Alinity c Glucose-15

Prepared by: Yusra Othman /Director/Supervisor-Chem **Date:** May/21/2024
signature/title

Reviewed by: Jordan Dillard /Instructor **Date:** July 08 2024
signature/title

Approved by: Stanford V. Carey, M.D /Chairman **Date:** July 9 2024
signature/title

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INTENDED USE

The Alinity c Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Blood glucose determinations are the most frequently performed clinical chemistry laboratory procedures, commonly used as an aid in the diagnosis and treatment of diabetes. Elevated glucose levels (hyperglycemia) may also occur with pancreatic neoplasm, hyperthyroidism, and adrenal cortical hyperfunction as well as other disorders. Decreased glucose levels (hypoglycemia) may result from excessive insulin therapy or various liver diseases.

PRINCIPLES OF THE PROCEDURE

Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD) to nicotinamide adenine dinucleotide reduced (NADH). One micromole of NADH is produced for each micromole of glucose consumed. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Methodology: Enzymatic (Hexokinase/G-6-PDH)

For additional information on system and assay technology, **refer to the Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity c Glucose Reagent Kit 07P55

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	07P5520	07P5530
Tests per cartridge	400	1100
Number of cartridges per kit	10	10
Tests per kit	4000	11 000
R1	26.5 mL	66.4 mL
R1 Active ingredients: ATP ·2Na (9.0 mg/mL), NAD (5.0 mg/mL), G-6-PDH (3000 U/L), Hexokinase (15 000 U/L). Preservative: sodium azide (0.05%).		

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1], [2], [3], [4]

The following warnings and precautions apply to: R1

Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or/and SDS folder.

For a detailed discussion of safety precautions during system operation**, refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 7.**

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Alinity c Glucose assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, **refer to the Alinity ci-series Operations Manual.**

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	0.0555	mmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin Sodium fluoride/potassium oxalate EDTA	
Urine (random specimens)	Clean plastic or glass container without preservatives	
Urine (24 hour)	Clean plastic or glass container with preservatives	Preserve samples by adding 5 mL glacial acetic acid to the container before starting the collection.[5]
Cerebrospinal Fluid (CSF)	Standard CSF collection vessel	Process immediately to avoid falsely low results.[6]

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Storage

Glucose in whole blood stored at room temperature is metabolized at a rate of approximately **5% per hour**.[7]

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/Plasma	20 to 25°C	2 days[8]	Stabilized with sodium fluoride/potassium oxalate.
	2 to 8°C	7 days[8, 9]	Stabilized with sodium fluoride/potassium oxalate.
	-20°C	3 months[10]	Stabilized with sodium fluoride/potassium oxalate.
Urine	20 to 25°C	2 hours[8]	
	2 to 8°C	2 hours[8, 9]	
	-20°C	2 days[8]	
CSF	20 to 25°C	5 hours[8]	
	2 to 8°C	3 days[8, 9]	
	-20°C	> 1 month[8]	

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[8]

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

07P55 Alinity c Glucose Reagent Kit

Materials Required but not Provided

- Alinity c Glucose assay file
- 08P6001 Alinity c Multiconstituent Calibrator Kit
- Commercially available controls containing glucose
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 2.0 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. **For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.**
- Refer to the Alinity c Multiconstituent Calibrator Kit package insert and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, **Section 9. Perform maintenance more frequently when required by laboratory procedures.**

Sample Dilution Procedures

Serum/Plasma

Serum and plasma samples with a glucose value exceeding 800 mg/dL (44.40 mmol/L) are flagged with the code "> 800 mg/dL" (> 44.40 mmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine/CSF

Urine and CSF samples with a glucose value exceeding 800 mg/dL (44.40 mmol/L) are flagged with the code "> 800 mg/dL" (> 44.40 mmol/L) and may be diluted with the Manual Dilution Procedure.

Serum/Plasma Automated Dilution Protocol

The system performs a **1:5** dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by

the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 5 mg/dL (0.28 mmol/L) for serum and plasma samples or 1 mg/dL (0.06 mmol/L) for urine and CSF samples, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately **30 days (720 hours),** but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the laboratory procedure. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- Two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by laboratory procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.*11*

Verification of Assay Claims

For protocols to verify package insert claims, **refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.**

RESULTS

Calculation

The Alinity c Glucose assay utilizes the Linear data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

Interpretation of Results

As with all analyte determinations, the glucose value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (mmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Glucose assay serum/plasma application is **5 to 800** mg/dL (0.28 to 44.40 mmol/L).

