DXC (GLUCm) GLUCOSE

☒ St. Joseph Medical Center Tacoma, WA ☒ St. Clare Hospital Lakewood, WA ☐ St. Elizabeth Hospital Enumclaw, WA
☒ St. Francis Hospital Federal Way, WA ☒ St. Anthony Hospital Gig Harbor, WA ☐ Highline Medical Center Burien, WA ☐ PSC

PURPOSE

To provide instructions for the quantitative determination of glucose on the DXC 600/800.

PRINCIPLE

GLUCm reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of Glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

BACKGROUND

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.

Methodology

The SYNCHRON® System(s) determines GLUCm concentration by an oxygen rate method employing a Beckman Coulter Oxygen electrode. A precise volume of sample (10 microliters) is injected in a reaction cup containing a glucose oxidase solution. The ratio used is one part sample to 76 parts reagent. The peak rate of oxygen consumption is directly proportional to the concentration of GLUCm in the sample.

Oxygen is consumed at the same rate as glucose reacts to form gluconic acid. Because oxygen consumption rather than peroxide formation is measured, the only requirement for peroxide is that it must be destroyed by a path not leading back to oxygen. The addition of ethanol to the reagent causes peroxide to be destroyed in the presence of catalase without yielding oxygen. To ensure complete destruction of the peroxide, iodide and molybdate are added to the enzyme reagent. The reaction is effective even after the catalase activity has diminished with length of storage.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators
J-F-CH1940	DXC 800 Analytical Measurement Range
M-F-CH0820	Chemistry Controls

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma, CSF or properly collected urine (random/timed) is the preferred specimen. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample. The use of fluoride as a glycolysis inhibitor is recommended.

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. 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.

3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.

4. CSF specimens should be centrifuged and analyzed without delay.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • 8 hours at 18-26°C • 48 hours at 2-8°C • After 48 hours, freeze at -15 to -20°C
Urine	0.5 mL	• Test within 2 hours of collection • Timed specimens are kept at 2-8° C • No preservative is required
CSF	0.5 mL	• CSF samples should be centrifuged before testing and analyzed without delay

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:

Two Glucose Reagent Bottles (2 x 2 L) Kit reorder #472500

Volume per Test	
Sample Volume	10 µL
Ordac Sample Volume	5 µL
Total Reagent Volume	765 µL

Reactive Ingredients	
Glucose Oxidase	150 U/mL
Denatured Ethanol	5%
Potassium Iodide	0.04 mol/L
Ammonium Molybdate	0.03 mol/L

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

Prior to use, allow the Glucose reagent to equilibrate to room temperature for at least 8 hours. A +25°C water bath may be used to warm reagent. Invert reagent 5 times to mix. Inspect for crystals and if present, see instructions for frozen reagent in Reagent Storage and Stability.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

Reagent Storage and Stability

GLUCm reagent stored unopened at +2°C to +8°C is stable until the expiration date indicated on each bottle. The reagent is stable on instrument for 30 days or until the expiration date, if sooner. If reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting bottle a least 10 times.

CALIBRATION

Calibrator Required

SYNCHRON® Systems AQUA CAL 1 and 2

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. If unopened, the calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.

2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

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

2. Under typical operating conditions the GLUCm assay must be calibrated every 48 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions for Use* (IFU) manual. Calibration may be required if the system is powered down for more than five minutes.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents DXC 800 Controls & Chemistry Controls

NOTE: Do not use controls containing diethylamine HCl.

STEPS

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® 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.

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	No significant Interference within ±4.0 mg/dL or 4%
Lithium Heparin	14 Units/mL	No significant Interference within ±4.0 mg/dL or 4%

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma Serum Bias (mg/dL)
Sodium Heparin	14 Units/mL	No significant Interference within ±4.0 mg/dL or 4%
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	No significant Interference within ±4.0 mg/dL or 4%

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Age	Reference Range	CRITICAL LOW	CRITICAL HIGH
Serum/ plasma	0 -2 days	40 – 90 mg/dL	<40 mg/dl	>200 mg/dL
Serum/ plasma	2 days – 1 month	60 – 105 mg/dL	<50 mg/dL	>200 mg/dL
Serum/ plasma	>1 month	65 – 99 mg/dL	<50 mg/dL	>450 mg/dL
CSF*	N/A	40 – 70 mg/dL	<30 mg/dL	
Body fluid*	N/A	None Established	N/A	N/A
Urine, timed*	N/A	0 – 500 mg/24hrs	N/A	N/A

**See Reference 7 below RE:Teitz*

For Critical Value reporting protocol, refer to FHS Policy
NOTE: In a healthy patient, the normal urine glucose value is zero.

Analytic Range

The SYNCHRON® System(s) method for this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum/Plasma/Urine/CSF	3 – 600 mg/dL
Serum/Plasma/Urine/CSF (ORDAC)	300 – 1200 mg/dL

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

Reporting results outside of analytical range

Lower limit of detection: serum, plasma, urine and CSF	3 mg/dL	Results below 3, report as <3 mg/dL
Upper limit of detection: serum, plasma, urine and CSF	1200 mg/dL	Results >1200 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >2400 should be reported as >2400 mg/dL

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for GLUCm determination is 3 mg/dL (0.2 mmol/L).

LIMITATIONS

1. If sodium fluoride is used as a preservative, a decrease of 9 mg/dL is seen during the first 2 hours.

2. If urine or CSF samples are cloudy or turbid or if CSF samples are visibly contaminated with blood, it is recommended that they be centrifuged before transfer to a sample cup.

3. Freshly prepared D-glucose solutions or commercial controls spiked with D-glucose must be allowed to mutarotate before analysis for accurate results.

4. Oxygenated samples will cause low results. Dilute samples 1:1 with saline or use the hexokinase cartridge method.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX 20	No significant Interference within ± 4.0 mg/dL or 4%
Hemoglobin	RBC hemolysate	500 mg/dL INDEX 10	No significant Interference within ± 4.0 mg/dL or 4%
Lipemia	Intralipid	320 mg/dL INDEX 8 Airfuge recommended	No significant Interference within ± 4.0 mg/dL or 4%

2. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.

3. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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