CELL-DYN 29 Plus Control (with Retic)

ABBOTT CELL-DYN SYSTEMS

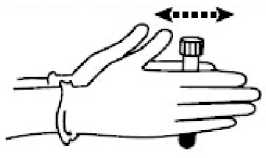
ASSAY SHEET

CONTROL L N H

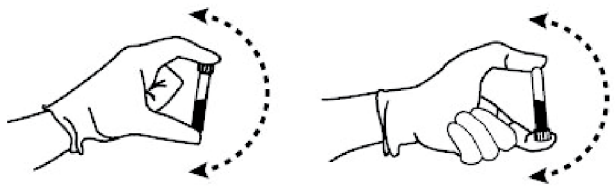
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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 Ruby:
   - Perform stain of CELL-DYN 29 Plus Control (with Retic) as a patient sample as described in the 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. 2026-05-01 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L60479		LOT N60479		LOT H60479	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	3.02	0.40	7.00	0.80	15.5	3.0
NEU 10^9/L	1.69	0.20	4.24	0.40	9.98	1.10
NEU %	56.1	6.0	60.5	5.0	64.4	6.0
LYM 10^9/L	0.89	0.20	1.79	0.50	3.29	1.00
LYM %	29.5	8.0	25.6	6.0	21.2	5.0
MONO 10^9/L	0.34	0.20	0.79	0.40	1.80	0.60
MONO %	11.1	6.0	11.3	5.0	11.6	3.0
EOS 10^9/L	0.10	0.10	0.17	0.17	0.39	0.19
EOS %	3.00	3.00	2.43	2.00	2.54	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	2.90	0.18	4.20	0.20	5.23	0.30
RBCo 10^{12}/L	2.98	0.18	4.23	0.20	5.19	0.30
HGB g/dL	7.94	0.30	11.9	0.5	16.1	0.8
HCT %	22.9	1.5	34.1	2.5	45.9	3.0
MCV fL	78.8	4.0	81.2	4.0	87.8	4.0
MCH pg	27.4	2.0	28.3	2.0	30.8	2.0
MCHC g/dL	34.7	2.3	34.9	2.3	35.1	2.3
RDW %	14.8	2.5	14.8	2.5	15.2	2.5
NRBC 10^9/L*	0.001	0.001	0.001	0.001	2.25	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.5	2.5
PLT 10^9/L	75.4	20.0	218	50	462	60
PLTi 10^9/L	81.8	20.0	237	50	485	60
MPV fL	9.58	2.00	8.42	2.00	8.03	2.00
RETC 10^9/L	235	50	137	50	102	50
%R	8.10	1.50	3.27	1.00	1.95	0.80
IRF	0.58	0.18	0.46	0.14	0.42	0.10

Exp. 2026-05-01 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L60479		LOT N60479		LOT H60479	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	3.1	0.4	7.0	0.7	15.7	2.5
NOC 10^9/L	3.1	0.4	7.2	1.0	18.2	2.5
NEU 10^9/L	1.7	0.3	4.3	0.8	10.2	2.0
NEU %	56.3	6.0	60.8	6.0	64.9	10.0
LYM 10^9/L	0.9	0.3	1.7	0.8	3.2	2.0
LYM %	28.6	7.0	24.2	6.0	20.2	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	8.9	5.0	9.4	4.5	9.9	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	2.6	1.0
BASO 10^9/L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.7	3.0	3.0	3.0	3.0	3.0
RBC 10^{12}/L	2.85	0.15	4.21	0.20	5.27	0.28
HGB g/dL	7.8	0.4	11.9	0.5	16.7	0.6
HCT %	21.5	1.5	32.8	2.3	44.0	3.5
MCV fL	75.4	4.0	77.9	4.0	83.5	4.0
MCH pg	27.4	2.0	28.3	2.0	31.7	2.0
MCHC g/dL	36.3	2.3	36.3	3.0	38.0	2.3
RDW %	12.5	2.5	12.3	2.5	11.7	2.5
PLT 10^9/L	77	20	232	30	510	60
MPV fL	7.1	2.0	6.5	2.0	6.5	2.0
Retic %***	5.2	1.5	1.9	1.0	1.0	0.8

Exp. 2026-05-01 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count[1]	LOT L60479		LOT N60479		LOT H60479	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.4	2.0	1.9	1.5	0.8	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.**

[1] **Manual values were obtained using the Miller Ocular method.**

CE

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