

CONTROL

L

N

H

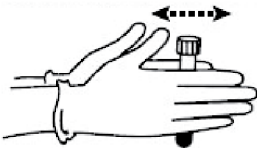
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

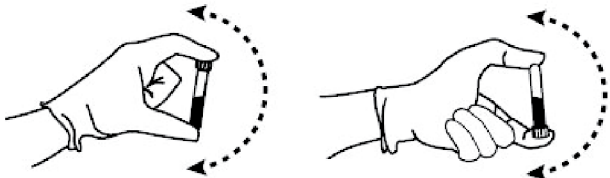
1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: (Do NOT mix mechanically or vortex.)

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>2024-05-03</div>	7 Consecutive Day Open-Vial Stability
---	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT L40509		LOT N40509		LOT H40509	
	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 ⁹ /L	2.96 0.40	6.56 0.80	15.9 3.0		
	NEU 10 ⁹ /L	1.65 0.20	3.88 0.40	10.2 1.1		
	NEU %	55.7 6.0	59.2 5.0	64.3 6.0		
	LYM 10 ⁹ /L	0.91 0.20	1.75 0.50	3.47 1.00		
	LYM %	30.7 8.0	26.7 6.0	21.8 5.0		
	MONO 10 ⁹ /L	0.31 0.20	0.68 0.40	1.70 0.60		
	MONO %	10.3 6.0	10.4 5.0	10.7 3.0		
	EOS 10 ⁹ /L	0.10 0.10	0.22 0.17	0.49 0.19		
	EOS %	3.00 3.00	3.35 2.00	3.06 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	3.00 0.18	4.24 0.20	5.28 0.30		
	RBCo 10 ¹² /L	3.09 0.18	4.27 0.20	5.24 0.30		
	HGB g/dL	8.05 0.30	12.2 0.5	16.9 0.8		
	HCT %	23.6 1.5	34.8 2.5	47.8 3.0		
	MCV fL	78.8 4.0	82.0 4.0	90.5 4.0		
	MCH pg	26.8 2.0	28.8 2.0	32.0 2.0		
	MCHC g/dL	34.1 2.3	35.1 2.3	35.3 2.3		
	RDW %	15.5 2.5	15.2 2.5	14.1 2.5		
	NRBC 10 ⁹ /L*	0.001 0.001	0.001 0.001	2.26 0.60		
	NRBC/100WBC*	0.001 0.001	0.001 0.001	14.2 2.5		
	PLT 10 ⁹ /L	70.6 20.0	216 50	467 60		
	PLTi 10 ⁹ /L	75.6 20.0	228 50	486 60		
	MPV fL	9.46 2.00	8.02 2.00	7.44 2.00		
	RETC 10 ⁹ /L	234 50	144 50	101 50		
	%R	7.79 1.50	3.38 1.00	1.91 0.80		
	IRF	0.57 0.18	0.51 0.14	0.38 0.10		

<div> Exp.</div> <div>2024-05-03</div>	7 Consecutive Day Open-Vial Stability
---	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT L40509		LOT N40509		LOT H40509	
	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 ⁹ /L	2.9 0.4	6.5 0.7	15.8 2.5		
	NOC 10 ⁹ /L	3.0 0.4	6.7 1.0	18.4 2.5		
	NEU 10 ⁹ /L	1.6 0.3	3.9 0.8	10.2 2.0		
	NEU %	55.8 6.0	59.6 6.0	64.3 10.0		
	LYM 10 ⁹ /L	0.9 0.3	1.7 0.8	3.2 2.0		
	LYM %	29.1 7.0	25.7 6.0	20.5 10.0		
	MONO 10 ⁹ /L	0.3 0.2	0.6 0.4	1.6 0.6		
	MONO %	9.9 5.0	9.2 4.5	9.8 3.0		
	EOS 10 ⁹ /L	0.1 0.1	0.2 0.2	0.5 0.2		
	EOS %	3.0 3.0	3.2 2.0	3.2 1.0		
	BASO 10 ⁹ /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 ¹² /L	2.95 0.15	4.28 0.20	5.35 0.28		
	HGB g/dL	7.8 0.4	12.1 0.5	17.2 0.6		
	HCT %	21.9 1.5	33.0 2.3	44.8 3.5		
	MCV fL	74.2 4.0	77.1 4.0	83.7 4.0		
	MCH pg	26.6 2.0	28.2 2.0	32.2 2.0		
	MCHC g/dL	35.8 2.3	36.6 3.0	38.4 2.3		
	RDW %	12.9 2.5	12.3 2.5	10.7 2.5		
	PLT 10 ⁹ /L	69 20	225 30	504 60		
	MPV fL	6.3 2.0	5.7 2.0	5.7 2.0		
	Retic %***	4.8 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> 2024-05-03	7 Consecutive Day Open-Vial Stability
---	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L40509		LOT N40509		LOT H40509	
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> 2024-05-03	7 Consecutive Day Open-Vial Stability
---	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L40509		LOT N40509		LOT H40509	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	4.3	2.0	1.9	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.



CELL-DYN, CELL-DYN Sapphire and CELL-DYN Ruby are trademarks of Abbott Laboratories in various jurisdictions.

Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064
USA

EC REP

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

MANUFACTURED FOR

Abbott Laboratories



REF 08H58-01, 08H58-02

