

CONTROL | L | N | H

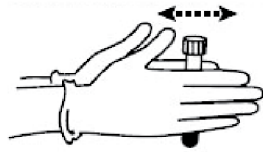
Refer to the appropriate system operator's manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

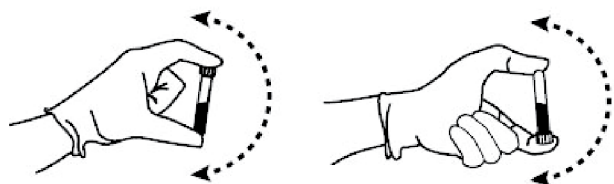
1. Remove a vial of the control from the refrigerator and warm to room temperature (18° to 30° C) for 15 minutes before use.
2. To mix: **(Do NOT mix mechanically or vortex.)**

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.

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7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Sapphire	LOT L51049		LOT N51049		LOT H51049	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WBC 10 ⁹ /L	2.96	0.40	6.51	0.80	15.9	3.0
NEU 10 ⁹ /L	1.68	0.20	3.77	0.40	9.89	1.10
NEU %	56.6	6.0	57.9	5.0	62.2	6.0
LYM 10 ⁹ /L	0.87	0.20	1.74	0.50	3.69	1.00
LYM %	29.4	8.0	26.8	6.0	23.2	5.0
MONO 10 ⁹ /L	0.31	0.20	0.76	0.40	1.76	0.60
MONO %	10.4	6.0	11.6	5.0	11.1	3.0
EOS 10 ⁹ /L	0.10	0.10	0.22	0.17	0.51	0.19
EOS %	3.00	3.00	3.42	2.00	3.23	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	2.85	0.18	4.27	0.20	5.18	0.30
RBCo 10 ¹² /L	2.94	0.18	4.31	0.20	5.15	0.30
HGB g/dL	7.85	0.30	11.9	0.5	16.3	0.8
HCT %	22.7	1.5	34.4	2.5	46.2	3.0
MCV fL	79.5	4.0	80.5	4.0	89.2	4.0
MCH pg	27.5	2.0	27.9	2.0	31.5	2.0
MCHC g/dL	34.6	2.3	34.6	2.3	35.3	2.3
RDW %	14.5	2.5	15.0	2.5	13.7	2.5
NRBC 10 ⁹ /L*	0.001	0.001	0.001	0.001	2.32	0.60
NRBC/100WBC*	0.001	0.001	0.001	0.001	14.6	2.5
PLT 10 ⁹ /L	73.9	20.0	221	50	474	60
PLTi 10 ⁹ /L	75.1	20.0	229	50	487	60
MPV fL	9.36	2.00	8.37	2.00	8.15	2.00
RETC 10 ⁹ /L	217	50	148	50	107	50
%R	7.62	1.50	3.47	1.00	2.07	0.80
IRF	0.62	0.18	0.54	0.14	0.40	0.10

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7 Consecutive Day Open-Vial Stability

SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN Ruby	LOT L51049		LOT N51049		LOT H51049	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	3.0	0.4	6.5	0.7	16.0	2.5
NOC 10 ⁹ /L	3.0	0.4	6.7	1.0	18.4	2.5
NEU 10 ⁹ /L	1.7	0.3	3.9	0.8	10.2	2.0
NEU %	57.4	6.0	59.3	6.0	63.6	10.0
LYM 10 ⁹ /L	0.8	0.3	1.6	0.8	3.5	2.0
LYM %	28.1	7.0	24.8	6.0	22.1	10.0
MONO 10 ⁹ /L	0.3	0.2	0.6	0.4	1.4	0.6
MONO %	8.4	5.0	9.3	4.5	8.5	3.0
EOS 10 ⁹ /L	0.1	0.1	0.2	0.2	0.5	0.2
EOS %	3.0	3.0	3.4	2.0	3.2	1.0
BASO 10 ⁹ /L	0.1	0.1	0.2	0.2	0.6	0.6
BASO %	3.4	3.0	3.2	3.0	3.0	3.0
RBC 10 ¹² /L	2.81	0.15	4.31	0.20	5.26	0.28
HGB g/dL	7.6	0.4	11.9	0.5	16.8	0.6
HCT %	21.3	1.5	33.2	2.3	44.4	3.5
MCV fL	75.8	4.0	77.0	4.0	84.4	4.0
MCH pg	27.0	2.0	27.6	2.0	31.9	2.0
MCHC g/dL	35.7	2.3	35.8	3.0	37.8	2.3
RDW %	12.5	2.5	12.6	2.5	10.7	2.5
PLT 10 ⁹ /L	78	20	231	30	512	60
MPV fL	6.9	2.0	6.3	2.0	6.1	2.0
Retic %***	5.3	1.5	2.0	1.0	1.1	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

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
CELL-DYN 3700	LOT L51049		LOT N51049		LOT H51049	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
WOC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
WIC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
WBC 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
NEU 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
NEU %	N/A	N/A	N/A	N/A	N/A	N/A
LYM 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
LYM %	N/A	N/A	N/A	N/A	N/A	N/A
MONO 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
MONO %	N/A	N/A	N/A	N/A	N/A	N/A
EOS 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
EOS %	N/A	N/A	N/A	N/A	N/A	N/A
BASO 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
BASO %	N/A	N/A	N/A	N/A	N/A	N/A
RBC 10 ¹² /L	N/A	N/A	N/A	N/A	N/A	N/A
HGB g/dL	N/A	N/A	N/A	N/A	N/A	N/A
HCT %	N/A	N/A	N/A	N/A	N/A	N/A
MCV fL	N/A	N/A	N/A	N/A	N/A	N/A
MCH pg	N/A	N/A	N/A	N/A	N/A	N/A
MCHC g/dL	N/A	N/A	N/A	N/A	N/A	N/A
RDW %	N/A	N/A	N/A	N/A	N/A	N/A
PLT 10 ⁹ /L	N/A	N/A	N/A	N/A	N/A	N/A
MPV fL	N/A	N/A	N/A	N/A	N/A	N/A
Retic % ¹	N/A	N/A	N/A	N/A	N/A	N/A
IRF ²	N/A	N/A	N/A	N/A	N/A	N/A

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SYSTEM	CONTROL L		CONTROL N		CONTROL H	
Manual Count ³	LOT L51049		LOT N51049		LOT H51049	
PARAMETER	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **	ASSAY VALUE	± MEAN RANGE **
Retic %	5.2	2.0	1.9	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.

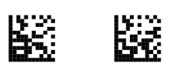


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Abbott Laboratories
 Diagnostics Division
 Abbott Park, IL 60064
 USA

EC REP Abbott GmbH & Co. KG
 Max-Planck-Ring 2
 65205 Wiesbaden
 Germany
 +49-6122-580

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 Abbott Laboratories



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