# CELL-DYN 29 Plus Control (with Retic)

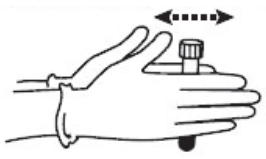
ABBOTT
CELL-DYN SYSTEMS
ASSAY SHEET

**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. 2021-04-09 | 7 Consecutive Day Open-Vial Stability |
|---|---|

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|---|---|---|---|---|---|---|
| CELL-DYN Sapphire | LOT L10259 | | LOT N10259 | | LOT H10259 | |
| PARAMETER | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** |
| WBC $10^9$/L | 3.06 | 0.40 | 6.94 | 0.80 | 16.1 | 3.0 |
| NEU $10^9$/L | 1.81 | 0.20 | 4.25 | 0.40 | 10.4 | 1.1 |
| NEU % | 59.3 | 6.0 | 61.2 | 5.0 | 64.4 | 6.0 |
| LYM $10^9$/L | 0.88 | 0.20 | 1.76 | 0.50 | 3.48 | 1.00 |
| LYM % | 28.7 | 8.0 | 25.3 | 6.0 | 21.6 | 5.0 |
| MONO $10^9$/L | 0.28 | 0.20 | 0.69 | 0.40 | 1.75 | 0.60 |
| MONO % | 9.28 | 6.00 | 9.96 | 5.00 | 10.9 | 3.0 |
| EOS $10^9$/L | 0.10 | 0.10 | 0.22 | 0.17 | 0.47 | 0.19 |
| EOS % | 3.00 | 3.00 | 3.21 | 2.00 | 2.93 | 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 | 2.77 | 0.18 | 4.20 | 0.20 | 5.20 | 0.30 |
| RBCo $10^{12}$/L | 2.88 | 0.18 | 4.27 | 0.20 | 5.20 | 0.30 |
| HGB g/dL | 7.60 | 0.30 | 11.9 | 0.5 | 16.8 | 0.8 |
| HCT % | 21.8 | 1.5 | 34.0 | 2.5 | 47.3 | 3.0 |
| MCV fL | 78.7 | 4.0 | 81.0 | 4.0 | 91.0 | 4.0 |
| MCH pg | 27.4 | 2.0 | 28.3 | 2.0 | 32.3 | 2.0 |
| MCHC g/dL | 34.9 | 2.3 | 35.0 | 2.3 | 35.5 | 2.3 |
| RDW % | 15.2 | 2.5 | 15.6 | 2.5 | 14.1 | 2.5 |
| NRBC $10^9$/L* | 0.001 | 0.001 | 0.001 | 0.001 | 2.03 | 0.60 |
| NRBC/100WBC* | 0.001 | 0.001 | 0.001 | 0.001 | 12.6 | 2.5 |
| PLT $10^9$/L | 70.3 | 20.0 | 206 | 50 | 452 | 60 |
| PLTi $10^9$/L | 76.1 | 20.0 | 222 | 50 | 471 | 60 |
| MPV fL | 9.02 | 2.00 | 7.99 | 2.00 | 7.39 | 2.00 |
| RETC $10^9$/L | 224 | 50 | 142 | 50 | 98.8 | 50.0 |
| %R | 8.09 | 1.50 | 3.39 | 1.00 | 1.90 | 0.80 |
| IRF | 0.56 | 0.18 | 0.47 | 0.14 | 0.40 | 0.10 |

