TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	4/11/2018
Department:	Core Lab	**Due Date:**	5/1/2018
		Implementation:	**TBA**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Intact Parathyroid Hormone (iPTH) by ADVIA Centaur CP SGAH.C74 v7

This has been converted to system SOP

Description of change(s):

Note: significant changes are related to change in reagent, other changes are mostly format updates

Section	Reason
Header	Add WAH
2	Modified to match new package insert
3.2	Changed R.T. stability to 25 hours and refrigerated stability to 14 days
4,5,6	Remove individual section labeling instructions and add general one
4.1	Added new reagent catalog number
5.2	Updated calibrator stability
5.3	Updated calibration frequency
7.2	Changed freezer range to match practice
10.4	Changed CRR upper limit
10.5	Review data moved from section 6
10.6	Changed upper value and action
11.1	Updated reference range to match pkg insert
14.1	Changed AMR upper limit
14.2,14.3	Modified data to match pkg insert
15	Updated to new standard wording
17	Added new reagent insert, update QC

Implementation date for this revised SOP will be announced.
(to be coordinated with LIS changes and receipt of reagent)

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

Electronic Document Control System

Document No.: SGAH.C74[7]
Title: Intact Parathyroid Hormone (iPTH) by ADVIA Centaur CP
Owner: LESLIE BARRETT
Status PRERELEASED
Effective Date: **Next Review Date:**

Review

REVIEW: **DEFAULT DOCUMENT**

Approver	Status	Sign-off Date
NICOLAS CACCIABEVE	APPROVED	3/5/18 2:39 pm
ROBERT A SANLUIS	APPROVED	3/5/18 12:24 pm
LESLIE BARRETT	APPROVED	3/2/18 12:17 pm

Technical SOP

Title	**Intact Parathyroid Hormone (iPTH) by ADVIA Centaur CP**
Prepared by	Ashkan Chini Date: 5/1/2012
Owner	Robert SanLuis Date: 11/9/2012

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**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Intact Parathyroid Hormone	ADVIA Centaur CP	IOIPTH, ITPTH

Synonyms/Abbreviations
iPTH, Intraoperative IPTH

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The ADVIA Centaur PTH assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two anti-human PTH antibodies. The first antibody in the Lite Reagent is a monoclonal mouse anti-human PTH (N-terminal) antibody labeled with acridinium ester. The second antibody is a biotinylated monoclonal mouse anti-human PTH (C-terminal) antibody that is bound to streptavidin-coated paramagnetic latex particles in the Solid Phase.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (K_2 EDTA) None
Collection Container	Lavender Top Tube
Volume - Optimum **- Minimum**	1 mL 0.5 mL
Transport Container and Temperature	Collection container or plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 25 hours
	Refrigerated: 2-8° C 14 days
	Frozen: Not recommended
Timing Considerations	Correct handling of patient samples is critical to ensure the integrity of the intact PTH molecule. Intact PTH has been demonstrated to be labile and is susceptible to fragmentation. This instability depends on both time and temperature.

Criteria	
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	Keep tubes stoppered at all times.

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 / Kits	Supplier & Catalog Number
ADVIA Centaur PTH Ready Pack	Siemens reagent cartridge Cat. No. 10699154
ADVIA Centaur R1 Acid Reagent	Siemens reagent Cat. No. 00497043
ADVIA Centaur R2 Base Reagent	Siemens reagent Cat. No. 00497043
ADVIA Centaur Wash 1 Solution	Siemens reagent Cat. No. 01137199
ADVIA Centaur CSC	Siemens reagent Cat. No. 09908593

4.2 Reagent Preparation and Storage

Assay Kit: ADVIA Centaur PTH Ready Pack (primary reagent pack)	
Storage	Store the reagent upright at 2-8°C Protect unopened reagent packs from all heat and light sources
Stability	Stable until expiration date stamped on the pack label. Onboard reagents are stable for 28 days.
Preparation	Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended.

Reagent	**ADVIA Centaur R1 Acid Reagent & R2 Base Reagent**
Container	Reagent bottle (300 mL)
Storage	Store at 2-25°C Use at 18-30°C
Stability	Stable until expiration date stamped on the pack label. Onboard reagents are stable for 30 days. Avoid exposure to light.
Preparation	This reagent is liquid and ready to use.

Reagent	**ADVIA Centaur Wash 1 Solution**
Container	Reagent bottle (1500 mL)
Storage	Store at 2-25°C
Stability	Stable until expiration date stamped on the pack label. Onboard reagents are stable for 30 days.
Preparation	This reagent is liquid and ready to use.

