TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	7/5/2018
Department:	Core Lab	**Due Date:**	7/31/2018
		Implementation:	**7/11/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Glucose by Dimension Vista® System SGAH.C82 v3

This has been converted to a system SOP

Description of change(s):

Note addition of GTT information & change to QC info and freezer range
Most other changes are format updates

Section	Reason
Header	Add WAH
1, 3.1	Add GTT with codes
3.2	Add grey top tube, Remove specimen onboard stability
4,5,6	Remove individual section labeling instructions and add general one
6.1, 6.2	Update QC material and storage
7.2	Change freezer range to -50C
10.5	Move patient review from section 6
10.6	Remove repeat value below AMR/CRR
11.3	Add comments for GTT
14.3	Add interfering medications
15	Update to new standard wording
16	Add GTT SOP, update titles
17	Update QC product and PI dates

This revised SOP will be implemented on July 11, 2018

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

Technical SOP

Title	**Glucose by Dimension Vista® System**	
Prepared by	Ashkan Chini	Date: 6/22/2012
Owner	Robert SanLuis	Date: 6/12/2014

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 Vista® System	GLUC
Glucose, nonfasting		GLUCN
Glucose, CSF		CGLUC
Glucose, Fluid		FGLUC
Glucose Tolerance Tests (GTT)		GTT1T, GTT2T, GTT3T, GTT5T
GTT, Gestational		GTT1P, GTT3P

Synonyms/Abbreviations
Glucose

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

Hexokinase (HK) catalyzes the phosphorylation of glucose in the presence of adenosine-5'-triphosphate (ATP) and magnesium to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (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.

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

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

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	Refer to Client Service procedure *Glucose Tolerance Tests* for details on GTT scheduling, restrictions and collection.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin), CSF, Body fluid Serum, Plasma (Sodium Fluoride Potassium Oxalate)
Collection Container	Plasma: Mint green top tube (PST), grey top tube Serum: Red top tube, Serum separator tube (SST) CSF / Body fluid: Sterile container
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature

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Criteria		
Stability & Storage Requirements	Room Temperature:	8 hours
	Refrigerated:	72 hours
	Frozen:	Not established
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.	
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 explanation of HMT (Specimen markedly hemolyzed)	
Other Considerations	Allow Red Top or SST 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. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

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. K1039

4.2 Reagent Preparation and Storage

Reagent	**Glucose**
Container	Reagent cartridge
Storage	Store at 2-8°C
Stability	• Stable until expiration date stamped on reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Open wells: 7 days for wells 1 - 12
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM 1 CAL	Siemens Dimension Vista®, Cat. No. KC110

5.2 Calibrator Preparation and Storage

Calibrator	CHEM 1 CAL
Preparation	Allow CHEM 1 Calibrator to thaw and equilibrate to room temperature (22 – 28°C) for 1 hour. Before use, **gently** invert the calibrator vials at least 10 times to ensure that the contents are thoroughly mixed. **Do not vortex.**
Storage/Stability	• Store at -25 to -15°C • **Unopened Calibrator:** until expiration date on the box. • **Opened Calibrator:** once the stopper is punctured, stable for 7 days when stored on board the Dimension Vista System.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHEM 1 CAL
Assay Range	1 – 500 mg/dL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

1. Place the required calibrator vials in a carrier. Make sure the barcode labels are entirely visible through the slots.
2. Place the carrier in the loading area.
3. Position the carrier with the labels facing away from the user.
4. Press the **Load** button.
5. Automatic calibration requires that calibrators be on the instrument. As the time for processing approaches, the instrument reviews onboard inventory for the appropriate calibrators.

Manual Calibration:

1. Verify that calibrators and reagents are in inventory on the instrument.
2. Press **System > Method Summary > Calibration**.
3. Select a method from the sidebar menu. Press the **Order Calibration** button on the screen.
4. Verify that the information on the screen is correct. Verify that the calibrator lot is correct using the drop-down menu.
   a. When calibrating using Vials press **OK**.
   b. When calibrating using Cups, check the Use Cups box. This displays the rack and cup position fields. For additional cups use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU. Scan the rack barcode and place calibrator cups in an adapter in position 1 on a rack. Press **OK** and load the rack on the instrument.
5. The status field in the calibration screen changes sequentially to Awaiting Scheduling, Preparing Calibrators and Processing.

