

CBC-X

HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803


2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	LOW		NORMAL		HIGH					
	LOT 23050801	Assay Mean ± Limit	Expected Range	LOT 23050802	Assay Mean ± Limit	Expected Range	LOT 23050803	Assay Mean ± Limit	Expected Range	
Sysmex XT2000i, XT-1800i (Manual Sampling)	Parameters									
	WBC (10 ⁹ /L)	3.85 ± 0.80	3.05 - 4.65	7.65 ± 1.00	6.65 - 8.65	20.25 ± 2.20	18.05 - 22.45			
	RBC (10 ¹² /L)	2.35 ± 0.15	2.20 - 2.50	4.65 ± 0.24	4.41 - 4.89	5.80 ± 0.30	5.50 - 6.10			
	HGB (g/dL)	6.1 ± 0.4	5.7 - 6.5	13.6 ± 0.6	13.0 - 14.2	18.1 ± 0.7	17.4 - 18.8			
	HCT (%)	18.6 ± 2.0	16.6 - 20.6	40.5 ± 2.5	38.0 - 43.0	53.9 ± 3.0	50.9 - 56.9			
	MCV (fL)	79.0 ± 5.0	74.0 - 84.0	87.0 ± 5.0	82.0 - 92.0	93.0 ± 5.0	88.0 - 98.0			
	MCH (pg)	26.0 ± 2.5	23.5 - 28.5	29.2 ± 2.5	26.7 - 31.7	31.2 ± 2.5	28.7 - 33.7			
	MCHC (g/dL)	32.9 ± 3.0	29.9 - 35.9	33.6 ± 3.0	30.6 - 36.6	33.6 ± 3.0	30.6 - 36.6			
	RDW-SD (fL)	44.5 ± 10.0	34.5 - 54.5	44.5 ± 10.0	34.5 - 54.5	45.5 ± 10.0	35.5 - 55.5			
	RDW-CV (%)	15.0 ± 5.0	10.0 - 20.0	15.5 ± 5.0	10.5 - 20.5	14.0 ± 5.0	9.0 - 19.0			
	PLT (10 ⁹ /L)	51 ± 20	31 - 71	202 ± 40	162 - 242	401 ± 65	336 - 466			
	MPV (fL)	8.9 ± 3.0	5.9 - 11.9	9.7 ± 3.0	6.7 - 12.7	10.1 ± 3.0	7.1 - 13.1			
	NEUT # (10 ⁹ /L)	2.46 ± 0.60	1.86 - 3.06	4.13 ± 1.00	3.13 - 5.13	12.45 ± 2.43	10.02 - 14.88			
	LYMPH # (10 ⁹ /L)	0.73 ± 0.35	0.38 - 1.08	2.30 ± 0.77	1.53 - 3.07	4.35 ± 2.02	2.33 - 6.37			
	MONO # (10 ⁹ /L)	0.10 ± 0.10	0.00 - 0.20	0.27 ± 0.27	0.00 - 0.54	0.51 ± 0.51	0.00 - 1.02			
	EO # (10 ⁹ /L)	0.56 ± 0.27	0.29 - 0.83	0.96 ± 0.54	0.42 - 1.50	2.94 ± 1.42	1.52 - 4.36			
	BASO # (10 ⁹ /L)	3.08 ± 1.20	1.88 - 4.28	5.74 ± 3.00	2.74 - 8.74	16.20 ± 5.00	11.20 - 21.20			
	NEUT%	64.0 ± 12.0	52.0 - 76.0	54.0 ± 12.0	42.0 - 66.0	61.5 ± 12.0	49.5 - 73.5			
	LYMPH%	19.0 ± 9.0	10.0 - 28.0	30.0 ± 10.0	20.0 - 40.0	21.5 ± 10.0	11.5 - 31.5			
	MONO%	2.5 ± 2.5	0.0 - 5.0	3.5 ± 3.5	0.0 - 7.0	2.5 ± 2.5	0.0 - 5.0			
	EO%	14.5 ± 7.0	7.5 - 21.5	12.5 ± 7.0	5.5 - 19.5	14.5 ± 7.0	7.5 - 21.5			
	BASO%	80.0 ± 20.0	60.0 - 100.0	75.0 ± 25.0	50.0 - 100.0	80.0 ± 20.0	60.0 - 100.0			
	The parameters with assay values listed below are provided to allow for quality control testing of your instrument only. These parameters are defined by the FDA as "FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES".									
	PLT-O (10 ⁹ /L)	41 ± 35	6 - 76	175 ± 65	110 - 240	380 ± 85	295 - 465			
	PCT (%)	0.05 ± 0.03	0.02 - 0.08	0.20 ± 0.07	0.13 - 0.27	0.39 ± 0.11	0.28 - 0.50			
	PDW (fL)	11.0 ± 5.0	6.0 - 16.0	12.0 ± 5.0	7.0 - 17.0	12.0 ± 5.0	7.0 - 17.0			
	P-LCR (%)	20.0 ± 20.0	0.0 - 40.0	20.0 ± 20.0	0.0 - 40.0	20.0 ± 20.0	0.0 - 40.0			
	IG # (10 ⁹ /L)	0.58 ± 0.50	0.08 - 1.08	1.03 ± 1.03	0.00 - 2.06	3.34 ± 2.00	1.34 - 5.34			
	IG %	15.0 ± 12.0	3.0 - 27.0	13.5 ± 13.5	0.0 - 27.0	16.5 ± 10.0	6.5 - 26.5			
	DIFF-X (ch)	139.0 ± 30.0	109.0 - 169.0	142.0 ± 30.0	112.0 - 172.0	143.0 ± 30.0	113.0 - 173.0			
DIFF-Y (ch)	56.0 ± 30.0	26.0 - 86.0	56.0 ± 30.0	26.0 - 86.0	50.0 ± 30.0	20.0 - 80.0				
BASO-X (ch)	109.0 ± 30.0	79.0 - 139.0	106.0 ± 30.0	76.0 - 136.0	109.0 ± 30.0	79.0 - 139.0				
BASO-Y (ch)	139.0 ± 40.0	99.0 - 179.0	136.0 ± 40.0	96.0 - 176.0	138.0 ± 40.0	98.0 - 178.0				
RBC-O (10 ¹² /L)*	2.46 ± 0.30	2.16 - 2.76	4.65 ± 0.50	4.15 - 5.15	5.84 ± 0.60	5.24 - 6.44				
RBC-X (ch)*	22.0 ± 15.0	7.0 - 37.0	24.0 ± 15.0	9.0 - 39.0	24.0 ± 15.0	9.0 - 39.0				
RBC-Y (ch)*	146.0 ± 35.0	111.0 - 181.0	162.0 ± 35.0	127.0 - 197.0	170.0 ± 35.0	135.0 - 205.0				

