GLUCOSE

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

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

CAL 1-2	Calibrators 1 and 2	REF	Catalog number/List number
CONC	Concentration	SN	Serial number
EC REP	Authorized Representative in the European Community		Consult instructions for use
INGRED	Ingredients		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limitation
LOT	Batch code/Lot number		Use by/Expiration date
R1	Reagent 1		

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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 **3L82-20**, R1 10 x 55 mL
Estimated tests per kit: 9,000*

REF **3L82-40**, R1 10 x 90 mL
Estimated tests per kit: 15,000*

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

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

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

Deterioration should be suspected if there are visible signs of leakage, extreme turbidity, microbial growth, or if quality control results are outside of the acceptable range defined by your laboratory.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. **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 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.

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. When processing samples, separate serum from blood cells or gel according to the specimen collection tube manufacturer's instructions.

  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. When processing samples, separate plasma from blood cells or gel according to the specimen collection tube manufacturer's instructions.
- **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 instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific 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	1 day	2 hours	3 days	8
2 to 8°C	7 days	2 hours	> 1 month	8, 9
-20°C	1 day	2 days	no recommendation	8

* Stablized 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

REF 3L82-20 or 3L82-40 Glucose Reagent Kit

Materials Required but not Provided

- REF 1E65 Multiconstituent Calibrator, CAL 1-2 3 x 5 mL
- 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 instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT *c* Systems and the AEROSET System have automatic dilution features; refer to *Section 2* of the instrument-specific 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 using 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 using the Manual Dilution Procedure, or an automatic dilution may be configured. Refer to *Section 2* of the instrument-specific operations manual for additional information.

PROCEDURE (Continued)

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 instrument-specific 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 instrument-specific 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 the instrument-specific operations manual for information on results calculations.

- **ARCHITECT System Operations Manual**—*Appendix C*
- **AEROSET System Operations Manual**—*Appendix A*

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".[10,11] Population reference ranges in various texts and publications may differ.

Serum/Plasma[12]

Fasting	Range (mg/dL)	Range (mmol/L)
Cord	45 to 96	2.50 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

EXPECTED VALUES (Continued)

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	3.33 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)

Where: V = 24 hour urine volume (mL)
c = analyte concentration (mg/dL)
24 hour excretion = $[(V \times c) \div 100{,}000]$ g/day

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

Where: V = 24 hour urine volume (mL)
c = analyte concentration (mmol/L)
24 hour excretion = $[(V \times c) \div 1000]$ mmol/day

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 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 µmol/L)	4	83.1	99.89
	60 mg/dL (1,026 µmol/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 µmol/L)	4	126.3	100.66
	60 mg/dL (1,026 µmol/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.

Interferences from medications or endogenous substances may affect results.[13]

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Precision

The imprecision of the Glucose assay is ≤ 5% Total CV for serum and CSF and ≤ 6% Total CV for urine. Representative data from studies using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP5-A[14] 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 ≤ 6% or ± 1 mg/dL, whichever is greater, and the Total Error for serum is ≤ 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.[15]

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

Method Comparison (Continued)

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

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. *Occupational Exposure to Bloodborne Pathogens.*
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; January 2007.
3. World Health Organization. *Laboratory Biosafety Manual*. Geneva: World Health Organization; 2004.
4. Sewell DL, Bove KE, Callihan DR, et al. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition (M29-A3)*. Wayne, PA: Clinical and Laboratory Standards Institute, 2005.
5. Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders; 1994:959–60.
6. Tietz NW, editor. *Clinical Guide to Laboratory Tests*, 3rd ed. Philadelphia, PA: WB Saunders; 1995:268–72.
7. Kaplan LA, Pesce AJ, editors. *Clinical Chemistry Theory, Analysis, and Correlation*, 3rd ed. St Louis, MO: CV Mosby; 1996:635.
8. Guder WG, Narayanan S, Wisser H, et al. List of analytes—preanalytical variables. Annex In: Samples: *From the Patient to the Laboratory*. Darmstadt, Germany: GIT Verlag; 1996:Annex 16–7, 38–9, 44–5.
9. US Pharmacopeial Convention, Inc. General notices. In: *US Pharmacopeia National Formulary*, 1995 ed (USP 23/NF 18). Rockville, MD: The US Pharmacopeial Convention, Inc; 1994:11.
10. Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care*. 2007;30(1):42–7.
11. Sacks DB, Bruns DE, Goldstein DE, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Clin Chem* 2002;48(3):436–72.
12. Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders; 1994:2190.
13. Young DS. *Effects of Drugs on Clinical Laboratory Tests*, 4th ed. Washington, DC: AACC Press; 1995:3-274–3-294.
14. Kennedy JW, Carey RN, Coolen RB, et al. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1999.
15. Krouwer JS, Tholen DW, Garber CC, et al. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (EP9-A2)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 2002.

TRADEMARKS

ARCHITECT®

Glucose Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **GluC** Type: **Photometric** Version: †
Number: **1069**

● Reaction definition O Reagent / Sample O 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**

O Reaction definition ● Reagent / Sample O Validity checks

R1
Reagent: **GLUC9** Reagent volume: **57**
Diluent: **Saline** Water volume: **143**
Diluent dispense mode: **Type 0** Dispense mode: **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**2.0**	___	___	___	=	**1:1.00**	●
1:5 :	**20.0**	**2.0**	**80**	___	=	**1:5.00**	O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **GluC** Calibration method: **Linear**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set:		Calibrator level:	Concentration:
MCC	Blank:	**Water**	**0** **
	Cal 1:	**MCC1**	‡
Replicates: **3** [Range 1 – 3]	Cal 2:	**MCC2**	‡

O Calibrators ● Volumes O Intervals O 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**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **720** (hours)
Calibration type:
Adjust type: **None**

O Calibrators O Volumes O Intervals ● 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

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **GluC**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**AMIK9**	**Water**	**345**	**1**
R1	**DIG00**	**Water**	**345**	**1**
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to version 2.2.

