Quest Diagnostics

TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	3/21/2013
Department:	Core	**Due Date:**	4/21/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Cardiac Troponin I by Dimension Vista® System	SGAH.C112.001	WAH.C108.001
Alanine Aminotransferase by Dimension Vista® System	SGAH.C86.001	WAH.C82.001
Aspartate Aminotransferase by Dimension Vista® System	SGAH.C87.001	WAH.C83.001
Lipase by Dimension Vista® System	SGAH.C117.001	WAH.C113.001

Dimension Vista® Limits Chart **Form #** **AG.F200.001**

Description of change(s):

Troponin

Section	Reason
4.2	Added CTNI Diluent onboard stability
10.5	Removed manual dilution, added on board manual dilution

ALT and AST

Section	Reason
4.1 & 4.2	Removed Enzyme Diluent, reagent no longer required
10.5	Removed manual dilution, added on board manual dilution

Lipase

Section	Reason
10.4	Revised CRR upper limit
10.5	Removed manual dilution, revised dilution factor for on board automatic dilution

Vista® Limits Chart

See changes noted by yellow highlights, also Hemoglobin A1c, Iron and TIBC were deleted from chart

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

Quest Diagnostics

DIMENSION VISTA® LIMITS CHART

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SPECIAL DILUTION ON VISTA	SGAH	WAH
ACTM	µg/mL	2	2.0 - 600.0	3	2.0 - 900.0	Drug 2 Cal Level 1, or Drug Free Serum	N/A	x	x
ALB	g/dL	4	0.0 - 32.0	Not Available	0.0 - 32.0	Do NOT Dilute	N/A	x	x
ALC	mg/dL	4	3 - 1,200	Not Available	3 - 1,200	Do NOT Dilute	N/A	x	x
ALP	U/L	2.33	4 - 2,330	10	4 - 10,000	Enzyme Diluent	N/A	x	x
ALTI	U/L	3.5	6 - 3,500	Not Available	6 - 10,000	Do NOT Dilute	10	x	x
AMON	µmol/L	2	25 - 2,000	3	25 - 3,000	Water	N/A	x	x
AMY	U/L	2	2 - 1,300	10	2 - 6,500	Enzyme Diluent	N/A	x	x
AST	U/L	2	3 - 2,000	Not Available	3 - 10,000	Do NOT Dilute	10	x	x
BUN	mg/dL	4	1 - 600	Not Available	1 - 600	Do NOT Dilute	N/A	x	x
CA	mg/dL	2	5.0 - 30.0	3	5.0 - 45.0	Water	N/A	x	x
CHOL	mg/dL	4	50 - 2,400	5	50 - 3,000	Water	N/A	x	x
CKI	U/L	7	7 - 7000	40	7 - 40,000	Water	N/A	x	x
CL	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	N/A	x	x
CRBM	µg/mL	4	0.5 - 80.0	Not Available	0.5 - 80.0	Do NOT Dilute	N/A	x	x
CREA	mg/dL	2	0.1 - 40.0	3	0.1 - 60.0	Water	N/A	x	x
CRP	mg/dL	20	0.3 - 380.0	Not Available	0.3 - 380.0	Do NOT Dilute	N/A	x	x
CTNI	ng/mL	5	0.02 - 200.00	Not Available	0.02 - 200.00	Do NOT Dilute	N/A	x	x
DBIL	mg/dL	4	0.1 - 64.0	5	0.1 - 80.0	Water	N/A	x	x
DGNA	ng/mL	Not Available	0.06 - 5.00	10	0.06 - 50.00	Drug 4 Cal. Level 1 or Digoxin-Free Serum	N/A	x	x
ECO2	mmol/L	Not Available	1 - 45	2	1 - 90	Water	N/A	x	x
FT4	ng/dL	Not Available	0.10 - 8.00	Not Available	0.10 - 8.00	Do NOT Dilute	N/A	x	x
GENT	µg/mL	4	0.2 - 48.0	Not Available	0.2 - 48.0	Do NOT Dilute	N/A	x	x
GGT	U/L	2	3 - 1,600	20	3 - 16,000	Enzyme Diluent	N/A	x	x
GLUC	mg/dL	4	1 - 2,000	5	1 - 2,500	Water	N/A	x	x
HCG	mIU/mL	200	1 - 200,000	5	1 - 1,000,000	Water	N/A	x	x
HDLC	mg/dL	4	3 - 600	Not Available	3 - 600	Do NOT Dilute	N/A	x	x
K	mmol/L	Not Available	1.0 - 10.0	Not Available	1.0 - 10.0	Do NOT Dilute	N/A	x	x
LA	mmol/L	4	0.1 - 60.0	Not Available	0.1 - 60.0	Do NOT Dilute	N/A	x	x
LDI	U/L	4	6 - 4,000	20	6 - 20,000	Enzyme Diluent	N/A	x	x
LI	mmol/L	Not Available	0.20 - 5.00	3	0.20 - 15.00	Lithium Free Serum	N/A	x	x
LIPL	U/L	20	10 – 30,000	Not Available	10 – 30,000	Do NOT Dilute	N/A	x	x
MG	mg/dL	2	0.2 - 40.0	3	0.2 - 60.0	Water	N/A	x	x
MMB	ng/mL	20	0.5 - 6,000.0	Not Available	0.5 - 6,000.0	Do NOT Dilute	N/A	x	x
MYO	ng/mL	20	1 - 20,000	Not Available	1 - 20,000	Do NOT Dilute	N/A	x	x