*Not available for the Sysmex XT-1800i

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AS148-008 Rev. 03/23

CBC-X

HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803



2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	LOW			NORMAL			HIGH		
	LOT	23050801		LOT	23050802		LOT	23050803	
Parameters	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range
WBC (10 ⁹ /L)	3.85	± 0.80	3.05 - 4.65	7.25	± 1.00	6.25 - 8.25	19.10	± 2.20	16.90 - 21.30
RBC (10 ¹² /L)	2.35	± 0.15	2.20 - 2.50	4.65	± 0.24	4.41 - 4.89	5.70	± 0.30	5.40 - 6.00
HGB (g/dL)	6.1	± 0.4	5.7 - 6.5	13.6	± 0.6	13.0 - 14.2	17.9	± 0.7	17.2 - 18.6
HCT (%)	18.6	± 2.0	16.6 - 20.6	40.5	± 2.5	38.0 - 43.0	53.0	± 3.0	50.0 - 56.0
MCV (fL)	79.0	± 5.0	74.0 - 84.0	87.0	± 5.0	82.0 - 92.0	93.0	± 5.0	88.0 - 98.0
MCH (pg)	26.0	± 2.5	23.5 - 28.5	29.2	± 2.5	26.7 - 31.7	31.4	± 2.5	28.9 - 33.9
MCHC (g/dL)	32.9	± 3.0	29.9 - 35.9	33.6	± 3.0	30.6 - 36.6	33.8	± 3.0	30.8 - 36.8
RDW-SD (fL)	44.5	± 10.0	34.5 - 54.5	44.5	± 10.0	34.5 - 54.5	45.5	± 10.0	35.5 - 55.5
RDW-CV (%)	15.0	± 5.0	10.0 - 20.0	15.5	± 5.0	10.5 - 20.5	14.0	± 5.0	9.0 - 19.0
PLT (10 ⁹ /L)	51	± 20	31 - 71	202	± 40	162 - 242	362	± 65	297 - 427
MPV (fL)	8.9	± 3.0	5.9 - 11.9	9.7	± 3.0	6.7 - 12.7	10.1	± 3.0	7.1 - 13.1
NEUT # (10 ⁹ /L)	2.46	± 0.60	1.86 - 3.06	3.92	± 1.00	2.92 - 4.92	11.75	± 2.29	9.46 - 14.04
LYMPH # (10 ⁹ /L)	0.73	± 0.35	0.38 - 1.08	2.18	± 0.73	1.45 - 2.91	4.11	± 1.91	2.20 - 6.02
MONO # (10 ⁹ /L)	0.10	± 0.10	0.00 - 0.20	0.25	± 0.25	0.00 - 0.50	0.48	± 0.48	0.00 - 0.96
EO # (10 ⁹ /L)	0.56	± 0.27	0.29 - 0.83	0.91	± 0.51	0.40 - 1.42	2.77	± 1.34	1.43 - 4.11
BASO # (10 ⁹ /L)	3.08	± 1.20	1.88 - 4.28	5.44	± 3.00	2.44 - 8.44	15.28	± 5.00	10.28 - 20.28
NEUT%	64.0	± 12.0	52.0 - 76.0	54.0	± 12.0	42.0 - 66.0	61.5	± 12.0	49.5 - 73.5
LYMPH%	19.0	± 9.0	10.0 - 28.0	30.0	± 10.0	20.0 - 40.0	21.5	± 10.0	11.5 - 31.5
MONO%	2.5	± 2.5	0.0 - 5.0	3.5	± 3.5	0.0 - 7.0	2.5	± 2.5	0.0 - 5.0
EO%	14.5	± 7.0	7.5 - 21.5	12.5	± 7.0	5.5 - 19.5	14.5	± 7.0	7.5 - 21.5
BASO%	80.0	± 20.0	60.0 - 100.0	75.0	± 25.0	50.0 - 100.0	80.0	± 20.0	60.0 - 100.0
The parameters with assay values listed below are provided to allow for quality control testing of your instrument only. These parameters are defined by the FDA as "FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES".									
PLT-O (10 ⁹ /L)	41	± 35	6 - 76	175	± 65	110 - 240	352	± 85	267 - 437
PCT (%)	0.05	± 0.03	0.02 - 0.08	0.20	± 0.07	0.13 - 0.27	0.39	± 0.11	0.28 - 0.50
PDW (fL)	11.0	± 5.0	6.0 - 16.0	12.0	± 5.0	7.0 - 17.0	12.0	± 5.0	7.0 - 17.0
P-LCR (%)	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0
IG # (10 ⁹ /L)	0.58	± 0.50	0.08 - 1.08	0.98	± 0.98	0.00 - 1.96	3.15	± 2.00	1.15 - 5.15
IG %	15.0	± 12.0	3.0 - 27.0	13.5	± 13.5	0.0 - 27.0	16.5	± 10.0	6.5 - 26.5
DIFF-X (ch)	139.0	± 30.0	109.0 - 169.0	142.0	± 30.0	112.0 - 172.0	143.0	± 30.0	113.0 - 173.0
DIFF-Y (ch)	56.0	± 30.0	26.0 - 86.0	56.0	± 30.0	26.0 - 86.0	50.0	± 30.0	20.0 - 80.0
BASO-X (ch)	109.0	± 30.0	79.0 - 139.0	106.0	± 30.0	76.0 - 136.0	109.0	± 30.0	79.0 - 139.0
BASO-Y (ch)	139.0	± 40.0	99.0 - 179.0	136.0	± 40.0	96.0 - 176.0	138.0	± 40.0	98.0 - 178.0
RBC-O (10 ¹² /L)*	2.46	± 0.30	2.16 - 2.76	4.65	± 0.50	4.15 - 5.15	5.84	± 0.60	5.24 - 6.44
RBC-X (ch)*	22.0	± 15.0	7.0 - 37.0	24.0	± 15.0	9.0 - 39.0	24.0	± 15.0	9.0 - 39.0
RBC-Y (ch)*	146.0	± 35.0	111.0 - 181.0	162.0	± 35.0	127.0 - 197.0	170.0	± 35.0	135.0 - 205.0

