1.0 Synonyms

None

2.0 Clinical Significance

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

3.0 Principle

3.1 UniCel DxC SYNCHRON Systems Glucose reagent (GLUH), when used in conjunction with UniCel DxC 600/800 SYNCHRON System(s) and SYNCHRON Systems AQUA CAL 1 and 3, is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

3.2 GLU reagent is used to measure the glucose concentration by a timed endpoint method.

3.3 In the reaction, hexokinase (HK) catalyses the transfer of a phosphate group from adenosine triphosphate (ATP) to glucose to form adenosine diphosphate (ADP) and glucose-6-phosphate. The glucose-6-phosphate is then oxidized to 6-phosphogluconate with the concomitant reduction of β-nicotinamide adenine dinucleotide (NAD) to reduced β-nicotinamide adenine dinucleotide (NADH) by the catalytic action of glucose-6-phosphate dehydrogenase (G6PDPH).

3.4 The SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of GLU in the sample and is used by the System to calculate and express GLU concentration.

3.5 Chemical Reaction Scheme

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NAD}^+ \xrightarrow{\text{G6PDH}} \text{6-phosphogluconate} + \text{NADH} + \text{H}^+$$

4.0 Specimen

4.1 Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma, or CSF is the preferred specimens. Acceptable anticoagulant at this facility is lithium heparin and fluoride. Whole blood and urine are not recommended for use as a sample. The use of fluoride as a glycolysis inhibitor is recommended.

4.2 Specimen Storage and Stability

4.2.1 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.

4.2.2 Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

4.2.3 CSF specimens should be centrifuged and analyzed without delay. Specimens may be refrigerated or frozen for 7 to 10 days for repeat determinations.

4.3 Sample Volume

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample.

4.4 Criteria for Unacceptable Specimen

Refer to the PROCEDURAL NOTES section of this chemistry information sheet or the SPECIMEN REQUIREMENTS section of this manual for information on unacceptable specimens.

4.5 Patient Preparation

No preparation is needed.

5.0 Reagents

5.1 Contents

Each kit contains the following items:

Two GLU Reagent Cartridges (2 x 300 tests)

5.2 Volumes per test

Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	273 µL
B	27 µL
C	– –

5.3 Reactive Ingredients

Reagent Constituents	
Adenosine Triphosphate	3.8 mmol/L
NAD+	2.7 mmol/L
Hexokinase	2.0 KIU/L

Reagent Constituents	
Glucose-6-phosphate dehydrogenase	3.0 KIU/L
Also non-reactive chemicals necessary for optimal system performance.	

5.4 Caution

Sodium azide preservative may form explosive compounds in metal drain lines.

5.5 Materials Needed but not Provided with Reagent Kit

5.5.1 Synchron Systems AQUA CAL 1 and Synchron Systems AQUA CAL 3

5.5.2 At least two levels of control material

5.5.3 Saline

5.6 Reagent Preparation

No preparation is required.

5.7 Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria, as defined in CONTROL PROCEDURES section of this manual.

5.8 Reagent Storage and Stability

GLUH reagent when stored unopened at +2°C to +8°C will obtain the shelf-life as indicated on the cartridge label. Once opened, the reagent is stable for 30 days unless the expiration date is exceeded. DO NOT FREEZE.

5.8 Reagent storage location: Chemistry Department Refrigerator.

7.0 Calibration

7.1 Calibrator

7.1.1 Calibrated Required

SYNCHRON Systems AQUA CAL 1
SYNCHRON Systems AQUA CAL 3

7.1.2 Calibrator Preparation

7.1.3 No preparation is required.

7.1.4 Calibrator Storage and Stability

If unopened, the SYNCHRON Systems AQUA CAL 1 and 3 should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Opened calibrators stored at room temperature are stable for 1 month unless the expiration date is exceeded.

7.2 CAUTION

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.

7.3 Calibration Information

7.3.1 The system must have valid calibration factors in memory before controls or patient samples can be run.

7.3.2 Under typical operating conditions the GLUH reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON UniCel DXC Operations Manual. This assay has within-lot calibration available. Refer to the SYNCHRON UniCel DxC Operations Manual for information on this feature.

7.3.3 For detailed calibration instructions, refer to the Operations Manual. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the Diagnostics and Trouble-shooting Manual.

7.4 Traceability

For Traceability information refer to the Calibrator instructions for use.

8.0 Quality Control

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the Operations Manual. At this facility, the Biorad Unassayed Chemistry Control levels 1 and 2 are used.

9.0 Testing Procedure

9.1 If necessary, load the reagent onto the system as directed in the Operations Manual.

9.2 After reagent load is completed, calibration may be required. Refer to the Operations Manual for details of the calibration procedure.

9.3 Program samples and controls for analysis as directed in Operations Manual.

9.4 After loading samples and controls onto the system, follow the protocols for system operation as directed in the Operations Manual.

10.0 Calculations

SYNCHRON DxC System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

11.0 Reporting Results

11.1 Reference Intervals

The reference intervals listed below were taken from literature and a study done on SYNCHRON Systems.

