Anexa nr. 10 la Formularul Specificații tehnice

Analizator hematologic automat 3diff, tip deschis, 40 probe

Specificatia tehnica solicitata	Specificatia tehnica ofertata Cell-Dyn Emerald OT18 (Abbott/USA)
Descriere- Analizator hematologic automat (3 diff), tip deschis 40 probe destinat analizei componenței sanguine cu sistem de tip deschis. Cod 150510 Parametrul Specificația Tip sistem deschis	Descriere- Analizator hematologic automat (3 diff) destinat analizei componenței sanguine cu sistem deschis de reactivi. Parametrul Specificația Tip sistem deschis. Sistem deschis care utilizeaza doar 3 reactivi:diluent, liza, cleaner (reactivul de liza este fara cianuri) Are posibilitate de inchidere programata si inchidere manuala; • Cititor de cod de bare extern, in echipare standard • Intretinere zilnica si saptaminala= ZERO • mai putin de o interventie service/an
Metode de analiză- 3 diff	Metode de analiză- 3 diff. CD Emerald are la baza tehnologie impedanta electronica pentru diferentierea RBC si PLT si WBC numar total si spectrofotometrie.
Procedura de curăţire- automată	Procedura de curăţire- automată. Mentananta CD Emerald este automata. Întreținerea zilnică este procedură automată și întreținerea saptamanala automata. **Avantaj:** Procedurile de intretinere sunt memorate in soft-ul aparatului si pot fi printate pentru documentatia laboratorului.
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)- ≥40 Diluarea- automată Afișaj graphic Imprimantă- încorporată	Parametri determinați și calculați: WBC RBC HGB HCT MCV MCH MCHC PLT LYM# MID# GRAN# LYM% MID% GRAN% RDW-SD RDW-CV PDW-SD PDW-CV MPV PCT Capacitate (probe/oră)- **Procesare 40 probe/ora** Diluarea- automată Afișaj graphic. Da, monitor color cu touch screen Imprimantă- încorporată.
Sistem ID pacient da	Sistem ID pacient da, posibilitate date demografice • datalog numeric • identificare alfanumerica a pacientului PID • identificare alfanumerica a probei SID • data/ora • nume pacient • hemoleucograma 3-part diff • sistem de flag si alerta
Introducerea datelor manual Interfaţa PC da	**Introducerea datelor manual** **Interfaţa PC** da. Posibilitate de conectare la internet: (TCP/IP) si RS232.
Afişarea histogramelor- da Stocarea datelor- da Calibrarea- automată Histograme: WBC- repartizarea leucocitelor după volum RBC - repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum Afişarea pe ecran a tuturor datelor histograme, rezultate grafice, rezultate din arhivă, date de service	**Afişarea histogramelor- da** **Stocarea datelor- da** **Calibrarea- automată** **Histograme:** WBC- repartizarea leucocitelor după volum RBC - repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum **Afişarea pe ecran a tuturor datelor histograme rezultate grafice rezultate din arhivă date de service**
Afişarea rezultatelor pe imprimantă - Parametri determinați și calculați - histograme pe parametrii de bază- RBC, WBC, PLT, date despre pacient	**Afişarea rezultatelor pe imprimantă - Da** -Aparatul are capacitatea de a accesa si printa datele in orice moment; Are posibilitate de printare automata (s) legare la o imprimanta externa
Indicatori de avertizare- da	• Raportul tiparit (printat) contine: Limitele de referinta cu atenționari (flag) pentru valorile care

Control al calităţii- în 3 nivele cu construirea graficelor Levey-Janings Limba de comunicare- rom/rus Memorie internă- > 1000 pacienţi Accesorii- Vas pentru deşeuri tuburi pentru reagenţi 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	depasesc limitele stabilite; • Are trei sisteme de unitati de masura: USA (Standard) , Sistem de Unitati Internationale (SI), SI modificat- mod in mmol. • Operatorul poate defini 4 seturi de valori de referinta - Parametri determinaţi şi calculaţi - histograme pe parametrii de bază- RBC, WBC, PLT, date despre pacient **Indicatori de avertizare-** da **Control al calității- 3 nivele de control- scazut, normal si crescut** , cate 2 din fiecare nivel; Control intern de calitate • 6 fisiere de control intern • 100 de teste/ fisier • grafice Levey-Jenings pentru interpretare control intern • posibilitate de incarcare/stergere fisiere control • Capacitatea de a incarca si descarca informatii despre QC Via port USB • Conexiune LIS graficelor Levey-Janings Limba de comunicare- rom/rus **Memorie internă- se pot memora pana la 1500 date de pacient cu histograme;** Functie de capacitatea USB se poate mari numarul de date pacient stocate pana la 60000 fisiere. **Accesorii**- Vas pentru deşeuri tuburi pentru reagenţi tuburi pentru spălare. Aparatul poate utiliza orice vas pentru deseuri- **Avantaj**- Aparatul adapteaza orice vas si se mentioneaza capacitatea acestuia in analizor- 1l, 5L, 10L apoi analizorul calculeaza waste-ul si avertizeaza ca vasul de deseuri este plin. Alimentare 220 V, 50 Hz . **Avantaj: Nu are pompe- este silentios** • Nu necesita ventilator, filtru sau sigurante pentru curatare si Maintenanta. Certificat-Certificat de la producător ce atestă pregătirea specialiștilor pentru întreținerea tehnică a echipamentului Reagenți Reagenți: Vor 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

