

**en**

GLUCOSE

REF 3L82-22 and 3L82-42

G95983R03**B3L8C0****ARCHITECT**

GLUCOSE






This package insert contains information to run the Glucose assay on the ARCHITECT *c* Systems.

Revised March 2022.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Service: Contact your local representative or find country-specific contact information on [www. corelaboratory.abbott](http://www.corelaboratory.abbott).

Key to Symbols

ISO 15223 Symbols	Other Symbols
 Consult instructions for use	CONTAINS: AZIDE Contains sodium azide. Contact with acids liberates very toxic gas.
 Manufacturer	DISTRIBUTED IN THE USA BY Distributed in the USA by
 Sufficient for	FOR USE WITH Identifies products to be used together
 Temperature limitation	INFORMATION FOR USA ONLY Information needed for United States of America only
 Use by/Expiration date	MANUFACTURED FOR Manufactured for
IVD <i>In Vitro</i> Diagnostic Medical Device	PRODUCT OF CANADA Product of Canada
LOT Batch code/Lot number	R1 Reagent 1
REF Catalog number/List number	Rx ONLY For use by or on the order of a physician only (applicable to USA classification only).
SN Serial number	

NAME

GLUCOSE

INTENDED USE

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

SUMMARY AND EXPLANATION OF 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 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: Hexokinase/G-6-PDH

REAGENTS

Reagent Kit

Glucose is supplied as a liquid, ready-to-use, single reagent kit which contains:

REF 3L82-22

R1 5 x 20 mL

Estimated tests per kit: 1500*

REF 3L82-42

R1 10 x 90 mL

Estimated tests per kit: 15000*

*Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients	Concentration
R1 ATP · 2Na	9.0 mg/mL
NAD	5.0 mg/mL
G-6-PDH	3,000 U/L
Hexokinase	15,000 U/L

Inactive Ingredients: **R1** contains sodium azide (0.05%) as a preservative.

REAGENT HANDLING AND STORAGE

Reagent Handling

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 30 days if the reagent is uncapped and onboard.

Indications of Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, extreme turbidity, microbial growth, if calibration does not meet the appropriate package insert and/or **ARCHITECT System Operations Manual** criteria, or if controls do not meet the appropriate criteria.

WARNINGS AND PRECAUTIONS

Precautions for Users

- IVD**
- For *In Vitro* Diagnostic Use.
- Rx ONLY**
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- 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.¹ Biosafety Level 2² or other appropriate biosafety practices^{3,4} should be used for materials that contain or are suspected of containing infectious agents.
- 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.com or contact your local representative.
- For a detailed discussion of safety precautions during system operation, refer to the **ARCHITECT System Operations Manual, Section 8**.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum, plasma, urine, and CSF are acceptable specimens.

- Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum from blood cells.
Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier), sodium heparin, sodium fluoride/potassium oxalate, and EDTA. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.
- Urine:** Preserve 24 hour samples by adding 5 mL glacial acetic acid to the container before starting the collection.⁵
- CSF:** Process immediately to avoid falsely low results.⁶

For total sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert and *Section 5* of the **ARCHITECT System Operations Manual**.

Specimen Storage

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

Temperature	Maximum Storage			Bibliographic Reference
	Serum/Plasma*	Urine	CSF	
20 to 25°C	2 days	2 hours	5 hours	8
2 to 8°C	7 days	2 hours	3 days	8, 9
-20°C	3 months	2 days	> 1 month	8, 10

* Stabilized with sodium fluoride/potassium oxalate.

Guder et al.⁸ suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

3L82 Glucose Reagent Kit

Materials Required but not Provided

- 1E65 Multiconstituent Calibrator
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

Specimen Dilution Procedures

The ARCHITECT cSystems have an automatic dilution feature; refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

Serum and Plasma: Specimens with glucose values exceeding 800 mg/dL (44 mmol/L) are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine and CSF: Specimens with glucose values exceeding 800 mg/dL (44 mmol/L) are flagged and may be diluted by following the Manual Dilution Procedure, or an automatic dilution may be configured. Refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

Serum/Plasma Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a 1:5 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

CALIBRATION

Calibration is stable for approximately 30 days (720 hours) and is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the **ARCHITECT System Operations Manual**.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

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".^{11,12} Population reference ranges in various texts and publications may differ.

