Anexa A

la Termenii si Condițiile de Livrare

Detalii specifice și standarde tehnice

Lotul nr. 1 Analizator hematologic, automat (5 diff), cu sistem de tip închis, imprimanta color

Nr.	Denumire produs	Specificații (minime obligatorii) solicitate		Specificații tehnice oferite
1.	**Analizator hematologic, automat (5 diff), cu sistem de tip închis, imprimanta color** **COD - 150540**	**Descriere**	**Analizator hematologic automat (5 diff) cu sistem de reactivi de tip închis destinat analizei componenței sanguine**	**CELL-DYN Ruby (cod: 08H67-01) (Abbott Laboratories Diagnostic Division/USA)**
		Parametru	**Specificația**	
		Tip sistem	închis	închis
		Metode de măsurare	impendansmetrică	impendansmetrică
			fotometrică	Fotometrica, cu reactv cian-free
			optică (5 diff)	optică (5 diff)
		Procedura de curățire	automată	automata
		Parametri determinați și calculați:	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/oră)	≥100	88 probe/h
		Diluarea	automată	automată
		Afişaj	grafic	grafic
		Imprimantă	color	color
		Introducerea datelor	manual	manual
		Interfaţa PC	da	da
		Afişarea histogramelor	Da	Da
		Stocarea datelor	da	da
		Calibrarea	automată	automată
			manuală	manuală
		Grafice	RBC (repartizarea eritrocitelor după volum)	RBC (repartizarea eritrocitelor după volum)
			PLT (repartizarea trombocitelor după volum)	PLT (repartizarea trombocitelor după volum)
		Scatergrame	WBC - 5 diff	WBC - 5 diff
		Afişarea pe ecran a tuturor datelor-	histograme	histograme
			rezultate	rezultate
			grafice	grafice
			rezultate din arhivă	rezultate din arhivă
			date de servis	date de servis
		Sistem ID reactiv	cititor barcod intergrat	cititor barcod intergrat
		Monitorizarea datelor pacientului	nume pacient	nume pacient
			ID pacient	ID pacient
			sex	sex
			vîrsta	vîrsta
		Monitorizarea datelor pacientului	numărul lotului	numărul lotului
			data expirării	data expirării
			volumul rămas	volumul rămas
		Afişarea rezultatelor pe imprimantă	Parametri determinaţi şi calculaţi	Parametri determinaţi şi calculaţi
			histograme pe parametrii de bază- RBC, WBC, PLT	histograme pe parametrii de bază- RBC, WBC, PLT
			date despre pacient	date despre pacient
		Indicatori de avertizare	da	da
		Control al calităţii	în 6 nivele	în 6 nivele
			Construirea tabelelor și graficelor Levey-Janings	Construirea tabelelor și graficelor Levey-Janings
		Memorie internă	> 1000 pacienți	10.000 de rezultate & grafice
		Alimentarea	220 V, 50 Hz	220 V, 50 Hz

		Accesorii	Vas pentru deșeuri	Vas pentru deșeuri
			tuburi pentru reagenți	tuburi pentru reagenți
			tuburi pentru spălare	tuburi pentru spălare
		Garanția	Min. 12 luni Prezența certificatului de garanție obligatorie	12 luni. Prezența certificatului de garanție
		CERTIFICĂRI	Se vor accepta doar dispozitive marcate CE certificate conform directivei 93/42 sau a Regulamentului 2017/745 și incluse în Registrul de Stat al Dispozitivelor Medicale; 1. Certificat de conformitate CE emis de către un organism de evaluare a conformității inclus în lista NANDO - https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main 2. Declarația de conformitate CE emisă în baza directivei 93/42 EEC sau a Regulamentului 2017/745 care face trimitere la certificatul de conformitate CE prin număr sau prin codul NOTIFY BODY. 3. ISO 13485/9001 - Sistemul de management al Calității 4. Raportul din documentația tehnică „ESSENTIAL REQUIEREMENT”	ISO 13485; ISO 9001; Declaratie de Conformitate STANDARDS & SAFETY COMPLIANCE:
		ETICHETA/MANUAL DE UTILIZARE	1. ETICHETA se prezintă în limba de stat și în una din limbile de circulație internațională conform H.G. 702 „pentru aprobarea Regulamentului privind condiţiile de introducere pe piaţă a dispozitivelor medicale” Secţiunea a 7-a. „Informaţii furnizate de producător” și anume pct. 48. 2. INSTRUCȚIUNEA DE UTILZARE - se prezintă în limba de stat și în una din limbile de circulație internațională conform H.G. 702 „pentru aprobarea Regulamentului privind condiţiile de introducere pe piaţă a dispozitivelor medicale” Secţiunea a 7-a. „Informaţii furnizate de producător” și anume pct. 51.	

