



Customer Service Organization Certificate of Technical Competence

This is to acknowledge that

Ion Negru

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certification Exam

Certificate is valid for two years from printed completion date

29/06/2018

Manager

I certify that this individual has completed the program requirements

I certify that on the dates above, this individual has completed the program requirements for Instrument Certification

Abbott Diagnostics Division

Abbott Laboratories 2016

Anexa 18. Analizator hematologic automat (5 diff) cu sistem de tip deschis

Descriere	Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componentei sanguine	Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componentei sanguine
Parametru	Specificatia	Specificatia ofertata CELL-Dyn Ruby (ABBOTT/USA)
Tip system	deschis	sistem mod de operare deschis
Metode de masurare	impedansmetrica	Tehnologie diferentiere leucocitara: flow-citometrie (tehnologie HeNe laser-MAPSS) cu devierea undei laser sub 4 unghiuri, concentrare hidrodinamica a fluxului celular
	fotometrica	Tehnologie masurare hemoglobina- spectrofotometrie cu reactiv cian-free
	optica (5 diff)	Tehnologie diferentiere leucocitara: flow-citometrie (tehnologie HeNe laser-MAPSS) cu devierea undei laser sub 4 unghiuri, concentrare hidrodinamica a fluxului celular Posibilitate de analiza optica tridimensionala a eritrocitelor (0,10 si 90 de grade); Posibilitate de analizare optica bidimensionala a trombocitelor (0 si 10 grade)
Procedura de curatire	automata	automata
Parametri determinati si calculati:	WBC	WBC
	RBC	RBC
	Hgb	Hgb
	Hct	Hct
	MCV	MCV
	MCH	MCH
	MCHC	MCHC
	PLT	PLT
	LYM #	LYM #
	MON#	MON#
	GRA#	GRA#
	NEU#	NEU#
	BAS#	BAS#
	EOS#	EOS#
	LYM%	LYM%
	MON%	MON%
	GRA%	GRA%
	NEU%	NEU%

	BAS%	BAS%
	EOS%	EOS%
	RDW	RDW
	PDW	PDW
	MPV	MPV
	PCT	PCT
Capacitate (probe/ora)	>60	Da 84 HLG/ora
Diluarea	automata	Da
Afisaj	grafic	Da
Imprimanta	color	Da
Introducerea datelor	manual	Manuala si/sau automata (Posibilitate de introducere si stocare a valorilor normale de referinta in functie de sex, virsta,date demografice (31 de seturi)
Interfata PC	da	Da, interfata bidirectionala
Afisarea histogramelor	da	Da
Stocarea datelor	da	Da (posibilitate de stocare 10000 de rezultate cu grafice)
Calibrarea	automata	Da (program autocalibrare-ghid online)
	manuala	Da metoda cu calibrator sau cu pool de pacient
Grafice	RBC (repartizarea eritrocitelor dupa volum)	Da
	PLT (repartizarea trombocitelor dupa volum)	Da
Scatergrame	WBC 5 diff	Da posibilitatea vizualizarii a 9 scaterograme diferite color
Afisarea pe ecran a tuturor datelor	histograme	Da
	rezultate	Da
	grafice	Da
	rezultate din arhiva	Da
	date de service	Da
Monitorizarea datelor pacientului	nume pacient	Da
(posibilitatea de introducere informatii complete pacient)	ID pacient	Da
	sex	Da
	virsta	Da
Monitorizarea datelor reactivului	numarul lotului	Da
	data expirarii	Da
	volumul ramas	Da
Afisarea rezultatelor pe imprimanta	Parametri determinate si calculati	Da
	histograme pe parametrii de baza RBC, WBC, PLT	Da
	date despre pacient	Da
Indicatori de avertizare	da	Da Sistem de avertizare asupra anomaliilor decelate privind