Serum/Plasma¹³

Fasting	Range (mg/dL)	Range (mmol/L)
Cord	45 to 96	2.50 to 5.33
Premature	20 to 60	1.11 to 3.33
Neonate	30 to 60	1.67 to 3.33
Newborn, 1 day	40 to 60	2.22 to 3.33
Newborn, > 1 day	50 to 80	2.78 to 4.44
Child	60 to 100	3.33 to 5.55
Adult	70 to 105	3.89 to 5.83
> 60 years	80 to 115	4.44 to 6.38
> 70 years	83 to 110	4.61 to 6.10

Urine¹³

	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 Fluid¹³

	Range (mg/dL)	Range (mmol/L)
Infant, Child	60 to 80	3.33 to 4.44
Adult	40 to 70	2.22 to 3.89

To convert results from mg/dL to mmol/L, multiply mg/dL by 0.0555.

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

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

24 Hour Urinary Excretion

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

24 hour excretion = $[(V \times c) \div 100,000]$ 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 = $[(V \times c) \div 1000]$ mmol/day

Where: V = 24 hour urine volume (mL)

c = analyte concentration (mmol/L)

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

Glucose serum is linear from 5 to 800 mg/dL (0.28 to 44.40 mmol/L). Glucose urine/CSF is linear from 1 to 800 mg/dL (0.06 to 44.40 mmol/L).

Limit of Detection (LOD)

The LOD for Glucose serum is 2.5 mg/dL (0.139 mmol/L). The LOD for Glucose urine/CSF is 1.0 mg/dL (0.056 mmol/L). The LOD is the lowest amount of analyte in a sample that can be detected with 95% probability.

Limit of Quantitation (LOQ)

The LOQ for Glucose in serum and plasma specimens is 5.0 mg/dL (0.278 mmol/L). The LOQ for Glucose in urine/CSF specimens is 1.0 mg/dL (0.056 mmol/L). The LOQ is the analyte concentration at which the CV = 20%.

Interfering Substances

Interference studies were conducted using an acceptance criteria of $\pm 6\%$ or 1 mg/dL from the target value.

Interference effects were assessed by Dose Response method at the medical decision levels of the analyte.

Medical Decision Level 1

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	30 mg/dL (513 μ mol/L)	4	83.1	99.89
	60 mg/dL (1,026 μ mol/L)	4	83.1	100.11
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	78.2	95.59
	2,000 mg/dL (20.0 g/L)	4	78.2	91.74
Intralipid	1,000 mg/dL (10.0 g/L)	4	81.0	98.21
	2,000 mg/dL (20.0 g/L)	4	81.0	97.84

Medical Decision Level 2

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Bilirubin	30 mg/dL (513 μ mol/L)	4	126.3	100.66
	60 mg/dL (1,026 μ mol/L)	4	126.3	101.14
Hemoglobin	1,000 mg/dL (10.0 g/L)	4	118.3	98.29
	2,000 mg/dL (20.0 g/L)	4	118.3	96.03
Intralipid	1,000 mg/dL (10.0 g/L)	4	119.1	99.70
	2,000 mg/dL (20.0 g/L)	4	119.1	99.58

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

For the urine application, protein up to 50 mg/dL, sodium oxalate up to 60 mg/dL, ascorbate up to 200 mg/dL, acetic acid (8.5 N) up to 6.25 mL/dL, boric acid up to 250 mg/dL, hydrochloric acid (6 N) up to 2.5 mL/dL, nitric acid (6 N) up to 5.0 mL/dL, sodium fluoride up to 400 mg/dL, and sodium carbonate up to 1.25 g/dL demonstrated less than 10% interference.

The following drugs were tested for interference at the concentrations indicated using an acceptance criteria of $\pm 6\%$ or 1 mg/dL from the target value.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Sulfapyridine	300 mg/L (1204.8 μ mol/L)	3	81.5	100.32
Sulfasalazine	300 mg/L (753.8 μ mol/L)	3	81.5	97.86
Temozolomide	20 mg/L (103.1 μ mol/L)	3	81.3	102.60

Interferences from medications or endogenous substances may affect results.¹⁴

Precision

The imprecision of the Glucose assay is $\leq 5\%$ Total CV for serum and CSF and $\leq 6\%$ Total CV for urine. Representative data from studies using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP5-A¹⁵ are summarized below.

