



Avantor Performance Materials India Limited
Regus Arcadia, 3rd Floor, Arcadia Centre, Room No. 320
Premise No. 31, Dr. Ambedkar Sarani, Kolkata-700046, India
Phone: (91-33) 66376140
Web: www.avantormaterials.com

Date- 17.02.2023

To Whom It May Concern

This is to certify that 5 part Hematology Analyzer Model – Mindray BC5150 (**Sn.No. - SR-7A002438**), installed at , **SHRIMEDSCAN IMAGING CENTRE (Department of Pathology)** ; has been calibrated as per the manufacture's recommendation on 16.02.2023

Calibrator used: SC CAL PLUS (Hematology Calibrator) of MINDRAY

Control Used: BC 5D (Hematology Control) of MINDRAY

The decontamination procedure has been performed as per the manufacturer's guidelines.

CALIBRATION DATE: 16.02.2023
CALLIBRATION DUE ON: 15.02.2024

For,
Avantor Performance Materials India Limited.

Aveek Sikdar
Aveek Sikdar (Area Service Manager)
Authorised Signatory

SC-Cal Plus Information

Product	Components			
	RBC	WBC	Platelet	Other
SC-Cal Plus	Human	Bovine	Porcine	N/A

The products listed above, manufactured by R&D Systems, Inc. contain human material that have been tested for all currently required FDA tests. Therefore, each human donor has been screened and found acceptable to donate blood for use in transfusion, and R&D Systems maintains traceability to each unit of human blood used in production of all whole blood products. The following cautionary statement:

POTENTIAL BIOHAZARDOUS MATERIAL



WARNING: POTENTIAL BIOHAZARDOUS MATERIAL. For in vitro diagnostic use. Each human donor/unit used in the preparation R&D Systems' products has been tested, and yielded non-reactive / negative results, according to FDA guidelines as contained in 21 CFR 610.40(a)(b). Specifically, a sample from each donation used has been tested by FDA-licensed tests and found nonreactive / negative for:

1. Antibodies to human immunodeficiency virus (anti-HIV 1,2), hepatitis C virus (anti-HCV), and antibodies to Trypanosoma cruzi (T cruzi, the causative agent of Chagas disease), and nonreactive for hepatitis B surface antigen (HBsAg)
2. Nucleic acid tests (NAT) for HCV ribonucleic acid (RNA), HIV-1 RNA, HBV deoxyribonucleic acid (DNA) and West Nile virus (WNV) RNA
3. Serologic test for syphilis

Because no test method can offer complete assurance that infectious agents are absent, material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures "

R&D Systems, Inc. also manufactures some products that contain cellular components from non-human, animal sources including bovine, porcine, caprine and avian cells. Both human and non-human cellular materials are chemically fixed with either glutaraldehyde or formaldehyde, washed extensively, and are suspended in anti-microbial solutions upon formulation into product.


In all cases, the raw materials are sourced from either USDA and/or FDA inspected establishments in the United States. The animals are verified to be clinically healthy at the time the materials are collected as judged by onsite veterinarians.

R&D Systems, Inc. is a registered Medical Device Establishment under the U.S. Food, Drug and Cosmetic Act; registration number 2182501. R&D Systems, Inc. is routinely inspected by the FDA.

Products are manufactured under the Food and Drug Administration's Good Manufacturing Practices Regulations; they are freely marketed in the U.S. and are in compliance with all U.S. laws and regulations.

