



# element

## Abbott Laboratories

GLP12415 SAL Alinity Basic Kit

FCC 2.1091:2022

RFID

Report: ABBO0080.7 Rev. 1, Issue Date: October 24, 2022



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# CERTIFICATE OF EVALUATION

Last Date of Evaluation: October 21, 2022  
Abbott Laboratories  
EUT: GLP12415 SAL Alinity Basic Kit

## RF Exposure Evaluation

### Standards

Specification	Method
FCC 2.1091:2022	FCC 447498 D01 General RF Exposure Guidance v06

### Results

Method Clause	Description	Applied	Results	Comments
7.1	Maximum Permissible Exposure	Yes	Pass	None

### Deviations From Evaluation Standards

None

### Approved By:

Donald Facteau, Process Architect

*Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing*

# REVISION HISTORY



<b>Revision Number</b>	<b>Description</b>	<b>Date</b> (yyyy-mm-dd)	<b>Page Number</b>
01	Recalculated using 100% duty cycle and updated output power values.	2022-10-21	9, 10
	Updated dates.	2022-10-21	2, 6
	Updated EUT name.	2022-10-24	1, 2, 6, 7

# ACCREDITATIONS AND AUTHORIZATIONS



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## United States

**FCC** - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

**A2LA** - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

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## Canada

**ISED** - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

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## European Union

**European Commission** – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

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## United Kingdom

**BEIS** – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

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## Australia/New Zealand

**ACMA** - Recognized by ACMA as a CAB for the acceptance of test data.

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## Korea

**MSIT / RRA** - Recognized by KCC's RRA as a CAB for the acceptance of test data.

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## Japan

**VCCI** - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

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## Taiwan

**BSMI** – Recognized by BSMI as a CAB for the acceptance of test data.

**NCC** - Recognized by NCC as a CAB for the acceptance of test data.

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**IDA** – Recognized by IDA as a CAB for the acceptance of test data.

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## Israel

**MOC** – Recognized by MOC as a CAB for the acceptance of test data.

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## Hong Kong

**OFCA** – Recognized by OFCA as a CAB for the acceptance of test data.

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## Vietnam

**MIC** – Recognized by MIC as a CAB for the acceptance of test data.

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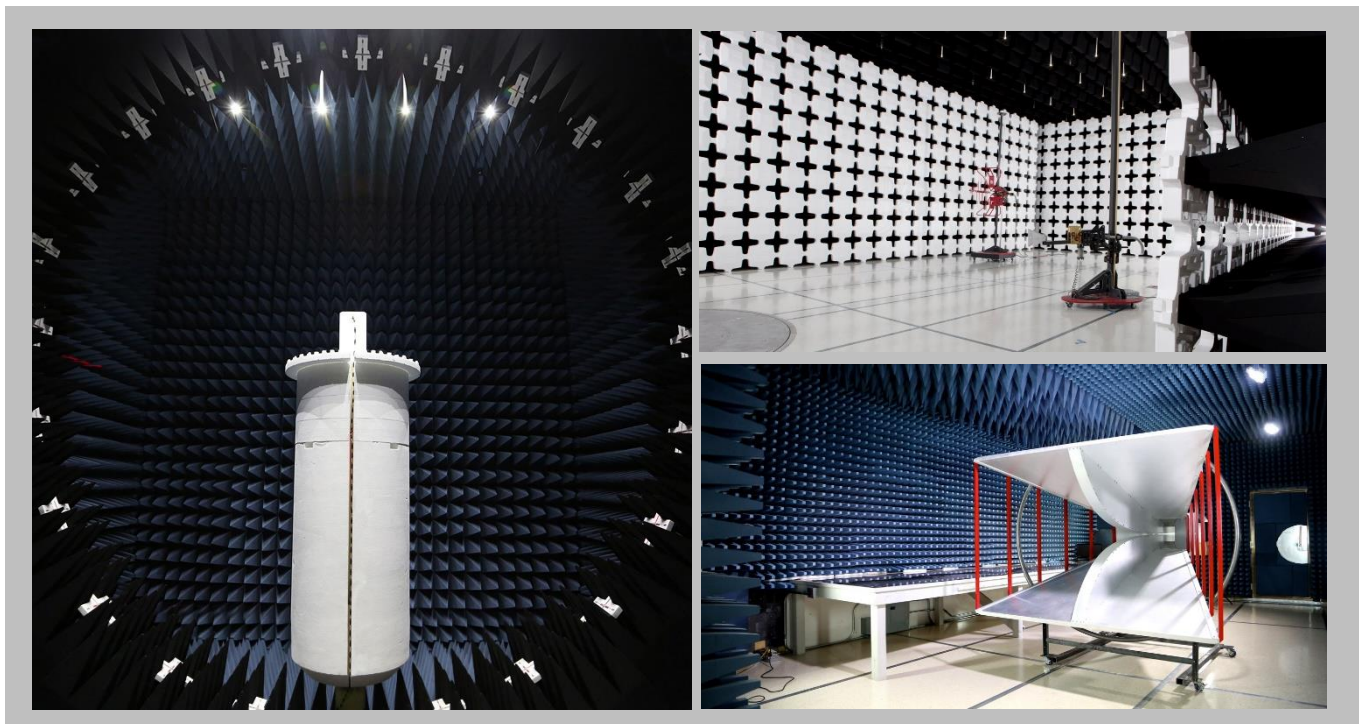
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<b>BSMI</b>				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
<b>VCCI</b>				
A-0029	A-0109	A-0108	A-0201	A-0110
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US0158	US0175	US0017	US0191	US0157





