

CONTROL | L | N | H

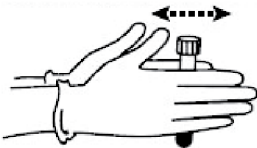
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

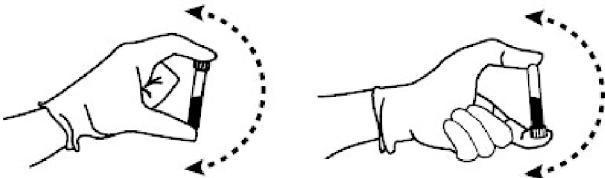
1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: **(Do NOT mix mechanically or vortex.)**

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.

<div> Exp.</div> <div>2024-12-13</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT	L42749	LOT	N42749	LOT	H42749
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.91	0.40	7.02	0.80	15.6	3.0
NEU 10 ⁹ /L	1.61	0.20	4.31	0.40	10.3	1.1
NEU %	55.3	6.0	61.4	5.0	66.3	6.0
LYM 10 ⁹ /L	0.92	0.20	1.81	0.50	3.09	1.00
LYM %	31.5	8.0	25.7	6.0	19.8	5.0
MONO 10 ⁹ /L	0.29	0.20	0.67	0.40	1.51	0.60
MONO %	10.1	6.0	9.61	5.00	9.70	3.00
EOS 10 ⁹ /L	0.10	0.10	0.20	0.17	0.60	0.19
EOS %	3.00	3.00	2.88	2.00	3.86	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	2.89	0.18	4.23	0.20	5.21	0.30
RBCo 10 ¹² /L	2.96	0.18	4.25	0.20	5.17	0.30
HGB g/dL	7.81	0.30	11.8	0.5	15.8	0.8
HCT %	22.3	1.5	33.6	2.5	45.0	3.0
MCV fL	77.3	4.0	79.6	4.0	86.3	4.0
MCH pg	27.0	2.0	28.0	2.0	30.3	2.0
MCHC g/dL	35.0	2.3	35.1	2.3	35.2	2.3
RDW %	15.3	2.5	14.8	2.5	13.5	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.30	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.7	2.5
PLT 10 ⁹ /L	70.7	20.0	211	50	474	60
PLTi 10 ⁹ /L	76.1	20.0	223	50	477	60
MPV fL	9.31	2.00	8.03	2.00	7.51	2.00
RETC 10 ⁹ /L	236	50	141	50	92.7	50.0
%R	8.18	1.50	3.34	1.00	1.78	0.80
IRF	0.53	0.18	0.46	0.14	0.39	0.10

<div> Exp.</div> <div>2024-12-13</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT	L42749	LOT	N42749	LOT	H42749
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	2.8	0.4	6.9	0.7	15.3	2.5
NOC 10 ⁹ /L	3.0	0.4	7.1	1.0	17.8	2.5
NEU 10 ⁹ /L	1.6	0.3	4.2	0.8	10.2	2.0
NEU %	56.1	6.0	61.3	6.0	66.7	10.0
LYM 10 ⁹ /L	0.8	0.3	1.7	0.8	2.9	2.0
LYM %	29.5	7.0	24.4	6.0	18.8	10.0
MONO 10 ⁹ /L	0.2	0.2	0.6	0.4	1.3	0.6
MONO %	8.7	5.0	8.4	4.5	8.6	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.2
EOS %	3.0	3.0	2.9	2.0	3.7	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.3	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.85	0.15	4.22	0.20	5.19	0.28
HGB g/dL	7.6	0.4	11.8	0.5	16.2	0.6
HCT %	20.9	1.5	32.0	2.3	42.3	3.5
MCV fL	73.4	4.0	75.8	4.0	81.5	4.0
MCH pg	26.7	2.0	27.9	2.0	31.2	2.0
MCHC g/dL	36.4	2.3	36.8	3.0	38.3	2.3
RDW %	12.9	2.5	12.1	2.5	10.5	2.5
PLT 10 ⁹ /L	70	20	222	30	513	60
MPV fL	6.5	2.0	6.2	2.0	6.1	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></div><div>Exp.</div></div> <div>2024-12-13</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L42749		LOT N42749		LOT H42749	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
WIC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
WBC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
NEU 10 ⁹ /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 ⁹ /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 ⁹ /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 ⁹ /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 ⁹ /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 ¹² /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 ⁹ /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 % ¹	N/A	N/A	N/A	N/A	N/A	N/A
IRF ²	N/A	N/A	N/A	N/A	N/A	N/A

<div><div><div></div></div><div>Exp.</div></div> <div>2024-12-13</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L42749		LOT N42749		LOT H42749	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.1	2.0	1.7	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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