SIEMENS

Dimension Vista® System

Lipase (LIP)

Current Revision and Date[a]	Rev. 01, 2021-11	
Product Name	Dimension Vista Lipase (LIP) Flex reagent cartridge	REF K3056A (11538128) (480 tests)
Abbreviated Product Name	Dimension Vista LIP	
Test Name/ID	LIP	
Systems	Dimension Vista System	
Materials Required but Not Provided	Dimension/Dimension Vista LIP CAL	REF DC56B (11538127)
Optional Materials	Dimension/Dimension Vista Enzyme Diluent	REF 790035901 (10444870)
Specimen Types	Serum, lithium heparin plasma	
Sample Volume	1.62 µL	
Measuring Interval	6–250 U/L	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

Intended Use

The LIP assay is an *in vitro* diagnostic test for the quantitative measurement of lipase in human serum and plasma on the Dimension® Vista System.

Summary and Explanation

Pancreatic lipase degrades dietary triglycerides to glycerol and free fatty acids in the duodendum in the presence of bile salts.

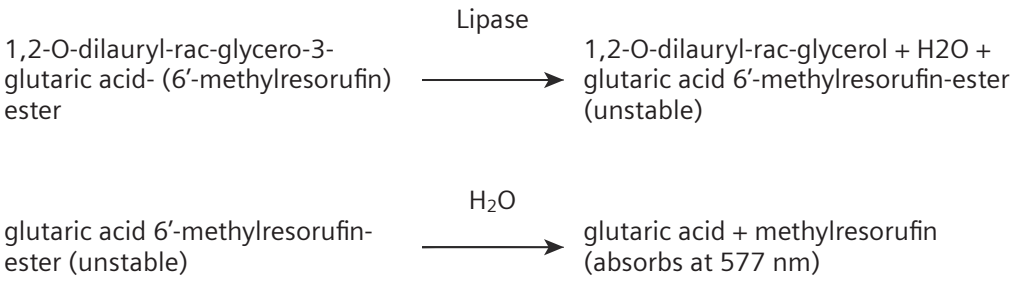
Lipase measurements are used to diagnose and monitor treatment of diseases of the pancreas, such as acute and chronic pancreatitis and obstruction of the pancreatic duct.[1,2]

The Dimension Vista LIP assay is an adaptation of a colorimetric method described by Neumann, et al.[3]

Principles of the Procedure

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.[4]

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 $CaCl_2$. This intermediate is then hydrolyzed by H_2O 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.



Reagents

Material Description	Storage	Stability[a]
Dimension Vista LIP	Unopened at 2–8°C	Until expiration date on product
Well 1–6[c] Reagent 1 (R1) 2.8 mL N,N-bis(2-hydroxyethyl)-glycine (50 mmol/L); Na desoxycholate (1.6 mmol/L); colipase- porcine pancreas (≥ 1.0 mg/L); calcium chloride (10 mmol/L); sodium azide (< 0.02%)[d]	Onboard[b] Open well	30 days 7 days
Wells 7–12[c] Reagent 2 (R2) 1.9 mL Tartrate Buffer (10 mmol/L); 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester (0.27 mmol/L); taurodesoxycholate (8.8 mmol/L); detergent; preservative[d]		

[a] Refer to *Storage and Stability*.
[b] Refer to *Onboard Stability*.
[c] Wells are numbered consecutively from the wide end of the cartridge.
[d] Nominal value per test at manufacture.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

Contains: N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]. May produce an allergic reaction. (Dimension Vista LIP Substrate Reagent).

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store reagents away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

For details about product material description, storage, and stability, refer to *Reagents*.

Onboard Stability

Discard products at the end of the onboard stability interval.

For details about product onboard stability, refer to *Reagents*.

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and lithium heparin plasma are the recommended specimen types for this assay.