# PRODUCT DESCRIPTION

## Client and Equipment Under Evaluation Information

<b>Company Name:</b>	Abbott Laboratories
<b>Address:</b>	6901 Preston Rd
<b>City, State, Zip:</b>	Plano, TX 75024
<b>Evaluation Requested By:</b>	Don Mendell
<b>EUT:</b>	GLP12415 SAL Alinity Basic Kit
<b>Date of Evaluation:</b>	10/21/2022

## Information Provided by the Party Requesting the Evaluation

### Functional Description of the Equipment:

The SAL Alinity CI series is the interface between the GLP systems Track and an Alinity CI-series analyzer. Patient samples to be analyzed by the Alinity CI System are taken directly from the sample tube in the CAR using the pipette unit of an Alinity C or Alinity I processing module. GLP12408 SAL Alinity c end section, which contains an access point and barcode reader, is used to interface with a single Alinity C analyzer.

A SAL Alinity Basic Kit may be used to link several Alinity CI-series analyzers together. The kit contains: 1 T-Element, 2 Track Segment Units, 1 24V Power Supply, and 1 SMC Section. 1 CrossSwitch with 2 RFID radios is contained within the T-Element.

### Objective:

To demonstrate compliance with FCC requirements for RF exposure for 2.1091 mobile/fixed devices

# RF EXPOSURE CONDITION



<b>The following RF Exposure conditions were used for the assessment documented in this report:</b>	
Intended Use	Mobile
Location on Body (if applicable)	NA
How is the Device Used	The GLP12409 SAL Alinity Basic Kit is used at a distance of greater than 20 cm from the user.
Radios Contained in the Same Host Device	RFID: Cross Switch 1 Radio 1 RFID: Cross Switch 1 Radio 2
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure



# MAXIMUM PERMISSIBLE EXPOSURE (MPE)



## OVERVIEW

Human exposure to RF emissions from mobile devices (47 CFR §2.1091) may be evaluated based on the MPE limits adopted by the FCC for electric and magnetic field strength and/or power density, as appropriate, since exposures are assumed to occur at distances of 20 cm or more from persons. ANSI C95.1:2005 + Amd 1:2010 specifies a minimum separation distance of 20 cm for performing reliable field measurements to determine adherence to MPE limits. If the minimum separation distance between a transmitter and nearby persons is more than 20 cm under normal operating conditions, compliance with MPE limits may be determined at such distance from the transmitter. When applicable, operation instructions and prominent warning labels may be used to alert the exposed persons to maintain a specified distance from the transmitter or to limit their exposure durations and usage conditions to ensure compliance. If the use of warning labels on a transmitter is not effective or desirable, the alternative of performing SAR evaluation with the device at its closest range to persons under normal operating conditions may be used. The field strength and power density limits adopted by the FCC are based on whole-body averaged exposure and the assumption of RF field levels relate most accurately to estimating whole-body averaged SAR. This means some local values of exposures exceeding the stated field strength and power density limits may not necessarily imply non-compliance if the spatial average of spatially averaged RF fields over the exposed portions of a person's body does not exceed the limits.

