

# Certificate of Approval

This is to certify that the Management System of:

## Abbott Laboratories Diagnostics Division

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

MDSAP Facility Identifier: 079226220

has been audited by LRQA and found to conform to the following audit criteria:

**ISO 13485:2016**

**Australia:**

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1  
(Excluding Part 1.6) – Full Quality Assurance Procedure

**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

**United States:**

21 CFR 820

21 CFR 803

21 CFR 806



Cliff Muckleroy - Area Operations Manager Americas  
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000646

Effective Date: 2018 October 13

Expiry Date: 2021 October 12

Certificate Issue Number: 10155325

Original Approval: MDSAP/ISO 13485 – 2017 December 7



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqusa.com/help-and-support/request-for-certificate-verification>

# Certificate Schedule

Certificate Issue Number: 10155325

Approval Number: MDSAP – 0015662

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases; 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; Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunology and Clinical Chemistry Systems; Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.



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Attachment 1: List of Items

CELL-DYN Systems

DATE: 21<sup>st</sup> November 2016

TO: **To whom it may concern**

FROM: Paolo Mellino  
 Manager Regulatory Affairs EU  
 Abbott GmbH & Co. KG

Max-Planck-Ring 2

65205 Wiesbaden-Dalheim  
 Germany

SUBJECT: **Classification of Instrument Paris**

To whom it may concern,

Abbott GmbH & Co. KG, Germany, is an authorized representative of Abbott Laboratories that is a worldwide manufacturer of medical equipment, reagents, tests, instruments, and accessories, with additional diagnostic manufacturing plants in the USA and Ireland.

The items listed in Attachment 1 are considered components of accessory kits or spare parts to the ARCHITECT and CELL-DYN Instruments.

The spare parts or components of the accessory kit are qualified as part of the respective instrument following the requirements of the IVD Directive 98/79/EC. Therefore these are not considered an IVD device in their own right and do not bear a CE-mark.

For the instruments which are qualified according to the IVD Directive 98/79/EC, a Declaration of Conformity is issued by the manufacturer and the CE-mark is applied, which confirms compliance to the provisions of the directive

Yours sincerely,

Paolo Mellino  
 Manager Regulatory Affairs EU  
 Abbott Diagnostics Division

Abbott GmbH & Co. KG  
 Max-Planck-Ring 2  
 65205 Wiesbaden

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HR A 4888  
 Persönlich haftende Gesellschafterin:  
 Abbott Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 12859

Geschäftsführer:  
 Stefan Boll  
 John Coitler  
 Vorsitzender des Aufsichtsrates:  
 Jaime A. Contreras



**Equipment, Parts, Accessories**

- 09H54-01 Accessory Kit (NOTE: For a list of items in the Kit, see the Accessory Kit)  
 07H79-01 Interface Specifications  
 07H78-01 Keyboard  
 92274-01 Aperture Plate WBC  
 92264-01 Aperture Plate RBC  
 28661-01 Lyse Syringe  
 04H36-01 Diluent Syringe  
 28514-01 Sample Syringe  
 21704-01 Waste Dummy Plug  
 93164-01 Sample Probe  
 54305-01 Aperture Brush  
 20005-01 Printer Cable  
 91012-01 Teal Line Filter Isolation  
 07H81-01 Bar Code Scanner  
 03H96-01 Pull Ring, Solenoid  
 99650-01 Code 39 Bar Code Labels  
 07H67-01 Lyse Cap for 960 ml container  
 09H85-01 Diluent Syringe

**Accessory Kit (L/N 03H54-01)**

- 1403204 Keyboard Cover  
 93501-01 Power Card  
 5406753 Allen Wrench 3/32"  
 5406754 Allen Wrench 7/64"  
 54305-01 Aperture Brush  
 91072-01 Reagent Line Kit  
 20005-01 Printer Cable  
 9150143 Instructions for Mixing and Handling  
 93476-01 Silicon Tubing (S2)  
**Reagent Line Kit (L/N 91072-01)**  
 03H82-01 Reagent Line Assembly; Lyse (L1)  
 03H92-01 Detergent Line Inlet Assy  
 92161-02 Waste Line Assembly  
 92163-01 Diluent Line Inlet Assembly  
 92178-01 Lyse Line Inlet Tube