SC-CAL PLUS

HEMATOLOGY CALIBRATOR

CALIBRATOR
LOT PLUS0223
 **2023-03-05**

Instrument	Parameter	Calibration Values	Acceptable Range
BC-6800, BC-6600	WBC x 10 ⁹ /L	8.64	8.44 - 8.84
	RBCx 10 ¹² /L	4.52	4.44 - 4.60
	HGB g/L	132	130 - 134
	MCV fL	90.9	88.9 - 92.9
	PLT x 10 ⁹ /L	261	249 - 273
BC-6800Plus BC-6700Plus BC-6600Plus	WBC x 10 ⁹ /L	8.65	8.45 - 8.85
	RBCx 10 ¹² /L	4.52	4.44 - 4.60
	HGB g/L	133	131 - 135
	MCV fL	91.1	89.1 - 93.1
	PLT x 10 ⁹ /L	258	246 - 270
BC-6200 BC-6100Plus, BC-6100 BC-6000Plus, BC-6000	WBC x 10 ⁹ /L	8.94	8.74 - 9.14
	RBCx 10 ¹² /L	4.59	4.51 - 4.67
	HGB g/L	135	133 - 137
	MCV fL	91.6	89.6 - 93.6
	PLT x 10 ⁹ /L	262	250 - 274
BC-5800, BC-5600	WBC x 10 ⁹ /L	8.99	8.79 - 9.19
	RBCx 10 ¹² /L	4.61	4.53 - 4.69
	HGB g/L	136	134 - 138
	MCV fL	85.9	83.9 - 87.9
	PLT x 10 ⁹ /L	270	258 - 282
BC-5390	WBC x 10 ⁹ /L	9.40	9.20 - 9.60
	RBCx 10 ¹² /L	4.59	4.51 - 4.67
	HGB g/L	133	131 - 135
	MCV fL	83.5	81.5 - 85.5
	PLT x 10 ⁹ /L	262	250 - 274
BC-5390CRP, BC-5180CRP BC-5310CRP BC-5100CRP	WBC x 10 ⁹ /L	9.44	9.24 - 9.64
	RBCx 10 ¹² /L	4.57	4.49 - 4.65
	HGB g/L	134	132 - 136
	MCV fL	83.8	81.8 - 85.8
	PLT x 10 ⁹ /L	259	247 - 271
BC-5380, BC-5180 BC-5300, BC-5300Vet BC-5100, BC-5100Vet <i>(Software version lower than 1.24.00.16860)</i>	WBC x 10 ⁹ /L	9.20	9.00 - 9.40
	RBCx 10 ¹² /L	4.55	4.47 - 4.63
	HGB g/L	134	132 - 136
	MCV fL	88.0	86.0 - 90.0
	PLT x 10 ⁹ /L	258	246 - 270
BC-5380, BC-5180 BC-5300, BC-5100 <i>(Software version 1.24.00.16860 or higher)</i>	WBC x 10 ⁹ /L	9.30	9.10 - 9.50
	RBCx 10 ¹² /L	4.54	4.46 - 4.62
	HGB g/L	135	133 - 137
	MCV fL	86.1	84.1 - 88.1
	PLT x 10 ⁹ /L	261	249 - 273
BC-5000, BC-5000Vet BC-5150, BC-5140 BC-5130, BC-5120	WBC x 10 ⁹ /L	8.98	8.78 - 9.18
	RBCx 10 ¹² /L	4.54	4.46 - 4.62
	HGB g/L	132	130 - 134
	MCV fL	87.2	85.2 - 89.2
	PLT x 10 ⁹ /L	259	247 - 271
BC-700[B], BC-700[R], BC-720[R], BC-760[B], BC-760[R], BC-780[R], BC-700[B] CS, BC-760[B] CS, BC-700[R] CS, BC-760[R] CS	WBC x 10 ⁹ /L	9.10	8.90 - 9.30
	RBCx 10 ¹² /L	4.58	4.50 - 4.66
	HGB g/L	134	132 - 136
	MCV fL	91.5	89.5 - 93.5
	PLT x 10 ⁹ /L	255	243 - 267
	ESR mm/h	13.83	
BC-7500[B] CRP, BC-7500[R] CRP, BC-7500[N] CRP, BC-7500[NR] CRP	WBC x 10 ⁹ /L	9.04	8.84 - 9.24
	RBCx 10 ¹² /L	4.58	4.50 - 4.66
	HGB g/L	135	133 - 137
	MCV fL	90.5	88.5 - 92.5
	PLT x 10 ⁹ /L	257	245 - 269

Before using, refer to the instruction sheet for mixing directions.

