

ADVIA® Chemistry XPT
Systems

Lipase (LIP)

Current Revision and Date ^a	Rev. H, 2020-02	
Product Name	ADVIA® Chemistry Lipase (LIP) Reagents	REF 01984894
Systems	ADVIA Chemistry XPT System	
Materials Required but Not Provided	ADVIA Chemistry Enzyme 1 Calibrator Reagent container adapters Commercially available controls	REF 10916057
Specimen Types	Human serum, plasma (lithium heparin)	
Assay Principle	Colorimetric rate	
Assay Range	Serum: 9–700 U/L Plasma: 9–700 U/L	
Reagent Storage	2–8°C	
Reagent On-System Stability	30 days	
Reagent Code	74050	

^a In Rev. F or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

This *in vitro* diagnostic method measures the concentration of lipase in human serum and plasma on ADVIA® Chemistry XPT systems. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas, such as acute pancreatitis and obstruction of the pancreatic duct.

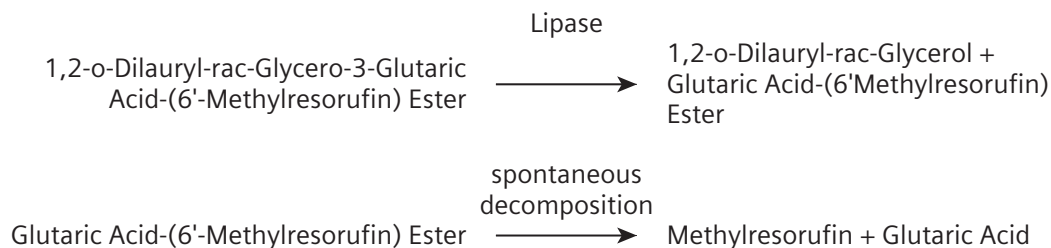
Summary and Explanation

The ADVIA Chemistry Lipase (LIP) assay measures the activity of the enzyme lipase in serum and plasma by the lipase enzymatic reaction producing methylresorufin, which is determined spectrophotometrically.^{1–3}

Principles of the Procedure

The chromogenic lipase substrate, DGGMR (1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester), is cleaved by the catalytic action of lipase to form 1,2-o-dilauryl-rac-glycerol and an unstable intermediate, glutaric acid-(6'-methyl resorufin) ester. This decomposes spontaneously in an alkaline solution to form glutaric acid and methylresorufin. The lipase activity in the specimen is proportional to the production of methylresorufin in the reaction and is determined spectrophotometrically.

Reaction Equation



Reagents

Reagent	Description	Storage	Reagent Stability
REF 01984894 ADVIA Chemistry Lipase (LIP) Reagents			
Lipase Reagent 1 LIP R1	18 mL in 20-mL containers TAPS buffer (N-Tris[hydroxymethyl]methyl-3-aminopropanesulfonic acid) (100 mmol/L) Sodium deoxycholate (34 mmol/L)	2–8°C	Unopened: Stable until the expiration date on product. On-system: ADVIA 1800: 10 days ADVIA 2400: 30 days
Lipase Reagent 2 LIP R2	10 mL in 20-mL containers (+) -Tartaric acid (9.5 mmol/L) Colipase (460 U/mL) 2-Propanol (0.65 mol/L) 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester (DGGMR) (0.4 mmol/L)	2–8°C	Unopened: Stable until the expiration date on product. On-system: ADVIA 1800: 10 days ADVIA 2400: 30 days

Warnings and Precautions

Safety data sheets (MSDS/SDS) available on [siemens.com/healthcare](https://www.siemens.com/healthcare).

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 the 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.

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

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Before use, gently invert the capped reagent to disrupt bubbles and ensure homogeneity. If bubbles still exist or foam is present, use a clean transfer pipette to aspirate them from the reagent container prior to use.

Storing and Stability

Unopened reagents are stable until the expiration date printed on the product label when stored at 2–8°C. Do not freeze reagents. Protect reagents from light.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated serum and plasma (lithium heparin) for the ADVIA Chemistry LIP assay.

Follow these guidelines for specimens used for this assay:

- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.⁴ Follow the instructions provided with your specimen collection device for use and processing.⁵
- Complete clot formation should take place before centrifugation.
- Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection.⁶
- Specimens should be free of particulate matter.
- Specimens should be as fresh as possible.

The purpose of handling and storage information is to provide guidance to users. 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.