		morfologia leucocitara, eritrocitara, trombocitara, evidentiarea valorilor anormale
Control al calitatii	in 6 nivele	Pe 3 nivele
	Construirea tabelelor si graficelor Levey Janings	Da Managementul controalelor de calitate (grafice Levey-Jenings, regulile Westgard, moving average)
Memorie interna	> 1000 pacienti	Da capacitate de stocare a 10.000 rezultate
Alimentarea	220 V, 50 Hz	Da
Accesorii	Vas pentru deseuri	Da
	tuburi pentru reagenti	Da
	tuburi pentru spalare	Da
Limba de comunicare	rom/rus	Engleza/Rus
Reagenti	"Să fie inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 1000 analize"	Da
Consumabile	Sa fie incluse ≥ 1000 eprubete 2,5 ml cu anti-coagulant, pentru colectarea singelui integru, compatibile cu analizorul oferit Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni	Da

CELL-DYN Ruby



CELL-DYN Ruby

HEMATOLOGY ANALYZER

GET IT RIGHT THE FIRST TIME

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/hematology



First Pass Efficiency. Getting It Right the First Time.



OPERATIONAL EFFICIENCY

- Offers 35 minutes of walkaway time with load up of 50 specimens
- Accommodates tubes of various sizes in open and closed modes
- Integrates with AlinIQ AMS and other popular middleware packages



FLEXIBLE AND EASY-TO-USE

- Screens are straightforward, intuitive and easy to navigate
- Features customizable views
- Quickly set up or change many analyzer options based on laboratory need or protocols



REAGENT MANAGEMENT

- Only 3 reagents required for CBC with differential
- Real-time reagent status monitoring
- RFID reagents work with AlinIQ Inventory Management System (IMS)



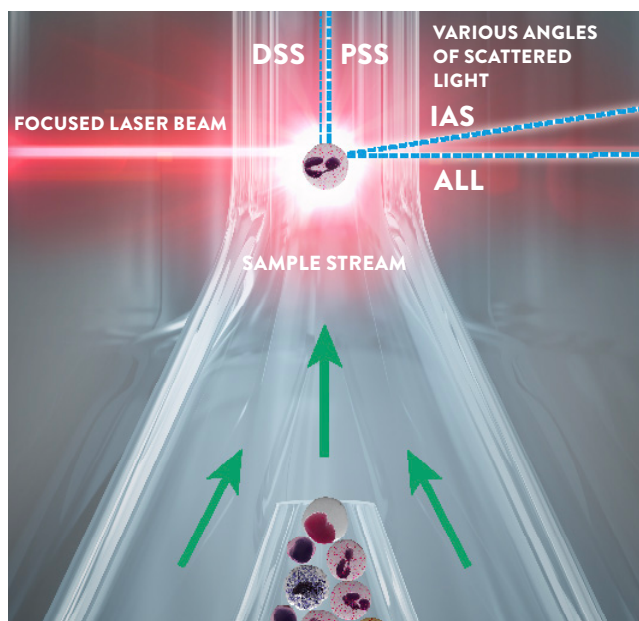
SINGLE-USE RETICULOCYTE OPTION

- Cost-effective stability until printed expiry date on package
- Reagent is available in 100 test package
- No refrigeration required



Enhanced first pass efficiency with MAPSS™ technology

HIGHLY DISCRIMINATE, SEQUENTIAL SEPARATION USING MAPSS™ TECHNOLOGY



MAPSS™ (MULTI-ANGLE POLARIZED SCATTER SEPARATION) TECHNOLOGY PROVIDES LASER-ACCURATE OPTICAL READINGS FOR WBCs AND DIFFERENTIALS

