TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	5/22/2017
Department:	Core	**Due Date:**	6/13/2017
		Implementation:	**6/13/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Glucose by Dimension® Xpand Chemistry Analyzer GEC.C09 v3

Description of change(s):

Changes are updates to the format or make SOP match current practice

Section	Reason
4,5,6	Remove individual section labeling instructions and add general one
5.1	Update product number
5.3	Remove specific calibration steps and reference separate SOP
10.5	Move patient review from section 6
11.2	Reformat value to eliminate ≥ and ≤ signs
14.3	Correct effect of bilirubin to increase
15	Update to new standard wording
17	Update Calibrator product & package insert dates

This revised SOP will be implemented on June 13, 2017

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Glucose by Dimension® Xpand Chemistry Analyzer**
Prepared by	Leslie Barrett Date: 9/3/2009
Owner	Robert SanLuis Date: 4/20/2015

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Glucose	Dimension® Xpand Chemistry Analyzer	GLUC
Glucose, nonfasting		GLUCN
Glucose, CSF		CGLUC
Glucose, Fluid		FGLUC

Synonyms/Abbreviations
GLUC

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

Hexokinase (HK) catalyzes the phosphorylation of glucose by adenosine-5'-triphosphate (ATP) to glucose-6-phosphate which is oxidized to 6-phosphogluconolactone by glucose-6-phosphate dehydrogenase (G-6-PDH) with simultaneous reduction of nicotinamide-adenine dinucleotide phosphate (NAD). 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.

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

$$\text{Glucose-6-phosphate} + \text{NAD} \xrightarrow{\text{G-6-PDH}} \text{6-phosphogluconolactone} + \text{NADH} + H^{+}$$

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting serum, plasma, CSF, and body fluid may be used for samples to be analyzed by this method. Avoid prolonged contact of the serum and plasma with separated red cells.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin), CSF, Body fluid Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST) CSF / Body fluid: Sterile container
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL

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Criteria		
Transport Container and Temperature	Serum/ Plasma: Plastic vial or spun barrier tube CSF / Body Fluid: Sterile specimen container All are transported at room temperature	
Stability & Storage Requirements	Room Temperature:	8 hours, separated
	Refrigerated:	(2-8°C) 72 hours
	Frozen:	(-20°C or colder) not established
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code	
Other Considerations	Allow to clot completely prior to centrifugation.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Glucose	Siemens, Flex® reagent cartridge, Cat. No. DF40

4.2 Reagent Preparation and Storage

Reagent	Glucose
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed or unhydrated cartridge wells on the instrument are stable for 42 days. • Once wells 1-6 have been entered by the instrument, they are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM I Calibrator	Siemens Dimension®, Cat. No. DC18C

5.2 Calibrator Preparation and Storage

Calibrator	CHEM I Calibrator
Preparation	• Remove vials from refrigerator and proceed directly to next step. • Remove stopper and add 2.00 ± 0.01 mL Purified Water Diluent or reagent grade water. The water should be at room temperature. • Replace stopper, and let stand for 5 minutes. Do not invert. • Swirl vials gently for 30 seconds, and then gently invert 10 times. • Let vials stand for 10 minutes, and then gently invert 10 times. • Let vial stand for 15 minutes. Then invert 10 times and swirl gently. • Use immediately or refrigerate at 2-8ºC for future use. Prior to use, invert 10 times and swirl gently.
Storage/Stability	• Store at 2–8°C. • The unopened calibrators are stable until the expiration date printed on the label • Assigned values are stable for 24 hours after reconstitution when stored at 2–8°C.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHEM I Calibrator
Assay Range	0-500 mg/dL
Calibration levels	See reagent package insert for lot specific assigned values in mg/dL

Frequency	• Every new reagent cartridge lot. • Every 3 months for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate
Assigned Coefficients	C_0 0.000 C_1 0.880
Procedure	Refer to Calibration / Verification Siemens Dimension® Xpand procedure for specific instructions.

