



EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c Processing Module
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03R67-01	Alinity c Processing Module	56676	W0201010108
Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA		
Manufacturer SRN	US-MF-000017777		
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany		
Authorized Representative SRN	DE-AR-000009457		
Produced by (Site of Manufacture) (Name and Address)	Canon Medical Systems Corporation 1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan		
Conformity Assessment Procedure	Annex II and III		

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Sr. Director, Instrument and Automation

Function: Quality

Signature: Thomas Creel

Date of Approval: 23-May-2022
Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive,
Irving, TX 75038

Full Name: Michele Smith-Waheed

Function: Associate Director, Regulatory Affairs

Signature: Michele Smith-Waheed

Date of Approval: 23-MAY-2022

Date Issued: 23-MAY-2022

Supersedes: N/A

Place Issued: Irving, Texas

Effective (Date or Lot Number): 23-MAY-2022

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Holds Certificate Number:

FM 762425

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2019-12-18

Latest Revision Date: 2022-12-16

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

Page: 1 of 1



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Holds Certificate Number:

MD 762422

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-06-13

Latest Revision Date: 2022-12-12

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Facility ID Number: F005921

Holds Certificate No:

MDSAP 762409

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

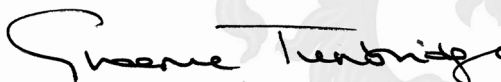
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-18

Effective Date: 2022-12-18

Expiry Date: 2025-12-17



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 762409**

Registered Scope:

Design, Development, Manufacture, Refurbishment, and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. 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.



Original Registration Date: 2019-12-18

Effective Date: 2022-12-18

Expiry Date: 2025-12-17

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Alinity



Alinity

ci-series

ALINITY | Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

Alinity ci-series System Specifications

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY



FEATURE	ALINITY c	ALINITY i	ALINITY ci
Dimension (H x W x D)	134 x 119 x 117 cm/1.39 m ²	134 x 119 x 117 cm/1.39 m ²	134 x 199 x 117 cm/2.33 m ²
Methods	Photometric, Potentiometric	Chemiluminescence	Photometric, Potentiometric, Chemiluminescence
Maximum Throughput	Up to 1350 TPH	Up to 200 TPH	Up to 1550 TPH
Throughput/m ²	Up to 971 TPH/m ²	Up to 144 TPH/m ²	Up to 665 TPH/m ²
Scalability	Up to 4 modules controlled by one System Control Module (SCM)		
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes		
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions		
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood
Sample Capacity	150	150	300
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar		
Sample Result Storage	200,000		
Dead Volume	50 µL (sample cup)		
Sample Volume*	1.5–35 µL	2–200 µL	Alinity c: 1.5–35 µL Alinity i: 2–200 µL
Sample Probe Carryover	≤0.1 parts per million†		
Reagent Capacity	Up to 70 refrigerated reagent cartridges onboard plus patented ISE (Na ⁺ , K ⁺ , and Cl ⁻)	Up to 47 refrigerated reagent cartridges onboard	Up to 117 refrigerated reagent cartridges onboard plus patented ISE (Na ⁺ , K ⁺ , and Cl ⁻)
Reagent Type	100% liquid ready-to-use		
Reagent Onboard Stability*	5–60 days	15–30 days	For Alinity c: 5–60 days For Alinity i: 15–30 days
Automated Onboard Calibrators and Controls*	Yes	Yes (controls only)	Alinity c: Yes Alinity i: Yes (controls only)
Calibration Frequency*	1–60 days	15–30 days	For Alinity c: 1–60 days For Alinity i: 15–30 days
Sample, Clot and Bubble Detection	Yes		
Reagent Pressure Monitoring	Yes		
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No	Yes; hemolysis, icterus, and lipemia (CC only)
On Board Maintenance Records	Yes		
Online Error Code Help	Yes		
Host Interface	HL7 or ASTM		
Remote Diagnostics	AbbottLink		
Weight	712 Kg	624 kg	1160 kg
Electrical Requirements	SCM: 90–264 V, 16 amp Each Instrument: 180–264 V, 16 amp		
Water Requirements	Average: 27 L/hr Max‡: <30 L/hr	Average: <10 L/hr Max‡: <30 L/hr	Average: ≤37 L/hr Max‡: <60 L/hr
Heat Output (processing)	Average 2005 Btu	Average 1634 Btu	Average 3639 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA Alinity i: 63.4 dBA		
Laboratory Automation Connection	ACCELERATOR a3600	ACCELERATOR a3600	ACCELERATOR a3600