Reagent	**ADVIA Centaur Cleaning Solution Concentrate (CSC)**
Container	Reagent bottle (70 mL)
Storage	Store at 2-8°C
Stability	Stable until expiration date stamped on the pack label. Prepared reagent is stable for 7 days.
Preparation	1. Carefully pour a container of ADVIA Centaur CP Cleaning Solution Concentrate into the cleaning bottle. 2. Add enough reagent grade water to the bottle or container to bring the total volume of cleaning solution to 2 liters.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
ADVIA Centaur PTH Calibrator	Each reagent pack includes a calibration set

5.2 Calibrator Preparation and Storage

Calibrator	**ADVIA Centaur PTH Calibrator**
Preparation	• Add 1.0 mL of reagent grade water to each calibrator vial. • Let stand for 30 minutes at room temperature (18-25°C) to allow the lyophilized material to dissolve. • Gently mix the calibrators before using.

Storage/Stability	• Store at 2-8°C • **Unopened:** until the expiration date on the vial. • **Reconstituted:** stable for 8 hours at 18-25°C. • **Reconstituted (frozen):** stable for 60 days at -20° C or colder immediately after reconstitution.

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	• Calibration Interval/Stability is 21 days • Prior to patient testing when the calibration interval has expired • A calibration is invalid • New lot or shipment of assay reagents • Controls are repeatedly out of range.

	Calibration Procedure
1.	From the main page, go to **Result** > **Pending**, and make sure nothing is pending for this method. **Note**: The instrument must be in a **Ready** mode before moving on to the next step.
2.	Get the **Centaur CP** Calibrator Master Curve card from the calibrator pack and reagent Master Curve card from the reagent box. From the main page, go to **Definition** > **Calibrators** > **Scan**, scan all 3 barcodes (on the Calibrator Master Curve) from top to bottom. Then go to **Definition** > **Master Curves** > **Scan**, scan all barcodes (on the Reagent Master Curve) from top to bottom. **Notes**: • The calibrator pack and reagent box include both Centaur CP and XP master curves. Be sure to scan the correct master curve. • Always scan the calibrator information first.
3.	Load the low and high calibrators into appropriate sample pour-off tubes that accommodate the Siemens-supplied barcode label. **Note**: The low and high calibrators provided in this kit are matched to the original primary reagent pack. Do not mix calibrator lots with different lot of reagent packs.
4.	Attach the Siemens-supplied barcode labels to the pour off tubes.
5.	Load the sample tubes into a sample rack. Move the tube type selector on the rack to position A.
6.	Load the rack in the sample compartment.
7.	On the Sample Compartment screen, select the lane containing the sample rack with the calibration material.
8.	Confirm or enter the calibrator information.
9.	Select **Close** to return to the workspace.
10.	At the workspace, select the primary reagent area.

	Calibration Procedure
11.	Select the assay to calibrate.
12.	Select **Calibrate**. The system automatically begins sampling the calibrator material. **NOTE:** The Calibrate button is not active on the Primary Reagent Screen in the following situations: • there are no calibrators defined • there are no Master Curves defined • there is no reagent onboard • the calibration material for defined lots is expired • there is no calibrator material in the sample compartment
13.	Select **Close** to return to the workspace.
14.	To check the time due for the calibration: a. At the workspace, select **Results**. b. Select the Calibrations tab to view the Time Due stamp for the assay you are calibrating. c. Select **Close**.

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 Specialty Immunoassay Control Levels 1, 2 and 3	Bio-Rad Laboratories Cat. No. 364, 365, 366

6.2 Control Preparation and Storage

Control	Liquichek Specialty Immunoassay Control Levels 1, 2 and 3
Preparation	• Allow the frozen control to stand at room temperature (18 - 25°C) until it is completely thawed. • Before sampling, gently swirl the vial several times to ensure homogeneity. • Promptly replace the stopper and return to 2-8° C storage after each use.

Storage/Stability	• Store at ≤ -20° C • **Unopened QC:** stable until expiration date on the vial. • **Opened QC:** Once thawed and opened, stable for 7 days when stored tightly capped at 2-8°C.

6.3 Frequency

Analyze all 3 Levels of QC material after each calibration.

SGMC: QC is run daily as follows: Levels 1 and 3 are run on day shift, Level 2 on evening shift, and either Level 1 or 3 on night shift.

WAH: PTH testing is only performed when a Parathyroid Surgery is scheduled. Prior to scheduled surgery, check calibration interval/stability, perform calibration if required (see section 5.3), and run all QC levels for PTH to ensure instrument and method are functioning properly. When PTH is in use, QC must be run once per shift.

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.

