TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	7/19/2013
Department:	Chemistry	**Due Date:**	8/15/2013
		Implementation:	**8/15/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

ADVIA Centaur CP Sample Processing, Startup and Maintenance	SGAH.C134.001	WAH.C127.001
B-type Natriuretic Peptide (BNP) by ADVIA Centaur CP	SGAH.C73.002	WAH.C68.002
Intact Parathyroid Hormone (iPTH) by ADVIA Centaur CP	SGAH.C74.002	WAH.C69.002

Description of change(s):

ADVIA Centaur CP Sample Processing, Startup and Maintenance

Section	Reason for Revision
5	Add instructions and labeling for Sample Cups; add instructions for emptying liquid waste and filling wash solution and DI water; add note for spills.
9	move maintenance log to section 6

B-type Natriuretic Peptide (BNP) by ADVIA Centaur CP

Section	Reason
5.2	Remove open storage at frozen temp
5.3	Shorten calibrator interval to 28 days
6.4	Removed GEC SOP as alternate method
15	Added specific safety notes

Intact Parathyroid Hormone (iPTH) by ADVIA Centaur CP

Section	Reason
4	Remove Multi-Diluent 1 (not used)
5.2	Remove open storage at frozen temp
10.4	Revised upper CRR
10.5	Removed onboard dilution

These revised SOPs will be implemented on August 15, 2013

Approved draft for training all sites (version 001)

Non-Technical SOP

Title	**ADVIA Centaur CP Sample Processing, Startup and Maintenance**
Prepared by	Ashkan Chini Date: 11/9/2012
Owner	Robert SanLuis Date: 11/9/2012

Laboratory Approval

Print Name and Title	Signature	Date
Refer to the electronic signature page for approval and approval dates.		

Local Issue Date: Local Effective Date:

Review:

Print Name	Signature	Date

Form revised 3/31/00

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1. PURPOSE

To outline the operational daily start up procedure for the ADVIA Centaur CP and describe all other maintenance that must be performed as scheduled.

2. SCOPE

This procedure applies to all Core Laboratory personnel working with the ADVIA Centaur CP instrument.

3. RESPONSIBILITY

Core Laboratory Personnel are responsible for performing and complying with this procedure.
The Technical Supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

None

5. PROCEDURE

A. General Information:

1. If a specimen is short, get an ADVIA Centaur Sample Cup and label it with patient's name and accession number. Then pour off patient's plasma in the Sample Cup.
2. Only handle one patient sample at a time.
3. Never pour specimen back (from Sample Cup) into the primary tube.
4. After testing is complete, if there is no specimen left in the primary tube, parafilm the top of the Sample Cup and save.
5. All saved specimens must be labeled with patient identification.

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The following instructions are used when performing sections B, C and D:

From the main page click on the **"i"** button, located on the top right side of the screen (It is a lower case i placed in a book image, next to the **"Set up"** button). Then on Top Left side of the screen click on **"Operator's Guide"**. Look on the left side of the screen and notice the following tabs **Overview**, **Operating the System**, **Calibrations and Controls**, **Maintenance** and **Troubleshooting Principles**.

When operating, maintaining or troubleshooting the ADVIA Centaur CP, use the **"i"** guide. It will provide step by step instructions including pictures to help operators run (samples, QC and calibrations), perform maintenance and troubleshoot the instrument if needed.

B. Operation:

1. Sign in the system
2. Empty the solid waste drawer
3. Empty the liquid waste container*
   a. Perform once per shift
   b. **Do NOT** transfer liquid waste into any other containers.
   c. Empty liquid waste directly from the container into the sink.
4. Load sample tips and cuvettes, if needed.
5. Ensure sufficient wash 1 Solution and DI water is on board.*
   a. When filling DI water, **do NOT** leave the container unattended while it is being filled.
   b. To avoid accidents, technologists **MUST** be present the entire time the container is being filled.
6. Replace Acid and Base reagents if needed (check for expiration date and ensure quantity is sufficient).
7. Ensure sufficient reagent is on board.
   a. If the number of tests left on that particular reagent is low check to ensure more reagents are available and if so, check the lot number.
   b. If there is different reagent lot number or same lot number but different shipment, then prepare for calibration.
8. Ensure that the calibration is not expired and QC for that specific shift has been successfully run.
9. Load samples into sample rack.
10. Open the sample rack door and place the rack on the position where the green light blinks. Close the door.
11. On the main screen, click on the rack section. Select the rack that was just put on and click on the sample/samples on that rack.
12. Select the desirable test/tests and close the page.
13. Press **START**, then **OK**

* **Note**:
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.