Serum

Control		Level 1	Level 2
N		80	80
Mean (mg/dL)		79.6	281.3
Within Run	SD	1.58	1.83
	%CV	1.98	0.65
Between Run	SD	0.67	2.62
	%CV	0.84	0.93
Between Day	SD	0.00	2.80
	%CV	0.00	0.99
Total	SD	1.71	4.24
	%CV	2.15	1.51

Urine

Control		Level 1	Level 2
N		50	50
Mean (mg/dL)		29.9	305.9
Within Run	SD	0.30	2.12
	%CV	0.99	0.69
Between Run	SD	0.40	3.55
	%CV	1.33	1.16
Between Day	SD	0.00	0.00
	%CV	0.00	0.00
Total	SD	0.49	4.13
	%CV	1.66	1.35

CSF

Control		Level 1	Level 2
N		50	50
Mean (mg/dL)		60.4	29.0
Within Run	SD	0.57	0.41
	%CV	0.95	1.41
Between Run	SD	0.74	0.27
	%CV	1.23	0.92
Between Day	SD	0.00	0.00
	%CV	0.00	0.00
Total	SD	0.94	0.49
	%CV	1.55	1.69

Accuracy

The bias for Glucose serum is $\leq 6\%$ or ± 1 mg/dL, whichever is greater, and the Total Error for serum is $\leq 16\%$. Representative data from studies using NIST traceable standards and comparing the results with NIST certified concentrations are summarized below.

N	12
Concentration	80.70
% Bias	2.70
Total Error Serum	4.82

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A2.¹⁶

Serum, urine, and CSF results from the Glucose assay on an ARCHITECT cSystem were compared with those from a commercially available hexokinase/G-6-PDH methodology.

Serum, urine, and CSF results from the Glucose assay on an ARCHITECT cSystem were compared with those from the Glucose assay on the AEROSET System.

Serum	ARCHITECT vs. Comparative Method	ARCHITECT vs. AEROSET
N	102	102
Y - Intercept	-4.54	0.85
Correlation Coefficient	0.9993	0.9996
Slope	1.06	0.97
Range (mg/dL)	13.3 to 663.9	14.4 to 734.2
Urine	ARCHITECT vs. Comparative Method	ARCHITECT vs. AEROSET
N	41	41
Y - Intercept	-2.67	-1.36
Correlation Coefficient	0.9998	0.9999
Slope	1.04	0.96
Range (mg/dL)	2.1 to 717.4	2.0 to 772.3
CSF	ARCHITECT vs. Comparative Method	ARCHITECT vs. AEROSET
N	52	52
Y - Intercept	-3.89	0.22
Correlation Coefficient	0.9997	0.9998
Slope	1.04	0.95
Range (mg/dL)	10.5 to 697.7	11.2 to 770.4

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TRADEMARKS

The ARCHITECT cSystem family of instruments consists of c4000, c8000, and c16000 instruments.

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ARCHITECT

Glucose Serum/Plasma—Conventional and SI Units

Configure assay parameters — General				
<input checked="" type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluC		Type: Photometric	Version: †	
Number: 1069		Run controls for onboard reagents by: Lot		
<input checked="" type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks		
Reaction mode: End up				
Primary		Secondary	Read times	
Wavelength: 340 / 380		Main: 14 – 14		
Last required read: 14		Color correction: — – —		
Absorbance range: -0.1 – 3.2000		Blank: 2 – 2		
Sample blank type Self				

<input type="radio"/> Reaction definition		<input checked="" type="radio"/> Reagent / Sample		<input type="radio"/> Validity checks	
Reagent: GLUC9		Reagent volume: 57		R1	
Diluent: Saline		Water volume: 143			
Diluent dispense mode: Type 0		Dispense mode: Type 0			
Dilution name	Sample	Diluted sample	Diluent	Water	Dilution factor
STANDARD	2.0	—	—	—	1:1.00
1:5	20.0	2.0	80	—	1:5.00
—	—	—	—	—	—

<input type="radio"/> Reaction definition		<input type="radio"/> Reagent / Sample		<input checked="" type="radio"/> Validity checks	
Reaction check: None					
Maximum absorbance variation: —					

Configure assay parameters — Calibration				
<input type="radio"/> General	<input checked="" type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluC		Calibration method: Linear		
<input checked="" type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks	
Calibrator set: MCC		Calibrator level: 0[†]		Concentration: ++
Blank: Water		Cal 1: MCC1		++
Replicates: 3 [Range 1 – 3]		Cal 2: MCC2		++

<input type="radio"/> Calibrators		<input checked="" type="radio"/> Volumes		<input type="radio"/> Intervals		<input type="radio"/> Validity checks	
Calibrator: MCC		Calibrator level		Sample	Diluted sample	Diluent	Water
Blank: Water		2.0		—	—	—	—
Cal 1: MCC1		2.0		—	—	—	—
Cal 2: MCC2		2.0		—	—	—	—

<input type="radio"/> Calibrators		<input type="radio"/> Volumes		<input checked="" type="radio"/> Intervals		<input type="radio"/> Validity checks	
Calibration intervals:							
Full interval: 720		(hours)					
Calibration type:							
Adjust type: None							