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 01984894	Reagent 1: 4 × 20-mL containers Reagent 2: 4 × 20-mL containers	4 × 160

Materials Required but Not Provided

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

Item	Description
REF 10916057	ADVIA Chemistry Enzyme 1 Calibrator
REF 10316975	20-mL reagent container adapter for 40-mL slot
REF 10723030	20-mL reagent container adapter for 70-mL slot
	Commercially available control materials

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry system.

For detailed information on performing the procedure, refer to the system operating instructions.

Preparing the System

For detailed information on preparing the system, refer to the system operating instructions.

Preparing the Samples

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

On-System Stability

The ADVIA Chemistry LIP reagent is stable on the system for 30 days.

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry LIP assay, use the ADVIA Chemistry Enzyme 1 Calibrator (REF 10916057).

Enter the lot-specific calibrator values that are provided with each lot of calibrator. Perform the calibration as described in the calibrator instructions for use.

Calibration Frequency

Calibrate the assay every 7 days.

Calibrate the assay after the following events:

- When the reagent lot number changes
- When a reagent pack is replaced by a new reagent pack with the same lot number, and the previous reagent pack was recalibrated during use
- When a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run on the previous reagent pack during use
- After replacing critical optical or hydraulic components
- When indicated by quality control procedures

Individual laboratory quality control programs and procedures may require more frequent calibration.

Reagent Blank (RBL) Frequency

The ADVIA Chemistry system measures the RBL during assay calibration.

Note Use deionized water as the sample for the RBL in the ADVIA Chemistry LIP assay.

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

At least once each day of use, analyze 2 levels (low and high) of a commercially available quality control (QC) material with known lipase concentrations.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme.

The actual frequency of control in a laboratory is based on many factors, such as workflow, system experience, and government regulation. Each laboratory should evaluate the controls based on the frequency established by their laboratory guidelines.

Also, assay controls under the following conditions:

- Whenever you use a new reagent lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration or an additional reagent blank

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Taking Corrective Action

If the quality control results do not fall within the expected control range or within the laboratory's established values, do not report results. Take the following actions:

1. Determine and correct the cause of the unacceptable control results:
 - a. Verify that the assay was performed according to the instructions for use.
 - b. Verify that the materials are not expired.
 - c. Verify that required maintenance was performed.
 - d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
 - e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat the prior step.
 - f. If necessary, contact your local technical support provider or distributor for assistance.
2. After corrective action is complete, repeat required testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

The system calculates and reports results based on the absorbance measurements of the test sample during the test, and of the calibrator(s) from calibration.

The instrument calculates the concentration of lipase in U/L (common units) or (SI units).

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

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.⁷

As with any chemical reaction, you must be alert to the possible effect on results 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.

Siemens has determined that there is a possibility for certain ADVIA Chemistry reagents to interact with the ADVIA Chemistry LIP assay when run on the same system. To mitigate these carryover events, the ADVIA Chemistry system software provides a Contamination Avoidance process. For further information and instructions to establish this process on your systems, refer to the Customer Bulletin entitled: *Consolidated Directory of Contamination Avoidance Settings for ADVIA Chemistry XPT Systems* (PN 10815606, latest revision).

Expected Values

The reference range for lipase is 12–53 U/L.⁸

Siemens provides this information for reference. As with all *in vitro* diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider these values as a guideline only.

Performance Characteristics

Analytical Measuring Range

This assay is linear from 9–700 U/L.

Results that are below the assay range are flagged < **Conc Range**. You should report the test result as < 9 U/L.

Results that are above the assay range are flagged > **Conc Range**.

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay that extends the reportable range to 3500 U/L. You may configure the system to trigger automatic reruns. Rerun results will be flagged **Autorepeat**.

Sensitivity

The ADVIA Chemistry LIP assay performance at low levels was analyzed as described in CLSI protocol EP17-A2⁹ and the limit of blank (LoB) and limit of detection (LoD) were determined.

The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the ADVIA Chemistry LIP assay is 7 U/L.

The LoD is the smallest amount that this assay can reliably detect to determine presence or absence of an analyte. The LoD for the ADVIA Chemistry LIP assay is 9 U/L.

The LoB and LoD values are determined with proportions of false positives (α) less than 5% and false negatives (β) less than 5%, based on 180 determinations with 120 blank and 60 low-level sample replicates.

Precision

The precision of the ADVIA Chemistry LIP assay was analyzed as described in CLSI protocol EP05-A2.¹⁰ Each sample was assayed 3 times per run, 2 runs per day, for at least 10 days.

