

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. 2021-08-27

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L11659	LOT	N11659	LOT	H11659
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.98	0.40	7.03	0.80	16.0	3.0
NEU 10 ⁹ /L	1.70	0.20	4.28	0.40	10.2	1.1
NEU %	56.9	6.0	60.8	5.0	63.6	6.0
LYM 10 ⁹ /L	0.90	0.20	1.80	0.50	3.52	1.00
LYM %	30.0	8.0	25.6	6.0	22.0	5.0
MONO 10 ⁹ /L	0.30	0.20	0.76	0.40	1.79	0.60
MONO %	10.1	6.0	10.8	5.0	11.2	3.0
EOS 10 ⁹ /L	0.10	0.10	0.17	0.17	0.48	0.19
EOS %	3.00	3.00	2.48	2.00	2.99	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	4.24	0.20	5.25	0.30
RBC _o 10 ¹² /L	3.00	0.18	4.30	0.20	5.26	0.30
HGB g/dL	7.79	0.30	11.7	0.5	16.3	0.8
HCT %	22.8	1.5	33.7	2.5	46.3	3.0
MCV fL	78.5	4.0	79.4	4.0	88.2	4.0
MCH pg	26.8	2.0	27.5	2.0	31.1	2.0
MCHC g/dL	34.2	2.3	34.7	2.3	35.3	2.3
RDW %	14.7	2.5	15.3	2.5	15.0	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.12	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	13.2	2.5
PLT 10 ⁹ /L	69.6	20.0	215	50	454	60
PLTi 10 ⁹ /L	73.1	20.0	224	50	465	60
MPV fL	8.74	2.00	7.78	2.00	7.25	2.00
RETC 10 ⁹ /L	217	50	137	50	97.0	50.0
%R	7.48	1.50	3.23	1.00	1.85	0.80
IRF	0.63	0.18	0.54	0.14	0.39	0.10

Exp. 2021-08-27

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
	LOT	L11659	LOT	N11659	LOT	H11659
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	7.1	0.7	16.3	2.5
NOC 10 ⁹ /L	3.0	0.4	7.2	1.0	18.5	2.5
NEU 10 ⁹ /L	1.7	0.3	4.3	0.8	10.4	2.0
NEU %	56.6	6.0	60.6	6.0	64.1	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.4	2.0
LYM %	28.9	7.0	25.0	6.0	21.0	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.1	5.0	9.5	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	3.0	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	2.89	0.15	4.28	0.20	5.35	0.28
HGB g/dL	7.6	0.4	11.7	0.5	16.8	0.6
HCT %	21.4	1.5	32.1	2.3	44.1	3.5
MCV fL	73.9	4.0	74.9	4.0	82.4	4.0
MCH pg	26.3	2.0	27.4	2.0	31.4	2.0
MCHC g/dL	35.6	2.3	36.5	3.0	38.1	2.3
RDW %	12.9	2.5	12.9	2.5	11.7	2.5
PLT 10 ⁹ /L	69	20	231	30	501	60
MPV fL	6.8	2.0	6.3	2.0	6.2	2.0
Retic %***	6.2	1.5	2.4	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. 2021-08-27	7 Consecutive Day Open-Vial Stability
-----------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L11659		LOT N11659		LOT H11659	
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	16.0	2.5
WIC 10 ⁹ /L	3.2	0.5	7.3	1.0	18.7	3.0
WBC 10 ⁹ /L	3.0	0.4	7.0	0.7	16.0	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.3	2.0
NEU %	56.6	6.0	60.4	6.0	64.4	10.0
LYM 10 ⁹ /L	0.9	0.3	1.8	0.8	3.3	2.0
LYM %	29.6	7.0	25.3	6.0	20.9	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	9.7	5.0	10.1	4.5	10.4	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	3.0	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	4.32	0.20	5.38	0.28
HGB g/dL	7.7	0.3	11.7	0.5	16.8	0.6
HCT %	24.6	1.5	37.0	2.3	51.7	3.5
MCV fL	83.1	4.0	85.7	4.0	96.0	4.0
MCH pg	26.0	2.0	27.2	2.0	31.1	2.0
MCHC g/dL	31.3	2.3	31.7	3.0	32.4	2.3
RDW %	18.0	2.5	18.6	2.5	18.1	2.5
PLT 10 ⁹ /L	65	20	212	30	441	60
MPV fL	6.9	2.0	6.7	2.0	6.6	2.0
Retic % ¹	6.0	1.5	2.3	1.0	1.1	0.8
IRF ²	0.62	0.38	0.46	0.30	0.38	0.20

Exp. 2021-08-27	7 Consecutive Day Open-Vial Stability
-----------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L11659		LOT N11659		LOT H11659	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.7	2.0	2.7	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.



CELL-DYN, CELL-DYN Sapphire and CELL-DYN Ruby are trademarks of Abbott Laboratories in various jurisdictions.

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



REF 08H58-01, 08H58-02

9231566B 350491-10 August 2018
©2017, 2018 Abbott Laboratories