C. Maintenance:

The ADVIA Centaur CP system monitors maintenance tasks and notifies the operator when a scheduled task is due. The system notifies the operator through a color change on the Maintenance status button and an **Overdue** icon next to the task on the Maintenance Schedule screen.

The system provides a maintenance schedule for the operator to record the completion of scheduled maintenance tasks. The system then uses this information to automatically update the maintenance schedule with the next time the task is due. At the workspace, the background of the Maintenance status button changes color to indicate status.

Yellow indicates that a maintenance task is due or overdue.
Red indicates that an automated maintenance procedure did not finish.

All maintenance is documented on the ADVIA Centaur CP Maintenance Log.

1. Daily Maintenance:

a. Automated Daily Cleaning
b. Aspirate Probe Bubble Detector Calibration

2. Weekly

a. Clean the incubation ring cover
b. Clean the exterior of the reagent probe
c. Clean the exterior of the waste probe
d. Clean the probe rails
e. Prepare a new CSC (Cleaning Solution Concentrate)
f. Perform automated weekly cleaning

3. Monthly Maintenance:

a. Maintain system data base
b. Perform automated monthly cleaning

4. Bimonthly Maintenance:

Clean Wash 1 Container

5. As Needed Maintenance:

a. Clean the Acid / Base compartment
b. Clean the solid waste drawer and liner
c. Clean the sample compartment
d. Clean the sample compartment shutter
e. Clean the sample racks
f. Clean the reagent compartment
g. Clean the reagent compartment shutter
h. Clean system exterior
i. Clean the workstation
j. Data base maintenance
k. Automated system prime

D. Troubleshoot:

1. Monitoring the Event Log

An event is a system activity or error recorded by the system in the Event Log. Events are designed to provide the operator with detailed information necessary to understand system activity and status. Each event contains a unique event code, the date and time of the event, the event message, the origin of the event, and the severity level of the event.
The Event Log button, located on the left side of the status bar, displays the most recent two events. The Event Log button changes color to indicate the current status of the system.

Neutral indicates that the system is operating correctly.
Yellow indicates that a system warning condition has occurred. The system continues to operate but requires your attention.
Red indicates that a system failure condition has occurred. The system stops operating and requires your attention.

2. Troubleshooting an Event

Most events do not require the operator to perform any action. Some events, however, identify a problem or error in the system or software that require you to perform some troubleshooting action. Use this procedure to troubleshoot an event using the system Event Log.

a. At the workspace, select the **Event Log** button.
b. Select the event you want to troubleshoot.
c. Carefully read the message, description, possible causes, and corrective actions.
d. Take the appropriate actions.
e. If the problem cannot be resolved with the information provided, contact the hot line technical support center.

6. RELATED DOCUMENTS

ADVIA Centaur CP Immunoassay System Operator's Guide
Quality Control Program, QA procedure
QC Responsibilities and Review, QA procedure
ADVIA Centaur CP Maintenance Log (AG.F182)

7. REFERENCES

ADVIA Centaur CP Immunoassay System Operator's Guide, Ireland, Revised 09/2005

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	6/20/2013	Section 5: Add instructions and labeling for Sample Cups; add instructions for emptying liquid waste and filling wash solution and DI water; add note for spills. Section 9: move maintenance log to section 6	A Chini	R SanLuis

9. ADDENDA AND APPENDICES

None

Technical SOP

Title	**B-type Natriuretic Peptide (BNP) by ADVIA Centaur CP**
Prepared by	Ashkan Chini Date: 5/1/2012
Owner	Robert SanLuis Date: 6/20/2013

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**

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
B-type Natriuretic Peptide	ADVIA Centaur CP	BNP

Synonyms/Abbreviations
BNP

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The ADVIA Centaur BNP assay is a fully automated two-site sandwich immunoassay using direct chemiluminescent technology, which uses constant amounts of two monoclonal antibodies. The first antibody, in the Lite Reagent, is an acridinium ester labeled monoclonal mouse anti-human BNP F(ab') fragment specific to the ring structure of BNP. The second antibody, in the Solid Phase, is a biotinylated monoclonal mouse anti-human antibody specific to the C-terminal portion of BNP, which is coupled to streptavidin magnetic particles.

