

GLUC - GLUCOSE

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.

Clinical Significance 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.

Methodology 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)

Specimen

Type of Specimen	Specimen Type	Collection Vessel
	- Serum	Serum Tubes (with or without gel barrier)
	- Plasma	Collection tubes Acceptable anticoagulants Lithium Heparin (with or without barrier) Sodium Heparin, Sodium fluoride/ Potassium oxalate and EDTA

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Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.
2. 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. Specimens should be free of bubbles.
3. 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.
4. Glucose in whole blood stored at room temperature is metabolized at a rate of approximately 5% per hour.

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/ Plasma	20 to 25°C	2 days	Stabilized with sodium fluoride/ potassium oxalate.
	2 to 8°C	7 days	
	-20°C	3 months	

5.

Sample Dilution Procedures

Serum/Plasma

Samples with a glucose value exceeding 800 mg/dL re 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.

Automated Dilution Protocol

Serum/Plasma

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.

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Reagents

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

Reagent Storage and Stability

	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.

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Calibration

Calibration Required

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 cartridge or lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. 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.

Calibration Preparation

Calibration material is the Alinity c Multiconstituent Calibrator Kit. Ready to Use. Prior to each use, mix by gentle inversion.

Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
MC Cal (CAL 1 and CAL 2)	Unopened: 2 to 8 (until expiration date).	2 to 8 °C: 7 days 15 to 30°C: 24 hours Onboard: 5 days

Calibration Information

1. Calibrator values may be configured using e-files accessed and imported from www.corelaboratory.abbott, or from Abbott Mail.
2. Verify that the correct calibrator values have been entered into the calibration file.
3. Calibration is performed by running Alinity c Multiconstituent Calibrator Kit.
4. For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.

Quality Control

See Policy [Chemistry Quality Control Policy](#)

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Specimen Processing See Policy [RIV-PPP-1199](#)

Reference Range Test unit= mg/dL for all ages and both sexes.

Test	Age Day Low	Age Day High	Age Year Low	Age Year High	Ref Low	Ref High
FBS	0	1			70	99
FBS	1	31			70	99
FBS	31			250	70	99
RBS	0	1			55	115
RBS	1	31			55	115
RBS	31			250	70	140

Analytic Range

AMR Low	AMR High	CRR Low	CRR High
5	800	5	4000

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