EDTA, potassium oxalate, sodium fluoride and citrate have been shown to inhibit lipase results and should not be used.[5]

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[6]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[7]
- Follow the instructions provided with your specimen collection device for use and processing.[8]
- Specimens with high turbidity or particulates should be centrifuged before analysis.
- 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.[9]
- For serum specimens, allow blood to clot completely before centrifugation.[10]
- Keep tubes capped at all times.[10]

Storing the Specimen

Specimen Type(s)	Storage Condition(s)	Storage Duration
Serum	2–8°C[11,12]	7 days
	Frozen at ≤ -20°C[11,12]	12 months
Lithium heparin plasma	2–8°C[11,12]	7 days
	Frozen at ≤ -20°C[11,12]	12 months

For separated specimens that are frozen:

- Avoid more than 3 freeze-thaw cycles.
- Thoroughly mix thawed samples and centrifuge before using.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 1.62 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the system operating instructions.

Do not use samples with apparent contamination. Bacterial contamination of the specimen may cause increased lipase values.[13]

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[10]

For a complete list of appropriate sample containers, refer to the system operating instructions.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
K3056A (11538128)	Dimension Vista LIP	4 x 120

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Dimension Vista System	
DC56B (11538127)	Dimension/Dimension Vista LIP CAL	2 x 1.0 mL calibrator level 1/A 2 x 1.0 mL calibrator level 2/B 2 x 1.0 mL calibrator level 3/C Calibrator lot-specific value sheet
	Commercially available quality control materials	

Optional Materials

The following materials may be used to perform this assay, but are not provided:

REF	Description	
790035901 (10444870)	Dimension/Dimension Vista Enzyme Diluent	10 bottles containing 10.0 mL/bottle

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 61 µL of Reagent 2 into a reaction cuvette.
2. Dispenses 100 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 1.62 µL of primary sample into a cuvette, then incubates for 97 seconds at 37°C.
4. Measures the absorbance after sample addition at 577 and 700 nm.
5. Reports results.

Test Duration: 2.7 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

For information about loading reagents, refer to the system operating instructions.

Performing Calibration

For calibration of the Dimension Vista LIP assay, use Dimension/Dimension Vista LIP CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Calibrate the assay every 45 days.

In addition, perform a calibration:

- At the end of the calibration interval.
- When changing lot numbers of reagents.

- When indicated by quality control results.
- After major maintenance or service.

Note When loading new reagents, recalibration is not required if there is a valid lot calibration. For information about the calibration interval, refer to the system operating instructions.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

At least once each day of use, analyze two levels of quality control (QC) material with known lipase concentration. Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

For information about entering quality control definitions, refer to the system operating instructions.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system operating instructions.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the system operating instructions. The system reports results in U/L.

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Dilutions

Dilute and retest serum and lithium heparin plasma specimens with lipase levels > 250 U/L to obtain accurate results. For information about dilution options, refer to the system operating instructions.

Ensure that sufficient sample volume is available to perform the dilution and that the appropriate dilution factor is selected when scheduling the test, as indicated in the table below. For additional instructions on running automatic dilutions, refer to the system operating instructions.

Specimen	Dilution Factor	Autodilution Sample Volume µL
Serum and plasma	20	10

If patient results exceed the measuring interval of the assay when using automated dilution, or if laboratory protocol requires manual dilution, manually dilute the patient sample.

For manual dilutions, perform the following actions:

- Use Dimension/Dimension Vista Enzyme Diluent to prepare a manual dilution. Refer to *Materials Required but Not Provided/Optional Materials*.
- For information about ordering tests for manually diluted samples, refer to the system operating instructions.
- Ensure that results are mathematically corrected for dilution. If a dilution factor is entered when scheduling the test, the system automatically calculates the result.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- The Dimension Vista LIP assay is limited to the detection of lipase in serum and lithium heparin plasma.
- As with any chemical reaction, you must be alert to the possible effect of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.
- A number of substances cause physiological changes in serum or plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potential interfering substances.[14]
- Do not use hemolyzed samples, as they may cause significant interference with this assay.
- In very rare cases, gammopathy, in particular type IgM (Waldenstrom's macroglobulinemia), may cause unreliable results.[15,16]

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c [17] and verified on the Dimension Vista System.[18]

The reference interval for lipase for healthy adults is 13–75 U/L for serum and lithium heparin plasma. This interval was obtained from a study of 128 healthy adults.[18] These data were established on the Dimension Vista System.