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	LOW			NORMAL			HIGH		
	LOT	23050801		LOT	23050802		LOT	23050803	
Parameters	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range
WBC-C (10 ⁹ /L)	4.00	± 1.20	2.80 - 5.20	7.95	± 1.80	6.15 - 9.75	21.00	± 3.00	18.00 - 24.00
WBC-D (10 ⁹ /L)	4.05	± 1.20	2.85 - 5.25	7.75	± 1.80	5.95 - 9.55	20.00	± 3.00	17.00 - 23.00
RBC (10 ¹² /L)	2.30	± 0.15	2.15 - 2.45	4.70	± 0.24	4.46 - 4.94	5.85	± 0.30	5.55 - 6.15
HGB (g/dL)	5.9	± 0.4	5.5 - 6.3	13.5	± 0.6	12.9 - 14.1	18.1	± 0.7	17.4 - 18.8
HCT (%)	18.3	± 2.0	16.3 - 20.3	41.4	± 2.5	38.9 - 43.9	54.7	± 3.0	51.7 - 57.7
MCV (fL)	79.5	± 5.0	74.5 - 84.5	88.0	± 5.0	83.0 - 93.0	93.5	± 5.0	88.5 - 98.5
MCH (pg)	25.7	± 2.5	23.2 - 28.2	28.7	± 2.5	26.2 - 31.2	30.9	± 2.5	28.4 - 33.4
MCHC (g/dL)	32.3	± 3.0	29.3 - 35.3	32.6	± 3.0	29.6 - 35.6	33.1	± 3.0	30.1 - 36.1
RDW-SD (fL)	45.0	± 10.0	35.0 - 55.0	46.0	± 10.0	36.0 - 56.0	45.5	± 10.0	35.5 - 55.5
RDW-CV (%)	16.0	± 5.0	11.0 - 21.0	15.5	± 5.0	10.5 - 20.5	14.5	± 5.0	9.5 - 19.5
PLT (10 ⁹ /L)	50	± 25	25 - 75	200	± 40	160 - 240	395	± 65	330 - 460
MPV (fL)	8.9	± 3.0	5.9 - 11.9	9.9	± 3.0	6.9 - 12.9	10.3	± 3.0	7.3 - 13.3
NEUT # (10 ⁹ /L)	2.23	± 1.01	1.22 - 3.24	3.57	± 1.16	2.41 - 4.73	10.50	± 4.00	6.50 - 14.50
LYMPH # (10 ⁹ /L)	0.77	± 0.49	0.28 - 1.26	2.44	± 1.16	1.28 - 3.60	4.60	± 2.40	2.20 - 7.00
MONO # (10 ⁹ /L)	0.10	± 0.10	0.00 - 0.20	0.23	± 0.23	0.00 - 0.46	0.50	± 0.50	0.00 - 1.00
EO # (10 ⁹ /L)	0.59	± 0.41	0.18 - 1.00	0.93	± 0.70	0.23 - 1.63	2.70	± 2.00	0.70 - 4.70
BASO # (10 ⁹ /L)	0.36	± 0.36	0.00 - 0.72	0.58	± 0.58	0.00 - 1.16	1.70	± 1.70	0.00 - 3.40
NEUT%	55.0	± 25.0	30.0 - 80.0	46.0	± 15.0	31.0 - 61.0	52.5	± 20.0	32.5 - 72.5
LYMPH%	19.0	± 12.0	7.0 - 31.0	31.5	± 15.0	16.5 - 46.5	23.0	± 12.0	11.0 - 35.0
MONO%	2.5	± 2.5	0.0 - 5.0	3.0	± 3.0	0.0 - 6.0	2.5	± 2.5	0.0 - 5.0
EO%	14.5	± 10.0	4.5 - 24.5	12.0	± 9.0	3.0 - 21.0	13.5	± 10.0	3.5 - 23.5
BASO%	9.0	± 9.0	0.0 - 18.0	7.5	± 7.5	0.0 - 15.0	8.5	± 8.5	0.0 - 17.0
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PCT (%)	0.04	± 0.03	0.01 - 0.07	0.20	± 0.07	0.13 - 0.27	0.41	± 0.11	0.30 - 0.52
PDW (fL)	12.0	± 5.0	7.0 - 17.0	12.5	± 5.0	7.5 - 17.5	13.0	± 5.0	8.0 - 18.0
P-LCR (%)	15.5	± 12.0	3.5 - 27.5	20.0	± 13.0	7.0 - 33.0	22.5	± 15.0	7.5 - 37.5
DIFF-X (ch)	148.5	± 30.0	118.5 - 178.5	145.0	± 30.0	115.0 - 175.0	147.0	± 30.0	117.0 - 177.0
DIFF-Y (ch)	53.0	± 30.0	23.0 - 83.0	53.5	± 30.0	23.5 - 83.5	56.0	± 30.0	26.0 - 86.0
FSC-X	29.5	± 10.0	19.5 - 39.5	28.5	± 10.0	18.5 - 38.5	29.5	± 15.0	14.5 - 44.5

