

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, Management of 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: 2024-09-19

Effective Date: 2024-10-13

Expiry Date: 2027-10-12



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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, Management of 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

Latest Revision Date: 2024-09-19

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

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

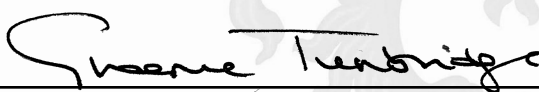
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture and Distribution 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, Installation, Service and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic medical devices including Analyzers, Reagents, and related Accessories for the identification of hematologic parameters.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-06-01

Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

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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.

Original Registration Date: 2021-06-01

Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

EU Declaration of Conformity

Basic UDI-DI: 038074MPH0173S4
Basic UDI-DI Name: CELL-DYN Sapphire and CELL-DYN Ruby Systems Diluent/Sheath
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
01H73-01	CELL-DYN Sapphire and CELL-DYN Ruby Systems Diluent/Sheath	58237	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
Conformity Assessment Procedure	Annex II and III

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan

Function: Site QA, Director Quality Assurance

Signature: *Cheryl Nowlan*

Date of Approval: 28 MAR 2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023

Supersedes: Oct 11, 2022

Full Name: Katie Bessette

Function: Director Regulatory Affairs

Signature: *Katie Bessette*

Date of Approval: 28 - MAR - 2023

Place Issued: Santa Clara, CA USA

Effective (Date or Lot Number): MAR 28 2023



EU Declaration of Conformity

Basic UDI-DI: 038074RUB0002TU
Basic UDI-DI Name: CELL-DYN Enzymatic Cleaner Concentrate
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
99644-01	CELL-DYN Enzymatic Cleaner Concentrate	59058	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
Conformity Assessment Procedure	Annex II and III

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Full Name: Cheryl Nowlan

Function: Site QA, Director Quality Assurance

Signature: Cheryl Nowlan

Date of Approval: 28 MAR 2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023

Supersedes: June 09, 2022

Full Name: Katie Bessette

Function: Director Regulatory Affairs

Signature: Katie Bessette

Date of Approval: 28-MAR-2023

Place Issued: Santa Clara, CA USA

Effective (Date or Lot Number): MAR 28 2023

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0380WZ
Basic UDI-DI Name: CELL-DYN Ruby CN-FREE HGB/NOC LYSE
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03H80-02	CELL-DYN Ruby CN-FREE HGB/NOC LYSE	61165	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
Conformity Assessment Procedure	Annex II and III

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan

Function: Site QA, Director Quality Assurance

Signature: *Cheryl Nowlan*

Date of Approval: 19 APR 2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: APR 19 2023

Supersedes: March 28, 2023

Full Name: Katie Bessette

Function: Director Regulatory Affairs

Signature: *Katie Bessette*

Date of Approval: 19 - APR - 2023

Place Issued: Santa Clara, CA USA

Effective (Date or Lot Number): APR 19 2023

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.

Signature: 

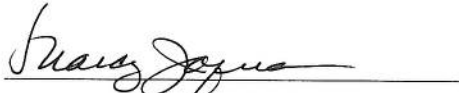
Full Name: Barry Simpson

Position: Site Quality Manager

Date of Approval: 18 June 2015

Date Issued: JUN 30 2015

Supersedes: IRIS V5
February 26, 2015

Signature: 

Full Name: Marcy Jaqua

Position: Director, Regulatory Affairs

Date of Approval: 30 June 2015

Place Issued: Abbott Santa Clara

Effective (Date or Lot Number): JUL 06 2015

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0852XM
Basic UDI-DI Name: CELL-DYN Ruby WBC Lyse
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08H52-01	CELL-DYN Ruby WBC Lyse	61165	W0103010105

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	ThermoFisher 8365 Valley Pike Middletown, VA 22645 USA
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Full Name: Cheryl Nowlan

Function: Site QA, Director Quality Assurance

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Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023

Supersedes: Oct 11, 2022

Full Name: Katie Bessette

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Date of Approval: 28-MAR-2023

Place Issued: Santa Clara, CA USA

Effective (Date or Lot Number): MAR 28 2023