

CBC-5DMRFor MINDRAY
HEMATOLOGY CONTROLS**CONTROL**

ASSAY VALUES AND EXPECTED RANGES

LOT BC2305B**2023-07-10**

Instrument	Parameter	Low		Normal		High	
		LOT	BC2305BL	LOT	BC2305BN	LOT	BC2305BH
BC-5800, BC-5600	WBC x 10 ⁹ /L		3.57 ± 0.50		8.13 ± 1.00		17.60 ± 2.50 +
QC Mode	Neu x 10 ⁹ /L		1.76 ± 0.32		4.66 ± 0.73		11.25 ± 1.59
	Lym x 10 ⁹ /L		1.39 ± 0.33		2.32 ± 0.66		3.59 ± 1.41
	Mon x 10 ⁹ /L		0.24 ± 0.18		0.54 ± 0.41		1.07 ± 0.88
	Eos x 10 ⁹ /L		0.14 ± 0.11		0.53 ± 0.41		1.51 ± 1.23
	Bas x 10 ⁹ /L		0.04 ± 0.04		0.08 ± 0.08		0.18 ± 0.18
	Neu %		49.4 ± 9.0		57.4 ± 9.0		63.9 ± 9.0
	Lym %		38.8 ± 9.0		28.5 ± 8.0		20.4 ± 8.0
	Mon %		6.8 ± 5.0		6.6 ± 5.0		6.1 ± 5.0
	Eos %		4.0 ± 3.0		6.5 ± 5.0		8.6 ± 7.0
	Bas %		1.0 ± 1.0		1.0 ± 1.0		1.0 ± 1.0
	RBC x 10 ¹² /L		2.08 ± 0.18		4.00 ± 0.24		4.72 ± 0.30
	HGB g/dL		5.8 ± 0.4		12.6 ± 0.6		16.2 ± 0.8
	HCT %		17.5 ± 1.5		37.9 ± 2.0		49.5 ± 2.4
	MCV fL		83.9 ± 5.0		94.7 ± 5.0		104.8 ± 5.0
	MCH pg		27.9 ± 2.5		31.5 ± 2.5		34.3 ± 2.5
	MCHC g/dL		33.2 ± 3.0		33.3 ± 3.0		32.8 ± 3.0
	RDW-CV %		15.4 ± 3.0		13.9 ± 3.0		13.3 ± 3.0
	RDW-SD fL		45.7 ± 10.0		47.8 ± 10.0		51.2 ± 10.0
	PLT x 10 ⁹ /L		48 ± 20		256 ± 40		505 ± 60
	MPV fL		9.5 ± 3.0		8.0 ± 3.0		7.7 ± 3.0
	PCT % *		0.046 ± 0.046		0.205 ± 0.100		0.389 ± 0.200
	PDW *		17.0 ± 3.0		15.8 ± 3.0		15.8 ± 3.0
	P-LCC x 10 ⁹ /L		17 ± 15		53 ± 25		95 ± 35
	P-LCR %		35.5 ± 10.0		20.8 ± 10.0		18.9 ± 10.0
BC-5390	WBC x 10 ⁹ /L		3.30 ± 0.50		7.90 ± 1.00		16.95 ± 2.50
QC Mode	Neu x 10 ⁹ /L		1.73 ± 0.30		4.74 ± 0.72		11.44 ± 1.53
	Lym x 10 ⁹ /L		1.20 ± 0.30		2.09 ± 0.71		3.05 ± 1.36
	Mon x 10 ⁹ /L		0.18 ± 0.13		0.47 ± 0.40		0.85 ± 0.68
	Eos x 10 ⁹ /L		0.18 ± 0.13		0.59 ± 0.48		1.61 ± 1.36
	Bas x 10 ⁹ /L		0.74 ± 0.33		2.17 ± 0.79		5.20 ± 1.70
	Neu %		52.5 ± 9.0		60.0 ± 9.0		67.5 ± 9.0
	Lym %		36.5 ± 9.0		26.5 ± 9.0		18.0 ± 8.0
	Mon %		5.5 ± 4.0		6.0 ± 5.0		5.0 ± 4.0
	Eos %		5.5 ± 4.0		7.5 ± 6.0		9.5 ± 8.0
	Bas %		22.5 ± 10.0		27.5 ± 10.0		30.7 ± 10.0
	RBC x 10 ¹² /L		2.01 ± 0.18		3.93 ± 0.24		4.71 ± 0.30
	HGB g/dL		5.2 ± 0.4		11.7 ± 0.6		15.0 ± 0.8
	HCT %		16.7 ± 1.5		36.9 ± 2.0		48.0 ± 2.4
	MCV fL		83.0 ± 5.0		94.0 ± 5.0		102.0 ± 5.0
	MCH pg		25.9 ± 2.5		29.8 ± 2.5		31.8 ± 2.5
	MCHC g/dL		31.2 ± 3.0		31.7 ± 3.0		31.2 ± 3.0
	RDW-CV %		14.5 ± 3.0		13.0 ± 3.0		13.0 ± 3.0
	RDW-SD fL		47.5 ± 8.0		47.5 ± 8.0		50.0 ± 8.0
	PLT x 10 ⁹ /L		49 ± 20		251 ± 40		491 ± 60
	MPV fL		12.7 ± 3.0		10.9 ± 3.0		10.4 ± 3.0

