

ADVIA® 1800
ADVIA® 2400
 Chemistry Systems

Pancreatic Amylase (PAMY)

Current Revision and Date ^a	Rev. F, 2020-02	
Product Name	ADVIA® Chemistry Pancreatic Amylase (PAMY) Reagents	REF 01410820
Systems	ADVIA 1800 Chemistry System ADVIA 2400 Chemistry System	
Materials Required but Not Provided	Reagent container adapters Commercially available controls	
Specimen Types	Human serum	
Assay Principle	Antibody-blocked colorimetric amylase	
Assay Range	Serum: 0–1500 U/L	
Reagent Storage	2–8°C	
Reagent On-System Stability	60 days	
Reagent Code	74056	

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

Intended Use

For *in vitro* diagnostic use in the quantitative determination of pancreatic amylase in human serum on ADVIA® Chemistry systems. Such measurements are used in the diagnosis and treatment pancreatic disorders.^{1–4}

Summary and Explanation

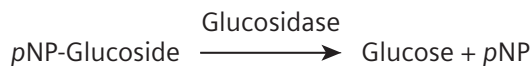
The ADVIA Chemistry Pancreatic Amylase (PAMY) assay measures pancreatic amylase activity in human serum by the amylase enzymatic reaction, with the non-pancreatic isoforms blocked by antibodies.

Principles of the Procedure

Two monoclonal antibodies are incubated with the sample to inhibit the salivary amylase present without affecting pancreatic amylase activity. This method uses ethylidene-*p*-nitrophenyl maltoheptaoside as the substrate. Pancreatic amylase present in the sample splits the substrate to produce oligosaccharides and *p*NP-G₂, *p*NP-G₃, and *p*NP-G₄.

Glucosidase is added as the indicator enzyme to release the *p*-nitrophenol (*p*-NP). The final result of the hydrolysis by amylase and glucosidase is free *p*-NP, which is detected by its absorbance at 410/694 nm. The terminal glucose is blocked preventing cleavage by the indicator enzyme.

Reaction Equation



Reagents

Reagent	Description	Storage	Reagent Stability
REF 01410820	ADVIA Chemistry Pancreatic Amylase (PAMY) Reagents		
Pancreatic Amylase Reagent 1 PAMY R1	14 mL in 20-mL containers Hepes buffer, pH 7.15 (52.5 mmol/L) Magnesium chloride (12.6 mmol/L) Sodium chloride (87 mmol/L) Glucosidase (≥ 4 U/mL) Monoclonal antibodies (mouse) (42 $\mu\text{g/mL}$) NaN ₃ (0.09%)	2–8°C	Unopened: Stable until the expiration date on product. On-system: 60 days
Pancreatic Amylase Reagent 2 PAMY R2	5.2 mL in 20-mL containers Ethylidene-G ₇ -pNP (22 mmol/L) NaN ₃ (0.09%)	2–8°C	Unopened: Stable until the expiration date on product. On-system: 60 days

Warnings and Precautions

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



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 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.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated serum for the ADVIA Chemistry PAMY 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.⁵ Follow the instructions provided with your specimen collection device for use and processing.⁶
- 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.⁷
- 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 01410820	Reagent 1: 7 × 20-mL containers Reagent 2: 7 × 20-mL containers	7 × 130

| Materials Required but Not Provided

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

Item	Description
REF 02404085 REF 00771668	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 PAMY reagents are stable on the system for 60 days.

Do not use reagents beyond the expiration date.

Performing Calibration

No calibration is required.

Calibration uses a fixed system factor value (FV), which is the same value used for the ADVIA Chemistry Amylase (AMYLAS) assay (total amylase). This value is based on the correlation of the ADVIA Chemistry AMYLAS assay to the IFCC Reference method for amylase. One unit of amylase activity is defined as that amount of enzyme, which catalyzes the production of 1 μmol of *p*-nitrophenol per minute under the conditions of the assay.

Reagent Blank (RBL) Frequency

Run an RBL every day.

Run an RBL when a reagent pack with a different lot number is placed on the system.

Note Use deionized water as the sample for the RBL in the ADVIA Chemistry PAMY 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 pancreatic amylase 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 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 automatically calculates and reports results based on the absorbance measurements of the test sample during the test, and the fixed-system Factor Value (FV).

The instrument calculates the concentration of pancreatic amylase 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 analyte concentrations. A comprehensive discussion of possible interfering substances, their serum 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.⁸

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.

Expected Values

The reference range for pancreatic amylase is 13–53 U/L.⁹

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 0–1500 U/L.

Results that are above the assay range are flagged H.

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay that extends the reportable range to 7500 U/L. You may configure the system to trigger automatic reruns. Rerun results will be flagged **Autorepeat**.

Precision

The precision of the ADVIA Chemistry PAMY assay was analyzed as described in CLSI protocol EP05-A2.¹⁰ Each sample was assayed 2 times per run, 1 or 2 runs per day, for at least 10 days.

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Specimen Type	Mean	Repeatability (Within-Run)		Within-Lab (Total)	
		SD ^a	CV ^b (%)	SD	CV (%)
Common Units (U/L)					
Control 1	126	0.7	0.5	3.3	2.6
Control 2	335	1.4	0.4	9.4	2.8

^a SD = standard deviation

^b CV = coefficient of variation

ADVIA 2400

Specimen Type	Mean	Repeatability (Within-Run)		Within-Lab (Total)	
		SD ^a	CV ^b (%)	SD	CV (%)
Common Units (U/L)					
Control 1	122	1.6	1.3	1.7	1.4
Control 2	334	1.9	0.6	2.4	0.7

^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 PAMY assay (y) was compared with the performance of the comparison assay on the indicated system (x).

ADVIA 1650/1800

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
Serum	Hitachi	103	0.999	$y = 1.00x + 1.9 \text{ U/L}$	4.0 U/L	15–1105 U/L

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Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
Serum	ADVIA 1650	100	0.99	$y = 0.94x - 0.5 \text{ U/L}$	0.9 U/L	1–91 U/L

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

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Interferent	Interferent Level	Pancreatic Amylase Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	25 mg/dL (428 µmol/L)	128 U/L	NSI ^a
Hemolysis (hemoglobin)	500 mg/dL (5.0 g/L)	121 U/L	NSI
Lipemia ^b (from triglycerides concentrate)	1000 mg/dL (11.3 mmol/L)	115 U/L	NSI
Lipemia ^b (from Intralipid)	1000 mg/dL (11.3 mmol/L)	124 U/L	NSI

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

^b SI units calculated as triolein

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Interferent	Interferent Level	Pancreatic Amylase Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	25 mg/dL (428 µmol/L)	45 U/L	NSI ^a
Hemolysis (hemoglobin)	1000 mg/dL (10.0 g/L)	47 U/L	NSI
Lipemia ^b (from Intralipid)	600 mg/dL (6.8 mmol/L)	41 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 PAMY assay is traceable to the IFCC reference method for total amylase. This traceability is results from the use of the same factor value (FV) as that used for ADVIA Chemistry AMYLAS assay (total amylase).

Technical Assistance

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




















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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
	<i>In vitro</i> diagnostic medical device	 REF	Catalog number
	Legal manufacturer	 EC REP	Authorized Representative in the European Community
	CE Mark	 0088	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

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