Abbott

DIAGNOSTICS

CELL-DYN Emerald 22

The Information You Need
The Size You Want

CHOOSE TRANSFORMATION

Packed with Results

FULL PERFORMANCE SOLUTION FOR SMALLER LABORATORIES

COMPACT DESIGN

Conserving valuable laboratory workspace with a small footprint and only 2 reagents plus on-board cleaner

EASE OF USE

- Decreasing manual entry errors and increasing compliance by use of barcoded reagents
- Reducing hands-on time with touch-free scheduled daily maintenance, startup and shutdown

FLEXIBLE USER INTERFACE

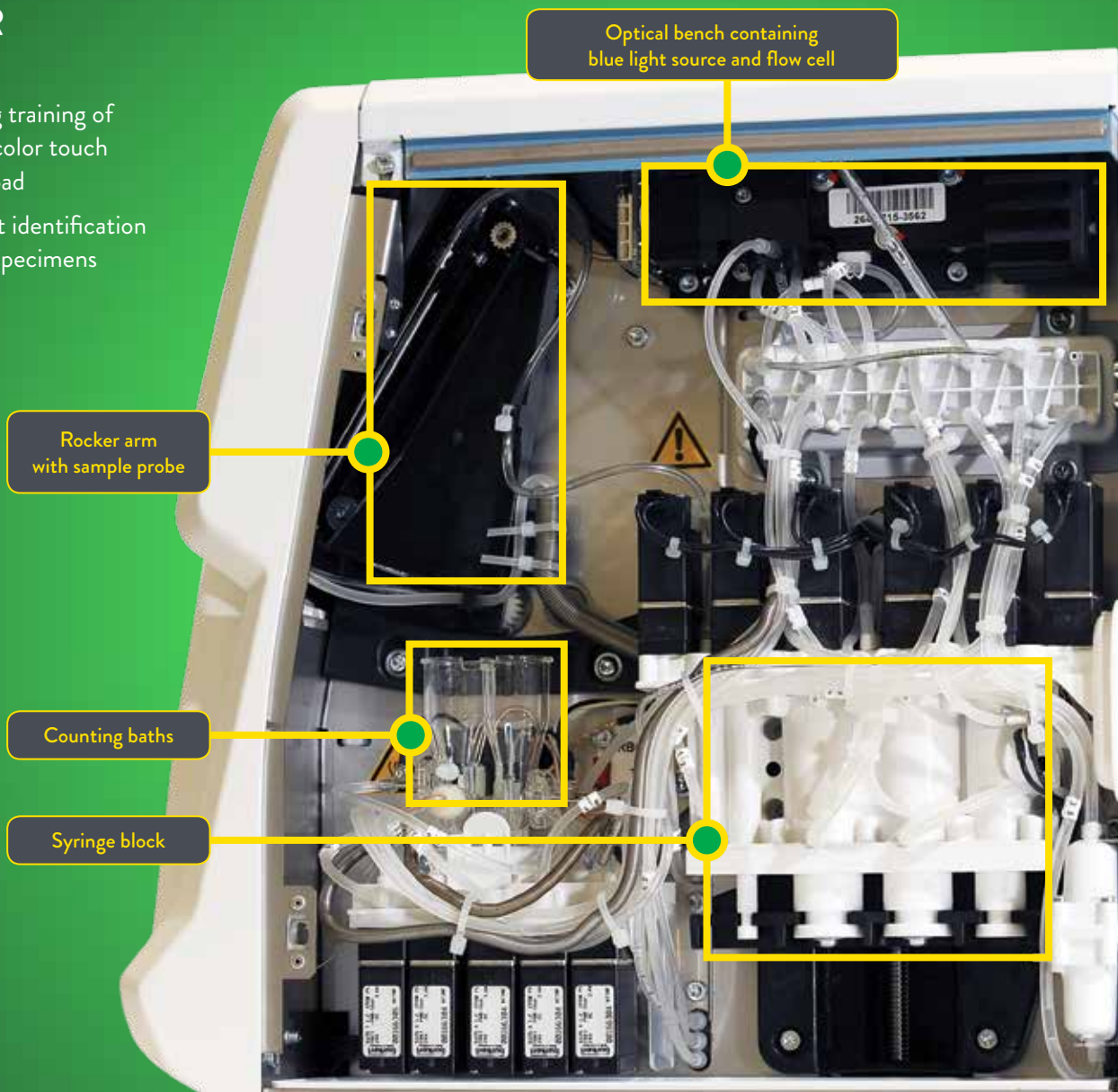
- Improving use and easing training of software functions with color touch screen and numeric keypad
- Providing positive patient identification with barcode reader for specimens