Step	Action
	• If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

IF the Quality Control …	THEN…
does not fall within the Expected Values	• Verify that the materials are not expired. • Verify that required maintenance was performed. • Verify that the assay was performed according to the instructions for use. • Rerun the assay with fresh quality control samples. • If necessary recalibrate the assay and repeat quality control

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

ADVIA Centaur CP Immunoassay 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

- Purified water (Millipore® or equivalent)
- Calibrated pipettes and disposable tips
- Cuvettes
- Tips

8. PROCEDURE

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	Loading samples into Sample Rack
1.	Position the barcode label vertically on the sample tube approximately 2 cm (0.8 in) from the top.
2.	Move the tube-type selector on the rack to position B for short and C for long sample tubes.
3.	Place the sample tubes in the rack.
4.	Ensure that there is only one type of sample tube in the rack and that the tube-type selector is positioned correctly for that tube type. Ensure that the barcode labels are clearly visible above or between the slots in the rack.

8.2	Loading Sample Racks into the System
1.	Open the sample compartment door.
2.	Slide the sample rack into the appropriate lane. Use one continuous motion. The sample barcodes are read as the rack is inserted into the system. If the rack stops, or reverses, during its insertion, the barcodes may not be read.
3.	Ensure that the sample rack is inserted correctly, and locked into place. When the sample rack is inserted correctly, you will hear and feel it click into place.
4.	Close the sample compartment door.

8.3	Scheduling Samples through the Sample Compartment Screen
1.	At the workspace, select the sample compartment. Select the Sample Rack. Select a sample

8.3	Scheduling Samples through the Sample Compartment Screen
2.	Select the sample type by toggling the sample selection button. The default is a routine patient sample (smp). If you want the sample to be processed before routine samples, select stat.
3.	Select the Sample ID field. The samples are numbered 1-12. Number 1 is the sample at the back of the sample compartment, and number 12 is the sample at the front of the sample compartment.
4.	If the sample ID was not entered using a barcode label on the sample tube, enter the sample ID and then press **Enter**.
5.	Select the assays or the profiles to process against the sample.
6.	Select **Close**.

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 PTH in pg/mL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results up to one decimal point.

10.3 Units of Measure

pg/mL

10.4 Clinically Reportable Range (CRR)

6.3 – 2,000.0 pg/mL

10.5 Review Patient Data

Each result is reviewed for error messages. Refer to the ADVIA Centaur CP system manual “Error messages” section for troubleshooting. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
< 6.3 pg/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 6.3 pg/mL
≥ 2,000.0 pg/mL	Report as ≥ 2000.0 pg/mL

11. EXPECTED VALUES

11.1 Reference Ranges

18.4 – 80.1 pg/mL

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

This assay is intended to be used to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy.

Parathyroid hormone (PTH), produced by the parathyroid gland, is the major circulating factor regulating extracellular calcium concentration. Abnormally low-ionized calcium concentrations trigger the secretion of PTH. The PTH molecules bind to type 1 parathyroid hormone receptors in target tissues and initiate a sequence of reactions resulting in increased extracellular calcium concentrations. PTH stimulates osteoclastic bone resorption resulting in the release of calcium from bone. PTH stimulates transcellular calcium reabsorption from the renal tubules and stimulates the kidney to produce 1,25-dihydroxyvitamin D which acts on the intestines to increase calcium reabsorption. In most clinical conditions, rising levels of extracellular calcium suppresses PTH secretion through a negative feedback mechanism.

Parathyroid hormone increases the rate of bone metabolism. Depending on the age of the patient, the bones involved, and the concentrations of the hormone in circulation over time, the effect on the bone can be either catabolic or anabolic. Consistently high concentrations of parathyroid hormone generally have a catabolic effect and intermittent, slightly elevated concentrations have an anabolic effect.

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 containing such error messages should be held for follow-up. Refer to your ADVIA Centaur CP Operator's Guide.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

6.3 – 2,000.0 pg/mL

14.2 Precision

Three samples were assayed 12 times, in each of 12 runs, on 3 systems over a period of 4 days. The following results were obtained:

Mean pg/mL	Within-Run % CV	Total CV %
13.1	4.02	7.9
415.6	2.86	4.13
1113.2	2.31	3.96

14.3 Interfering Substances

Interferent	Highest Concentration Tested	Observed Interference %
Bilirubin (Conjugated)	60 mg/dL	5.9
Bilirubin (Unconjugated)	60 mg/dL	-2.2
Hemoglobin	500 mg/dL	-4.5
Triglycerides	3275 mg/dL	-0.4

14.4 Clinical Sensitivity/Specificity/Predictive Values

None

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.

