

**Lab Location:** WOMC  
**Department:** Core Lab \_ Chemistry

**Date Distributed:** 2/14/24  
**Due Date:** ASAP  
**Implementation:** 2/14/24

**DESCRIPTION OF PROCEDURE REVISION**

<b>Name of procedure:</b>
WOMC.C 2009 Lipase (LIP) by Dimension Vista® System
<b>Description of change(s):</b>
<p>New Vista Lipase method <b>implemented February 14, 2024.</b></p> <ul style="list-style-type: none"> <li>• <b>Retired:</b> (WOMC.C117) Lipase by Dimension Vista® System (Remove and destroy)</li> <li>• <b>New Flex:</b> Lipase (LIP) Cat. No. 11538128</li> <li>• <b>New Calibrator:</b> LIP CAL</li> <li>• <b>AMR:</b> 6 – 250 U/L</li> <li>• <b>CRR:</b> 6 – 5,000 U/L</li> <li>• <b>Reference Range:</b> Adult (&gt;or = 19 years) 13 - 75 U/L</li> <li>• <b>Analytical Principle</b></li> <li>• <b>Reject grossly hemolyzed specimens. Hemolysis <u>will</u> affect results.</b></li> <li>• Note: Reagent contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides.</li> </ul> <p><b>Review the new Lipase method SOP</b> (attached). The changes are highlighted in yellow.</p>

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

# WOMC.C 2009 Lipase (LIP) by Dimension Vista® System

Copy of version 1.0 (in review)

Effective Date 2/13/2024

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

## Version History

This document has no approved or retired versions.

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Adventist HealthCare  
Site: White Oak Medical Center

Title: **Lipase (LIP) by Dimension Vista® System**

### Technical SOP

<b>Title</b>	<b>Lipase (LIP) by Dimension Vista® System</b>	
<b>Prepared by</b>	Ashkan Chini	Date: 1/18/24
<b>Owner</b>	Robert SanLuis	Date: 1/18/24

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

### TABLE OF CONTENTS

1.	Test Information.....	2
2.	Analytical Principle .....	2
3.	Specimen Requirements.....	2
4.	Reagents.....	3
5.	Calibrators/Standards.....	4
6.	Quality Control .....	5
7.	Equipment And Supplies .....	7
8.	Procedure .....	8
9.	Calculations.....	9
10.	Reporting Results And Repeat Criteria.....	9
11.	Expected Values.....	10
12.	Clinical Significance.....	10
13.	Procedure Notes .....	11
14.	Limitations Of Method .....	11
15.	Safety .....	11
16.	Related Documents .....	11
17.	References.....	12
18.	Revision History .....	12
19.	Addenda .....	12

**1. TEST INFORMATION**

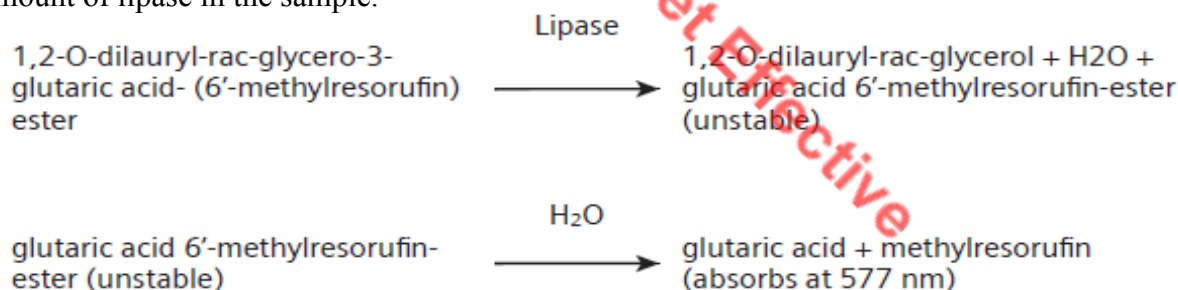
Assay	Method/Instrument	Test Code
Lipase	Dimension Vista® System	LIPA

