SIEMENS Healthineers

# Lipase (Lip)

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| **Current Revision and Date**[a] | Rev. 03, 2022-10 | |
| **Product Name** | Atellica CH Lipase (Lip) | REF 11097606 (1280 tests) |
| **Abbreviated Product Name** | Atellica CH Lip | |
| **Test Name/ID** | Lip | |
| **Systems** | Atellica CI Analyzer | |
| **Materials Required but Not Provided** | Atellica CH ENZ 1 CAL | REF 11099317 |
| **Specimen Types** | Serum and plasma (lithium heparin) | |
| **Sample Volume** | 3 µL | |
| **Measuring Interval** | 8–700 U/L | |

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

CE

## Intended Use

The Atellica® CH Lipase (Lip) assay is for *in vitro* diagnostic use in the quantitative determination of lipase in human serum and plasma (lithium heparin) using the Atellica® CI Analyzer. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas, such as acute pancreatitis and obstruction of the pancreatic duct.

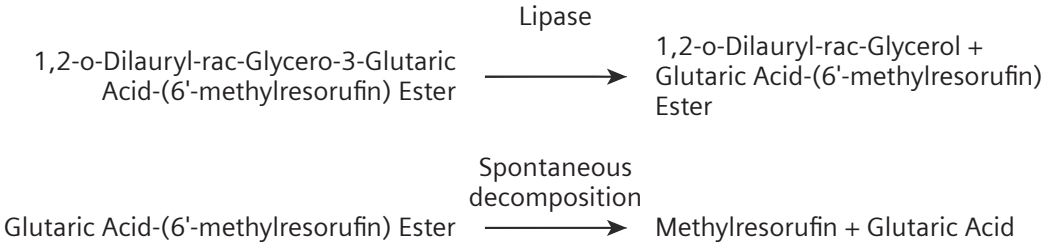
## Summary and Explanation

The Atellica CH 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'-methylresorufin) 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. The Atellica CH Lip measurement wavelengths are 571/694 nm.

## Reaction Equation




# Reagents

| Material Description | Storage | Stability[a] |
|---|---|---|
| **Atellica CH Lip** | Unopened at 2–8°C | Until expiration date on product |
| **Pack 1 (P1)** | Onboard per well | 9 days |
| Well 1 (W1)<br>Reagent 1 (R1)<br>18.0 mL<br>TAPS (100 mmol/L);<br>sodium azide (0.05%);<br>sodium deoxycholate (34 mmol/L) | | |
| Well 2 (W2)<br>Reagent 1 (R1)<br>18.0 mL<br>TAPS (100 mmol/L);<br>sodium azide (0.05%);<br>sodium deoxycholate (34 mmol/L) | | |
| **Pack 2 (P2)** | | |
| Well 1 (W1)<br>Reagent 2 (R2)<br>10.3 mL<br>(+) -tartaric acid (9.5 mmol/L);<br>sodium hydroxide (19 mmol/L);<br>colipase (460 U/mL);<br>2-Propanol (0.65 mol/L);<br>DGGMR (0.4 mmol/L) | | |
| Well 2 (W2)<br>Reagent 2 (R2)<br>10.3 mL<br>(+) -tartaric acid (9.5 mmol/L);<br>sodium hydroxide (19 mmol/L);<br>colipase (460 U/mL);<br>2-Propanol (0.65 mol/L);<br>DGGMR (0.4 mmol/L) | | |

[a] Refer to *Storage and Stability*.

## 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.

**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.

**Note** For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

## Storage and Stability

Protect the product from light sources. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

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

## Onboard Stability

Discard reagents 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 plasma (lithium heparin) are the recommended sample types for this assay.

## Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[4]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[5]
- Follow the instructions provided with your specimen collection device for use and processing.[6]
- Allow blood specimens to clot completely before centrifugation.[7]
- Keep tubes capped at all times.[7]

## Storing the Specimen

Specimens may be stored for up to 24 hours at room temperature or for up to 7 days at 2–8°C or stored frozen for up to a year at -20°C or colder.[8]

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.

## 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 3 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 online help.