Quest Diagnostics

DIMENSION VISTA® LIMITS CHART

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SPECIAL DILUTION ON VISTA	SGAH	WAH
NA	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	N/A	x	x
PHNO	µg/mL	4	2.1 - 320.0	Not Available	2.1 - 320.0	Do NOT Dilute	N/A	x	x
PHOS	mg/dL	2	0.1 - 18.0	5	0.1 - 45.0	Water	N/A	x	x
PTN	µg/mL	4	0.4 - 160.0	Not Available	0.4 - 160.0	Do NOT Dilute	N/A	x	x
SAL	mg/dL	3	1.7 - 300.0	Not Available	1.7 - 300.0	Do NOT Dilute	N/A	x	x
TBIL	mg/dL	4	0.1 - 100.0	5	0.1 - 125.0	Water	N/A	x	x
TGL	mg/dL	4	2 - 4,000	5	2- 5,000	Water	N/A	x	x
THEO	µg/mL	4	2.0 - 160.0	Not Available	2.0 - 160.0	Do NOT Dilute	N/A	x	x
TOBR	µg/mL	4	0.3 - 48.0	Not Available	0.3 – 48.0	Do NOT Dilute	N/A	x	x
TP	g/dL	2	0.0 - 24.0	3	0.0 - 36.0	Water	N/A	x	x
TSH	µIU/mL	5	0.01 - 500.00	Not Available	0.01 - 500.00	Do NOT Dilute	N/A	x	x
UCFP (CSF)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	N/A	x	x
URCA	mg/dL	4	0.2 - 60.0	5	0.2 - 75.0	Water	N/A	x	x
VALP	µg/mL	2	3.0 - 300.0	3	3.0- 450.0	Drug 2 Cal Level 1, Drug Free serum, or Water	N/A	x	x
VANC	µg/mL	Not Available	0.8 - 50.0	3	0.8 - 150.0	Drug Cal 2 Level 1, Drug Free Serum, or Water	N/A	x	x

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SGAH	WAH
Urine CREA	mg/dL	Not Available	0.1 - 200.0	3	0.1 - 600.0	Enzyme Diluent	x	x
Urine K	mmol/L	Not Available	1.0 - 300.0	Do Not Dilute	1.0 - 300.0	Do Not Dilute	x	x
Urine SOD	mmol/L	Not Available	5 - 300	Do Not Dilute	5 - 300	Do Not Dilute	x	x
UCFP (urine only)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	x	x

Technical SOP

Title	**Cardiac Troponin I by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/25/2012

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**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Troponin I	Dimension Vista® System	TROPI1

Synonyms/Abbreviations
Troponin, Tropi, CTNI, Included in Batteries/Packages: CIEP4

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The CTNI method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI technology. The LOCI reagents include two synthetic bead reagents and a biotinylated anti-cardiac troponin I monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-cardiac troponin I monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form bead-cardiac troponin I-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the cardiac troponin I concentration in the sample.

