SIEMENS Healthineers

Amylase_2 (AMY_2)

Current Revision and Date[a]	Rev. 02, 2022-10	
Product Name	Atellica® CH Amylase_2 (AMY_2)	REF 11097649 (1050 tests)
Abbreviated Product Name	Atellica CH AMY_2	
Test Name/ID	AMY_2	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH SPCL CHEM CAL	REF 11099438
Specimen Types	Serum, plasma (lithium heparin), urine	
Sample Volume	16 µL	
Measuring Interval	20–1500 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 Amylase_2 (AMY_2) assay is for *in vitro* diagnostic use in the quantitative determination of amylase activity in human serum, plasma (lithium heparin), and urine using the Atellica® CI Analyzer. Such measurements are used primarily in the diagnosis and monitoring of acute pancreatitis (inflammation of the pancreas).

Summary and Explanation

The Atellica CH Amylase_2 (AMY_2) assay is based on the procedure of Jensen and Wydeveld.[1]

Principles of the Procedure

The Atellica CH AMY_2 assay uses ethylidene blocked *p*-nitrophenyl-maltoheptaoside as substrate. The indicator enzyme α-glucosidase, used to release *p*-nitrophenol (PNP), is also employed in the assay. The terminal glucose of the substrate is chemically blocked, preventing cleavage by the indicator enzymes. The released *p*-nitrophenol is measured at 410/694 nm.

Reaction Equation

$$\text{Ed-G7PNP} \xrightarrow{\alpha\text{-Amylase}} \text{Ed-G}_n + \text{G}_n\text{-PNP}$$

$$\text{G}_n\text{-PNP} \xrightarrow{\alpha\text{-Glucosidase}} \text{PNP} + \text{Glucose}$$

Reagents

Material Description	Storage	Stability[a]
Atellica CH AMY_2	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	90 days
Well 1 (W1) Reagent 1 (R1) 18.7 mL α-Glucosidase (≥ 4 kU/L); sodium azide (0.09%)		
Well 2 (W2) Reagent 1 (R1) 18.7 mL α-Glucosidase (≥ 4 kU/L); sodium azide (0.09%)		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 6.5 mL Ethylidene-4-NP-G7 (22 mmol/L); sodium azide (0.09%)		
Well 2 (W2) Reagent 2 (R2) 6.5 mL Ethylidene-4-NP-G7 (22 mmol/L); sodium azide (0.09%)		

[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.

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

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, plasma (lithium heparin), and urine 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.[2]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[3]
- Follow the instructions provided with your specimen collection device for use and processing.[4]
- Allow blood specimens to clot completely before centrifugation.[5]
- Keep tubes capped at all times.[5]

Storing the Specimen

Separated serum and plasma specimens may be stored for up to 8 days at room temperature[6] or for up to 31 days at 2–8°C[6] or stored frozen for at least 1 year at -20°C.[7]

Urine amylase is unstable in acidic urine. Adjust urine to a pH ≥ 7 before storage.[8,9] Adjusted urine specimens may be stored for up to 10 days at room temperature[6] or for up to 31 days at 2–8°C.[6]

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 16 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.[5]

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
11097649	**Pack 1 (P1)** Well 1 (W1) 18.7 mL of Atellica CH AMY_2 Reagent 1 Well 2 (W2) 18.7 mL of Atellica CH AMY_2 Reagent 1 **Pack 2 (P2)** Well 1 (W1) 6.5 mL of Atellica CH AMY_2 Reagent 2 Well 2 (W2) 6.5 mL of Atellica CH AMY_2 Reagent 2	3 x 350

Materials Required but Not Provided

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

REF	Description	
	Atellica CI Analyzer[a]	
11099438	Atellica CH SPCL CHEM CAL (calibrator)	10 x 5.0 mL calibrator CAL 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. For urine, dispenses 16 µL of primary sample and 224 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 80 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 16 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 16 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance after Reagent 2 addition.
8. Reports results.

Test Duration: 10 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 AMY_2 assay, use Atellica CH SPCL CHEM 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	62
Pack Calibration	90

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 AMY_2 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 online help.

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 AMY_2 assay is limited to the detection of amylase in human serum, plasma (lithium heparin), and urine.

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.[10]

The reference interval for adults is 30–118 U/L for serum and plasma,[6] and ≤ 650 U/L for urine.[8]

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.[10]

Performance Characteristics

Measuring Interval

The Atellica CH AMY_2 assay is linear from 20–1500 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 4500 U/L for serum, plasma, and urine. 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), LoD ≤ limit of quantitation (LoQ), and LoQ ≤ 20 U/L for serum, plasma and urine.

The LoD corresponds to the lowest concentration of amylase that can be detected with a probability of 95%. The LoD for the Atellica CH AMY_2 assay is 7 U/L for serum and plasma, and 9 U/L for urine, and was determined using 450 determinations, with 225 blank and 225 low level replicates, and an LoB of 1 U/L for serum, plasma, and urine.

The LoQ for the Atellica CH AMY_2 assay is 20 U/L for serum, plasma, and urine. This is the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error ≤ 30%.

