

**Anexa nr.1 la Formularul Specificații tehnice**

**Analizator hematologic, automat (3diff), tip deschis, 30 probe**

**model CELL-Dyn Emerald (ABBOTT, SUA)**

| SPECIFICATII TEHNICE SOLICITATE    |                                                                                                              | SPECIFICAȚII TEHNICE OFERTATE, model CELL-Dyn Emerald, de producție ABBOTT, SUA.                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Descriere                          | Analizator hematologic automat (3 diff) destinat analizei componentei sanguine cu sistem deschis de reactivi | CELL-Dyn Emerald – analizor automat de hematologie 3 diff<br><b>Aparat de sine statator</b> , unitate de masurare fara sursa de alimentare externa sau modul pneumatic extern.<br><b>Avantaj:</b> Aparatul este foarte mic si compact( poate fi plasat si in biroul medicului)- brosură atasată <ul style="list-style-type: none"> <li>• Rezultat in mai puțin de 60 secunde</li> </ul> Poate fi programat sa porneasca automat dimineata la o anumita ora si sa se inchida automat seara |
| Tip sistem                         | deschis                                                                                                      | Sistem deschis care utilizeaza doar 3 reactivi (diluent, liza, cleaner) <ul style="list-style-type: none"> <li>• Cititor de cod de bare extern, in echipare standard</li> <li>• Intretinere zilnica si saptaminala= ZERO</li> </ul>                                                                                                                                                                                                                                                       |
| Metode de analiza                  | 3 diff                                                                                                       | <ul style="list-style-type: none"> <li>• CD Emerald are la baza tehnologia de impedanta electronica pentru diferentierea RBC si PLT si WBC numar total si Spectrofotometrie.</li> </ul>                                                                                                                                                                                                                                                                                                   |
| Procedura de curatire              | automata                                                                                                     | Mentenanța CELL-Dyn Emerald este automata.<br>Întreținerea zilnică este procedură automată și întreținerea săptămânală automata.<br><b>Avantaj:</b> Procedurile de intretinere sunt memorate in soft-ul aparatului si pot fi printate pentru documentatia laboratorului.                                                                                                                                                                                                                  |
| Parametri determinati si calculati |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                    | WBC                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | RBC                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | HGB                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | HCT                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | MCV                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | MCH                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | MCHC                                                                                                         | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | PLT                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | LYM                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | MID                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | GRA                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | LYM%                                                                                                         | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | MID%                                                                                                         | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | GRA%                                                                                                         | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | RDW-SD                                                                                                       | RDW                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                    | RDW-CV                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                    | PDW-SD                                                                                                       | PDW                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                    | PDW-CV                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                    | MPV                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                    | PCT                                                                                                          | DA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Capacitate (probe/ora)             | >30                                                                                                          | Procesare 60 probe/ora                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Diluarea                           | automata                                                                                                     | Volumul de proba necesar foarte mic 9.8 uL- de aceea                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                            |                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                            |                                                  | nu are nevoie de dilutie automata<br><b>Avantaj:</b> liniaritate foarte buna pentru WBC, RBC, PLT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Afisaj</b>                              | <b>grafic</b>                                    | Da, monitor color cu touch screen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Imprimantă</b>                          | <b>incorporata</b>                               | Da, aparatul este dotat cu imprimata                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Sistem ID pacient</b>                   | <b>da</b>                                        | Da, si posibilitate Date demografice <ul style="list-style-type: none"> <li>• datalog numeric</li> <li>• identificare alfanumerica a pacientului PID</li> <li>• identificare alfanumerica a probei SID</li> <li>• data/ora</li> <li>• nume pacient</li> <li>• hemoleucograma 3-part diff</li> <li>• sistem de flag si alerta</li> </ul>                                                                                                                                                                                                                                                                           |
| <b>Introducerea datelor manual</b>         | <b>da</b>                                        | Da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Interfata PC</b>                        | <b>da</b>                                        | Posibilitate de conectare la internet: (TCP/IP) si RS232                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Afisarea histogramelor</b>              | <b>da</b>                                        | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Stocarea datelor</b>                    | <b>da</b>                                        | <ul style="list-style-type: none"> <li>• Computer intern si nu necesita PC extern; memorie interna cu 15000 ;intre 10.000 si 60.000 prin cablu USB</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Calibrarea</b>                          | <b>automata</b>                                  | <b>da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Histograme</b>                          | <b>WBC-repartizarea leucocitelor dupa volum</b>  | <b>da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                            | <b>RBC-repartizarea eritrocitelor dupa volum</b> | <b>da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                            | <b>PLT-repartizarea trombocitelor dupa volum</b> | <b>da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Afisarea pe ecran a tuturor datelor</b> | histograme                                       | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | rezultate                                        | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | grafice                                          | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | rezultate din arhiva                             | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | date de service                                  | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Afisarea rezultatelor pe imprimanta</b> | Parametri determinate si calculati               | <ul style="list-style-type: none"> <li>• Da -Aparatul are capacitatea de a accesa si printa datele in orice moment ; Are posibilitate de printare automata si legare la o imprimanta externa</li> <li>• Raportul tiparit ( printat) cuprinde:</li> </ul> <p>Limitele de referinta cu atentionari ( flag) pentru valorile care depasesc limitele stabilite;</p> <ul style="list-style-type: none"> <li>• Are trei sisteme de unitati de masura: USA ( Standard) , Sistem de Unitati Internationale ( SI), SI modificat- mod in mmol.</li> <li>• Operatorul poate defini 4 seturi de valori de referinta</li> </ul> |
|                                            | histograme pe parametrii de baza RBC, WBC, PLT   | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | date despre pacient                              | da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Indicatori de avertizare</b>            | <b>da</b>                                        | Da<br><b>Avantaj:</b> CELL-Dyn Emerald oferă semnalizarea cu acuratete ( flag-uri) pentru depasirea celule anormale sau valori de panica ;<br>Sistem de alerta <ul style="list-style-type: none"> <li>• limite de valori crescute/panica setate de</li> </ul>                                                                                                                                                                                                                                                                                                                                                     |

