



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.

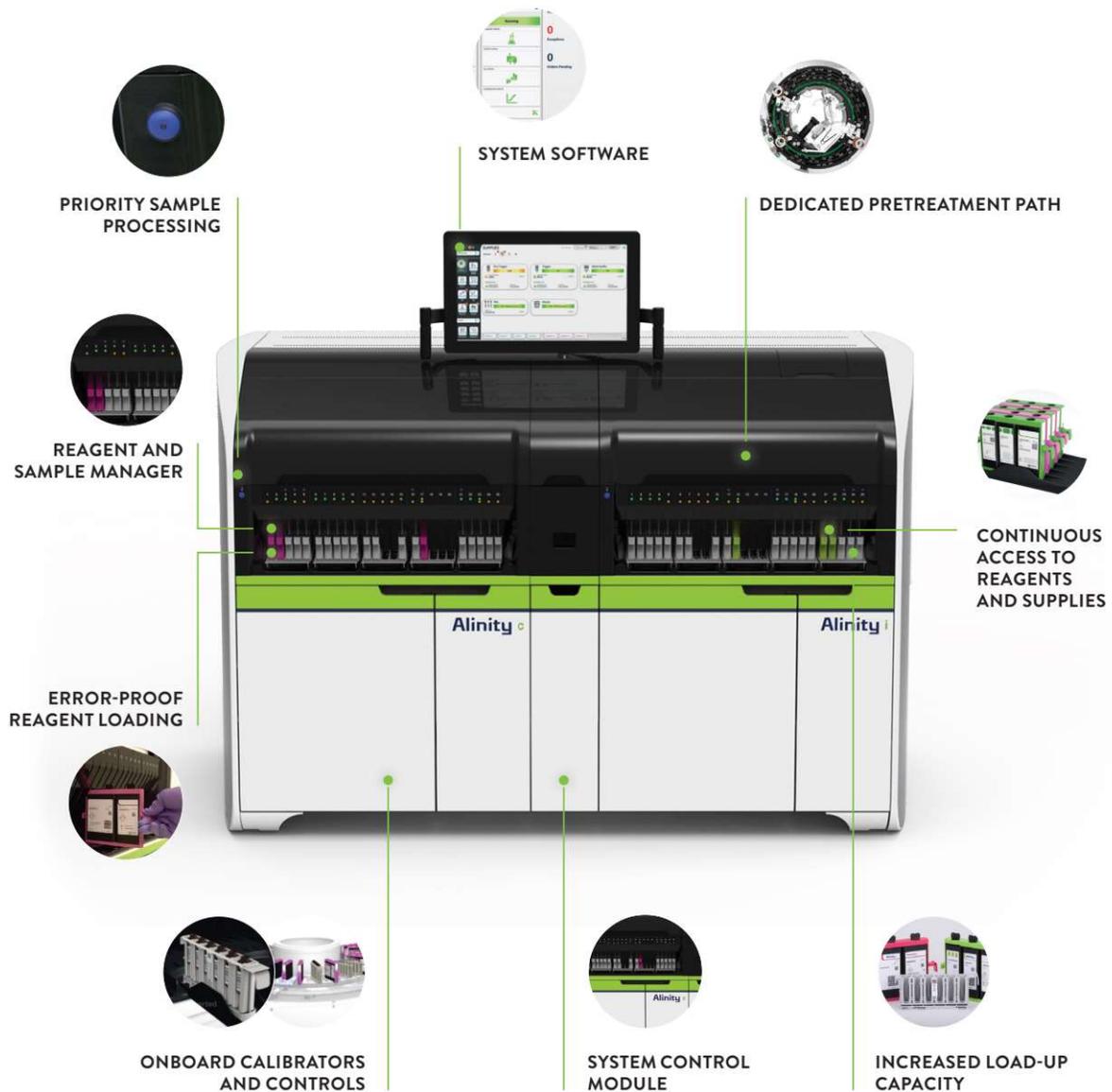


## ALINITY CI-SERIES

# 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



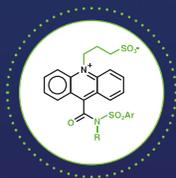
### ICT Module

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



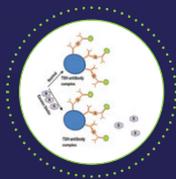
### SmartWash Technology

SmartWash technology prevents clinically significant sample-to-sample carryover ( $\leq 0.1$  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.



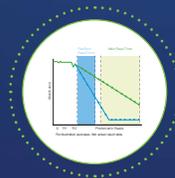
### No Biotin Interference

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



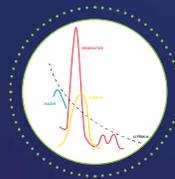
### Clot and Bubble Detection

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](https://www.alinity.com)

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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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

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

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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 Global Regulatory & Quality

Original Registration Date: 2019-12-18

Effective Date: 2024-12-09

Expiry Date: 2027-11-01



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

...making excellence a habit.™

Certificate No: **MDSAP 762409**

## Registered Scope:

Design, development, manufacture, and distribution 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.  
Design, development, and manufacture of In Vitro Diagnostic products including instruments, reagents, and accessories for Hematology.



Original Registration Date: 2019-12-18

Effective Date: 2024-12-09

Expiry Date: 2027-11-01

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://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.



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

**Abbott Ireland Diagnostics Division**  
Lisnamuck - Longford  
Co. Longford  
Ireland

has established and applies  
a Quality Management System for

**Design and Development,  
Manufacture and Distribution of  
In-Vitro Diagnostic Reagents for  
Clinical Chemistry and Immunochemistry.**

An audit was performed, Order No. **707120365**.

Proof has been furnished that the requirements  
according to

**DIN EN ISO 9001:2015**

are fulfilled.

The certificate is valid from **2023-09-01** until **2026-08-31**.

Certificate Registration No.: **12 100 60456 TMS**.

Head of Certification Body  
Munich, 2023-06-02



CERTIFICAT



CERTIFICADO



СЕРТИФИКАТ



認證證書



CERTIFICATE



ZERTIFIKAT

# 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, reagents, and accessories for immunoassay, clinical chemistry, and hematology 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 Global Regulatory & Quality

Original Registration Date: 2022-06-13

Latest Revision Date: 2024-12-12

Effective Date: 2024-12-12

Expiry Date: 2027-11-01

Page: 1 of 1



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**Abbott**

# Customer Service Organization Certificate of Technical Competence

This is to acknowledge that

**Vasilii Semeniuc**

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has met Abbott's Service Certification Criteria for

**Alinity c series Certification Exam - Distributors**

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**Certificate is valid for two years from printed completion date**

Doka Ioan Aurelian

Manager

*I certify that this individual has completed the program requirements*

31 March - 4 April  
Bucharest - Romania

04/04/2025

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*I certify that on the dates above, this individual has completed the program requirements for Instrument Certification*