CELL-DYN 29 Plus Control (with Retic)

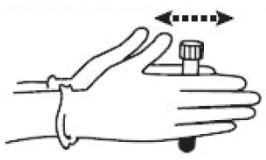
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

CONTROL L N H

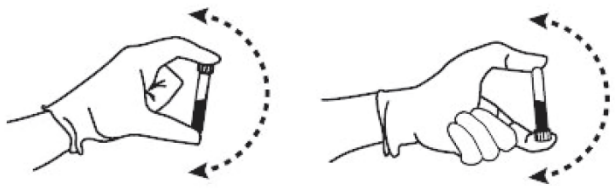
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

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. 2021-09-24 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L11939		LOT N11939		LOT H11939	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	2.94	0.40	6.92	0.80	16.0	3.0
NEU 10^9/L	1.69	0.20	4.25	0.40	10.4	1.1
NEU %	57.6	6.0	61.4	5.0	64.9	6.0
LYM 10^9/L	0.87	0.20	1.77	0.50	3.44	1.00
LYM %	29.7	8.0	25.6	6.0	21.4	5.0
MONO 10^9/L	0.29	0.20	0.70	0.40	1.70	0.60
MONO %	9.83	6.00	10.1	5.0	10.6	3.0
EOS 10^9/L	0.10	0.10	0.18	0.17	0.46	0.19
EOS %	3.00	3.00	2.55	2.00	2.85	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	2.92	0.18	4.20	0.20	5.19	0.30
RBCo 10^{12}/L	3.00	0.18	4.25	0.20	5.21	0.30
HGB g/dL	7.59	0.30	11.7	0.5	16.3	0.8
HCT %	22.4	1.5	33.9	2.5	45.4	3.0
MCV fL	77.0	4.0	80.7	4.0	87.4	4.0
MCH pg	26.0	2.0	27.9	2.0	31.3	2.0
MCHC g/dL	33.8	2.3	34.6	2.3	35.8	2.3
RDW %	15.6	2.5	15.2	2.5	13.4	2.5
NRBC 10^9/L*	0.001	0.001	0.001	0.001	2.27	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.1	2.5
PLT 10^9/L	71.3	20.0	215	50	459	60
PLTi 10^9/L	74.7	20.0	225	50	471	60
MPV fL	9.76	2.00	8.17	2.00	7.59	2.00
RETC 10^9/L	234	50	139	50	91.2	50.0
%R	8.02	1.50	3.30	1.00	1.76	0.80
IRF	0.62	0.18	0.54	0.14	0.39	0.10

Exp. 2021-09-24 — 7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L11939		LOT N11939		LOT H11939	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	2.9	0.4	7.0	0.7	15.9	2.5
NOC 10^9/L	3.0	0.4	7.1	1.0	18.3	2.5
NEU 10^9/L	1.6	0.3	4.3	0.8	10.3	2.0
NEU %	57.1	6.0	61.6	6.0	64.7	10.0
LYM 10^9/L	0.8	0.3	1.7	0.8	3.3	2.0
LYM %	28.2	7.0	24.9	6.0	20.9	10.0
MONO 10^9/L	0.3	0.2	0.6	0.4	1.6	0.6
MONO %	9.9	5.0	8.8	4.5	9.7	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	2.87	0.15	4.23	0.20	5.29	0.28
HGB g/dL	7.5	0.4	11.7	0.5	16.8	0.6
HCT %	20.8	1.5	32.0	2.3	43.1	3.5
MCV fL	72.5	4.0	75.7	4.0	81.5	4.0
MCH pg	25.9	2.0	27.7	2.0	31.7	2.0
MCHC g/dL	35.8	2.3	36.6	3.0	38.9	2.3
RDW %	13.6	2.5	12.7	2.5	10.3	2.5
PLT 10^9/L	70	20	227	30	506	60
MPV fL	6.7	2.0	6.3	2.0	6.3	2.0
Retic %***	5.7	1.5	2.3	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. 2021-09-24	7 Consecutive Day Open-Vial Stability

SYSTEM CELL-DYN 3700	CONTROL L		CONTROL N		CONTROL H	
	LOT L11939		LOT N11939		LOT H11939	
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	15.8	2.5
WIC 10^9/L	3.2	0.5	7.2	1.0	18.5	3.0
WBC 10^9/L	3.0	0.4	7.0	0.7	15.8	2.5
NEU 10^9/L	1.7	0.3	4.3	0.8	10.3	2.0
NEU %	57.7	6.0	61.3	6.0	65.3	10.0
LYM 10^9/L	0.9	0.3	1.7	0.8	3.2	2.0
LYM %	28.4	7.0	24.9	6.0	20.3	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	10.1	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	2.8	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	2.96	0.15	4.27	0.20	5.35	0.28
HGB g/dL	7.6	0.3	11.8	0.5	16.8	0.6
HCT %	24.2	1.5	37.4	2.3	51.4	3.5
MCV fL	81.9	4.0	87.6	4.0	96.0	4.0
MCH pg	25.7	2.0	27.7	2.0	31.4	2.0
MCHC g/dL	31.4	2.3	31.6	3.0	32.7	2.3
RDW %	19.2	2.5	18.4	2.5	16.5	2.5
PLT 10^9/L	67	20	213	30	462	60
MPV fL	7.3	2.0	7.1	2.0	7.0	2.0
Retic %[1]	5.8	1.5	2.1	1.0	1.0	0.8
IRF [2]	0.62	0.38	0.44	0.30	0.38	0.20

Exp. 2021-09-24	7 Consecutive Day Open-Vial Stability

SYSTEM Manual Count[3]	CONTROL L		CONTROL N		CONTROL H	
	LOT L11939		LOT N11939		LOT H11939	
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