TPH=tests per hour

*Assay dependent

†Excluding whole blood

‡Maximum of two minutes during the prime of the wash buffer dilution assembly

FEATURE	ALINITY cc	ALINITY ii	ALINITY cic
Dimension (H x W x D)	134 x 199 x 117 cm/2.33 m ²	134 x 199 x 117 cm/2.33 m ²	134 x 280 x 117 cm/3.28 m ²
Methods	Photometric, Potentiometric	Chemiluminescence	Photometric, Potentiometric, Chemiluminescence
Maximum Throughput	Up to 2700 TPH	Up to 400 TPH	Up to 2900 TPH
Throughput/m ²	1158 TPH/m ²	171 TPH/m ²	884 TPH/m ²
Scalability	Up to 4 modules controlled by one System Control Module (SCM)		
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes		
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions		
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood
Sample Capacity	300	300	450
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar		
Sample Result Storage	200,000		
Dead Volume	50 µL (sample cup)		
Sample Volume*	1.5–35 µL	2–200 µL	Alinity c: 1.5–35 µL Alinity i: 2–200 µL
Sample Probe Carryover	≤0.1 parts per million [†]		
Reagent Capacity	Up to 140 refrigerated reagent cartridges onboard plus patented ISE (Na ⁺ , K ⁺ , and Cl ⁻)	Up to 94 refrigerated reagent cartridges onboard	Up to 187 refrigerated reagent cartridges onboard plus patented ISE (Na ⁺ , K ⁺ , and Cl ⁻)
Reagent Type	100% liquid ready-to-use		
Reagent Onboard Stability*	5–60 days	15–30 days	For Alinity c: 5–60 days For Alinity i: 15–30 days
Automated Onboard Calibrators and Controls*	Yes	Yes (controls only)	Alinity c: Yes Alinity i: Yes (controls only)
Calibration Frequency*	1–60 days	15–30 days	For Alinity c: 1–60 days For Alinity i: 15–30 days
Sample, Clot and Bubble Detection	Yes		
Reagent Pressure Monitoring	Yes		
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No	Yes; hemolysis, icterus, and lipemia (CC only)
On Board Maintenance Records	Yes		
Online Error Code Help	Yes		
Host Interface	HL7 or ASTM		
Remote Diagnostics	AbbottLink		
Weight	1248 kg	1071 kg	1697 kg
Electrical Requirements	SCM: 90–264 V, 16 amp Each Instrument: 180–264 V, 16 amp		
Water Requirements	Average: ≤54 L/hr Max [‡] : <60 L/hr	Average: ≤20 L/hr Max [‡] : ≤60 L/hr	Average: ≤64 L/hr Max [‡] : ≤90 L/hr
Heat Output (processing)	Average 4010 Btu	Average 3268 Btu	Average 5644 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA Alinity i: 63.4 dBA		
Laboratory Automation Connection	ACCELERATOR a3600	ACCELERATOR a3600	ACCELERATOR a3600

TPH=tests per hour

*Assay dependent

[†]Excluding whole blood

[‡]Maximum of two minutes during the prime of the wash buffer dilution assembly

FEATURE	ALINITY cccc	ALINITY iiiii
Dimension (H x W x D)	134 x 362 x 117 cm/4.24 m ²	134 x 362 x 117 cm/4.24 m ²
Methods	Photometric, Potentiometric	Chemiluminescence
Maximum Throughput	Up to 5,400 TPH	Up to 800 TPH
Throughput/m ²	1273 TPH/m ²	189 TPH/m ²
Scalability	Up to 4 modules controlled by one System Control Module (SCM)	
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes	
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions	
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine
Sample Capacity	600	
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar	
Sample Result Storage	200,000	
Dead Volume	50 µL (sample cup)	
Sample Volume*	1.5–35 µL	2–200 µL
Sample Probe Carryover	≤ 0.1 parts per million†	
Reagent Capacity	Up to 280 refrigerated reagent cartridges onboard plus patented ISE (Na ⁺ , K ⁺ , and Cl ⁻)	Up to 188 refrigerated reagent cartridges onboard
Reagent Type	100% liquid ready-to-use	
Reagent Onboard Stability*	5–60 days	15–30 days
Automated Onboard Calibrators and Controls*	Yes	
Calibration Frequency*	1–60 days	15–30 days
Sample, Clot and Bubble Detection	Yes	
Reagent Pressure Monitoring	Yes	
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No
On Board Maintenance Records	Yes	
Online Error Code Help	Yes	
Host Interface	HL7 or ASTM	
Remote Diagnostics	AbbottLink	
Weight	2321 kg	1968 kg
Electrical Requirements	SCM: 90–264 V, 16 amp. Each Instrument: 180–264 V, 16 amp	
Water Requirements	Average: ≤108 L/hr, Max‡: <120 L/hr	Average: ≤40 L/hr, Max‡: ≤120 L/h
Heat Output (processing)	Average 8020 Btu	Average 6536 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA, Alinity i: 63.4 dBA	
Laboratory Automation Connection	In development	In development

