CBC-3K

HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

QCP DATA MONTHS: **SEPTEMBER, OCTOBER**

LOT **KK091**

2019-11-05

Instrument	Parameter	Low LOT KK091L	Normal LOT KK091N	High LOT KK091H
CELL-DYN® Sapphire™	WBC 10^9/L	3.00 ± 0.40	7.85 ± 0.80	20.50 ± 2.20
	NEU 10^9/L	1.47 ± 0.60	4.63 ± 1.34	14.5 ± 3.50
	NEU %	49.0 ± 12.0	59.0 ± 10.0	73.0 ± 9.00
	LYM 10^9/L	1.11 ± 0.56	2.04 ± 0.99	2.77 ± 2.07
	LYM %	37.0 ± 12.0	26.0 ± 9.00	14.0 ± 8.00
	MONO 10^9/L	0.27 ± 0.27	0.63 ± 0.63	1.09 ± 1.09
	MONO %	9.00 ± 9.00	8.00 ± 8.00	5.50 ± 5.50
	EOS 10^9/L	0.09 ± 0.09	0.39 ± 0.39	1.19 ± 1.19
	EOS %	3.00 ± 3.00	5.00 ± 5.00	6.00 ± 6.00
	BASO 10^9/L	0.06 ± 0.06	0.16 ± 0.16	0.30 ± 0.30
	BASO %	2.00 ± 2.00	2.00 ± 2.00	1.50 ± 1.50
	RBC 10^{12}/L	2.37 ± 0.18	4.76 ± 0.20	5.30 ± 0.24
	RBCo 10^{12}/L	2.39 ± 0.18	4.76 ± 0.20	5.25 ± 0.24
	HGB g/dL	5.90 ± 0.30	13.3 ± 0.70	16.0 ± 1.00
	HGB g/L	59.0 ± 3.00	133 ± 7.00	160 ± 10.0
	HGB mmol/L	3.66 ± 0.20	8.25 ± 0.50	9.92 ± 0.70
	HCT %	16.9 ± 1.80	40.9 ± 2.40	48.5 ± 3.00
	HCT L/L	0.17 ± 0.02	0.41 ± 0.02	0.48 ± 0.03
	MCV fL	71.5 ± 5.00	86.0 ± 5.00	91.5 ± 5.00
	MCH pg	24.9 ± 2.80	27.9 ± 2.00	30.2 ± 2.00
	MCH fmol	1.54 ± 0.18	1.73 ± 0.16	1.87 ± 0.16
	MCHC g/dL	34.8 ± 3.60	32.5 ± 2.80	33.0 ± 2.80
	MCHC g/L	348 ± 36.0	325 ± 28.0	330 ± 28.0
	MCHC mmol/L	21.6 ± 2.30	20.1 ± 1.80	20.5 ± 1.80
	RDW %	17.0 ± 3.00	14.0 ± 3.00	13.5 ± 3.00
	NRBC 10^9/L*	.001 ± .001	.001 ± .001	2.10 ± 2.00
	NRBC/100WBC*	.001 ± .001	.001 ± .001	10.2 ± 9.70
	PLT 10^9/L	80.0 ± 20.0	235 ± 50.0	445 ± 80.0
	PLTi 10^9/L	95.0 ± 20.0	255 ± 50.0	475 ± 80.0
	MPV fL	11.0 ± 3.00	8.70 ± 3.00	8.50 ± 3.00
	PCT % **	0.08 ± 0.03	0.200 ± 0.04	0.380 ± 0.08
	PCT mL/L **	0.80 ± 0.30	2.00 ± 0.40	3.80 ± 0.80
	PDW**	16.0 ± 3.00	16.5 ± 2.50	17.0 ± 2.50
MANUAL / SEMI-AUTOMATED				
	WBC 10^9/L	3.1 ± 0.6	7.8 ± 1.2	22.9 ± 2.6
Coulter Counter® F, FN, Z series Cyanmethemoglobin (manual) Centrifuged microhematocrit Hemocytometer Plt and WBC count	RBC 10^{12}/L	2.27 ± 0.18	4.66 ± 0.22	5.20 ± 0.25
	HGB g/dL	6.0 ± 0.4	13.6 ± 0.5	16.5 ± 0.8
	HGB g/L	60 ± 4	136 ± 5	165 ± 8
	HGB mmol/L	3.7 ± 0.2	8.4 ± 0.3	10.2 ± 0.5
	Spun HCT %	15.5 ± 2.5	36.5 ± 3.0	44.5 ± 4.0
	Spun HCT L/L	0.155 ± 0.025	0.365 ± 0.030	0.445 ± 0.040
	PLT 10^9/L	75 ± 20	243 ± 50	465 ± 80

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

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NOTES: CBC-3K may yield specimen status alert messages on the Cell-Dyn Sapphire instrument.