Furnizor: « GBG-MLD » SRL
Adresa Furnizorului: str. Albisoara 64/2, mun. Chisinau, MD 2005.
Tel: 022 54 73 73 Fax: 022 54 73 73
E-mail: office@gbg.md
Semnătura autorizată: _____
Numele si funcția semnatarului: Tudor CEAICOVSCHI, Director General
Data: 05.12.2022 L.Ş.

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

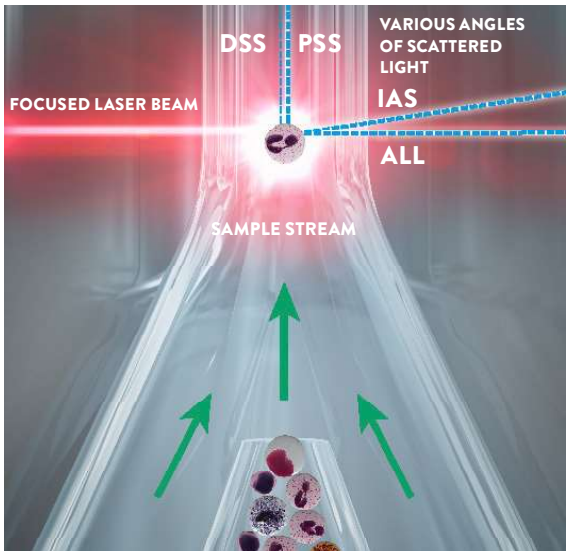
- Only 3 reagents required for CBC with differential
- Real-time reagent status monitoring
- RFID reagents work with AlinIQ Inventory Management System (IMS)

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

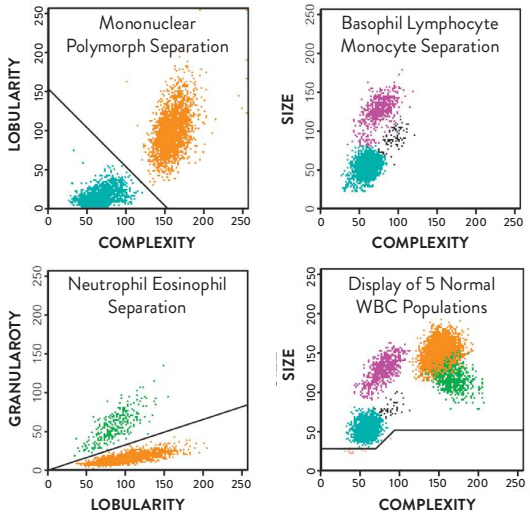
- Axial Light Loss (ALL) provides total count and size of each cell
- Intermediate Angle Scatter (IAS) indicates complexity of intracellular structure
- Polarized Side Scatter (PSS) provides details on granularity and nuclear lobularity, separating mononuclear from polymorphonuclear cells
- Depolarized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



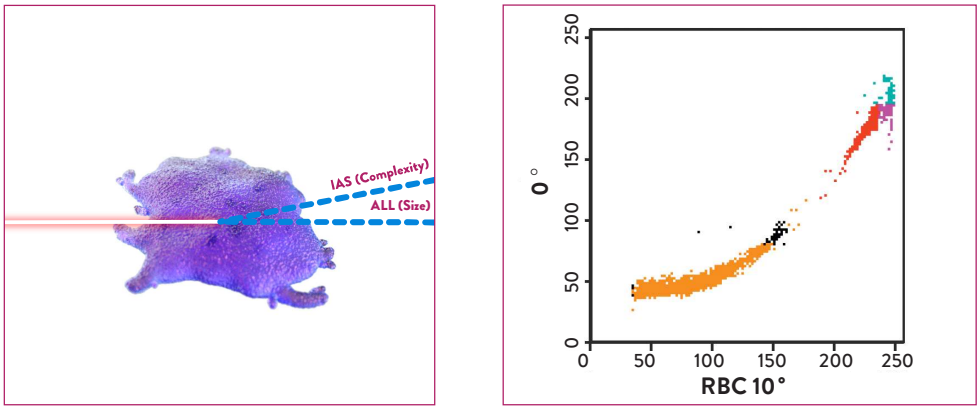
How MAPSS™ differentiates and classifies