**Note** Do not use specimens with apparent contamination.

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

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

**Note** Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[7]

**Note** For a complete list of appropriate sample containers, refer to the online help.

# Procedure

## Materials Provided

The following materials are provided:

| REF | Contents | Number of Tests |
|---|---|---|
| 11097606 | **Pack 1 (P1)**<br>Well 1 (W1) 18.0 mL of Atellica CH Lip Reagent 1<br>Well 2 (W2) 18.0 mL of Atellica CH Lip Reagent 1<br><br>**Pack 2 (P2)**<br>Well 1 (W1) 10.3 mL of Atellica CH Lip Reagent 2<br>Well 2 (W2) 10.3 mL of Atellica CH Lip Reagent 2 | 4 x 320 |

## Materials Required but Not Provided

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

| REF | Description | |
|---|---|---|
| | Atellica CI Analyzer[a] | |
| 11099317 | Atellica CH ENZ 1 CAL (calibrator) | 6 x 2.5 mL calibrator CAL<br>Calibrator lot-specific value sheet CAL LOT VAL |
| | Commercially available quality control materials | |

[a] Additional system fluids are required to operate the system. For system fluid instructions for use, refer to the Document Library.

## Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 80 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 3 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 40 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance rate after Reagent 2 addition.
8. Reports results.

Test Duration: 8 minutes

## Preparing the Reagents

All reagents are liquid and ready to use.

## Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

## Performing Calibration

For calibration of the Atellica CH Lip assay, use Atellica CH ENZ 1 CAL. Use the calibrators in accordance with the calibrator instructions for use.

### Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

| Stability Interval | Days |
|---|---|
| Lot Calibration | 61 |
| Pack Calibration | 9 |

For information about lot calibration and pack calibration intervals, refer to the online help.

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

## Performing Quality Control

For quality control of the Atellica CH Lip assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. For assistance in identifying a quality control material, refer to the *Atellica CH Quality Control Material Supplement* available on siemens-healthineers.com. 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.

For the assigned values, refer to the lot-specific value sheet provided.

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.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. 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 assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

# Results

## Calculation of Results

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

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

## 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 Atellica CH Lip assay is limited to the detection of lipase in human serum and plasma (lithium heparin).

# Expected Values

## Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified by analysis for the Atellica CI Analyzer.[9]

The reference interval for lipase is 12–53 U/L for adults.[10]

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.[9]

# Performance Characteristics

## Measuring Interval

The Atellica CH Lip assay is linear from 8–700 U/L. The system flags all values that are outside the specified measuring interval.

## Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 3500 U/L for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

## Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[11] The assay is designed to have a limit of blank (LoB) < limit of detection (LoD) and LoD ≤ 8 U/L.

The LoD corresponds to the lowest concentration of lipase that can be detected with a probability of 95%. The LoD for the Atellica CH Lip assay is 6 U/L, and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 3 U/L.

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

## Precision

The Repeatability precision of the Atellica CH Lip assay is designed to have the following characteristics:

- CV ≤ 9.0% at 30–300 U/L
- CV ≤ 9.0% at 550–700 U/L

The Within-Laboratory precision of the Atellica CH Lip assay is designed to have the following characteristics:

- CV ≤ 12.0% at 30–300 U/L
- CV ≤ 12.0% at 550–700 U/L

Precision was determined in accordance with CLSI Document EP05-A3.[12] Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

| | | | Repeatability | | Within-Laboratory Precision | |
|---|---|---|---|---|---|---|
| **Sample Type** | **N** | **Mean U/L** | **SD[a] U/L** | **CV[b] (%)** | **SD U/L** | **CV (%)** |
| Serum QC | 80 | 37 | 0.8 | 2.2 | 1.0 | 2.7 |
| Serum 1 | 80 | 238 | 2.3 | 1.0 | 4.7 | 2.0 |
| Serum 2 | 80 | 663 | 4.7 | 0.7 | 16.5 | 2.5 |

[a] Standard deviation.

[b] Coefficient of variation.

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

## Reproducibility

The assay is designed to have the following reproducibility:

| | | Total Reproducibility | |
|---|---|---|---|
| Sample | Concentration U/L | SD U/L | CV (%) |
| Serum | 30–300 | N/A | ≤ 15.0 |
| Serum | 550–700 | N/A | ≤ 15.0 |

Reproducibility was determined in accordance with CLSI Document EP05-A3.[12] Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

| | | | Repeatability | | Between-Day | | Between-Lot | | Between-Instrument | | Total Reproducibility | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sample | N[a] | Mean U/L | SD[b] U/L | CV[c] (%) | SD U/L | CV (%) | SD U/L | CV (%) | SD U/L | CV (%) | SD U/L | CV (%) |
| QC Serum | 225 | 37 | 0.9 | 2.4 | 0.8 | 2.2 | 0.8 | 2.2 | 0.7 | 1.9 | 1.6 | 4.3 |
| Serum 1 | 225 | 239 | 2.1 | 0.9 | 4.9 | 2.1 | 2.6 | 1.1 | 6.0 | 2.5 | 8.4 | 3.5 |
| Serum 2 | 225 | 662 | 5.7 | 0.9 | 13.2 | 2.0 | 6.0 | 0.9 | 20.9 | 3.2 | 26.1 | 3.9 |

