

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. 2022-05-06

7 Consecutive Day Open-Vial Stability

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|--------------------------------------|-------------|-----------------|-------------|-----------------|-------------|-----------------|
| | LOT | L20529 | LOT | N20529 | LOT | H20529 |
| PARAMETER | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** |
| WBC 10 ⁹ /L | 3.19 | 0.40 | 7.16 | 0.80 | 16.3 | 3.0 |
| NEU 10 ⁹ /L | 1.85 | 0.20 | 4.38 | 0.40 | 10.5 | 1.1 |
| NEU % | 57.9 | 6.0 | 61.1 | 5.0 | 64.7 | 6.0 |
| LYM 10 ⁹ /L | 0.94 | 0.20 | 1.84 | 0.50 | 3.45 | 1.00 |
| LYM % | 29.4 | 8.0 | 25.7 | 6.0 | 21.2 | 5.0 |
| MONO 10 ⁹ /L | 0.30 | 0.20 | 0.74 | 0.40 | 1.80 | 0.60 |
| MONO % | 9.41 | 6.00 | 10.3 | 5.0 | 11.0 | 3.0 |
| EOS 10 ⁹ /L | 0.10 | 0.10 | 0.18 | 0.17 | 0.45 | 0.19 |
| EOS % | 3.00 | 3.00 | 2.58 | 2.00 | 2.76 | 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 | 3.02 | 0.18 | 4.24 | 0.20 | 5.29 | 0.30 |
| RBC _o 10 ¹² /L | 3.10 | 0.18 | 4.30 | 0.20 | 5.26 | 0.30 |
| HGB g/dL | 7.91 | 0.30 | 11.9 | 0.5 | 16.8 | 0.8 |
| HCT % | 23.4 | 1.5 | 34.6 | 2.5 | 47.4 | 3.0 |
| MCV fL | 77.6 | 4.0 | 81.5 | 4.0 | 89.6 | 4.0 |
| MCH pg | 26.2 | 2.0 | 28.0 | 2.0 | 31.9 | 2.0 |
| MCHC g/dL | 33.8 | 2.3 | 34.4 | 2.3 | 35.6 | 2.3 |
| RDW % | 15.7 | 2.5 | 15.7 | 2.5 | 14.0 | 2.5 |
| NRBC 10 ⁹ /L* | 0.001 | 0.001 | 0.001 | 0.001 | 2.22 | 0.60 |
| NRBC/100WBC* | 0.001 | 0.001 | 0.001 | 0.001 | 13.6 | 2.5 |
| PLT 10 ⁹ /L | 72.8 | 20.0 | 213 | 50 | 464 | 60 |
| PLTi 10 ⁹ /L | 76.0 | 20.0 | 227 | 50 | 480 | 60 |
| MPV fL | 9.87 | 2.00 | 8.22 | 2.00 | 7.77 | 2.00 |
| RETC 10 ⁹ /L | 245 | 50 | 148 | 50 | 95.8 | 50.0 |
| %R | 8.11 | 1.50 | 3.50 | 1.00 | 1.81 | 0.80 |
| IRF | 0.54 | 0.18 | 0.48 | 0.14 | 0.39 | 0.10 |

Exp. 2022-05-06

7 Consecutive Day Open-Vial Stability

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|-------------------------|-------------|-----------------|-------------|-----------------|-------------|-----------------|
| | LOT | L20529 | LOT | N20529 | LOT | H20529 |
| PARAMETER | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** |
| WOC 10 ⁹ /L | 3.2 | 0.4 | 7.2 | 0.7 | 16.5 | 2.5 |
| NOC 10 ⁹ /L | 3.3 | 0.4 | 7.3 | 1.0 | 18.5 | 2.5 |
| NEU 10 ⁹ /L | 1.8 | 0.3 | 4.4 | 0.8 | 10.7 | 2.0 |
| NEU % | 56.2 | 6.0 | 60.7 | 6.0 | 65.2 | 10.0 |
| LYM 10 ⁹ /L | 0.9 | 0.3 | 1.8 | 0.8 | 3.3 | 2.0 |
| LYM % | 28.5 | 7.0 | 24.7 | 6.0 | 20.0 | 10.0 |
| MONO 10 ⁹ /L | 0.3 | 0.2 | 0.7 | 0.4 | 1.6 | 0.6 |
| MONO % | 9.9 | 5.0 | 9.5 | 4.5 | 9.9 | 3.0 |
| EOS 10 ⁹ /L | 0.1 | 0.1 | 0.2 | 0.2 | 0.4 | 0.2 |
| EOS % | 3.0 | 3.0 | 2.7 | 2.0 | 2.7 | 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 | 3.02 | 0.15 | 4.31 | 0.20 | 5.41 | 0.28 |
| HGB g/dL | 7.7 | 0.4 | 11.9 | 0.5 | 17.3 | 0.6 |
| HCT % | 21.9 | 1.5 | 32.8 | 2.3 | 44.9 | 3.5 |
| MCV fL | 72.5 | 4.0 | 76.0 | 4.0 | 83.1 | 4.0 |
| MCH pg | 25.7 | 2.0 | 27.6 | 2.0 | 32.0 | 2.0 |
| MCHC g/dL | 35.4 | 2.3 | 36.3 | 3.0 | 38.5 | 2.3 |
| RDW % | 13.8 | 2.5 | 13.3 | 2.5 | 10.8 | 2.5 |
| PLT 10 ⁹ /L | 74 | 20 | 225 | 30 | 521 | 60 |
| MPV fL | 6.5 | 2.0 | 6.1 | 2.0 | 6.1 | 2.0 |
| Retic %*** | 5.3 | 1.5 | 2.1 | 1.0 | 1.0 | 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. 2022-05-06 | 7 Consecutive Day Open-Vial Stability |
|-----------------|---------------------------------------|