|                                                                     |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                     |                                                                                                                                    | <p>operator</p> <ul style="list-style-type: none"> <li>• flag pentru posibile interferente si probe cu anomalii</li> <li>• flag pentru posibila prezenta de populatii anormale in seria alba</li> <li>• valori de referinta definite in sistem</li> </ul>                                                                                                                                                                                                                                       |
| <b>Control calitatii</b>                                            | al in 3 nivele                                                                                                                     | <p>6 fisiere de control- 3 nivele de control- scazut, normal si crescut , cate 2 din fiecare nivel; Control intern de calitate</p> <ul style="list-style-type: none"> <li>• 6 fisiere de control intern</li> <li>• 100 de teste/ fisier</li> <li>• grafice Levey-Jenings pentru interpretare control intern</li> <li>• posibilitate de incarcare/stergere fisiere control</li> <li>• Capacitatea de a incarca si descarca informatii despre QC Via port USB</li> <li>• Conexiune LIS</li> </ul> |
|                                                                     | Construirea tabelor si graficelor Levey Jenings                                                                                    | <p>Da</p> <p><b>Avantaj:</b> Programul de control intern QC trebuie sa includa 6 fisiere QC cu stocare pentru 100 teste per Fisier</p> <p><b>Se ofera gratuit posibilitate de control interlaboratoare eQC</b></p>                                                                                                                                                                                                                                                                              |
| <b>Limba de comunicare</b>                                          | rom/rus                                                                                                                            | rom/rus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Memorie interna</b>                                              | > 500 pacienti                                                                                                                     | Da - 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                                                                                                                                                                                                                                                                                                                                   |
| <b>Accesorii</b>                                                    | Vas pentru deseuri                                                                                                                 | <p>Aparatul poate utiliza orice vas pentru deseuri-</p> <p><b>Avantaj-</b> 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.</p>                                                                                                                                                                                                                                   |
|                                                                     | tuburi pentru reagenti                                                                                                             | Da                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                     | tuburi pentru spalare                                                                                                              | <p>da</p> <p><b>Avantaj:</b> Aparatul are un sistem propriu de curatare intern si extern pentru acul de proba pentru a minimiza biohazard-ul</p>                                                                                                                                                                                                                                                                                                                                                |
| <b>Alimentarea</b>                                                  | 220 V, 50 Hz                                                                                                                       | <p><b>220 V, 50 Hz;</b></p> <p><b>Avantaj: Nu are pompe- este silentios</b></p> <ul style="list-style-type: none"> <li>• Nu necesita ventilator, filtru sau sigurant pentru curatare si Maintinanta</li> </ul>                                                                                                                                                                                                                                                                                  |
| <b>Reagenti</b>                                                     | Sa fie inclusi toti reagentii necesari pentru efectuarea analizelor si buna functionare pentru $\geq 1000$ probe                   | <b>Da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Accesorii, consumabile</b>                                       | Sa fie incluse toate accesoriile, consumabilele necesare pentru efectuarea analizelor si buna functionare pentru $\geq 1000$ probe | <b>Da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Perioada de valabilitate a reagentilor din momentul livrarii</b> | $\geq 6$ luni                                                                                                                      | <b>Da</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |



