Anexa nr.38 la Formularul Specificații tehnice

Analizator hematologic automat 5diff, tip deschis, 60 probe

Specificatia tehnica solicitata	Specificatia tehnica ofertata CELL-DYN Ruby (cod: 08H67-01) (Abbott/USA)
Descriere- Analizator hematologic automat (5 diff), tip deschis 60 probe destinat analizei componenței sanguine cu sistem de tip deschis. Cod 150530 Parametrul Specificația Tip sistem deschis Metode de analiză- 5 diff Procedura de curățire- automată Parametri determinați și calculați: WBC RBC HGB HCT MCV MCH MCHC PLT LYM MID GRA LYM% MID% GRA% RDW-SD RDW-CV PDW-SD PDW-CV MPV PCT. Capacitate (probe/oră)- ≥60 Diluarea- automată Afișaj graphic Imprimantă- încorporată Sistem ID pacient da Introducerea datelor manual Interfața PC da Afișarea histogramelor- da Stocarea datelor- da Calibrarea- automată Histograme: WBC- repartizarea leucocitelor după volum RBC - repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum Afișarea pe ecran a tuturor datelor histograme, rezultate grafice, rezultate din arhivă, date de service Afișarea rezultatelor pe imprimantă - Parametri determinați și calculați - histograme pe parametrii de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare- da Control al calității- în 3 nivele cu construirea graficelor Levey-Janings Limba de comunicare- rom/rus Memorie internă- > 1000 pacienți Accesorii- Vas pentru deșeuri tuburi pentru reagenți tuburi pentru spălare Alimentare 220 V, 50 Hz Certificat- Certificat de la producător ce atestă pregătirea specialiștilor pentru întreținerea tehnică a echipamentului Reagenți Reagenți: "Să fie inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 500 analize" Accesorii, consumabile: Să fie incluse toate acesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 analize Perioada de valabilitate a reagentilor din momentul livrarii ≥ 6 luni	Descriere- Analizator hematologic automat (5 diff), tip deschis 60 probe destinat analizei componenței sanguine cu sistem de tip deschis. Cod 150530 Parametrul Specificația Tip sistem deschis Metode de analiză- 5 diff Procedura de curățire- automată Parametri determinați și calculați: WBC RBC HGB HCT MCV MCH MCHC PLT LYM MID GRA LYM% MID% GRA% RDW-SD RDW-CV PDW-SD PDW-CV MPV PCT. Capacitate (probe/oră)- 88 Diluarea- automată Afișaj graphic Imprimantă- încorporată Sistem ID pacient da Introducerea datelor manual Interfața PC da Afișarea histogramelor- da Stocarea datelor- da Calibrarea- automată Histograme: WBC- repartizarea leucocitelor după volum RBC - repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum Afișarea pe ecran a tuturor datelor histograme, rezultate grafice, rezultate din arhivă, date de service Afișarea rezultatelor pe imprimantă - Parametri determinați și calculați - histograme pe parametrii de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare- da Control al calității- în 3 nivele cu construirea graficelor Levey-Janings Limba de comunicare- rom/rus Memorie internă- 10.000 de rezultate & grafice Accesorii- Vas pentru deșeuri tuburi pentru reagenți tuburi pentru spălare Alimentare 220 V, 50 Hz Certificat- Certificat de la producător ce atestă pregătirea specialiștilor pentru întreținerea tehnică a echipamentului Reagenți Reagenți: "vor fi inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 500 analize" Accesorii, consumabile: vor fi incluse toate acesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 analize Perioada de valabilitate a reagentilor din momentul livrarii ≥ 6 luni Digitally signed by Ceaicovschi Tudor Date: 2022.09.15 12:42:40 EEST Reason: MoldSign Signature Location: Moldova

