



Declaration of Conformity

Certificate Identification: SC-08H59

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division



Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

<p>Signature: </p> <p>Full Name: <u>Barry Simpson</u></p> <p>Position: <u>Site Quality Manager</u></p> <p>Date of Approval: <u>18 June 2015</u></p> <p>Date Issued: <u>JUN 30 2015</u></p> <p>Supersedes: <u>IRIS V5</u> <u>February 26, 2015</u></p>	<p>Signature: </p> <p>Full Name: <u>Marcy Jaqua</u></p> <p>Position: <u>Director, Regulatory Affairs</u></p> <p>Date of Approval: <u>30 June 2015</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JUL 06 2015</u></p>
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CELL-DYN HemCal Plus Calibrator

ABBOTT
CELL-DYN
SYSTEMS

ASSAY SHEET



Refer to the appropriate System Operator's Manual for proper use of CELL-DYN Calibrator and Control Products.

IMPORTANT: Mixing and Handling

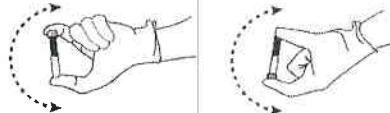
Before use, refer to the information sheet for complete product information.

1. Allow vial to warm to room temperature (18-30°C) for 15 minutes.
2. To mix: (Do NOT mix mechanically or vortex.)

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).

FOR AUTOMATED SAMPLING (CELL-DYN Sapphire System)

FOR OPEN-VIAL SAMPLING

- Aspirate a sample from the vial.
- Wipe the threads of both vial and cap with a lint-free tissue.
- Replace the cap, ensuring it is on tight.

3. After sampling, return vial(s) to refrigerator for maximum open-vial stability.

CELL-DYN HemCal Plus Calibrator

CALIBRATOR

Cap	5 Consecutive Day Open-Vial Stability	LOT
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PARAMETER	CELL-DYN Sapphire	CELL-DYN 3700	CELL-DYN Ruby	Tolerance Limits \pm
WBC 10 ⁹ /L				
WBC 10 ⁹ /L				
NOG 10 ⁹ /L				
RBC 10 ⁹ /L				
HGB g/dL				
MCV fL				
PLT 10 ⁹ /L				
MPV fL				

* Tolerance Limits do not apply to results obtained through Auto-Cal Calibration.
 ** If the assigned assay value exceeds the Auto-Calibration pre-set limits, use the Manual Method for calibration.
 Refer to the Operator's Manual for more information.



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MANUFACTURED FOR
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REF 08H57.01

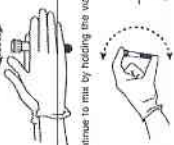


CONTROL L | N | H

8 Consecutive Day Open-Vial Stability

IMPORTANT: The barcode is for use only on the CELL-DYN Ruby. 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 20° C) for 15 minutes before use. To mix: (Do NOT mix mechanically or vortex.) For a video demonstration, visit www.cell-dyn.com and navigate to the Customer Portal → Technical Library → Other Reference Documents → Hematology Aids.
 2. Hold the vial vertically and air for each vial between the palms of the hands for 15-20 seconds.



3. 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.
4. Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
5. Steps are then repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open vials, cup piercing).



6. Refer to the appropriate CELL-DYN System Operator's Manual for information about analyzing control specimens.
7. 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 after returning to refrigerator.

SYSTEM	PARAMETER	CONTROL L		CONTROL N		CONTROL H	
		LOT	MEAN RANGE *	LOT	MEAN RANGE *	LOT	MEAN RANGE *
CELL-DYN 26 Plus SYSTEM	WBC (10 ⁹ /L)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
CELL-DYN Ruby SYSTEM	WBC (10 ⁹ /L)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						
	WBC (10 ⁹ /mm ³)						
	WBC (10 ⁶ /mm ³)						
	WBC (%)						

* The [MEAN RANGE] does not represent standard deviations (SD).
NOTE: Pips may occur with control materials and should be disregarded.



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CELL-DYN 26 Plus Control