# CELL-DYN EMERALD

## HEMATOLOGY ANALYZER

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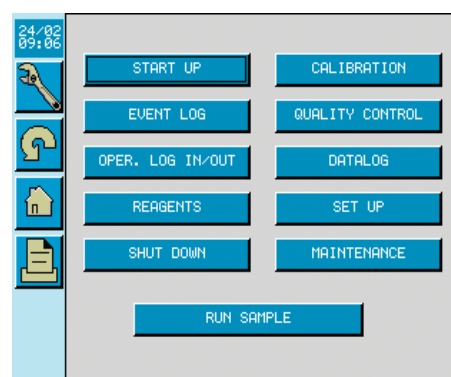
| ITEM                                     | SPECIFICATIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Technology &amp; Methods</b>          | <ul style="list-style-type: none"> <li>Electronic impedance</li> <li>Absorption spectrophotometry</li> <li>Electronic valves</li> <li>Cyanide-free lyse reagent</li> <li>LCD color touch screen</li> <li>RS232 and TCP/IP LIS interface</li> <li>USB ports</li> </ul>                                                                                                                                                                                                          |
| <b>Throughput</b>                        | <ul style="list-style-type: none"> <li>Up to 57 samples per hour</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sample Size</b>                       | <ul style="list-style-type: none"> <li>~9.8 µL</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Specimen Data Management</b>          | <ul style="list-style-type: none"> <li>Search by date or sequence number</li> <li>Flagging for patient limit sets</li> <li>Flagging for panic values</li> <li>1,500 records with histograms on internal memory</li> <li>Up to 300,000 records on external USB thumb drive</li> <li>Programmable patient limits</li> <li>Programmable report units</li> <li>Barcode reader (reads code 128, code 39, interleaved 2 of 5, and others listed in the Operator's Manual)</li> </ul> |
| <b>Quality Control</b>                   | <ul style="list-style-type: none"> <li>6 control files</li> <li>100 runs per file</li> <li>Levey-Jennings graphs</li> <li>Upload/download control information</li> <li>eQC Online peer review program</li> </ul>                                                                                                                                                                                                                                                               |
| <b>Demographics</b>                      | <ul style="list-style-type: none"> <li>Sequence number</li> <li>Alphanumeric specimen ID</li> <li>Alphanumeric patient ID</li> <li>Date &amp; time analyzed</li> <li>Patient name</li> <li>CBC with 3-part differential</li> <li>Flagging and Alerts</li> </ul>                                                                                                                                                                                                                |
| <b>Dispersional Data Alert</b>           | <ul style="list-style-type: none"> <li>Operator-defined patient limits for high and panic values</li> <li>System-defined limits for reportable range and analytical measurement range</li> <li>Suspect parameter flags caused by interfering substances or sample abnormalities</li> <li>Suspect parameter flags generated when WBC data indicates possible presence of an abnormal population</li> </ul>                                                                      |
| <b>Standards &amp; Safety Compliance</b> | <ul style="list-style-type: none"> <li>IEC 61010-1</li> <li>EN 61326-1</li> <li>CE Mark</li> </ul>                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Peripheral Devices</b>                | <ul style="list-style-type: none"> <li>Inkjet or laser printer</li> <li>USB thumb drive</li> <li>Handheld barcode scanner</li> </ul>                                                                                                                                                                                                                                                                                                                                           |
| <b>Physical Dimensions</b>               | <ul style="list-style-type: none"> <li>Height 13.8 in. (35 cm)</li> <li>Width 9.8 in. (25 cm)</li> <li>Depth 13.8 in. (35 cm)</li> <li>Weight 19.8 lbs. (9 kg) (without on-board reagents)</li> </ul>                                                                                                                                                                                                                                                                          |