PIC/POC errors may occur. Verify that the control is performing within assay range.

* The assay value of .001 and mean range of +/- .001 for NRBC and NRBC/100WBC is entered for the Low level and Normal level controls since the instrument will not accept a value of zero. The NRBC concentration for the Low and Normal levels is below the detectable level of the instrument and such serves as the NRBC negative control.

** Clinical significance has not been established for these parameters. They are provided for laboratory use only.

R&D Systems, Inc.
614 McKinley Place NE
Minneapolis, MN 55413 USA

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LOT **KK091**

2019-11-05

Instrument	Parameter	Low LOT KK091L	Normal LOT KK091N	High LOT KK091H
CELL-DYN 3200	WBC (WOC) K/µL	2.9 ± 0.4	7.6 ± 1.0	20.0 ± 2.5
	WBC (NOC) K/µL	3.0 ± 0.4	7.8 ± 1.0	22.0 ± 2.5
Software Version 1.8 or higher	NEU K/µL	1.4 ± 0.7	4.6 ± 1.5	14.6 ± 4.1
	NEU %	50.0 ± 12.0	61.0 ± 10.0	73.0 ± 10.0
	LYM K/µL	1.1 ± 0.6	2.0 ± 1.2	3.2 ± 2.5
	LYM %	37.0 ± 12.0	26.5 ± 10.0	16.0 ± 9.0
Assay values established	MONO K/µL	0.3 ± 0.3	0.5 ± 0.5	0.8 ± 0.8
in QC file.	MONO %	9.0 ± 9.0	7.0 ± 7.0	4.0 ± 4.0
	EOS K/µL	0.1 ± 0.1	0.3 ± 0.3	1.2 ± 1.2
	EOS %	3.0 ± 3.0	4.5 ± 4.5	6.0 ± 6.0
	BASO K/µL	0.1 ± 0.1	0.1 ± 0.1	0.2 ± 0.2
	BASO %	1.0 ± 1.0	1.0 ± 1.0	1.0 ± 1.0
	RBC M/µL	2.32 ± 0.18	4.70 ± 0.24	5.25 ± 0.28
	HGB g/dL	5.6 ± 0.4	13.4 ± 0.6	16.5 ± 0.8
	HGB g/L	56 ± 4	134 ± 6	165 ± 8
	HGB mmol/L	3.5 ± 0.3	8.3 ± 0.4	10.2 ± 0.5
	HCT %	16.0 ± 1.8	38.5 ± 2.5	45.7 ± 3.5
	HCT L/L	0.160 ± 0.018	0.385 ± 0.025	0.457 ± 0.035
	MCV fL	69.0 ± 5.0	82.0 ± 5.0	87.0 ± 5.0
	MCH pg	24.1 ± 2.8	28.5 ± 2.4	31.4 ± 2.4
	MCH fmol	1.50 ± 0.18	1.77 ± 0.16	1.95 ± 0.16
	MCHC g/dL	35.0 ± 3.6	34.8 ± 3.0	36.1 ± 3.0
	MCHC g/L	350 ± 36	348 ± 30	361 ± 30
	MCHC mmol/L	21.7 ± 2.3	21.6 ± 1.8	22.4 ± 1.8
	RDW %	14.5 ± 3.0	12.5 ± 3.0	11.0 ± 3.0
	PLT K/µL	85 ± 22	270 ± 50	510 ± 80
	MPV fL	6.0 ± 3.0	5.5 ± 3.0	5.5 ± 3.0
CELL-DYN Ruby™	WBC (WOC) K/µL	2.9 ± 0.4	7.6 ± 1.0	20.0 ± 2.5
	WBC (NOC) K/µL	3.0 ± 0.4	7.8 ± 1.0	22.0 ± 2.5
	NEU K/µL	1.4 ± 0.7	4.6 ± 1.5	14.6 ± 4.1
	NEU %	50.0 ± 12.0	61.0 ± 10.0	73.0 ± 10.0
	LYM K/µL	1.1 ± 0.6	2.0 ± 1.2	3.2 ± 2.5
	LYM %	37.0 ± 12.0	26.5 ± 10.0	16.0 ± 9.0
Assay values established	MONO K/µL	0.3 ± 0.3	0.5 ± 0.5	0.8 ± 0.8
in QC file.	MONO %	9.0 ± 9.0	7.0 ± 7.0	4.0 ± 4.0
	EOS K/µL	0.1 ± 0.1	0.3 ± 0.3	1.2 ± 1.2
	EOS %	3.0 ± 3.0	4.5 ± 4.5	6.0 ± 6.0
	BASO K/µL	0.1 ± 0.1	0.1 ± 0.1	0.2 ± 0.2
	BASO %	1.0 ± 1.0	1.0 ± 1.0	1.0 ± 1.0
	RBC M/µL	2.32 ± 0.18	4.70 ± 0.24	5.25 ± 0.28
	HGB g/dL	5.6 ± 0.4	13.4 ± 0.6	16.5 ± 0.8
	HGB g/L	56 ± 4	134 ± 6	165 ± 8
	HGB mmol/l	3.5 ± 0.3	8.3 ± 0.4	10.2 ± 0.5
	HCT %	16.0 ± 1.8	38.5 ± 2.5	45.7 ± 3.5
	HCT L/L	0.160 ± 0.018	0.385 ± 0.025	0.457 ± 0.035
	MCV fL	69.0 ± 5.0	82.0 ± 5.0	87.0 ± 5.0
	MCH pg	24.1 ± 2.8	28.5 ± 2.4	31.4 ± 2.4
	MCH fmol	1.50 ± 0.18	1.77 ± 0.16	1.95 ± 0.16
	MCHC g/dL	35.0 ± 3.6	34.8 ± 3.0	36.1 ± 3.0
	MCHC g/L	350 ± 36	348 ± 30	361 ± 30
	MCHC mmol/L	21.7 ± 2.3	21.6 ± 1.8	22.4 ± 1.8
	RDW %	14.5 ± 3.0	12.5 ± 3.0	11.0 ± 3.0
	PLT K/µL	85 ± 22	270 ± 50	510 ± 80
	MPV fL	6.0 ± 3.0	5.5 ± 3.0	5.5 ± 3.0

