

CBC-3K**HEMATOLOGY CONTROLS****CONTROL**

ASSAY VALUES AND EXPECTED RANGES

QCP DATA MONTHS: **MAY, JUNE****LOT** **KK113****2023-07-05**

Instrument	Parameter	Low		Normal		High	
		LOT	KK113L	LOT	KK113N	LOT	KK113H
CELL-DYN® Sapphire™	WBC 10 ⁹ /L		3.15 ± 0.40		8.20 ± 0.80		21.2 ± 2.20
	NEU 10 ⁹ /L		1.48 ± 0.61		4.63 ± 1.54		15.7 ± 4.00
	NEU %		47.0 ± 12.0		56.5 ± 12.0		74.0 ± 10.0
	LYM 10 ⁹ /L		1.26 ± 0.59		2.50 ± 1.33		3.18 ± 2.20
	LYM %		40.0 ± 12.0		30.5 ± 12.0		15.0 ± 8.00
	MONO 10 ⁹ /L		0.25 ± 0.25		0.62 ± 0.62		1.06 ± 1.06
	MONO %		8.00 ± 8.00		7.50 ± 7.50		5.00 ± 5.00
	EOS 10 ⁹ /L		0.09 ± 0.09		0.29 ± 0.29		0.95 ± 0.95
	EOS %		3.00 ± 3.00		3.50 ± 3.50		4.50 ± 4.50
	BASO 10 ⁹ /L		0.06 ± 0.06		0.16 ± 0.16		0.32 ± 0.32
	BASO %		2.00 ± 2.00		2.00 ± 2.00		1.50 ± 1.50
	RBC 10 ¹² /L		2.22 ± 0.18		4.62 ± 0.20		5.15 ± 0.24
	RBCo 10 ¹² /L		2.27 ± 0.18		4.62 ± 0.20		5.08 ± 0.24
	HGB g/dL		5.80 ± 0.30		13.3 ± 0.50		16.3 ± 0.70
	HGB g/L		58.0 ± 3.00		133 ± 5.00		163 ± 7.00
	HGB mmol/L		3.60 ± 0.20		8.25 ± 0.30		10.1 ± 0.50
	HCT %		16.4 ± 1.80		39.3 ± 2.40		47.4 ± 3.00
	HCT L/L		0.16 ± 0.02		0.39 ± 0.02		0.47 ± 0.03
	MCV fL		74.0 ± 5.00		85.0 ± 5.00		92.0 ± 5.00
	MCH pg		26.1 ± 2.80		28.8 ± 2.00		31.7 ± 2.00
	MCH fmol		1.62 ± 0.18		1.78 ± 0.16		1.96 ± 0.16
	MCHC g/dL		35.3 ± 3.60		33.9 ± 2.80		34.4 ± 2.80
	MCHC g/L		353 ± 36.0		339 ± 28.0		344 ± 28.0
	MCHC mmol/L		21.9 ± 2.30		21.0 ± 1.80		21.3 ± 1.80
	RDW %		15.5 ± 3.00		14.0 ± 3.00		13.0 ± 3.00
	NRBC 10 ⁹ /L*		.001 ± .001		.001 ± .001		2.10 ± 1.80
	NRBC/100WBC*		.001 ± .001		.001 ± .001		9.91 ± 8.50
	PLT 10 ⁹ /L		72.0 ± 20.0		227 ± 40.0		447 ± 70.0
	PLTi 10 ⁹ /L		87.0 ± 20.0		253 ± 40.0		480 ± 70.0
	MPV fL		9.90 ± 3.00		8.40 ± 3.00		7.80 ± 3.00
PCT % **		0.07 ± 0.03		0.19 ± 0.04		0.34 ± 0.08	
PCT mL/L **		0.70 ± 0.30		1.90 ± 0.40		3.40 ± 0.80	
PDW**		16.0 ± 3.00		17.5 ± 2.50		17.5 ± 2.50	
MANUAL / SEMI-AUTOMATED							
Coulter Counter® F, FN, Z series Cyanmethemoglobin (manual) Centrifuged microhematocrit Hemocytometer Ptt and WBC count	WBC 10 ⁹ /L		3.2 ± 0.6		8.2 ± 1.2		23.6 ± 2.6
	RBC 10 ¹² /L		2.12 ± 0.18		4.52 ± 0.22		5.05 ± 0.25
	HGB g/dL		5.9 ± 0.4		13.6 ± 0.5		16.8 ± 0.8
	HGB g/L		59 ± 4		136 ± 5		168 ± 8
	HGB mmol/L		3.7 ± 0.2		8.4 ± 0.3		10.4 ± 0.5
	Spun HCT %		15.0 ± 2.5		36.0 ± 3.0		44.0 ± 4.0
	Spun HCT L/L		0.150 ± 0.025		0.360 ± 0.030		0.440 ± 0.040
	PLT 10 ⁹ /L		67 ± 20		235 ± 40		467 ± 70