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

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R&D Systems, Inc.

614 McKinley Place NE

Minneapolis, MN 55413 USA

AS136-014 Rev. 09/22

CBC-5DMRFor MINDRAY
HEMATOLOGY CONTROLS**CONTROL**

ASSAY VALUES AND EXPECTED RANGES

LOT BC2305B**2023-07-10**

Instrument	Parameter	Low		Normal		High		
		LOT	BC2305BL	LOT	BC2305BN	LOT	BC2305BH	
BC-5390 CRP	WBC x 10 ⁹ /L		3.27 ± 0.50		7.98 ± 1.00		16.88 ± 2.50	++
BC-5310 CRP	Neu x 10 ⁹ /L		1.72 ± 0.30		4.78 ± 0.72		11.40 ± 1.52	
QC Mode	Lym x 10 ⁹ /L		1.21 ± 0.30		2.18 ± 0.64		3.07 ± 1.35	
	Mon x 10 ⁹ /L		0.16 ± 0.15		0.44 ± 0.40		0.81 ± 0.76	
	Eos x 10 ⁹ /L		0.18 ± 0.16		0.58 ± 0.48		1.60 ± 1.35	
	Bas x 10 ⁹ /L		0.74 ± 0.33		2.20 ± 0.80		5.18 ± 1.69	
	Neu %		52.6 ± 9.0		59.9 ± 9.0		67.5 ± 9.0	
	Lym %		36.9 ± 9.0		27.3 ± 8.0		18.2 ± 8.0	
	Mon %		4.9 ± 4.5		5.5 ± 5.0		4.8 ± 4.5	
	Eos %		5.6 ± 5.0		7.3 ± 6.0		9.5 ± 8.0	
	Bas %		22.6 ± 10.0		27.6 ± 10.0		30.7 ± 10.0	
	RBC x 10 ¹² /L		2.02 ± 0.18		3.95 ± 0.24		4.69 ± 0.30	
	HGB g/dL		5.3 ± 0.4		11.7 ± 0.6		15.0 ± 0.8	
	HCT %		16.6 ± 1.5		36.9 ± 2.0		47.9 ± 2.4	
	MCV fL		82.1 ± 5.0		93.4 ± 5.0		102.2 ± 5.0	
	MCH pg		26.2 ± 2.5		29.6 ± 2.5		32.0 ± 2.5	
	MCHC g/dL		32.0 ± 3.0		31.7 ± 3.0		31.3 ± 3.0	
	RDW-CV %		15.2 ± 3.0		13.7 ± 3.0		13.5 ± 3.0	
	RDW-SD fL		46.2 ± 8.0		47.2 ± 8.0		50.1 ± 8.0	
	PLT x 10 ⁹ /L		45 ± 20		247 ± 40		483 ± 60	
	MPV fL		10.9 ± 3.0		9.0 ± 3.0		8.4 ± 3.0	