Synonyms/Abbreviations
LIP

Department
Chemistry

**2. ANALYTICAL PRINCIPLE**

The Dimension Vista LIP assay 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 CaCl. This intermediate is then hydrolyzed by H<sub>2</sub>O to yield free methylresorufin which absorbs at 577 nm. Lipase activity is measured as a bichromatic rate reaction at 577 nm/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	
<b>Type</b> -Preferred -Other Acceptable	Plasma (Lithium Heparin) Serum
<b>Collection Container</b>	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
<b>Volume</b> - Optimum - Minimum	1.0 mL 0.5 mL
<b>Transport Container and Temperature</b>	Collection container or plastic vial at room temperature
<b>Stability &amp; Storage Requirements</b>	Room Temperature: 24 hours
	Refrigerated: 7 days
	Frozen: 12 months
<b>Timing Considerations</b>	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.
<b>Unacceptable Specimens &amp; Actions to Take</b>	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for “test not performed” message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
<b>Compromising Physical Characteristics</b>	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
<b>Other Considerations</b>	Allow Red Top or SST to clot completely prior to centrifugation.

**NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.**

## 4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

### 4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Lipase (LIP)	Siemens, Flex® reagent cartridge, Cat. No. 11538128

#### 4.2 Reagent Preparation and Storage

<b>Reagent</b>	<b>Lipase (LIP)</b>
<b>Container</b>	Reagent cartridge
<b>Storage</b>	Store at 2-8°C. Protect from light and heat.
<b>Stability</b>	<ul style="list-style-type: none"> <li>• Stable until expiration date stamped on package.</li> <li>• Sealed wells on the instrument are stable for 30 days.</li> <li>• Open well stability: 7 days for wells 1 - 12</li> </ul>
<b>Preparation</b>	All reagents are liquid and ready to use.

### 5. CALIBRATORS/STANDARDS

#### 5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
LIP CAL	Siemens Dimension Vista®, Cat. No. 11538127

#### 5.2 Calibrator Preparation and Storage

<b>Calibrator</b>	LIP CAL
<b>Preparation</b>	Calibrators are liquid and ready to use.
<b>Storage/Stability</b>	<ul style="list-style-type: none"> <li>• Store at 2-8°C in an upright position, away from light and heat.</li> <li>• <b>Unopened Calibrator:</b> until expiration date on the box.</li> <li>• <b>Opened Calibrator:</b> once the stopper is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System.</li> <li>• <b>Opened Calibrator:</b> once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2-8°C. <b>Do not use this vial on board the instrument.</b></li> </ul>

#### 5.3 Calibration Parameter

Criteria	Special Notations
<b>Reference Material</b>	LIP CAL
<b>Assay Range</b>	6 – 250 U/L
<b>Suggested Calibration Level</b>	See Reagent Package Insert for lot specific assigned values in U/L.
<b>Frequency</b>	<ul style="list-style-type: none"> <li>• Every new reagent cartridge lot.</li> <li>• Every 45 days for any one lot</li> <li>• When major maintenance is performed on the analyzer.</li> <li>• When control data indicates a significant shift in assay.</li> </ul>

## 5.4 Calibration Procedure

### Auto Calibration:

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

### Manual Calibration:

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

## 5.5 Tolerance Limits

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

## 6. QUALITY CONTROL

### 6.1 Controls Used

Controls	Supplier and Catalog Number
Liquid Assayed Multiquel® Levels 1 and 3	Bio-Rad Laboratories Cat. No. 337 and 339

## 6.2 Control Preparation and Storage

<b>Control</b>	Liquid Assayed Multiquel® Levels 1 and 3
<b>Preparation</b>	Allow the frozen control to stand at room temperature (18-25°C) for 30 minutes or until completely thawed. Gently swirl the contents to ensure homogeneity.
<b>Storage/Stability</b>	<b>Frozen:</b> stable until the expiration date at -20 to -50°C. <b>Thawed and Unopened:</b> When stored at 2-8°C and the stopper is not punctured, it will be stable for 30 days for Lipase. <b>Thawed and Opened:</b> Once the stopper is punctured, all analytes will be stable for 5 days on board Dimension Vista.