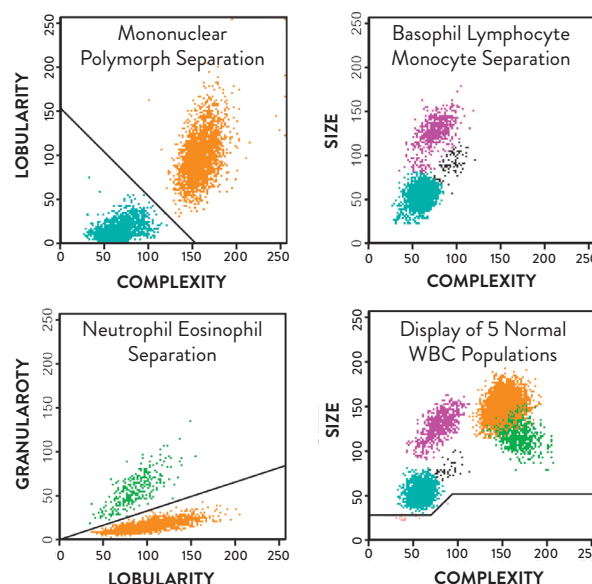
- Axial Light Loss (ALL) provides total count and size of each cell
- Intermediate Angle Scatter (IAS) indicates complexity of intracellular structure
- Polarized Side Scatter (PSS) provides details on granularity and nuclear lobularity, separating mononuclear from polymorphonuclear cells
- Depolarized Side Scatter (DSS) separates neutrophils from eosinophils

MAPSS™ LASER TECHNOLOGY A HIGHER LEVEL OF INTERROGATION

- Analysis performed on up to 10,000 cells from a single dilution, using a single reagent
- Captures up to 40,000 data points

MAPSS™ RESULTS ARE DISPLAYED IN MULTIPLE ELEGANT, COLOR-CODED SCATTERPLOTS

- Discriminates between neutrophils, eosinophils, basophils, monocytes and lymphocytes
- Identifies and flags immature cells and interfering substances



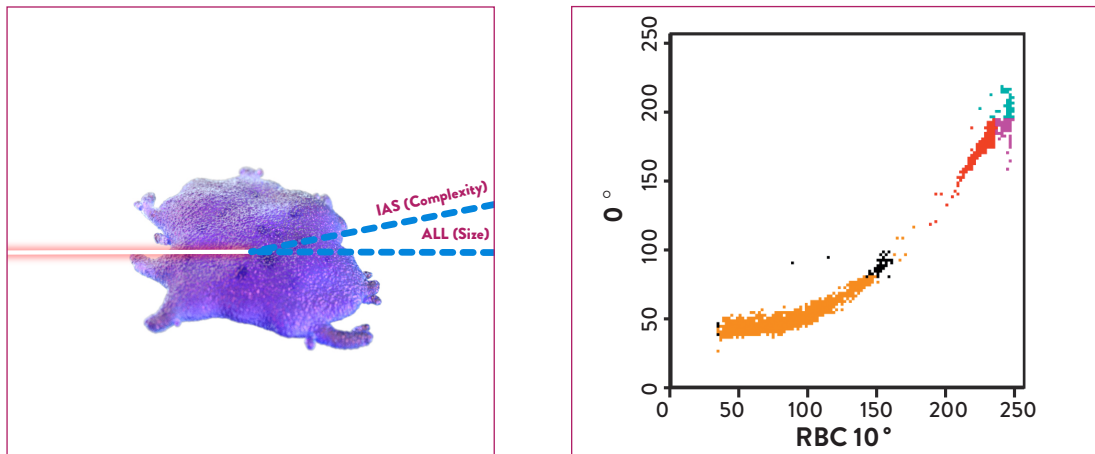
How MAPSS™ differentiates and classifies

	Size	Complexity	Lobularity	Granularity	Classification			
Cell	0°	10°	90°	90° Depolarized	1st	2nd	3rd	4th
1	165	162	116	32	POLY	NEU	–	–
2	60	64	15	6	MONO	–	–	LYM
3	140	79	21	99	MONO	–	–	MONO
4	148	182	104	118	POLY	EOS	–	–
5	90	110	28	8	MONO	–	BASO	–