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	LOW			NORMAL			HIGH		
	LOT	23050801		LOT	23050802		LOT	23050803	
Parameters	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range
WBC (10 ⁹ /L)	3.85	± 0.80	3.05 - 4.65	7.65	± 1.00	6.65 - 8.65	20.25	± 2.20	18.05 - 22.45
RBC (10 ¹² /L)	2.35	± 0.15	2.20 - 2.50	4.65	± 0.24	4.41 - 4.89	5.80	± 0.30	5.50 - 6.10
HGB (g/dL)	6.1	± 0.4	5.7 - 6.5	13.6	± 0.6	13.0 - 14.2	18.1	± 0.7	17.4 - 18.8
HCT (%)	18.6	± 2.0	16.6 - 20.6	40.5	± 2.5	38.0 - 43.0	53.9	± 3.0	50.9 - 56.9
MCV (fL)	79.0	± 5.0	74.0 - 84.0	87.0	± 5.0	82.0 - 92.0	93.0	± 5.0	88.0 - 98.0
MCH (pg)	26.0	± 2.5	23.5 - 28.5	29.2	± 2.5	26.7 - 31.7	31.2	± 2.5	28.7 - 33.7
MCHC (g/dL)	32.9	± 3.0	29.9 - 35.9	33.6	± 3.0	30.6 - 36.6	33.6	± 3.0	30.6 - 36.6
RDW-SD (fL)	44.5	± 10.0	34.5 - 54.5	44.5	± 10.0	34.5 - 54.5	45.5	± 10.0	35.5 - 55.5
RDW-CV (%)	15.0	± 5.0	10.0 - 20.0	15.5	± 5.0	10.5 - 20.5	14.0	± 5.0	9.0 - 19.0
PLT (10 ⁹ /L)	51	± 20	31 - 71	202	± 40	162 - 242	401	± 65	336 - 466
MPV (fL)	8.9	± 3.0	5.9 - 11.9	9.7	± 3.0	6.7 - 12.7	10.1	± 3.0	7.1 - 13.1
NEUT # (10 ⁹ /L)	2.46	± 0.60	1.86 - 3.06	4.13	± 1.00	3.13 - 5.13	12.45	± 2.43	10.02 - 14.88
LYMPH # (10 ⁹ /L)	0.73	± 0.35	0.38 - 1.08	2.30	± 0.77	1.53 - 3.07	4.35	± 2.02	2.33 - 6.37
MONO # (10 ⁹ /L)	0.10	± 0.10	0.00 - 0.20	0.27	± 0.27	0.00 - 0.54	0.51	± 0.51	0.00 - 1.02
EO # (10 ⁹ /L)	0.56	± 0.27	0.29 - 0.83	0.96	± 0.54	0.42 - 1.50	2.94	± 1.42	1.52 - 4.36
BASO # (10 ⁹ /L)	3.08	± 1.20	1.88 - 4.28	5.74	± 3.00	2.74 - 8.74	16.20	± 5.00	11.20 - 21.20
NEUT%	64.0	± 12.0	52.0 - 76.0	54.0	± 12.0	42.0 - 66.0	61.5	± 12.0	49.5 - 73.5
LYMPH%	19.0	± 9.0	10.0 - 28.0	30.0	± 10.0	20.0 - 40.0	21.5	± 10.0	11.5 - 31.5
MONO%	2.5	± 2.5	0.0 - 5.0	3.5	± 3.5	0.0 - 7.0	2.5	± 2.5	0.0 - 5.0
EO%	14.5	± 7.0	7.5 - 21.5	12.5	± 7.0	5.5 - 19.5	14.5	± 7.0	7.5 - 21.5
BASO%	80.0	± 20.0	60.0 - 100.0	75.0	± 25.0	50.0 - 100.0	80.0	± 20.0	60.0 - 100.0
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PLT-O (10 ⁹ /L)	41	± 35	6 - 76	175	± 65	110 - 240	380	± 85	295 - 465
PCT (%)	0.05	± 0.03	0.02 - 0.08	0.20	± 0.07	0.13 - 0.27	0.39	± 0.11	0.28 - 0.50
PDW (fL)	11.0	± 5.0	6.0 - 16.0	12.0	± 5.0	7.0 - 17.0	12.0	± 5.0	7.0 - 17.0
P-LCR (%)	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0
IG # (10 ⁹ /L)	0.58	± 0.50	0.08 - 1.08	1.03	± 1.03	0.00 - 2.06	3.34	± 2.00	1.34 - 5.34
IG %	15.0	± 12.0	3.0 - 27.0	13.5	± 13.5	0.0 - 27.0	16.5	± 10.0	6.5 - 26.5
DIFF-X (ch)	139.0	± 30.0	109.0 - 169.0	142.0	± 30.0	112.0 - 172.0	143.0	± 30.0	113.0 - 173.0
DIFF-Y (ch)	56.0	± 30.0	26.0 - 86.0	56.0	± 30.0	26.0 - 86.0	50.0	± 30.0	20.0 - 80.0
BASO-X (ch)	109.0	± 30.0	79.0 - 139.0	106.0	± 30.0	76.0 - 136.0	109.0	± 30.0	79.0 - 139.0
BASO-Y (ch)	139.0	± 40.0	99.0 - 179.0	136.0	± 40.0	96.0 - 176.0	138.0	± 40.0	98.0 - 178.0
RBC-O (10 ¹² /L)	2.46	± 0.30	2.16 - 2.76	4.65	± 0.50	4.15 - 5.15	5.84	± 0.60	5.24 - 6.44
RBC-X (ch)	22.0	± 15.0	7.0 - 37.0	24.0	± 15.0	9.0 - 39.0	24.0	± 15.0	9.0 - 39.0
RBC-Y (ch)	146.0	± 35.0	111.0 - 181.0	162.0	± 35.0	127.0 - 197.0	170.0	± 35.0	135.0 - 205.0