## 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 and the Dimension Vista® Quick Reference Guide.

## 6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	<b>Run Rejection Criteria</b> <ul style="list-style-type: none"> <li>Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported.</li> <li>The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.</li> </ul>
3	<b>Corrective Action:</b> <ul style="list-style-type: none"> <li>All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be <u>reanalyzed according to the Laboratory QC Program</u>. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program.</li> <li>Corrective action documentation must follow the Laboratory Quality Control Program.</li> </ul>



Step	Action
4	<p><b>Review of QC</b></p> <ul style="list-style-type: none"> <li>• QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.</li> <li>• If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.</li> </ul>

## 6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

## 6.6 Quality Assurance Program

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

## 7. EQUIPMENT and SUPPLIES

### 7.1 Assay Platform

Dimension Vista® System

## 7.2 Equipment

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

## 7.3 Supplies

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

## 8. PROCEDURE

LIP Flex® reagent cartridge Cat. No. 11538128 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.**

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.

8.2	Specimen Testing
4.	Follow protocol in Section 10.6 “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.

**NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.**

## 9. CALCULATIONS

The instrument automatically calculates the concentration of 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)

6 – 5,000 U/L

### 10.5 Review Patient Data

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

### 10.6 Repeat Criteria and Resulting

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

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is ...	THEN...
< 6 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 6 U/L
≥ 250 U/L	<b>On Board Automated Dilution:</b> Results ≥ 250 U/L will automatically have repeat testing performed into the instrument using dilution factor of 20. No multiplication is necessary.
> 5,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 5,000 U/L-REP" Bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

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

**11. EXPECTED VALUES**

**11.1 Reference Ranges**

Lipase	Male and Female
<b>Adult (&gt;19 years):</b>	13 - 75 U/L
<b>Pediatric:</b>	
17 - 18 years	58 - 260 U/L
11 - 16 years	46 - 211 U/L
7 - 10 years	44 - 199 U/L
2 - 6 years	44 - 199 U/L
1 year	44 - 199 U/L
3 - 11 months	43 - 190 U/L
0 - 2 months	44 - 174 U/L

**11.2 Critical Values**

None established

**11.3 Standard Required Messages**

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.

**14. LIMITATIONS OF METHOD****14.1 Analytical Measurement Range (AMR)**

6 – 250 U/L

**14.2 Precision**

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Control 1	22	4	5
Control 2	43	3	3
Control 3	151	1	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	1000 mg/dL	75	27
Bilirubin (unconjugated)	40 mg/dL	79	7
Bilirubin (conjugated)	40 mg/dL	77	1
Lipemia Intralipid®	3000 mg/dL	70	0

**14.4 Clinical Sensitivity/Specificity/Predictive Values**

Not available

**15. SAFETY**

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides.

**16. RELATED DOCUMENTS**

1. Dimension Vista® Clinical Chemistry System Operator's Manual
2. Dimension Vista® Calibration/Verification Procedure
3. Dimension Vista® Cal Accept Guidelines
4. Dimension Vista® Calibration summary
5. Dimension Vista® Sample Processing, Startup and Maintenance procedure
6. Laboratory Quality Control Program
7. QC Schedule for Siemens Dimension Vista®
8. Laboratory Safety Manual
9. Safety Data Sheets (SDS)
10. Dimension Vista® Limits Chart (AG.F200)
11. Retention of Records and Materials (Lab Policy)
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
14. Specimen Acceptability Requirements (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at  
[http://questnet1.qdx.com/Business\\_Groups/Medical/qc/docs/qc\\_bpt\\_tea.xls](http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls)
17. Current package insert LIP Flex® Reagent Cartridge 11538128

**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, LIP Flex® Reagent, Siemens Healthcare Diagnostics Inc., 11/2021.
3. Package Insert, LIP CAL, Siemens Healthcare Diagnostics Inc., 11/2021.
4. Package Insert, Liquid Assayed Multiqual Controls, Bio-Rad Laboratories, 09/2023.

**18. REVISION HISTORY**

Version	Date	Section	Reason	Reviser	Approval

**19. ADDENDA**

None