

## CONTROL | L | N | H

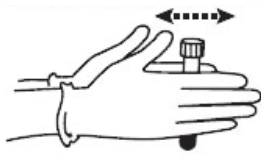
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

**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](http://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.



2019-11-22

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L92529	LOT	N92529	LOT	H92529
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 <sup>9</sup> /L	2.91	0.40	6.99	0.80	15.8	3.0
NEU 10 <sup>9</sup> /L	1.62	0.20	4.14	0.40	9.91	1.10
NEU %	55.6	6.0	59.2	5.0	62.7	6.0
LYM 10 <sup>9</sup> /L	0.93	0.20	1.92	0.50	3.65	1.00
LYM %	31.8	8.0	27.4	6.0	23.1	5.0
MONO 10 <sup>9</sup> /L	0.28	0.20	0.75	0.40	1.72	0.60
MONO %	9.78	6.00	10.8	5.0	10.9	3.0
EOS 10 <sup>9</sup> /L	0.10	0.10	0.17	0.17	0.47	0.19
EOS %	3.00	3.00	2.45	2.00	2.98	1.00
BASO 10 <sup>9</sup> /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 <sup>12</sup> /L	2.87	0.18	4.23	0.20	5.22	0.30
RBCo 10 <sup>12</sup> /L	2.92	0.18	4.27	0.20	5.19	0.30
HGB g/dL	7.75	0.30	11.7	0.5	16.2	0.8
HCT %	22.4	1.5	33.7	2.5	46.2	3.0
MCV fL	78.0	4.0	79.7	4.0	88.6	4.0
MCH pg	27.0	2.0	27.7	2.0	31.0	2.0
MCHC g/dL	34.6	2.3	34.7	2.3	35.1	2.3
RDW %	15.1	2.5	14.4	2.5	14.9	2.5
NRBC 10 <sup>9</sup> /L*	0.001	0.001	0.001	0.001	2.27	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.4	2.5
PLT 10 <sup>9</sup> /L	69.1	20.0	210	50	447	60
PLTi 10 <sup>9</sup> /L	77.5	20.0	229	50	466	60
MPV fL	8.96	2.00	7.87	2.00	7.46	2.00
RETC 10 <sup>9</sup> /L	232	50	139	50	97.6	50.0
%R	8.07	1.50	3.29	1.00	1.87	0.80
IRF	0.66	0.18	0.55	0.14	0.42	0.10



2019-11-22

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L92529	LOT	N92529	LOT	H92529
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 <sup>9</sup> /L	2.9	0.4	6.9	0.7	15.4	2.5
NOC 10 <sup>9</sup> /L	2.9	0.4	6.9	1.0	17.6	2.5
NEU 10 <sup>9</sup> /L	1.6	0.3	4.1	0.8	9.7	2.0
NEU %	55.7	6.0	59.6	6.0	62.8	10.0
LYM 10 <sup>9</sup> /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	29.5	7.0	25.8	6.0	21.8	10.0
MONO 10 <sup>9</sup> /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.9	5.0	10.0	4.5	10.4	3.0
EOS 10 <sup>9</sup> /L	0.1	0.1	0.2	0.2	0.4	0.2
EOS %	3.0	3.0	2.3	2.0	2.9	1.0
BASO 10 <sup>9</sup> /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 <sup>12</sup> /L	2.85	0.15	4.25	0.20	5.30	0.28
HGB g/dL	7.5	0.4	11.7	0.5	16.6	0.6
HCT %	20.9	1.5	32.0	2.3	43.9	3.5
MCV fL	73.5	4.0	75.4	4.0	82.8	4.0
MCH pg	26.3	2.0	27.5	2.0	31.3	2.0
MCHC g/dL	35.9	2.3	36.6	3.0	37.8	2.3
RDW %	12.6	2.5	11.7	2.5	11.3	2.5
PLT 10 <sup>9</sup> /L	72	20	225	30	501	60
MPV fL	6.8	2.0	6.2	2.0	6.2	2.0
Retic %***	5.9	1.5	2.3	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**

Exp. 2019-11-22	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L92529		LOT N92529		LOT H92529	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 <sup>9</sup> /L	3.0	0.4	6.9	0.7	15.5	2.5
WIC 10 <sup>9</sup> /L	3.1	0.5	7.4	1.0	18.8	3.0
WBC 10 <sup>9</sup> /L	3.0	0.4	6.9	0.7	15.5	2.5
NEU 10 <sup>9</sup> /L	1.7	0.3	4.1	0.8	9.8	2.0
NEU %	55.7	6.0	59.9	6.0	63.0	10.0
LYM 10 <sup>9</sup> /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	30.1	7.0	26.0	6.0	22.0	10.0
MONO 10 <sup>9</sup> /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.8	5.0	10.1	4.5	10.5	3.0
EOS 10 <sup>9</sup> /L	0.1	0.1	0.2	0.2	0.4	0.2
EOS %	3.0	3.0	2.3	2.0	2.9	1.0
BASO 10 <sup>9</sup> /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 <sup>12</sup> /L	2.91	0.15	4.24	0.20	5.25	0.28
HGB g/dL	7.7	0.3	11.7	0.5	16.6	0.6
HCT %	24.3	1.5	36.9	2.3	50.9	3.5
MCV fL	83.6	4.0	87.0	4.0	97.0	4.0
MCH pg	26.5	2.0	27.6	2.0	31.6	2.0
MCHC g/dL	31.7	2.3	31.7	3.0	32.6	2.3
RDW %	18.8	2.5	17.4	2.5	17.7	2.5
PLT 10 <sup>9</sup> /L	71	20	214	30	441	60
MPV fL	6.9	2.0	6.8	2.0	6.7	2.0
Retic % <sup>1</sup>	5.8	1.5	2.0	1.0	1.0	0.8
IRF <sup>2</sup>	0.60	0.38	0.40	0.30	0.40	0.20

Exp. 2019-11-22	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count <sup>3</sup>	LOT L92529		LOT N92529		LOT H92529	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.7	2.0	2.6	1.5	0.8	0.8

\*\* The mean range does not represent standard deviations (SD).

<sup>1</sup> Retic % values will not load from the Assay Disk. Please enter these values manually.

<sup>2</sup> IRF is reportable on the CELL-DYN 3700 System, Version 1.1 and higher.

<sup>3</sup> Manual values were obtained using the Miller Ocular method.



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