**Consumables**

- 30005-01 OKIDATA@ Graphics Paper  
 13491-01 Ribbon-OKIDATA@320  
 03H10-04 HP Printer Cartridge (Black)  
 99605-02 (International) CELL-DYN Counting Cups  
 99606-02 (International) CELL-DYN Counting Cups

**Accessories Kit (List Number 06H88-01)**

- 02H33-01 CD 3700 Interface Specification  
 \*1403216 Keyboard Cover  
 20005-01 6ft Interface Cable  
 21704-01 Waste Sensor Dummy Plug

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HR A 4888  
 Persönlich haftende Gesellschafterin:  
 Abbott Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 12859

Geschäftsführer:  
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 Vorsitzender des Aufsichtsrates:  
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- \*2400502 Cord Power, 125V
- \*3001008 Computer Printer Paper 8-1/2" X 11"
- \*5100105 Fuse, 8 Amp T (Slo-Bio)
- \*5100201 Fuse Fast, 1.6 Amp
- \*5406754 Allen Wrench, Hex, Short "L" 7
- 54305-01 Aperture Brush
- \*5100104 Fuse, 4 Amp T (Slo-Bio)
- 70048-01 Allen Wrench
- 91482-01 Reagent Line Kit
- 91484-01 Peristaltic Pump Tubing- Small
- 91485-01 Peristaltic Pump Tubing- Medium
- 912230 Sample Aspiration Tubing (Sample Loader)
- 92532-01 Serial Loop Back Device
- 03H99-01 CD 3700 SL Needle
- 03H96-01 Solenoid Ring Pull
- 95519-01 Data Station Cable
- 03H98-02 Waste Bottle Cable

**Sample Loader Accessories Kit**  
04H91-04 Sample Loader Racks

**Optional Accessories**

- 25860-01 Bar Code Label Dispenser
- 99650-01 Bar Code Tube ID Labels
- 99652-01 QC Bar Code Labels
- 04H34-01 Syringe, 10 mL
- 28561-01 Syringe, 2.5 mL
- 28560-01 Syringe, 500 µL
- 03H99-01 Needle, Vent/Aspiration
- 03H76-01 CELL-DYN 3700 Shear Valve Center Section
- 99624-01 Pre-Printed Tickets
- \*Orderable by Abbott personnel only

**CELL-DYN Ruby**

**Hardware**

- 07H40-02 Bar Code Reader, Hand-Held, Trigger Activated
- 05H00-02 Display, Flat Panel
- 07H96-01 Keyboard
- 09H41-01 Mouse
- 08H07-01 Printer, Graphics (color laser with USB port connector)
- 08H78-16 Printer, Graphics (Color desktop)
- 08H60-05 OKI B4600 220V Printer Mono Laser Printer

**Accessories Kit List Number 09H04-01/09H04-03**

- 8952087701\* Cable, Data Station (HSSI)
- 09H00-01 Cable, (Printer), 10'
- 8240051601\* Cable, Power, 6'7"
- 06H92-01 Diluent/Sheath Filter
- 09H06-01 Needle, SL
- 21704-01 Plug, Dummy, Waste
- 03H96-01 Ring, Pull Solenoids
- 92532-01 Serial Loop Back Device (RS232)
- 09H38-02 Tubing, Reagent WBC Lyse
- 09H44-01 Mouse, Digital USB
- 07H40-02 Bar Code Reader, Handheld, Trigger Activated
- 08H43-01 Tubing, Diluent/Sheath

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HR 3 4388  
 Persönlich haftende Gesellschafterin:  
 Abbert Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HR 2 3389

Geschäftsführer:  
 Stefan Boll  
 John Coullier  
 Vorsitzender des Aufsichtsrates:  
 Janine A. Cortezas