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 (Heparin) Serum	
Collection Container	Plasma: Green top tube 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:	8 hours
	Refrigerated:	2 days
	Frozen:	8 weeks
	Instrument on board aliquot stability	2 hours

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Criteria	
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.

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	Supplier & Catalog Number
Cardiac Troponin I	Siemens, Flex® reagent cartridge, Cat. No. K6421
CTNI Sample Diluent	Siemens Healthcare Diagnostics, Cat. No. KD692

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.

Reagent	Cardiac Troponin I
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days.

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	• Once wells 1 - 12 have been entered by the instrument, they are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

Reagent	**CTNI Sample Diluent**
Container	Reagent plastic bottle
Storage	Store at 2-8° C
Stability	• Unopened diluent is stable until expiration date stamped on the reagent bottle. • Once opened, diluent is stable for 30 days when recapped and stored at 2-8° C. **Do not use this vial on board the instrument.** • Once the stopper of the vial is punctured, diluent is stable for 30 days on board the instrument.
Preparation	CTNI SDIL is ready for use. No preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CTNI CAL	Siemens Dimension Vista®, Cat. No. KC678

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	CTNI CAL
Preparation	Before use, thaw at room temperature (22 – 28° C), swirl and invert gently to mix. **Do not use glass pipettes when transferring calibrators to sample cups.**
Storage/Stability	• Store at -20 to -10° C • **Unopened calibrator (frozen)** is stable until expiration date stamped on the box. • **Unopened calibrator (thawed)** is stable for 7 days when stored at 2-8°C • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 7 days when recapped immediately after use

	and stored at 2-8°C. **Do not use this vial on board the instrument.**

5.3 Calibration Parameter

Criteria	**Special Notations**
Reference Material	CTNI CAL
Assay Range	0.02 – 40.00 ng/mL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in ng/mL
Frequency	• Every new reagent cartridge lot. • Every 30 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	6 levels, n = 3

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
Liquichek™ Cardiac Markers Plus Control Levels 1, 2 and 3	Bio-Rad Laboratories Cat # 181, 182 and 183

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 Controls, Level 1, 2 and 3
Preparation	Allow the frozen control to thaw at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Unthawed controls are stable until the expiration date at -20 to -70° C. Once the control is thawed and opened, Troponin I will be stable for 10 days when stored tightly capped 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 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 documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

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

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

Dimension Vista® 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

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

8. PROCEDURE

CTNI Flex® reagent cartridge Cat. No. K6421 is required to perform this test.

Cardiac Troponin I 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.

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

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

Test Conditions	
Sample Volume:	20 µL
Chemibead Reagent Volume:	20 µL
Biotinylated Antibody Volume:	20 µL
Sensibead Reagent Volume:	13 µL
Assay Buffer Volume:	100 µL
Reaction Time:	10 minutes
Test Temperature:	37° C
Wavelength:	680 & 612 nm
Type of measurement:	Chemiluminescence

9. CALCULATIONS

The instrument automatically calculates the concentration of Cardiac Troponin I in ng/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 two decimal points.

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

0.02 – 200.00 ng/mL

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…
< 0.02 ng/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.02 ng/mL

≥ 40.00 ng/mL	**On Board Automated Dilution:** Results ≥ 40.00 ng/mL will automatically have repeat testing performed into the instrument using dilution factor of 5. No multiplication is necessary.
> 200.00 ng/mL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 200.00 ng/mL-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

0.00 – 0.10 ng/mL

11.2 Critical Values

≥ 0.60 ng/mL

Treatment of **Subsequent critical values** for Troponin-I:
Only the first critical value for each hospital encounter must be called. Subsequent critical values for troponin must be documented by appending the code **TROPC** to the result. This code translates to "Laboratory value indicates a critical value previously reported."

