Serial No.: K11042036144

Calibration Done Date: 02-12-2021

Next Calibration Due Date On or Before: 03/12/2022

Lab In-charge: Dr. Ish Pandhi

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, MCV and PLT) according to the standard procedures provided by Erba Lachema s.r.o, Karasek.

Calibration at site performed by
Rajpal Singh Rana
FSM
Transasia Bio-Medicals Ltd
Chandigarh

Incl:

1. Certificate of Inspection
2. Assay Sheet of Hematology Calibrator (H Cal)
3. Printouts
4. Traceability Document

L-J QC Table

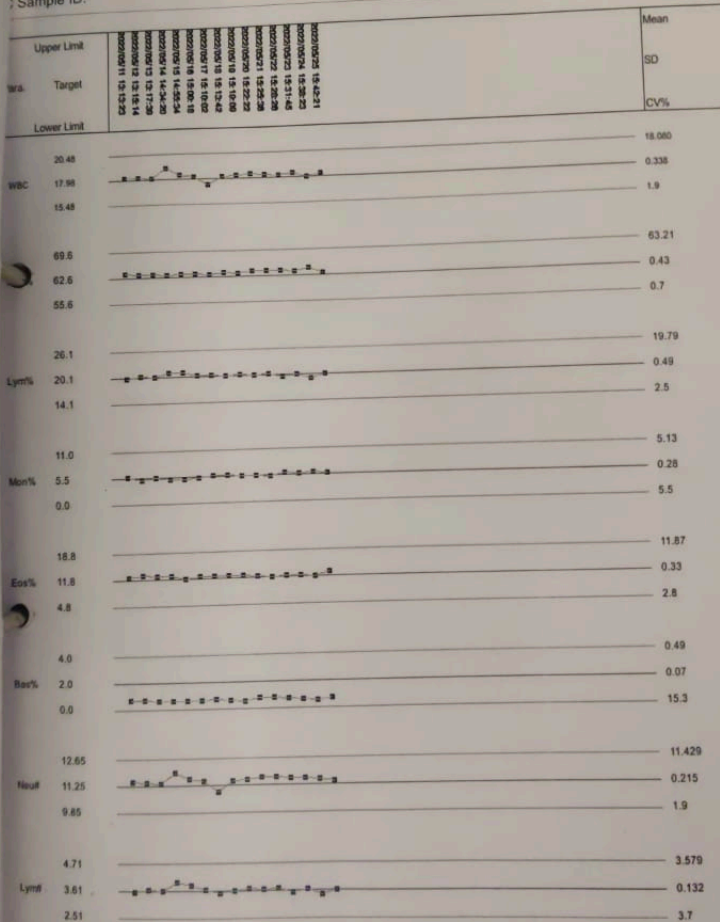
Editor: admin QC Mode: Whole Blood-CBC+DIFF Lot No.: EH2205
 Existing / Total: 15/500 Level: High Date Range: 2022/05/11-2022/05/25
 QC Sample ID: Exp. Date: 2022/07/10 Print Time: 2022/05/28 17:06:35