<input type="radio"/> Calibrators		<input type="radio"/> Volumes		<input type="radio"/> Intervals		<input checked="" type="radio"/> Validity checks	
Blank absorbance range: — – —		Span: Blank – Blank					
Span absorbance range: — – —		Expected cal factor: 0.00					
Expected cal factor tolerance %: 0							

Configure assay parameters — SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluC				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	AMIK9	Detergent A	345	1
R1	DIG00	Detergent A	345	1
R1	VANCO	Detergent A	345	1
R1	GENT9	Detergent A	345	1
R1	TOBRA	Detergent A	345	1
R1	DGT0B	Detergent A	345	1

Glucose Serum/Plasma—Conventional Units

Configure assay parameters — Results				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluC		Assay number: 1069		
Dilution default range:		Result units: mg/dL		
Low-Linearity: 5				
High-Linearity: 800				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
Either	0 – 130 (Y)	70 – 99		

Configure result units	
Assay: GluC	Version: †
Result units: mg/dL	Decimal places: 0 [Range 0 – 4]
Correlation factor: 1.0000	Intercept: 0.0000

Glucose Serum/Plasma—SI Units

Configure assay parameters — Results				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluC		Assay number: 1069		
Dilution default range:		Result units: mmol/L		
Low-Linearity: 0.28				
High-Linearity: 44.40				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
Either	0 – 130 (Y)	3.89 – 5.50		

Configure result units	
Assay: GluC	Version: †
Result units: mmol/L	Decimal places: 2 [Range 0 – 4]
Correlation factor: 1.0000	Intercept: 0.0000

† Due to differences in instrument systems and unit configurations, version numbers may vary.

‡ Displays the number of decimal places defined in the decimal places parameter field.

++ Refer to the concentration specified on calibrator labeling or value sheet. These values are defined on the Configure calibrator set screen.

ARCHITECT

Glucose Urine/CSF—Conventional and SI Units

Configure assay parameters — General				
<input checked="" type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluCU		Type: Photometric	Version: †	
Number: 1095		Run controls for onboard reagents by: Lot		
<input checked="" type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks		
Reaction mode: End up				
Primary		Secondary	Read times	
Wavelength: 340 / 380		Main: 14 – 14		
Last required read: 14				
Absorbance range: -0.1 – 3.2000		Color correction: — —		
Sample blank type Self		Blank: 2 – 2		

<input type="radio"/> Reaction definition	<input checked="" type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks
Reagent: GLUC9		
Diluent: Saline		
Diluent dispense mode: Type 0		
Dilution name	Sample	Diluted sample
STANDARD	2.0	—
—	—	—
—	—	—
Dilution factor: 1:1.00		
Default dilution: —		

<input type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input checked="" type="radio"/> Validity checks
Reaction check: None		
Maximum absorbance variation: —		

Configure assay parameters — Calibration				
<input type="radio"/> General	<input checked="" type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluCU		Calibration method: Use Cal Factor/Blank		
		Use Cal factor from: GluC		

Configure assay parameters — SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: GluCU				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	AMIK9	Detergent A	345	1
R1	DIG00	Detergent A	345	1
R1	VANCO	Detergent A	345	1
R1	GENT9	Detergent A	345	1
R1	TOBRA	Detergent A	345	1
R1	DGT0B	Detergent A	345	1

Glucose Urine/CSF—Conventional Units

Configure assay parameters — Results			
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results
Assay: GluCU		Assay number: 1095	
Dilution default range:		Result units: mg/dL	
Low-Linearity: 1			
High-Linearity: 800			
Gender and age specific ranges:			
GENDER	AGE (UNITS)	NORMAL	EXTREME

Configure result units	
Assay: GluCU	Version: †
Result units: mg/dL	Decimal places: 0 [Range 0 – 4]
Correlation factor: 1.0000	Intercept: 0.0000

Glucose Urine/CSF—SI Units

Configure assay parameters — Results			
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results
Assay: GluCU		Assay number: 1095	
Dilution default range:		Result units: mmol/L	
Low-Linearity: 0.06			
High-Linearity: 44.40			
Gender and age specific ranges:			
GENDER	AGE (UNITS)	NORMAL	EXTREME

Configure result units	
Assay: GluCU	Version: †
Result units: mmol/L	Decimal places: 2 [Range 0 – 4]
Correlation factor: 1.0000	Intercept: 0.0000

† Due to differences in instrument systems and unit configurations, version numbers may vary.