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Troponin is the contractile regulatory protein complex of striated muscle. It is found periodically along the thin filament of the myofibrils, in conjunction with the protein tropomyosin. The troponin complex consists of three distinct polypeptide components: troponin-C (the calcium binding element), troponin-I (the actinomyosin ATPase inhibitory element), and troponin-T (the tropomyosin binding element). The complex serves to regulate the calcium dependent interaction of myosin and actin and thus plays an integral role in muscle contraction.1 Troponin-I exists in three distinct molecular forms which correspond to specific isotypes found in fast-twitch skeletal muscle, slow-twitch skeletal muscle, and heart, respectively.
Several reports in the literature have indicated that cardiac troponin-I is released into blood within hours of the onset of symptoms of myocardial infarction and that it remains elevated

for several days post-infarction. The cumulative data from these reports indicate that troponin-I levels become abnormal 4–8 hours following onset of chest pain, peak at 12–16 hours, and remain elevated for 5–9 days following an infarction.

Measurement of cardiac troponin-I levels provide sensitive and specific determination of myocardial injury over a wide diagnostic window. Elevations in cardiac troponin-I levels have been observed across a spectrum of acute coronary syndromes including Q-wave MI, non-Q-wave MI and unstable angina. A significantly higher incidence of mortality has been observed in patients with non-Q-wave MI and unstable angina who have detectable levels of cardiac troponin-I. This suggests that cardiac troponin-I provides a means for risk stratification of these individuals.

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 Cardiac Troponin I concentrations are:

CTNI Concentration	Acceptable S.D. Maximum
0.5 ng/mL	0.063 ng/mL
8.0 ng/mL	0.939 ng/mL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.02 – 40.00 ng/mL

14.2 Precision

Material	Mean ng/mL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Serum Pool	0.123	0.005 (4.2)	0.007 (5.8)
Serum Pool	0.55	0.012 (2.3)	0.016 (2.9)
Serum Pool	31.4	0.95 (3.0)	1.18 (3.8)

14.3 Interfering Substances

HIL Interference:
The CTNI 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	CTNI ng/mL	Bias %
Hemoglobin (hemolysate)	500 mg/dL	0.945	<10
Bilirubin (unconjugated)	40 mg/dL	0.907	<10
Bilirubin (conjugated)	40 mg/dL	0.879	<10
Lipemia Intralipid®	500 mg/dL 3000 mg/dL	0.941 0.970	<10

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. Material Safety Data Sheets (MSDS)
10. Siemens Dimension Vista® Limits Chart
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
17. Current package insert CTNI Flex® Reagent Cartridge K6421

17. REFERENCES

1. Package Insert, CTNI Flex® Reagent Cartridge K6421, Siemens Healthcare Diagnostics Inc., 06/11/2012.
2. Package Insert, CTNI CAL, Siemens Healthcare Diagnostics Inc., 03/2008.
3. Package Insert, Liquichek Cardiac Markers PlusControl, Bio-Rad Laboratories, 11/2011.
4. Package Insert, CTNI Sample Diluent, Siemens Healthcare Diagnostics Inc., 04/2012.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/8/2013	4.2	Added CTNI Diluent onboard stability	A Chini	R SanLuis
000	3/8/2013	10.5	Removed manual dilution, added on board manual dilution	A Chini	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Alanine Aminotransferase by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/25/2012

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**

Form revised 2/02/2007

Quest Diagnostics Nichols Institute
Site: Shady Grove Adventist Hospital
Title: **Alanine Aminotransferase by Dimension Vista® System**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Alanine Aminotransferase	Dimension Vista® System	SGPT

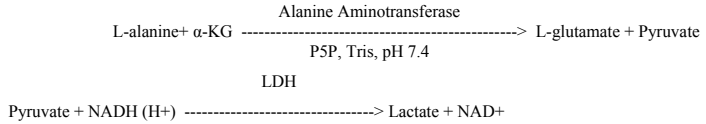
Synonyms/Abbreviations
ALT, SGPT, Included in Batteries/Packages: COMP, LIVP

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

Alanine aminotransferase catalyzes the transamination of L-alanine to α-ketoglutarate (α-KG), forming L-glutamate and pyruvate. The pyruvate formed is reduced to lactate by lactate dehydrogenase (LDH) with simultaneous oxidation of reduced nicotinamide-adenine dinucleotide (NADH). The change in absorbance is directly proportional to the alanine aminotransferase activity and is measured using a bichromatic (340, 700 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 (Heparin) Serum
Collection Container	Plasma: Green top tube 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: 8 hours
	Refrigerated: 7 days
	Frozen: 1 month
	Instrument on board aliquot stability 2 hours

Form revised 2/02/2007

Criteria	
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.