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Before using, refer to the instruction sheet for mixing directions.
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NOTES: CBC-3K may yield specimen status alert messages on the Cell-Dyn 3200 and Ruby instruments.
Occasionally leukocyte cell populations are incorrectly identified. If this occurs, please rerun the sample.
Neut/Eos flips may occur after Reticulocyte analysis. Please prime analyzer with whole blood to avoid.

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LOT **KK091**

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Instrument	Parameter	Low LOT KK091L	Normal LOT KK091N	High LOT KK091H
CELL-DYN 3500	WBC (WOC) K/µL	2.8 ± 0.4	7.2 ± 1.0	19.3 ± 2.5
	WIC K/µL	3.1 ± 0.4	7.9 ± 1.0	22.6 ± 2.5
CELL-DYN 3700	NEU K/µL	1.5 ± 0.6	4.5 ± 1.6	14.5 ± 4.0
	NEU %	52.0 ± 12.0	62.5 ± 11.0	75.0 ± 10.0
	LYM K/µL	1.0 ± 0.6	1.8 ± 1.0	2.7 ± 2.1
	LYM %	37.0 ± 12.0	25.0 ± 9.0	14.0 ± 8.0
	MONO K/µL	0.2 ± 0.2	0.5 ± 0.5	0.8 ± 0.8
	MONO %	7.0 ± 7.0	7.0 ± 7.0	4.0 ± 4.0
	EOS K/µL	0.1 ± 0.1	0.3 ± 0.3	1.2 ± 1.2
	EOS %	3.0 ± 3.0	4.5 ± 4.5	6.0 ± 6.0
	BASO K/µL	0.1 ± 0.1	0.1 ± 0.1	0.2 ± 0.2
	BASO %	1.0 ± 1.0	1.0 ± 1.0	1.0 ± 1.0
	RBC M/µL	2.41 ± 0.18	4.72 ± 0.24	5.21 ± 0.28
	HGB g/dL	5.9 ± 0.4	13.5 ± 0.6	16.5 ± 0.8
	HGB g/L	59 ± 4	135 ± 6	165 ± 8
	HGB mmol/L	3.7 ± 0.3	8.4 ± 0.4	10.2 ± 0.5
	HCT %	18.6 ± 1.8	43.4 ± 2.5	51.1 ± 3.5
	HCT L/L	0.186 ± 0.018	0.434 ± 0.025	0.511 ± 0.035
	MCV fL	77.0 ± 5.0	92.0 ± 5.0	98.0 ± 5.0
	MCH pg	24.5 ± 2.8	28.6 ± 2.4	31.7 ± 2.4
	MCH fmol	1.52 ± 0.18	1.77 ± 0.16	1.96 ± 0.16
	MCHC g/dL	31.8 ± 3.6	31.1 ± 3.0	32.3 ± 3.0
	MCHC g/L	318 ± 36	311 ± 30	323 ± 30
	MCHC mmol/L	19.7 ± 2.3	19.3 ± 1.8	20.0 ± 1.8
	RDW %	18.0 ± 3.0	17.5 ± 3.0	17.0 ± 3.0
	PLT K/µL	82 ± 22	255 ± 50	460 ± 80
	MPV fL	7.5 ± 3.0	7.5 ± 3.0	7.7 ± 3.0

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