5.5 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
Liquid Assayed Multiqual® Levels 1 and 3	Bio-Rad Laboratories Cat. No. 337 and 339
Liquichek™ Spinal Fluid Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 303 and 304

6.2 Control Preparation and Storage

Control	Liquid Assayed Multiqual® Levels 1 and 3
Preparation	Allow the frozen control to stand at room temperature (18-25°C) for 30 minutes or 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	**Frozen**: stable until the expiration date at -20 to -50°C. **Thawed and Unopened**: When stored at 2-8°C and the stopper is not punctured, it will be stable for 30 days for Glucose. This product can be used for 7 days when stored on-board the Siemens Dimension Vista at 2-8°C. **Thawed and Opened**: Once the stopper is punctured, all analytes will be stable for 5 days when stored at 2-8°C. Store away from light.

Control	Liquichek Spinal Fluid Control, Levels 1 and 2
Preparation	Before loading vials onto the instrument, swirl gently to ensure homogeneity.
Storage/Stability	**Unopened:** until the expiration date when the stopper is not punctured and stored at 2 - 8°C. **Opened or punctured:** stable for 30 days when stored on-board the instrument.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Dimension Vista® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension Vista® 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

Step	Action
	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.

6.6 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 Vista® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

7.3 Supplies

- Aliquot Plates
- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

GLU Flex® reagent cartridge Cat. No. K1039 is required to perform this test.

Glucose is performed on the Dimension Vista® 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	Sample Processing
1.	A sample rack holding tubes or cups is placed on the rack input lane.
2.	The sample shuttle moves the rack to the barcode reader which identifies the rack and samples to the system.
3.	The rack moves into the sample server and to the rack positioner.
4.	At the same time, aliquot plates move from the aliquot loader into position.
5.	The aliquot probe aspirates the sample from the tubes or cups and dispenses it into the wells of the aliquot plates.
6.	After each aspirate-dispense action, the probe is thoroughly rinsed inside and out to prevent sample carryover.
7.	When sample aspiration is completed, the sample server moves the rack back to the sample shuttle, where it is placed on the output lane and can be removed by the operator.

8.2	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension Vista® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension Vista® Operator's Manual

8.2	Specimen Testing
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 Vista® 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). 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 Volume:	1.2 µL
Reagent 1 Volume:	22.4 µL
Reaction Time:	2 minutes
Test Temperature:	37°C
Wavelength:	340 & 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 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)

1 – 2,500 mg/dL

10.5 Review Patient Data

Each result is reviewed for error messages. Refer to the Dimension Vista system manual "Error messages" section for troubleshooting. 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 below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 1 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 1 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 4. No multiplication is necessary.
> 2,000 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**: WATER Enter dilution factor as a whole number. Re-assay. Readout is corrected for dilution.
> 2,500 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 2,500 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.

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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	≤ 30 mg/dL	≥ 300 mg/dL
> 1 month	≤ 40 mg/dL	≥ 500 mg/dL

11.3 Standard Required Messages

The following comment is automatically appended to GTT 2 hour and GTT 3 hour (non-pregnancy) tests by the LIS:

Diabetes mellitus may be diagnosed if any of the following criteria are met, alone or in combination, on two separate days:
1). Symptoms of diabetes plus random plasma glucose >=200 mg/dL.
2). Fasting plasma glucose >=126 mg/dL.
3). 2 hr plasma glucose >=200 mg/dL during OGTT (75g. glucose load).

Reference: Diabetes Care 29:S43-S48, 2006

The following comment is automatically appended to gestational GTT 1 hour test by the LIS:

If 1Hr plasma glucose value >=140 mg/dL, after 50g load, the American Diabetes Assn. recommends scheduling patient for a 3 hour, 100g OGTT for a confirmation of Gestational Diabetes.
A cutoff of 140 mg/dL detects 80% of patients with GDM.

Reference: Diabetes Care 29:S43-S48, 2006

The following comment is automatically appended to gestational GTT 3 hour test by the LIS:

Diagnosis criteria for GDM using the 100 gram OGTT
Diagnosis of GDM requires any two values to meet or exceed those listed below.

Fasting	95 mg/dL
1 hour	180 mg/dL
2 hour	155 mg/dL
3 hour	140 mg/dL

Reference: Diabetes Care 29:S43-S48, 2006

12. CLINICAL SIGNIFICANCE

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. 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.

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 Vista Operator's Guide.