Hemolyzed and icteric samples were also excluded from the study.

Specimens were collected prospectively from apparently healthy subjects. The reference interval was determined by calculating the 2.5 and 97.5 percentiles of the distribution of values.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[17] Consider these values as guidance only.

Performance Characteristics

Measuring Interval

The Dimension Vista LIP assay provides results from 6 U/L to 250 U/L. The system flags all values that are outside the specified measuring interval.

The lower end of the measuring interval is defined by the limit of detection (LoD). Report results below the measuring interval as ≤ 6 U/L.

Samples with results less than the low end of the measuring interval are reported as "< 6 U/L".

Samples with results greater than the high end of the measuring interval should be repeated on dilution.

When sample results exceed the measuring interval, refer to *Dilutions*.

Detection Capability

The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB < 6 U/L.

The Limit of Detection (LoD) corresponds to the lowest concentration of lipase that can be detected with a probability of 95%. The assay is designed to have an LoD < 6 U/L.

Detection capability was determined in accordance with CLSI Document EP17-A2.[19]

The following results were obtained:

Specimen Type	Detection Capability	Result U/L
Serum	LoB	1.12
	LoD	2.91

The LoD was determined using 75 determinations, with 5 blank and 5 low-level replicates, and a LoB of < 6 U/L.

Assay results obtained at individual laboratories may vary from the data presented.

Precision

The assay is designed to have the following precision:

- Repeatability: CV ≤ 6% at > 34 U/L
- Within–Laboratory: CV ≤ 8% at > 34 U/L

Precision was determined in accordance with CLSI Document EP05-A3.[20] Samples were assayed on the Dimension Vista System in duplicate in 2 runs per day for 20 days.

The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean U/L	SD[b] U/L	CV[c] (%)	SD U/L	CV (%)
Control 1	80	22	0.9	4	1.1	5
Control 2	80	43	1.3	3	1.4	3

Specimen Type	N[a]	Mean U/L	Repeatability SD[b] U/L	Repeatability CV[c] (%)	Within-Laboratory Precision SD U/L	Within-Laboratory Precision CV (%)
Control 3	80	151	1.8	1	2.7	2
Lithium heparin plasma	80	89	1.8	2	2.5	3
Serum	80	34	1.3	4	1.5	1

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

The expected maximum observed standard deviations for repeatability using 5 replicates are shown below.

Maximum Observed Repeatability

Analyte Concentration U/L	Acceptable SD Maximum U/L
51	3.9
130	5.5

If there is a system malfunction, the acceptable SD maximum is exceeded.

Assay Comparison

The Dimension Vista LIP assay (y) was designed to have a slope of 1.00 ± 0.10 and a Y-intercept ± 10 U/L compared to Roche Cobas LipC assay. Assay comparison was determined using the Passing Bablok regression model in accordance with CLSI Document EP09-A3.[21] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]
Serum	Roche Cobas LipC	y = 1.06x + 0.6 U/L	13–277 U/L	103

[a] Number of samples tested.

Agreement of the assays may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined using the Passing-Bablok regression model in accordance with CLSI Document EP09c.[22] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]
Serum	Lithium heparin plasma	y = 1.02x - 1.9 U/L	14–244 U/L	50

[a] Number of samples tested.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. The Dimension Vista 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.