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CBC-X

HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803



2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	LOW			NORMAL			HIGH		
	LOT	23050801		LOT	23050802		LOT	23050803	
Parameters	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range	Assay Mean	± Limit	Expected Range
WBC (10 ⁹ /L)	3.85	± 0.80	3.05 - 4.65	7.25	± 1.00	6.25 - 8.25	19.10	± 2.20	16.90 - 21.30
RBC (10 ¹² /L)	2.35	± 0.15	2.20 - 2.50	4.65	± 0.24	4.41 - 4.89	5.70	± 0.30	5.40 - 6.00
HGB (g/dL)	6.1	± 0.4	5.7 - 6.5	13.6	± 0.6	13.0 - 14.2	17.9	± 0.7	17.2 - 18.6
HCT (%)	18.6	± 2.0	16.6 - 20.6	40.5	± 2.5	38.0 - 43.0	53.0	± 3.0	50.0 - 56.0
MCV (fL)	79.0	± 5.0	74.0 - 84.0	87.0	± 5.0	82.0 - 92.0	93.0	± 5.0	88.0 - 98.0
MCH (pg)	26.0	± 2.5	23.5 - 28.5	29.2	± 2.5	26.7 - 31.7	31.4	± 2.5	28.9 - 33.9
MCHC (g/dL)	32.9	± 3.0	29.9 - 35.9	33.6	± 3.0	30.6 - 36.6	33.8	± 3.0	30.8 - 36.8
RDW-SD (fL)	44.5	± 10.0	34.5 - 54.5	44.5	± 10.0	34.5 - 54.5	45.5	± 10.0	35.5 - 55.5
RDW-CV (%)	15.0	± 5.0	10.0 - 20.0	15.5	± 5.0	10.5 - 20.5	14.0	± 5.0	9.0 - 19.0
PLT (10 ⁹ /L)	51	± 20	31 - 71	202	± 40	162 - 242	362	± 65	297 - 427
MPV (fL)	8.9	± 3.0	5.9 - 11.9	9.7	± 3.0	6.7 - 12.7	10.1	± 3.0	7.1 - 13.1
NEUT # (10 ⁹ /L)	2.46	± 0.60	1.86 - 3.06	3.92	± 1.00	2.92 - 4.92	11.75	± 2.29	9.46 - 14.04
LYMPH # (10 ⁹ /L)	0.73	± 0.35	0.38 - 1.08	2.18	± 0.73	1.45 - 2.91	4.11	± 1.91	2.20 - 6.02
MONO # (10 ⁹ /L)	0.10	± 0.10	0.00 - 0.20	0.25	± 0.25	0.00 - 0.50	0.48	± 0.48	0.00 - 0.96
EO # (10 ⁹ /L)	0.56	± 0.27	0.29 - 0.83	0.91	± 0.51	0.40 - 1.42	2.77	± 1.34	1.43 - 4.11
BASO # (10 ⁹ /L)	3.08	± 1.20	1.88 - 4.28	5.44	± 3.00	2.44 - 8.44	15.28	± 5.00	10.28 - 20.28
NEUT%	64.0	± 12.0	52.0 - 76.0	54.0	± 12.0	42.0 - 66.0	61.5	± 12.0	49.5 - 73.5
LYMPH%	19.0	± 9.0	10.0 - 28.0	30.0	± 10.0	20.0 - 40.0	21.5	± 10.0	11.5 - 31.5
MONO%	2.5	± 2.5	0.0 - 5.0	3.5	± 3.5	0.0 - 7.0	2.5	± 2.5	0.0 - 5.0
EO%	14.5	± 7.0	7.5 - 21.5	12.5	± 7.0	5.5 - 19.5	14.5	± 7.0	7.5 - 21.5
BASO%	80.0	± 20.0	60.0 - 100.0	75.0	± 25.0	50.0 - 100.0	80.0	± 20.0	60.0 - 100.0
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PLT-O (10 ⁹ /L)	41	± 35	6 - 76	175	± 65	110 - 240	352	± 85	267 - 437
PCT (%)	0.05	± 0.03	0.02 - 0.08	0.20	± 0.07	0.13 - 0.27	0.39	± 0.11	0.28 - 0.50
PDW (fL)	11.0	± 5.0	6.0 - 16.0	12.0	± 5.0	7.0 - 17.0	12.0	± 5.0	7.0 - 17.0
P-LCR (%)	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0	20.0	± 20.0	0.0 - 40.0
IG # (10 ⁹ /L)	0.58	± 0.50	0.08 - 1.08	0.98	± 0.98	0.00 - 1.96	3.15	± 2.00	1.15 - 5.15
IG %	15.0	± 12.0	3.0 - 27.0	13.5	± 13.5	0.0 - 27.0	16.5	± 10.0	6.5 - 26.5
DIFF-X (ch)	139.0	± 30.0	109.0 - 169.0	142.0	± 30.0	112.0 - 172.0	143.0	± 30.0	113.0 - 173.0
DIFF-Y (ch)	56.0	± 30.0	26.0 - 86.0	56.0	± 30.0	26.0 - 86.0	50.0	± 30.0	20.0 - 80.0
BASO-X (ch)	109.0	± 30.0	79.0 - 139.0	106.0	± 30.0	76.0 - 136.0	109.0	± 30.0	79.0 - 139.0
BASO-Y (ch)	139.0	± 40.0	99.0 - 179.0	136.0	± 40.0	96.0 - 176.0	138.0	± 40.0	98.0 - 178.0
RBC-O (10 ¹² /L)	2.46	± 0.30	2.16 - 2.76	4.65	± 0.50	4.15 - 5.15	5.84	± 0.60	5.24 - 6.44
RBC-X (ch)	22.0	± 15.0	7.0 - 37.0	24.0	± 15.0	9.0 - 39.0	24.0	± 15.0	9.0 - 39.0
RBC-Y (ch)	146.0	± 35.0	111.0 - 181.0	162.0	± 35.0	127.0 - 197.0	170.0	± 35.0	135.0 - 205.0

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HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803