- 08H41-01 Tubing, HB Lyse
- 02H96-01/02H96-02 Waste Tubing Kit

**Optional Accessories**

- 07H67-02 Cap (large), Reagent line tubing
- 99650-01 Labels
- 99652-01 Labels, Bar Code, Q-Labels
- 09H31-02 Labels, Bar Code, Background
- 06H62-01 Labels, CELL-DYN Rack Bar Code, set of 100
- 06H64-01 CELL-DYN Shear Valve Center Section
- 04H34-01 Syringe, 10 mL
- 28561-01 Syringe, 2.5 mL
- 04H40-01 Syringe Kit, 2.5 mL
- 28560-01 Syringe, 500 µL
- 08H06-01 Kit Rack, Autoloader
- 09H32-01 Open Mode Probe
- 91485-01 Tubing Set, Transfer Pump
- 09H57-01 CDK TANK FILTER ASSY (Common Right Side)
- 03H86-01 Check Valve
- \*Orderable by Abbott personnel only

**CELL-DYN Emerald**

**Accessories**

- 09H52-01 Bar Code Scanner
- 09H58-01 Emerald Grease (gum)
- 09H54-02 European Power Cord
- 09H54-04 Flat Screwdriver/Key
- 09H50-01 Diluent Reagent line whitcap
- 09H51-01 Waste line with cap

**Consumables**

- 03B96-02 Printer paper 8.5 x 11" sheets
- 99550-01 Bar Code Labels, Tube ID 1000 labels per roll

**CELL-DYN Sapphire**

**Hardware**

- 08H01-05 CELL-DYN Sapphire Data Station Computer
- 07H40-02 Bar Code Reader, Hand-held, Trigger Activated
- 08H02-01 Display, Flat Panel 17 inch
- 08H02-04 Display, Flat Panel 19 inch
- 08H14-01 Keyboard Standard - (Plex style), English
- 07H96-02 Keyboard Standard, English
- 01H08-01 Mouse Printing Device
- 08H07-08 Printer, Graphics (color laser with USB port connector) 110 VAC
- 20825-01 1 Printer, Ticket (with parallel port connector) 110 VAC
- 20826-01 1 Printer, Ticket (with parallel port connector) 220 VAC

**Accessories Kit (List Number 08H03-02/08H03-06)**

- 54305-01 Brush, Impedance Aperture Made of Camel Hair
- 08H08-01 Cable, Data, Analyzer to Data Station
- 08H54-01 Cable, Data, Test Interface
- 08H53-04 Vent Assembly
- 02H63-02 Probe, Sample Aspiration, Nitinol
- 92532-01 Serial Loop Back Connector
- 02H88-01 Tubing set, Reagent Inlet and Waste Outlet
- 02H88-02 Tubing set, Reagent Inlet and Waste Outlet

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 John Coullier  
 Vorsitzender des Aufsichtsrates:  
 Janine A. Cortezas

91485-01 Tubing set, Sample Transfer Pump  
21704-01 Waste Sensor Plug

**Optional Accessories**

09H00-01 Cable, USB Printer  
07H67-01 Cap, small, Reagent line tubing  
07H67-02 Cap, large, Reagent line tubing  
99650-01 Labels, Bar Code, Tube ID  
99651-01 Labels, Bar Code, Tube ID  
99652-01 Labels, Bar Code, Q-Labels  
01H59-01 Labels, Bar Code, Q-Labels  
01H62-01 Labels, Bar Code, Rack  
08H06-01 Rack, Autoloader  
08H06-02 Rack, Autoloader  
08H06-04 Rack, Autoloader (Pedia Rack 1)  
08H06-06 Rack, Autoloader (Pedia Rack 2)  
09F99-01 Rack Completion Indicators  
08H13-01/08H13-02 Syringe, Diluent/Sheath, 10mL  
08H49-04 Syringe, Hemoglobin 5mL  
08H46-01 Syringe, Impedance Injection/Metering, 100µL  
08H48-01 Syringe, Retinolocyte Reagent and WBC Reagent – Part A, 2.5mL  
08H47-01 Syringe, Optical Injection/Metering, 500µL  
08H45-01 Syringe, WBC Reagent – Part B, 250µL  
02H90-01 Tubing, Reagent, Diluent/Sheath (Red-striped)  
02H90-02/02H90-03 Tubing, Reagent Diluent/Sheath (clear, no stripes)  
02H91-01 Tubing, Reagent, Hemoglobin  
02H98-01 Tubing, Reagent, WBC – Part A  
02H99-01 Tubing, Reagent, WBC – Part B  
02H96-01 Tubing, Waste Outlet  
02H58-01/02H58-02 Slo-Blow 5A 250V Fuse