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

Precision

The Repeatability and Within-Laboratory precision of the Atellica CH AMY_2 assay are designed to have the following characteristics:

Specimen Type	Concentration U/L	Repeatability Results	Within-Laboratory Results
Serum/Plasma	30–100	≤ 3.0%	≤ 5.0%
Serum/Plasma	120–300	≤ 2.0%	≤ 3.0%
Serum/Plasma	1000–1500	≤ 2.0%	≤ 3.0%
Urine	30–100	≤ 3.0%	≤ 5.0%
Urine	120–300	≤ 2.0%	≤ 3.0%
Urine	1000–1500	≤ 2.0%	≤ 3.0%

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 1	80	51	0.4	0.8	0.4	0.8
Serum 2	80	182	0.5	0.3	0.6	0.3
Serum 3	80	1069	2.2	0.2	3.2	0.3
Urine 1	80	52	0.8	1.5	1.2	2.3
Urine 2	80	175	0.6	0.3	1.1	0.6
Urine 3	80	1280	3.2	0.3	9.5	0.7

[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:

Sample	Concentration U/L	Total Reproducibility SD U/L	Total Reproducibility CV (%)
Serum/Plasma	30–119	N/A	≤ 7.5
Serum/Plasma	120–1500	N/A	≤ 4.5
Urine	30–119	N/A	≤ 8.5
Urine	120–1500	N/A	≤ 4.5

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 (%)
Serum 1	225	51	0.4	0.8	0.3	0.6	0.1	0.2	0.4	0.8	0.7	1.4
Serum 2	225	182	0.5	0.3	1.4	0.8	0.2	0.1	1.9	1.0	2.4	1.3
Serum 3	225	1069	2.6	0.2	7.1	0.7	1.5	0.1	11.7	1.1	14.0	1.3
Urine 1	225	57	0.6	1.1	0.8	1.4	4.4	7.7	0.8	1.4	4.6	8.1
Urine 2	225	179	0.5	0.3	1.1	0.6	2.4	1.3	1.6	0.9	3.1	1.7
Urine 3	225	1334	3.3	0.2	8.5	0.6	38.3	2.9	16.4	1.2	42.6	3.2

[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 AMY_2 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 ± 0.15 for serum and urine. Assay comparison was determined using a 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[c]	Atellica CH AMY_2 on Atellica CH Analyzer	y = 1.01x - 0 U/L	23–1418 U/L	105	1.000
Urine[d]	Atellica CH AMY_2 on Atellica CH Analyzer	y = 1.03x + 4 U/L	21–1456 U/L	107	0.992

[a] Number of samples tested.
[b] Correlation coefficient.
[c] Deming regression
[d] Passing & Bablok regression

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]
Plasma (Lithium heparin)	Serum	y = 1.00x + 0 U/L	36–1419 U/L	66	1.000

[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 AMY_2 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 AMY_2 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.

Serum

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration U/L	Percent Bias
Hemoglobin	500 mg/dL (0.310 mmol/L) 500 mg/dL (0.310 mmol/L)	100 383	-1 -1
Bilirubin, conjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	105 398	-9 -7
Bilirubin, unconjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	105 398	-6 -7
Lipemia (Intralipid®)	650 mg/dL (7.3 mmol/L) 650 mg/dL (7.3 mmol/L)	102 386	3 -1

Urine

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration U/L	Percent Bias
Hemoglobin	500 mg/dL (0.310 mmol/L) 500 mg/dL (0.310 mmol/L)	96 402	-3 -2
Bilirubin, conjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	95 395	-5 -2

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration U/L	Percent Bias
Bilirubin, unconjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	95 395	-5 3
Lipemia (Intralipid®)	650 mg/dL (7.3 mmol/L) 650 mg/dL (7.3 mmol/L)	94 394	4 0

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

Non-Interfering Substances

The following substances do not interfere with the Atellica CH AMY_2 assay when present at the concentrations indicated in the table below. Bias due to these substances is ≤ 10% at an analyte concentration listed in the tables below.

Serum

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration U/L	Percent Bias
Acetaminophen	30 mg/dL (1985 µmol/L) 30 mg/dL (1985 µmol/L)	99 375	1 0
Acetylsalicylic acid	200 mg/dL (11.1 mmol/L) 200 mg/dL (11.1 mmol/L)	97 379	-4 -4
Ascorbic acid	20 mg/dL (1136 µmol/L) 20 mg/dL (1136 µmol/L)	100 379	-1 0

Urine

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration U/L	Percent Bias
Acetaminophen	30 mg/dL (1985 µmol/L) 30 mg/dL (1985 µmol/L)	96 398	0 -1
Acetylsalicylic acid	200 mg/dL (11.1 mmol/L) 200 mg/dL (11.1 mmol/L)	106 363	-2 -1
Ascorbic acid	20 mg/dL (1136 µmol/L) 20 mg/dL (1136 µmol/L)	96 397	0 -1

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

Standardization

The Atellica CH AMY_2 (AMY_2) assay is traceable to the IRMM/IFCC-456 reference material and commutable to the IFCC Alpha-Amylase Primary Reference Procedure as established by patient sample correlation.

Assigned values for calibrators are traceable to this standardization.[6]

Technical Assistance

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

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References

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10. 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.
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
 <…/eifu>	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
UNITS C	Common Units	UNITS SI	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
CHECKSUM	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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