TPH=tests per hour

*Assay dependent

†Excluding whole blood

‡Maximum of two minutes during the prime of the wash buffer dilution assembly



HARMONIZED SYSTEMS

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO TRANSFORM YOUR LABORATORY



Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

ALINITY.COM

Alinity ci-series

YOUR VISION. **OUR INNOVATION.** DESIGNED FOR YOU, **BY YOU.**

Alinity is Abbott's next generation of systems that span key laboratory disciplines and are designed to simplify diagnostics and help you deliver results that drive better patient outcomes.

With Alinity, critical interactions between individuals, systems and informatics are streamlined, enabling you to redefine performance in your laboratory and your institution.

Alinity



Achieve **measurably better** healthcare performance with our **personalized solutions** consisting of our **resourceful advocates**, **harmonized systems** and **intelligent insights**.



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

ALINITY.

YOUR TOTAL LABORATORY SOLUTION, DESIGNED TO DELIVER:



UNIFORMITY

Standardize operations in your lab and across your network through common intuitive processes across systems.

- Intuitive, user-driven design simplifies touch points and interactions.
- Easy-to-use graphic user interface with common software and iconography provides a consistent experience.



FLEXIBILITY

Discover flexible solutions that help you adapt to the day-to-day and long-term unpredictability of changing lab volumes.

- Scalable design allows for module additions and system reconfiguration as needs change with growing testing volumes.
- Multiple track-connectivity options provide open, customized automation for third-party systems to connect multiple departments across the lab and network.**



OPERATIONAL PRODUCTIVITY

Utilize your laboratory's space to its fullest potential with compact systems that provide more tests per square meter.

- Increased sample and reagent load-up capacity means more tests per square meter for maximized throughput, resulting in a compact footprint.***
- Continuous reagent access maintains uptime without interruption to tests in progress for greater operational productivity.



CONFIDENCE

Have confidence in the results you deliver to physicians through proven technology and assay design.

- Error-proof design and proven technology provides accurate results across platforms.
- Assay harmonization to Clinical and Laboratory Standards Institute guidelines ensures clear performance parameter definitions.

**Alinity m track connectivity is not yet available.

***As compared to ARCHITECT i2000 and ARCHITECT c8000.

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO **TRANSFORM YOUR LABORATORY**

The Alinity ci-series consists of compact, **scalable systems** to **maximize throughput** and **efficiency**, making today's high-performing laboratories run at their best, today and into the future.



Alinity c
Clinical Chemistry



Alinity i
Immunoassay



Alinity ci-series
Integrated Clinical Chemistry
and Immunoassay



IMPROVE OPERATIONS ACROSS PLATFORMS WITH **COMMON USER EXPERIENCE**

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.

USER-DRIVEN DESIGN

Loading samples, prioritizing STATs, replacing reagent cartridges and bulk solutions and utilizing the user interface are just a few of the critical interactions that are consistent across systems.



Alinity ci-series

Integrated Clinical Chemistry and Immunoassay



Alinity h-series

Hematology



Alinity s

Blood and Plasma Screening



Alinity m

Molecular



FLEXIBILITY

SEAMLESS SCALABILITY THAT ADAPTS TO CHANGING LABORATORY VOLUMES

Alinity ci-series



INTEGRATE UP TO FOUR MODULES IN VARYING COMBINATIONS

- The **flexible and scalable** Alinity ci-series offers increased throughput and capacity, allowing you to easily add modules as your volume grows, without replacing your current systems.
- **Integrate up to four modules** of multiple clinical chemistry and immunoassay systems, up to 14 configurations, all controlled by a single system control module.