SC-CAL PLUS

HEMATOLOGY CALIBRATOR

CALIBRATOR
LOT PLUS0223
2023-03-05

Instrument	Parameter	Calibration Values	Acceptable Range
BC-3600, BC-3300	WBC x 10 ⁹ /L	9.2	9.0 - 9.4
	RBCx 10 ¹² /L	4.61	4.53 - 4.69
	HGB g/L	135	133 - 137
	MCV fL	85.2	83.2 - 87.2
	PLT x 10 ⁹ /L	270	258 - 282
BC-3200, BC-3000 CT	WBC x 10 ⁹ /L	9.7	9.5 - 9.9
	RBCx 10 ¹² /L	4.64	4.56 - 4.72
	HGB g/L	136	134 - 138
	MCV fL	86.7	84.7 - 88.7
	PLT x 10 ⁹ /L	262	250 - 274
BC-3000 Plus, BC-2900 BC-1800	WBC x 10 ⁹ /L	9.5	9.3 - 9.7
	RBCx 10 ¹² /L	4.71	4.63 - 4.79
	HGB g/L	137	135 - 139
	MCV fL	85.8	83.8 - 87.8
	PLT x 10 ⁹ /L	264	252 - 276
BC-2800, BC-2600 BC-2800Vet, BC-2600Vet	WBC x 10 ⁹ /L	9.3	9.1 - 9.5
	RBCx 10 ¹² /L	4.60	4.52 - 4.68
	HGB g/L	136	134 - 138
	MCV fL	87.2	85.2 - 89.2
	PLT x 10 ⁹ /L	257	245 - 269
BC-2300, BC-2100	WBC x 10 ⁹ /L	9.3	9.1 - 9.5
	RBCx 10 ¹² /L	4.44	4.34 - 4.54
	HGB g/L	135	133 - 137
	MCV fL	85.7	83.7 - 87.7
	PLT x 10 ⁹ /L	255	240 - 270
BC-20s, BC-21s BC-30, BC-30s, BC-30e BC-31, BC-31s	WBC x 10 ⁹ /L	9.2	9.0 - 9.4
	RBCx 10 ¹² /L	4.49	4.39 - 4.59
	HGB g/L	136	134 - 138
	MCV fL	88.2	86.2 - 90.2
	PLT x 10 ⁹ /L	261	246 - 276
BC-10, BC-10e, BC-11 BC-20, BC-21	WBC x 10 ⁹ /L	9.0	8.8 - 9.2
	RBCx 10 ¹² /L	4.49	4.39 - 4.59
	HGB g/L	135	133 - 137
	MCV fL	88.2	86.2 - 90.2
	PLT x 10 ⁹ /L	253	238 - 268

Before using, refer to the instruction sheet for mixing directions.


Mindray

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building, Keji 12th Road South, Hi-Tech Industrial Park, Nanshan, Shenzhen 518057, P.R.China

Tel: +86 755 81888998

Fax: +86 755 26582680

EC REP

Shanghai International Holding Corp. GmbH (Europe)

Effestraße 80 20537 Hamburg, Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

Calibration verification Mindray BC 5150

Serial No.	7A002438							
Mode	AL-WB-CBC							
Substance	SC-CAL PLUS							
Number of Summaries	10							
Lot No.	PLUS0223							
Running cycle no	Select	Date/Time	Operator	WBC	RBC	HGB	MCV	PLT
10	Yes	16-02-23 13:14	service	9	4.67	13.5	91.3	268
9	Yes	16-02-23 13:13	service	8.99	4.58	13.6	91.5	258
8	Yes	16-02-23 13:11	service	9.06	4.66	13.6	91.6	263
7	Yes	16-02-23 13:10	service	8.98	4.61	13.5	91.3	273
6	Yes	16-02-23 13:09	service	9.22	4.54	13.5	91.2	265
5	Yes	16-02-23 13:08	service	8.95	4.67	13.6	91.2	267
4	Yes	16-02-23 13:07	service	8.99	4.66	13.6	91.5	265
3	Yes	16-02-23 13:06	service	9	4.6	13.5	91.4	263
2	Yes	16-02-23 13:05	service	8.89	4.64	13.6	91.6	265
1	Yes	16-02-23 13:04	service	9.03	4.58	13.5	91.9	262
Mean				9.01	4.62	13.6	91.5	265
SD				0.086	0.046	0.04	0.22	4
Min				8.89	4.54	13.5	91.2	258
Max				9.22	4.67	13.6	91.9	273
R				0.33	0.13	0.1	0.7	15
d(Min)				0.01	0.01	0	0	0
d(Max)				0.21	0.08	0.1	0.5	8
CV%				1	1	0.3	0.2	1.5
Limit(%)				2.5	1.5	1	1	4
Acceptable Range				8.74 - 9.14	4.51 - 4.67	13.3 - 13.7	89.6 - 93.6	250 - 274
Result				Pass	Pass	Pass	Pass	Pass

