



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.

www.corelaboratory.abbott/cell-dyn-emerald

 **Abbott**

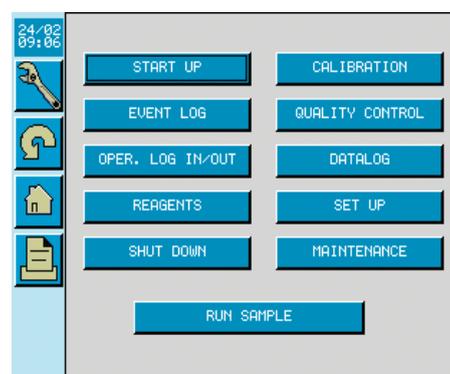
ITEM	SPECIFICATIONS
Technology & Methods	<ul style="list-style-type: none"> Electronic impedance Absorption spectrophotometry Electronic valves Cyanide-free lyse reagent LCD color touch screen RS232 and TCP/IP LIS interface USB ports
Throughput	<ul style="list-style-type: none"> Up to 57 samples per hour
Sample Size	<ul style="list-style-type: none"> ~9.8 μL
Specimen Data Management	<ul style="list-style-type: none"> 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 style="list-style-type: none"> 6 control files 100 runs per file Levey-Jennings graphs Upload/download control information eQC Online peer review program
Demographics	<ul style="list-style-type: none"> Sequence number Alphanumeric specimen ID Alphanumeric patient ID Date & time analyzed Patient name CBC with 3-part differential Flagging and Alerts
Dispersional Data Alert	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> IEC 61010-1 EN 61326-1 CE Mark
Peripheral Devices	<ul style="list-style-type: none"> Inkjet or laser printer USB thumb drive Handheld barcode scanner
Physical Dimensions	<ul style="list-style-type: none"> Height 13.8 in. (35 cm) Width 9.8 in. (25 cm) Depth 13.8 in. (35 cm) Weight 19.8 lbs. (9 kg) (without on-board reagents)

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

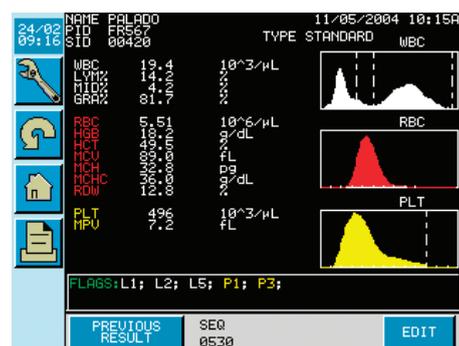
REAGENTS	
Reagent Description	Size and List Number
CN-Free Diff Lyse	960 mL (List No. 09H47-02)
Diluent	10 L (List No. 09H48-02)
Cleaner	960 mL (List No. 09H46-02)

CONTROLS & CALIBRATORS	
CELL-DYN 18 Plus Calibrator	09H70-01
CELL-DYN 18 Plus Control	09H69-01 09H69-02

MAIN MENU



DATALOG FILE



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

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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 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.

Signature:

Signature:

Full Name:

Barry Simpson

Full Name:

Marcy Jaqua

Position:

Site Quality Manager

Position:

Director, Regulatory Affairs

Date of Approval:

02 Dec 2015

Date of Approval:

01 DEC 2015

Date Issued:

DEC 02 2015

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V6
July 6, 2015

Effective (Date or Lot Number):

DEC 03 2015

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
09H69-02	55866	CELL-DYN 18 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

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

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

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

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan


TRAINER NAME

ABBOTT DIAGNOSTICS


TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

Abbott