

CONTROL

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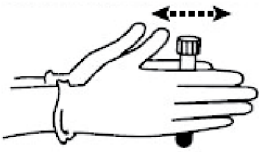
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

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](http://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.

<div> Exp. 2024-11-15</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT L42469		LOT N42469		LOT H42469	
	PARAMETER	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **
CELL-DYN Sapphire	WBC 10 <sup>9</sup> /L	3.13 0.40	6.52 0.80	16.0 3.0		
	NEU 10 <sup>9</sup> /L	1.74 0.20	4.07 0.40	10.4 1.1		
	NEU %	55.4 6.0	62.4 5.0	64.9 6.0		
	LYM 10 <sup>9</sup> /L	0.96 0.20	1.56 0.50	3.40 1.00		
	LYM %	30.6 8.0	24.0 6.0	21.2 5.0		
	MONO 10 <sup>9</sup> /L	0.32 0.20	0.66 0.40	1.62 0.60		
	MONO %	10.2 6.0	10.1 5.0	10.1 3.0		
	EOS 10 <sup>9</sup> /L	0.10 0.10	0.21 0.17	0.56 0.19		
	EOS %	3.00 3.00	3.20 2.00	3.50 1.00		
	BASO 10 <sup>9</sup> /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 <sup>12</sup> /L	2.97 0.18	4.24 0.20	5.23 0.30		
	RBCo 10 <sup>12</sup> /L	3.04 0.18	4.30 0.20	5.20 0.30		
	HGB g/dL	7.99 0.30	12.0 0.5	16.0 0.8		
	HCT %	23.0 1.5	34.3 2.5	46.0 3.0		
	MCV fL	77.5 4.0	81.0 4.0	88.1 4.0		
	MCH pg	26.9 2.0	28.3 2.0	30.6 2.0		
	MCHC g/dL	34.7 2.3	34.9 2.3	34.7 2.3		
	RDW %	15.5 2.5	14.2 2.5	13.6 2.5		
	NRBC 10 <sup>9</sup> /L*	0.001 0.001	0.001 0.001	2.25 0.60		
	NRBC/100WBC*	0.001 0.001	0.001 0.001	14.0 2.5		
	PLT 10 <sup>9</sup> /L	69.9 20.0	215 50	481 60		
	PLTi 10 <sup>9</sup> /L	75.8 20.0	225 50	484 60		
	MPV fL	9.55 2.00	7.80 2.00	7.43 2.00		
	RETC 10 <sup>9</sup> /L	236 50	141 50	106 50		
	%R	7.94 1.50	3.32 1.00	2.04 0.80		
	IRF	0.49 0.18	0.45 0.14	0.42 0.10		

<div> Exp. 2024-11-15</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT L42469		LOT N42469		LOT H42469	
	PARAMETER	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **	ASSAY VALUE ± MEAN RANGE **
CELL-DYN Ruby	WOC 10 <sup>9</sup> /L	3.1 0.4	6.6 0.7	16.0 2.5		
	NOC 10 <sup>9</sup> /L	3.1 0.4	6.5 1.0	18.2 2.5		
	NEU 10 <sup>9</sup> /L	1.7 0.3	4.1 0.8	10.4 2.0		
	NEU %	56.3 6.0	61.9 6.0	65.0 10.0		
	LYM 10 <sup>9</sup> /L	0.9 0.3	1.5 0.8	3.2 2.0		
	LYM %	28.7 7.0	23.2 6.0	20.0 10.0		
	MONO 10 <sup>9</sup> /L	0.3 0.2	0.6 0.4	1.4 0.6		
	MONO %	8.6 5.0	8.6 4.5	8.8 3.0		
	EOS 10 <sup>9</sup> /L	0.1 0.1	0.2 0.2	0.6 0.2		
	EOS %	3.0 3.0	3.4 2.0	3.6 1.0		
	BASO 10 <sup>9</sup> /L	0.1 0.1	0.2 0.2	0.6 0.6		
	BASO %	3.4 3.0	3.0 3.0	3.0 3.0		
	RBC 10 <sup>12</sup> /L	2.85 0.15	4.21 0.20	5.26 0.28		
	HGB g/dL	7.6 0.4	11.8 0.5	16.4 0.6		
	HCT %	21.0 1.5	32.2 2.3	43.5 3.5		
	MCV fL	73.6 4.0	76.5 4.0	82.7 4.0		
	MCH pg	26.7 2.0	28.0 2.0	31.2 2.0		
	MCHC g/dL	36.3 2.3	36.6 3.0	37.7 2.3		
	RDW %	12.8 2.5	11.5 2.5	10.5 2.5		
	PLT 10 <sup>9</sup> /L	66 20	218 30	515 60		
Retic %***	MPV fL	6.4 2.0	6.0 2.0	6.0 2.0		
		5.3 1.5	2.1 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

<div><div><div></div></div><div>Exp.</div></div> <div>2024-11-15</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L42469		LOT N42469		LOT H42469	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
WIC 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
WBC 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
NEU 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
NEU %	N/A	N/A	N/A	N/A	N/A	N/A
LYM 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
LYM %	N/A	N/A	N/A	N/A	N/A	N/A
MONO 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
MONO %	N/A	N/A	N/A	N/A	N/A	N/A
EOS 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
EOS %	N/A	N/A	N/A	N/A	N/A	N/A
BASO 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
BASO %	N/A	N/A	N/A	N/A	N/A	N/A
RBC 10 <sup>12</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
HGB g/dL	N/A	N/A	N/A	N/A	N/A	N/A
HCT %	N/A	N/A	N/A	N/A	N/A	N/A
MCV fL	N/A	N/A	N/A	N/A	N/A	N/A
MCH pg	N/A	N/A	N/A	N/A	N/A	N/A
MCHC g/dL	N/A	N/A	N/A	N/A	N/A	N/A
RDW %	N/A	N/A	N/A	N/A	N/A	N/A
PLT 10 <sup>9</sup> /L	N/A	N/A	N/A	N/A	N/A	N/A
MPV fL	N/A	N/A	N/A	N/A	N/A	N/A
Retic % <sup>1</sup>	N/A	N/A	N/A	N/A	N/A	N/A
IRF <sup>2</sup>	N/A	N/A	N/A	N/A	N/A	N/A

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count <sup>3</sup>	LOT L42469		LOT N42469		LOT H42469	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.4	2.0	1.8	1.5	0.8	0.8

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



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