

CONTROL

L

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H

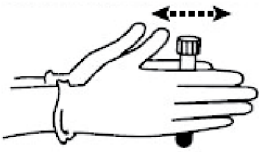
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

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](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>2024-05-31</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L40789		LOT N40789		LOT H40789	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 <sup>9</sup> /L	3.02	0.40	6.98	0.80	16.0	3.0
NEU 10 <sup>9</sup> /L	1.62	0.20	4.18	0.40	10.2	1.1
NEU %	53.5	6.0	59.9	5.0	63.8	6.0
LYM 10 <sup>9</sup> /L	1.00	0.20	1.84	0.50	3.56	1.00
LYM %	33.1	8.0	26.3	6.0	22.3	5.0
MONO 10 <sup>9</sup> /L	0.32	0.20	0.72	0.40	1.64	0.60
MONO %	10.6	6.0	10.3	5.0	10.3	3.0
EOS 10 <sup>9</sup> /L	0.10	0.10	0.23	0.17	0.53	0.19
EOS %	3.00	3.00	3.26	2.00	3.30	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	2.98	0.18	4.25	0.20	5.27	0.30
RBCo 10 <sup>12</sup> /L	3.08	0.18	4.31	0.20	5.27	0.30
HGB g/dL	8.10	0.30	12.2	0.5	16.6	0.8
HCT %	23.3	1.5	34.6	2.5	47.0	3.0
MCV fL	78.2	4.0	81.4	4.0	89.1	4.0
MCH pg	27.2	2.0	28.7	2.0	31.4	2.0
MCHC g/dL	34.7	2.3	35.3	2.3	35.2	2.3
RDW %	14.5	2.5	14.2	2.5	13.7	2.5
NRBC 10 <sup>9</sup> /L*	0.001	0.001	0.001	0.001	2.31	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.5	2.5
PLT 10 <sup>9</sup> /L	70.2	20.0	209	50	462	60
PLTi 10 <sup>9</sup> /L	76.0	20.0	220	50	478	60
MPV fL	8.64	2.00	7.57	2.00	7.17	2.00
RETC 10 <sup>9</sup> /L	240	50	144	50	97.9	50.0
%R	8.06	1.50	3.39	1.00	1.86	0.80
IRF	0.53	0.18	0.48	0.14	0.40	0.10

<div> Exp.</div> <div>2024-05-31</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L40789		LOT N40789		LOT H40789	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 <sup>9</sup> /L	3.0	0.4	6.9	0.7	15.8	2.5
NOC 10 <sup>9</sup> /L	3.1	0.4	7.0	1.0	18.0	2.5
NEU 10 <sup>9</sup> /L	1.6	0.3	4.2	0.8	10.2	2.0
NEU %	53.9	6.0	60.2	6.0	64.3	10.0
LYM 10 <sup>9</sup> /L	0.9	0.3	1.7	0.8	3.4	2.0
LYM %	30.8	7.0	24.6	6.0	21.2	10.0
MONO 10 <sup>9</sup> /L	0.3	0.2	0.7	0.4	1.4	0.6
MONO %	9.7	5.0	9.5	4.5	9.0	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	3.2	2.0	3.3	1.0
BASO 10 <sup>9</sup> /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.1	3.0	3.0	3.0	3.0	3.0
RBC 10 <sup>12</sup> /L	2.95	0.15	4.27	0.20	5.34	0.28
HGB g/dL	7.8	0.4	12.0	0.5	16.9	0.6
HCT %	21.9	1.5	32.9	2.3	44.6	3.5
MCV fL	74.0	4.0	76.9	4.0	83.4	4.0
MCH pg	26.6	2.0	28.2	2.0	31.7	2.0
MCHC g/dL	35.9	2.3	36.6	3.0	38.0	2.3
RDW %	12.2	2.5	11.7	2.5	10.5	2.5
PLT 10 <sup>9</sup> /L	68	20	213	30	499	60
MPV fL	6.3	2.0	5.7	2.0	5.7	2.0
Retic %***	5.2	1.5	2.0	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>Exp.</div></div> 2024-05-31	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L40789		LOT N40789		LOT H40789	
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>Exp.</div></div> 2024-05-31	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count <sup>3</sup>	LOT L40789		LOT N40789		LOT H40789	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.3	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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