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 Certifcation Exam

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

Customer Service Organization Certificate of Technical Competence

This is to acknowledge that

Sergiu Sorocovici

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certifcation Exam

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

CELL-DYN Ruby

HEMATOLOGY ANALYZER

GET IT RIGHT THE FIRST TIME

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/hematology

Abbott

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

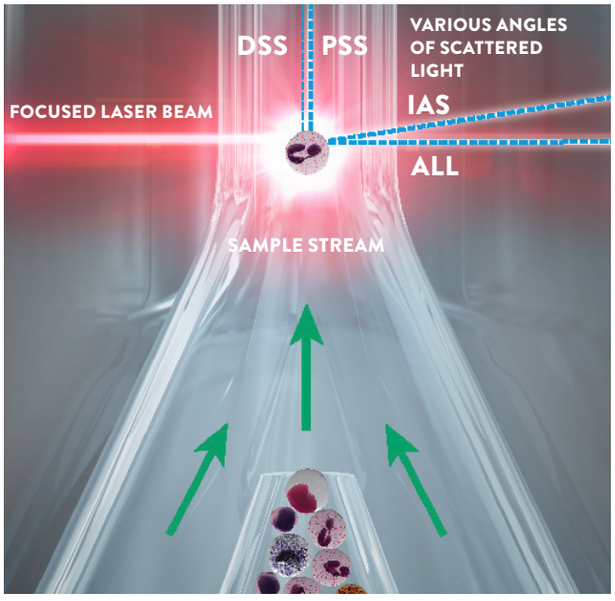
- Only 3 reagents required for CBC with differential
- Real-time reagent status monitoring
- RFID reagents work with AlinIQ Inventory Management System (IMS)

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

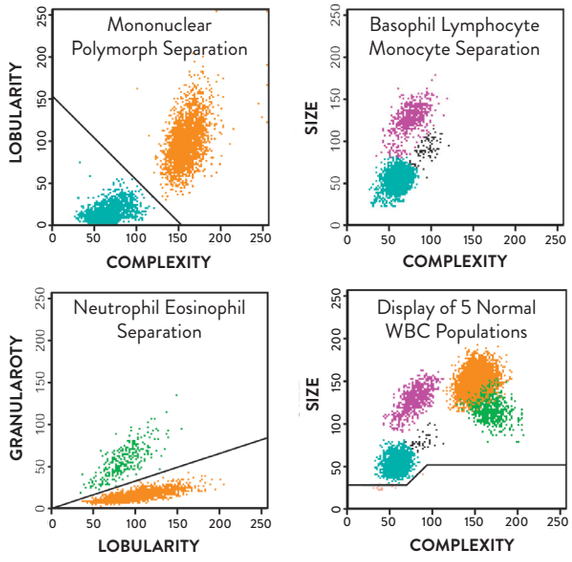
- Axial Light Loss (ALL) provides total count and size of each cell
- Intermediate Angle Scatter (IAS) indicates complexity of intracellular structure
- Polarized Side Scatter (PSS) provides details on granularity and nuclear lobularity, separating mononuclear from polymorphonuclear cells
- Depolarized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



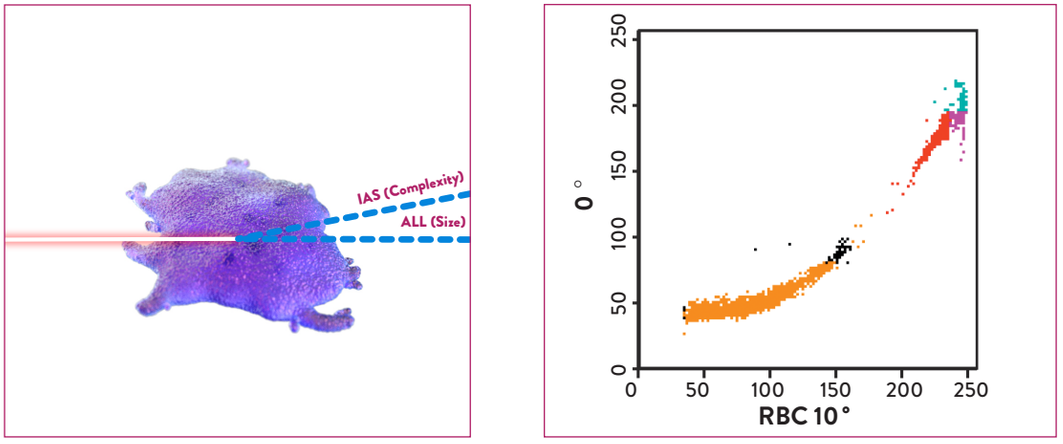
How MAPSS™ differentiates and classifies

