Brown Clinic Northridge
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BROWN CLINIC
LABORATORY PROCEDURE MANUAL

PROCEDURE: Glucose

INTENDED USE
The GLU method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of glucose in **serum**, **plasma**, **urine** and **cerebrospinal fluid**.

SUMMARY
The glucose method is an adaptation of the hexokinase-glucose-6-phosphate dehydrogenase method, presented as a general clinical laboratory method by Kunst, et al.[1] The hexokinase method is the generally accepted reference method for measuring glucose. Glucose measurements are used in the diagnosis and treatment of disorders of carbohydrate metabolism such as diabetes mellitus, neonatal hypoglycemia and insulinoma.

PRINCIPLES

Hexokinase (HK) catalyzes the phosphorylation of glucose by adenosine-5'-triphosphate (ATP) and magnesium to form glucose-6-phosphate (G-6-P) and adenosinediphosphate (ADP). (G-6-P) is then oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) in the presence of nicotinamide adenine dinucleotide (NAD) to produce 6-phoshogluonate and NADH. One mole of NAD is reduced to one mole of NADH for each mole of glucose present. The absorbance due to NADH (and thus the glucose concentration) is determined using a biometric (340 and 383 nm) endpoint technique.

$$\text{Glucose} + \text{ATP} \xrightarrow[MG^{++}]{HK} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NADP} \xrightarrow{G\text{-}6\text{-}PDH} \text{6-phosphogluconolactone} + \text{NADPH}$$

INSTRUMENT, REAGENTS & SUPPLIES:

Wells[a]	Form	Ingredient	Concentration[b]	Source
1-6	Liquid	HK	15 U/mL	Yeast
		G-6-PDH	30 U/mL	Yeast
		ATP	15 mmol/L	
		MG++	7.4mmol/L	
		NAD	8 mmol/L	
		Buffers		
		Stabilizer		

a. Wells are numbered consecutively from the wide end of the cartridge.

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Precautions: Contains sodium azide(<0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.

Use cuvettes contain human body fluids: handle with appropriate care to avoid skin contact and ingestion.

Safety data sheets(MSDS/DSD) available on www.siemens.com/healthcare

For *in vitro* diagnostic use

Reagent Preparation: All reagents are liquid and ready for use.

STORAGE & STABILITY:
Store at 2 – 8° C.

Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or unhydrated cartridge wells on the instrument are stable for 42 days. Once wells have been entered by the instrument, they are stable for7 days for wells 1-6.

SPECIMEN REQUIREMENTS:
Normal procedures for collecting and storing serum, plasma, urine and cerebrospinal fluid may be used for samples to be analyzed by this method. Sodium heparin, lithium heparin, EDTA and potassium oxalate do not interfere with the GLUC method.

Following the instructions provided with your specimen collection device for use and processing.

Specimens should be free of particulate matter. To prevent this appearance of fibrin in serum samples, complete clot formation should take place before centrifugation. Clotting time may be increased due to thrombolytic or anticoagulation therapy.

Glycolysis decreased serum glucose by approximately 5% to 7% per hour in normal uncentrifuged coagulated blood at room temperature.[3] In separated, non-hemolyzed sterile serum, the glucose concentration is generally stable for as long as 8 hours at 25^{o}C and up to 72 hours at 4^{o}C; variable stability is observed with longer storage conditions.[3] Glycolysis can be inhibited and glucose stabilized for as long as 3 days at room temperature by addition of sodium iodoacetate or sodium flouride(NaF) to the serum.[3]

- patient preparation: fasting specimen preferred
- specimen type: serum or heparinized plasma
- handling: analyze immediately or refrigerate at 2-8 degrees C

CONTROLS:

At least once daily run solutions at two levels of a quality control material with known concentrations.

For further details, refer to your Dimension® system manual. The result obtained should fall within limits defined by the day-to-day variability of the system as measured in the user's laboratory. If the results fall outside the laboratory's acceptable limits, follow the procedure in the quality control policy.

PROCEDURE:

The GLUC Flex® reagent cartridge, Cat. No. DF40, is required to perform the GLUC test. This test is performed on the Dimension® clinical chemistry system after the method is calibrated.

Materials Required But Not Provided

CHEM I Calibrator (Cat. No. DC18B or DC 18C). Quality control is also required.

Test Steps Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® system. For details of this processing, refer to your Dimension® system manual.

The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus dead volume. Precise container filling is not required.

Test Steps

Sampling[b], reagent delivery, mixing, processing, and printing of results are performed automatically performed by the Dimension® system. For details of this processing, refer to your Dimension® Operator's Guide.

The sampling container(if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus dead volume.

- Sample Size: 3 µL
- Reagent 1 Volume: 56 µL
- Diluent Volume: 321 µL
- Test Temperature: 37° C
- Wavelength: 340 and 383 nm
- Type of Measurement: bichromatic endpoint

Calibration

The general calibration procedure is described in your Dimension® system manual (also see Appendix B). The following information should be considered when calibrating the glucose method:

Assay Range:	0–500 mg/dL [0 - 27.8 mmol/L]
Calibration Material:	CHEM I Calibrator (Cat. No. DC18B or DC 18C)
Typical Calibration Levels:	0, 250, 550 mg/dL [0, 13.9, 30.5 mmol/L]
Calibration Scheme:	Three levels in triplicate
Calibration Frequency:	Every new reagent cartridge lot Every 90 days for any one lot
	For each new lot of Flex® reagent cartridges
	After major maintenance or service, if indicated by quality control results
	As indicated in laboratory quality control procedures.
	When required by Government regulations
Assigned Coefficients	C_0 0.000
	C_1 0.880

Backup Process:
Refer to Brown Clinic Back-up Policy

INTERPRETATION:
The instrument automatically calculates and prints the concentration of glucose in mg/dL [mmol/L] using the calculation scheme illustrated in your Dimension® Operators Guide.

For purposes of diagnosis and treatment, results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Reference Range:

Serum: 70-99 mg/dL

Each laboratory should establish its own reference interval for glucose method as performed on the Dimension® system.

REPORTING:
report format: mg/dl

LIMITATIONS:

Results:	>500 mg/dL [27.8 mmol/L]
Manual dilutions:	Serum/Plasma: Make the appropriate dilutions with Reagent Grade Water to obtain result within the assay range. Enter dilution factor.. Serum/Plasma/: Reassay. Resulting readout is corrected for dilution.

Autodilution (AD) (for serum & plasma): See the Dimension® system literature.

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension® system manual.

Analytical Specificity

For Known Interfering Substances section refer to package insert.

For Known Non-Interfering Substance refer to package insert.

For Additional Technical Information refer to package insert.

Origination Date: 9-10-07
Date of Implementation: 9-7-10
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Written By: ____Lori Murray MT(ASCP)_____ Date: _7-13-10_____

Approved By: _____Aaron Shives, MD_____ Date: ___10/21/2017_____
Laboratory Director

REVIEW - REVISION SUMMARY DOCUMENTATION

Date	By	Revision Summary
07/10	Lori Murray	New format
05/15	Amy Harms	Package Insert Updated 07/15/13
8-27-15	Sam Legg	Updated Calibration Material per package insert dated 07-30-2014
9/17/15	Sam Legg	Updated Reference Range per validation
3-2016	Lori Murray	Reference Range adjustment per Lab Director
2/21/17	LMurray	updated backup information
10/18/17	Heather Hall	Modified Backup method, updated information to package Insert dated 2/26/2016