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

For technical assistance in the USA and Canada call Technical Service at (800) 523-3395.

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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.

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ASSAY VALUES AND EXPECTED RANGES

QCP DATA MONTHS: **MAY, JUNE****LOT** **KK113****2023-07-05**

Instrument	Parameter	Low	Normal	High	++
		LOT KK113L	LOT KK113N	LOT KK113H	
CELL-DYN 3200	WBC (WOC) K/ μ L	3.0 \pm 0.4	7.7 \pm 1.0	20.3 \pm 2.5	
	WBC (NOC) K/ μ L	3.2 \pm 0.4	8.1 \pm 1.0	23.2 \pm 2.5	
Software Version 1.8 or higher	NEU K/ μ L	1.5 \pm 0.5	4.5 \pm 1.5	15.2 \pm 4.2	
	NEU %	48.5 \pm 10.0	58.5 \pm 10.0	75.0 \pm 10.0	
	LYM K/ μ L	1.1 \pm 0.5	2.3 \pm 1.3	2.8 \pm 2.4	
	LYM %	36.5 \pm 12.0	29.5 \pm 12.0	14.0 \pm 9.0	
Assay values established in QC file.	MONO K/ μ L	0.3 \pm 0.3	0.5 \pm 0.5	0.8 \pm 0.8	
	MONO %	9.5 \pm 9.5	6.0 \pm 6.0	4.0 \pm 4.0	
	EOS K/ μ L	0.1 \pm 0.1	0.3 \pm 0.3	1.0 \pm 1.0	
	EOS %	3.5 \pm 3.5	4.0 \pm 4.0	5.0 \pm 5.0	
	BASO K/ μ L	0.1 \pm 0.1	0.2 \pm 0.2	0.4 \pm 0.4	
	BASO %	2.0 \pm 2.0	2.0 \pm 2.0	2.0 \pm 2.0	
	RBC M/ μ L	2.22 \pm 0.18	4.67 \pm 0.24	5.17 \pm 0.28	
	HGB g/dL	5.6 \pm 0.4	13.3 \pm 0.6	16.6 \pm 0.8	
	HGB g/L	56 \pm 4	133 \pm 6	166 \pm 8	
	HGB mmol/L	3.5 \pm 0.3	8.2 \pm 0.4	10.3 \pm 0.5	
	HCT %	16.0 \pm 1.8	38.3 \pm 2.5	45.2 \pm 3.5	
	HCT L/L	0.160 \pm 0.018	0.383 \pm 0.025	0.452 \pm 0.035	
	MCV fL	72.0 \pm 5.0	82.0 \pm 5.0	87.5 \pm 5.0	
	MCH pg	25.2 \pm 2.8	28.5 \pm 2.4	32.1 \pm 2.4	
	MCH fmol	1.56 \pm 0.18	1.77 \pm 0.16	1.99 \pm 0.16	
	MCHC g/dL	35.0 \pm 3.6	34.7 \pm 3.0	36.7 \pm 3.0	
MCHC g/L	350 \pm 36	347 \pm 30	367 \pm 30		
MCHC mmol/L	21.7 \pm 2.3	21.5 \pm 1.8	22.8 \pm 1.8		
RDW %	12.5 \pm 3.0	11.5 \pm 3.0	10.0 \pm 3.0		
PLT K/ μ L	74 \pm 22	255 \pm 45	484 \pm 70		
MPV fL	4.9 \pm 3.0	5.0 \pm 3.0	4.3 \pm 3.0		
CELL-DYN Ruby™	WBC (WOC) K/ μ L	3.0 \pm 0.4	7.7 \pm 1.0	20.3 \pm 2.5	
