**CHEM.DIMENSION.ASSAY.20.0 GLUCOSE BY DIMENSION**

**INTENDED USE**

The GLUC method used for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of glucose in serum, plasma and cerebrospinalfluid (CSF).

**PRINCIPLE**

Hexokinase catalyzes the phosphorylation of glucose in the presence of 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-phosphogluconate 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 bichromatic (340 and 383 nm) endpoint technique.

**DOCUMENT OWNER**

Manager, St. Vincent Jennings Hospital Laboratory

**RELATED DOCUMENTS**

CHEM.DIMENSION.1.0 *Operation of the Siemens Dimension RxL MAX, Xpand and EXL Clinical Chemistry*

*Systems*

CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**SPECIMEN**

A. Patient Preparation:

1. Fasting glucose: a fast of 8 or more hours is recommended to obtain a true fasting glucose result.

2. Random glucose: None.

3. Cerebrospinal fluid (CSF) glucose: None

B. Sample Size:

 1. Primary tube: Compare the tube to the filling gauge supplied with the Dimension.

 2. SSC or Dimension sample cup: 3 µL plus 50 µL dead space volume.

C. Specimen Type:

1. Serum

2. Plasma:

a. Lithium or sodium heparin, potassium oxalate and EDTA do not interfere with the GLUC method at concentrations normally found in blood collection tubes.

b. Sodium fluoride will inhibit glycolysis and stabilize the glucose; it is the preferred anticoagulant when testing is delayed.

 3. Cerebrospinal fluid (CSF): Collected in a sterile tube with no preservative.

D. Specimen Preparation:

1. Complete clot formation should be allowed to take place before centrifugation to obtain

serum samples.

2. Serum or plasma samples should be separated from the red cells as soon as possible

after centrifugation.

3. Bloody cerebrospinal fluid (CSF) should be centrifuged and the supernatant separated from the red cells as soon as possible after collection.

E. Storage and Stability for Separated Specimens:

 1. Up to 8 hours at room temperature

 2. Up to 3 days at room temperature when collected with sodium fluoride

 3. Up to 72 hours at 4 ⁰C

**REAGENTS**

A. GLUC Flex® reagent cartridge, Cat. No. DF40

1. Preparation: All reagents are liquid and ready to use.

2. Storage and Stability:

a. Unopened reagent cartridges are stable until the date given on the packaging

when stored at 2 – 8 ⁰C.

 b. On board stability:

1) Sealed cartridge wells are stable for 42 days.

2) Open well stability is 7 days.

**EQUIPMENT**

Siemens Dimension® RxL MAX®, Xpand® or EXL™Clinical Chemistry System

**CALIBRATION**

A. Calibration Material: CHEM I Calibrator, Cat. No. DC18A or DC18B

 1. Three levels: typical calibrator levels are 0, 250, and 550 mg/dL; see the package

insert for exact values for the lot in use.

 2. See the package insert for preparation, storage and stability.

B. Calibration Frequency:

 1. For each new lot of Flex® reagent cartridges.

 2. Every 90 days for any one lot of reagent cartridges.

 3. After major maintenance or service if indicated by quality control results.

 4. When indicated by unacceptable QC data.

C. Procedure: See CHEM.DIMENSION.2.0 *Dimension Calibration Procedure*

**QUALITY CONTROL**

A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure, HBL.GEN.7.0 for specific details.

**PROCEDURE**

Sampling, reagent delivery, mixing and processing are automatically performed by the Dimension® System. For details of this processing, refer to the Dimension® Operator’s Guide.

**RESULTS**

A. The instrument automatically calculates and prints the concentration of glucose in mg/dL using the calculation scheme outlined in your Dimension® Operator’s Guide.

B. Results of the test should always be interpreted in conjunction with the patient’s medical history, clinical presentation and other findings.

**REPORTING RESULTS**

A. Expected values:

1. Serum or plasma (mg/dl):

Female Male

0 Days 40 – 89 0 Days 40 - 110

1 Days 47 – 110 1 Days 47 - 110

8 Days 54 – 117 8 Days 54 - 117

29 Days 65 – 99 29 Days 65 - 99

2. Cerebrospinal fluid (CSF): 40 – 70 mg/dl

B. Critical values:

 1. Specimen type:

a. Serum or plasma:

1) Patients aged 28 days or less: GLUC results less than 40 mg/dl or greater than 150 mg/dL are considered critical.