	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*

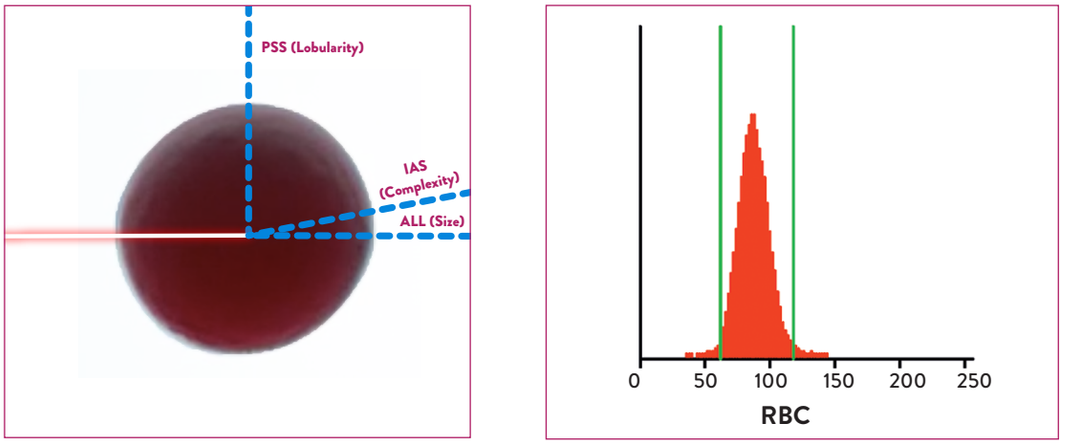


First Pass Optical Platelet Count: Platelets and RBCs are accurately sized and counted by multidimensional laser light scatter. Whole blood is diluted into a proprietary reagent system that optimizes the separation of platelets and RBCs, spheres the RBCs and reduces interference by microcytic red cells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

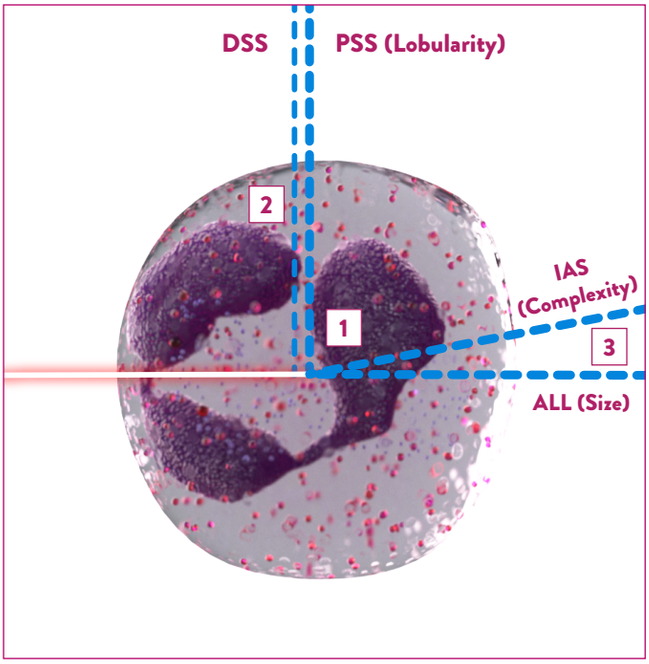


Red cell size and size distributions are displayed using a histogram constructed from the cell-by-cell volume calculated using the 0°, 10° and 90° light scatter measurements of each sphered red blood cell.

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.

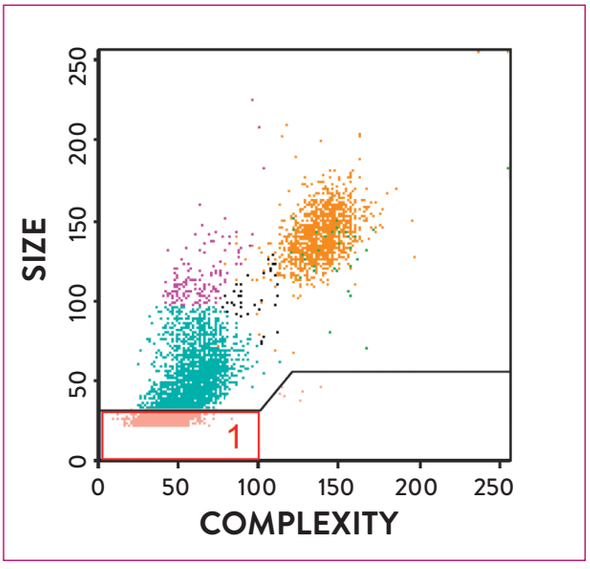


Figure 1: The occurrence of a significant population of cells occurring below the dynamic WBC Optical Count (WOC) threshold can suggest the presence of lysis-resistant RBCs.

