SIEMENS Healthineers

Amylase_2 (AMY_2)

Current Revision and Date[a]	Rev. 02, 2019-08	
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 CH 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® CH 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	31 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.com/healthineers.

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

Reagents are stable onboard the system for 31 days per well. Discard reagents at the end of the onboard stability interval. 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 CH 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: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. 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: 9 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	31
Reagent Onboard Stability	31

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. 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. 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. 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.

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

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 on the Atellica CH 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 provides results 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 480 determinations, with 240 blank and 240 low level replicates, and a 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

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

			Repeatability		Designed to be	Within-Lab Precision		Designed to be
Sample Type	N	Mean U/L	SD[a] U/L	CV[b] (%)	CV (%)	SD U/L	CV (%)	CV (%)
Sample 1	80	52	0.6	1.1	≤ 3.0	0.7	1.4	≤ 5.0
Serum QC	80	187	0.8	0.4	≤ 2.0	1.1	0.6	≤ 3.0
Sample 2	80	1128	2.2	0.2	≤ 2.0	4.3	0.4	≤ 3.0
Urine QC	80	58	1.0	1.7	≤ 3.0	1.3	2.2	≤ 5.0
Urine 1	80	183	0.8	0.4	≤ 2.0	2.3	1.3	≤ 3.0
Urine 2	80	1260	9.3	0.7	≤ 2.0	21.5	1.7	≤ 3.0

[a] Standard deviation.
[b] Coefficient of variation.

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

Assay Comparison

The Atellica CH AMY_2 assay is designed to have a correlation coefficient of > 0.950, and a slope of 1.00 ± 0.15 for serum and urine compared to Roche cobas® AMYL2. Assay comparison was determined using the weighted Deming linear regression model in accordance with CLSI Document EP09-A3.[13] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Roche cobas AMYL2	y = 1.09x + 0 U/L	28–1294 U/L	118	0.996
Urine	Roche cobas AMYL2	y = 1.11x - 1 U/L	20–1194 U/L	114	0.998

[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.[13] 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	39–1419 U/L	66	1.000

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

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)

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.[14]

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
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.

siemens.com/healthineers

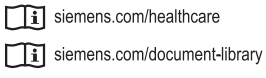
References

1. Jensen AP, Wydeveld A. α-(p-nitrophenyl) malto hexaoside as a substrate for the assay of amylase. *Nature*. 1958;182:525–526.
2. 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.
3. 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.

4. 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.
5. 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.
6. Data on file at Siemens Healthcare Diagnostics.
7. Wilding P, Zilva JF, Wilde CE. Transport of specimens for clinical chemistry analysis. *Ann Clin Biochem*. 1977;14(6):301-306.
8. Wu AHB. *Tietz Clinical Guide to Laboratory Tests*. 4th ed. St. Louis, MO: Saunders; 2006:22-25,102,104.
9. Clinical and Laboratory Standards Institute. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2001. CLSI Document GP16-A2.
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; 2013. CLSI Document EP09-A3.
14. 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 and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.

Symbol	Symbol Title and Description
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
IVD	*In vitro* diagnostic medical device

Symbol	Symbol Title and Description
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material

Symbol	Symbol Title and Description
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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