RELIABILITY

Helping you keep your commitments

OPTICAL 5-PART DIFFERENTIAL

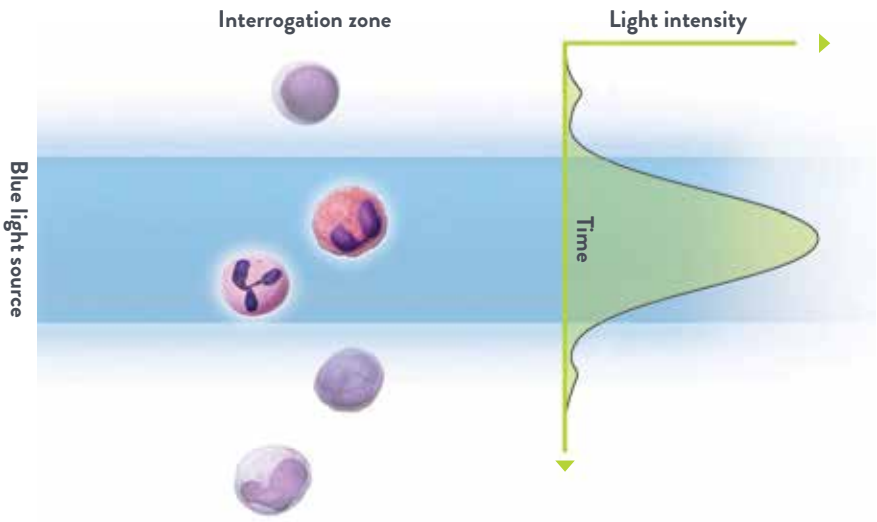
Delivering comprehensive results for your doctors and patients



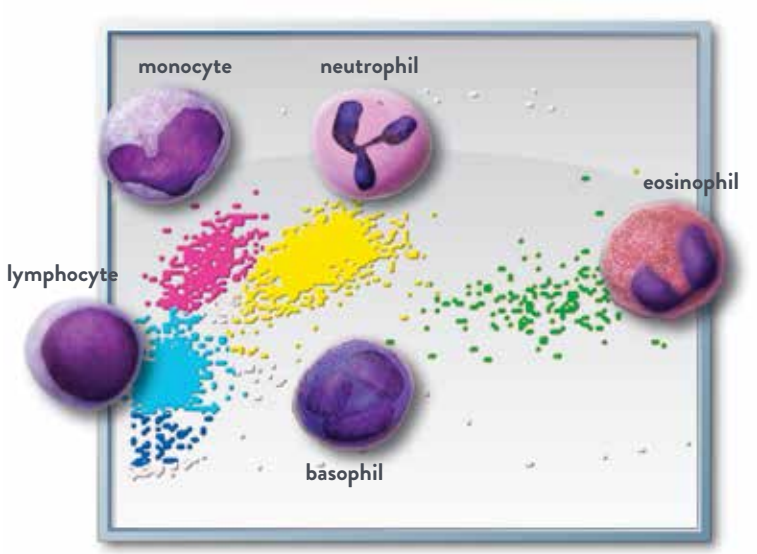
True Optical 5-Part Differential System

CELL-DYN Emerald 22 uses UNI-FLOW technology, which includes a cyanide- and formaldehyde-free Lyse, flow cell, and optical bench. The Lyse destroys the red blood cell stroma and stabilizes the white blood cells, while it creates a chromagen for hemoglobin measurement using the same dilution.

For each cell entering the optical detection area in the interrogation zone, two pulses are generated – Axial Light Loss and Forward Side Scatter measurement. The five-part differential is obtained by scattergram analysis after action of the Lyse, with no dyes, stains, or special channel measurements.