	WBC (NOC) K/ μ L	3.2 \pm 0.4	8.1 \pm 1.0	23.2 \pm 2.5	
	NEU K/ μ L	1.5 \pm 0.5	4.5 \pm 1.5	15.2 \pm 4.2	
	NEU %	48.5 \pm 10.0	58.5 \pm 10.0	75.0 \pm 10.0	
	LYM K/ μ L	1.1 \pm 0.5	2.3 \pm 1.3	2.8 \pm 2.4	
	LYM %	36.5 \pm 12.0	29.5 \pm 12.0	14.0 \pm 9.0	
Assay values established in QC file.	MONO K/ μ L	0.3 \pm 0.3	0.5 \pm 0.5	0.8 \pm 0.8	
	MONO %	9.5 \pm 9.5	6.0 \pm 6.0	4.0 \pm 4.0	
	EOS K/ μ L	0.1 \pm 0.1	0.3 \pm 0.3	1.0 \pm 1.0	
	EOS %	3.5 \pm 3.5	4.0 \pm 4.0	5.0 \pm 5.0	
	BASO K/ μ L	0.1 \pm 0.1	0.2 \pm 0.2	0.4 \pm 0.4	
	BASO %	2.0 \pm 2.0	2.0 \pm 2.0	2.0 \pm 2.0	
	RBC M/ μ L	2.22 \pm 0.18	4.67 \pm 0.24	5.17 \pm 0.28	
	HGB g/dL	5.6 \pm 0.4	13.3 \pm 0.6	16.6 \pm 0.8	
	HGB g/L	56 \pm 4	133 \pm 6	166 \pm 8	
	HGB mmol/l	3.5 \pm 0.3	8.2 \pm 0.4	10.3 \pm 0.5	
	HCT %	16.0 \pm 1.8	38.3 \pm 2.5	45.2 \pm 3.5	
	HCT L/L	0.160 \pm 0.018	0.383 \pm 0.025	0.452 \pm 0.035	
	MCV fL	72.0 \pm 5.0	82.0 \pm 5.0	87.5 \pm 5.0	
	MCH pg	25.2 \pm 2.8	28.5 \pm 2.4	32.1 \pm 2.4	
	MCH fmol	1.56 \pm 0.18	1.77 \pm 0.16	1.99 \pm 0.16	
	MCHC g/dL	35.0 \pm 3.6	34.7 \pm 3.0	36.7 \pm 3.0	
MCHC g/L	350 \pm 36	347 \pm 30	367 \pm 30		
MCHC mmol/L	21.7 \pm 2.3	21.5 \pm 1.8	22.8 \pm 1.8		
RDW %	12.5 \pm 3.0	11.5 \pm 3.0	10.0 \pm 3.0		
PLT K/ μ L	74 \pm 22	255 \pm 45	484 \pm 70		
MPV fL	4.9 \pm 3.0	5.0 \pm 3.0	4.3 \pm 3.0		

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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INTENDED USE

CBC-3K 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-3K is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.



PRECAUTION

CBC-3K is intended for *in vitro* diagnostic use only by trained personnel.



WARNING:

POTENTIAL 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-3K 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 8 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 - 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.
4. After sampling:
 - a) If tube has been open 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.