OPERATIONAL PRODUCTIVITY

INNOVATIVE ENGINEERING FOR **MAXIMUM THROUGHPUT AND CAPACITY**

In today's uncertain environment, labs need to be able to quickly adapt to daily changes, as well as plan for the long term to ensure consistent delivery of services.



PERFORM MORE TESTS PER SQUARE METER***

Even when faced with limited space and resources, Alinity can more efficiently and effectively process **increased volumes** in a compact footprint.

Innovative engineering, combined with the **space-saving design** of the Alinity ci-series, which stacks reagent storage and sample processing areas, increases throughput without compromising space.



***As compared to ARCHITECT i2000 and ARCHITECT c8000.



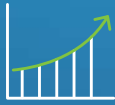
ALINITY CI-SERIES

FASTER. SIMPLER. SMARTER.

Simplify and streamline interactions with systems thoughtfully designed around the way you work.

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity**, **flexibility**, **operational productivity** and **confidence**.





CONFIDENCE

QUALITY ASSAY PERFORMANCE BUILT ON PROVEN TECHNOLOGY AND DESIGN

You face pressure every day to provide accurate and timely results. Our **broad menu** of differentiated assays delivers consistent, **commutable results** across platforms.

THE VALUE OF PROVEN TECHNOLOGY



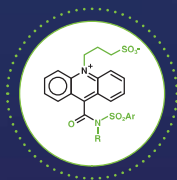
ICT Module

A single simple-to-install, integrated chip generates Na⁺, K⁺ and Cl⁻ results with CVs of 1% or less. Each module delivers 60,000 determinations, and maintenance is automated.



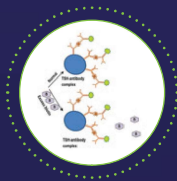
SmartWash Technology

SmartWash technology prevents clinically significant sample-to-sample carryover (≤ 0.1 ppm) and eliminates the need for additional consumables.



CHEMIFLEX

A refined chemiluminescence-detection technology with flexible assay protocols, combined with optimized assay design, provides enhanced assay performance.



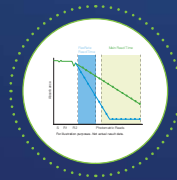
No Biotin Interference

Assays designed without streptavidin capture method. Ensures accuracy of results and timely analysis.



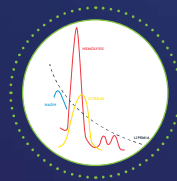
Clot and Bubble Detection

Sample pressure differential technology can detect bubbles, foam and clots to confirm sample integrity and aspiration accuracy.



FlexRate

FlexRate extends the linear ranges of enzyme assays for better first-time results and fewer repeats.



Sample Interference Indices

Measurement of hemolysis, icterus and lipemia levels reduces the risk of reporting incorrect results due to interference.

Alinity PRO

INFORMATICS*

CENTRALIZED MANAGEMENT ACROSS YOUR ALINITY SYSTEMS

Together with your Alinity systems, Alinity PRO is designed to fully maximize your systems' potential. Alinity PRO software works with Alinity systems to **enhance operational productivity** throughout your network, allowing for easier and consolidated system monitoring anytime, anywhere.

Consolidated Real-time Dashboards

- Remote dashboard capabilities enable staff to capitalize on system walkaway time via immediate notifications.

“Plan My Day” Checklists

- Forward-looking “Plan My Day” checklists help minimize planned downtime.

Real-time Mobile Notifications†

- Management of alert preferences is simplified through on/off toggle switches, allowing customization of what information staff receives to efficiently explore data and identify problems.



SHARE REAGENTS BETWEEN SYSTEMS AND REDUCE WASTE

- Reduce waste and inventory management by enabling staff to seamlessly transfer inventory between systems.



Alinity ci-series

YOUR PERSONALIZED SOLUTION — ALINITY

SIMPLIFYING DIAGNOSTICS AND REDEFINING LABORATORY PERFORMANCE

Achieve measurably better healthcare performance with **our personalized solutions**, consisting of our resourceful advocates, harmonized systems and intelligent insights.



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

The Alinity family of systems, including the Alinity ci-series, the Alinity m, the Alinity h-series, the Alinity s and the i-STAT Alinity, is for *in vitro* diagnostic use only. Not all products are available in all regions. This material is for use outside of the United States.

ALINITY.COM

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Alinity



Alinity

ci-series

ALINITY | Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

HARMONIZED SYSTEMS

Clinical chemistry, immunoassay
and integrated systems to transform
your laboratory.