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

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

## Assay Comparison

The performance of the Atellica CH Lip assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of > 0.950 and a slope of 1.00 ± 0.10. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.[13] The following results were obtained:

| Specimen | Comparative Assay (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Serum | ADVIA® Chemistry LIP on ADVIA® Chemistry 1800 System | y = 0.95x + 2 U/L | 17–636 U/L | 110 | 1.000 |
| Serum | Atellica CH Lip on Atellica CH Analyzer | y = 1.01x + 2 U/L | 15–606 U/L | 110 | 0.999 |

[a] Number of samples tested.
[b] Correlation coefficient.

The agreement of the assay 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 Deming linear regression model in accordance with CLSI Document EP09-A3.[14] The following results were obtained:

| Specimen (y) | Reference Specimen (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Lithium heparin plasma | Serum | y = 0.96x - 1 U/L | 25–683 U/L | 55 | 0.999 |

[a] Number of samples tested.

[b] Correlation coefficient.

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer. 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

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.

### Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Lip assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH Lip assay.[15]

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. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

| Substance | Substance Test Concentration Common Units (SI Units) | Analyte Concentration U/L | Percent Bias |
|---|---|---|---|
| Hemoglobin | 200 mg/dL (0.12 mmol/L)<br>500 mg/dL (0.31 mmol/L) | 50<br>251 | 7<br>-2 |
| Bilirubin, conjugated | 25 mg/dL (428 µmol/L)<br>25 mg/dL (428 µmol/L) | 54<br>254 | 3<br>1 |
| Bilirubin, unconjugated | 25 mg/dL (428 µmol/L)<br>25 mg/dL (428 µmol/L) | 51<br>234 | -1<br>6 |
| Lipemia (Intralipid®) | 1000 mg/dL (11.3 mmol/L)<br>1000 mg/dL (11.3 mmol/L) | 52<br>250 | 10<br>-3 |

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

## Standardization

The Atellica CH Lip assay is traceable to an internal standard.

Assigned values for calibrators are traceable to this standardization.[10]

# Technical Assistance

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

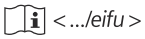
siemens-healthineers.com

## References


1. Tietz NW, Shuey DF. Lipase in serum-the elusive enzyme: an overview. *Clin Chem*. 1993;39(5):746–756.
2. Steinberg WM, Goldstein SS, Davis ND, *et al*. Diagnostic assays in acute pancreatitis. A study of sensitivity and specificity. *Ann Intern Med*. 1985;102(5):576–580.
3. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. *Adv Clin Enzymol*. 1986;4:60–67.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
5. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
6. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
7. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
8. Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 3rd ed. Washington, DC: AACC Press, 2007:612.
9. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
10. Data on file at Siemens Healthcare Diagnostics.
11. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
12. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
13. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP09c-ed3.
14. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
15. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.

# 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 |  | Authorized representative in Switzerland |
|  | Catalog number |  | Batch code |
|  | Consult Instructions for Use |  | Contains sufficient for <n> tests |
|   | Internet URL address to access the electronic instructions for use |   | Version of Instructions for Use |
|   | *In vitro* diagnostic medical device |   | Revision |
| **RxOnly** | Prescription device (US only) |   | Unique Device Identifier |
|   | CE Marking with Notified Body |  | CE Marking |
|  | Temperature limit |  | Keep away from sunlight |
|  | Upper limit of temperature |  | Lower limit of temperature |
|  | Do not re-use |  | Do not freeze |
|  | Recycle |  | This way up |
|  | Biological risks |  | Caution |
|   | Common Units |   | International System of Units |
| **YYYY-MM-DD** | Date format (year-month-day) | **YYYY-MM** | Date format (year-month) |
|  | Document face up[a] |  | Handheld barcode scanner |
|  | Target |  | Mixing of substances |
|   | Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid. |  | Interval |

| Symbol | Symbol Title | Symbol | Symbol Title |
|---|---|---|---|
| MATERIAL ID | Unique material identification number | MATERIAL | Material |
| CONTROL TYPE | Type of control | CONTROL NAME | Name of control |
| CONTROL LOT VAL | Quality control lot value | CAL LOT VAL | Calibrator lot value |

[a] Indicates Assay-eNote

## Legal Information



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