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 (K2 EDTA) None
Collection Container	Lavender Top Tube
Volume - Optimum **- Minimum**	Full Tube 1 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature, **as BNP is unstable in glass containers.**
Stability & Storage Requirements	Room Temperature: Not recommended
	Refrigerated: 2-8° C 24 hours
	Frozen: -70° C N/A
Timing Considerations	After centrifugation, store separated plasma samples at 2 - 8° C until testing.
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.

Criteria	
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	None

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
ADVIA Centaur BNP	Siemens reagent cartridge Cat. No. 02816634
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. 112351
ADVIA Centaur CSC	Siemens reagent Cat. No. 112748

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit: ADVIA Centaur BNP Ready Pack (primary reagent pack)	
Reagent a	Lite Reagent (Volume 10.5 mL)
Reagent b	Solid Phase (Volume 21 mL)
Manufacturer's Information	Centaur CP BNP Master Curve Cards
Storage	Store the reagent up right at 2 - 8° C
Stability	Reagent is stable until expiration date stamped on the pack label. Onboard reagents are stable for 41.6 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	Reagent is 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	Reagent is 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**
Container	Reagent bottle (70 mL)
Storage	Store at 2 - 8° C
Stability	Reagent is 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
Low and High Calibrator	Siemens BNP calibrator, Cat. No. 02817266

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	**BNP Calibrator (Low & High)**
Preparation	• Add 2.0 mL of reagent grade water into each calibrator vial. • Let the calibrators stand for 15 to 20 minutes at room temperature (20 - 30° C) to allow the lyophilized material to dissolve. • Gently swirl and invert the vials until homogeneous.
Storage/Stability	• Store at 2 - 8° C • **Unopened Calibrator** is stable until the expiration date on the vial. • **Opened Calibrator:** once reconstituted use immediately and freeze the rest. The frozen calibrator is stable for 60 days when stored at ≤ -20° C. **Freeze-thaw is recommended one time only after reconstitution.**

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	• When the calibration interval expires • Calibration Interval is 28 days • A calibration is invalid • New lot or shipment of assay reagents • Controls are repeatedly out of range.
Procedure	1. Enter the calibrator information provided on the ADVIA Centaur CP side of the calibrator assignment value card. Ensure you use the ADVIA Centaur CP side of the card. 2. Enter the Master Curve information from the cards provided with the primary reagent packs. Ensure you use the ADVIA Centaur CP side of the card. 3. Load the low and high calibrators into appropriate sample pour-off tubes that accommodate the Siemens-supplied barcode label. 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. 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**.

5.5 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
Liquichek™ Cardiac Markers Plus Control levels 1, 2 and 3	Bio-Rad Laboratories Cat. No. 181, 182 and 183

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6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquichek™ Cardiac Markers Plus Control levels 1, 2 and 3
Preparation	• Allow the frozen control to thaw at room temperature (18-25°C) for 30 minutes or until completely thawed prior to use. • Before sampling, gently swirl the vials several times to ensure homogeneity. • After each use, promptly replace the stopper and return to 2 - 8°C storage.
Storage/Stability	• Store at -20 to -70° C • **Unopened Quality Control** is stable until the expiration date on the vial. • **Opened Quality Control:** is stable for 15 days when stored tightly capped at 2 - 8° C.

6.3 Frequency

Analyze all 3 levels of QC material after each calibration. Each day of patient testing QC Levels 1 and 3 are run on day shift, Level 2 on evening shift, and either Level 1 or 3 on night shift.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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

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Step	Action
	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.

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 • If unable to resolve issue and/or instrument is inoperable, testing may be performed on alternative method B-type Natriuretic Peptide (BNP) by Triage Meter. Refer to one of the appropriate SOPs: WAH.H11 or SGAH.H11 for instructions.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Centaur Operator's Guide 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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 Lead Technologist 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

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 -70°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.

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.

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
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**.

9. CALCULATIONS

The instrument automatically calculates the concentration of BNP 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 in whole numbers.

10.3 Units of Measure

pg/mL

10.4 Clinically Reportable Range (CRR)

5 - 5,000 pg/mL

10.5 Repeat Criteria and Resulting

IF the result is …	THEN…
< 5 pg/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 5 pg/mL
≥ 5000 pg/mL	Report as ≥ 5000 pg/mL

When manually entering results in the LIS, use SHE1 (at SGAH) or WHE1 (at WAH) worksheet with the Centaur default method code CS1 (at SGAH) or CW1 (at WAH).