	PCT % *		0.049 ± 0.049		0.222 ± 0.100		0.406 ± 0.200	
	PDW *		16.2 ± 3.0		16.0 ± 3.0		15.9 ± 3.0	
	P-LCC x 10 ⁹ /L		16 ± 15		48 ± 25		78 ± 35	
	P-LCR %		35.1 ± 10.0		19.5 ± 10.0		16.1 ± 10.0	
BC-5300, BC-5100	WBC x 10 ⁹ /L		3.30 ± 0.50		7.85 ± 1.00		17.05 ± 2.50	
BC-5380, BC-5180	Neu x 10 ⁹ /L		1.78 ± 0.30		4.93 ± 0.71		11.68 ± 1.54	
QC Mode	Lym x 10 ⁹ /L		1.24 ± 0.30		2.14 ± 0.71		3.24 ± 1.37	
(Software version lower than 1.24.00.16860)	Mon x 10 ⁹ /L		0.10 ± 0.10		0.24 ± 0.24		0.51 ± 0.51	
	Eos x 10 ⁹ /L		0.18 ± 0.17		0.55 ± 0.48		1.62 ± 1.37	
	Bas x 10 ⁹ /L		1.63 ± 0.33		5.32 ± 0.79		13.21 ± 1.71	
	Neu %		54.0 ± 9.0		62.8 ± 9.0		68.5 ± 9.0	
	Lym %		37.5 ± 9.0		27.2 ± 9.0		19.0 ± 8.0	
	Mon %		3.0 ± 3.0		3.0 ± 3.0		3.0 ± 3.0	
	Eos %		5.5 ± 5.0		7.0 ± 6.0		9.5 ± 8.0	
	Bas %		49.3 ± 10.0		67.8 ± 10.0		77.5 ± 10.0	
	RBC x 10 ¹² /L		2.04 ± 0.18		3.98 ± 0.24		4.70 ± 0.30	
	HGB g/dL		5.4 ± 0.4		11.7 ± 0.6		15.0 ± 0.8	
	HCT %		17.5 ± 1.5		38.4 ± 2.0		50.1 ± 2.4	
	MCV fL		86.0 ± 5.0		96.5 ± 5.0		106.5 ± 5.0	
	MCH pg		26.5 ± 2.5		29.4 ± 2.5		31.9 ± 2.5	
	MCHC g/dL		30.8 ± 3.0		30.5 ± 3.0		30.0 ± 3.0	
	RDW-CV %		15.3 ± 3.0		13.8 ± 3.0		13.3 ± 3.0	
	RDW-SD fL		57.3 ± 8.0		59.3 ± 8.0		62.0 ± 8.0	
	PLT x 10 ⁹ /L		44 ± 20		240 ± 40		477 ± 60	
	MPV fL		10.5 ± 3.0		8.6 ± 3.0		8.0 ± 3.0	
	PCT % *		0.046 ± 0.046		0.205 ± 0.100		0.380 ± 0.200	
	PDW *		16.5 ± 3.0		16.1 ± 3.0		15.9 ± 3.0	

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ASSAY VALUES AND EXPECTED RANGES