2) Patients aged 29 days or more: GLUC results less than 40 mg/dl or greater than 500 mg/dL are considered critical.

b. Cerebrospinal fluid (CSF): GLUC results less than 21 mg/dl are considered critical.

2. Per MACL Policy QA.REPORT.1.0 *Critical Values--Reporting of Significant Results*, all

 critical values must be called and documented.

C. Sunquest Computer Entry

1. Manual Entry

Function: MEM

Worksheet: Site specific

Test Code: FBS (fasting) or GLU (random) or CSFGL

1. Online Entry

Function: OEM

Device: Site specific

Test Code: FBS (fasting) or GLU (random) or CSFGL

D. QLS Computer Entry

1. Enter: 3, 3, 1
2. Worksheet: Enter worksheet from QLS label.
3. Accession number: Enter JI number.

E. If the HIS or LIS system is down, see the appropriate Laboratory Computer Downtime Policy.

**PROCEDURE NOTES**

A. Expected Turnaround Time (TAT): Nursing units are to be notified if the turnaround time is unable to be met per current MACL network turnaround time standards.

B. Backup method: When testing cannot be performed, the testing site’s backup policy should be followed.

**LIMITATIONS**

A. AMR: 0 – 500 mg/dL

1. Patient samples with GLUC levels that exceed 500 mg/dL will autodilute. If a valid result cannot be obtained a manual dilution should be made.

2. If a manual dilution is required, the specimen should be handled as follows:

a. Make an appropriate dilution with reagent grade water to obtain results within the assay range.

b. Enter the dilution factor into the instrument when programming the sample.

c. Reassay. The resulting readout will be corrected for the dilution.

3. Do not manually dilute greater than times 3. If a result cannot be obtained using x3 dilution, report the result as >2250 mg/dl.

B. Interfering Substances:

1. The GLUC method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NACCLS EP7-P. Bias exceeding 10% is considered “interference”.

a. Hemoglobin (hemolysate):

1) Hemoglobin at 500 mg/dL did **not** interfere with a GLUC result of 50 mg/dL.

2) Hemoglobin at 500 mg/dL decreases a GLUC result of 50 mg/dL by 11%.

3) Hemoglobin at 1000 mg/dL did **not** interfere with a GLUC result of 120 mg/dL.

b. Bilirubin (unconjugated):

1) Bilirubin at 20 mg/dL did **not** interfere with a GLUC result of 50 mg/dL.

2) Bilirubin at 60 mg/dl increases a GLUC result of 50 mg/dl by 13%.

c. Lipemia (Intralipid):

1) Lipemia at 50 mg/dL did **not** interfere with a GLUC result of 50 mg/dL.

2) Lipemia at 200 mg/dL increases a GLUC result of 50 mg/dl by 10%.

3) Lipemia at 400 mg/dL did **not** interfere with a GLUC result of120 mg/dL.

2. Pralidoxime iodide (PAM) is used as an antidote in the treatment of poisoning due to pesticides and chemicals of the organophosphate class which have anticholinesterase activity; and in the control of overdosage by anticholinesterase drugs used in the treatment of myasthenia gravis.

 1) PAM at 512 µg/ml increases a GLUC result of 78 mg/dl by 17%.

 2) PAM at 1024 µg/ml increases a GLUC result of 204 mg/dl by 13%.

3. Other substances: The GLUC package insert contains a lengthy list of common drugs and other substances that do not interfere.

**CLINICAL SIGNIFICANCE**

Serum or plasma glucose measurements are used in the diagnosis and treatment of disorders of carbohydrate metabolism such as diabetes mellitus, neonatal hypoglycemia and insulinoma.

Increased CSF glucose levels are not very useful and usually only confirm hyperglycemia. Decreased CSF glucose levels are useful in the diagnosis of bacterial, tuberculous, or fungal meningitis, systemic hyperglycemia and other diseases involving the central nervous system. A plasma glucose level should be obtained at the same time as a CSF glucose level to aid in the clinical interpretation of the CSF value.

**REFERENCES**

A. Siemens Dimension® Clinical Chemistry System GLUC Flex® reagent cartridge package insert #717040.001 – US , Siemens Healthcare Diagnostics, Inc., Newark, DE, 2/29/2008.

B. Anderson, S. C. & Cockayne, S. (1993). *Clinical Chemistry Concepts and Applications*. Philadelphia, PA: W. Saunders Company.