

CELL-DYN 29 Plus Control (with Retic)

ABBOTT
CELL-DYN SYSTEMS



CONTROL | L | N | H

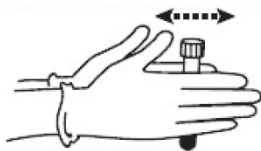
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2021-10-22

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L12219	LOT	N12219	LOT	H12219
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.94	0.40	7.09	0.80	15.7	3.0
NEU 10 ⁹ /L	1.67	0.20	4.39	0.40	10.2	1.1
NEU %	57.0	6.0	61.9	5.0	64.9	6.0
LYM 10 ⁹ /L	0.88	0.20	1.77	0.50	3.32	1.00
LYM %	30.0	8.0	25.0	6.0	21.1	5.0
MONO 10 ⁹ /L	0.30	0.20	0.74	0.40	1.71	0.60
MONO %	10.1	6.0	10.5	5.0	10.9	3.0
EOS 10 ⁹ /L	0.10	0.10	0.17	0.17	0.45	0.19
EOS %	3.00	3.00	2.36	2.00	2.86	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	2.93	0.18	4.26	0.20	5.28	0.30
RBC _o 10 ¹² /L	3.04	0.18	4.33	0.20	5.31	0.30
HGB g/dL	7.89	0.30	12.1	0.5	16.7	0.8
HCT %	23.2	1.5	34.4	2.5	47.6	3.0
MCV fL	79.0	4.0	80.9	4.0	90.1	4.0
MCH pg	26.9	2.0	28.4	2.0	31.6	2.0
MCHC g/dL	34.0	2.3	35.2	2.3	35.1	2.3
RDW %	15.2	2.5	14.2	2.5	14.5	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.30	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.6	2.5
PLT 10 ⁹ /L	73.7	20.0	214	50	474	60
PLTi 10 ⁹ /L	76.6	20.0	225	50	484	60
MPV fL	8.34	2.00	7.30	2.00	7.17	2.00
RETC 10 ⁹ /L	236	50	139	50	96.2	50.0
%R	8.06	1.50	3.26	1.00	1.82	0.80
IRF	0.65	0.18	0.56	0.14	0.39	0.10



Exp. 2021-10-22

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L12219	LOT	N12219	LOT	H12219
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	2.9	0.4	7.4	0.7	16.1	2.5
NOC 10 ⁹ /L	3.0	0.4	7.4	1.0	18.5	2.5
NEU 10 ⁹ /L	1.7	0.3	4.6	0.8	10.5	2.0
NEU %	57.2	6.0	61.8	6.0	65.4	10.0
LYM 10 ⁹ /L	0.8	0.3	1.8	0.8	3.2	2.0
LYM %	28.1	7.0	24.0	6.0	19.9	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.8	5.0	9.5	4.5	9.9	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.5	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	2.91	0.15	4.32	0.20	5.43	0.28
HGB g/dL	7.8	0.4	12.3	0.5	17.3	0.6
HCT %	21.5	1.5	32.7	2.3	45.2	3.5
MCV fL	73.7	4.0	75.7	4.0	83.2	4.0
MCH pg	26.8	2.0	28.5	2.0	31.9	2.0
MCHC g/dL	36.4	2.3	37.6	3.0	38.4	2.3
RDW %	13.1	2.5	11.7	2.5	11.4	2.5
PLT 10 ⁹ /L	75	20	231	30	520	60
MPV fL	6.6	2.0	6.2	2.0	6.1	2.0
Retic %***	6.0	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. 2021-10-22	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L12219		LOT N12219		LOT H12219	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	7.0	0.7	15.6	2.5
WIC 10 ⁹ /L	3.0	0.5	7.1	1.0	17.9	3.0
WBC 10 ⁹ /L	3.0	0.4	7.0	0.7	15.6	2.5
NEU 10 ⁹ /L	1.7	0.3	4.3	0.8	10.2	2.0
NEU %	57.2	6.0	62.0	6.0	65.4	10.0
LYM 10 ⁹ /L	0.9	0.3	1.7	0.8	3.1	2.0
LYM %	28.4	7.0	24.3	6.0	20.1	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	10.2	5.0	9.6	4.5	10.2	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.4	0.2
EOS %	3.0	3.0	2.4	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	3.01	0.15	4.31	0.20	5.40	0.28
HGB g/dL	7.9	0.3	12.3	0.5	17.4	0.6
HCT %	25.1	1.5	37.5	2.3	52.4	3.5
MCV fL	83.4	4.0	87.0	4.0	97.0	4.0
MCH pg	26.3	2.0	28.5	2.0	32.2	2.0
MCHC g/dL	31.6	2.3	32.8	3.0	33.2	2.3
RDW %	18.3	2.5	17.2	2.5	17.6	2.5
PLT 10 ⁹ /L	69	20	213	30	455	60
MPV fL	6.7	2.0	6.6	2.0	6.7	2.0
Retic % ¹	5.7	1.5	2.0	1.0	1.0	0.8
IRF ²	0.62	0.38	0.43	0.30	0.40	0.20

Exp. 2021-10-22	7 Consecutive Day Open-Vial Stability
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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L12219		LOT N12219		LOT H12219	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.6	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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