CELL-DYN 29 Plus Control (with Retic)

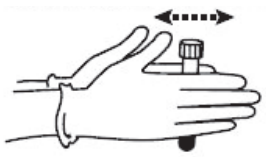
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

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. 2020-11-20	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L02519		LOT N02519		LOT H02519	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10^9/L	3.07	0.40	7.08	0.80	16.1	3.0
NEU 10^9/L	1.71	0.20	4.23	0.40	10.5	1.1
NEU %	55.7	6.0	59.7	5.0	64.9	6.0
LYM 10^9/L	0.98	0.20	1.82	0.50	3.32	1.00
LYM %	31.8	8.0	25.7	6.0	20.6	5.0
MONO 10^9/L	0.30	0.20	0.82	0.40	1.84	0.60
MONO %	9.74	6.00	11.6	5.0	11.4	3.0
EOS 10^9/L	0.10	0.10	0.20	0.17	0.46	0.19
EOS %	3.00	3.00	2.79	2.00	2.88	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	2.73	0.18	4.07	0.20	5.07	0.30
RBCo 10^{12}/L	2.80	0.18	4.10	0.20	5.02	0.30
HGB g/dL	7.18	0.30	11.5	0.5	16.0	0.8
HCT %	21.2	1.5	33.0	2.5	45.9	3.0
MCV fL	77.6	4.0	81.0	4.0	90.6	4.0
MCH pg	26.3	2.0	28.3	2.0	31.6	2.0
MCHC g/dL	33.9	2.3	34.8	2.3	34.9	2.3
RDW %	16.2	2.5	15.4	2.5	14.4	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	71.7	20.0	200	50	442	60
PLTi 10^9/L	78.6	20.0	219	50	465	60
MPV fL	9.26	2.00	7.64	2.00	7.04	2.00
RETC 10^9/L	224	50	141	50	100	50
%R	8.22	1.50	3.46	1.00	1.98	0.80
IRF	0.53	0.18	0.46	0.14	0.41	0.10

Exp. 2020-11-20	7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L02519		LOT N02519		LOT H02519	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10^9/L	3.1	0.4	7.1	0.7	16.1	2.5
NOC 10^9/L	3.1	0.4	7.1	1.0	18.4	2.5
NEU 10^9/L	1.7	0.3	4.2	0.8	10.5	2.0
NEU %	55.0	6.0	59.6	6.0	65.2	10.0
LYM 10^9/L	0.9	0.3	1.7	0.8	3.1	2.0
LYM %	29.6	7.0	24.5	6.0	19.5	10.0
MONO 10^9/L	0.3	0.2	0.8	0.4	1.7	0.6
MONO %	10.1	5.0	11.0	4.5	10.3	3.0
EOS 10^9/L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	2.9	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	2.70	0.15	4.11	0.20	5.16	0.28
HGB g/dL	7.1	0.4	11.4	0.5	16.5	0.6
HCT %	19.8	1.5	31.5	2.3	43.7	3.5
MCV fL	73.4	4.0	76.7	4.0	84.7	4.0
MCH pg	26.3	2.0	27.7	2.0	32.0	2.0
MCHC g/dL	35.9	2.3	36.2	3.0	37.8	2.3
RDW %	14.1	2.5	12.9	2.5	11.1	2.5
PLT 10^9 /L	73	20	211	30	489	60
MPV fL	6.6	2.0	6.3	2.0	6.1	2.0
Retic %***	6.9	1.5	2.8	1.0	1.4	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. 2020-11-20	7 Consecutive Day Open-Vial Stability

SYSTEM CELL-DYN 3700	**CONTROL L** **LOT** L02519		**CONTROL N** **LOT** N02519		**CONTROL H** **LOT** H02519	
PARAMETER	**ASSAY VALUE**	± **MEAN RANGE** **	**ASSAY VALUE**	± **MEAN RANGE** **	**ASSAY VALUE**	± **MEAN RANGE** **
WOC 10^9/L	3.2	0.4	7.1	0.7	16.0	2.5
WIC 10^9/L	3.2	0.5	7.3	1.0	19.0	3.0
WBC 10^9/L	3.2	0.4	7.1	0.7	16.0	2.5
NEU 10^9/L	1.8	0.3	4.2	0.8	10.5	2.0
NEU %	55.0	6.0	59.6	6.0	65.5	10.0
LYM 10^9/L	1.0	0.3	1.8	0.8	3.1	2.0
LYM %	30.0	7.0	24.8	6.0	19.2	10.0
MONO 10^9/L	0.3	0.2	0.8	0.4	1.7	0.6
MONO %	10.7	5.0	11.3	4.5	10.7	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	3.0	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	2.78	0.15	4.13	0.20	5.12	0.28
HGB g/dL	7.2	0.3	11.5	0.5	16.7	0.6
HCT %	22.9	1.5	36.2	2.3	50.7	3.5
MCV fL	82.4	4.0	87.6	4.0	99.0	4.0
MCH pg	25.9	2.0	27.8	2.0	32.6	2.0
MCHC g/dL	31.4	2.3	31.8	3.0	32.9	2.3
RDW %	19.5	2.5	19.4	2.5	17.5	2.5
PLT 10^9/L	75	20	210	30	446	60
MPV fL	6.6	2.0	6.4	2.0	6.5	2.0
Retic %[1]	6.9	1.5	2.7	1.0	1.3	0.8
IRF [2]	0.62	0.38	0.61	0.30	0.39	0.20

Exp. 2020-11-20	7 Consecutive Day Open-Vial Stability

SYSTEM Manual Count[3]	**CONTROL L** **LOT** L02519		**CONTROL N** **LOT** N02519		**CONTROL H** **LOT** H02519	
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.

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