Specimen Type	N	Mean (U/L)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
			SD ^a (U/L)	CV ^b (%)	SD (U/L)	CV (%)	SD (U/L)	CV (%)	SD (U/L)	CV (%)
Serum Control 1	60	22	1.0	4.5	0.0	0.0	0.3	1.5	1.1	4.8
Serum Control 2	60	52	1.1	2.1	0.3	0.6	0.6	1.1	1.3	2.4
Serum Control 3	60	207	1.5	0.7	1.9	0.9	1.6	0.8	2.9	1.4

Specimen Type	N	Mean (U/L)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
			SD ^a (U/L)	CV ^b (%)	SD (U/L)	CV (%)	SD (U/L)	CV (%)	SD (U/L)	CV (%)
Serum Pool 1	60	53	1.0	1.9	0.9	1.6	0.0	0.0	1.3	2.5
Serum Pool 2	60	145	1.2	0.8	0.9	0.6	1.7	1.2	2.3	1.6
Serum Pool 3	60	403	1.8	0.4	2.6	0.6	5.0	1.2	5.8	1.4

^a SD = standard deviation

^b CV = coefficient of variation

Actual results will vary depending on the study design, and on the sample and sample population used. Results obtained at individual laboratories may vary from the data provided.

Accuracy / Method Comparison

The performance of the ADVIA Chemistry LIP assay (y) was compared with the performance of the comparison assay on the indicated system (x).

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
Serum	ADVIA 2400 LIP	104	1.000	y = 1.04x + 0.2 U/L	3.6 U/L	12–635 U/L
Serum	ADVIA 1800 LIP	104	1.000	y = 1.01x - 0.9 U/L	3.1 U/L	11–653 U/L
Plasma (Lithium Heparin)	ADVIA 1800 LIP	56	1.000	y = 1.01x + 0.5 U/L	1.2 U/L	26–633 U/L
Plasma ^a (Lithium Heparin) ADVIA 1650/1800	ADVIA 1650/1800 LIP - Serum	49	0.985	y = 0.95x + 1.9 U/L	2.0 U/L	9–71 U/L

^a Matrix comparison. Correlations between serum and plasma samples on ADVIA 1650/1800 Chemistry systems are provided for reference.

The correlation of the assay may vary depending on the study design, comparable method, and sample population. Results obtained at individual laboratories may vary from the data provided.

Interferences

Siemens tested the following potential interferents and found the results shown below.

Interferent	Interferent Level	Lipase Sample Concentration	Interference
Bilirubin (conjugated)	50 mg/dL (855 µmol/L)	56 U/L	NSI ^a
	50 mg/dL (855 µmol/L)	162 U/L	NSI
Bilirubin (unconjugated)	50 mg/dL (855 µmol/L)	56 U/L	NSI
	50 mg/dL (855 µmol/L)	158 U/L	NSI

Interferent	Interferent Level	Lipase Sample Concentration	Interference
Hemolysis (hemoglobin)	125 mg/dL (1.25 g/L)	54 U/L	NSI
	187.5 mg/dL (1.9 g/L)	54 U/L	+13.0%
	1000 mg/dL (10 g/L)	157 U/L	NSI
Lipemia ^b (triglycerides from Intralipid)	1000 mg/dL (11.3 mmol/L)	57 U/L	NSI
	1000 mg/dL (11.3 mmol/L)	163 U/L	NSI

^a NSI = No significant interference. A percentage effect $\geq 10\%$ is considered a significant interference.

^b SI units calculated as triolein

Note There is poor correlation between turbidity and triglyceride concentration in a lipemic sample.¹¹

Actual results will vary depending on the study design, the levels of the potential interferences tested, and the samples used. Results obtained at individual laboratories may vary from the data provided.

Standardization

The ADVIA Chemistry LIP assay is traceable to an internal standard.

Technical Assistance

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




















[siemens.com/healthcare](https://www.siemens.com/healthcare)

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
	In vitro diagnostic medical device	 REF	Catalog number
	Legal manufacturer		Authorized Representative in the European Community
	CE Mark		CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Keep away from sunlight and heat		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Do not freeze (> 0°C)		Up
	Use by		Contains sufficient for (n) tests
	Recycle		Printed with soy ink
Rev.	Revision	YYYY-MM-DD	Date format (year-month-day)
	Batch code	RxOnly	Prescription Device (US only)

Trademarks

ADVIA is a trademark of Siemens Healthcare Diagnostics.

Intralipid is a trademark of Fresenius Kabi AB.

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