Abbott

Declaration of Conformity

Certificate Identification:	SC-09H39
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
09H39-01	35476	CELL-DYN Emerald Instrument	**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 C2 Diagnostics, Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
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:	Kevin Richardson	Signature:	Rosemarie Lulu
Full Name:	Kevin Richardson	Full Name:	Rosemarie Lulu
Position:	Manager, Supplier Quality	Position:	Regulatory Affairs Project Manager
Date of Approval:	29 JUNE 2016	Date of Approval:	28 June 2016
Date Issued:	JUN 29 2016	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 (Feb 26, 2015)	Effective (Date or Lot Number):	JUL 01 2016

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan

TRAINER NAME

ABBOTT DIAGNOSTICS

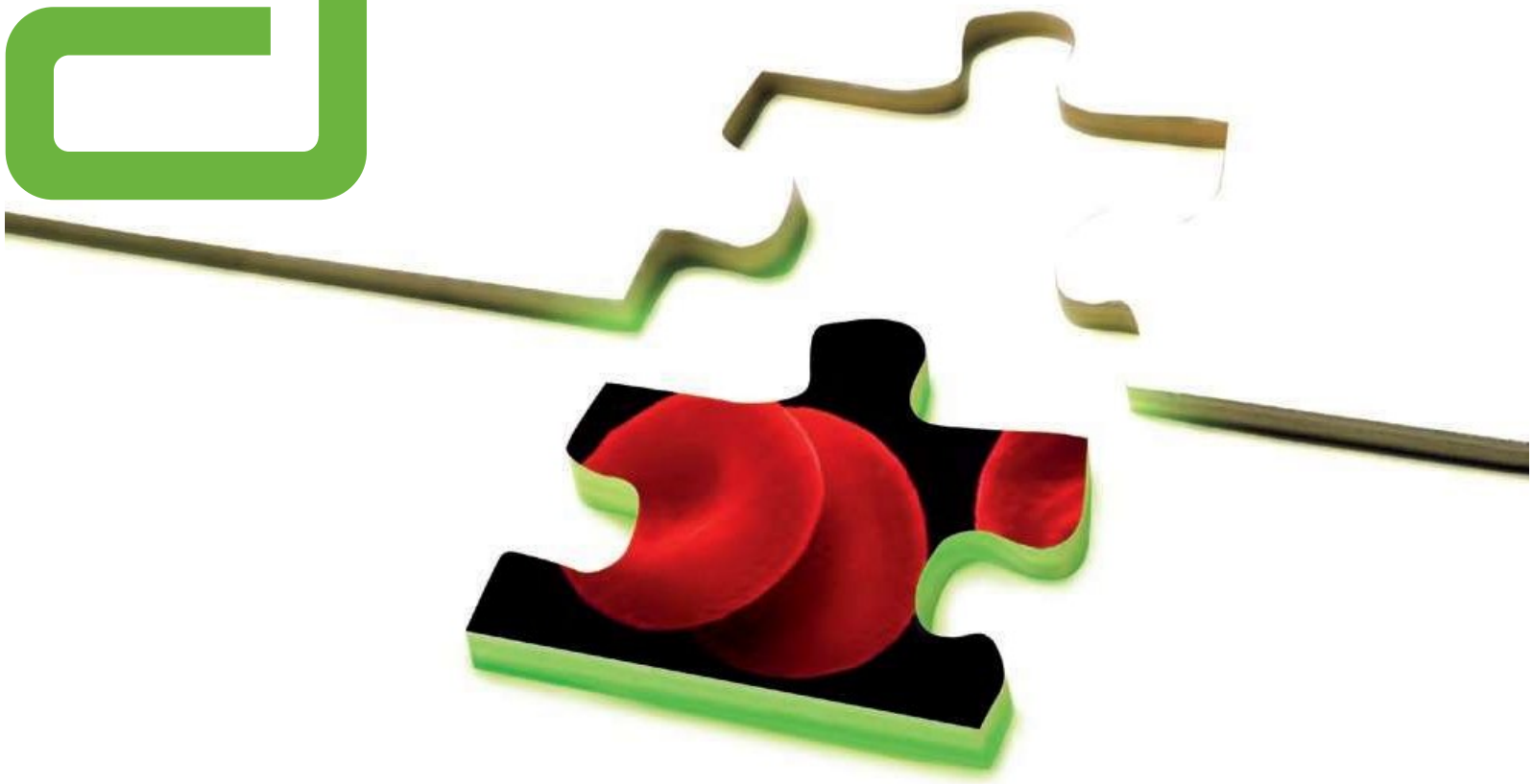
TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

Abbott



Компактный. Мощный. Безупречно точный.