CALIBRATION DATA

Calibration 7A002438

Lot No.	PLUS0223		Exp. Date	05/03/2023			
Operator	Admin		Calibration complete time	16/02/2023			
WB calibration data							
			Parameters				
Running Cycle No.	Select	Target→	WBC	RBC	HGB	MCV	PLT
WB 1#	Yes		8.94	4.59	13.5	91.6	262
WB 2#	Yes		8.72	4.54	13.4	92.1	245
WB 3#	Yes		8.75	4.46	13.3	92	240
WB 4#	Yes		8.99	4.51	13.4	91.6	245
WB 5#	Yes		8.94	4.53	13.4	91.4	239
WB 6#	Yes		9.01	4.48	13.4	91.8	244
WB 7#	Yes		9.01	4.49	13.4	91.8	241
WB 8#	Yes		8.71	4.45	13.3	91.8	230
WB 9#	Yes		8.96	4.49	13.4	91.5	236
WB 10#	Yes		8.96	4.47	13.3	91.6	241
Mean			8.92	4.49	13.3	91.4	230
CV%			1.575	0.641	0.17	91.7	239
Old Factor (%)			97.28	100	99.12	100	111.07
New Factor (%)			100.26	102.21	101.14	99.88	109.59

CARRY OVER DATA

Serial No.	7A002438							
Mode	CT-WB-CBC							
Substance	Blood sample							
	Date/Time	Operator	WBC	RBC	HGB	HCT	PLT	
High-Level 1	16-02-23 12:18	service	8.52	6.27	16.2	49.9	289	
High-Level 2	16-02-23 12:19	service	8.73	6.33	16.2	50.3	293	
High-Level 3	16-02-23 12:20	service	8.71	6.28	16.2	50	297	
Low-Level 1	16-02-23 12:21	service	0	0	0	0	0	
Low-Level 2	16-02-23 12:22	service	0	0	0	0	0	
Low-Level 3	16-02-23 12:23	service	0	0	0	0	0	
Carryover%			0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Limit%			≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%

Precision-AUTO LOADER

Serial No.	7A002438								
Mode	CT-WB-CBC								
Substance	Blood sample								
Number of Summaries	10								
Lot No.	2523010951								
Running cycle no	Select	Date/Time	Operator	WBC	RBC	HGB	MCV	PLT	
10	Yes	16-02-23 12:16	service	10.92	4.68	13.1	86.3	155	
9	Yes	16-02-23 12:15	service	10.52	4.7	13.1	86.2	156	
8	Yes	16-02-23 12:15	service	10.64	4.69	13.1	86.4	161	
7	Yes	16-02-23 12:14	service	10.64	4.7	13.1	86.2	153	
6	Yes	16-02-23 12:13	service	10.61	4.72	13.1	86.2	153	
5	Yes	16-02-23 12:13	service	10.59	4.72	13.1	86.2	161	
4	Yes	16-02-23 12:12	service	10.77	4.64	13.1	86.3	156	
3	Yes	16-02-23 12:12	service	10.64	4.61	13.1	86.1	161	
2	Yes	16-02-23 12:11	service	10.75	4.69	13.1	86	155	
1	Yes	16-02-23 12:10	service	10.87	4.66	13.1	85.9	156	
Mean				10.7	4.68	13.1	86.2	156	
SD				0.128	0.035	0.04	0.15	3.16	
Min				10.52	4.61	13.1	85.9	153	
Max				10.92	4.72	13.1	86.4	161	
R				0.4	0.11	0.1	0.5	8	
d(Min)				0.05	0	0	0	1	
d(Max)				0.23	0.07	0.1	0.3	4	
CV%				1.2	0.7	0.3	0.2	2.03	
Limit(%)				2.5	1.5	1	1	4	
Result				Pass	Pass	Pass	Pass	Pass	

