

CONTROL | L | N | H

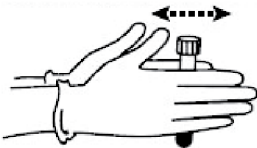
Refer to the appropriate system operator’s manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2024-04-05</div>	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT	L40229	LOT	N40229	LOT	H40229
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	3.01	0.40	6.74	0.80	15.9	3.0
NEU 10 ⁹ /L	1.67	0.20	4.07	0.40	10.3	1.1
NEU %	55.4	6.0	60.5	5.0	64.9	6.0
LYM 10 ⁹ /L	0.93	0.20	1.74	0.50	3.44	1.00
LYM %	31.0	8.0	25.8	6.0	21.7	5.0
MONO 10 ⁹ /L	0.31	0.20	0.71	0.40	1.62	0.60
MONO %	10.3	6.0	10.6	5.0	10.2	3.0
EOS 10 ⁹ /L	0.10	0.10	0.19	0.17	0.46	0.19
EOS %	3.00	3.00	2.80	2.00	2.92	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	2.90	0.18	4.20	0.20	5.24	0.30
RBCo 10 ¹² /L	2.98	0.18	4.25	0.20	5.21	0.30
HGB g/dL	7.86	0.30	11.8	0.5	16.5	0.8
HCT %	22.6	1.5	33.5	2.5	46.4	3.0
MCV fL	77.8	4.0	79.9	4.0	88.5	4.0
MCH pg	27.1	2.0	28.2	2.0	31.4	2.0
MCHC g/dL	34.8	2.3	35.2	2.3	35.5	2.3
RDW %	14.8	2.5	14.8	2.5	13.8	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.24	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.1	2.5
PLT 10 ⁹ /L	69.9	20.0	209	50	451	60
PLTi 10 ⁹ /L	76.5	20.0	222	50	467	60
MPV fL	9.17	2.00	7.88	2.00	7.45	2.00
RETC 10 ⁹ /L	234	50	150	50	105	50
%R	8.07	1.50	3.57	1.00	2.00	0.80
IRF	0.48	0.18	0.43	0.14	0.40	0.10

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT	L40229	LOT	N40229	LOT	H40229
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	2.9	0.4	6.6	0.7	15.9	2.5
NOC 10 ⁹ /L	3.1	0.4	6.9	1.0	18.3	2.5
NEU 10 ⁹ /L	1.6	0.3	4.1	0.8	10.5	2.0
NEU %	56.2	6.0	61.0	6.0	65.6	10.0
LYM 10 ⁹ /L	0.8	0.3	1.6	0.8	3.2	2.0
LYM %	28.4	7.0	24.4	6.0	20.3	10.0
MONO 10 ⁹ /L	0.3	0.2	0.6	0.4	1.5	0.6
MONO %	9.6	5.0	9.3	4.5	9.2	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.9	2.0	2.9	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	2.85	0.15	4.24	0.20	5.34	0.28
HGB g/dL	7.6	0.4	11.7	0.5	16.8	0.6
HCT %	20.9	1.5	32.3	2.3	44.3	3.5
MCV fL	73.5	4.0	76.0	4.0	83.1	4.0
MCH pg	26.7	2.0	27.5	2.0	31.5	2.0
MCHC g/dL	36.3	2.3	36.2	3.0	37.9	2.3
RDW %	12.7	2.5	12.2	2.5	10.5	2.5
PLT 10 ⁹ /L	69	20	217	30	487	60
MPV fL	6.2	2.0	5.8	2.0	5.7	2.0
Retic %***	5.4	1.5	2.4	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> 2024-04-05	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L40229		LOT N40229		LOT H40229	
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> 2024-04-05	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L40229		LOT N40229		LOT H40229	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	4.5	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.



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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

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