CELL-DYN 29 Plus Control (with Retic)

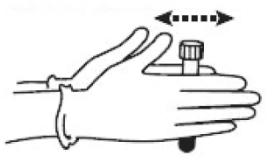
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

CONTROL L N H

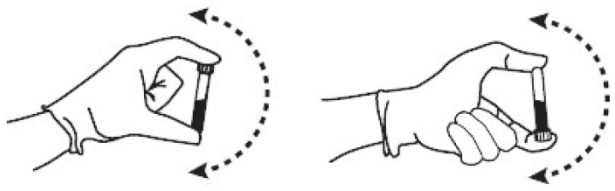
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2022-01-14 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L13059		LOT N13059		LOT H13059	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	3.17	0.40	7.06	0.80	16.5	3.0
NEU 10^9/L	1.80	0.20	4.24	0.40	10.8	1.1
NEU %	56.9	6.0	60.0	5.0	65.6	6.0
LYM 10^9/L	0.95	0.20	1.85	0.50	3.52	1.00
LYM %	30.0	8.0	26.2	6.0	21.3	5.0
MONO 10^9/L	0.32	0.20	0.74	0.40	1.58	0.60
MONO %	9.97	6.00	10.5	5.0	9.56	3.00
EOS 10^9/L	0.10	0.10	0.21	0.17	0.53	0.19
EOS %	3.00	3.00	2.95	2.00	3.20	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	4.36	0.20	5.32	0.30
RBCo 10^{12}/L	3.04	0.18	4.43	0.20	5.34	0.30
HGB g/dL	7.80	0.30	12.0	0.5	16.7	0.8
HCT %	22.9	1.5	35.2	2.5	47.6	3.0
MCV fL	77.9	4.0	80.6	4.0	89.4	4.0
MCH pg	26.6	2.0	27.5	2.0	31.4	2.0
MCHC g/dL	34.1	2.3	34.2	2.3	35.1	2.3
RDW %	15.9	2.5	16.0	2.5	13.7	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	14.1	2.5
PLT 10^9/L	75.0	20.0	224	50	473	60
PLTi 10^9/L	78.8	20.0	237	50	485	60
MPV fL	9.07	2.00	8.17	2.00	7.31	2.00
RETC 10^9/L	228	50	146	50	94.1	50.0
%R	7.78	1.50	3.34	1.00	1.77	0.80
IRF	0.48	0.18	0.44	0.14	0.38	0.10

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L13059		LOT N13059		LOT H13059	
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	17.0	2.5
NOC 10^9/L	3.3	0.4	7.2	1.0	19.0	2.5
NEU 10^9/L	1.8	0.3	4.4	0.8	11.1	2.0
NEU %	56.4	6.0	60.4	6.0	65.7	10.0
LYM 10^9/L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	28.3	7.0	24.6	6.0	20.0	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.5	0.6
MONO %	9.5	5.0	9.5	4.5	8.9	3.0
EOS 10^9/L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.9	2.0	3.2	1.0
BASO 10^9/L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.2	3.0	3.0	3.0	3.0	3.0
RBC 10^{12}/L	2.89	0.15	4.35	0.20	5.39	0.28
HGB g/dL	7.7	0.4	12.1	0.5	17.4	0.6
HCT %	21.1	1.5	32.8	2.3	44.8	3.5
MCV fL	73.0	4.0	75.6	4.0	83.1	4.0
MCH pg	26.8	2.0	27.9	2.0	32.3	2.0
MCHC g/dL	36.7	2.3	37.0	3.0	38.8	2.3
RDW %	13.7	2.5	13.3	2.5	10.7	2.5
PLT 10^9/L	73	20	239	30	515	60
MPV fL	6.3	2.0	5.9	2.0	5.8	2.0
Retic %***	5.7	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. 2022-01-14	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L13059		LOT N13059		LOT H13059	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	3.3	0.4	7.1	0.7	16.7	2.5
WIC 10^9/L	3.4	0.5	7.3	1.0	19.2	3.0
WBC 10^9/L	3.3	0.4	7.1	0.7	16.7	2.5
NEU 10^9/L	1.9	0.3	4.3	0.8	11.0	2.0
NEU %	56.2	6.0	60.6	6.0	65.6	10.0
LYM 10^9/L	1.0	0.3	1.8	0.8	3.4	2.0
LYM %	29.0	7.0	25.0	6.0	20.3	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	10.2	5.0	9.7	4.5	9.4	3.0
EOS 10^9/L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	3.0	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	2.95	0.15	4.34	0.20	5.34	0.28
HGB g/dL	7.9	0.3	12.2	0.5	17.4	0.6
HCT %	24.5	1.5	37.7	2.3	52.3	3.5
MCV fL	82.9	4.0	86.9	4.0	98.0	4.0
MCH pg	26.7	2.0	28.2	2.0	32.6	2.0
MCHC g/dL	32.2	2.3	32.4	3.0	33.3	2.3
RDW %	19.6	2.5	18.9	2.5	16.8	2.5
PLT 10^9/L	73	20	227	30	469	60
MPV fL	7.0	2.0	6.8	2.0	6.7	2.0
Retic %[1]	5.9	1.5	2.1	1.0	1.0	0.8
IRF [2]	0.62	0.38	0.44	0.30	0.41	0.20

Exp. 2022-01-14	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count[3]	LOT L13059		LOT N13059		LOT H13059	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.4	2.0	2.4	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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