## COMPLIANCE WITH FCC 2.1091

### 47 CFR §1.1307

*“(b)(1) Requirements. (i) With respect to the limits on human exposure to RF provided in §1.1310 of this chapter, applicants to the Commission for the grant or modification of construction permits, licenses or renewals thereof, temporary authorities, equipment authorizations, or any other authorizations for radiofrequency sources must either:*

*(A) Determine that they qualify for an exemption pursuant to §1.1307(b)(3);*

*(B) Prepare an evaluation of the human exposure to RF radiation pursuant to §1.1310 and include in the application a statement confirming compliance with the limits in §1.1310; or*

*(C) Prepare an Environmental Assessment if those RF sources would cause human exposure to levels of RF radiation in excess of the limits in §1.1310.*

### 47 CFR §2.1091

*“A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the RF source's radiating structure(s) and the body of the user or nearby persons. In this context, the term “fixed location” means that the device is physically secured at one location and is not able to be easily moved to another location while transmitting. Transmitting devices designed to be used by consumers or workers that can be easily re-located, such as wireless devices associated with a personal desktop computer, are considered to be mobile devices if they meet the 20-centimeter separation requirement.”*

**The device will only be used with a separation distance between the antenna and the body of the user or nearby persons as shown in the table below and can therefore be considered a mobile transmitter per 47 CFR 2.1091(b).**

## COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.



# MAXIMUM PERMISSIBLE EXPOSURE (MPE)



Devices operating in standalone mobile device exposure conditions may contain a single transmitter or multiple transmitters that do not transmit simultaneously are covered in section 7.1.

Devices containing multiple transmitters capable of simultaneous transmissions are covered in section 7.2.

## LIMITS

### Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm <sup>2</sup> )	Averaging Time (minutes)
0.3 - 1.34	614	1.63	*(100)	30
1.34 - 30	824/f	2.19/f	*(180/f <sup>2</sup> )	30
30 - 300	27.5	0.073	0.2	30
300 - 1500			f/1500	30
1500 - 100000			1	30

f = frequency in MHz

\* = Plane-wave equivalent power density

## ASSESSMENT

The exposure level for the radio is evaluated at a 20 cm distance from the radio's transmitting antenna using the general equation:

$$S = \frac{P * G}{4 * \pi * R^2}$$

Where: S = power density (mW/cm<sup>2</sup>)

P = power input to the antenna (mW)

G = numeric power gain relative to an isotropic radiator

R = distance to the center of the radiation of the antenna (20 cm = limit for MPE estimates)

P\*G = EIRP

Solving for S, the maximum power density 20 cm from the transmitting antenna is determined. This level is then compared to the applicable limit for the transmit frequency. If limits were not met at the 20 cm boundary the evaluation distance is increased until the limit is met as shown in the table below.

For co-located radios, the ratio of the calculated level to the limit is determined. The ratios for each co-located radio are summed. If the sum is less than or equal to one, then the device is excluded from testing and is deemed compliant.

# MAXIMUM PERMISSIBLE EXPOSURE (MPE)



The standalone MPE and summed MPE ratios are summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm <sup>2</sup> )	Limit (mW/cm <sup>2</sup> )	Compliant
RFID: Cross Switch 1 Radio 2	13.56	19.9 dBuV/m @ 30m	0.0	100.0%	20	0.0	1.0	Yes
RFID: Cross Switch 1 Radio 1	13.56	25.6 dBuV/m @ 30m	0.0	100.0%	20	0.0	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. Customer supplied information and Element report ABBO0080.5 Rev. 1

Evaluator: Jay Whitworth

End of Test Report