Two-dimensional Optical Platelet (PLT) Analysis

REPORTABLE PLATELET COUNTS ACROSS A WIDE VARIETY OF ABNORMAL CONDITIONS

- First Pass two-angle analysis separates the PLT and RBC populations
- Reduces interference from microcytic RBCs, schistocytes and non-platelet particles
- Obtain reportable results in the presence of giant or clumped PLTs and on thrombocytopenic samples *without reflexing or extra reagents*

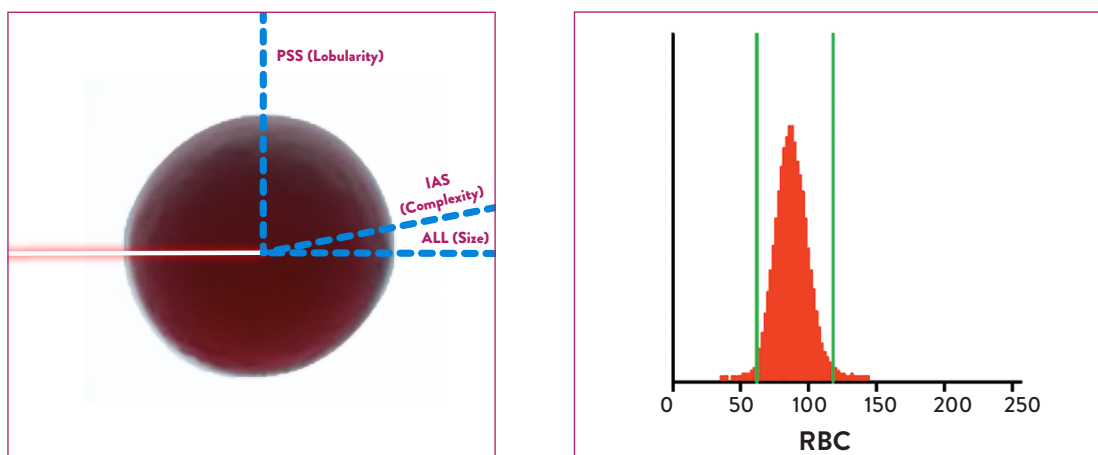


First Pass Optical Platelet Count: Platelets and RBCs are accurately sized and counted by multidimensional laser light scatter. Whole blood is diluted into a proprietary reagent system that optimizes the separation of platelets and RBCs, spheres the RBCs and reduces interference by microcytic red cells and non-platelet particles.

Three-dimensional Optical Red Blood Cell (RBC) Analysis

IMPROVES THE ACCURACY OF RED CELL MEASUREMENTS, INCLUDING RETICULOCYTES

- Comprehensive cell-by-cell measurements with readings taken at 0°, 10° and 90° by light scatter detectors enable exquisite accuracy of RBCs and reticulocytes
- Reticulocyte assay based upon NCCLS/ICSH methods

