CELL-DYN 29 Plus Control (with Retic)

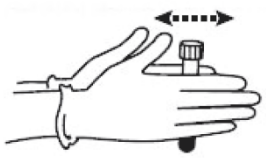
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

CONTROL L N H

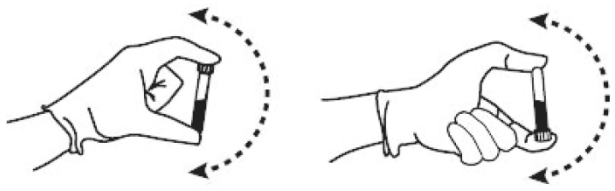
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2022-06-03 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L20809		LOT N20809		LOT H20809	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	3.00	0.40	7.21	0.80	16.5	3.0
NEU 10^9/L	1.75	0.20	4.49	0.40	10.6	1.1
NEU %	58.3	6.0	62.4	5.0	64.5	6.0
LYM 10^9/L	0.92	0.20	1.80	0.50	3.61	1.00
LYM %	30.6	8.0	25.0	6.0	21.9	5.0
MONO 10^9/L	0.24	0.20	0.70	0.40	1.67	0.60
MONO %	7.88	6.00	9.65	5.00	10.1	3.0
EOS 10^9/L	0.10	0.10	0.20	0.17	0.53	0.19
EOS %	3.00	3.00	2.71	2.00	3.23	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	2.89	0.18	4.25	0.20	5.26	0.30
RBCo 10^{12}/L	2.97	0.18	4.28	0.20	5.22	0.30
HGB g/dL	7.81	0.30	11.9	0.5	16.8	0.8
HCT %	22.6	1.5	34.5	2.5	47.5	3.0
MCV fL	78.1	4.0	81.1	4.0	90.4	4.0
MCH pg	27.0	2.0	28.1	2.0	31.9	2.0
MCHC g/dL	34.6	2.3	34.6	2.3	35.3	2.3
RDW %	14.8	2.5	15.7	2.5	14.5	2.5
NRBC 10^9/L*	0.001	0.001	0.001	0.001	2.28	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	13.8	2.5
PLT 10^9/L	71.7	20.0	214	50	455	60
PLTi 10^9/L	76.4	20.0	223	50	466	60
MPV fL	9.10	2.00	8.30	2.00	7.63	2.00
RETC 10^9/L	229	50	137	50	95.1	50.0
%R	7.91	1.50	3.23	1.00	1.81	0.80
IRF	0.54	0.18	0.45	0.14	0.39	0.10

Exp. 2022-06-03 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L20809		LOT N20809		LOT H20809	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	3.0	0.4	7.2	0.7	16.6	2.5
NOC 10^9/L	3.1	0.4	7.2	1.0	18.8	2.5
NEU 10^9/L	1.7	0.3	4.4	0.8	10.7	2.0
NEU %	55.5	6.0	61.4	6.0	64.7	10.0
LYM 10^9/L	0.9	0.3	1.7	0.8	3.4	2.0
LYM %	28.6	7.0	24.0	6.0	20.6	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.5	0.6
MONO %	10.6	5.0	9.4	4.5	9.3	3.0
EOS 10^9/L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.7	2.0	3.3	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	2.87	0.15	4.25	0.20	5.33	0.28
HGB g/dL	7.6	0.4	12.0	0.5	17.2	0.6
HCT %	21.0	1.5	32.4	2.3	44.5	3.5
MCV fL	73.4	4.0	76.2	4.0	83.6	4.0
MCH pg	26.7	2.0	28.1	2.0	32.3	2.0
MCHC g/dL	36.3	2.3	36.9	3.0	38.7	2.3
RDW %	12.7	2.5	13.1	2.5	11.1	2.5
PLT 10^9/L	72	20	225	30	499	60
MPV fL	6.6	2.0	6.0	2.0	5.9	2.0
Retic %***	5.4	1.5	2.1	1.0	1.0	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. 2022-06-03	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L20809		LOT N20809		LOT H20809	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
WIC 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
WBC 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
NEU 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
NEU %	N/A	N/A	N/A	N/A	N/A	N/A
LYM 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
LYM %	N/A	N/A	N/A	N/A	N/A	N/A
MONO 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
MONO %	N/A	N/A	N/A	N/A	N/A	N/A
EOS 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
EOS %	N/A	N/A	N/A	N/A	N/A	N/A
BASO 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
BASO %	N/A	N/A	N/A	N/A	N/A	N/A
RBC 10^{12}/L	N/A	N/A	N/A	N/A	N/A	N/A
HGB g/dL	N/A	N/A	N/A	N/A	N/A	N/A
HCT %	N/A	N/A	N/A	N/A	N/A	N/A
MCV fL	N/A	N/A	N/A	N/A	N/A	N/A
MCH pg	N/A	N/A	N/A	N/A	N/A	N/A
MCHC g/dL	N/A	N/A	N/A	N/A	N/A	N/A
RDW %	N/A	N/A	N/A	N/A	N/A	N/A
PLT 10^9/L	N/A	N/A	N/A	N/A	N/A	N/A
MPV fL	N/A	N/A	N/A	N/A	N/A	N/A
Retic %[1]	N/A	N/A	N/A	N/A	N/A	N/A
IRF [2]	N/A	N/A	N/A	N/A	N/A	N/A

Exp. 2022-06-03	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count[3]	LOT L20809		LOT N20809		LOT H20809	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.5	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.

CE

Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064
USA

EC REP Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

MANUFACTURED FOR
Abbott Laboratories

Abbott

REF 08H58-01, 08H58-02

9231566B 350491-10 August 2018