CHOOSE TRANSFORMATION

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY



Your vision. Our innovation. Designed for you, by you.*

Alinity is Abbott's next generation of systems, across key laboratory disciplines, designed to simplify diagnostics and help you deliver results that drive better patient outcomes. With Alinity, critical interactions between individuals, systems and information are streamlined, enabling you to redefine performance in your laboratory and your institution.



Alinity

Alignment | Innovation | Unity

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

Alinity. Your total lab solution, designed to deliver:*



UNIFORMITY

Standardize operations across your lab and network, and optimize your limited resources.

- User-driven design
- Intuitive user experience
- Easy-to-use graphic user interface



FLEXIBILITY

Adapt to day-to-day and long-term unpredictability of changing lab volumes.

- Scalable design
- Multiple track-connectivity options
- Open informatics and automation



OPERATIONAL PRODUCTIVITY

Address limited space and increasing demand with increased throughput and capacity.

- Maximized throughput in a compact footprint
- Increased sample and reagent load-up capacity
- Continuous reagent access



CONFIDENCE

Provide consistent high-quality service to physicians, and reduce waste.

- Error-proof design elements that safeguard against erroneous results
- High-quality assays with proven technology and design
- Assay harmonization to CLSI guidelines, ensuring clear performance parameter definitions



HARMONIZED SYSTEMS ACROSS ALL KEY LABORATORY DISCIPLINES

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

ALINITY CI-SERIES

Introducing clinical chemistry, immunoassay and integrated systems to transform your laboratory

The Alinity ci-series consists of compact, **scalable systems** to **maximize throughput** and **efficiency**, making today's high-performing laboratories run at their best, today and into the future.



Alinity c
Clinical Chemistry



Alinity ci-series
Integrated Clinical Chemistry
and Immunoassay



Alinity i
Immunoassay

KEY FEATURES



UNIFORMITY

COMMON USER EXPERIENCE

Standardize operations in your lab and across your network through common intuitive processes across systems.



FLEXIBILITY

SCALABLE SYSTEMS

Discover flexible solutions that help you adapt to the day-to-day and long-term unpredictability of changing lab volumes.



OPERATIONAL PRODUCTIVITY

MAXIMUM THROUGHPUT IN A SMALLER FOOTPRINT

Utilize your laboratory's space to its fullest potential with compact systems that provide more tests per square meter.



CONFIDENCE

QUALITY ASSAY PERFORMANCE

Have confidence in the results you deliver with proven technology and assay design.

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.



COMMON USER EXPERIENCE

Standardize operations across your laboratory and network.*

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.



USER-DRIVEN DESIGN

- Loading samples and reagents, prioritizing STATs, replacing solutions, and utilizing the user interface are just a few of the critical interactions that are consistent across systems.

Alinity ci-series

Integrated Clinical Chemistry and Immunoassay



Alinity h-series

Hematology



Alinity s

Blood and Plasma
Screening

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available. For illustrative purposes only.



SCALABILITY AND MAXIMIZED THROUGHPUT

Realize the full potential of your existing resources, optimizing your performance, now and in the future.

In today's uncertain environment, labs need to be able to quickly adapt to daily changes, as well as plan for the long-term to ensure consistent delivery of services.

The **flexible and scalable** Alinity ci-series offers increased throughput and capacity, allowing you to easily add modules as your volume grows, without replacing your current systems. **Integrate up to four* modules** of multiple clinical chemistry and immunoassay combinations, all controlled by a single system control module.

Alinity ci-series INTEGRATE UP TO FOUR* MODULES IN VARYING COMBINATIONS.



PERFORM MORE TESTS PER SQUARE METER

Even when faced with limited space and resources, Alinity can more efficiently and effectively **process increased volumes** in a compact footprint.

Innovative engineering, combined with the Alinity ci-series **space-saving design**, which stacks reagent storage and sample processing areas, increases throughput without compromising space.

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.



QUALITY ASSAY PERFORMANCE

Greater confidence for your lab operations

You face pressure every day to provide accurate and timely results. Our **broad menu** of differentiated assays delivers consistent, **commutable results** across platforms that may improve clinical decision making and patient outcomes.

- Alinity ci-series assays are **harmonized** to Clinical and Laboratory Standards Institute (CLSI) guidelines, ensuring clear performance parameter definitions.