The measuring interval of the Alinity c Glucose assay urine/CSF application is 1 to 800 mg/dL (0.06 to 44.40 mmol/L).

LIMITATIONS OF THE PROCEDURE

- The Alinity c Glucose assay using the serum application is susceptible to interference effects from unconjugated bilirubin at > 30 mg/dL.

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

The reference ranges provided in the table below are from Burtis et al., 2012.[12]

Reference Range

The American Diabetes Association recommends use of a fasting glucose concentration of 99 mg/dL (5.5 mmol/L) as the upper limit of "normal".[13], [14] Population reference ranges in various texts and publications may differ.

Serum/Plasma[12]

Fasting	**Range (mg/dL)**	**Range (mmol/L)**
Cord	45 to 96	2.5 to 5.3
Premature	20 to 60	1.1 to 3.3
Neonate	30 to 60	1.7 to 3.3
Newborn, 1 day	40 to 60	2.2 to 3.3
Newborn, > 1 day	50 to 80	2.8 to 4.5
Child	60 to 100	3.3 to 5.6

Fasting	Range (mg/dL)	Range (mmol/L)
Adult	74 to 100	4.1 to 5.6
> 60 years	82 to 115	4.6 to 6.4
> 90 years	75 to 121	4.2 to 6.7

Urine[12]		
	Range	**Range**
Random	1 to 15 mg/dL	0.1 to 0.8 mmol/L
24 hour	< 0.5 g/day	< 2.8 mmol/day

Cerebrospinal Fluid[12]		
	Range (mg/dL)	**Range (mmol/L)**
Infant, Child	60 to 80	3.3 to 4.5
Adult	40 to 70	2.2 to 3.9

24-Hour Urinary Excretion

To convert results from mg/dL to g/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 100 000] g/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mg/dL)

To convert results from mmol/L to mmol/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 1000] mmol/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mmol/L)

To convert results from g/day to mmol/day, multiply g/day by 5.55.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

The Alinity c analyzer and the ARCHITECT System utilize the same reagents and sample/reagent ratios.

Precision

Within-Laboratory Precision

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A2.*15* Testing was conducted using 2 lots of the Alinity c Glucose Reagent Kit, 2 lots of the Alinity c Multiconstituent Calibrator Kit, 2 lots of commercially available controls and 2 instruments. Three controls and 3 human serum panels were assayed in a minimum of 2 replicates (target of 3 replicates) at 2 separate times per day on 22 different days.

				Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**Control Lot**	**n[b]**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[c])**	**%CV (Range[c])**
Control Level 1	1	264	55	0.6	1.1	0.7 (0.5-0.8)	1.2 (1.0-1.4)
	2	264	55	0.5	0.9	0.6 (0.5-0.7)	1.1 (0.9-1.2)
Control Level 2	1	264	128	1.1	0.8	1.3 (1.1-1.4)	1.0 (0.9-1.1)
	2	263	128	0.9	0.7	1.3 (1.1-1.4)	1.0 (0.9-1.1)
Control Level 3	1	264	315	2.2	0.7	2.8 (2.5-3.1)	0.9 (0.8-1.0)
	2	260	311	2.1	0.7	2.5 (2.1-2.9)	0.8 (0.7-0.9)
Panel A	N/A	527	7	0.1	1.9	0.1 (0.0-0.2)	1.9 (0.0-2.8)
Panel B	N/A	528	106	0.8	0.8	1.0 (0.8-1.2)	0.9 (0.7-1.2)
Panel C	N/A	523	728	5.6	0.8	5.9 (4.4-7.6)	0.8 (0.6-1.1)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a