LOT BC2305B**2023-07-10**

Instrument	Parameter	Low		Normal		High		
		LOT	BC2305BL	LOT	BC2305BN	LOT	BC2305BH	
BC-5300, BC-5100	WBC x 10 ⁹ /L		3.21 ± 0.50		7.85 ± 1.00		16.56 ± 2.50	+++
BC-5380, BC-5180	Neu x 10 ⁹ /L		1.73 ± 0.29		4.87 ± 0.71		11.36 ± 1.49	
QC Mode	Lym x 10 ⁹ /L		1.20 ± 0.29		2.19 ± 0.63		3.16 ± 1.33	
(Software version 1.24.00.16860 or higher)	Mon x 10 ⁹ /L		0.08 ± 0.08		0.21 ± 0.21		0.43 ± 0.43	
	Eos x 10 ⁹ /L		0.20 ± 0.17		0.58 ± 0.47		1.61 ± 1.33	
	Bas x 10 ⁹ /L		1.61 ± 0.32		5.33 ± 0.79		12.95 ± 1.66	
	Neu %		54.1 ± 9.0		62.0 ± 9.0		68.6 ± 9.0	
	Lym %		37.3 ± 9.0		27.9 ± 8.0		19.1 ± 8.0	
	Mon %		2.4 ± 2.4		2.7 ± 2.7		2.6 ± 2.6	
	Eos %		6.2 ± 5.0		7.4 ± 6.0		9.7 ± 8.0	
	Bas %		50.2 ± 10.0		67.9 ± 10.0		78.2 ± 10.0	
	RBC x 10 ¹² /L		2.05 ± 0.18		3.95 ± 0.24		4.64 ± 0.30	
	HGB g/dL		5.4 ± 0.4		11.7 ± 0.6		15.0 ± 0.8	
	HCT %		17.1 ± 1.5		37.3 ± 2.0		48.4 ± 2.4	
	MCV fL		83.4 ± 5.0		94.4 ± 5.0		104.3 ± 5.0	
	MCH pg		26.3 ± 2.5		29.6 ± 2.5		32.3 ± 2.5	
	MCHC g/dL		31.6 ± 3.0		31.4 ± 3.0		31.0 ± 3.0	
	RDW-CV %		15.5 ± 3.0		14.1 ± 3.0		13.6 ± 3.0	
	RDW-SD fL		53.9 ± 8.0		55.8 ± 8.0		59.4 ± 8.0	
	PLT x 10 ⁹ /L		43 ± 20		248 ± 40		483 ± 60	
	MPV fL		10.1 ± 3.0		8.2 ± 3.0		7.8 ± 3.0	
	PCT % *		0.043 ± 0.043		0.203 ± 0.100		0.377 ± 0.200	
	PDW *		16.4 ± 3.0		16.0 ± 3.0		15.9 ± 3.0	
BC-5000, BC-5150, BC-5140	WBC x 10 ⁹ /L		3.44 ± 0.50		8.05 ± 1.00		17.18 ± 2.50	
BC-5130, BC-5120, BC-5000Vet	Neu x 10 ⁹ /L		1.74 ± 0.42		4.70 ± 0.97		11.33 ± 2.06	
QC Mode	Lym x 10 ⁹ /L		1.24 ± 0.31		2.24 ± 0.65		3.01 ± 1.21	
	Mon x 10 ⁹ /L		0.24 ± 0.24		0.54 ± 0.54		1.07 ± 1.07	
	Eos x 10 ⁹ /L		0.19 ± 0.19		0.48 ± 0.48		1.51 ± 1.51	
	Bas x 10 ⁹ /L		0.03 ± 0.03		0.09 ± 0.09		0.26 ± 0.26	
	Neu %		50.4 ± 12.0		58.4 ± 12.0		66.0 ± 12.0	
	Lym %		36.1 ± 9.0		27.8 ± 8.0		17.5 ± 7.0	
	Mon %		6.9 ± 6.9		6.7 ± 6.7		6.2 ± 6.2	
	Eos %		5.6 ± 5.6		6.0 ± 6.0		8.8 ± 8.8	
	Bas %		1.0 ± 1.0		1.1 ± 1.1		1.5 ± 1.5	
	RBC x 10 ¹² /L		2.04 ± 0.18		3.98 ± 0.24		4.72 ± 0.30	
	HGB g/dL		5.4 ± 0.4		11.8 ± 0.6		15.3 ± 0.8	
	HCT %		16.8 ± 1.5		36.8 ± 2.0		47.4 ± 2.4	
	MCV fL		82.5 ± 5.0		92.5 ± 5.0		100.4 ± 5.0	
	MCH pg		26.5 ± 2.5		29.6 ± 2.5		32.4 ± 2.5	
	MCHC g/dL		32.1 ± 3.0		32.1 ± 3.0		32.3 ± 3.0	
	RDW-CV %		18.9 ± 3.0		16.6 ± 3.0		15.9 ± 3.0	
	RDW-SD fL		56.5 ± 8.0		56.5 ± 8.0		59.0 ± 8.0	
	PLT x 10 ⁹ /L		44 ± 20		245 ± 40		497 ± 60	
	MPV fL		11.8 ± 3.0		10.1 ± 3.0		9.4 ± 3.0	
	PCT % *		0.052 ± 0.050		0.247 ± 0.100		0.467 ± 0.200	
	PDW *		15.8 ± 3.0		16.1 ± 3.0		16.2 ± 3.0	
	P-LCC x 10 ⁹ /L**		18 ± 15		67 ± 25		115 ± 35	
	P-LCR %**		41.9 ± 10.0		27.5 ± 10.0		23.1 ± 10.0	

