

**CONTROL | L | N | H**

Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: **(Do NOT mix mechanically or vortex.)**

For a video demonstration, visit www.corelaboratory.abbott and navigate to the Customer Portal → Technical Library → Other Reference Documents → Hematology Aids.

- a. Hold the vial vertically and roll each vial between the palms of the hands for 15-20 seconds.



- b. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vial 20 times end-over-end using a very quick turning motion of the wrist.



- c. Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
- d. Steps a-c must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).

3. Refer to the appropriate CELL-DYN System Operator's Manual for information about analyzing control specimens.

NOTE: For CELL-DYN 3700 and CELL-DYN Ruby:

- Perform stain of CELL-DYN 29 Plus Control (with Retic) as a patient sample as described in the CELL-DYN 3700 and CELL-DYN Ruby Reticulocyte Reagent package insert, except limit the staining time to between 15 and 30 minutes.

4. FOR AUTOMATED SAMPLING OR MANUAL CLOSED SAMPLING (CS):

- Refer to the appropriate CELL-DYN Operator's Manual. Remove the vial from the sample handler immediately after sampling.

FOR OPEN-VIAL SAMPLING:

- Aspirate a sample from the vial.
- Carefully wipe the vial rim and cap with a lint-free tissue.
- Replace the cap, ensuring it is on tight.

After sampling, return vial to refrigerator for maximum open-vial stability. If run in the open mode, wipe the threads of both vial and cap before replacing cap and returning to refrigerator.

Exp. 2021-12-17

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L12779	LOT	N12779	LOT	H12779
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	3.09	0.40	7.05	0.80	16.4	3.0
NEU 10 ⁹ /L	1.77	0.20	4.23	0.40	10.5	1.1
NEU %	57.2	6.0	60.1	5.0	63.9	6.0
LYM 10 ⁹ /L	0.92	0.20	1.84	0.50	3.50	1.00
LYM %	29.9	8.0	26.1	6.0	21.3	5.0
MONO 10 ⁹ /L	0.30	0.20	0.75	0.40	1.88	0.60
MONO %	9.82	6.00	10.6	5.0	11.5	3.0
EOS 10 ⁹ /L	0.10	0.10	0.20	0.17	0.51	0.19
EOS %	3.00	3.00	2.90	2.00	3.09	1.00
BASO 10 ⁹ /L	0.10	0.10	0.25	0.25	0.50	0.50
BASO %	1.50	1.50	1.50	1.50	1.50	1.50
RBC 10 ¹² /L	2.98	0.18	4.27	0.20	5.25	0.30
RBC _o 10 ¹² /L	3.08	0.18	4.33	0.20	5.26	0.30
HGB g/dL	7.97	0.30	11.8	0.5	16.7	0.8
HCT %	23.0	1.5	33.9	2.5	47.2	3.0
MCV fL	77.4	4.0	79.4	4.0	89.9	4.0
MCH pg	26.8	2.0	27.6	2.0	31.8	2.0
MCHC g/dL	34.6	2.3	34.8	2.3	35.4	2.3
RDW %	15.8	2.5	15.9	2.5	14.4	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.22	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	13.5	2.5
PLT 10 ⁹ /L	70.2	20.0	208	50	461	60
PLTi 10 ⁹ /L	74.7	20.0	218	50	471	60
MPV fL	9.01	2.00	8.03	2.00	7.38	2.00
RETC 10 ⁹ /L	218	50	142	50	101	50
%R	7.33	1.50	3.33	1.00	1.92	0.80
IRF	0.54	0.18	0.47	0.14	0.39	0.10

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7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L12779	LOT	N12779	LOT	H12779
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.1	0.4	7.1	0.7	16.4	2.5
NOC 10 ⁹ /L	3.1	0.4	7.0	1.0	18.4	2.5
NEU 10 ⁹ /L	1.8	0.3	4.3	0.8	10.5	2.0
NEU %	57.1	6.0	60.1	6.0	64.2	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	28.6	7.0	24.9	6.0	20.6	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.2	5.0	9.6	4.5	10.0	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.9	2.0	3.0	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.0	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.94	0.15	4.31	0.20	5.37	0.28
HGB g/dL	7.8	0.4	11.8	0.5	17.2	0.6
HCT %	21.3	1.5	32.2	2.3	44.8	3.5
MCV fL	72.6	4.0	74.6	4.0	83.4	4.0
MCH pg	26.7	2.0	27.2	2.0	32.1	2.0
MCHC g/dL	36.7	2.3	36.5	3.0	38.5	2.3
RDW %	13.4	2.5	13.4	2.5	11.0	2.5
PLT 10 ⁹ /L	68	20	217	30	506	60
MPV fL	6.4	2.0	6.1	2.0	6.0	2.0
Retic %***	5.3	1.5	2.4	1.0	1.1	0.8

NOTE: Flags may occur with control materials. PIC/POC alarms may be seen with this control when used on the CELL-DYN Sapphire. The alarms may be disregarded if the control is performing within the assay ranges.

* NOTE: The Assay Value of .001 and Mean Range of ± .001 for NRBC and NRBC/100WBC is entered for the Level L and Level N controls since the instrument will not accept a value of zero. The NRBC concentration for Levels L and N is below the detectable level of the instrument and as such serves as the NRBC negative control. The Level H is the NRBC positive control.

** The mean range does not represent standard deviations (SD).

*** Retic % values for CELL-DYN Ruby are included as separate files on assay disk.

CELL-DYN 29 Plus Control (with Retic)

CONTROL L N H

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L12779		LOT N12779		LOT H12779	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.2	0.4	7.1	0.7	16.4	2.5
WIC 10 ⁹ /L	3.3	0.5	7.3	1.0	18.9	3.0
WBC 10 ⁹ /L	3.2	0.4	7.1	0.7	16.4	2.5
NEU 10 ⁹ /L	1.8	0.3	4.2	0.8	10.5	2.0
NEU %	57.3	6.0	60.0	6.0	64.2	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	29.2	7.0	25.1	6.0	20.7	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	9.1	5.0	10.0	4.5	10.4	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	3.0	2.0	3.1	1.0
BASO 10 ⁹ /L	0.1	0.1	0.3	0.3	0.6	0.6
BASO %	3.0	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	3.02	0.15	4.31	0.20	5.27	0.28
HGB g/dL	8.0	0.3	11.9	0.5	17.3	0.6
HCT %	25.0	1.5	37.0	2.3	51.6	3.5
MCV fL	82.8	4.0	85.8	4.0	98.0	4.0
MCH pg	26.5	2.0	27.6	2.0	32.9	2.0
MCHC g/dL	32.0	2.3	32.2	3.0	33.5	2.3
RDW %	19.7	2.5	19.2	2.5	17.7	2.5
PLT 10 ⁹ /L	70	20	212	30	449	60
MPV fL	7.0	2.0	6.8	2.0	6.7	2.0
Retic % ¹	5.9	1.5	2.3	1.0	1.0	0.8
IRF ²	0.62	0.38	0.46	0.30	0.41	0.20

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L12779		LOT N12779		LOT H12779	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.5	2.0	2.6	1.5	0.8	0.8

** The mean range does not represent standard deviations (SD).
¹ Retic % values will not load from the Assay Disk. Please enter these values manually.
² IRF is reportable on the CELL-DYN 3700 System, Version 1.1 and higher.
³ Manual values were obtained using the Miller Ocular method.



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