Interference testing was performed in accordance with CLSI Document EP07-ED3.[23] The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Hemoglobin	1000 mg/dL (0.6 µmol/L) 600 mg/dL (0.4 µmol/L) 500 mg/dL (0.3 µmol/L)	75 U/L 151 U/L 79 U/L	27 8 8
Bilirubin, conjugated	40 mg/dL (474.5 µmol/L)	77 U/L 154 U/L	1 1
Bilirubin, unconjugated	40 mg/dL (683.8 µmol/L)	79 U/L 159 U/L	7 5
Lipemia (Intralipid®)	3000 mg/dL (33.9 µmol/L)	70 U/L 140 U/L	0 0

Assay results obtained at individual laboratories may vary from the data presented.

Non-Interfering Substances

The Dimension Vista LIP assay is designed to have ≤ 10% interference from the substances shown in the table below.

Interference testing was performed in accordance with CLSI Document EP07-A2.[24]

The following substances do not interfere with the Dimension Vista LIP assay when present in serum and lithium heparin plasma at the concentrations indicated in the table below.

Substance	Substance Concentration mg/dL (µmol/L)	Analyte Concentration U/L	Bias %
Acetaminophen	20 (1321.1) 20 (1321.1)	73 152	0 0
Dipyrone	10 (460.8) 10 (460.8)	73 152	0 0
N-Acetyl-L-cysteine	80 (4902.3) 80 (4902.3)	73 152	0 0
NAPQI	2 (134.1) 2 (134.1)	73 151	0 0

Assay results obtained at individual laboratories may vary from the data presented.

Linearity

The Dimension Vista LIP assay is designed to be linear across the measuring interval 6–250 U/L.

The linear interval of Dimension Vista LIP assay was established based on CLSI Document EP06-A[25] using the Dimension Vista System.

Linearity was evaluated using a sample that contained a high level of lipase, which was mixed in various proportions with a sample at a low level of lipase. The resulting sample mixtures (10 combinations) were assayed for lipase.

The Dimension Vista LIP assay is linear from 6–250 U/L.

Dilution Recovery

Dilution recovery of the Dimension Vista LIP assay was established based on CLSI Document EP28-A3c.[26]

Serum and lithium heparin plasma samples were diluted onboard the Dimension Vista system. The following results were obtained:

Autodilution

Sample	Dilution	Expected U/L	Observed U/L	Recovery %
Lithium heparin plasma 1	1:20	367	386	105
Lithium heparin plasma 2	1:20	372	391	105
Lithium heparin plasma 3	1:20	359	378	105
Lithium heparin plasma 4	1:20	362	381	105
Lithium heparin plasma 5	1:20	372	391	105
Serum 1	1:20	392	412	105
Serum 2	1:20	399	419	105
Serum 3	1:20	395	415	105
Serum 4	1:20	407	427	105
Serum 5	1:20	417	437	105

Manual Dilution

Sample	Dilution	Expected U/L	Observed U/L	Recovery %
Lithium heparin plasma 1	1:20	1377	1396	101
Lithium heparin plasma 2	1:20	1339	1358	101
Lithium heparin plasma 3	1:20	1180	1199	102
Lithium heparin plasma 4	1:20	1069	1088	102
Lithium heparin plasma 5	1:20	1321	1340	101
Serum 1	1:20	389	408	105
Serum 2	1:20	357	376	105
Serum 3	1:20	367	386	105
Serum 4	1:20	367	386	105
Serum 5	1:20	362	381	105

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

Assigned values for calibrators are traceable to an internal standard.

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

For customer support, contact your local technical support provider or distributor.

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References

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code
	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier

Symbol	Symbol Title	Symbol	Symbol Title
RxOnly	Prescription device (US only)	CE	CE Marking
CE XXXX	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution
	Biological risks		Document face up[a]
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Mixing of substances		Interval
NON STERILE	Non-sterile	CONTENTS	**Contents**
	Reconstitution volume	LEVEL	Level
SCALERS	Scalers	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

Legal Information

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