

CONTROL | L | N | H

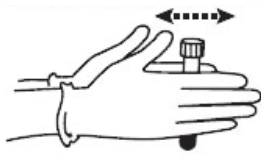
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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.

Exp. 2021-01-15

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L03079		LOT N03079		LOT H03079	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	3.06	0.40	7.16	0.80	16.0	3.0
NEU 10 ⁹ /L	1.73	0.20	4.32	0.40	10.3	1.1
NEU %	56.5	6.0	60.3	5.0	64.5	6.0
LYM 10 ⁹ /L	0.92	0.20	1.88	0.50	3.38	1.00
LYM %	30.0	8.0	26.2	6.0	21.1	5.0
MONO 10 ⁹ /L	0.31	0.20	0.76	0.40	1.84	0.60
MONO %	10.2	6.0	10.6	5.0	11.5	3.0
EOS 10 ⁹ /L	0.10	0.10	0.20	0.17	0.45	0.19
EOS %	3.00	3.00	2.79	2.00	2.82	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	2.76	0.18	4.20	0.20	5.18	0.30
RBCo 10 ¹² /L	2.85	0.18	4.25	0.20	5.19	0.30
HGB g/dL	7.39	0.30	11.6	0.5	16.8	0.8
HCT %	21.6	1.5	33.5	2.5	48.0	3.0
MCV fL	78.2	4.0	79.7	4.0	92.6	4.0
MCH pg	26.8	2.0	27.6	2.0	32.4	2.0
MCHC g/dL	34.2	2.3	34.6	2.3	35.0	2.3
RDW %	15.3	2.5	15.9	2.5	13.1	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.29	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.3	2.5
PLT 10 ⁹ /L	70.8	20.0	206	50	440	60
PLTi 10 ⁹ /L	77.3	20.0	227	50	470	60
MPV fL	9.29	2.00	8.06	2.00	7.50	2.00
RETC 10 ⁹ /L	218	50	148	50	94.3	50.0
%R	7.91	1.50	3.52	1.00	1.82	0.80
IRF	0.55	0.18	0.48	0.14	0.39	0.10

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7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L03079		LOT N03079		LOT H03079	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	7.2	0.7	16.0	2.5
NOC 10 ⁹ /L	3.1	0.4	7.3	1.0	18.7	2.5
NEU 10 ⁹ /L	1.7	0.3	4.3	0.8	10.3	2.0
NEU %	56.1	6.0	60.4	6.0	64.4	10.0
LYM 10 ⁹ /L	0.8	0.3	1.8	0.8	3.2	2.0
LYM %	28.1	7.0	24.5	6.0	19.9	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	10.2	5.0	10.0	4.5	10.8	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.8	2.0	2.9	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	2.73	0.15	4.20	0.20	5.22	0.28
HGB g/dL	7.3	0.4	11.7	0.5	17.6	0.6
HCT %	20.3	1.5	31.9	2.3	44.9	3.5
MCV fL	74.3	4.0	75.9	4.0	86.1	4.0
MCH pg	26.7	2.0	27.9	2.0	33.7	2.0
MCHC g/dL	36.0	2.3	36.7	3.0	39.2	2.3
RDW %	13.2	2.5	13.2	2.5	9.9	2.5
PLT 10 ⁹ /L	75	20	219	30	488	60
MPV fL	6.5	2.0	6.0	2.0	6.1	2.0
Retic %***	7.2	1.5	3.2	1.0	1.5	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

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L03079		LOT N03079		LOT H03079	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.2	0.4	7.2	0.7	16.0	2.5
WIC 10 ⁹ /L	3.4	0.5	7.7	1.0	19.4	3.0
WBC 10 ⁹ /L	3.2	0.4	7.2	0.7	16.0	2.5
NEU 10 ⁹ /L	1.8	0.3	4.3	0.8	10.3	2.0
NEU %	55.6	6.0	60.2	6.0	64.4	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.2	2.0
LYM %	29.2	7.0	25.2	6.0	20.2	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.8	0.6
MONO %	10.7	5.0	10.3	4.5	11.2	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.8	2.0	2.9	1.0
BASO 10 ⁹ /L	0.1	0.1	0.3	0.3	0.6	0.6
BASO %	3.0	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.81	0.15	4.22	0.20	5.22	0.28
HGB g/dL	7.4	0.3	11.8	0.5	17.5	0.6
HCT %	23.5	1.5	36.6	2.3	53.2	3.5
MCV fL	83.5	4.0	86.8	4.0	102	4
MCH pg	26.3	2.0	28.0	2.0	33.5	2.0
MCHC g/dL	31.5	2.3	32.2	3.0	32.9	2.3
RDW %	19.0	2.5	19.7	2.5	16.0	2.5
PLT 10 ⁹ /L	74	20	221	30	453	60
MPV fL	7.0	2.0	6.8	2.0	6.9	2.0
Retic % ¹	7.1	1.5	3.1	1.0	1.3	0.8
IRF ²	0.62	0.38	0.60	0.30	0.44	0.20

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L03079		LOT N03079		LOT H03079	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.5	2.0	2.6	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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Abbott Laboratories



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