

CELL-DYN 29 Plus Control (with Retic)

ABBOTT
CELL-DYN SYSTEMS



CONTROL | L | N | H

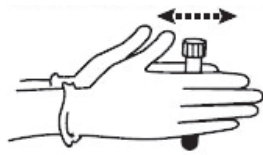
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2020-12-18

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L02799		LOT N02799		LOT H02799	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.94	0.40	7.03	0.80	16.2	3.0
NEU 10 ⁹ /L	1.67	0.20	4.30	0.40	10.4	1.1
NEU %	56.7	6.0	61.1	5.0	64.0	6.0
LYM 10 ⁹ /L	0.88	0.20	1.81	0.50	3.37	1.00
LYM %	29.9	8.0	25.8	6.0	20.8	5.0
MONO 10 ⁹ /L	0.29	0.20	0.71	0.40	1.91	0.60
MONO %	10.0	6.0	10.1	5.0	11.8	3.0
EOS 10 ⁹ /L	0.10	0.10	0.20	0.17	0.52	0.19
EOS %	3.00	3.00	2.83	2.00	3.19	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	2.77	0.18	4.32	0.20	5.40	0.30
RBCo 10 ¹² /L	2.86	0.18	4.37	0.20	5.38	0.30
HGB g/dL	7.55	0.30	12.0	0.5	17.0	0.8
HCT %	22.0	1.5	34.8	2.5	48.8	3.0
MCV fL	79.5	4.0	80.6	4.0	90.4	4.0
MCH pg	27.3	2.0	27.8	2.0	31.5	2.0
MCHC g/dL	34.3	2.3	34.5	2.3	34.8	2.3
RDW %	15.8	2.5	15.2	2.5	14.2	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.22	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	13.8	2.5
PLT 10 ⁹ /L	69.0	20.0	209	50	469	60
PLTi 10 ⁹ /L	76.4	20.0	227	50	492	60
MPV fL	9.05	2.00	8.02	2.00	7.50	2.00
RETC 10 ⁹ /L	204	50	137	50	104	50
%R	7.37	1.50	3.18	1.00	1.93	0.80
IRF	0.57	0.18	0.47	0.14	0.40	0.10

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7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L02799		LOT N02799		LOT H02799	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	2.9	0.4	7.1	0.7	16.2	2.5
NOC 10 ⁹ /L	3.0	0.4	7.2	1.0	18.7	2.5
NEU 10 ⁹ /L	1.6	0.3	4.2	0.8	10.5	2.0
NEU %	55.6	6.0	59.8	6.0	64.8	10.0
LYM 10 ⁹ /L	0.8	0.3	1.8	0.8	3.2	2.0
LYM %	28.3	7.0	24.7	6.0	19.7	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	10.2	5.0	10.4	4.5	10.4	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	3.1	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.1	3.0	3.0	3.0	3.0	3.0
RBC 10 ¹² /L	2.74	0.15	4.37	0.20	5.54	0.28
HGB g/dL	7.5	0.4	12.1	0.5	17.8	0.6
HCT %	20.5	1.5	33.3	2.3	46.7	3.5
MCV fL	74.7	4.0	76.2	4.0	84.3	4.0
MCH pg	27.4	2.0	27.7	2.0	32.1	2.0
MCHC g/dL	36.6	2.3	36.3	3.0	38.1	2.3
RDW %	13.5	2.5	12.7	2.5	11.0	2.5
PLT 10 ⁹ /L	72	20	230	30	534	60
MPV fL	6.8	2.0	6.4	2.0	6.2	2.0
Retic %***	6.6	1.5	2.7	1.0	1.4	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

Exp. 2020-12-18	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L02799		LOT N02799		LOT H02799	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	7.1	0.7	16.2	2.5
WIC 10 ⁹ /L	3.3	0.5	7.9	1.0	20.2	3.0
WBC 10 ⁹ /L	3.0	0.4	7.1	0.7	16.2	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.4	2.0
NEU %	55.6	6.0	59.7	6.0	64.5	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.2	2.0
LYM %	29.3	7.0	24.8	6.0	19.7	10.0
MONO 10 ⁹ /L	0.3	0.2	0.8	0.4	1.8	0.6
MONO %	10.5	5.0	10.9	4.5	11.0	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	3.2	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	2.79	0.15	4.31	0.20	5.42	0.28
HGB g/dL	7.5	0.3	12.0	0.5	17.6	0.6
HCT %	23.5	1.5	37.7	2.3	53.7	3.5
MCV fL	84.2	4.0	87.4	4.0	99.0	4.0
MCH pg	26.9	2.0	27.8	2.0	32.5	2.0
MCHC g/dL	31.9	2.3	31.8	3.0	32.8	2.3
RDW %	20.0	2.5	18.5	2.5	17.6	2.5
PLT 10 ⁹ /L	71	20	221	30	474	60
MPV fL	7.0	2.0	6.9	2.0	6.8	2.0
Retic % ¹	6.5	1.5	2.3	1.0	1.2	0.8
IRF ²	0.62	0.38	0.58	0.30	0.41	0.20

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L02799		LOT N02799		LOT H02799	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.4	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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REF 08H58-01, 08H58-02

9231566B 350491-10 August 2018
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