Notes:

- The liquid waste container must be emptied once per shift. **Do NOT** transfer liquid waste into any other containers. Empty liquid waste directly from the container into the sink.
- When filling the DI water container; **do NOT** leave the container unattended while it is being filled. To avoid accidents, technologists **MUST** be present the entire time the container is being filled.
- If an accident occurs and biohazard waste, DI water or any other liquid spills on the floor, immediately notify the supervisor and all staff of the situation. Warn others to

stay away from the accident area. Do **NOT** leave the site of the spill. Remain there to warn others not to walk on the wet floor and to prevent falls. Ask a colleague to get the Wet Floor Sign and some paper towels. Then immediately call the Environmental Services for help with clean up.

16. RELATED DOCUMENTS

1. ADVIA Centaur CP Operator's Manual
2. Laboratory Quality Control Program
3. QC Schedule for ADVIA Centaur CP
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Quest Diagnostics Records Management Procedure
7. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
8. Hemolysis, Icteria and Lipemia Interference (Lab policy)
9. Repeat Testing Requirement (Lab policy)
10. ADVIA Centaur CP Sample Processing, Startup and Maintenance (Chemistry SOP)
11. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
12. Current package insert Intact PTH Reagent Cartridge

17. REFERENCES

1. Liquichek™ Specialty Immunoassay Control, Bio-Rad Laboratories revised 04/2016
2. Package Insert, Intact PTH reagent pack, Siemens Diagnostics revised 07/2017

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	11/9/12		Update owner	L Barrett	R SanLuis
000	11/9/12	3.2	Remove centrifugation requirement	L Barrett	R SanLuis
001	6/20/13	3.2	Add frozen storage	A Chini	R SanLuis
001	6/20/13	4	Remove Multi-Diluent 1 (not used)	A Chini	R SanLuis
001	6/20/13	5.2	Remove open storage at frozen temp	A Chini	R SanLuis
001	6/20/13	10.4	Revised upper CRR	A Chini	R SanLuis
001	6/20/13	10.5	Removed onboard dilution	A Chini	R SanLuis
001	6/20/13	14.3	Updated Interfering Substances	A Chini	R SanLuis
001	6/20/13	15	Added specific safety notes	A Chini	R SanLuis
001	6/20/13	16	Added Centaur operation SOP	L Barrett	R SanLuis
002	4/15/15	1	Add new test code	L Barrett	R SanLuis
002	4/15/15	3.2	Add statement to keep tubes capped	A Chini	R SanLuis
002	4/15/15	4.1, 5.1	Update catalog numbers	A Chini	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
002	4/15/15	6.3	Change QC frequency	A Chini	R SanLuis
002	4/15/15	6.4, 6.6	Replace LIS with Unity Real Time	A Chini	R SanLuis
002	4/15/15	10.4,10.5 14.1	Change lower limit of AMR & CRR to match updated package insert (PI)	A Chini	R SanLuis
002	4/15/15	14	Change data to match updated PI	A Chini	R SanLuis
002	4/15/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
3	7/7/15	1	Correct test code from INPTH to ITPTH	L Barrett	R SanLuis
3	7/7/15	6.3	Change frequency to daily to match log	L Barrett	R SanLuis
4	3/22/16	4.2	Add hazard information	A Chini	R SanLuis
4	3/22/16	5.3	Update steps 1 - 3	A Chini	R SanLuis
4	3/22/16	6.2	Change open control from 23 days to 7	A Chini	R SanLuis
4	3/22/16	17	Update package inserts	A Chini	R SanLuis
5	6/16/16	5.3	Specify calibration when interval expires	A Chini	R SanLuis
5	6/16/16	6.3	Update QC frequency for WAH	A Chini	R SanLuis
6		Header	Add WAH	L Barrett	R SanLuis
6	2/26/18	2	Modified to match new package insert	A Chini	R SanLuis
6	2/26/18	3.2	Changed R.T. stability to 25 hours and refrigerated stability to 14 days	A Chini	R SanLuis
6	2/26/18	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
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6	2/26/18	7.2	Changed freezer range to match practice	L Barrett	R SanLuis
6	2/26/18	10.4	Changed upper limit	A Chini	R SanLuis
6	2/26/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
6	2/26/18	10.6	Changed upper value and action	A Chini	R SanLuis
6	2/26/18	11.1	Updated range to match pkg insert	A Chini	R SanLuis
6	2/26/18	14.1	Changed upper limit	A Chini	R SanLuis
6	2/26/18	14.2,14.3	Modified data to match pkg insert	A Chini	R SanLuis
6	2/26/18	15	Updated to new standard wording	L Barrett	R SanLuis
6	2/26/18	17	Added new reagent insert, update QC	A Chini	R SanLuis

19. ADDENDA

None