Qcm	Time	WBC	Neut%	Lymph%	Mon%	Eosin%	Bas%	Neut	Lymph	Mon	Eosin	Bas	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-SD	PLV-CV	PCT	PLV-DC	PLV-CC	
Target	/	17.80	62.8	20.1	5.5	11.8	2.0	11.25	3.61	0.99	2.12	0.36	6.41	17.0	52.9	97.7	31.8	32.5	14.1	56.1	489	9.1	12.4	17.0	0.447	36.6	150	
Unit (M)	/	2.50	7.0	6.0	5.5	7.0	2.0	1.40	1.10	0.99	1.30	0.30	0.50	0.8	4.0	6.0	2.8	3.0	3.0	12.0	60	3.0	3.0	0.200	8.0	35		
1	2022/05/25	15.42/21	16.11	62.8	15.8	5.3	12.5	0.6	11.34	3.55	0.96	2.26	0.10	5.22	16.5	50.4	96.5	31.5	32.7	14.3	55.8	508	11.0	13.2	17.6	0.456	32.7	155
14	2022/05/24	15.38/23	17.86	64.2	15.8	5.6	11.4	0.4	11.46	3.36	1.00	2.64	0.07	5.22	16.4	50.3	96.4	31.4	32.5	14.4	52.1	467	11.1	13.0	17.8	0.471	33.4	153
13	2022/05/23	16.31/48	16.19	63.4	15.6	5.3	11.7	0.5	11.53	3.57	0.96	2.13	0.08	5.22	16.4	50.2	96.3	31.5	32.7	14.3	55.9	490	11.0	12.7	17.3	0.485	33.3	159
12	2022/05/22	15.28/26	18.08	63.7	16.1	5.5	11.7	0.5	11.52	3.45	0.99	2.12	0.09	5.20	16.5	50.7	96.3	31.4	32.6	15.3	52.0	505	11.1	12.6	18.1	0.444	34.0	168
11	2022/05/21	15.25/26	18.17	63.8	20.0	4.9	11.5	0.6	11.56	3.80	0.89	2.09	0.11	5.20	16.6	50.2	96.5	31.8	33.0	15.1	55.1	499	11.1	15.0	18.8	0.455	33.2	160
9	2022/05/20	15.22/22	18.23	63.6	19.7	5.1	11.6	0.6	11.40	3.56	0.93	2.11	0.11	5.25	16.6	50.9	96.8	31.5	32.6	15.3	56.8	501	11.0	15.1	19.0	0.457	33.2	159
8	2022/05/18	15.19/42	18.01	63.2	18.7	5.3	11.9	0.4	11.45	3.64	0.93	2.16	0.07	5.28	16.6	51.0	97.1	31.5	32.5	14.1	55.2	497	11.0	14.7	18.9	0.384	33.0	167
7	2022/05/17	15.10/20	17.24	62.8	20.0	5.3	11.9	0.6	10.83	3.43	0.91	2.05	0.10	5.24	16.5	50.8	97.0	31.5	32.5	15.1	57.6	497	11.0	13.6	19.2	0.459	33.1	158
6	2022/05/16	15.07/18	16.82	63.1	20.0	4.9	12.0	0.4	11.38	3.60	0.88	2.16	0.08	5.25	16.6	50.9	97.1	31.7	32.6	15.1	61.3	508	10.3	13.9	18.1	0.508	30.5	148
5	2022/05/15	14.95/34	18.20	63.1	20.7	4.6	11.4	0.4	11.42	3.78	0.88	2.06	0.08	5.18	16.6	50.2	96.9	32.0	33.1	15.8	60.3	490	11.0	15.0	18.8	0.452	33.2	159
4	2022/05/14	14.54/20	18.92	62.6	20.6	4.7	12.1	0.5	11.84	3.90	0.89	2.29	0.09	5.43	17.4	53.0	97.6	32.0	32.8	15.0	61.8	495	11.1	14.8	19.0	0.442	33.7	160
3	2022/05/13	13.17/20	17.89	63.0	18.8	5.1	12.1	0.5	11.28	3.54	0.91	2.16	0.09	5.26	16.6	51.8	96.5	31.6	32.1	15.2	63.0	491	10.6	15.1	19.0	0.446	32.1	161
2	2022/05/12	13.15/14	18.03	63.0	19.9	4.7	12.4	0.5	11.35	3.90	0.85	2.24	0.09	5.22	16.6	51.3	96.4	31.6	32.3	15.0	58.0	489	11.0	14.0	18.4	0.482	32.9	160
1	2022/05/11	13.13/22	18.01	63.2	19.4	5.4	12.0	0.5	11.39	3.49	0.97	2.16	0.09	5.26	16.7	51.5	96.2	31.6	32.3	14.7	56.9	487	11.0	13.7	18.2	0.482	33.3	172

L-J QC Graph

Lot No.: EH2205
 Exp. Date: 2022/07/10
 Current Page/All: 15/15
 Print Time: 2022/05/26 17:

tor: admin Level: High
 No.: 12 QC Mode: Whole Blood-CBC+DIFF
 te Range: 2022/05/11 - 2022/05/25
 Sample ID:



Date: 02/12/2021
Effective Date: 02/12/2021

Certificate of Inspection

1. Model: Automated Hematology Analyzer H560
2. Serial No.: K11042036144
3. Calibration Date: 02-12-2021
4. Material used: H Cal (Lot No. PLUS1121, Expiry date: 10-Dec-2021)

By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\mu\text{L}$ or Less
RBC	0.00	$0.02 \times 10^6/\mu\text{L}$ or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	$10 \times 10^3/\mu\text{L}$ or Less