11. EXPECTED VALUES

11.1 Reference Ranges

0 – 100 pg/mL

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

This assay is indicated for the measurement of plasma BNP as an aid in the diagnosis and assessment of the severity of heart failure. In patients with acute coronary syndromes (ACS), this test, in conjunction with other known risk factors, can also be used to predict survival as well as to predict the likelihood of future heart failure.

Heart failure is an important clinical syndrome which compromises left ventricular systolic or diastolic function or a combination of both. Heart failure occurs when the heart is unable to pump blood at a rate sufficient for metabolic requirements. Its most common causes are

coronary artery disease, hypertension, valvular heart diseases and cardiomyopathies. Accurate and early diagnosis is important since effective therapeutic interventions (e.g., angiotensin converting enzyme inhibitors, beta-blockers) are available, which improve both morbidity and mortality. Based on clinical signs and symptoms, the severity of heart failure is classified into four classes of increasing disease progression according to the New York Heart Association classification.

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 you ADVIA Centaur CP Operator's Guide.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

5 - 5000 pg/mL

14.2 Precision

Six samples were assayed 4 times, in 20 runs, on 2 systems over a period of 20 days. The following results were obtained:

Mean pg/mL	Within-Run % CV	Run-to-Run % CV	Total CV %
29.4	4.3	1.9	4.7
48.5	2.5	2.1	3.5
410	1.8	1.9	2.8
458	2.0	1.5	2.8
1452	2.0	0.5	2.3
1736	2.1	1.7	2.9

14.3 Interfering Substances

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

Specimens that are….	Demonstrate ≤ 10 % change in results up to…
Lipemic	800 mg/dL of triglycerides 1000 mg/dL of cholesterol
Uremic	200 mg/dL of urea 2.5 mg/dL of creatinine

Specimens that are….	Demonstrate ≤ 10 % change in results up to…
Icteric	25 mg/mL of unconjugated bilirubin
Hemolyzed	100 mg/dL of hemoglobin

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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. Material Safety Data Sheets (MSDS)
6. Quest Diagnostics Records Management Procedure
7. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
8. Hemolysis, Icteria and Lipemia; Interference from (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 BNP Reagent Cartridge

17. REFERENCES

1. Liquichek™ Cardiac Markers Plus Control, Bio-Rad Laboratories revised 11/2011
2. Package Insert, BNP Calibrator, Siemens Diagnostics revised 07/2008
3. Package Insert, BNP reagent pack, Siemens Diagnostics revised 2012

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/1/12	3.2	Remove centrifugation requirement	J.Buss	J.Buss, RSL
000	6/1/12	4.1, 4.2	Remove Multi-Diluent 1 (not used)	J.Buss	J.Buss, RSL
000	6/1/12	10.4	Edit CRR at Medical Director request	J.Buss	J.Buss, RSL
000	6/1/12	10.5	Match CRR; No dilutions performed. Add LIS worksheet & method codes	J.Buss	J.Buss, RSL
000	6/1/12	14.1	Edit lower AMR	J.Buss	J.Buss, RSL
001	6/20/13		Update owner	L Barrett	R SanLuis
001	6/20/13	5.2	Remove open storage at frozen temp	AChini	R SanLuis
001	6/20/13	5.3	Shorten calibrator interval to 28 days	AChini	R SanLuis
001	6/20/13	6.4	Removed GEC SOP as alternate method	AChini	R SanLuis
001	6/20/13	14.3	Revise % change and add hemolyzed	AChini	R SanLuis
001	6/20/13	15	Added specific safety notes	AChini	R SanLuis
001	6/20/13	16	Added Centaur operation SOP	L Barrett	R SanLuis

19. ADDENDA

None

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**

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TABLE OF CONTENTS

1. TEST INFORMATION

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

Synonyms/Abbreviations
iPTH

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The ADVIA Centaur iPTH assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of an antihuman PTH antibody in the Lite Reagent and an antihuman PTH antibody in the Solid Phase Reagent. The first antibody is a polyclonal goat antihuman PTH (N-terminal 1-34) antibody labeled with acridinium ester. The second antibody is a biotinylated polyclonal goat antihuman PTH (39-84 region) antibody. Streptavidin in the Solid Phase is covalently coupled to paramagnetic latex particles.