2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	Parameters	LOW		NORMAL		HIGH		
		LOT 23050801	Expected Range	LOT 23050802	Expected Range	LOT 23050803	Expected Range	
		Assay Mean ± Limit		Assay Mean ± Limit		Assay Mean ± Limit		
Sysmex XN Series	WBC (10 ⁹ /L)	3.85 ± 1.20	2.65 - 5.05	7.55 ± 1.80	5.75 - 9.35	20.75 ± 3.00	17.75 - 23.75	
	WBC-D (10 ⁹ /L)	3.75 ± 1.20	2.55 - 4.95	7.45 ± 1.80	5.65 - 9.25	20.20 ± 3.00	17.20 - 23.20	
	RBC (10 ¹² /L)	2.27 ± 0.15	2.12 - 2.42	4.65 ± 0.24	4.41 - 4.89	5.80 ± 0.30	5.50 - 6.10	
	HGB (g/dL)	6.0 ± 0.4	5.6 - 6.4	13.6 ± 0.6	13.0 - 14.2	18.0 ± 0.7	17.3 - 18.7	
	HCT (%)	17.8 ± 2.0	15.8 - 19.8	40.5 ± 2.5	38.0 - 43.0	53.9 ± 3.0	50.9 - 56.9	
	MCV (fL)	78.5 ± 5.0	73.5 - 83.5	87.0 ± 5.0	82.0 - 92.0	93.0 ± 5.0	88.0 - 98.0	
	MCH (pg)	26.4 ± 2.5	23.9 - 28.9	29.2 ± 2.5	26.7 - 31.7	31.0 ± 2.5	28.5 - 33.5	
	MCHC (g/dL)	33.7 ± 3.0	30.7 - 36.7	33.6 ± 3.0	30.6 - 36.6	33.4 ± 3.0	30.4 - 36.4	
	RDW-SD (fL)	45.0 ± 10.0	35.0 - 55.0	47.0 ± 10.0	37.0 - 57.0	47.5 ± 10.0	37.5 - 57.5	
	RDW-CV (%)	16.5 ± 5.0	11.5 - 21.5	15.5 ± 5.0	10.5 - 20.5	15.0 ± 5.0	10.0 - 20.0	
	PLT (10 ⁹ /L)	42 ± 20	22 - 62	197 ± 40	157 - 237	410 ± 65	345 - 475	
	MPV (fL)	10.2 ± 3.0	7.2 - 13.2	10.1 ± 3.0	7.1 - 13.1	9.8 ± 3.0	6.8 - 12.8	
	NEUT # (10 ⁹ /L)	2.25 ± 0.38	1.87 - 2.63	3.78 ± 0.76	3.02 - 4.54	11.72 ± 2.07	9.65 - 13.79	
	LYMPH # (10 ⁹ /L)	0.73 ± 0.38	0.35 - 1.11	2.23 ± 0.76	1.47 - 2.99	4.36 ± 2.08	2.28 - 6.44	
	MONO # (10 ⁹ /L)	0.10 ± 0.10	0.00 - 0.20	0.19 ± 0.19	0.00 - 0.38	0.52 ± 0.52	0.00 - 1.04	
	EO # (10 ⁹ /L)	0.58 ± 0.27	0.31 - 0.85	0.98 ± 0.53	0.45 - 1.51	3.11 ± 1.45	1.66 - 4.56	
	BASO # (10 ⁹ /L)	0.19 ± 0.19	0.00 - 0.38	0.38 ± 0.38	0.00 - 0.76	1.04 ± 1.04	0.00 - 2.08	
	NEUT%	58.5 ± 10.0	48.5 - 68.5	50.0 ± 10.0	40.0 - 60.0	56.5 ± 10.0	46.5 - 66.5	
	LYMPH%	19.0 ± 10.0	9.0 - 29.0	29.5 ± 10.0	19.5 - 39.5	21.0 ± 10.0	11.0 - 31.0	
	MONO%	2.5 ± 2.5	0.0 - 5.0	2.5 ± 2.5	0.0 - 5.0	2.5 ± 2.5	0.0 - 5.0	
	EO%	15.0 ± 7.0	8.0 - 22.0	13.0 ± 7.0	6.0 - 20.0	15.0 ± 7.0	8.0 - 22.0	
	BASO%	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0	
	NRBC# (10 ⁹ /L)	0.40 ± 19.60	0.00 - 20.00	0.40 ± 19.60	0.00 - 20.00	0.40 ± 19.60	0.00 - 20.00	
	NRBC% (/100 WBC)	2.0 ± 98.0	0.0 - 100.0	2.0 ± 98.0	0.0 - 100.0	2.0 ± 98.0	0.0 - 100.0	
	The parameters with assay values listed below are provided to allow for quality control testing of your instrument only. These parameters are defined by the FDA as "FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES".							
		PLT-O (10 ⁹ /L)	52 ± 38	14 - 90	225 ± 65	160 - 290	460 ± 85	375 - 545
		PCT (%)	0.05 ± 0.03	0.02 - 0.08	0.20 ± 0.07	0.13 - 0.27	0.40 ± 0.11	0.29 - 0.51
		PDW (fL)	11.5 ± 5.0	6.5 - 16.5	11.5 ± 5.0	6.5 - 16.5	11.5 ± 5.0	6.5 - 16.5
		P-LCR (%)	27.5 ± 20.0	7.5 - 47.5	26.5 ± 20.0	6.5 - 46.5	24.0 ± 20.0	4.0 - 44.0
		IPF (%)	20.0 ± 20.0	0.0 - 40.0	20.0 ± 20.0	0.0 - 40.0	20.0 ± 20.0	0.0 - 40.0
		IG # (10 ⁹ /L)	0.56 ± 0.30	0.26 - 0.86	0.94 ± 0.40	0.54 - 1.34	2.91 ± 1.60	1.31 - 4.51
		IG%	14.5 ± 5.0	9.5 - 19.5	12.5 ± 5.0	7.5 - 17.5	14.0 ± 5.0	9.0 - 19.0
	RBC-O (10 ¹² /L)	2.28 ± 0.30	1.98 - 2.58	4.60 ± 0.50	4.10 - 5.10	5.75 ± 0.60	5.15 - 6.35	

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HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803