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** These parameters are not provided on BC-5000/BC-5000Vet analyzers

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LOT BC2305B**2023-07-10**

Instrument	Parameter	Low		Normal		High		
		LOT	BC2305BL	LOT	BC2305BN	LOT	BC2305BH	
BC-5300 Vet, BC-5100Vet QC Mode	WBC x 10 ⁹ /L		3.30 ± 0.50		7.85 ± 1.00		17.05 ± 2.50	****
	Neu x 10 ⁹ /L		1.78 ± 0.30		4.93 ± 0.71		11.68 ± 1.54	
	Lym x 10 ⁹ /L		1.24 ± 0.30		2.14 ± 0.71		3.24 ± 1.37	
	Mon x 10 ⁹ /L		0.10 ± 0.10		0.24 ± 0.24		0.51 ± 0.51	
	Eos x 10 ⁹ /L		0.18 ± 0.17		0.55 ± 0.48		1.62 ± 1.37	
	Neu %		54.0 ± 9.0		62.8 ± 9.0		68.5 ± 9.0	
	Lym %		37.5 ± 9.0		27.2 ± 9.0		19.0 ± 8.0	
	Mon %		3.0 ± 3.0		3.0 ± 3.0		3.0 ± 3.0	
	Eos %		5.5 ± 5.0		7.0 ± 6.0		9.5 ± 8.0	
	RBC x 10 ¹² /L		2.04 ± 0.18		3.98 ± 0.24		4.70 ± 0.30	
	HGB g/dL		5.4 ± 0.4		11.7 ± 0.6		15.0 ± 0.8	
	HCT %		17.5 ± 1.5		38.4 ± 2.0		50.1 ± 2.4	
	MCV fL		86.0 ± 5.0		96.5 ± 5.0		106.5 ± 5.0	
	MCH pg		26.5 ± 2.5		29.4 ± 2.5		31.9 ± 2.5	
	MCHC g/dL		30.8 ± 3.0		30.5 ± 3.0		30.0 ± 3.0	
	RDW-CV %		15.3 ± 3.0		13.8 ± 3.0		13.3 ± 3.0	
	RDW-SD fL		57.3 ± 8.0		59.3 ± 8.0		62.0 ± 8.0	
	PLT x 10 ⁹ /L		44 ± 20		240 ± 40		477 ± 60	
	MPV fL		10.5 ± 3.0		8.6 ± 3.0		8.0 ± 3.0	
PCT % *		0.046 ± 0.046		0.205 ± 0.100		0.380 ± 0.200		
PDW *		16.5 ± 3.0		16.1 ± 3.0		15.9 ± 3.0		

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CBC-5DMR

HEMATOLOGY CONTROLS

CONTROL

INTENDED USE

CBC-5DMR is an assayed whole blood control designed to monitor values on multi parameter hematology cell counters. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

CBC-5DMR is an *in vitro* diagnostic reagent composed of human erythrocytes and mammalian leukocytes and platelets suspended in a plasma-like fluid with preservatives.



PRECAUTION

CBC-5DMR is intended for *in vitro* diagnostic use only by trained personnel.



WARNING:

POTENTIALLY BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this 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.



STABILITY AND STORAGE

Store CBC-5DMR upright at 2° - 8° C (35° - 46° F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 14 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**



INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
 - b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - c) Gently invert the tube 8 - 10 times immediately before sampling.

3. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
After sampling:
 - a) If tube has been opened for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - b) Return tubes to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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IS136-002 Rev 07/13



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