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	Supplier & Catalog Number
Alanine Aminotransferase	Siemens, Flex® reagent cartridge, Cat. No. K2143

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.

Reagent	**Alanine Aminotransferase**
Container	Reagent cartridge
Storage	Store at 2-8° C

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Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 – 2 and 11 - 12 have been entered by the instrument, they are stable for 10 days. • Once wells 3 - 10 have been entered by the instrument, they are stable for 5 days.
Preparation	Hydration, mixing and diluting are automatically performed by the instrument.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
ENZ 2 CAL	Siemens Dimension Vista®, Cat. No. KC321

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	ENZ 2 CAL
Preparation	Calibrator is ready for use. No preparation is required.
Storage/Stability	• Store at 2 - 8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2-8° C. **Do not use this vial on board the instrument.**

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	ENZ 2 CAL
Assay Range	6 – 1000 U/L

Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

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

Manual Calibration:

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

5.5 Tolerance Limits

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

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat # 691 and 692

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

6.3 Frequency

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

Step	Action
	• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

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

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

Dimension Vista® 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

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

8. PROCEDURE

ALTI Flex® reagent cartridge Cat. No. K2143 is required to perform this test.

Alanine Aminotransferase 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.

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

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

Test Conditions	
Sample Volume:	14.6 µL
Reagent 1 Volume:	58.3 µL
Reagent 2 Volume:	49.2 µL
Reaction Time:	5.6 minutes
Test Temperature:	37° C
Wavelength:	340 & 700 nm
Type of measurement:	Bichromatic rate

9. CALCULATIONS

The instrument automatically calculates the concentration of Alanine Aminotransferase 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)

6 – 10,000 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…
< 6 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 6 U/L
≥ 1000 U/L	**On Board Automated Dilution:** Results ≥ 1000 U/L will automatically have repeat testing performed into the instrument using dilution factor of 3.5. No multiplication is necessary.
> 3,500 U/L	**On Board Manual Dilution:** If dilution factor 3.5 does not bring the result within the clinically reportable range, repeat the test utilizing dilution factor of 10 on board the instrument: From Home page → Patient Samples → Manual Order Entry → fill out the required information and for the **Special Dilution** choose the **1/10** option. No multiplication is necessary.

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> 10,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 10,000 U/L-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>19 years):	11-66 U/L	11-66 U/L
Pediatric:		
0 – 7 days	21-54	20-54
8 days – 30 days	22-46	24-54
1 – 3 months	26-61	27-54
4 – 6 months	26-51	26-55
7 – 11 months	26-55	26-59
1 – 3 years	24-59	19-59
4 – 9 years	24-49	24-49
10 – 11 years	24-44	24-49
12 – 13 years	24-44	24-68
14 – 15 years	19-44	24-59
16 – 19 years	19-49	24-54

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Measurements of alanine aminotransferase are used in the diagnosis and treatment of certain liver diseases and heart diseases. Significant elevations of alanine aminotransferase are found in diseases of the liver, such as hepatitis, necrosis, jaundice and cirrhosis. Alanine aminotransferase levels can be elevated even before clinical jaundice appears.

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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 alanine aminotransferase concentrations are:

ALTI Concentration	Acceptable S.D. Maximum
24 U/L	2.3 U/L
100 U/L	4.8 U/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

6 – 1000 U/L

14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	24	0.6 (2.6)	1.1 (4.8)
Level 2	77	1.0 (1.4)	1.4 (1.9)
Level 3	175	1.7 (1.0)	3.4 (1.9)

14.3 Interfering Substances

Bilirubin (conjugated) at 40 mg/dL decreases ALTI results at an activity of 70 U/L by -12%.
Bilirubin (conjugated) at 60 mg/dL decreases ALTI results at an activity of 144 U/L by -13%.
Triglycerides above 400 mg/dL tripped a test report message; therefore the magnitude of the interference could not be determined.
Lipemia (Intralipid®) of 600 mg/dL and above tripped a test report message; therefore the magnitude of the interference could not be determined.