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

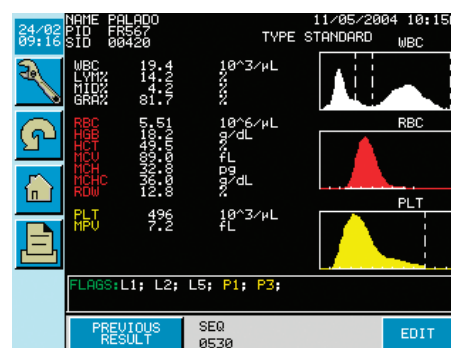
| REAGENTS            |                            |
|---------------------|----------------------------|
| Reagent Description | Size and List Number       |
| CN-Free Diff Lyse   | 960 mL (List No. 09H47-02) |
| Diluent             | 10 L (List No. 09H48-02)   |
| Cleaner             | 960 mL (List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

| CONTROLS & CALIBRATORS      |                      |
|-----------------------------|----------------------|
| CELL-DYN 18 Plus Calibrator | 09H70-01             |
| CELL-DYN 18 Plus Control    | 09H69-01<br>09H69-02 |

### MAIN MENU



### DATALOG FILE



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

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## Declaration of Conformity

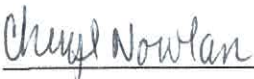
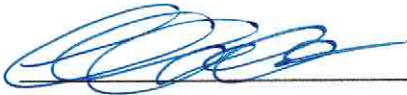
|                                      |                           |
|--------------------------------------|---------------------------|
| <b>Certificate Identification:</b>   | SC-09H39                  |
| <b>Legal Manufacturer's Name:</b>    | Abbott Laboratories       |
| <b>Legal Manufacturer's Address:</b> | Diagnostics Division      |
|                                      | 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  |

|                                                                   |                                                                                                                                                                                                         |
|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Authorized European Representative (Name and Address)</b>      | Abbott GmbH<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany                                                                                                                                            |
| <b>Storage site of technical documentation (Name and Address)</b> | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054<br><br>BIT Group France,<br>Parc Euromedécine II,<br>Rue de la Valsière,<br>CEDEX 5, CS 14287<br>34 099 – Montpellier FRANCE |
| <b>Harmonized Standards</b>                                       | 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.**

|                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Signature: <u></u></p> <p>Full Name: <u>Cheryl Nowlan</u></p> <p>Position: <u>Director Quality Assurance</u></p> <p>Date of Approval: <u>14 JAN 2021</u></p> <p>Date Issued: <u>JAN 14 2021</u></p> <p>Supersedes: <u>IRIS V7 (July 1, 2016)</u></p> | <p>Signature: <u></u></p> <p>Full Name: <u>Thao Phan</u></p> <p>Position: <u>Associate Director Regulatory Affairs</u></p> <p>Date of Approval: <u>14 JAN 2021</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JAN 14 2021</u></p> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

**Stefan Dumitras**

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

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

**November 5<sup>th</sup>-9<sup>th</sup>, 2018**

Gustavo Rodriguez/ Srinivasan Gopalan

  
TRAINER NAME

ABBOTT DIAGNOSTICS



TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

# Abbott