GEC.C 281 Lipase (LIP) by Dimension® EXL Chemistry Analyzer

Copy of version 1.0 (approved and current)

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Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	7/29/2023	1.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	Core lab approvals	7/28/2023	1.0	Robert SanLuis Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	7/28/2023	8/25/2023	Indefinite

Technical SOP

Title	**Lipase by Dimension® EXL Chemistry Analyzer**	
Prepared by	Ashkan Chini	Date: 7/28/23
Owner	Robert SanLuis	Date: 7/28/23

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

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1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Lipase	Dimension® EXL Chemistry Analyzer	LIPA

Synonyms/Abbreviations
LIP

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Dimension LIP assay uses as a substrate 1,2-O-dilauryl-rac-glycero-3-glutaric acid-ester. Lipase catalyzes the hydrolysis of this substrate in the presence of colipase, bile salt, and CaCl2 at alkaline pH. The hydrolysis produces 1,2-O-dilauryl-rac-glycerol and glutaric acid-6'-methylresorufin ester. Glutaric acid-6'-methylresorufin ester is an unstable reaction intermediate and breaks down to yield chromogenic free methylresorufin in proportion to the activity of lipase in the sample. The rate of production of methylresorufin is measured by a bichromatic rate reaction at 577 and 700 nm.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

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

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL

Criteria		
Transport Container and Temperature	Collection container or plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	24 hours
	Refrigerated:	(2-8°C) 7 days
	Frozen:	(-20°C or colder) 12 months
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 redraw. Credit the test with the appropriate LIS English text code.	
Other Considerations	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.

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	Siemens, Flex® reagent cartridge, Cat. No. 11538126
Enzyme Diluent	Siemens Cat. No. 790035901

4.2 Reagent Preparation and Storage

Reagent	Lipase
Container	Reagent cartridge
Storage	Store at 2-8°C away from light.
Stability	• Stable until expiration date stamped on reagent cartridges. • Reagent cartridge remains stable onboard for 30 days. • Open well remains stable for 7 days.

Preparation	Reagents are supplied ready for use. No additional preparation is required.

Reagent	**Enzyme Diluent**
Container	Glass vial
Storage	Store at 2-8°C
Stability	• Stable until expiration date stamped on the vial. • After reconstitution the reagent remains stable for 7 days. Note: Discard the reagent if visible turbidity appears.
Preparation	• Remove stopper and reconstitute the reagent with 10 mL of reagent grade water. • Replace stopper and invert gently 10 times. • Let the reagent sit for 15 minutes, then invert gently 10 times. • Let the reagent to sit for an additional 15 minutes. Then invert 10 times and swirl gently. • Use immediately or refrigerate at 2 – 8 °C. Note: Before use, allow product to come to room temperature, then invert 10 times and swirl gently.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Lipase Calibrator (LIP CAL)	Siemens Dimension®, Cat. No. 11538127

5.2 Calibrator Preparation and Storage

Calibrator	Lipase Calibrator
Preparation	Calibrators are supplied ready for use. No additional preparation is required.
Storage/Stability	• Store at 2-8°C in an upright position away from light. • Once the cap is removed, assigned values are stable for 30 days when re-capped immediately after use and stored at 2-8°C.

5.3 Calibration Parameter

Criteria	**Special Notations**
Reference Material	**Lipase Calibrator**
Assay Range	See Package Insert for specific assay ranges.
Calibration levels	See reagent package insert for lot specific assigned values in U/L.

Frequency	• Every new reagent cartridge lot. • Every 3 months for any one lot. • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate.
Assigned Coefficients	C_0 C_1
Procedure	Refer to Calibration / Verification Siemens Dimension® EXL procedure for specific instructions.

5.4 Tolerance Limits

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

6. QUALITY CONTROL

6.1 Controls Used

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

6.2 Control Preparation and Storage

Control	Liquichek Unassayed Chemistry Control Levels 1 & 2
Preparation	Allow the frozen product to thaw at room temperature (18 to 25°C) for 1 hour or until completely thawed. Gently swirl the contents until homogeneous.
Storage/Stability	**Frozen:** until the expiration date if unopened at -20 to -70°C. **Thawed and Opened**: 15 days at 2 to 8°C for Lipase. Note: stabiligy varies by assay

6.3 Frequency

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

Refer to the Dimension EXL QC Schedule and the Dimension® 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	**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 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 EXL® 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

- Calibrated pipettes and disposable tips
- Plastic serum tubes and serum cups
- Reagent grade water (Millipore® or equivalent)

8. PROCEDURE

Lipase (LIP) Flex® reagent cartridge Cat. No. DF56A is required to perform this test.

Lipase is performed on the Dimension EXL® 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	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® EXL procedure.

8.1	Instrument Set-Up Protocol
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® EXL system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® EXL segments for analysis by the instrument. Refer to the Sample Processing, Dimension® EXL procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® EXL QC Schedule.
2.	Follow the instructions, outlined in the Dimension® EXL Operators 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® EXL system manual "Error messages" section for troubleshooting.
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 and prints 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 – 25,000 U/L

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension EXL® 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.

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 policy 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	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 100 **Diluent:** Enzyme Diluent Enter dilution factor as a whole number on the "Enter Sample Data" screen.
> 25,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: ">25000 U/L-REP" Check for integrity issues prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

16 – 77 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 presence of bile salts. Lipase measurements are used in the diagnosis of diseases of the pancreas, such as acute 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 EXL 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	Precision
Control 1	24	0.3	0.8
Control 2	45	0.5	0.9
Lithium Heparin Plasma	92	0.8	1.4
Serum	38	0.5	0.7

14.3 Interfering Substances

HIL Interference:
The Dimension LIP assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Substance tested	Test Concentration SI Units	U/L	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	75	31
Bilirubin (unconjugated)	40 gm/dL	76	4
Lipemia (Intralipid®)	3000 mg/dL	69	1

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.

16. RELATED DOCUMENTS

1. Dimension EXL® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® EXL procedure
3. Dimension EXL® Cal Accept Guidelines
4. Dimension EXL® Calibration summary
5. Sample Processing, Dimension® EXL procedure
6. Maintenance, Siemens Dimension® EXL procedure
7. Laboratory Quality Control Program
8. Dimension EXL QC Schedule
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Dimension EXL Limits Chart
12. Retention of Records and Materials (Lab Policy)
13. Dimension EXL® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Specimen Acceptability Requirements (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
18. Current package insert of Lipase reagent

17. REFERENCES

1. Package Insert, LIP reagent, Siemens Healthcare Diagnostics Inc., 11/2021.
2. Package Insert, LIP CAL, Siemens Healthcare Diagnostics Inc., 11/2021.
3. Package Insert, Enzyme Diluent, Siemens Healthcare Diagnostics Inc., 05/2022.
4. Package insert, Liquichek Unassayed Control, Bio-Rad Laboratories, date 03/2023.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None