Technical Service Department
Transasia Bio-Medicals Ltd

6. PRECISION STUDY PERFORMED ON THE ANALYSER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

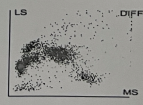
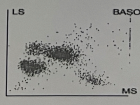
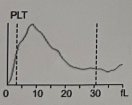
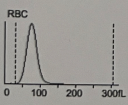
SMP NO	WBC	RBC	HGB	MCV	PLT
2	5.77	5.38	14.3	85.5	146
3	5.78	5.34	14.3	85.6	143
4	5.5	5.37	14.3	85.7	148
5	5.68	5.39	14.3	85.6	142
6	5.88	5.42	14.4	85.8	143
7	5.73	5.43	14.5	85.8	140
8	5.76	5.46	14.5	85.7	142
9	5.82	5.4	14.3	85.7	145
10	5.71	5.4	14.2	85.5	134
11	5.79	5.49	14.4	85.6	140
Mean	5.74	5.41	14.35	85.65	142.30
SD	0.10	0.04	0.10	0.11	3.86
CV%	1.78	0.81	0.68	0.13	2.71
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	PASS	PASS	PASS	PASS	PASS

Technical Service Department
 Transasia Bio Medicals Ltd

L-J QC Analysis

File No.: 1 Lot No.: EH2111 Level: Low
 Operator: admin Exp. Date: 2022/01/10 Run Time: 2021/12/02 11:45
 Print Time: 2021/12/02 11:49 QC Mode: Whole Blood-CBC+DIFF QC Sample ID:

Parameter	Result	Ref. Range	Unit
1 WBC	3.42	2.92-3.92	10 ³ /uL
2 Neu%	48.4	40.0-58.0	%
3 Lym%	39.2	29.0-47.0	%
4 Mon%	5.9	2.2-10.2	%
5 Eos%	6.5	1.8-11.8	%
6 Bas%	2.0	0.0-5.2	%
7 Neu#	1.66	1.28-2.08	10 ³ /uL
8 Lym#	1.34	0.90-1.70	10 ³ /uL
9 Mon#	0.20	0.07-0.35	10 ³ /uL
10 Eos#	0.22	0.08-0.38	10 ³ /uL
11 Bas#	0.07	0.00-0.18	10 ³ /uL
12 RBC	2.36	2.15-2.51	10 ⁶ /uL
13 HGB	5.9	5.4-6.2	g/dL
14 HCT	19.0	16.6-20.6	%
15 MCV	80.4	74.6-84.6	fL
16 MCH	25.0	22.5-27.5	pg
17 MCHC	31.1	28.4-34.4	g/dL
18 RDW-CV	15.3	12.8-18.8	%
19 RDW-SD	51.1	43.2-63.2	fL
20 PLT	76	49-89	10 ³ /uL
21 MPV	9.8	6.6-12.6	fL
22 PDW-SD	13.6	11.3-17.3	fL
23 PDW-CV	16.8	13.8-19.8	%
24 PCT	0.075	0.017-0.117	%
25 P-LCR	36.4	27.3-43.3	%
26 P-LCC	28	10-40	10 ³ /uL



EMI
 28
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YACIU2

Calibrator

Lot No.: PLUS1121
 Calibration Mode: Whole Blood

Exp. Date: 2021/12/10
 Print Time: 2021/12/02 11:39:50

Para.	WBC	RBC	HGB	MCV	PLT
Target	8.81	4.57	13.3	92.0	261
√ 1	8.63	4.59	13.2	93.5	256
√ 2	8.60	4.54	13.2	93.9	245
√ 3	8.46	4.52	13.2	93.9	249
√ 4	8.42	4.59	13.2	93.9	244
√ 5	8.50	4.51	13.2	93.7	237
√ 6	8.51	4.56	13.1	93.8	243
√ 7	8.52	4.53	13.1	93.8	244
√ 8	8.74	4.57	13.3	94.0	249
√ 9	8.51	4.55	13.1	93.8	246
√ 10	8.64	4.54	13.2	93.9	235
Mean	8.553	4.550	13.18	93.82	244.8
CV(%)	1.1	0.6	0.5	0.1	2.4
New Calibration Coefficient (%)	103.00	100.44	100.91	98.06	106.62
Original Calibration Coefficient (%)	100.00	100.00	96.00	100.00	100.00