**ARCHITECT Systems**

**Accessory kit 1 (4400) - LN 02P68-01/02P68-02 Installation components**

10 Micron Filter, Water Bath  
High Concentration Waste Tubing Kit  
ICT O-Ring, Probe, and Probe Holder  
Large Cartridge Segment, Inner 02P80-01  
Large Cartridge Segment, Outer (Target) 02P83-01  
Large Cartridge Segment, Outer 02P84-01  
Small Cartridge Segment, Inner 02P79-01  
Small Cartridge Segment, Outer 02P81-01  
Small Cartridge Segment, Inner (Target) 02P82-01  
Reagent Probe 01G47-03  
Reagent Probe Tubing 02P76-01  
Sample Probe 01G48-04  
Sample Probe Tubing 02P77-01  
Sample Wash Solution Carrier 02P78-01  
Waste and Water Tubing Kit  
**Maintenance components**  
10 mm Wrench  
Container, Parts Case  
Cuvette Segment Alignment Tool 02P86-01  
Nozzle, Cleaning Wire 09D50-02

Stefan Geseleschalt, Wiesbaden  
Arbeitsgemeinschaft Wiesbaden FRA 4888  
Gesellschaft für anfallende Gesellschaften:  
Abteilungsmanagement GmbH  
Stütz der Gesellschaft, Wiesbaden  
Arbeitsgemeinschaft Wiesbaden HRB 12889

Gesellschaftsführer:  
Stefan Boll  
John Coulter  
Vorstandsvorsitzender der Aufsichtsrats:  
Jaimie A. Cortezus

Phillips Screwdriver  
Slotted Screwdriver

**Spare components**

1 mL Syringe 09D41-02  
20 mL reagent Cartridge Adaptor 09D22-12  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 01G46-02  
ICT Probe 09D63-03  
ICT Probe Holder  
Mixer 09D59-02  
Probe Screw, Sample / Reagent  
Reagent Probe 01G47-03  
Reagent Probe Tubing, 04000 02P76-01  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample Probe 01G48-04  
Sample Probe Tubing, 04000 02P77-01  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02  
**Accessory kit 2 (4400) - LN 02P73-01/02P73-02 Carrier Calibration Tool 01P16-01**  
Pressure Monitor PCB  
Sample Carriers  
SH Bar code Tool 06E09-01

**Customer maintenance kit (4400) - LN 02P69-01**

1 mL Syringe 09D41-02  
ICT Reference Solution Check Valve 09D35-02  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip # 1 09D39-02  
Reagent Syringe Seal Tip # 2 09D40-02  
Sample/Wash Solution Syringe O-ring 109D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 109D38-02  
Source Lamp 09D45-02

**Accessory kit 1 (8000) - LN 01G09-02/01G09-03 Installation components**

Power Cable - UL and IEC Plug 02J54-01  
Waste and Water Tubing Kit  
High Concentration Waste Tubing Kit  
ICT Probe 09D63-03  
ICT Probe Holder  
Reagent Probe 01G47-03/01G47-04 Reagent Probe Tubing 01G47-02  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02  
68000 (R1)/016000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01  
68000 (R1)/016000 (R1 and R2) Small Cartridge, Segment A, B, C 01G51-01  
68000 (R1)/016000 (R1 and R2) Segment D (Target) 04J32-01  
R2, Small Cartridge, Segment A (Target) 04J29-01  
R2, Large Cartridge, Segment B, C, and D 04J31-01  
R2, Small Cartridge, Segment B, C, and D 01G52-01  
**Maintenance components**  
Phillips Screwdriver  
Slotted Screwdriver  
10 mm Wrench

Stefan Geseleschalt, Wiesbaden  
Arbeitsgemeinschaft Wiesbaden FRA 4888  
Gesellschaft für anfallende Gesellschaften:  
Abteilungsmanagement GmbH  
Stütz der Gesellschaft, Wiesbaden  
Arbeitsgemeinschaft Wiesbaden FRA 12889