	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*

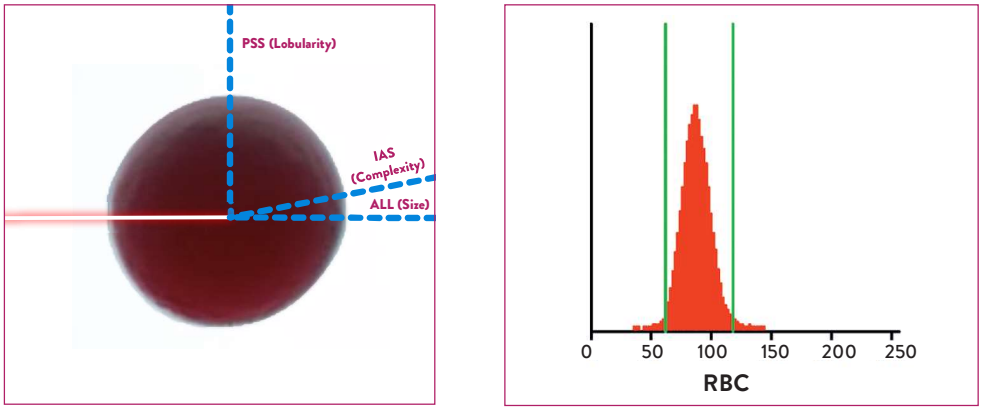


First Pass Optical Platelet Count: Platelets and RBCs are accurately sized and counted by multidimensional laser light scatter. Whole blood is diluted into a proprietary reagent system that optimizes the separation of platelets and RBCs, spheres the RBCs and reduces interference by microcytic red cells 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 0º, 10º and 90º by light scatter detectors enable exquisite accuracy of RBCs and reticulocytes
- Reticulocyte assay based upon NCCLS/ICSH methods

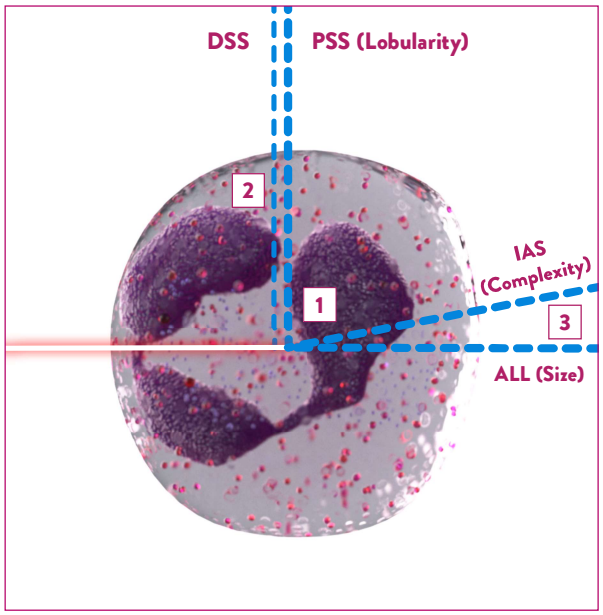


Red cell size and size distributions are displayed using a histogram constructed from the cell-by-cell volume calculated using the 0°, 10° and 90° light scatter measurements of each sphered red blood cell.

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.

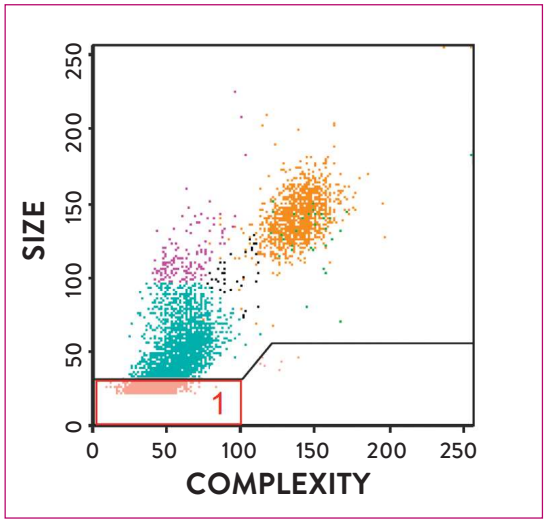


Figure 1: The occurrence of a significant population of cells occurring below the dynamic WBC Optical Count (WOC) threshold can suggest the presence of lysis-resistant RBCs.

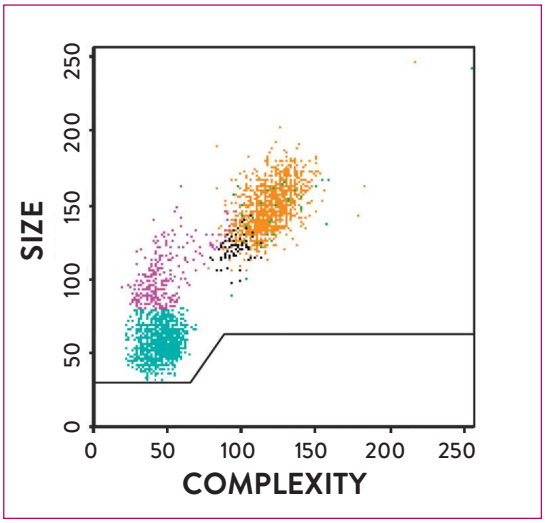


Figure 2: In cases where lysis-resistant RBCs occur, the sample is re-run in the resistant RBC mode to provide the 5 part differential.

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

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
Effective Date: 2021-10-13
Latest Revision Date: 2022-04-12
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

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

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

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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

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

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Certificates may be verified by visiting the Online Certifications Directory on UL.com.

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

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

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

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