HIL Interference:
The ALTI 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	ALTI U/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	46, 132	<10
Bilirubin (unconjugated)	80 mg/dL	68, 138	<10
Bilirubin (conjugated)	30 mg/dL 40 mg/dL	70 144	<10
Lipemia Intralipid®	200 mg/dL 600 mg/dL	47, 135	<10

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®

Quest Diagnostics Nichols Institute
Site: Shady Grove Adventist Hospital
Title: **Alanine Aminotransferase by Dimension Vista® System**

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8. Laboratory Safety Manual
9. Material Safety Data Sheets (MSDS)
10. Siemens Dimension Vista® Limits Chart
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
17. Current package insert ALTI Flex® Reagent Cartridge K2143

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, ALTI Flex® Reagent Cartridge K2143, Siemens Healthcare Diagnostics Inc., 06/02/2011.
3. Package Insert, ENZ 2 CAL, Siemens Healthcare Diagnostics Inc., 01/2011.
4. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 12/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/9/2013	4.1 & 4.2	Removed Enzyme Diluent, reagent no longer required	A Chini	R SanLuis
000	3/9/2013	10.5	Removed manual dilution, added on board manual dilution	A Chini	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Aspartate Aminotransferase by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/25/2012

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**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Aspartate Aminotransferase	Dimension Vista® System	SGOT

Synonyms/Abbreviations
AST, SGOT

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

Aspartate aminotransferase (AST) catalyzes the transamination from L-aspartate to α-ketoglutarate, forming L-glutamate and oxalacetate. The oxalacetate formed is reduced to malate by malate dehydrogenase (MDH) with simultaneous oxidation of reduced nicotinamide adenine dinucleotide (NADH). The change in absorbance with time due to the conversion of NADH to NAD is directly proportional to the AST activity and is measured using a bichromatic (340, 700 nm) rate technique.

$$\text{L-aspartate} + \alpha\text{-ketoglutarate} \xrightarrow[\text{pH 7.8}]{\text{AST}} \text{L-glutamate} + \text{Oxalacetate}$$

$$\text{Oxalacetate} + \text{NADH} \xrightarrow{\text{MDH}} \text{Malate} + \text{NAD}$$

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 (Heparin) Serum
Collection Container	Plasma: Green top tube 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: 3 days
	Refrigerated: 7 days
	Frozen: 1 month
	Instrument on board aliquot stability: 2 hours

Form revised 2/02/2007

Criteria	
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Reject hemolyzed samples and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.

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	Supplier & Catalog Number
Aspartate Aminotransferase	Siemens, Flex® reagent cartridge, Cat. No. K2041

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.

Reagent	Aspartate Aminotransferase
Container	Reagent cartridge
Storage	Store at 2-8° C

Form revised 2/02/2007

Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 2 - 11 have been entered by the instrument, they are stable for 7 days.
Preparation	Hydration, mixing and diluting are automatically performed by the instrument.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
ENZ 2 CAL	Siemens Dimension Vista®, Cat. No. KC321

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	ENZ 2 CAL
Preparation	Calibrator is ready for use. No preparation is required.
Storage/Stability	• Store at 2 - 8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2-8° C. **Do not use this vial on board the instrument.**

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	ENZ 2 CAL
Assay Range	3 – 1000 U/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L

Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

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

Manual Calibration:

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

5.5 Tolerance Limits

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

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat # 691 and 692

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 Unassayed Chemistry Controls, Level 1 and 2
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Once the control is thawed, AST will be stable for 9 days at 2-8°C. Unthawed controls are stable until the expiration date at -20 to -70°C.

6.3 Frequency

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

Step	Action
	• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

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

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

Dimension Vista® 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

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

8. PROCEDURE

AST Flex® reagent cartridge Cat. No. K2041 is required to perform this test.

Aspartate Aminotransferase 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.

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

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

Test Conditions	
Sample Volume:	13.33 µL
Reagent 1 Volume:	33.33 µL
Reagent 2 Volume:	21.67 µL
Reaction Time:	5.3 minutes
Test Temperature:	37° C
Wavelength:	340 & 700 nm
Type of measurement:	Bichromatic rate

9. CALCULATIONS

The instrument automatically calculates the concentration of Aspartate Aminotransferase 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)

3 – 10,000 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…
< 3 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 3 U/L
≥ 1,000 U/L	**On Board Automated Dilution:** Results ≥ 1,000 U/L will automatically have repeat testing performed into the instrument using dilution factor of 2. No multiplication is necessary.
> 2,000 U/L	**On Board Manual Dilution:** If dilution factor 2 does not bring the result within the clinically reportable range, repeat the test utilizing dilution factor of 10 on board the instrument: From Home page → Patient Samples → Manual Order Entry → fill out the required information and for the **Special Dilution** choose the **1/10** option. No multiplication is necessary.