5.4 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

Control	Liquichek Unassayed Chemistry Controls, Level 1 and 2
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Once control is thawed, all analytes will be stable for 15 days at 2-8°C. Unopened and unthawed controls are stable until the expiration date at -20 to -70°C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension X-pand® Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining –20 to -70°C.
- Centrifuge

7.3 Supplies

- Calibrated pipettes and disposable tips
- Plastic serum tubes and serum cups
- Purified Water

8. PROCEDURE

GLUC Flex® reagent cartridge Cat. No. DF40 is required to perform this test.

Glucose is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® Xpand system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Repeat critical values and document according to Critical Values procedure. Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

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

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of glucose in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

0-2,500 mg/dL

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
0 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: 0 mg/dL
> 500 mg/dL	**On Board Automated Dilution:** Results > 500 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 1.5. No multiplication is necessary.

IF the result is …	THEN…
> 750 mg/dL	**Manual Dilution**: Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 5 **Diluent**: reagent grade water Enter dilution factor as a whole number on the "Enter Sample Data" screen.
> 2500 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 2500 mg/dL - REP" Bring to the attention of your supervisor prior to releasing result.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Plasma/ Serum Glucose	Female	Male
Adult (>18 years):	74 – 105 mg/dL	74 – 105 mg/dL
Pediatric:		
1 month-18 years	70 - 110	70 - 110
8–30 days	54 - 117	54 - 117
1–7 days	47 - 110	47 - 110
0–1 day	36 - 89	36 - 110

Glucose, fasting 65 – 99 mg/dL
Glucose, nonfasting (Post Prandial) 70 – 139 mg/dL
Glucose, CSF 40 – 75 mg/dL

11.2 Critical Values

Plasma / Serum Glucose

Age	LOW	HIGH
0 – 30 days	< 31 mg/dL	> 299 mg/dL
> 1 month	< 41 mg/dL	> 499 mg/dL

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The most common disease associated with abnormal carbohydrate metabolism is diabetes mellitus, with its accompanying high blood glucose levels. Other conditions which may also result in abnormal blood glucose levels include: disorders of the pituitary gland, hyperthyroidism, Cushing's disease, traumatic injury, convulsive disorders, mental stress and pheochromocytoma. Acute and chronic infection, eclampsia, hypertension and severe liver disease may also exhibit transitory elevation of blood glucose level. On the other hand, hyperinsulinism from either exogenous insulin overdose or from lesions of the pancreas can result in low level of blood glucose.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

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 Xpand Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

Concentration	**S.D.**
78 mg/dL	>4.7 mg/dL
264 mg/dL	>12.0 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0 - 500 mg/dL

14.2 Precision

Material	**Mean mg/dL**	**Standard Deviation (%CV)**	
		Within-run	**Between-day**
Bio-Rad Multiqual serum control			
Level 1	55	0.6 (1.0)	0.9 (1.6)
Level 2	118	0.6 (0.5)	1.4 (1.2)
Level 3	350	1.8 (0.5)	5.0 (1.4)
Bio-Rad Liquichek Urine Control			
Level 1	31	0.5 (1.5)	0.5 (1.7)
Level 2	286	1.4 (0.5)	3.3 (1.1)
Bio-Rad Liquichek Spinal Fluid Control			
Level 1	59	0.4 (0.6)	0.8 (1.4)
Level 2	29	0.4 (1.5)	0.6 (2.2)

Serum Pool	191	1.0 (0.5)	1.9 (1.0)
Urine Pool	139	0.7 (0.5)	1.4 (1.0)
CSF Pool	192	0.9 (0.4)	2.7 (1.4)
Plasma Pool	193	0.8 (0.4)	2.0 (1.0)

14.3 Interfering Substances

- Pralidoxime iodide (PAM) concentration of 1024 µg/mL increases a GLUC result at 204 mg/dL by 13%.
- Pralidoxime iodide (PAM) concentration of 512 µg/mL increases a GLUC result at 78 mg/dL by 17%.
- Hemoglobin of 1000 mg/dL decreases a GLUC result at 50 mg/dL by 11%.
- Unconjugated bilirubin at 60 mg/dL increases a GLUC result at 50 mg/dL by 13%
- Lipemia at 200 mg/dL increases a GLUC result at 50 mg/dL by 10%.

