

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.



2021-06-04

7 Consecutive Day Open-Vial Stability



2021-06-04

7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L10819		LOT N10819		LOT H10819	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.87	0.40	6.85	0.80	15.7	3.0
NEU 10 ⁹ /L	1.69	0.20	4.23	0.40	10.1	1.1
NEU %	58.8	6.0	61.8	5.0	64.7	6.0
LYM 10 ⁹ /L	0.82	0.20	1.71	0.50	3.27	1.00
LYM %	28.5	8.0	25.0	6.0	20.8	5.0
MONO 10 ⁹ /L	0.28	0.20	0.72	0.40	1.76	0.60
MONO %	9.84	6.00	10.5	5.0	11.2	3.0
EOS 10 ⁹ /L	0.10	0.10	0.17	0.17	0.49	0.19
EOS %	3.00	3.00	2.55	2.00	3.15	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
RBC _o 10 ¹² /L	2.98	0.18	4.37	0.20	5.26	0.30
HGB g/dL	7.64	0.30	11.9	0.5	16.4	0.8
HCT %	22.6	1.5	34.5	2.5	46.1	3.0
MCV fL	77.2	4.0	79.1	4.0	86.8	4.0
MCH pg	26.1	2.0	27.3	2.0	30.8	2.0
MCHC g/dL	33.8	2.3	34.5	2.3	35.5	2.3
RDW %	16.7	2.5	15.3	2.5	14.2	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.24	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.3	2.5
PLT 10 ⁹ /L	75.8	20.0	213	50	457	60
PLTi 10 ⁹ /L	76.8	20.0	224	50	473	60
MPV fL	9.39	2.00	7.76	2.00	7.28	2.00
RETC 10 ⁹ /L	234	50	148	50	94.1	50.0
%R	7.98	1.50	3.40	1.00	1.77	0.80
IRF	0.57	0.18	0.49	0.14	0.37	0.10

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L10819		LOT N10819		LOT H10819	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	2.9	0.4	6.9	0.7	15.7	2.5
NOC 10 ⁹ /L	2.9	0.4	6.9	1.0	18.0	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.2	2.0
NEU %	57.9	6.0	61.4	6.0	64.6	10.0
LYM 10 ⁹ /L	0.8	0.3	1.6	0.8	3.1	2.0
LYM %	27.1	7.0	23.9	6.0	19.8	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	9.8	5.0	9.7	4.5	10.2	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	3.1	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	2.85	0.15	4.33	0.20	5.40	0.28
HGB g/dL	7.5	0.4	12.0	0.5	16.8	0.6
HCT %	20.7	1.5	32.5	2.3	44.1	3.5
MCV fL	72.8	4.0	75.0	4.0	81.7	4.0
MCH pg	26.3	2.0	27.6	2.0	31.2	2.0
MCHC g/dL	36.1	2.3	36.8	3.0	38.2	2.3
RDW %	14.3	2.5	12.8	2.5	11.1	2.5
PLT 10 ⁹ /L	78	20	223	30	506	60
MPV fL	6.4	2.0	6.0	2.0	6.0	2.0
Retic %***	7.1	1.5	3.2	1.0	1.5	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. 2021-06-04	7 Consecutive Day Open-Vial Stability
-----------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L10819		LOT N10819		LOT H10819	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	6.9	0.7	15.6	2.5
WIC 10 ⁹ /L	3.2	0.5	7.4	1.0	19.0	3.0
WBC 10 ⁹ /L	3.0	0.4	6.9	0.7	15.6	2.5
NEU 10 ⁹ /L	1.7	0.3	4.2	0.8	10.1	2.0
NEU %	58.4	6.0	61.2	6.0	64.7	10.0
LYM 10 ⁹ /L	0.8	0.3	1.7	0.8	3.1	2.0
LYM %	27.6	7.0	24.3	6.0	19.7	10.0
MONO 10 ⁹ /L	0.3	0.2	0.7	0.4	1.7	0.6
MONO %	9.9	5.0	10.2	4.5	10.9	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.6	2.0	3.1	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	2.94	0.15	4.34	0.20	5.37	0.28
HGB g/dL	7.6	0.3	12.0	0.5	16.9	0.6
HCT %	24.3	1.5	37.4	2.3	51.5	3.5
MCV fL	82.9	4.0	86.2	4.0	95.9	4.0
MCH pg	26.0	2.0	27.7	2.0	31.5	2.0
MCHC g/dL	31.3	2.3	32.1	3.0	32.8	2.3
RDW %	20.2	2.5	18.7	2.5	17.3	2.5
PLT 10 ⁹ /L	70	20	211	30	448	60
MPV fL	6.9	2.0	6.8	2.0	6.8	2.0
Retic % ¹	6.9	1.5	3.0	1.0	1.4	0.8
IRF ²	0.62	0.38	0.60	0.30	0.45	0.20

Exp. 2021-06-04	7 Consecutive Day Open-Vial Stability
-----------------	---------------------------------------

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L10819		LOT N10819		LOT H10819	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.6	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.



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