> 10,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 10,000 U/L-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>19 years):	15-37 U/L	15-37 U/L
Pediatric:		
0–7 days	20-93	26-98
8 – 30 days	20-69	16-67
1 – 3 months	16-61	16-60
4 – 6 months	16-60	16-62
7 – 11 months	16-60	16-52
1 – 4 years	16-57	16-57
5 – 6 years	10-47	10-47
7 – 11 years	5-36	10-36
12 – 15 years	5-26	10-36
16 – 19 years	0-26	10-41

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

The aspartate aminotransferase method is an adaptation of the methodology recommended by the International Federation of Clinical Chemistry (IFCC). The method uses the coenzyme pyridoxal-5- phosphate (P5P) to activate the apoenzyme and lactic acid dehydrogenase (LDH) to eliminate pyruvate interference. Significant elevations of AST are found in diseases of the liver such as hepatitis, necrosis, jaundice, and cirrhosis. AST levels can be elevated even before clinical jaundice appears.

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 aspartate aminotransferase concentrations are:

AST Concentration	Acceptable S.D. Maximum
34 U/L	4.65 U/L
196 U/L	7.39 U/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

3 – 1000 U/L

14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	34	1.1 (3.3)	2.7 (7.8)
Level 2	196	1.8 (0.9)	3.9 (2.0)

14.3 Interfering Substances

Triglycerides at 3000 mg/dL increase AST results by 44% at 37 U/L AST activity.

HIL Interference:
The AST 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	AST U/L	Bias %
Hemoglobin (hemolysate)	25 mg/dL 50 mg/dL	44	<10 15
Bilirubin (unconjugated)	40 mg/dL 60 mg/dL	36	<10 13
Bilirubin (conjugated)	60 mg/dL	31	<10
Lipemia Intralipid®	200 mg/dL 400 mg/dL	35	<10 12

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. Material Safety Data Sheets (MSDS)
10. Siemens Dimension Vista® Limits Chart
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
17. Current package insert AST Flex® Reagent Cartridge K2041

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, AST Flex® Reagent Cartridge K2041, Siemens Healthcare Diagnostics Inc., 02/17/2012.
3. Package Insert, ENZ 2 CAL, Siemens Healthcare Diagnostics Inc., 01/2011.
4. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 12/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/9/2013	4.1 & 4.2	Removed Enzyme Diluent, reagent no longer required	A Chini	R SanLuis
000	3/9/2013	10.5	Removed manual dilution, added on board manual dilution	A Chini	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Lipase by Dimension Vista® System**	
Prepared by	Ashkan Chini	Date: 6/25/2012
Owner	Robert SanLuis	Date: 6/25/2012

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**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Lipase	Dimension Vista® System	LIPA

Synonyms/Abbreviations
LIPL

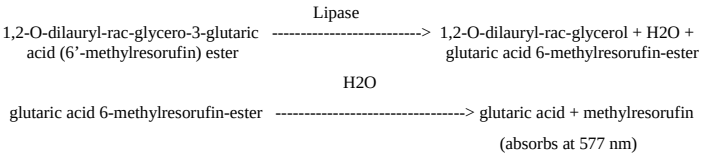
Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The LIPL method uses a chromogenic ester of methylresorufin as a substrate. Colipase and alkaline pH in the reaction specifically activates pancreatic lipase, the bile salts emulsify the substrate, and cholates suppress other esterase activities in the sample.

Lipase hydrolyzes the substrate 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester to an unstable intermediate: glutaric acid-6-methylresorufin ester in the presence of colipase, bile salt, and CaCl2. This intermediate is then hydrolyzed by H2O to yield free methylresorufin which absorbs at 577 nm. Lipase activity is measured as a bichromatic rate reaction at 577/700 nm. The rate of the reaction is proportional to the amount of lipase in the sample.