Enhanced Scattering Efficiency



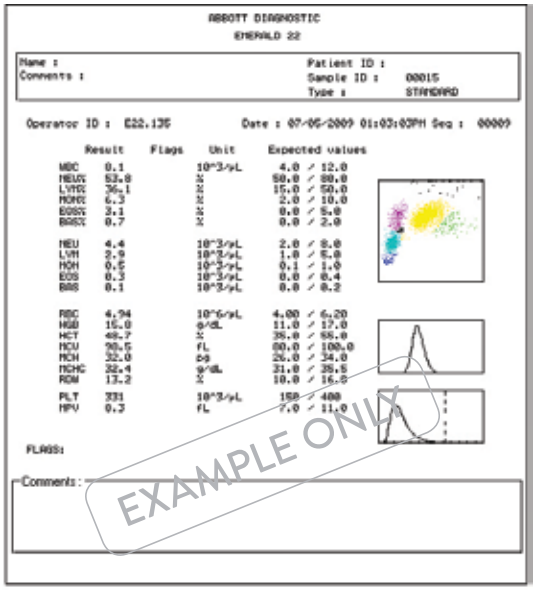
The cluster separation is enhanced with the low wavelength (455 nm) blue solid state LED. This wavelength enhances differentiation of intracellular contents, improving the identification and separation of eosinophils and monocytes from neutrophils.

The unique flow cell design, enhanced LED light source, and simple optical bench provide a true five-part differential in a small, easy-to-use, and reliable analyzer.

CELL-DYN
Emerald 22

CELL-DYN Emerald 22 Specifications

PATIENT REPORT EXAMPLE



PARAMETERS

White Cells	Red Cells	Platelets
WBC	RBC	PLT
NEUT # %	HGB	MPV
LYM # %	HCT	
MONO # %	MCV	
EOS # %	MCH	
BASO # %	MCHC	
	RDW	

CELL-DYN EMERALD 22 REAGENTS

Reagent Description	List Number
CELL-DYN Emerald 22 Easy Cleaner	09H60-01
CELL-DYN Emerald 22 Lyse	09H61-01
CELL-DYN Emerald 22 Diluent	09H62-01

CELL-DYN EMERALD 22 CONTROLS AND CALIBRATORS

Calibrator/Control	List Number
CELL-DYN 22 Plus Calibrator	09H73-01
CELL-DYN 22 Plus Control Full-Pack (12 tubes)	09H72-01
CELL-DYN 22 Plus Control Half Pack (6 tubes)	09H72-02

TECHNOLOGY & OPTICAL METHODS

- Optical Flow Cytometry technology
- Electrical impedance
- Absorption spectrophotometry
- Electronic valves
- Cyanide-free lyse reagent
- LCD color touch screen
- RS232 and TCP/IP LIS interface
- USB ports

THROUGHPUT

- 45 samples per hour

SAMPLE SIZE

- ~ 28µL

SPECIMEN DATA MANAGEMENT

- Search by date or sequence number
- Flagging for patient limit sets
- Flagging for panic values
- 1,000 records with histograms on internal memory
- Up to 300,000 records USB external data storage
- Programmable patient limits
- Programmable report units
- Standard barcode reader (reads code 128, code 39, and interleaved 2 of 5)

QUALITY CONTROL

- 6 control files
- 100 runs per file
- Levey-Jennings graphs
- Upload/download control information

DEMOGRAPHICS

- Sequence number
- Alphanumeric specimen ID
- Date and time analyzed
- Patient name
- CBC with or without 5-part WBC differential
- Flagging and alerts

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

- UL 61010-1
- CAN/CSA-C22.2 No. 61010-1
- IEC 61010-1
- IEC 61326-1
- IEC 61326-2-6
- FCC part.15
- CE Mark
- ETL Mark

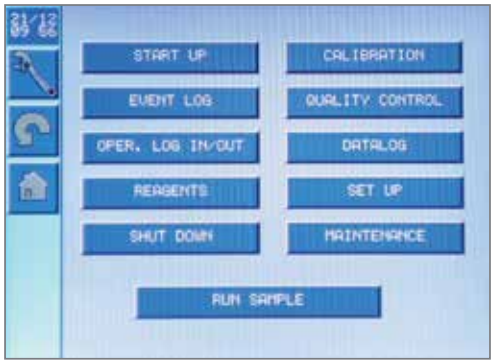
PERIPHERAL DEVICES

- Inkjet printer
- USB thumb drive
- Handheld barcode scanner

PHYSICAL DIMENSIONS

- Height 13.8” (35cm)
- Width 9.8” (25cm)
- Depth 13.8” (35cm)
- Weight ~ 24.2lbs (11kg) (without on-board reagents)

MAIN MENU



See Operations Manual for warnings, precautions, and limitations for proper use of the instrument.