Gesellschaftsführer:  
Stefan Boll  
John Coulter  
Vorstandsvorsitzender der Aufsichtsrats:  
Jaimie A. Cortezus



c8000 Cuvette Segment Alignment Tool 02J93-01  
Nozzle, Cleaning Wire 09D50-02  
Container, Parts case

**Accessories**

20 mL Reagent Cartridge Adapter 09D22 (-11 01-12)  
Small Reagent Cartridge Adapter 09D22-07  
Spare components

1 mL Syringe 09D41-02  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 01G46-02  
ICT O-ring 09P93-02  
Mixer 09D59-02

Reagent Probe 01G47-03  
Reagent Probe Tubing 01G47-02  
Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip #1 09D39-02  
Reagent Syringe Seal Tip #2 09D40-02

Reagent/Sample Probe Screw 02J51-01  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02

Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Customer maintenance kit (c8000) - LN 02J53-01**

1 mL Syringe 209D41-02  
ICT Reference Solution Check Valve 09D35-02

Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip #1 09D39-02  
Reagent Syringe Seal Tip #2 09D40-02

Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Accessory kit 1 (a16000) - LN 08L71-02/08L71-03/Installation components**

Power Cable - UL and IEC Plug 02J54-01  
Waste and Water Tubing Kit  
High Concentration Waste Tubing Kit  
ICT Probe 09D63-03  
ICT Probe Holder

Reagent Probe - R1A/R2B (L) 09D48-02/09D48-03/Reagent Probe - R1B/R2A(L) 09D49-02/09D49-03/Tubing, Joint to R Probe, R1 & 2A/09D48-05  
Tubing, Joint to R Probe, R1 & 2B/09D49-05  
Sample Probe/01G48-04

Sample Probe Tubing 01G48-02  
08000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01  
08000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 04J33-01  
08000 (R1)/c16000 (R1 and R2) Segment D (Target) 04J32-01  
10 micron filter, waterbath  
Maintenance components  
Phillips Screwdriver  
Slotted Screwdriver  
10 mm Wrench  
c16000 Cuvette Segment Alignment Tool 08L73-01  
Nozzle Cleaning Wire 09D50-02

Sitz der Gesellschaft: Wiesbaden  
Antragsteller: Wiesbaden HRA 4888  
Personlich haftende Gesellschafterin:  
Abbot Management GmbH  
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Geschäftsführer:  
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Vorstand der Aufsichtsrats:  
Jürgen A. Contarius

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Container, Parts case  
Accessories

**Accessories**

20 mL Reagent Cartridge Adapter 09D22 (-11 01-12)  
Small Reagent Cartridge Adapter 09D22-07  
Spare components

1 mL Syringe 09D41-02  
Cuvette Dry Tip 09D51-02  
Cuvette Pair Replacement Set 09D33-03  
ICT O-ring 09F93-02  
Peristaltic Pump Tubing Kit  
Mixer 09D59-02

Pipettor Arm Cover Screw 09D46-20  
Reagent Probe R1A/R2B 09D48-02/09D48-03/Reagent Probe R1B/R2A 09D49-02/09D49-03/Reagent Probe  
Screw 09D48-10  
Tubing, Joint to R Probe, R1 & 2A 09D48-05  
Tubing, Joint to R Probe, R1 & 2B 09D49-05  
Reagent Syringe O-ring 09D53-02

Reagent Syringe Seal Tip #1 09D39-02  
Reagent Syringe Seal Tip #2 09D40-02  
Sample Probe 01G48-04  
Sample Probe Tubing 01G48-02

Probe Screw, c8000 (Reagent and Sample)/c16000 (Sample) 02J51-01  
Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**Customer maintenance kit (c16000) - LN 08L72-01**

1 mL Syringe 09D41-02  
ICT Reference Solution Check Valve 09D35-02

Reagent Syringe O-ring 09D53-02  
Reagent Syringe Seal Tip #1 09D39-02  
Reagent Syringe Seal Tip #2 09D40-02