| Exp. 2021-04-09 | 7 Consecutive Day Open-Vial Stability |
|---|---|

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|---|---|---|---|---|---|---|
| CELL-DYN Ruby | LOT L10259 | | LOT N10259 | | LOT H10259 | |
| 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 | 16.3 | 2.5 |
| NOC $10^9$/L | 3.1 | 0.4 | 7.2 | 1.0 | 18.3 | 2.5 |
| NEU $10^9$/L | 1.7 | 0.3 | 4.3 | 0.8 | 10.4 | 2.0 |
| NEU % | 57.7 | 6.0 | 61.2 | 6.0 | 64.1 | 10.0 |
| LYM $10^9$/L | 0.8 | 0.3 | 1.7 | 0.8 | 3.3 | 2.0 |
| LYM % | 27.3 | 7.0 | 24.5 | 6.0 | 20.5 | 10.0 |
| MONO $10^9$/L | 0.3 | 0.2 | 0.6 | 0.4 | 1.7 | 0.6 |
| MONO % | 10.1 | 5.0 | 8.9 | 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 | 3.0 | 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 | 2.82 | 0.15 | 4.30 | 0.20 | 5.40 | 0.28 |
| HGB g/dL | 7.4 | 0.4 | 11.8 | 0.5 | 17.2 | 0.6 |
| HCT % | 20.9 | 1.5 | 32.8 | 2.3 | 45.6 | 3.5 |
| MCV fL | 74.1 | 4.0 | 76.2 | 4.0 | 84.4 | 4.0 |
| MCH pg | 26.2 | 2.0 | 27.4 | 2.0 | 31.9 | 2.0 |
| MCHC g/dL | 35.4 | 2.3 | 36.0 | 3.0 | 37.7 | 2.3 |
| RDW % | 13.1 | 2.5 | 12.9 | 2.5 | 10.8 | 2.5 |
| PLT $10^9$ /L | 71 | 20 | 214 | 30 | 502 | 60 |
| MPV fL | 6.5 | 2.0 | 6.0 | 2.0 | 6.1 | 2.0 |
| Retic %*** | 7.1 | 1.5 | 2.9 | 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. 2021-04-09 | 7 Consecutive Day Open-Vial Stability |
|---|---|

| **SYSTEM** CELL-DYN 3700 | **CONTROL** L | | **CONTROL** N | | **CONTROL** H | |
|---|---|---|---|---|---|---|
| | **LOT** L10259 | | **LOT** N10259 | | **LOT** H10259 | |
| **PARAMETER** | **ASSAY VALUE** | ± **MEAN RANGE** ** | **ASSAY VALUE** | ± **MEAN RANGE** ** | **ASSAY VALUE** | ± **MEAN RANGE** ** |
| WOC $10^9$/L | 3.2 | 0.4 | 7.0 | 0.7 | 16.2 | 2.5 |
| WIC $10^9$/L | 3.2 | 0.5 | 7.3 | 1.0 | 18.8 | 3.0 |
| WBC $10^9$/L | 3.2 | 0.4 | 7.0 | 0.7 | 16.2 | 2.5 |
| NEU $10^9$/L | 1.8 | 0.3 | 4.3 | 0.8 | 10.4 | 2.0 |
| NEU % | 57.8 | 6.0 | 61.3 | 6.0 | 64.2 | 10.0 |
| LYM $10^9$/L | 0.9 | 0.3 | 1.7 | 0.8 | 3.4 | 2.0 |
| LYM % | 28.3 | 7.0 | 24.8 | 6.0 | 20.7 | 10.0 |
| MONO $10^9$/L | 0.3 | 0.2 | 0.7 | 0.4 | 1.7 | 0.6 |
| MONO % | 10.2 | 5.0 | 9.3 | 4.5 | 10.5 | 3.0 |
| EOS $10^9$/L | 0.1 | 0.1 | 0.2 | 0.2 | 0.5 | 0.2 |
| EOS % | 3.0 | 3.0 | 3.0 | 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 | 2.86 | 0.15 | 4.27 | 0.20 | 5.29 | 0.28 |
| HGB g/dL | 7.6 | 0.3 | 12.0 | 0.5 | 17.4 | 0.6 |
| HCT % | 23.9 | 1.5 | 37.2 | 2.3 | 52.4 | 3.5 |
| MCV fL | 83.4 | 4.0 | 87.1 | 4.0 | 99.0 | 4.0 |
| MCH pg | 26.6 | 2.0 | 28.1 | 2.0 | 32.9 | 2.0 |
| MCHC g/dL | 31.8 | 2.3 | 32.3 | 3.0 | 33.2 | 2.3 |
| RDW % | 19.0 | 2.5 | 19.2 | 2.5 | 17.0 | 2.5 |
| PLT $10^9$/L | 70 | 20 | 210 | 30 | 457 | 60 |
| MPV fL | 6.9 | 2.0 | 6.8 | 2.0 | 6.8 | 2.0 |
| Retic %[1] | 6.9 | 1.5 | 2.7 | 1.0 | 1.4 | 0.8 |
| IRF [2] | 0.62 | 0.38 | 0.58 | 0.30 | 0.43 | 0.20 |

| Exp. 2021-04-09 | 7 Consecutive Day Open-Vial Stability |
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| **SYSTEM** Manual Count[3] | **CONTROL** L | | **CONTROL** N | | **CONTROL** H | |
|---|---|---|---|---|---|---|
| | **LOT** L10259 | | **LOT** N10259 | | **LOT** H10259 | |
| **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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