run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

Sample	Control Lot	n[b]	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])
Control Level 1	1	264	3.03	0.031	1.0	0.035 (0.029-0.041)	1.2 (1.0 -1.4)
	2	264	3.03	0.027	0.9	0.032 (0.029-0.036)	1.1 (0.9-1.2)
Control Level 2	1	264	7.12	0.059	0.8	0.071 (0.064-0.077)	1.0 (0.9-1.1)
	2	263	7.09	0.052	0.7	0.071 (0.064-0.078)	1.0 (0.9-1.1)
Control Level 3	1	264	17.50	0.122	0.7	0.156 (0.140-0.169)	0.9 (0.8-1.0)
	2	260	17.26	0.119	0.7	0.139 (0.116-0.160)	0.8 (0.7-0.9)
Panel A	N/A	527	0.39	0.007	1.8	0.007 (0.000-0.010)	1.8 (0.0-2.7)
Panel B	N/A	528	5.88	0.046	0.8	0.054 (0.044-0.067)	0.9 (0.7-1.1)
Panel C	N/A	523	40.38	0.309	0.8	0.329 (0.247-0.421)	0.8 (0.6-1.1)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

Urine

A study was performed based on guidance from CLSI EP05-A2.[15] Testing was conducted using 2 lots of the Alinity c Glucose Reagent Kit, 2 lots of the Alinity c Multiconstituent Calibrator Kit, 2 lots of commercially available controls and 2 instruments. Two controls and

4 panels were assayed in a minimum of 2 replicates (target of 3 replicates) at 2 separate times per day on 22 different days.

				Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**Control Lot**	**n[b]**	**Mean (mg/dL)**	**SD**	**%CV**	**SD (Range[c])**	**%CV (Range[c])**
Control Level 1	1	264	38	0.4	1.0	0.5 (0.5-0.5)	1.3 (1.3-1.3)
	2	263	38	0.3	0.9	0.6 (0.5-0.6)	1.4 (1.4-1.5)
Control Level 2	1	260	359	2.9	0.8	3.4 (2.9-4.0)	1.0 (0.8-1.1)
	2	264	353	2.4	0.7	3.0 (2.5-3.3)	0.8 (0.7-0.9)
Panel A	N/A	527	3	0.1	3.8	0.1 (0.0-0.2)	3.8 (0.0-6.4)
Panel B	N/A	526	60	1.0	1.6	1.2 (1.1-1.5)	2.1 (1.8-2.5)
Panel C	N/A	528	110	2.4	2.2	3.1 (2.5-4.2)	2.8 (2.3-3.8)
Panel D	N/A	525	712	6.2	0.9	8.1 (7.4-8.7)	1.1 (1.0-1.2)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

				Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**Control Lot**	**n[b]**	**Mean (mmol/L)**	**SD**	**%CV**	**SD (Range[c])**	**%CV (Range[c])**
Control Level 1	1	264	2.12	0.020	0.9	0.026	1.2

Sample	Control Lot	n[b]	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])
						(0.024-0.028)	(1.1-1.3)
	2	263	2.13	0.019	0.9	0.030	1.4
						(0.029-0.030)	(1.4-1.4)
Control Level 2	1	260	19.92	0.163	0.8	0.191	1.0
						(0.159-0.219)	(0.8-1.1)
	2	264	19.61	0.133	0.7	0.164	0.8
						(0.140-0.184)	(0.7-0.9)
Panel A	N/A	527	0.17	0.006	3.6	0.006	3.6
						(0.000-0.010)	(0.0-6.1)
Panel B	N/A	526	3.31	0.054	1.6	0.070	2.1
						(0.063-0.082)	(1.9-2.5)
Panel C	N/A	528	6.12	0.132	2.2	0.173	2.8
						(0.140-0.234)	(2.3-3.8)
Panel D	N/A	525	39.53	0.343	0.9	0.450	1.1
						(0.409-0.482)	(1.0-1.2)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

CSF

A study was performed based on guidance from CLSI EP05-A2.*15* Testing was conducted using 2 lots of the Alinity c Glucose Reagent Kit, 2 lots of the Alinity c Multiconstituent Calibrator Kit, 2 lots of commercially available controls and 2 instruments. Two controls and 4 human CSF panels were assayed in a minimum of 2 replicates (target of 3 replicates) at 2 separate times per day on 22 different days.