Glucose Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **GluC** Result units: **mg/dL**
Assay defaults:
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

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **GluC** Result units: **mmol/L**
Assay defaults:
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 concentration specified on calibrator labeling or value sheet.

ARCHITECT®

Glucose Urine/CSF—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **GluCU** Type: **Photometric** Version: †
Number: **1095**

● Reaction definition O Reagent / Sample O 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**

O Reaction definition ● Reagent / Sample O Validity checks

R1

Reagent: **GLUC9** Reagent volume: **57**
Diluent: **Saline** Water volume: **143**
Diluent dispense mode: **Type 0** Dispense mode: **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**2.0**	___	___	___	=	**1:1.00**	●
_____ :	___	___	___	___	=		O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **GluCU** Calibration method: **Use Cal Factor/Blank**
Use Cal factor from: **GluC**

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **GluCU**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**AMIK9**	**Water**	**345**	**1**
R1	**DIG00**	**Water**	**345**	**1**
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to version 2.2.

Glucose Urine/CSF—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **GluCU** Result units: **mg/dL**
Assay defaults:
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

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **GluCU** Result units: **mmol/L**
Assay defaults:
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.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET®

Glucose Serum/Plasma—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
GluC	69	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	70	99	0.0	0.0*	*
		5	L-Linear Range-H	800		

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	340 / 380	14 – 14 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
GluC (69)	2 – 2	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	20.0	2.0	80	0	Diluent:	DILUENT C–10*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	GLUC951‡‡– ___*	57	143	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	mg/dL

Assay Configuration: Calibration Page

Calib Mode					Interval (H)	
Linear					720	
Blank/Calib Replicates		**Extrapolation %**			**Span**	**Span Abs Range**
3 / 3		0			**BLK** – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	2.0	0.0	0	0	0.0 – 0.0
C1	MCC 1	2.0	0.0	0	0	**Cal Deviation**
C2	MCC 2	2.0	0.0	0	0	0.0
						FAC Limit (%)
						10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
AMIK941	Water	345
DIG0051	Water	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Glucose Serum/Plasma—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
GluC	69	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	3.89	5.50	0.0	0.0*	*
		0.28	L-Linear Range-H	44.40		

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	340 / 380	14 – 14 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
GluC (69)	2 – 2	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	20.0	2.0	80	0	Diluent:	DILUENT C–10*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	GLUC951‡‡ – ___*	57	143	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	2	mmol/L

Assay Configuration: Calibration Page

Calib Mode					Interval (H)	
Linear					720	
Blank/Calib Replicates		**Extrapolation %**			**Span**	**Span Abs Range**
3 / 3		0			**BLK** – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	2.0	0.0	0	0	0.0 – 0.0
C1	MCC 1	2.0	0.0	0	0	**Cal Deviation**
C2	MCC 2	2.0	0.0	0	0	0.0
						FAC Limit (%)
						10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
AMIK941	Water	345
DIG0051	Water	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

‡‡ Rgt Name listed is for 3L82-20. For **3L82-40**, change Reagent 1 name to **GLUC961**.

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Glucose Urine/CSF—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
GluCU	95	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	0.0	0.0	0.0*	*
		1	L-Linear Range-H	800		

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	340 / 380	14 – 14 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
GluCU (95)	2 – 2	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	2.0	0.0	0	0	Diluent:	____ _ – __*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	GLUC951‡‡– ___*	57	143	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	mg/dL

Assay Configuration: Calibration Page

Calib Mode	Use Cal Factor from	Interval (H)
UseFac/Blk	GluC (69)	720
Blank/Calib Replicates	**Extrapolation %**	**Span** / **Span Abs Range**
0 / 0	0	BLK – 1 / 0.0 – 0.0

Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	2.0	0.0	0	0	0.0 – 0.0
C1	2.0	0.0	0	0	Cal Deviation
C2	2.0	0.0	0	0	0.0
					FAC Limit (%)
					10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
AMIK941	Water	345
DIG0051	Water	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Glucose Urine/CSF—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
GluCU	95	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	0.0	0.0	0.0*	*
		0.06	L-Linear Range-H	44.40		

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	340 / 380	14 – 14 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
GluCU (95)	2 – 2	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	2.0	0.0	0	0		Rgt Name/Pos
Dil 1	2.0	0.0	0	0	Diluent:	____ _ – __*
Dil 2	2.0	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	GLUC951‡‡– ___*	57	143	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	2	mmol/L

Assay Configuration: Calibration Page

Calib Mode	Use Cal Factor from	Interval (H)
UseFac/Blk	GluC (69)	720
Blank/Calib Replicates	**Extrapolation %**	**Span** / **Span Abs Range**
0 / 0	0	BLK – 1 / 0.0 – 0.0

Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	2.0	0.0	0	0	0.0 – 0.0
C1	2.0	0.0	0	0	Cal Deviation
C2	2.0	0.0	0	0	0.0
					FAC Limit (%)
					10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
AMIK941	Water	345
DIG0051	Water	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

‡‡ Rgt Name listed is for 3L82-20. For **3L82-40**, change Reagent 1 name to **GLUC961**.