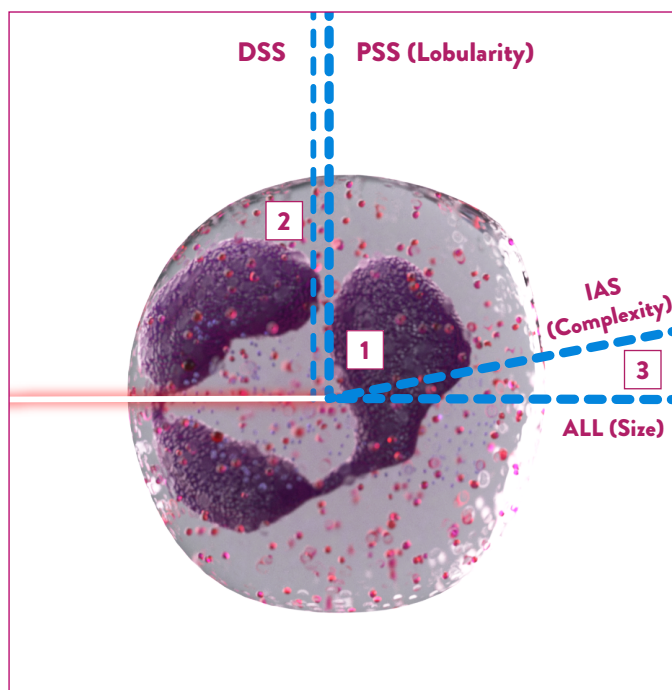


Red cell size and size distributions are displayed using a histogram constructed from the cell-by-cell volume calculated using the 0°, 10° and 90° light scatter measurements of each sphered red blood cell.

Four-dimensional White Blood Cells (WBC) Analysis

WBCs ARE COUNTED AND CLASSIFIED SO THAT RESULTS CAN BE REPORTED ON THE FIRST RUN, EVEN WHEN ABNORMAL CELLS AND INTERFERING SUBSTANCES ARE PRESENT

- Reduce manual reviews due to interference from NRBCs, clumped platelets and debris
- MAPSS™ technology can detect potential interference from lysis-resistant RBCs; the flagged samples can be re-run in the lysis-resistant mode without microscopic review (Figure 1 and 2)



- 1 Neutrophils and eosinophils are separated from lymphocytes, monocytes and basophils by differences in their complexity and lobularity.
- 2 Neutrophils are separated from eosinophils by virtue of their different characteristics in scattering polarized (PSS) and depolarized (DSS) light.
- 3 Basophils are separated using both size (ALL) and complexity (IAS) readings, allowing lymphocytes and monocytes to be separated by size (ALL) information.

The net result of the simultaneous laser scatter readings is excellent discrimination among the 5 normal cell populations.

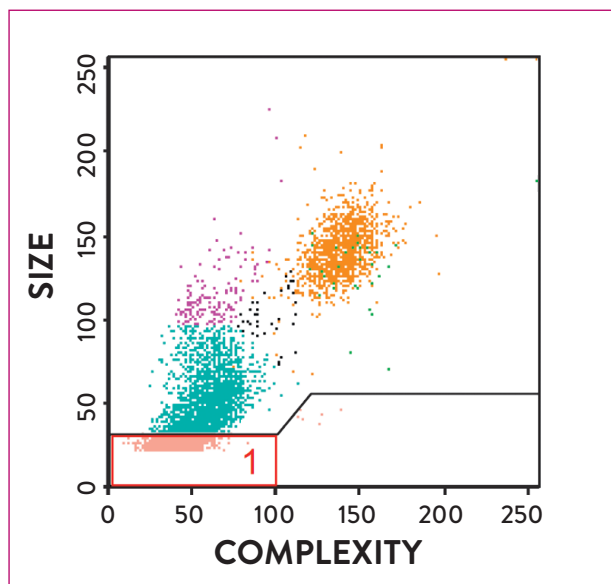


Figure 1: The occurrence of a significant population of cells occurring below the dynamic WBC Optical Count (WOC) threshold can suggest the presence of lysis-resistant RBCs.