Sample/Wash Solution Syringe O-ring 09D52-02  
Sample/Wash Solution Syringe Seal Tip #1 09D37-02  
Sample/Wash Solution Syringe Seal Tip #2 09D38-02  
Source Lamp 09D45-02

**ARCHITECT i System accessory kits - LN 08C94-01 (i2000), LN 03M77-01/03M77-10 (i2000SR), and LN 01L87-01/01L87-03 (i1000SR)**

i2000SR and i2000SR components - LN 08C94-01 and LN 03M77-01/03M77-10  
i2000SR Add-On R3H 02L4721  
i2000SR Standard IAS Kit 07L3012  
Bag, Biohazard  
EFFECTIA UPS MH3000 07G52-10

External Waste Tubing  
Filter, Card Cage/Supply 08C94-07  
Filter, Processing Center 08C94-14  
Inlet assembly, buffer Maintenance Kit  
Bar Code Calibration Tool 06E67-01  
Carrier Calibration Tool 05L13-01  
Flashlight  
Fuse Kit  
Gense

• Lens Paper  
• Maintenance Cleaning Bottle 02E16-09

Sitz der Gesellschaft: Wiesbaden  
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- Optics Cap
- WZ Probe Maintenance Water Bottle 06E68-01
- Screwdriver #1 Phillips
- Screwdriver #2 Phillips
- SH Bar Code Tool 06E69-01
- Thermistor Removal Wrench
- Valve Removal Tool
- LOD Touchscreen Monitor 07D03-20
- Power cord kit
- Probe, Wash Zone 08C94-35
- Probe (Sample/Reagent) 08C94-42
- Probe/Tubing, Waste Arm 08C94-89
- Sensor, Level, Buffer 08C94-25/08C94-65/Sensor, Level, Trigger 08C94-26/08C94-66/Sensor, Level, Pre-Tubing, Wash Buffer Transfer 08C94-21
- Tubing, Wash Buffer Transfer 08C94-21
- Wash Buffer Preparation Container 08C94-56
- Wash Buffer Reservoir

**2000 components - LN 08C94-01**

- Internal component cover 1 06E27-10
- Internal component cover 2 & 3 06E27-20
- Internal component cover 4 (2000 accessory kit only) 06E27-30
- Internal component cover 4 (2000 accessory kit only) 06E27-40
- Internal component cover 5 (2000 accessory kit only) 06E27-40
- Internal component cover 6 (2000 accessory kit only) 06E27-50
- Internal component cover 7 (2000 accessory kit only) 06E27-50
- Internal component cover 8 (2000 accessory kit only) 06E27-70
- 2000SR components - LN 03M77-01 / 03M77-10STAT Probe Tubing (2000SR accessory kit only) 03M77-49**
- Internal component cover 1 06E27-11
- Internal component cover 2 & 3 06E27-21
- Internal component cover 4 (2000SR accessory kit only) 02163-14
- Internal component cover 5 (2000SR accessory kit only) 02163-15
- Internal component cover 6 (2000SR accessory kit only) 02163-16
- Internal component cover 7 (2000SR accessory kit only) 02163-17

**ARCHITECT i1000SR components - LN 01L87-01/01L87-03**

- Bag, Biohazard
- Bleach Preparation Container 08C94-63
- Buffer filter 08C94-29
- Buffer outlet assembly 01P12-01
- Card cage/SOC door filter 03L99-01
- Card cage filter 06L00-01
- External Waste Tubing
- Internal Deacon Extension Tubing/Cable Kit 01P83-01
- Maintenance Kit:
  - Bar Code Calibration Tool 06E67-01
  - Buffer Reservoir Cap
  - Carrier Calibration Tool 01P16-01
  - Flashlight
  - Fuse Kit
  - Lens Paper
  - Maintenance Cleaning Bottle 02G16-99
  - Optics Cap
  - WZ Probe Maintenance Water Bottle 06S68-01
  - Screwdriver #1 Phillips
  - Screwdriver #2 Phillips
  - SH Bar Code Tool 06E66-01