Высокая производительность при очень компактных размерах

- Надежные и точные результаты
- Внешний считыватель штрих-кода
- Русскоязычное меню
- Включение одной кнопкой
- Автоматическое выключение
- Бесшумный и легкий

Быстрый и простой в использовании

- Результат CBC менее, чем за 60 секунд
- Небольшой объем образца (9,8 мкл)
- Экономичный расход реагентов
- Нет ежедневного и еженедельного обслуживания

Put science on your side.

Abbott
A Promise for Life

CELL-DYN Emerald

Технические характеристики

Основное меню

Технологии и методы
- Электрический импедансный подсчет
- Адсорбционная спектрофотометрия
- Электронные клапаны
- Бесцианидные реагенты
- Цветной жидкокристаллический сенсорный экран
- RS-232 и TCP/IP LIS интерфейсы
- USB порты

Производительность
- До 60 образцов в час

Объем образца
- 9,8 мкл

Система управления данными
- Поиск по дате и порядковому номеру
- Расстановка флагов для границ нормальных значений
- Расстановка флагов для критических значений
- Хранение в памяти до 1500 результатов с гистограммами
- Сохранение до 60000 результатов на внешнем USB-носителе (флэшке)
- Программируемые границы нормальных значений
- Программируемые единицы измерения (для вывода на печать)
- Внешний считыватель штрих-кода (считывает code 128, code 39, interleaved 2 of 5)

Система контроля качества
- 6 контрольных файлов
- 100 измерений в файле
- Графики Леви-Дженнингса
- Возможность загрузки контрольной информации с внешнего носителя
- Программа внешнего контроля качества в режиме on-line.

Данные пациента
- Порядковый номер
- Буквенно-цифровая идентификация образца
- Буквенно-цифровая идентификация пациента
- Время и дата проведения анализа
- Имя пациента
- CBC с подсчетом 3-х популяций лейкоцитов
- Расстановка флагов и предупреждений

Предупреждение о разбросе данных
- Определяемые оператором границы верхнего и критического значений для пациента
- Определяемые системой границы аналитических измерений и регистрируемых значений
- Флаги о сомнительных результатах вследствие интерференции или патологии образца
- Флаги о сомнительных результатах, когда подсчет лейкоцитов свидетельствует о возможном наличии патологической популяции

Соответствие стандартам и требованиям безопасности
- UL61010A-1
- CE Mark (Европейское соответствие)
- CAN/CSA C22.2 No.1010.1-92
- ETL Mark (США)
- IEC 61000-3-2, 3-3, 4-2, 4-3, 4-4, 4-5, 4-6, 4-8, 4-11
- Harmonic emissions
- EN 55011 и EN 61000

Периферийные устройства
- Матричный или струйный принтер
- USB носитель (флэшка)
- Внешний считыватель штрих-кода

Габариты
- Высота 35 см
- Ширина 25 см
- Глубина 35 см
- Вес 9 кг (без учета реагентов)

Определяемые параметры

Лейкоциты	Эритроциты	Тромбоциты
WBC	RBC	PLT
LYM #	HGB	MPV
LYM %	HCT	PDW*
MID #	MCV	PCT*
MID %	MCH	
GRAN #	MCHC	
GRAN %	RDW	

* Клиническая значимость для этих величин не установлена и они не используются в лабораториях США.

Реагенты для CELL-DYN Emerald

Описание	Объем	Каталожный номер
Лизирующий реагент, бесцианидный (CN-Free Diff Lyse)	960 мл	09H47-02
Дилюент (Diluent)	10 л	09H48-02
Очищающий реагент (Cleaner)	960 мл	09H46-02

Контроли и калибраторы для CELL-DYN Emerald

Описание	Объем	Каталожный номер
Калибратор CELL-DYN 18 Plus Calibrator	2 x 2,5 мл	99110-01
Контроль CELL-DYN 18 Plus Control	12 x 2,5 мл	99109-01
Контроль CELL-DYN 18 Plus Control	6 x 2,5 мл	99105-01

ООО «Эбботт Лэбораториз»
Диагностическое отделение
141400, Россия, Московская область,
г. Химки, ул. Ленинградская,
владение 39, строение 5,
Тел.: (495) 258 42 70
Факс: (495) 258 42 71
www.abbottdiagnostics.com