BACKGROUND

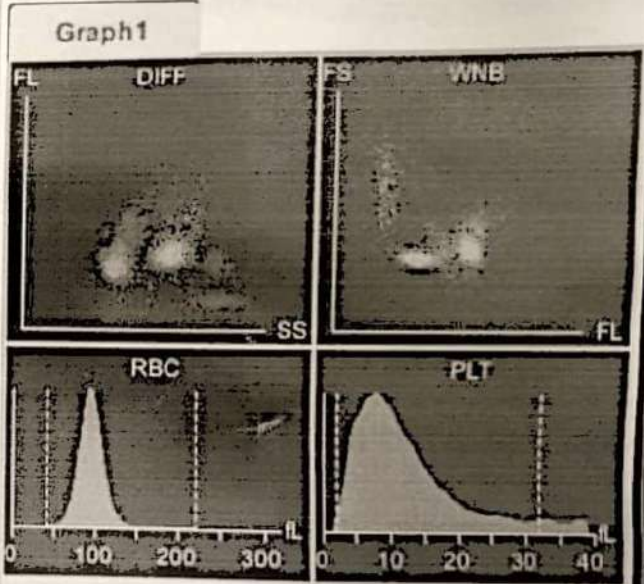
Serial No.	7A002438						
Mode	CT-WB-CBC						
Number of Summaries	6						
	Select	Date/Time	Operator	WBC	RBC	HGB	PLT
6	Yes	16-02-23 12:06	service	0	0	0	2
5	Yes	16-02-23 12:06	service	0	0	0	0
4	Yes	16-02-23 12:05	service	0.01	0	0	0
3	Yes	16-02-23 12:04	service	0	0	0	2
2	Yes	16-02-23 12:03	service	0	0	0	0
1	Yes	16-02-23 12:02	service	0	0	0	2
Limit				0.1	0.02	0.1	5
Result				Pass	Pass	Pass	Pass

File No. 58 Lot No. MB0123AN Level Normal Exp. Date 10/03/2023

Type Mindray Mode AL-WB-CD QC Sample ID MB0123AN

Parameter	Result	Unit	Parameter	Result	Unit
WBC	7.93	10 ³ /uL	RBC	4.40	10 ⁶ /uL
Neut#	4.19	10 ³ /uL	HGB	12.8	g/dL
Lym#	2.80	10 ³ /uL	HCT	40.4	%
Mon#	0.23	10 ³ /uL	MCV	91.9	fL
Eos#	0.66	10 ³ /uL	MCH	29.1	pg
Bas#	0.05	10 ³ /uL	MCHC	31.6	g/dL
IMG#	0.04	10 ³ /uL	RDW-CV	14.8	%
Neu%	52.9	%	RDW-SD	50.2	fL
Lym%	35.3	%	PLT	209	10 ³ /uL
Mon%	2.9	%	MPV	11.4	fL
Eos%	8.3	%	PDW	16.8	%
Bas%	0.6	%	PCT	0.238	%
IMG%	0.5	%	P-LCC	76	10 ⁹ /L
			P-LCR	36.4	%
			NRBC#	0.378	10 ³ /uL
			NRBC%	4.77	#00WBC

Time 16/02/2023 13:22



Post calibration QC

QC Table Count Previous Next RUO Para.