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|-------------------------|-------------|-----------------|-------------|-----------------|-------------|-----------------|
| CELL-DYN 3700 | LOT L20529 | | LOT N20529 | | LOT H20529 | |
| PARAMETER | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** | ASSAY VALUE | ± MEAN RANGE ** |
| WOC 10 ⁹ /L | 3.3 | 0.4 | 7.1 | 0.7 | 16.0 | 2.5 |
| WIC 10 ⁹ /L | 3.4 | 0.5 | 7.2 | 1.0 | 18.0 | 3.0 |
| WBC 10 ⁹ /L | 3.3 | 0.4 | 7.1 | 0.7 | 16.0 | 2.5 |
| NEU 10 ⁹ /L | 1.8 | 0.3 | 4.3 | 0.8 | 10.4 | 2.0 |
| NEU % | 56.2 | 6.0 | 60.8 | 6.0 | 65.2 | 10.0 |
| LYM 10 ⁹ /L | 1.0 | 0.3 | 1.8 | 0.8 | 3.2 | 2.0 |
| LYM % | 29.1 | 7.0 | 24.8 | 6.0 | 19.9 | 10.0 |
| MONO 10 ⁹ /L | 0.3 | 0.2 | 0.7 | 0.4 | 1.7 | 0.6 |
| MONO % | 10.2 | 5.0 | 10.0 | 4.5 | 10.4 | 3.0 |
| EOS 10 ⁹ /L | 0.1 | 0.1 | 0.2 | 0.2 | 0.4 | 0.2 |
| EOS % | 3.0 | 3.0 | 2.7 | 2.0 | 2.8 | 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 | 3.03 | 0.15 | 4.25 | 0.20 | 5.31 | 0.28 |
| HGB g/dL | 7.8 | 0.3 | 11.9 | 0.5 | 17.2 | 0.6 |
| HCT % | 24.7 | 1.5 | 37.0 | 2.3 | 52.1 | 3.5 |
| MCV fL | 81.8 | 4.0 | 87.1 | 4.0 | 98.0 | 4.0 |
| MCH pg | 25.9 | 2.0 | 28.0 | 2.0 | 32.4 | 2.0 |
| MCHC g/dL | 31.7 | 2.3 | 32.2 | 3.0 | 33.1 | 2.3 |
| RDW % | 19.0 | 2.5 | 18.3 | 2.5 | 17.0 | 2.5 |
| PLT 10 ⁹ /L | 70 | 20 | 210 | 30 | 454 | 60 |
| MPV fL | 7.5 | 2.0 | 7.3 | 2.0 | 7.2 | 2.0 |
| Retic % ¹ | 4.7 | 1.5 | 1.9 | 1.0 | 0.9 | 0.8 |
| IRF ² | 0.53 | 0.38 | 0.39 | 0.30 | 0.41 | 0.20 |

| | |
|-----------------|---------------------------------------|
| Exp. 2022-05-06 | 7 Consecutive Day Open-Vial Stability |
|-----------------|---------------------------------------|

| SYSTEM | CONTROL L | | CONTROL N | | CONTROL H | |
|---------------------------|-------------|-----------------|-------------|-----------------|-------------|-----------------|
| Manual Count ³ | LOT L20529 | | LOT N20529 | | LOT H20529 | |
| 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