

# **CELL-DYN EMERALD**

**HEMATOLOGY ANALYZER** 

## Fast, Accurate, with Easy Results Everytime

High performance in an affordable, compact design

- Reliable and accurate patient results
- Barcode reader
- Multiple languages available
- Open-mode one touch operation
- Auto startup and shutdown
- Lightweight only 19.8 lbs. (9 kg)

Fast and easy to use

- Results in approximately 60 seconds
- Small sample size
- Low reagent consumption
- Zero daily and weekly maintenance

### CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.



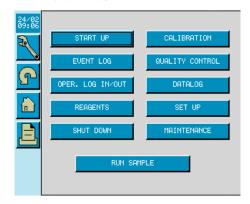
### **CELL-DYN EMERALD**

ITEM	SPECIFICATIONS
Technology & Methods	Electronic impedance     Absorption spectrophotometry     Electronic valves     Cyanide-free lyse reagent     LCD color touch screen     RS232 and TCP/IP LIS interface     USB ports
Throughput	Up to 57 samples per hour
Sample Size	• ~9.8 µL
Specimen Data Management	Search by date or sequence number Flagging for patient limit sets Flagging for panic values 1,500 records with histograms on internal memory Up to 300,000 records on external USB thumb drive Programmable patient limits Programmable report units Barcode reader (reads code 128, code 39, interleaved 2 of 5, and others listed in the Operator's Manual)
Quality Control	<ul> <li>6 control files</li> <li>100 runs per file</li> <li>Levey-Jennings graphs</li> <li>Upload/download control information</li> <li>eQC Online peer review program</li> </ul>
Demographics	<ul> <li>Sequence number</li> <li>Alphanumeric specimen ID</li> <li>Alphanumeric patient ID</li> <li>Date &amp; time analyzed</li> <li>Patient name</li> <li>CBC with 3-part differential</li> <li>Flagging and Alerts</li> </ul>
Dispersional Data Alert	Operator-defined patient limits for high and panic values     System-defined limits for reportable range and analytical measurement range     Suspect parameter flags caused by interfering substances or sample abnormalities     Suspect parameter flags generated when WBC data indicates possible presence of an abnormal population
Standards & Safety Compliance	• IEC 61010-1 • EN 61326-1 • CE Mark
Peripheral Devices	Inkjet or laser printer     USB thumb drive     Handheld barcode scanner
Physical Dimensions	<ul> <li>Height 13.8 in. (35 cm)</li> <li>Width 9.8 in. (25 cm)</li> <li>Depth 13.8 in. (35 cm)</li> <li>Weight 19.8 lbs. (9 kg) (without on-board reagents)</li> </ul>

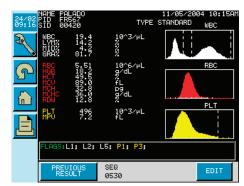
PARAMETERS			
White Cells	Red Cells	Platelets	
WBC	RBC	PLT	
LYM #	HGB	MPV	
LYM %	HCT		
MID#	MCV		
MID %	MCH		
GRAN	MCHC		
GRAN %	RDW		

REAGENTS		
Reagent Description	Size and List Number	
CN-Free Diff Lyse	960 mL (List No. <mark>09H47-02)</mark>	
Diluent	10 L (List No. <mark>09H48-02)</mark>	
Cleaner	960 mL (List No. <mark>09H46-02</mark> )	
CONTROLS & CALIBRATORS		
CELL-DYN 18 Plus Calibrator	09H70-01	
CELL-DYN 18 Plus Control	09H69-01 <mark>09H69-02</mark>	

### MAIN MENU



### **DATALOG FILE**



### **CHOOSE TRANSFORMATION™**

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/cell-dyn-emerald

For In Vitro Diagnostic Use Only. Refers to the Operator's Manual for operational precautions, limitations, and hazards.

CELL-DYN Emerald and CHOOSE TRANSFORMATION are trademarks of Abbott Laboratories in various jurisdictions.

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### **Declaration of Conformity**

Certificate Identification:

SC-09H46

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
09H46-02	58236	CELL-DYN Emerald CLEANER	Self-declared
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	Self-declared
09H48-02	58237	CELL-DYN Emerald DILUENT	Self-declared

Authorized European	ABBOTT	
Representative	Max-Planck-Ring-2	
(Name and Address)	65205 Wiesbaden, Germany	
Storage site of technical	Abbott Laboratories	
documentation	4551 Great America Parkway	
(Name and Address)	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.

Signature:

0 13

Signature:

Marcy Jaqua

Full Name:

Barry Simpson

Full Name:

Position:

Director, Regulatory Affairs

Position:

02. Dec. 2015

Site Quality Manager

Date of Approval:

01 DEC 2015

Date Issued:

Date of Approval:

DEC 0 2 2015

Place Issued:

Abbott Santa Clara

.

IRIS V6

Effective (Date or

DEC 0 3 2015

July 6, 2015

Lot Number):



### **Declaration of Conformity**

Certificate Identification: SC-09H69

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
09H69-01	55866	CELL-DYN 18 Plus Control, Full Pack	Self-declared
09Н69-02	55866	CELL-DYN 18 Plus Control, Half Pack	Self-declared

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

Signature:	Barry Spo	Signature:	Shara Jagua
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18. June 2015	Date of Approval:	30 June 2015

Date Issued:

JUN 30 2015

Place Issued:

Abbott Santa Clara

IRIS V5

Supersedes:

February 26, 2015

Lot Number):

Abbott Santa Clara

# Abbott

# CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5<sup>th</sup>-9<sup>th</sup>, 2018

Gustavo Rodriguez/ Srinivasan Gopalan

TRAINER NAME

PRAINER SIGNATURE

ABBOTT DIAGNOSTICS

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim