

## TRAINING UPDATE

**Lab Location:** SGMC & WAH  
**Department:** Core

**Date Distributed:** 7/20/2016  
**Due Date:** 8/8/2016  
**Implementation:** 8/9/2016

### DESCRIPTION OF PROCEDURE REVISION

**Name of procedure:**

**Amylase by Dimension Vista® System SGAH.C89 v1**

**Note:** this has been converted to a system SOP

**Description of change(s):**

Section	Reason
Header	Add WAH
4.2	Add safety instructions
5.2	Update open calibrator stability
6.1, 6.2	Update QC product – <i>new QC is already in use</i>
6.4, 6.6	Replace LIS with Unity Real Time
7.2	Change freezer range to -50C
16	Update document titles
17	Update QC, PI revision dates

**This revised SOP will be implemented on August 9, 2016**

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

Technical SOP

<b>Title</b>	<b>Amylase by Dimension Vista® System</b>	
<b>Prepared by</b>	Ashkan Chini	Date: 6/25/2012
<b>Owner</b>	Robert SanLuis, Jean Buss	Date: 6/27/2016

<b>Laboratory Approval</b>	<b>Local Effective Date:</b>	
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		

<b>Review</b>		
Print Name	Signature	Date

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**1. TEST INFORMATION**

<b>Assay</b>	<b>Method/Instrument</b>	<b>Local Code</b>
Amylase	Dimension Vista® System	AMYL

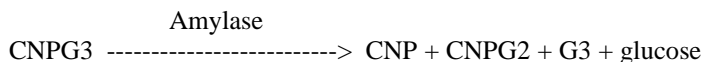
<b>Synonyms/Abbreviations</b>
AMY

<b>Department</b>
Chemistry

Form revised 2/02/2007

**2. ANALYTICAL PRINCIPLE**

α-amylase (α-1, 4-glucan, 4-glucanohydrolase; EC 3.2.1.1) catalyzes the hydrolysis of a defined synthetic substrate, 2-chloro-4-nitrophenyl-α-D-maltotriose (CNPG3), to yield 2-chloro-4-nitrophenol (CNP), 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3) and glucose. After an incubation of 70 seconds at 37 °C, the absorbance due to the formation of 2-chloro-4-nitrophenol (CNP) is measured using a bichromatic (405, 577 nm) rate technique.



**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 serum and 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 (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum - Minimum	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 7 days
	Refrigerated: 6 months
	Frozen: 6 months and longer
	Instrument on board aliquot stability 2 hours
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.

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Criteria	
<b>Unacceptable Specimens &amp; Actions to Take</b>	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.
<b>Compromising Physical Characteristics</b>	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
<b>Other Considerations</b>	Allow Red Top or SST to clot completely prior to centrifugation.

#### 4. REAGENTS

Refer to the Safety Data Sheet (SDS) 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	Supplier & Catalog Number
Amylase	Siemens, Flex® reagent cartridge, Cat. No. K3017
Enzyme Diluent	Siemens Diagnostics Healthcare REF: 790035901

##### 4.2 Reagent Preparation and Storage

**NOTES:** Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. Refer to the Safety Data Sheet (SDS) 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.

**Contains sodium azide as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Wear protective clothing, gloves and eye/face protection.**

<b>Reagent</b>	Amylase
<b>Container</b>	Reagent cartridge
<b>Storage</b>	Store at 2-8° C
<b>Stability</b>	<ul style="list-style-type: none"> <li>Reagent is stable until expiration date stamped on the reagent cartridges.</li> </ul>

	<ul style="list-style-type: none"> <li>Sealed wells on the instrument are stable for 30 days.</li> <li>Once wells 1 - 12 have been entered by the instrument, they are stable for 5 days.</li> </ul>
<b>Preparation</b>	All reagents are liquid and ready to use.

<b>Reagent</b>	<b>Enzyme Diluent</b>
<b>Container</b>	Reagent vial
<b>Storage</b>	Store at 2-8° C
<b>Stability</b>	<ul style="list-style-type: none"> <li>Reagent is stable until expiration date stamped on the reagent vial.</li> <li>Discard after 7 days following reconstitution or immediately if visible turbidity appears.</li> </ul>
<b>Preparation</b>	<ul style="list-style-type: none"> <li>Remove vial from refrigerator and proceed directly with next step.</li> <li>Remove stopper and volumetrically add 10.0 mL of reagent grade water.</li> <li>Replace stopper and invert gently 10 times.</li> <li>Sit vials for 15 minutes, then invert gently 10 times.</li> <li>Sit vials for an additional 15 minutes, then invert 10 times and swirl gently.</li> <li>Use immediately or store at 2-8° C.</li> </ul>

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
ENZ 1 CAL	Siemens Dimension Vista®, Cat. No. KC310

### 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) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.**

<b>Calibrator</b>	ENZ 1 CAL
<b>Preparation</b>	Calibrator is ready for use. No preparation is required.
<b>Storage/Stability</b>	<ul style="list-style-type: none"> <li>Store at 2-8° C</li> <li><b>Unopened calibrator</b> is stable until expiration date stamped on the box.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Opened Calibrator:</b> once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System.</li> </ul>
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### 5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	ENZ 1 CAL
Assay Range	2 – 650 U/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L
Frequency	<ul style="list-style-type: none"> <li>• Every new reagent cartridge lot.</li> <li>• Every 90 days for any one lot</li> <li>• When major maintenance is performed on the analyzer.</li> <li>• When control data indicates a significant shift in assay.</li> </ul>
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 Multiquel Levels 1 & 3	Bio-Rad Laboratories Cat. No. 337 & 339

### 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. A barcode label is produced and placed on the vial.

<b>Control</b>	Liquid Assayed Multiquel, Levels 1 and 3
<b>Preparation</b>	Allow the frozen control to stand at room temperature (18-25°C) for 30 minutes or until completely thawed. A precipitate may be present that dissolves upon mixing. Before loading vials, gently swirl the contents to ensure homogeneous with no visible sign of precipitate. (Do not use a mechanical mixer)
<b>Storage/Stability</b>	Unthawed controls are stable until the expiration date at -20 to -50°C. Once the product stopper is punctured, all analytes will be stable for 5 days when stored at 2 - 8°C.

### 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

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and <b>Unity Real Time</b> , and may be posted near the instrument for use during computer downtime.
2	<p><b>Run Rejection Criteria</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.</li> </ul>
3	<p><b>Corrective Action:</b></p> <ul style="list-style-type: none"> <li>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 <u>reanalyzed according to the Laboratory QC Program</u>. 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.</li> <li>Corrective action documentation must follow the Laboratory Quality Control Program.</li> </ul>
4	<p><b>Review of QC</b></p> <ul style="list-style-type: none"> <li>QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.</li> <li>If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.</li> </ul>

### 6.5 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.

### 6.6 Documentation

- QC tolerance limits are programmed into the instrument and **Unity Real Time**; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.

- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

## **6.7 Quality Assurance Program**

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

## **7. EQUIPMENT and SUPPLIES**

### **7.1 Assay Platform**

Dimension 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**

AMY Flex® reagent cartridge Cat. No. K3017 is required to perform this test.

Amylase 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.**

**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.**

<b>8.1</b>	<b>Sample Processing</b>
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.

<b>8.2</b>	<b>Specimen Testing</b>
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
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.

<b>Test Conditions</b>	
Sample Volume:	5.25 µL
Reagent 1 Volume:	82.1 µL
Reaction Time:	3.4 minutes
Test Temperature:	37° C
Wavelength:	405 & 577 nm
Type of measurement:	Bichromatic rate

**9. CALCULATIONS**

The instrument automatically calculates the concentration of Amylase in U/L.