2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	LOW		NORMAL		HIGH	
	LOT 23050801		LOT 23050802		LOT 23050803	
Parameters	Assay Mean ± Limit	Expected Range	Assay Mean ± Limit	Expected Range	Assay Mean ± Limit	Expected Range
WBC-C (10 ⁹ /L)	3.80 ± 1.20	2.60 - 5.00	7.65 ± 2.00	5.65 - 9.65	20.80 ± 3.20	17.60 - 24.00
WBC-D (10 ⁹ /L)	3.60 ± 1.20	2.40 - 4.80	7.20 ± 2.00	5.20 - 9.20	19.85 ± 3.20	16.65 - 23.05
RBC (10 ¹² /L)	2.25 ± 0.15	2.10 - 2.40	4.63 ± 0.24	4.39 - 4.87	5.83 ± 0.30	5.53 - 6.13
HGB (g/dL)	6.0 ± 0.4	5.6 - 6.4	13.6 ± 0.6	13.0 - 14.2	18.1 ± 0.7	17.4 - 18.8
HCT (%)	18.0 ± 2.0	16.0 - 20.0	40.7 ± 2.5	38.2 - 43.2	54.2 ± 3.0	51.2 - 57.2
MCV (fL)	80.0 ± 5.0	75.0 - 85.0	88.0 ± 5.0	83.0 - 93.0	93.0 ± 5.0	88.0 - 98.0
MCH (pg)	26.7 ± 2.5	24.2 - 29.2	29.4 ± 2.5	26.9 - 31.9	31.0 ± 2.5	28.5 - 33.5
MCHC (g/dL)	33.3 ± 3.0	30.3 - 36.3	33.4 ± 3.0	30.4 - 36.4	33.4 ± 3.0	30.4 - 36.4
RDW-SD (fL)	47.0 ± 10.0	37.0 - 57.0	48.5 ± 10.0	38.5 - 58.5	48.5 ± 10.0	38.5 - 58.5
RDW-CV (%)	16.5 ± 5.0	11.5 - 21.5	15.5 ± 5.0	10.5 - 20.5	14.0 ± 5.0	9.0 - 19.0
PLT (10 ⁹ /L)	46 ± 20	26 - 66	198 ± 40	158 - 238	410 ± 65	345 - 475
MPV (fL)	10.3 ± 3.0	7.3 - 13.3	10.4 ± 3.0	7.4 - 13.4	10.2 ± 3.0	7.2 - 13.2
NEUT # (10 ⁹ /L)	1.94 ± 0.36	1.58 - 2.30	3.28 ± 0.72	2.56 - 4.00	10.42 ± 1.98	8.44 - 12.40
LYMPH # (10 ⁹ /L)	0.72 ± 0.36	0.36 - 1.08	2.27 ± 0.72	1.55 - 2.99	4.57 ± 1.99	2.58 - 6.56
MONO # (10 ⁹ /L)	0.09 ± 0.09	0.00 - 0.18	0.18 ± 0.18	0.00 - 0.36	0.50 ± 0.50	0.00 - 1.00
EO # (10 ⁹ /L)	0.54 ± 0.32	0.22 - 0.86	0.94 ± 0.65	0.29 - 1.59	2.78 ± 1.39	1.39 - 4.17
BASO # (10 ⁹ /L)	0.31 ± 0.31	0.00 - 0.62	0.54 ± 0.54	0.00 - 1.08	1.59 ± 1.59	0.00 - 3.18
NEUT%	54.0 ± 10.0	44.0 - 64.0	45.5 ± 10.0	35.5 - 55.5	52.5 ± 10.0	42.5 - 62.5
LYMPH%	20.0 ± 10.0	10.0 - 30.0	31.5 ± 10.0	21.5 - 41.5	23.0 ± 10.0	13.0 - 33.0
MONO%	2.5 ± 2.5	0.0 - 5.0	2.5 ± 2.5	0.0 - 5.0	2.5 ± 2.5	0.0 - 5.0
EO%	15.0 ± 9.0	6.0 - 24.0	13.0 ± 9.0	4.0 - 22.0	14.0 ± 7.0	7.0 - 21.0
BASO%	8.5 ± 8.5	0.0 - 17.0	7.5 ± 7.5	0.0 - 15.0	8.0 ± 8.0	0.0 - 16.0
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PLT-O (10 ⁹ /L)	52 ± 38	14 - 90	208 ± 65	143 - 273	440 ± 85	355 - 525
PCT (%)	0.05 ± 0.03	0.02 - 0.08	0.20 ± 0.07	0.13 - 0.27	0.42 ± 0.11	0.31 - 0.53
PDW (fL)	11.5 ± 5.0	6.5 - 16.5	12.5 ± 5.0	7.5 - 17.5	12.5 ± 5.0	7.5 - 17.5
P-LCR (%)	25.0 ± 20.0	5.0 - 45.0	27.5 ± 20.0	7.5 - 47.5	25.0 ± 20.0	5.0 - 45.0
IG # (10 ⁹ /L)	0.52 ± 0.30	0.22 - 0.82	0.86 ± 0.40	0.46 - 1.26	2.78 ± 1.60	1.18 - 4.38
IG%	14.5 ± 5.0	9.5 - 19.5	12.0 ± 5.0	7.0 - 17.0	14.0 ± 5.0	9.0 - 19.0
RBC-O (10 ¹² /L)	2.22 ± 0.30	1.92 - 2.52	4.48 ± 0.50	3.98 - 4.98	5.70 ± 0.60	5.10 - 6.30

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ASSAY VALUES AND EXPECTED RANGES

