

CONTROL

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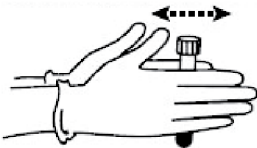
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

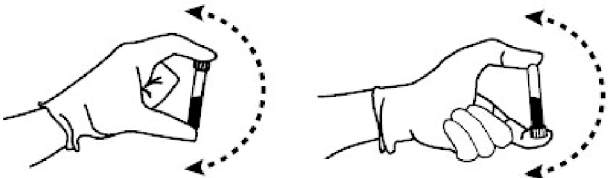
1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: (Do NOT mix mechanically or vortex.)

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.</div> <div>2024-08-23</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT	L41629	LOT	N41629	LOT	H41629
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 <sup>9</sup> /L	2.97	0.40	6.86	0.80	15.7	3.0
NEU 10 <sup>9</sup> /L	1.57	0.20	4.06	0.40	10.2	1.1
NEU %	52.7	6.0	59.2	5.0	64.9	6.0
LYM 10 <sup>9</sup> /L	0.99	0.20	1.79	0.50	3.19	1.00
LYM %	33.3	8.0	26.0	6.0	20.3	5.0
MONO 10 <sup>9</sup> /L	0.33	0.20	0.81	0.40	1.79	0.60
MONO %	11.1	6.0	11.8	5.0	11.4	3.0
EOS 10 <sup>9</sup> /L	0.10	0.10	0.19	0.17	0.50	0.19
EOS %	3.00	3.00	2.74	2.00	3.21	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	2.96	0.18	4.28	0.20	5.24	0.30
RBCo 10 <sup>12</sup> /L	3.02	0.18	4.31	0.20	5.21	0.30
HGB g/dL	7.78	0.30	11.7	0.5	15.7	0.8
HCT %	22.9	1.5	34.2	2.5	45.3	3.0
MCV fL	77.1	4.0	79.9	4.0	86.5	4.0
MCH pg	26.2	2.0	27.5	2.0	29.9	2.0
MCHC g/dL	34.0	2.3	34.4	2.3	34.5	2.3
RDW %	15.4	2.5	15.1	2.5	14.8	2.5
NRBC 10 <sup>9</sup> /L*	0.001	0.001	0.001	0.001	2.23	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.2	2.5
PLT 10 <sup>9</sup> /L	68.4	20.0	201	50	452	60
PLTi 10 <sup>9</sup> /L	73.1	20.0	213	50	470	60
MPV fL	9.91	2.00	8.11	2.00	7.48	2.00
RETC 10 <sup>9</sup> /L	241	50	147	50	97.2	50.0
%R	8.14	1.50	3.44	1.00	1.85	0.80
IRF	0.54	0.18	0.47	0.14	0.39	0.10

<div> Exp.</div> <div>2024-08-23</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT	L41629	LOT	N41629	LOT	H41629
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 <sup>9</sup> /L	2.9	0.4	6.9	0.7	15.8	2.5
NOC 10 <sup>9</sup> /L	3.0	0.4	6.9	1.0	18.1	2.5
NEU 10 <sup>9</sup> /L	1.6	0.3	4.1	0.8	10.4	2.0
NEU %	52.8	6.0	59.6	6.0	65.7	10.0
LYM 10 <sup>9</sup> /L	0.9	0.3	1.7	0.8	3.0	2.0
LYM %	32.1	7.0	25.3	6.0	19.2	10.0
MONO 10 <sup>9</sup> /L	0.3	0.2	0.7	0.4	1.5	0.6
MONO %	9.7	5.0	9.8	4.5	9.4	3.0
EOS 10 <sup>9</sup> /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.8	2.0	3.2	1.0
BASO 10 <sup>9</sup> /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 <sup>12</sup> /L	2.83	0.15	4.15	0.20	5.17	0.28
HGB g/dL	7.5	0.4	11.6	0.5	16.0	0.6
HCT %	20.5	1.5	31.2	2.3	41.9	3.5
MCV fL	72.5	4.0	75.3	4.0	81.0	4.0
MCH pg	26.5	2.0	28.0	2.0	31.0	2.0
MCHC g/dL	36.6	2.3	37.2	3.0	38.3	2.3
RDW %	12.8	2.5	12.2	2.5	11.2	2.5
PLT 10 <sup>9</sup> /L	66	20	206	30	489	60
MPV fL	6.7	2.0	6.2	2.0	6.1	2.0
Retic %***	5.9	1.5	2.2	1.0	1.0	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>2024-08-23</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L41629		LOT N41629		LOT H41629	
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

<div><div><div></div></div><div>Exp.</div></div> <div>2024-08-23</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count <sup>3</sup>	LOT L41629		LOT N41629		LOT H41629	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.3	2.0	2.2	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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