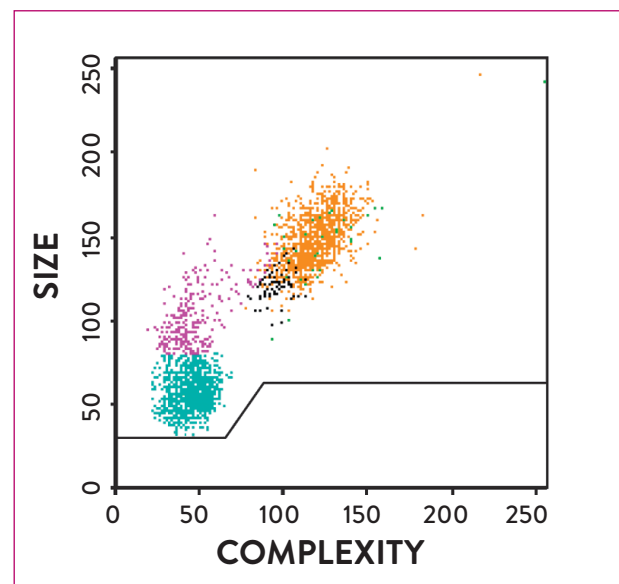


Figure 2: In cases where lysis-resistant RBCs occur, the sample is re-run in the resistant RBC mode to provide the 5 part differential.

Touch-Screen Convenience & Flexibility With Multifaceted Software

ENHANCE WORKFLOW EFFICIENCY WITH QC MANAGEMENT, USER-DEFINABLE DECISION RULES, SMART SOFTWARE FEATURES AND ABBOTTLINK

QUALITY CONTROL

- Users can store up to 500 quality control files
- Multiple Westgard Rules are available to select from
- Moving averages available for RBC, WBC, differential, PLT, and reticulocyte parameters

DATA MANAGEMENT

- Rules-based result annotations allow you to standardize lab processes to meet your laboratory's needs
- Program up to 100 rules and up to 48 result annotations to help streamline your data management processes

USER-FRIENDLY SOFTWARE PACKAGE

- Context-sensitive help menus
- Calibration wizard
- On-board maintenance videos available
- Software available in multiple languages

AbbottLink® DRM

- AbbottLink® is a Device Relationship Management system that allows Abbott to gather system data
- Data is encrypted and transferred over the internet to help improve the troubleshooting process

Harmonize Laboratory Data With AlinIQ AMS Middleware

INCREASE OPERATIONAL EFFICIENCY

With AlinIQ AMS (Analyzer Management System) middleware, you can standardize operations across your laboratory system to increase resource utilization. AlinIQ AMS is an open, scalable solution that can connect virtually any analyzer or automation system to the LIS to better manage the flow of data throughout the entire workflow process.

AlinIQ AMS FUNCTIONALITY

- **Test Management:** Hematology results views and advanced autoverification rules for consistent results management
- **Sample Management:** Monitor steps in the sample workflow and tube logistics between facilities
- **Historical Reports:** Better understand and manage laboratory performance
- **Equipment Management:** Centralize the monitoring and control of analyzers and automation systems
- **Quality Management:** Tools designed to help with ISO 17025 compliance

CELL-DYN Ruby

SPECIFICATIONS		DESCRIPTIONS		
Product Information				
Throughput	CBC + Differential up to 84 per hour			
Sample Size	Open mode ≤ 150 µL, Sample Loader ≤ 230 µL			
Reagents	Only 3 reagents plus optional reticulocyte reagent			
Technology				
WBC and Differential	Optical MAPSS™ Multiple Scatterplot Analysis			
RBC and Platelet	Optical analysis with no additional reagent or reflex testing requirement for PLTs			
Reticulocyte	Optical analysis with New Methylene Blue NCCLS method, supravital staining technique			
PARAMETERS				
White Cells	Red Cells		Platelets	
WBC	RBC	RDW	PLT	
NEU # and %	HGB	RETIC	MPV	
LYM # and %	HCT		PCT*	
MONO # and %	MCV		PDW*	
EOS # and %	MCH		*Clinical significance has not been established for PCT and PDW. Therefore, they are not reportable in the US.	
BASO # and %	MCHC			
ANALYTICAL MEASUREMENT RANGES				
Parameter	AMR		Units	
WBC	0.02 – 246.8		x 10 ³ /µL	
RBC	0.00 – 7.50		x 10 ⁶ /µL	
HGB	0.0 – 25.0		g/dL	
HCT	8.3 – 79.8		%	
MCV	58 – 139		fL	
RDW	10.0 – 29.8		%	
PLT	0.00 – 3000		x 10 ³ /µL	
MPV	4.3 – 17.2		fL	
ELECTRICAL REQUIREMENTS				
Module	Voltage	Frequency	Max current	Max power consumption
Analyzer	100 – 240 VAC	50/60 Hz	5.0 – 2.2 amps	550 watts
Display	100 – 240 VAC	50/60 Hz	1.5 amps	50 watts
SYSTEM MEASUREMENTS				
Module	Height	Width	Depth	Weight
Analyzer	49.9 cm (19.25 in.)	86.4 cm (34.0 in.)	76.8 cm (30.25 in.)	105.2 kg (232.0 lbs.)
Printer	Refer to the printer manufacturer’s specifications			

