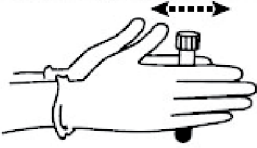
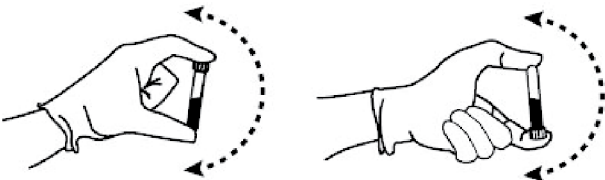




CONTROL | L | N | H

- Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.
- IMPORTANT: Mixing and Handling**
- Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
 - 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.
 - Hold the vial vertically and roll each vial between the palms of the hands for 15-20 seconds.


 - 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.


 - Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
 - 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).
 - 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.
 - 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> 2024-07-26			7 Consecutive Day Open-Vial Stability			
<div>SYSTEM</div>	<div>CONTROL</div> <div>L</div>		<div>CONTROL</div> <div>N</div>		<div>CONTROL</div> <div>H</div>	
CELL-DYN Sapphire	<div>LOT</div> L41349		<div>LOT</div> N41349		<div>LOT</div> H41349	
<div>PARAMETER</div>	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **
WBC 10 ⁹ /L	2.98	0.40	6.61	0.80	16.1	3.0
NEU 10 ⁹ /L	1.53	0.20	4.02	0.40	10.5	1.1
NEU %	51.4	6.0	60.8	5.0	65.3	6.0
LYM 10 ⁹ /L	1.04	0.20	1.64	0.50	3.28	1.00
LYM %	34.9	8.0	24.8	6.0	20.4	5.0
MONO 10 ⁹ /L	0.32	0.20	0.71	0.40	1.67	0.60
MONO %	10.8	6.0	10.7	5.0	10.4	3.0
EOS 10 ⁹ /L	0.10	0.10	0.23	0.17	0.61	0.19
EOS %	3.00	3.00	3.42	2.00	3.78	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	2.93	0.18	4.28	0.20	5.25	0.30
RBCo 10 ¹² /L	3.01	0.18	4.34	0.20	5.26	0.30
HGB g/dL	7.80	0.30	11.7	0.5	16.1	0.8
HCT %	22.8	1.5	34.4	2.5	46.3	3.0
MCV fL	77.8	4.0	80.4	4.0	88.3	4.0
MCH pg	26.7	2.0	27.4	2.0	30.8	2.0
MCHC g/dL	34.3	2.3	34.1	2.3	34.8	2.3
RDW %	15.9	2.5	15.2	2.5	13.7	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.32	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.4	2.5
PLT 10 ⁹ /L	67.7	20.0	213	50	454	60
PLTi 10 ⁹ /L	75.0	20.0	226	50	480	60
MPV fL	9.51	2.00	8.15	2.00	7.55	2.00
RETC 10 ⁹ /L	240	50	147	50	93.8	50.0
%R	8.22	1.50	3.44	1.00	1.79	0.80
IRF	0.60	0.18	0.50	0.14	0.38	0.10

<div>Exp.</div> 2024-07-26			7 Consecutive Day Open-Vial Stability			
<div>SYSTEM</div>	<div>CONTROL</div> <div>L</div>		<div>CONTROL</div> <div>N</div>		<div>CONTROL</div> <div>H</div>	
CELL-DYN Ruby	<div>LOT</div> L41349		<div>LOT</div> N41349		<div>LOT</div> H41349	
<div>PARAMETER</div>	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **	<div>ASSAY VALUE</div>	<div>±</div> <div>MEAN RANGE</div> **
WOC 10 ⁹ /L	2.9	0.4	6.5	0.7	16.0	2.5
NOC 10 ⁹ /L	3.0	0.4	6.7	1.0	18.2	2.5
NEU 10 ⁹ /L	1.5	0.3	4.0	0.8	10.5	2.0
NEU %	51.0	6.0	61.5	6.0	66.0	10.0
LYM 10 ⁹ /L	1.0	0.3	1.5	0.8	3.0	2.0
LYM %	33.2	7.0	22.8	6.0	18.8	10.0
MONO 10 ⁹ /L	0.3	0.2	0.6	0.4	1.4	0.6
MONO %	10.0	5.0	9.8	4.5	8.9	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.2
EOS %	3.0	3.0	3.5	2.0	3.9	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.2	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.83	0.15	4.22	0.20	5.24	0.28
HGB g/dL	7.6	0.4	11.8	0.5	16.7	0.6
HCT %	20.7	1.5	31.9	2.3	43.0	3.5
MCV fL	72.9	4.0	75.6	4.0	82.1	4.0
MCH pg	26.8	2.0	27.9	2.0	31.9	2.0
MCHC g/dL	36.8	2.3	36.9	3.0	38.8	2.3
RDW %	13.1	2.5	12.3	2.5	10.3	2.5
PLT 10 ⁹ /L	70	20	229	30	505	60
MPV fL	6.5	2.0	6.1	2.0	6.2	2.0
Retic %***	5.0	1.5	2.1	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>Exp.</div></div><div>2024-07-26</div></div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT	L41349	LOT	N41349	LOT	H41349
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>Exp.</div></div><div>2024-07-26</div></div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT	L41349	LOT	N41349	LOT	H41349
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	6.2	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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