CELL-DYN 29 Plus Control (with Retic)

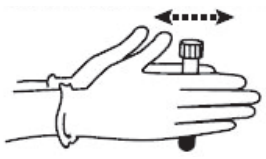
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

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. 2021-02-12	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L03359		LOT N03359		LOT H03359	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	2.96	0.40	6.98	0.80	15.6	3.0
NEU 10^9/L	1.73	0.20	4.29	0.40	10.0	1.1
NEU %	58.5	6.0	61.5	5.0	64.3	6.0
LYM 10^9/L	0.83	0.20	1.74	0.50	3.35	1.00
LYM %	27.9	8.0	24.9	6.0	21.5	5.0
MONO 10^9/L	0.32	0.20	0.73	0.40	1.70	0.60
MONO %	10.9	6.0	10.5	5.0	10.9	3.0
EOS 10^9/L	0.10	0.10	0.20	0.17	0.48	0.19
EOS %	3.00	3.00	2.82	2.00	3.09	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	2.74	0.18	4.19	0.20	5.19	0.30
RBCo 10^{12}/L	2.83	0.18	4.23	0.20	5.18	0.30
HGB g/dL	7.34	0.30	11.5	0.5	16.5	0.8
HCT %	21.1	1.5	33.1	2.5	46.2	3.0
MCV fL	77.0	4.0	78.9	4.0	89.0	4.0
MCH pg	26.8	2.0	27.4	2.0	31.8	2.0
MCHC g/dL	34.8	2.3	34.7	2.3	35.7	2.3
RDW %	15.2	2.5	15.1	2.5	14.0	2.5
NRBC 10^9/L*	0.001	0.001	0.001	0.001	2.34	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	15.0	2.5
PLT 10^9/L	70.7	20.0	213	50	445	60
PLTi 10^9/L	79.6	20.0	234	50	476	60
MPV fL	8.91	2.00	7.96	2.00	7.39	2.00
RETC 10^9/L	225	50	141	50	99.1	50.0
%R	8.21	1.50	3.36	1.00	1.91	0.80
IRF	0.59	0.18	0.50	0.14	0.39	0.10

Exp. 2021-02-12	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L03359		LOT N03359		LOT H03359	
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	15.6	2.5
NOC 10^9/L	3.1	0.4	7.1	1.0	18.0	2.5
NEU 10^9/L	1.7	0.3	4.3	0.8	10.1	2.0
NEU %	58.2	6.0	61.7	6.0	64.6	10.0
LYM 10^9/L	0.8	0.3	1.7	0.8	3.2	2.0
LYM %	26.9	7.0	23.8	6.0	20.6	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.5	0.6
MONO %	9.8	5.0	9.3	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	2.9	2.0	3.2	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	2.74	0.15	4.22	0.20	5.30	0.28
HGB g/dL	7.2	0.4	11.5	0.5	16.9	0.6
HCT %	19.7	1.5	31.2	2.3	43.6	3.5
MCV fL	71.9	4.0	73.9	4.0	82.2	4.0
MCH pg	26.3	2.0	27.3	2.0	31.9	2.0
MCHC g/dL	36.5	2.3	36.9	3.0	38.8	2.3
RDW %	13.1	2.5	12.6	2.5	10.7	2.5
PLT 10^9 /L	73	20	229	30	508	60
MPV fL	6.4	2.0	6.1	2.0	6.1	2.0
Retic %***	7.6	1.5	3.1	1.0	1.6	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. 2021-02-12	7 Consecutive Day Open-Vial Stability

SYSTEM CELL-DYN 3700	**CONTROL** L		**CONTROL** N		**CONTROL** H	
	LOT L03359		**LOT** N03359		**LOT** H03359	
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	15.8	2.5
WIC 10^9/L	3.3	0.5	7.5	1.0	19.0	3.0
WBC 10^9/L	3.1	0.4	7.0	0.7	15.8	2.5
NEU 10^9/L	1.8	0.3	4.3	0.8	10.2	2.0
NEU %	58.1	6.0	61.6	6.0	64.6	10.0
LYM 10^9/L	0.9	0.3	1.7	0.8	3.3	2.0
LYM %	27.5	7.0	24.1	6.0	20.6	10.0
MONO 10^9/L	0.3	0.2	0.7	0.4	1.6	0.6
MONO %	10.2	5.0	9.8	4.5	10.1	3.0
EOS 10^9/L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.8	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	2.79	0.15	4.20	0.20	5.23	0.28
HGB g/dL	7.3	0.3	11.6	0.5	17.1	0.6
HCT %	23.0	1.5	36.0	2.3	51.3	3.5
MCV fL	82.3	4.0	85.8	4.0	98.0	4.0
MCH pg	26.2	2.0	27.6	2.0	32.7	2.0
MCHC g/dL	31.7	2.3	32.2	3.0	33.3	2.3
RDW %	19.1	2.5	19.1	2.5	17.2	2.5
PLT 10^9/L	73	20	221	30	447	60
MPV fL	6.8	2.0	6.7	2.0	6.7	2.0
Retic %[1]	7.9	1.5	3.5	1.0	1.5	0.8
IRF [2]	0.62	0.38	0.62	0.30	0.44	0.20

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SYSTEM Manual Count[3]	**CONTROL** L		**CONTROL** N		**CONTROL** H	
	LOT L03359		**LOT** N03359		**LOT** H03359	
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

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