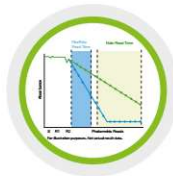


THE VALUE OF PROVEN TECHNOLOGY



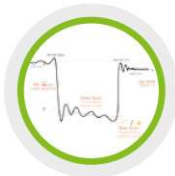
ICT MODULE

A single simple-to-install, integrated chip generates Na⁺, K⁺ and Cl⁻ results with CVs of 1% or less. Each module delivers 60,000 determinations, and maintenance is automated.



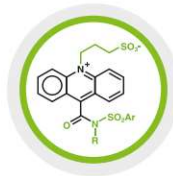
FLEXRATE

Extends the linear ranges of enzyme assays for better first-time results and fewer repeats.



CLOT AND BUBBLE DETECTION

Sample pressure differential technology can detect bubbles, foam, and clots to confirm sample integrity and aspiration accuracy.



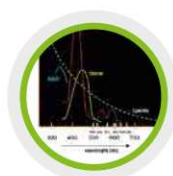
CHEMIFLEX

A refined chemiluminescence-detection technology with flexible assay protocols, combined with optimized assay design, provides enhanced assay performance.



SMARTWASH TECHNOLOGY

SmartWash technology prevents clinically significant sample-to-sample carryover (≤ 0.1 ppm) and eliminates the need for additional consumables.



SAMPLE INTERFERENCE INDICES

Measurement of hemolysis, icterus and lipemia levels reduces the risk of reporting incorrect results due to interference.

Alinity ci-series

ALINITY CI-SERIES

Faster. Simpler. Smarter.

Simplify and streamline interactions with systems thoughtfully designed around the way you work.



ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

ALINITY CI-SERIES

Thoughtfully designed around the way you work

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity, flexibility, operational productivity** and **confidence**.



SYSTEM SOFTWARE

Seamlessly work across systems with common, intuitive, easy-to-use software.



PRIORITY SAMPLE PROCESSING

Flexible options prioritize the most critical samples based on your workflow.



DEDICATED PRETREATMENT PATH

A dedicated pretreatment path allows continuous processing of routine and STAT immunoassays without compromise to turnaround times.



REAGENT AND SAMPLE MANAGER

Deliver samples, reagents and other solutions to any module with a single random-access robotic transport system without compromising STATs



CONTINUOUS ACCESS TO REAGENTS AND SUPPLIES

Continually load and unload supplies, no need to stop or pause the system. Load on the fly while the system continues to run.



ERROR-PROOF REAGENT LOADING

Prevent reagent mix-ups, retesting and probe crashes with built-in safeguards.



INCREASED LOAD-UP CAPACITY

Load up to 150 samples and up to 70 clinical chemistry or 47 immunoassay reagents per module.



ONBOARD CALIBRATORS AND CONTROLS

Load bar-coded calibrators and controls at any time, store them on the system, and automatically run them at user-defined intervals.



SYSTEM CONTROL MODULE

Control all modules of an integrated system from a single control unit

Alinity ci-series

INFORMATICS

Centralized management across your Alinity systems

Together with your Alinity systems, Alinity PRO is designed to fully maximize your systems' potential. Alinity PRO software works with Alinity systems to **enhance operational productivity** throughout your network, allowing for easier and consolidated system monitoring anytime, anywhere.

Designed with:

CONSOLIDATED REAL-TIME DASHBOARDS

- Remote dashboard capabilities enable staff to capitalize on system “walkaway time” via immediate notifications.

“PLAN MY DAY” – CHECKLISTS

- Forward-looking “Plan My Day” checklists help minimize interruptions.



Alinity PRO

DESIGNED TO SHARE REAGENTS BETWEEN SYSTEMS AND REDUCE WASTE.

- Reduce waste and inventory management by enabling staff to seamlessly transfer inventory between systems.



ABBOTT DIAGNOSTICS

Achieve measurably better healthcare performance with our personalized solutions.

We've reengineered our entire organization to support you and your changing needs, helping you achieve measurably better healthcare performance with our personalized solutions:



RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.



HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.



INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

HARMONIZED SYSTEMS

A unified, holistic family of systems delivering unprecedented integration*



UNIFORMITY across the laboratory



FLEXIBILITY to adapt to a changing environment



OPERATIONAL PRODUCTIVITY to improve performance and workflow



CONFIDENCE in systems and performance



ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

YOUR PERSONALIZED SOLUTION

Choose tomorrow's approach today.
Alinity ci-series adapts to your laboratory's
needs, allowing you to achieve measurably
better healthcare performance.

Alinity

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Achieve measurably better healthcare performance
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