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 (K2 EDTA) None
Collection Container	Lavender Top Tube
Volume - Optimum **- Minimum**	Full Tube 1 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 8 hours
	Refrigerated: 2-8° C 72 hours
	Frozen: -70° C 8 months
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	None

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
ADVIA Centaur iPTH Ready Pack	Siemens reagent cartridge Cat. No. 129501
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. 112351
ADVIA Centaur CSC	Siemens reagent Cat. No. 112748

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit: ADVIA Centaur iPTH Ready Pack (primary reagent pack)	
Reagent a	Lite Reagent (Volume 5 mL)
Reagent b	Solid Phase (Volume 20 mL)
Manufacturer's Information	Centaur CP iPTH Master Curve Card
Storage	Store the reagent upright at 2 - 8° C

Stability	Reagent is 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	Reagent is 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	Reagent is 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**
Container	Reagent bottle (70 mL)
Storage	Store at 2 - 8° C
Stability	Reagent is 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
Low and High Calibrator	Siemens Intact PTH calibrator, Cat. No. 02698011

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5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	**Intact PTH Calibrator (Low & High)**
Preparation	• Add 1.0 mL of reagent grade water into each calibrator vial. • Let the calibrators 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 ≤ -20° C • **Unopened Calibrator** is stable until the expiration date on the vial. • **Opened Calibrator:** once reconstituted the calibrator is stable for 4 hours at 18 – 25° C.

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	• When the calibration interval expires • Calibration Interval is every 14 days • A calibration is invalid • New lot or shipment of assay reagents • Controls are repeatedly out of range.
Procedure	1. Enter the calibrator information provided on the ADVIA Centaur CP side of the calibrator assignment value card. Ensure you use the ADVIA Centaur CP side of the card. 2. Enter the Master Curve information from the cards provided with the primary reagent packs. Ensure you use the ADVIA Centaur CP side of the card. 3. Load the low and high calibrators into appropriate sample pour-off tubes that accommodate the Siemens-supplied barcode label. 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.

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	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. 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**.

5.5 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
Liquichek Specialty Immunoassay Control Levels 1, 2 and 3	Bio-Rad Laboratories Cat. No. 364, 365 and 366

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

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 Quality Control** is stable until the expiration date on the vial. • **Opened Quality Control:** Once the product is thawed and opened, Intact PTH will be stable for 23 days when stored tightly capped at 2-8° C.

6.3 Frequency

Analyze all 3 Levels of QC material after each calibration. Each day of patient testing, Levels 1 and 3 are run prior to patient samples. Level 2 QC is run at conclusion of patient testing for the day.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

Step	Action
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.

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 Review Patient Data

Technologist must review each result with error messages. Refer to the Centaur Operator's Guide 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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

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 -70°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.

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.

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
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**.

9. CALCULATIONS

The instrument automatically calculates the concentration of iPTH 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)

2.5 – 1,900.0 pg/mL

10.5 Repeat Criteria and Resulting

IF the result is …	THEN…
< 2.5 pg/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 2.5 pg/mL
≥ 1,900.0 pg/mL	Report as ≥ 1,900.0 pg/mL

11. EXPECTED VALUES

11.1 Reference Ranges

11.0 – 80.0 pg/mL

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

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)

2.5 – 1900.0 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	Run-to-Run % CV	Total CV %
40.4	5.2	5.8	7.8
223.8	3.4	1.5	7.0
859.3	3.5	2.8	4.6

14.3 Interfering Substances

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

Specimens that are….	Demonstrate ≤ 10 % change in results up to…
Hemolyzed	200 mg/dL of hemoglobin
Lipemic	3000 mg/dL of triglycerides
Icteric	40 mg/dL of bilirubin

14.4 Clinical Sensitivity/Specificity/Predictive Values

The cross-reactivity of the ADVIA Centaur Intact PTH assay was determined by spiking samples with the PTH fragments and compounds listed below at the indicated levels. There was no significant effect on the intact PTH measurement.

Cross-reactant	Amount added (pg/mL)	% Cross-reactivity
PTH 1 - 34 fragment	300	0.74
PTH 39 – 68 fragment	100,000	0.005
PTH 39 – 84 fragemnt	100,000	0.024
PTH 44 – 68 fragment	100,000	0.007
PTH 53 – 84 fragment	100,000	0.003
Calcitonin	100,000	0.0004

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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. Material Safety Data Sheets (MSDS)
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 09/2012
2. Package Insert, Intact PTH Calibrator, Siemens Diagnostics revised 2011
3. Package Insert, Intact PTH reagent pack, Siemens Diagnostics revised 2011

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	11/9/12		Update owner	L Barrett	R SanLuis
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001	6/20/13	3.2	Add frozen stroage	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

19. ADDENDA

None