Table 2 Reference Intervals Data shown was collected using SYNCHRON Systems

Intervals	Sample Type	Conventional Units
Literature	Serum or Plasma	74 – 106 mg/dL
	Urine	1 – 15 mg/dL
	Urine (timed)	< 0.5 g/24 hrs
	CSF	40 – 70 mg/dL
SYNCHRON	Serum or Plasma	79 – 115 mg/dL
This facility	Serum or Plasma	65 – 110 fasting

For details on reference interval validation, refer to Lxi or DxC validation data.

12.0 Limitations

None identified.

13.0 Interference

Table 5 Interferences Data shown was collected using SYNCHRON CX Systems.

Substance	Source	Maximum Level Tested	Observed Effect Plus (+) or minus (-) signs in this column signify positive or negative interference.
Hemoglobin	RBC hemolysate	(4+) 400 mg/dL	≤±3.2 mg/dL or ±3.2%
Bilirubin	Bovine	24 mg/dL	≤±3.2 mg/dL or ±3.2%
Lipemia	Intralipid	(4+) 400 mg/dL	≤±3.2 mg/dL or ±3.2%
Ascorbic Acid	NA NA = Not applicable.	3.0 mg/dL	≤±3.2 mg/dL or ±3.2%
Urea	NA	500 mg/dL	≤±3.2 mg/dL or ±3.2%
Uric acid	NA	20 mg/dL	≤±3.2 mg/dL or ±3.2%
EDTA	NA	8 mg/dL	≤±3.2 mg/dL or ±3.2%
Creatinine	NA	30 mg/dL	≤±3.2 mg/dL or ±3.2%

14.0 Analytic Range (Linearity)

The SYNCHRON LX and DxC Systems method for the determination of this analyte provides the following analytical ranges:

Table 6 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS
Serum, Plasma or CSF	5 – 700 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

15.0 Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for GLU determination is 5 mg/dL (0.3 mmol/L).

16.0 Equivalency

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or Plasma,UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 5 – 69mg/dL)

Y (SYNCHRON UniCel DxC 600 Systems GLUH) = 0.98x – 1.02 N = 120
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 118
MEAN X (SYNCHRON UniCel DxC Systems GLU) = 121
CORRELATION COEFFICIENT (r) = 1.000

Serum or Plasma, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 5 – 69mg/dL)
Y (SYNCHRON UniCel DxC 800 Systems GLUH) = 1.00x – 1.60
N = 120
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 118
MEAN X (SYNCHRON UniCel DxC Systems GLU) = 120
CORRELATION COEFFICIENT (r) = 1.000

CSF, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 9 – 693 mg/dL)
Y (SYNCHRON UniCel DxC 600 Systems GLUH) = 0.98x + 1.25 N = 100
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 108
MEAN X (SYNCHRON UniCel DxC Systems GLU) = 109
CORRELATION COEFFICIENT (r) = 1.000

CSF, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 8 – 675 mg/dL)
Y (SYNCHRON UniCel DxC 800 Systems GLUH) = 1.00x – 0.61 N = 100
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 108
MEAN X (SYNCHRON UniCel DxC Systems GLU) = 108

CORRELATION COEFFICIENT (r) = 1.000

Urine, UniCel DxC 600/800 SYNCHRON System(s) GLUCm (Range 8 – 671 mg/dL)
Y (SYNCHRON UniCel DxC 600 Systems GLUH) = 1.00x - 0.21 N = 103
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 218
MEAN X (SYNCHRON UniCel DxC Systems GLUCm)= 218
CORRELATION COEFFICIENT (r) = 0.999

Urine, UniCel DxC 600/800 SYNCHRON System(s) GLUCm (Range 9 – 687 mg/dL)
Y (SYNCHRON UniCel DxC 800 Systems GLUH) =1.00x + 0.46 N = 98
MEAN Y (SYNCHRON UniCel DxC Systems GLUH) = 228
MEAN X (SYNCHRON UniCel DxC Systems GLUCm) = 227
CORRELATION COEFFICIENT (r) = 1.000

Refer to References (18) for guidelines on performing equivalency testing.

16.0 Precision

A properly operating LX or DxC System should exhibit precision values less than or equal to the following:

Table 8 Precision Values

Type of Precision	Sample Type	1 SD		Changeover Value		% CV
		mg/dL	mmol/L	mg/dL	mmol/L	
Within-run	Serum/Plasma, Urine or CSF	2.0	0.11	100.0	5.5	2.0
Total	Serum/Plasma, Urine or CSF	3.0	0.17	100.0	5.5	3.0

For details of precision done at this facility, refer to DxC validation data.

17.0 Backup Procedure

This assay is available on both the DXC600 instruments. Call Beckman Coulter Technical Support at 800-854-3633 for trouble shooting assistance. If necessary, a service call may be arranged.

18.0 References

18.1 Beckman Coulter DXC Chemistry Information Manual

18.2 Beckman Coulter DXC Operation Manual.

Procedure Prepared by: _____ Date: 1/29/16

Procedure Approved by: _____ Date: 1/29/16

Marina del Rey Hospital

Procedure Annual Review

Procedure: Glucose

Reviewed by	Review Date
	8/22/11
	8/23/11
	8/28/12
	8/29/13
	8/25/13
	8/30/2013
	7/1/15
	7/1/15

FormGen001/2008