DATA MANAGEMENT

Microsoft Windows based Operating System

Rules-based result annotations

- Decision rules
- Up to 100 rules
- Up to 48 result annotations
- Fully customizable

Touch Screen Monitor

Full on-board QC

- Summary statistics and Levey-Jennings plots
- Moving averages (including WBC differential)
- Westgard rules

10,000 results stored with graphics

Work list capability

Programmable patient and report limits

Complete patient demographics

Bar code reading: Code 39, Codabar, Code 128, Interleaved 2 of 5, ISBT

Auto-calibration online guide

On-board diagnostics and help videos

OPERATING ENVIRONMENT TEMPERATURE

15°C (59°F) to 30°C (86°F)

HUMIDITY

≤ 80 % relative humidity, non-condensing indoor use

STANDARDS & SAFETY COMPLIANCE

- UL 61010-1
- CAN/CSA-C22.2 No. 61010-1
- ETL
- CE Mark
- IEC 61010-1
- IEC 60825-1
- IEC 61326-1
- IEC 61325-2-6

ORDERING INFORMATION

- 08H67-01 CELL-DYN Ruby analyzer
- 09H04-03 Accessory kit (RoHS)
- 08H02-06 19" Touch screen flat panel display
- 08H14-01 Membrane keyboard

AlinIQ ALWAYS ON

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/hematology

CELL-DYN Ruby is a Class 1 laser product. For *in vitro* diagnostic use only.

Refer to the Operator's Manual for operational precautions, limitations, and hazards. Manuals may be found on the www.corelaboratory.abbott website.

CELL-DYN Ruby, AlinIQ, AbbottLink and CHOOSE TRANSFORMATION are trademarks of Abbott Laboratories in various jurisdictions.

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Rx Only



Declaration of Conformity

Certificate Identification:	SC-08H67
Legal Manufacturer's Name:	Abbott Laboratories
Legal Manufacturer's Address:	Diagnostics Division
	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H67-01	35476	CELL-DYN Ruby	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 and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, 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: Eric Rowsey Position: Director of Quality Date of Approval: 8/18/2016 Date Issued: AUG 25 2016 Supersedes: N/A	Signature:  Full Name: Rosemarie Lulu Position: Regulatory Affairs Project Manager Date of Approval: 30 JUL 2016 Place Issued: Abbott Santa Clara Effective (Date or Lot Number): AUG 29 2016
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Declaration of Conformity

Certificate Identification: SC-08H67
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
08H67-03	35476	CELL-DYN Ruby	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 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: </p> <p>Full Name: <u>Eric Rowsey</u></p> <p>Position: <u>Director of Quality</u></p> <p>Date of Approval: <u>8/18/2016</u></p> <p>Date Issued: <u>AUG 25 2016</u></p> <p>Supersedes: <u>IRIS V6, February 26, 2015</u></p>	<p>Signature: </p> <p>Full Name: <u>Rosemarie Lulu</u></p> <p>Position: <u>Regulatory Affairs Project Manager</u></p> <p>Date of Approval: <u>10 Aug 2016</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>AUG 29 2016</u></p>
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Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018

Expiry date: 12 October 2021

Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

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



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Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



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