Intended Use: The CELL-DYN Emerald 22 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for the following parameters: WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K2 EDTA anti-coagulated blood.

The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

www.abbottdiagnostics.com
1-877-4ABBOTT

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Declaration of Conformity

Certificate Identification: SC-09H59

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
09H59-01	35476	CELL-DYN Emerald 22 Instrument	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH 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 BIT Group France, Parc Euromédecine II, Rue de la Valsière, CEDEX 5, CS 14287 34 099 – Montpellier FRANCE
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, and Directive 2011/65/EU and amending Directive (EU) 2015/863, the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

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

Signature:	Cheryl Nowlan	Signature:	
Full Name:	Cheryl Nowlan	Full Name:	Suzanne Cheang
Position:	Director of Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	26 JUL 2021	Date of Approval:	July 26, 2021
Date Issued:	JUL 26 2021	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V3 (July 22, 2021)	Effective (Date or Lot Number):	JUL 26 2021

Abbott

Declaration of Conformity

Certificate Identification: SC-09H60

Legal Manufacturer's Name: Abbot 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
09H60-01	58236	CELL-DYN Emerald 22 Easy Cleaner	Self-Declared
09H60-03	58236	CELL-DYN Emerald 22 Easy Cleaner	Self-Declared

Authorized European Representative (name and address)	Abbott GmbH 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 USA Avantor Performance Materials Poland, S.A ul. Sowinskiego 11 44-101 Gliwice, Poland
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, and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, 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 Annex VI of the ROHS Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Cheryl Nowlan	Signature:	
Full Name:	Cheryl Nowlan	Full Name:	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	12 OCT 2020	Date of Approval:	12 OCT 2020
		Date of Issue:	OCT 12 2020
		Place Issued:	Abbott Santa Clara
		Supersedes:	September 24, 2020
		Effective (Date or Lot Number)	OCT 12 2020

Abbott

Declaration of Conformity

Certificate Identification: SC-09H61

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
09H61-01	61165	CELL-DYN Emerald 22 LYSE	**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 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
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:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H62

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
09H62-01	58237	CELL-DYN Emerald 22 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 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
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:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRI S V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H72

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

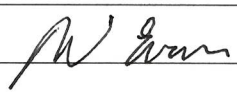
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

