

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-06-01

Latest Revision Date: 2021-10-05

Effective Date: 2021-10-13

Expiry Date: 2022-04-12

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...making excellence a habit.™

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	Distribution of In Vitro Diagnostics Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

Original Registration Date: 2021-06-01

Latest Revision Date: 2021-10-05

Effective Date: 2021-10-13

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Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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: <u></u></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 February 26, 2015</u></p>	<p>Signature: <u></u></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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Declaration of Conformity



Certificate Identification: SC-01H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	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: <u></u>	Signature: <u></u>
Full Name: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity

Certificate Identification: SC-99644
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
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	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 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:  Full Name: <u>Barry Simpson</u> Position: <u>Quality Manager</u> Date of Approval: <u>04. Sept. 2015</u> Date Issued: <u>SEP 04 2015</u> Supersedes: <u>IRIS V4, January 10, 2014</u>	Signature:  Full Name: <u>Marcy Jaqua</u> Position: <u>Regulatory Affairs, Director</u> Date of Approval: <u>04 Sep 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>SEP 11 2015</u>
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Declaration of Conformity


Certificate Identification: SC-03H80
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
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC 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
Harmonized Standards	Listed in the Technical Documentation

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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: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun. 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity



Certificate Identification: SC-08H52
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

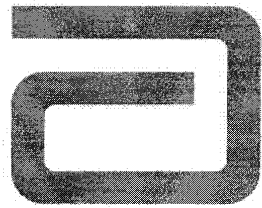
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

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
Harmonized Standards	Listed in the Technical Documentation

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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: <u>Barry Simpson</u> Position: <u>Site Quality Manager</u> Date of Approval: <u>29 Jun 2015</u> Date Issued: <u>JUN 30 2015</u> Supersedes: <u>IRIS V2, January 10, 2014</u>	Signature:  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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Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

has completed

Ruby

Service Training

TSOBANIDIS VLASSIS

Trainer.....

Athens, 29-31/10/2014