- Thermistor Removal Wrench
- Valve Removal Tool
- Ground strap
- O-Ring Removal Tool Probe (Sample/Reagent) 08C94-42
- Probe, Wash Zone 08C94-35
- Reagent Carriers
- Sample Carriers
- Sensor, Level, Buffer 06L01-01
- Sensor, Level, Pre-Trigger 80C94-27
- Sensor, Level, Trigger 80C94-26
- Tubing, Probe 06L04-01
- Tubing, Sensor, Temp, WZ 08C94-87
- Tubing, Wash Buffer Transfer 08C94-21
- Unloader
- Wash Cup Baffle 01P41-01
- Wash Buffer Preparation Container 08C94-56
- Wash Buffer Reservoir 06L06-01

**Waste Pressure Switch to floor tubing**

**Additional accessories**

- Alternate 08000/c16000 Reagent Supply Center Segments:
  - 08000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 04J33-01
  - R2, large cartridge, segments B, C, and D 04J31-01
  - R2, small cartridge, segments B, C, and D1 01G52-01
- Alternate c4000 Reagent Supply Center Segments:
  - Large Cartridge Segment, Inner 02P80-01
  - Large Cartridge Segment, Outer 02P84-01
  - Large Cartridge Segment, Outer (Target) 02P83-01
  - Small Cartridge Segment, Inner 02P79-01
  - Small Cartridge Segment, Outer 02P81-01
- Small Cartridge Segment, Inner (Target) 02P82-01
- ARCHITECT ARM (Automated Reconstruction Module) accessory 08C95-89
- Cuvette Segment (c4000) 02P75-01
- Cuvette Segment (08000) 01G46-01
- Cuvette Segment (c6000) 09D32-05
- External Waste Pump:
  - 12000/2000SR 08C94-19
  - c System 09D61-03
- High Concentration Waste Bottle 03E50-26
- High Concentration Float Switch Cable 03E50-31
- LAS Sample Carousel ID Labels (2000) sheet 08C96-25
- LAS Sample Carousels (2000) 08C96-07
- Liquid Waste Container (1000SR) 06L05-01
- Pump Poppet Valve Set (c System) 09D36-02
- Reagent carriers (1000SR) 08L20-01
- RSH Sample Carrier Trays 04L49-01
- Sample Carousel (08000/c16000) 02J50-01
- Sample Carousel (c6000/c16000) 02J45-01
- Sample Carriers 05E15-01
- Thermometer, External (c System) 08C94-88
- Tubing, probe (2000/2000SR) 08C94-49
- AERO/CRK CUVETTE WIPPER 09D42-02

**SOC components**

**Required**

- English Keyboard 07D11-01
- English Keyboard (black) 07D11-02

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 4388  
 Persönlich haftende Gesellschafterin:  
 Albrecht Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 23889

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 4388  
 Persönlich haftende Gesellschafterin:  
 Albrecht Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRB 23889



- French Keyboard 07D11-20
- French Keyboard (black) 07D11-22
- German Keyboard 07D11-30
- German Keyboard (black) 07D11-32
- Italian Keyboard 07D11-40
- Italian Keyboard (black) 07D11-42
- Spanish Keyboard 07D11-50
- Spanish Keyboard (black) 07D11-52
- Monitor - Touchscreen FlatScreen 07D03-15
- Monitor - Touchscreen LCD (dark gray) 07D03-22
- Mouse 07D01-99
- Mouse (black) 07D02-01
- Network HUB (USB Powered) 07D04-60
- Optional
- Bar Code Scanner 07D09-13/ 07D09-14
- Component Stand 09D19-01

Printer:

- Printer (110V) 07D08-11
- Printer (220V) 07D08-22
- UPS for SOC only:
- UPS 100V 07D06-11
- UPS 220V 07D06-22

**ACCELERATOR P540**

- 7170-01 P540 Aliquot Tip Cartridge
- 7171-01 P540 secondary tubes
- 7171-02 P540 secondary tubes

Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRZ 4888  
 Persönlich haftende Gesellschafterin:  
 Abbott Management GmbH  
 Sitz der Gesellschaft: Wiesbaden  
 Amtsgericht Wiesbaden HRZ 12889

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 Stefan Boll  
 John Coulter  
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 Jaimie A. Conrath