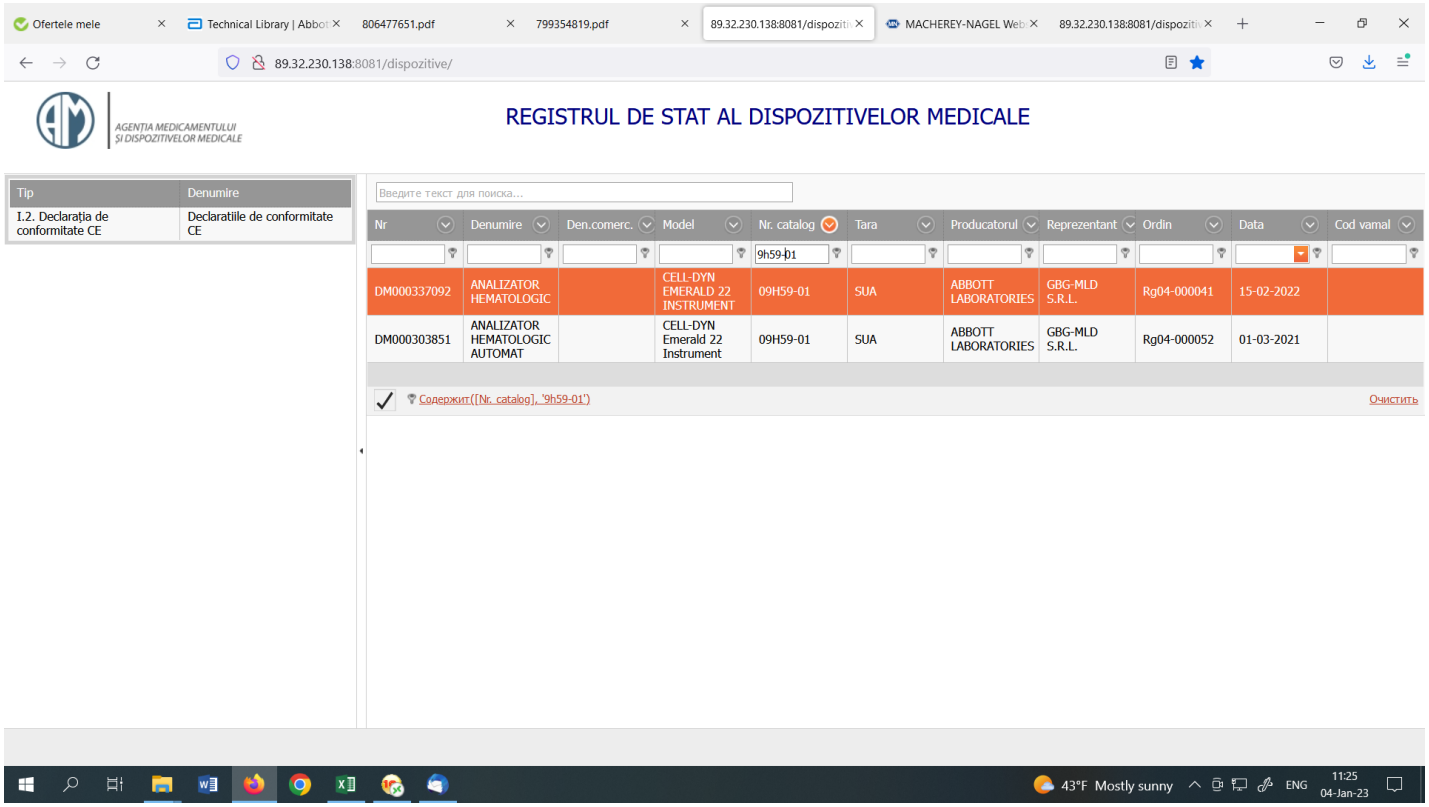
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H72-01	55866	CELL-DYN 22 Plus Control, Full Pack	**Self-declared**
09H72-02	55866	CELL-DYN 22 Plus Control, Half Pack	**Self-declared**

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 Streck, Inc. 7002 S. 109th Street La Vista, NE 68128 USA
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:	Alfred Evans	Full Name:	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	May 9, 2019	Date of Approval:	May 9, 2019
Date Issued:	MAY 09 2019	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1 April 15, 2016	Effective (Date or Lot Number):	MAY 09 2019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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: FM 743464

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2018-10-12
Latest Revision Date: 2022-04-12

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

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Certificate No: FM 743464

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2018-10-12

Effective Date: 2021-10-13

Latest Revision Date: 2022-04-12

Expiry Date: 2024-10-12

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: **MD 743461**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-01
Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

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Certificate No: **MD 743461**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design and Development of in vitro diagnostics products including test kits and reagents.

Original Registration Date: 2021-06-01

Effective Date: 2021-10-13

Latest Revision Date: 2022-06-22

Expiry Date: 2024-10-12

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Facility ID Number: F004943

Holds Certificate No: **MDSAP 743463**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-12-07 Effective Date: 2022-10-03 Expiry Date: 2024-10-12

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 743463**

Registered Scope:

Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring.

Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.

Original Registration Date: 2017-12-07 Effective Date: 2022-10-03 Expiry Date: 2024-10-12

Certificate No: **MDSAP 743463**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA Facility ID Number: F004943	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA Facility ID Number: F004943	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA Facility ID Number: F004943	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan Facility ID Number: F005418	Design and development in vitro diagnostics products including test kits, reagents, and accessories.

Original Registration Date: 2017-12-07 Effective Date: 2022-10-03 Expiry Date: 2024-10-12

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