

CONTROL | L | N | H

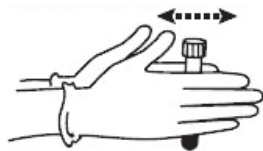
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2020-08-28

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L01679		LOT N01679		LOT H01679	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.99	0.40	7.12	0.80	16.0	3.0
NEU 10 ⁹ /L	1.69	0.20	4.26	0.40	10.3	1.1
NEU %	56.5	6.0	59.8	5.0	64.1	6.0
LYM 10 ⁹ /L	0.95	0.20	1.94	0.50	3.52	1.00
LYM %	31.9	8.0	27.3	6.0	22.0	5.0
MONO 10 ⁹ /L	0.27	0.20	0.73	0.40	1.78	0.60
MONO %	8.99	6.00	10.2	5.0	11.1	3.0
EOS 10 ⁹ /L	0.10	0.10	0.18	0.17	0.43	0.19
EOS %	3.00	3.00	2.49	2.00	2.69	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	2.79	0.18	4.27	0.20	5.29	0.30
RBCo 10 ¹² /L	2.89	0.18	4.28	0.20	5.26	0.30
HGB g/dL	7.55	0.30	11.8	0.5	16.1	0.8
HCT %	22.0	1.5	34.2	2.5	46.4	3.0
MCV fL	79.0	4.0	80.0	4.0	87.8	4.0
MCH pg	27.1	2.0	27.6	2.0	30.4	2.0
MCHC g/dL	34.3	2.3	34.5	2.3	34.7	2.3
RDW %	14.6	2.5	14.6	2.5	14.1	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.32	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.5	2.5
PLT 10 ⁹ /L	78.0	20.0	214	50	480	60
PLTi 10 ⁹ /L	79.8	20.0	230	50	495	60
MPV fL	8.79	2.00	7.94	2.00	7.46	2.00
RETC 10 ⁹ /L	228	50	145	50	96.8	50.0
%R	8.16	1.50	3.39	1.00	1.83	0.80
IRF	0.59	0.18	0.50	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 L01679		LOT N01679		LOT H01679	
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	16.1	2.5
NOC 10 ⁹ /L	3.1	0.4	7.2	1.0	18.9	2.5
NEU 10 ⁹ /L	1.6	0.3	4.2	0.8	10.2	2.0
NEU %	54.8	6.0	59.8	6.0	63.6	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	30.5	7.0	25.9	6.0	21.2	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	9.9	5.0	9.6	4.5	10.6	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.4	0.2
EOS %	3.0	3.0	2.5	2.0	2.7	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	2.71	0.15	4.21	0.20	5.28	0.28
HGB g/dL	7.3	0.4	11.7	0.5	16.5	0.6
HCT %	20.4	1.5	32.1	2.3	43.8	3.5
MCV fL	75.2	4.0	76.2	4.0	82.9	4.0
MCH pg	26.9	2.0	27.8	2.0	31.3	2.0
MCHC g/dL	35.8	2.3	36.4	3.0	37.7	2.3
RDW %	12.5	2.5	12.0	2.5	10.9	2.5
PLT 10 ⁹ /L	76	20	231	30	530	60
MPV fL	6.8	2.0	6.5	2.0	6.3	2.0
Retic %***	7.6	1.5	2.9	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 L01679		LOT N01679		LOT H01679	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.1	0.4	7.1	0.7	16.1	2.5
WIC 10 ⁹ /L	3.2	0.5	7.5	1.0	19.3	3.0
WBC 10 ⁹ /L	3.1	0.4	7.1	0.7	16.1	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.3	2.0
NEU %	54.0	6.0	59.4	6.0	63.8	10.0
LYM 10 ⁹ /L	1.0	0.3	1.9	0.8	3.4	2.0
LYM %	31.8	7.0	26.3	6.0	21.0	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.8	0.6
MONO %	10.2	5.0	10.3	4.5	11.0	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.4	0.2
EOS %	3.0	3.0	2.5	2.0	2.7	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	2.78	0.15	4.19	0.20	5.22	0.28
HGB g/dL	7.4	0.3	11.8	0.5	16.6	0.6
HCT %	23.5	1.5	36.8	2.3	50.6	3.5
MCV fL	84.7	4.0	87.9	4.0	97.0	4.0
MCH pg	26.6	2.0	28.2	2.0	31.8	2.0
MCHC g/dL	31.5	2.3	32.1	3.0	32.8	2.3
RDW %	17.7	2.5	17.4	2.5	17.5	2.5
PLT 10 ⁹ /L	76	20	224	30	490	60
MPV fL	7.1	2.0	7.0	2.0	6.9	2.0
Retic % ¹	7.0	1.5	2.6	1.0	1.3	0.8
IRF ²	0.62	0.38	0.57	0.30	0.44	0.20

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L01679		LOT N01679		LOT H01679	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.5	2.0	2.8	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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