HIL Interference:
The GLUC method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NCCLS EP7-P. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Test Concentration SI Units	GLUC Conc mg/dL	Bias %
Hemoglobin (hemolysate)	500 mg/dL [0.31 mmol/L] (momomer)	50 [2.8]	<10
Bilirubin	20 mg/dL [86 µmol/L]	50 [2.8]	<10
Lipemia (Intralipid®)	50 mg/dL [0.57 mmol/L]	50 [2.8]	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program

8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Siemens Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Critical Values (Lab policy)
18. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert, GLUC Flex® Reagent Cartridge DF40

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144
2. Package Insert, GLUC Flex® Reagent Cartridge DF40, Siemens Healthcare Diagnostics Inc., 02/26/2016.
3. Package insert, CHEM I CAL DC18C, Siemens Healthcare Diagnostics, 10/2015.
4. Package insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 05/2014.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C064.000		
000	1/12/12		Update owner	L. Barrett	J. Buss
000	1/12/12	2	Edit principle to match PI	A. Chini	J. Buss
000	1/12/12	3.2	Edit Temperatures	A. Chini	J. Buss
000	1/12/12	4.1	Update reagent cartridge number	A. Chini	J. Buss
000	1/12/12	4.2	Update reagent stability	A. Chini	J. Buss
000	1/12/12	5.3	Edit calibration levels	A. Chini	J. Buss
000	1/12/12	5.5	Correct second entry of ‘and’ to ‘or’	A. Chini	J. Buss
000	1/12/12	6.1 & 6.2	Update QC product # and preparation	A. Chini	J. Buss
000	1/12/12	6.7	Add use of TEA for lot to lot runs, remove testing new calibrator lots as unknowns prior to use	A. Chini	J. Buss
000	1/12/12	10.2	Edit rounding to whole number	A. Chini	J. Buss

000	1/12/12	10.5	Update repeat criteria & dilutions Remove instruction to repeat all critical values; remove code QNSR	A. Chini L. Barrett	J. Buss
000	1/12/12	11.2	Title change to local terminology	L. Barrett	J. Buss
000	1/12/12	11.3	Remove SGAH specific preop value	L. Barrett	J. Buss
000	1/12/12	14.2, 14.3	Update to match PI	A. Chini	J. Buss
000	1/12/12	15	Update to standard wording	A. Chini	J. Buss
000	1/12/12	16	Update document list titles	A. Chini	J. Buss
000	1/12/12	17	Update revision dates	A. Chini	J. Buss
000	1/12/12	19	Remove package insert	L. Barrett	J. Buss
001	4/20/15		Update owner	L Barrett	R SanLuis
001	4/20/15	1, 7.1	Add analyzer name	L Barrett	R SanLuis
001	4/20/15	3.2	Specify anticoagulant, delete synovial fluid	L Barrett	R SanLuis
001	4/20/15	6.4,6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
001	4/20/15	8.2	Remove Lynx	L Barrett	R SanLuis
001	4/20/15	10.5	Remove use of code REP from dilutions	L Barrett	R SanLuis
001	4/20/15	16	Update titles	L Barrett	R SanLuis
001	4/20/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
2	5/5/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	5/5/17	5.1	Update product number	E Thang	R SanLuis
2	5/5/17	5.3	Remove specific calibration steps and reference separate SOP	L Barrett	R SanLuis
2	5/5/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
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2	5/5/17	15	Update to new standard wording	L Barrett	R SanLuis
2	5/5/17	17	Update Calibrator product and PI dates	L Barrett	R SanLuis

19. ADDENDA

None