Count

QC

File No. 57

Lot No. MB0123AL

Level Low

Exp. Date 10/03/2023

Type Mindray

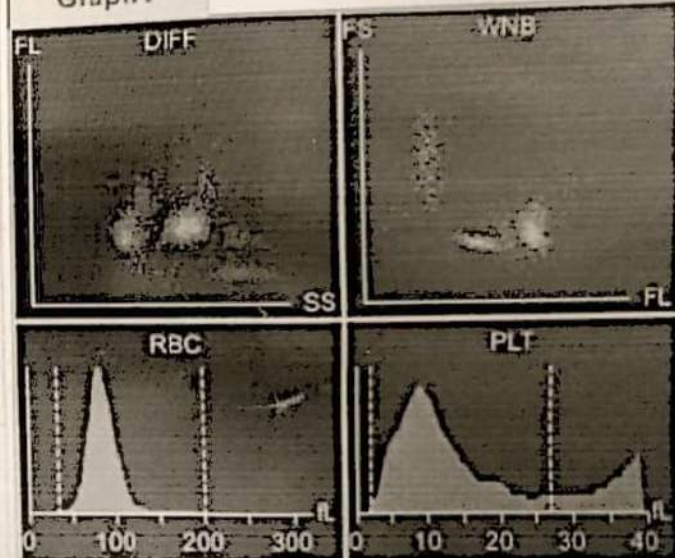
Mode AL-WB-CD

QC Sample ID MB0123AL

Time 16/02/2023 13:21

Parameter	Result	Unit	Parameter	Result	Unit
WBC	4.01	10 ³ /uL	RBC	2.40	10 ⁶ /uL
Neut#	2.46	10 ³ /uL	HGB	6.1	g/dL
Lym#	0.98	10 ³ /uL	HCT	19.7	%
Mon#	0.07	10 ³ /uL	MCV	82.2	fL
Eos#	0.48	10 ³ /uL	MCH	25.5	pg
Bas#	0.02	10 ³ /uL	MCHC	31.0	g/dL
IMG#	0.05	10 ³ /uL	RDW-CV	17.6	%
Neu%	61.5	%	RDW-SD	52.9	fL
Lym%	24.4	%	PLT	52	10 ³ /uL
Mon%	1.8	%	MPV	11.2	fL
Eos%	11.8	%	PDW	15.8	%
Bas%	0.5	%	PCT	0.058	%
IMG%	1.2	%	P-LCC	18	10 ⁹ /L
			P-LCR	33.7	%
			NRBC#	0.350	10 ³ /uL
			NRBC%	8.72	/100WBC

Graph 1



QC Table

Count

Previous

Next

RUO Para.

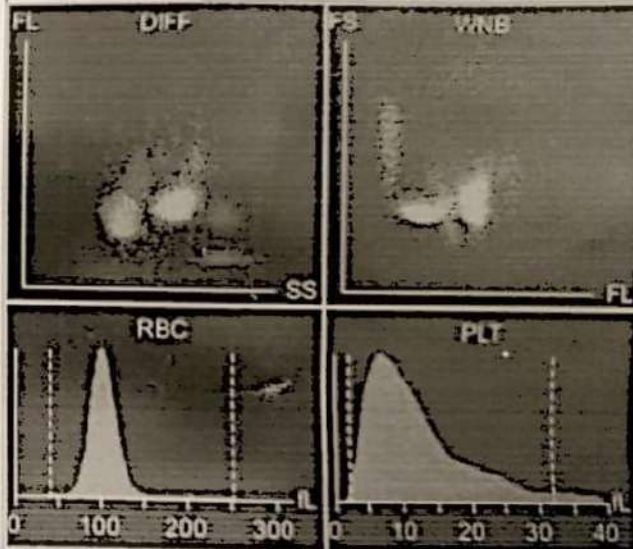
QC

File No. 56 Lot No. MB0123AH Level High Exp. Date 10/03/2023
 Type Mindray Mode AL-WB-CD QC Sample ID MB0123AH

Parameter	Result	Unit	Parameter	Result	Unit
WBC	21.35	10 ³ /uL	RBC	4.98	10 ⁶ /uL
Neu#	12.18	10 ³ /uL	HGB	16.1	g/dL
Lym#	6.91	10 ³ /uL	HCT	49.3	%
Mon#	0.64	10 ³ /uL	MCV	99.0	fL
Eos#	1.51	10 ³ /uL	MCH	32.3	pg
Bas#	0.11	10 ³ /uL	MCHC	32.6	g/dL
IMG#	0.18	10 ³ /uL	RDW-CV	14.3	%
Neu%	57.0	%	RDW-SD	52.4	fL
Lym%	32.4	%	PLT	398	10 ³ /uL
Mon%	3.0	%	MPV	11.5	fL
Eos%	7.1	%	PDW	16.9	%
Bas%	0.5	%	PCT	0.456	%
IMG%	0.8	%	P-LCC	146	10 ⁹ /L
			P-LCR	36.7	%
			NRBC#	0.597	10 ³ /uL
			NRBC%	2.80	/100WBC

Time 16/02/2023 13:23

Graph1



QC Table

Count

Previous

Next

RUO Para.