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	Plasma (Heparin)
-Other Acceptable	Serum
Collection Container	Plasma: Green top tube Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum	1.0 mL
- Minimum	0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage	Room Temperature: 24 hours

Form revised 2/02/2007

Criteria		
Requirements	Refrigerated:	7 days
	Frozen:	1 year
	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.	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)	
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.	

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	Supplier & Catalog Number
Lipase	Siemens, Flex® reagent cartridge, Cat. No. K3056

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.

Reagent	Lipase
Container	Reagent cartridge
Storage	Store at 2-8° C. **Protect from light after opening.**

Form revised 2/02/2007

Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 12 have been entered by the instrument, they are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
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) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	ENZ 1 CAL
Preparation	Calibrator is ready for use. No preparation is required.
Storage/Stability	• Store at 2-8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2-8° C. **Do not use this vial on board the instrument.**

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	ENZ 1 CAL
Assay Range	10 – 1500 U/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L

Frequency	• Every new reagent cartridge lot. • Every 45 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

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

Manual Calibration:

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

5.5 Tolerance Limits

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

6. QUALITY CONTROL

6.1 Controls Used

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

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

6.3 Frequency

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

Step	Action
	• The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

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

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

Dimension Vista® 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

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

8. PROCEDURE

LIPL Flex® reagent cartridge Cat. No. K3056 is required to perform this test.

Lipase 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.

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

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

Test Conditions	
Sample Volume:	1.62 µL
Reagent 1 Volume:	100 µL
Reagent 2 Volume:	61 µL
Reaction Time:	2.3 minutes
Test Temperature:	37° C
Wavelength:	577 & 700 nm
Type of measurement:	Bichromatic rate

9. CALCULATIONS

The instrument automatically calculates the concentration of Lipase 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)

10 – 30,000 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…
< 10 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 10 U/L
≥ 1500 U/L	**On Board Automated Dilution:** Results ≥ 1500 U/L will automatically have repeat testing performed into the instrument using dilution factor of 20. No multiplication is necessary.
> 30,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 30,000 U/L-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

Lipase	Male and Female
Adult (>19 years):	63-286 U/L
Pediatric:	
0 - 2 months	44-174 U/L
3 - 11 months	43-190 U/L
1 year	44-199 U/L
2 - 6 years	44-199 U/L
7 - 10 years	44-199 U/L
11 - 16 years	46-211 U/L
17 - 18 years	58-260 U/L

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Pancreatic lipase degrades dietary triglycerides to glycerol and free fatty acids in the duodenum in the presence of bile salts.
Lipase measurements are used to diagnose and monitor treatment of diseases of the pancreas, such as acute and chronic pancreatitis and obstruction of the pancreatic duct.

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 lipase concentrations are:

LIPL Concentration	Acceptable S.D. Maximum
72 U/L	8 U/L
150 U/L	11 U/L
519 U/L	32 U/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

10 – 1500 U/L

14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	72	2 (3)	2 (3)
Level 2	150	3 (2)	4 (3)
Level 3	519	8 (2)	12 (2)

14.3 Interfering Substances

HIL Interference:
The LIPL method was evaluated for interference according to CLSI/NCCLS EP7-A2.

Substance tested	Substance Concentration	LIPL U/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	200, 1200	<10
Bilirubin (unconjugated)	80 mg/dL	200, 1200	<10
Bilirubin (conjugated)	80 mg/dL	200, 1200	<10
Lipemia Intralipid®	3000 mg/dL	200, 1200	<10

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. Material Safety Data Sheets (MSDS)
10. Siemens Dimension Vista® Limits Chart
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
17. Current package insert LIPL Flex® Reagent Cartridge K3056

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, LIPL Flex® Reagent Cartridge K3056, Siemens Healthcare Diagnostics Inc., 02/24/2012.
3. Package Insert, ENZ 1 CAL, Siemens Healthcare Diagnostics Inc., 12/2008.
4. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 12/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/9/2013	10.4	Revised CRR upper limit	A Chini	R SanLuis
000	3/9/2013	10.5	Removed manual dilution, revised dilution factor for on board automatic dilution	A Chini	R SanLuis

19. ADDENDA

None