Sample	Control Lot	n[b]	Mean (mg/dL)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])

Sample	Control Lot	n[b]	Mean (mg/dL)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])
Control Level 1	1	264	60	0.5	0.9	0.6 (0.6-0.7)	1.1 (1.0-1.1)
	2	264	61	0.5	0.7	0.6 (0.6-0.6)	1.0 (1.0-1.0)
Control Level 2	1	264	30	0.3	0.9	0.3 (0.3-0.4)	1.1 (0.9-1.2)
	2	263	31	0.4	1.1	0.4 (0.2-0.5)	1.3 (0.8-1.6)
Panel A	N/A	527	3	0.1	4.8	0.1 (0.1-0.2)	4.8 (2.9 -7.5)
Panel B	N/A	528	57	0.4	0.8	0.5 (0.4-0.6)	0.9 (0.8-1.0)
Panel C	N/A	527	107	0.7	0.7	0.8 (0.7-1.0)	0.8 (0.6-1.0)
Panel D	N/A	526	700	3.8	0.5	4.8 (4.3-5.3)	0.7 (0.6-0.8)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

Sample	Control Lot	n[b]	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])
Control Level 1	1	264	3.34	0.031	0.9	0.038 (0.035-0.040)	1.1 (1.0-1.2)
	2	264	3.41	0.026	0.8	0.035	1.0

Sample	Control Lot	n[b]	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[c])	Within-Laboratory (Total)[a] %CV (Range[c])
						(0.035-0.035)	(1.0-1.0)
Control Level 2	1	264	1.67	0.015	0.9	0.018	1.1
						(0.014-0.021)	(0.8-1.3)
	2	263	1.71	0.018	1.1	0.020	1.2
						(0.013-0.025)	(0.8-1.5)
Panel A	N/A	527	0.17	0.008	4.4	0.008	4.4
						(0.004-0.012)	(2.6-7.0)
Panel B	N/A	528	3.17	0.025	0.8	0.030	0.9
						(0.022-0.034)	(0.7-1.1)
Panel C	N/A	527	5.92	0.038	0.6	0.044	0.8
						(0.037-0.057)	(0.6-1.0)
Panel D	N/A	526	38.86	0.208	0.5	0.268	0.7
						(0.238-0.295)	(0.6-0.8)

[a] Includes within-run, between-run, and between-day variability.

[b] If no result was obtained for one of the target three replicates for a panel or control within a run, the lost replicate was not retested.

[c] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

Accuracy

Representative data from studies using **NIST traceable serum** standards and comparing the results with NIST certified concentrations are summarized below.

N	22
Concentration (mg/dL)	75.56
% Bias	1.2
% Total Error Serum	2.5

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[16] Testing was conducted using 3 lots of the Alinity c Glucose Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD), and Limit

of Quantitation (LoQ) values are summarized below.

Serum/Plasma

	mg/dL	mmol/L
LoB[a]	0.33	0.02
LoD[b]	0.55	0.03
LoQ[c]	**2.25**	0.12

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Urine/CSF

	mg/dL	mmol/L
LoB[a]	0.23	0.01
LoD[b]	0.40	0.02
LoQ[c]	0.86	0.05

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Linearity

A study was performed based on guidance from CLSI EP06-A.*17*

The serum/plasma application of the Alinity c Glucose assay is linear across the measuring interval of **5 to 800 mg/dL** (0.28 to 44.40 mmol/L).

The urine/CSF application of the Alinity c Glucose assay is linear across the measuring interval of 1 to 800 mg/dL (0.06 to 44.40 mmol/L).

Interference

Potentially Interfering Substances

A study was performed based on guidance from CLSI EP07-A2.*18*

Serum/Plasma

For serum/plasma, a bias of > 6% or > 1 mg/dL was considered significant interference.