The expected maximum observed standard deviations for repeatability using n = 5 replicates at the following Glucose concentrations are:

GLU Concentration	Acceptable S.D. Maximum
75 mg/dL	5.6 mg/dL
375 mg/dL	17.8 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1 – 500 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Control (Serum)			
Level 1	75	1 (2)	2 (3)
Level 2	379	4 (1)	8 (2)
Liquichek (Spinal Fluid)			
Level 1	58	2 (4)	3 (5)
Level 2	28	1 (3)	1 (4)

14.3 Interfering Substances

HIL Interference:
The GLU method was evaluated for interference according to CLSI/NCCLS EP7-A2. 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	Substance Concentration	GLU mg/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	94	<10
Bilirubin (unconjugated)	60 mg/dL	90	<10
Bilirubin (conjugated)	60 mg/dL	90	<10
Lipemia Intralipid®	100 mg/dL 200 mg/dL 400 mg/dL	74	<10 13 24

- Venipuncture should occur prior to sulfasalazine administration due to the potential for falsely depressed results.
- Venipuncture should occur prior to sulfapyridine administration due to the potential for falsely elevated results.

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 Vista® Clinical Chemistry System Operator's Manual
2. Dimension Vista® Calibration/Verification Procedure
3. Dimension Vista® Cal Accept Guidelines
4. Dimension Vista® Calibration summary

5. Dimension Vista® Sample Processing, Startup and Maintenance procedure
6. Laboratory Quality Control Program
7. QC Schedule for Siemens Dimension Vista®
8. Laboratory Safety Manual
9. Safety Data Sheets (SDS)
10. Dimension Vista® Limits Chart (AG.F200)
11. Quest Diagnostics Records Management Procedure
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Functions Checks
14. Specimen Acceptability Requirements (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Glucose Tolerance Tests (Client Service procedure)
17. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
18. Current package insert GLU Flex® Reagent Cartridge K1039

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, GLU Flex® Reagent Cartridge K1039, Siemens Healthcare Diagnostics Inc., 08/29/2017.
3. Package Insert, CHEM I CAL, Siemens Healthcare Diagnostics Inc., 03/2015.
4. Package Insert, Liquid Assayed Multiqual® Chemistry Controls, Bio-Rad Laboratories, 05/2017.
5. Package Insert, Liquichek Spinal Fluid Controls, Bio-Rad Laboratories, 07/2015.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/12/14		Update owner	L Barrett	R SanLuis
000	6/12/14	1, 3.2	Removed synovial fluid	A Chini	R SanLuis
000	6/12/14	2	Corrected formula	A Chini	R SanLuis
000	6/12/14	5.2	Updated open calibrator stability	A Chini	R SanLuis
000	6/12/14	6.1, 6.2	Added CSF controls	A Chini	R SanLuis
000	6/12/14	17	Added CSF control package insert	A Chini	R SanLuis
000	6/12/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
1	2/25/16	3.2	Specify anticoagulant	L Barrett	R SanLuis
1	2/25/16	4.2	Add hazard/chemical warning	A Chini	R SanLuis
1	2/25/16	6.1, 6.2	Edit CSF control information	A Chini	R SanLuis
1	2/25/16	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
1	2/25/16	17	Update package insert information	A Chini	R SanLuis
2	6/15/18	Header	Add WAH	L Barrett	R SanLuis
	6/15/18	1, 3.1	Add GTT with codes	L Barrett	R SanLuis
2	6/15/18	3.2	Add grey top tube, remove specimen onboard stability	L Barrett	R SanLuis
2	6/15/18	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	6/15/18	6.1, 6.2	Update QC material and storage	L Barrett	R SanLuis
2	6/15/18	7.2	Change freezer range to -50C	L Barrett	R SanLuis
2	6/15/18	10.5	Move patient review from section 6	L Barrett	R SanLuis
2	6/15/18	10.6	Remove repeat value below AMR/CRR	L Barrett	R SanLuis
2	6/15/18	11.3	Add comments for GTT	L Barrett	R SanLuis
2	6/15/18	14.3	Add interfering medications	L Barrett	R SanLuis
2	6/15/18	15	Update to new standard wording	L Barrett	R SanLuis
2	6/15/18	16	Add GTT SOP, update titles	L Barrett	R SanLuis
2	6/15/18	17	Update QC insert, update PI dates	L Barrett	R SanLuis

19. ADDENDA

None