The CELL-DYN® LOAD FROM DISK Procedure For CELL-DYN 3200, 3500 and 3700 Systems

The [LOAD FROM DISK] key is used to enter assay values and ranges directly from the Assay Disk into a QC File. When this option is used, the mean value and limits (either for the QC Range Entry or QC Means/Limits Entry) are automatically entered in the selected file. The information is entered for each level, one level at a time. The values may be edited when they are displayed on the screen.

1. Confirm that the control name, lot number and expiration date on the disk label are correct for the assay values to be loaded. Insert the Assay Disk into the CD3200, CD3500 or CD3700 disk drive.

NOTE: For CELL-DYN systems with an Integrated Data Station, fold down the Alpha Entry keyboard on the Data Station to expose the disk drive.

2. From the MAIN MENU screen, press [QUALITY CONTROL].
3. Use the Arrow keys on the keyboard to move the cursor to the desired file. Type the file name (e.g., Low L0035) and press the Enter key on the keyboard to save the name and to advance the cursor to the next file.

NOTE: The file must be empty in order to receive the information.

4. When the desired files have been named, use the Arrow keys on the keyboard to move the cursor back into the appropriate file.
5. Press [QC LIMITS] followed by [MEANS/LIMITS] or [RANGE ENTRY] to display the QC MEANS/LIMITS ENTRY or RANGE ENTRY screen for the selected field.
6. Press [LOAD FROM DISK] to display the LOAD FROM DISK screen.
7. Check the status box to be sure the correct file is selected, then press the appropriate soft key:

[LOAD LOW] to load the low control assay
[LOAD NORMAL] to load the normal control assay
[LOAD HIGH] to load the high control assay

8. The limits are displayed for the selected file.

NOTE: Be certain to check that the assay values and ranges are the same as those on the control's insert sheet. Review the QC section in the Cell-Dyn Operator's Manual for instructions about the editing of assay ranges and the use of control materials.

9. Press [RETURN] to return to the QC MENU screen.
10. Select the next file and repeat steps 7 - 9 to load the assay data for the appropriate level of control.
11. Repeat steps 7 - 11, until the assay data for each level has been loaded.
12. When all the assay data has been loaded, remove the Assay Disk from the drive.
13. Discard disk when lot has expired.

The CELL-DYN® LOAD FROM DISK Procedure For CELL-DYN 1700 and 1800 Systems

The [LOAD FROM DISK] key is used to enter lot specific assay data directly from the Assay Disk. When this option is used, the mean value and limits (either for the QC Range Entry or QC Means/Limits Entry) are automatically entered in the selected file. The information is entered for each level, one level at a time. The values may be edited when they are displayed on the screen.

1. Confirm that the control name, lot number and expiration date on the disk label are correct for the assay values to be loaded. Insert the Assay Disk into the CD1700 or CD1800 disk drive.
2. From the MAIN MENU screen, press [SETUP] followed by [QC SETUP].
3. Press the [LOW CONTROL] key to load assay values for the low control. When the list of QC files displays, use the keyboard arrow keys to move the cursor to the desired file.

NOTE: The file must be empty in order to receive the disk information.

4. Press [FILE SETUP] followed by [MEANS/LIMITS]. When the screen displays, press [LOAD FROM DISK] followed by [CONFIRM LOAD].
5. After assay values are displayed, press [PRINT] to print the assay values.
6. Press [RETURN] and verify off the screen that the lot number, assay values and ranges are correctly displayed for the selected control level.

NOTE: Be certain to check that the assay values and ranges are the same as those on the control's insert sheet. Review the QC section in the Cell-Dyn Operator's Manual for instructions about the editing of assay ranges and the use of control materials.

7. Press [RETURN] twice to display the QC SETUP menu screen.
8. Repeat steps 3 through 7 to load assay values for the normal and high controls using the [NORMAL CONTROL] and [HIGH CONTROL] keys respectively.
9. When all assay values are loaded, press [RETURN] and then [MAIN] to return to the Main Menu. Remove the Assay Disk from the drive.
10. Discard disk when lot has expired.

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