LOT 23050801, 23050802, 23050803



2023-07-05

QCP DATA MONTHS: **MAY, JUNE**

	LOW			NORMAL			HIGH			
	LOT 23050801	Assay Mean ± Limit	Expected Range	LOT 23050802	Assay Mean ± Limit	Expected Range	LOT 23050803	Assay Mean ± Limit	Expected Range	
MINDRAY BC-6800, BC-6600 QC Mode	Parameters									
	WBC (10 ⁹ /L)	3.85 ± 0.50	3.35 - 4.35	7.30 ± 1.00	6.30 - 8.30	20.50 ± 2.50	18.00 - 23.00			
	Neu # (10 ⁹ /L)	2.56 ± 0.38	2.18 - 2.94	4.23 ± 0.58	3.65 - 4.81	13.02 ± 1.64	11.38 - 14.66			
	Lym # (10 ⁹ /L)	0.69 ± 0.31	0.38 - 1.00	2.01 ± 0.51	1.50 - 2.52	3.90 ± 1.44	2.46 - 5.34			
	Mon # (10 ⁹ /L)	0.10 ± 0.10	0.00 - 0.20	0.26 ± 0.26	0.00 - 0.52	0.62 ± 0.62	0.00 - 1.24			
	Eos # (10 ⁹ /L)	0.44 ± 0.38	0.06 - 0.82	0.69 ± 0.51	0.18 - 1.20	2.67 ± 1.85	0.82 - 4.52			
	Bas # (10 ⁹ /L)	0.06 ± 0.20	-0.14 - 0.26	0.11 ± 0.37	-0.26 - 0.48	0.31 ± 1.03	-0.72 - 1.34			
	Neu %	66.5 ± 10.0	56.5 - 76.5	58.0 ± 8.0	50.0 - 66.0	63.5 ± 8.0	55.5 - 71.5			
	Lym %	18.0 ± 8.0	10.0 - 26.0	27.5 ± 7.0	20.5 - 34.5	19.0 ± 7.0	12.0 - 26.0			
	Mon %	2.5 ± 2.5	0.0 - 5.0	3.5 ± 3.5	0.0 - 7.0	3.0 ± 3.0	0.0 - 6.0			
	Eos %	11.5 ± 10.0	1.5 - 21.5	9.5 ± 7.0	2.5 - 16.5	13.0 ± 9.0	4.0 - 22.0			
	Bas %	1.5 ± 5.0	-3.5 - 6.5	1.5 ± 5.0	-3.5 - 6.5	1.5 ± 5.0	-3.5 - 6.5			
	RBC (10 ¹² /L)	2.31 ± 0.18	2.13 - 2.49	4.65 ± 0.24	4.41 - 4.89	5.80 ± 0.30	5.50 - 6.10			
	HGB (g/dL)	6.1 ± 0.4	5.7 - 6.5	13.6 ± 0.6	13.0 - 14.2	18.0 ± 0.8	17.2 - 18.8			
	HCT (%)	19.4 ± 2.0	17.4 - 21.4	43.5 ± 2.5	41.0 - 46.0	57.7 ± 3.0	54.7 - 60.7			
	MCV (fL)	84.0 ± 5.0	79.0 - 89.0	93.5 ± 5.0	88.5 - 98.5	99.5 ± 5.0	94.5 - 104.5			
	MCH (pg)	26.4 ± 2.5	23.9 - 28.9	29.2 ± 2.5	26.7 - 31.7	31.0 ± 2.5	28.5 - 33.5			
	MCHC (g/dL)	31.4 ± 3.0	28.4 - 34.4	31.3 ± 3.0	28.3 - 34.3	31.2 ± 3.0	28.2 - 34.2			
	RDW-CV (%)	16.5 ± 3.0	13.5 - 19.5	15.5 ± 3.0	12.5 - 18.5	15.0 ± 3.0	12.0 - 18.0			
	RDW-SD (fL)	47.5 ± 6.0	41.5 - 53.5	50.0 ± 6.0	44.0 - 56.0	50.0 ± 8.0	42.0 - 58.0			
	PLT (10 ⁹ /L)	46 ± 20	26 - 66	212 ± 40	172 - 252	425 ± 60	365 - 485			
	MPV (fL)	9.7 ± 3.0	6.7 - 12.7	10.4 ± 3.0	7.4 - 13.4	10.6 ± 3.0	7.6 - 13.6			
	PDW	16.0 ± 3.0	13.0 - 19.0	16.5 ± 3.0	13.5 - 19.5	16.5 ± 3.0	13.5 - 19.5			
	PCT (%)	0.050 ± 0.050	0.000 - 0.100	0.220 ± 0.100	0.120 - 0.320	0.451 ± 0.200	0.251 - 0.651			
	P-LCR (%)	26.5 ± 10.0	16.5 - 36.5	30.5 ± 10.0	20.5 - 40.5	31.0 ± 10.0	21.0 - 41.0			
	P-LCC (10 ⁹ /L)	12 ± 8	4 - 20	65 ± 24	41 - 89	130 ± 50	80 - 180			
	IMG # (10 ⁹ /L)	0.19 ± 0.19	0.00 - 0.38	0.37 ± 0.37	0.00 - 0.74	1.03 ± 1.03	0.00 - 2.06			
	IMG%	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0			
	IPF (%)	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0	5.0 ± 5.0	0.0 - 10.0			
	The parameters with assay values listed below are provided to allow for quality control testing of your instrument only. These parameters are defined by the FDA as "FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES".									
	PLT-O (10 ⁹ /L)	39 ± 20	19 - 59	173 ± 40	133 - 213	350 ± 60	290 - 410			

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AS148-008 Rev. 03/23

R&D SYSTEMS

a biotechnie brand

CBC-X

HEMATOLOGY CONTROLS

CONTROL

INTENDED USE

CBC-X is a control designed to monitor values on Sysmex® hematology analyzers. 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.



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



POTENTIAL BIOHAZARDOUS MATERIAL For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested, and yielded non-reactive / negative results for all conditions referenced in 21 CFR 610.40 (a) (b), as required by the FDA. Testing was conducted using FDA-licensed tests. Additional details can be found at:

<http://www.rndheme.com/TechnicalInformation.aspx>.

No test method can offer complete assurance that infectious agents are absent; therefore 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.



Store CBC-X 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 product is stable for 15 days or 15 pierces, whichever comes first, 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.**



1. Remove tubes from the refrigerator and allow to warm to room temperature (15° - 30° C or 59° - 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. **QC material must be run in the QXN mode on the XN-L models.**
 4. 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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IS148-009 Rev. 01/21



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