Abbott Hematology

CELL-DYN EMERALD

HEMATOLOGY ANALYZER

Fast, Accurate, with Easy Results Everytime

High performance in an affordable, compact design

- Reliable and accurate patient results
- Barcode reader
- Multiple languages available
- Open-mode one touch operation
- Auto startup and shutdown
- Lightweight - only 19.8 lbs. (9 kg)

Fast and easy to use

- Results in approximately 60 seconds
- Small sample size
- Low reagent consumption
- Zero daily and weekly maintenance

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/cell-dyn-emerald

Abbott

CELL-DYN EMERALD

TECHNICAL SPECIFICATIONS

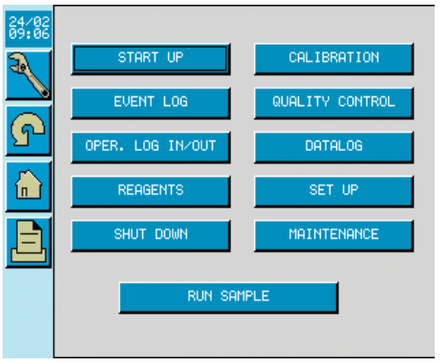
ITEM	SPECIFICATIONS
Technology & Methods	• Electronic impedance • Absorption spectrophotometry • Electronic valves • Cyanide-free lyse reagent • LCD color touch screen • RS232 and TCP/IP LIS interface • USB ports
Throughput	• Up to 57 samples per hour
Sample Size	• ~9.8 µL
Specimen Data Management	• Search by date or sequence number • Flagging for patient limit sets • Flagging for panic values • 1,500 records with histograms on internal memory • Up to 300,000 records on external USB thumb drive • Programmable patient limits • Programmable report units • Barcode reader (reads code 128, code 39, interleaved 2 of 5, and others listed in the Operator's Manual)
Quality Control	• 6 control files • 100 runs per file • Levey-Jennings graphs • Upload/download control information • eQC Online peer review program
Demographics	• Sequence number • Alphanumeric specimen ID • Alphanumeric patient ID • Date & time analyzed • Patient name • CBC with 3-part differential • Flagging and Alerts
Dispersional Data Alert	• Operator-defined patient limits for high and panic values • System-defined limits for reportable range and analytical measurement range • Suspect parameter flags caused by interfering substances or sample abnormalities • Suspect parameter flags generated when WBC data indicates possible presence of an abnormal population
Standards & Safety Compliance	• IEC 61010-1 • EN 61326-1 • CE Mark
Peripheral Devices	• Inkjet or laser printer • USB thumb drive • Handheld barcode scanner
Physical Dimensions	• Height 13.8 in. (35 cm) • Width 9.8 in. (25 cm) • Depth 13.8 in. (35 cm) • Weight 19.8 lbs. (9 kg) (without on-board reagents)

PARAMETERS		
White Cells	**Red Cells**	**Platelets**
WBC	RBC	PLT
LYM #	HGB	MPV
LYM %	HCT	
MID #	MCV	
MID %	MCH	
GRAN	MCHC	
GRAN %	RDW	

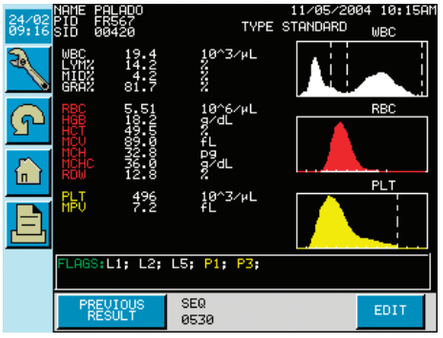
REAGENTS	
Reagent Description	**Size and List Number**
CN-Free Diff Lyse	960 mL (List No. 09H47-02)
Diluent	10 L (List No. 09H48-02)
Cleaner	960 mL (List No. 09H46-02)

CONTROLS & CALIBRATORS	
CELL-DYN 18 Plus Calibrator	09H70-01
CELL-DYN 18 Plus Control	09H69-01 09H69-02

MAIN MENU



DATALOG FILE



CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance.

www.corelaboratory.abbott/cell-dyn-emerald

For In Vitro Diagnostic Use Only. Refers to the Operator's Manual for operational precautions, limitations, and hazards.

Abbott

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				09H39					
DM000337091	ANALIZATOR HEMATOLOGIC		CELL-DYN EMERALD INSTRUMENT	09H39-01	SUA	ABBOTT LABORATORIES	GBG-MLD S.R.L.	Rg04-000041	15-02-2022
DM000303850	ANALIZATOR HEMATOLOGIC AUTOMAT		CELL-DYN Emerald Instrument	09H39-01	SUA	ABBOTT LABORATORIES	GBG-MLD S.R.L.	Rg04-000052	01-03-2021

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.
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

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.
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