

CONTROL | L | N | H

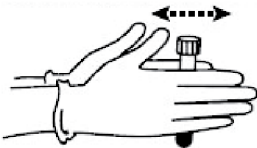
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

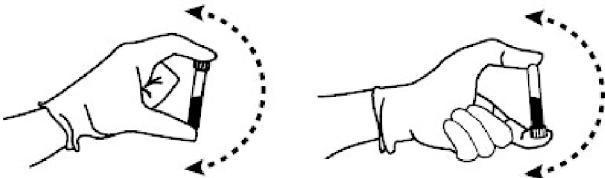
1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: (Do NOT mix mechanically or vortex.)

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. 2024-10-18</div>	7 Consecutive Day Open-Vial Stability
----------------------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT	L42189	LOT	N42189	LOT	H42189
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	3.11	0.40	7.03	0.80	16.1	3.0
NEU 10 ⁹ /L	1.71	0.20	4.17	0.40	10.6	1.1
NEU %	55.2	6.0	59.4	5.0	65.8	6.0
LYM 10 ⁹ /L	1.00	0.20	1.92	0.50	3.30	1.00
LYM %	32.2	8.0	27.3	6.0	20.4	5.0
MONO 10 ⁹ /L	0.31	0.20	0.74	0.40	1.68	0.60
MONO %	9.90	6.00	10.5	5.0	10.4	3.0
EOS 10 ⁹ /L	0.10	0.10	0.18	0.17	0.51	0.19
EOS %	3.00	3.00	2.52	2.00	3.17	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	2.88	0.18	4.18	0.20	5.19	0.30
RBCo 10 ¹² /L	2.95	0.18	4.21	0.20	5.16	0.30
HGB g/dL	7.84	0.30	11.5	0.5	15.5	0.8
HCT %	22.4	1.5	32.8	2.5	44.2	3.0
MCV fL	77.6	4.0	78.4	4.0	85.1	4.0
MCH pg	27.2	2.0	27.4	2.0	29.8	2.0
MCHC g/dL	35.0	2.3	35.0	2.3	35.0	2.3
RDW %	14.3	2.5	15.1	2.5	14.4	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.35	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.6	2.5
PLT 10 ⁹ /L	73.5	20.0	215	50	472	60
PLTi 10 ⁹ /L	78.1	20.0	225	50	477	60
MPV fL	9.07	2.00	8.32	2.00	7.62	2.00
RETC 10 ⁹ /L	228	50	141	50	98.9	50.0
%R	7.90	1.50	3.36	1.00	1.91	0.80
IRF	0.57	0.18	0.47	0.14	0.43	0.10

<div>Exp. 2024-10-18</div>	7 Consecutive Day Open-Vial Stability
----------------------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT	L42189	LOT	N42189	LOT	H42189
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	7.0	0.7	16.2	2.5
NOC 10 ⁹ /L	3.1	0.4	7.1	1.0	18.3	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.8	2.0
NEU %	55.2	6.0	59.4	6.0	66.5	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.1	2.0
LYM %	29.2	7.0	26.0	6.0	19.3	10.0
MONO 10 ⁹ /L	0.3	0.2	0.6	0.4	1.4	0.6
MONO %	9.8	5.0	9.3	4.5	8.8	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.6	2.0	3.0	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.4	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.85	0.15	4.21	0.20	5.29	0.28
HGB g/dL	7.6	0.4	11.4	0.5	15.8	0.6
HCT %	20.9	1.5	31.4	2.3	42.6	3.5
MCV fL	73.4	4.0	74.6	4.0	80.5	4.0
MCH pg	26.8	2.0	27.0	2.0	29.9	2.0
MCHC g/dL	36.5	2.3	36.1	3.0	37.2	2.3
RDW %	11.9	2.5	12.5	2.5	11.2	2.5
PLT 10 ⁹ /L	76	20	225	30	512	60
MPV fL	6.6	2.0	6.3	2.0	6.2	2.0
Retic %***	5.3	1.5	2.0	1.0	1.1	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> 2024-10-18	7 Consecutive Day Open-Vial Stability
--	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L42189		LOT N42189		LOT H42189	
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>Exp.</div></div> 2024-10-18	7 Consecutive Day Open-Vial Stability
--	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L42189		LOT N42189		LOT H42189	
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.



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