**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**

U/L

**10.4 Clinically Reportable Range (CRR)**

2 – 6,500 U/L

**10.5 Repeat Criteria and Resulting**

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

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

IF the result is ...	THEN...
< 2 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 2 U/L
≥ 650 U/L	<b>On Board Automated Dilution:</b> Results ≥ 650 U/L will automatically have repeat testing performed into the instrument using dilution factor of 2. No multiplication is necessary.
> 1300 U/L	<b>Manual Dilution:</b> Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 10 <b>DILUENT:</b> ENZYME DILUENT Enter dilution factor as a whole number. Re-assay. Readout is corrected for dilution.

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> 6,500 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: “> 6,500 U/L-REP” Bring to the attention of your supervisor prior to releasing result.
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Message	Code
Verified by repeat analysis	Append –REP to the result.

## 11. EXPECTED VALUES

### 11.1 Reference Ranges

Age	Male/Female
<b>Adult (&gt;17 years):</b>	25 - 115 U/L
<b>Pediatric:</b>	
1 – 17 years	0 - 105
6 – 11 months	0 - 80
31 – 183 days	0 - 42
0 – 30 days	0 - 17

### 11.2 Critical Values

None established

### 11.3 Standard Required Messages

None established

## 12. CLINICAL SIGNIFICANCE

Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis. The AMY method responds to both pancreatic and salivary amylase isoenzymes.

## 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 amylase concentrations are:

AMY Concentration	Acceptable S.D. Maximum
44 U/L	3.6 U/L
421 U/L	16.9 U/L

## 14. LIMITATIONS OF METHOD

### 14.1 Analytical Measurement Range (AMR)

2 – 650 U/L

### 14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiquel Unassayed Control			
Level 1	44	1 (2)	1 (3)
Level 3	421	4 (1)	9 (2)

### 14.3 Interfering Substances

Total protein at 12 g/dL increased AMY results by 96.6% at activity of 115 U/L.  
Immunoglobulin G at 5 g/dL increased AMY results by 12.6% at activity of 115 U/L.  
Triglycerides at 3000 mg/dL increased AMY results by 13.5% at activity of 115 U/L.

#### HIL Interference:

The AMY 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	AMY U/L	Bias %
Hemoglobin (hemolysate)	500 mg/dL	120	<10
	1000 mg/dL		-15
Bilirubin (unconjugated)	60 mg/dL	118	<10
Bilirubin (conjugated)	60 mg/dL	118	<10
Lipemia Intralipid®	1000 mg/dL	108	<10
	3000 mg/dL		38

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

## 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.

## 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 (Lab policy)
14. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications  
at [http://questnet1.qdx.com/Business\\_Groups/Medical/qc/docs/qc\\_bpt\\_tea.xls](http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls)
17. Current package insert AMY Flex® Reagent Cartridge K3017

**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, AMY Flex® Reagent Cartridge K3017, Siemens Healthcare Diagnostics Inc., 07/19/2013.
3. Package Insert, ENZ 1 CAL, Siemens Healthcare Diagnostics Inc., 03/2014.
4. Package Insert, Liquid Assayed Multiqual, Bio-Rad Laboratories, 09/2015.
5. Package Insert, Enzyme Diluent, Siemens Healthcare Diagnostics Inc., 10/2012.

**18. REVISION HISTORY**

Version	Date	Section	Reason	Reviser	Approval
000	6/27/16		Update owner	L Barrett	R SanLuis
000	6/27/16	Header	Add WAH	L Barrett	R SanLuis
000	6/27/16	3.2	Specify anticoagulant	L Barrett	R SanLuis
000	6/27/16	4.2	Add safety instructions	A Chini	R SanLuis
000	6/27/16	5.2	Update open calibrator stability	A Chini	R SanLuis
000	6/27/16	6.1, 6.2	Update QC product	A Chini	R SanLuis
000	6/27/16	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
000	6/27/16	7.2	Change freezer range to -50C	L Barrett	R SanLuis
000	6/27/16	16	Update document titles	L Barrett	R SanLuis
000	6/27/16	17	Update QC, PI revision dates	A Chini	R SanLuis
000	6/27/16	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis

**19. ADDENDA**

None