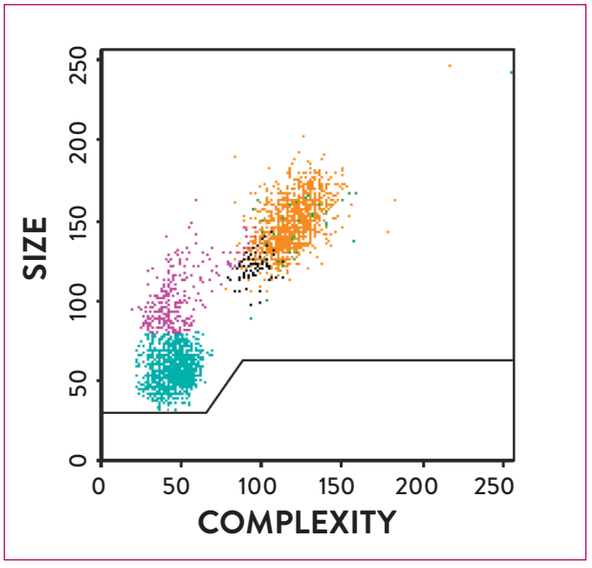


Figure 2: In cases where lysis-resistant RBCs occur, the sample is re-run in the resistant RBC mode to provide the 5 part differential.

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

USER-FRIENDLY SOFTWARE PACKAGE

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

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

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

AlinIQ AMS

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

Rx Only

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.

Abbott

DM000337094	ANALIZATOR HEMATOLOGIC		CELL-DYN RUBY	08H67-01	SUA	ABBOTT LABORATORIES	GBG-MLD S.R.L.	Rg04-000041	15-02-2022

Abbott

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
08H67-01	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:		Signature:	
Full Name:	Eric Rowsey	Full Name:	Rosemarie Lulu
Position:	Director of Quality	Position:	Regulatory Affairs Project Manager
Date of Approval:	8/18/2016	Date of Approval:	30 JUL 2016
Date Issued:	AUG 25 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	AUG 29 2016

Abbott

Declaration of Conformity

Certificate Identification: SC-08H67

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

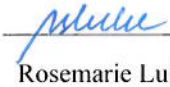
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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.

Signature:		Signature:	
Full Name:	Eric Rowsey	Full Name:	Rosemarie Lulu
Position:	Director of Quality	Position:	Regulatory Affairs Project Manager
Date of Approval:	8/18/2016	Date of Approval:	10 Aug 2016
Date Issued:	AUG 25 2016	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6, February 26, 2015	Effective (Date or Lot Number):	AUG 29 2016

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

...making excellence a habit.™

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

Abbott Laboratories

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 UNITED STATES

D-U-N-S ID No. 001307602

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design, development and manufacture of diagnostic test kits and reagents.

The design and manufacture of in-vitro diagnostic medical devices, used in the screening of blood donor units for transmissible diseases. The 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.

With additional locations listed on Addendum: 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A18075	Cycle Start Date	December 1, 2017
Certificate Number	1068.180319	Effective Date	March 19, 2018
Initial Issue Date	December 1, 2017	Expiry Date	November 30, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE OF REGISTRATION

Abbott Laboratories

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 UNITED STATES

D-U-N-S ID No. 001307602

Addendum 1

2 - OS
Located at:

Route 41 & Martin Luther King Drive
North Chicago , IL 60064 UNITED STATES
D-U-N-S ID No. **078524918**

Performing: QC inspection of incoming materials and products. The storage and distribution of in vitro diagnostic reagents, test kits and accessories.

3 - S
Located at:

6131 RFD Oakwood Road
Long Grove , IL 60064 UNITED STATES
D-U-N-S ID No. **113839302**

Performing: Antibody production.

File Number	A18075	Cycle Start Date	December 1, 2017
Certificate Number	1068.180319	Effective Date	March 19, 2018
Initial Issue Date	December 1, 2017	Expiry Date	November 30, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
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UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

00-MB-S0043 Issue 15.0

CERTIFICATE OF REGISTRATION

Abbott Laboratories

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 UNITED STATES

D-U-N-S ID No. 001307602

Additional Regulatory Requirements
Australia:
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [if design controls are part of the certification];

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 (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

File Number	A18075	Cycle Start Date	December 1, 2017
Certificate Number	1068.180319	Effective Date	March 19, 2018
Initial Issue Date	December 1, 2017	Expiry Date	November 30, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
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333 Pfingsten Road
Northbrook, IL 60062-2096 USA