Potentially	Interferent Level	Glucose

Interfering Substance	Default Units	Alternate Units	Target Level mg/dL	Recovery (% of Target)
Unconjugated Bilirubin	30 mg/dL	513 µmol/L	93.2	99.5
			136.9	99.5
	60 mg/dL	1026 µmol/L	87.4	91.8*
			128.0	92.6*
Conjugated Bilirubin	20 mg/dL	237 µmol/L	92.7	98.5
			134.4	100.1
	30 mg/dL	356 µmol/L	91.8	98.4
			134.5	98.8
	60 mg/dL	712 µmol/L	92.2	98.4
			135.7	98.4
Hemoglobin	1000 mg/dL	10.0 g/L	88.4	97.3
			130.2	97.8
	2000 mg/dL	20.0 g/L	81.5	95.8
			120.4	96.6
Triglycerides	1000 mg/dL	10.0 g/L	90.6	99.8
			134.0	100.3
	2000 mg/dL	20.0 g/L	86.6	100.1
			127.5	99.5
Ascorbic Acid	6 mg/dL	341 µmol/L	91.3	100.3
			133.4	100.1
Acetaminophen	20 mg/dL	1323 µmol/L	91.4	100.2
			133.6	99.9
Ibuprofen	50 mg/dL	2424 µmol/L	91.3	99.9
			132.4	100.7
Acetylcysteine	167 mg/dL	10.2 mmol/L	91.0	100.6
			133.3	100.3

Potentially Interfering Substance	Interferent Level		Glucose	
	Default Units	Alternate Units	Target Level mg/dL	Recovery (% of Target)
Acetylsalicylic Acid	66 mg/dL	3.7 mmol/L	91.2	99.8
			133.4	100.0
Sodium Salicylate	70 mg/dL	4.4 mmol/L	91.5	100.0
			133.5	100.0

* > 6% Interference

Urine

For urine, a bias of > 10% or > 1 mg/dL was considered significant interference.

Potentially Interfering Substance	Interferent Level		Glucose	
	Default Units	Alternate Units	Target Level (mg/dL)	Recovery (% of Target)
Protein	50 mg/dL	0.5 g/L	14.6	99.4
			90.3	99.9
Ascorbate	200 mg/dL	11.4 mmol/L	14.4	100.7
			90.2	99.0
8.5N Acetic Acid	6.25 mL/dL	531 mmol/L	13.7	102.0
			85.2	102.3
Boric Acid	250 mg/dL	40.4 mmol/L	14.4	101.3
			90.1	100.6
6N Hydrochloric Acid	2.5 mL/dL	150 mmol/L	13.4	103.8
			85.3	100.8
6N Nitric Acid	5.0 mL/dL	300 mmol/L	13.7	101.4
			84.6	100.9
Sodium Oxalate	60 mg/dL	4.5 mmol/L	14.4	99.5
			89.2	99.7
Sodium Carbonate	1.25 g/dL	117.9 mmol/L	14.3	99.0

Potentially Interfering Substance	Interferent Level		Glucose	
	Default Units	Alternate Units	Target Level (mg/dL)	Recovery (% of Target)
			89.1	99.3
Sodium Fluoride	400 mg/dL	95.3 mmol/L	14.4	98.3
			88.7	98.9
Acetaminophen	20 mg/dL	1323 µmol/L	14.7	100.1
			91.7	98.8
Ibuprofen	50 mg/dL	2424 µmol/L	14.7	99.6
			91.1	99.8
Acetylcysteine	167 mg/dL	10.2 mmol/L	14.6	100.1
			91.0	100.2

The following drugs were tested on the ARCHITECT c System for interference at the concentrations indicated using an acceptance criteria of ± 6% or 1 mg/dL, whichever is greater, from the target value.

Potentially Interfering Substance	Interferent Level		Glucose	
	Default Units	Alternate Units	Target Level (mg/dL)	Recovery (% of Target)
Sulfapyridine	300 mg/L	1204.8 µmol/L	81.5	100.32
Sulfasalazine	300 mg/L	753.8 µmol/L	81.5	97.86
Temozolomide	20 mg/L	103.1 µmol/L	81.3	102.60

Interferences from medication or endogenous substances may affect results.[19]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[20]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Glucose vs ARCHITECT Glucose	Serum	mg/dL	98	1.00	-1.78	1.00	8 - 791
		mmol/L	98	1.00	-0.09	1.00	0.44 - 43.87
	Urine	mg/dL	118	1.00	0.24	0.99	4 - 785
		mmol/L	118	1.00	0.01	0.99	0.22 - 43.57

	Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
CSF	mg/dL	90	1.00	0.50	1.00	4 - 740
	mmol/L	90	1.00	0.03	1.00	0.22 - 41.07

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