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**ADVIA® Chemistry XPT**
Systems

# Pancreatic Amylase (PAMY)

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| **Current Revision and Date**[a] | Rev. F, 2020-02 | |
| **Product Name** | ADVIA® Chemistry Pancreatic Amylase (PAMY) Reagents | REF 01410820 |
| **Systems** | ADVIA Chemistry XPT System | |
| **Materials Required but Not Provided** | Reagent container adapters<br>Commercially available controls | |
| **Specimen Types** | Human serum | |
| **Assay Principle** | Antibody-blocked colorimetric amylase | |
| **Assay Range** | Serum: 2–1500 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 XPT systems. Such measurements are used in the diagnosis and treatment pancreatic disorders.[1–4]

## Summary and Explanation

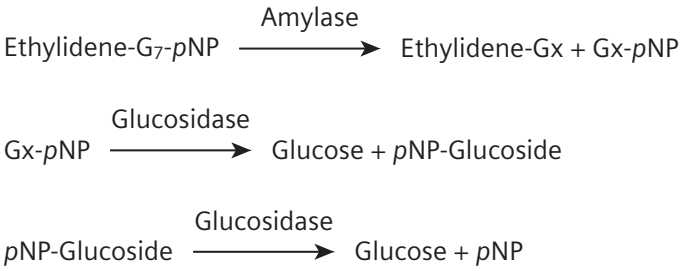
The ADVIA Chemistry Pancreatic Amylase (PAMY) assay measures pancreatic amylase activity in human serum by the amylase enzymatic reaction, with the non-pancreatic isoforms blocked by antibodies.

## 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-$G_2$, *p*NP-$G_3$, and *p*NP-$G_4$.

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<br>PAMY R1 | 14 mL in 20-mL containers<br>Hepes buffer, pH 7.15 (52.5 mmol/L)<br>Magnesium chloride (12.6 mmol/L)<br>Sodium chloride (87 mmol/L)<br>Glucosidase (≥ 4 U/mL)<br>Monoclonal antibodies (mouse) (42 µg/mL)<br>$NaN_3$ (0.09%) | 2–8°C | **Unopened:** Stable until the expiration date on product.<br>**On-system:** 60 days |
| Pancreatic Amylase Reagent 2<br>PAMY R2 | 5.2 mL in 20-mL containers<br>Ethylidene-$G_7$-*p*NP (22 mmol/L)<br>$NaN_3$ (0.09%) | 2–8°C | **Unopened:** Stable until the expiration date on product.<br>**On-system:** 60 days |

## Warnings and Precautions

Safety data sheets (MSDS/SDS) available on 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<br>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 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 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 2–1500 U/L.

Results that are below the low end of the assay range are flagged **< Conc Range**. You should report the test result as < 2 U/L.

Results that are above the high end of 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 7500 U/L. You may configure the system to trigger automatic reruns. Rerun results will be flagged **Autorepeat**.

## Sensitivity

The ADVIA Chemistry PAMY assay performance at low levels was analyzed as described in CLSI guideline EP17-A2, and the limit of blank (LoB) and limit of detection (LoD) were determined.[10]

The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the ADVIA Chemistry PAMY assay is 0 U/L (rounded to reportable digits).

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 PAMY assay is 2 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 PAMY assay was analyzed as described in CLSI protocol EP05-A2.[11] Each sample was assayed 3 times per run, 1 or 2 runs per day, for at least 10 days.

| | | | Repeatability (Within-Run) | | Between-Run | | Between-Day | | Within-Lab (Total) | |
|---|---|---|---|---|---|---|---|---|---|---|
| Specimen Type | N | Mean (U/L) | SD[a] (U/L) | CV[b] (%) | SD (U/L) | CV (%) | SD (U/L) | CV (%) | SD (U/L) | CV (%) |
| Serum Control 1 | 60 | 46 | 0.5 | 1.2 | 0.5 | 1.1 | 0.2 | 0.4 | 0.8 | 1.6 |
| Serum Control 2 | 60 | 339 | 1.0 | 0.3 | 1.6 | 0.5 | 1.3 | 0.4 | 2.3 | 0.7 |
| Serum Pool 1 | 60 | 54 | 0.4 | 0.8 | 0.3 | 0.6 | 0.3 | 0.5 | 0.6 | 1.1 |
| Serum Pool 2 | 60 | 121 | 0.5 | 0.4 | 0.5 | 0.4 | 0.3 | 0.3 | 0.8 | 0.7 |
| Serum Pool 3 | 60 | 1189 | 4.1 | 0.3 | 5.7 | 0.5 | 0.0 | 0.0 | 7.0 | 0.6 |

[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).

| Specimen Type | Comparison Assay (x) | N | r | Regression Equation | Sy.x | Sample Range |
|---|---|---|---|---|---|---|
| Serum | ADVIA 2400 PAMY | 157 | 1.000 | y = 1.00x + 1.4 U/L | 3.9 U/L | 2–1460 U/L |
| Serum | ADVIA 1800 PAMY | 158 | 1.000 | y = 1.01x - 2.6 U/L | 4.5 U/L | 3–1451 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

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

| Interferent | Interferent Level | Pancreatic Amylase Sample Concentration | Interference |
|---|---|---|---|
| Bilirubin (conjugated) | 50 mg/dL (855 µmol/L) | 46 U/L | NSI[a] |
| | 50 mg/dL (855 µmol/L) | 53 U/L | NSI |
| | 50 mg/dL (855 µmol/L) | 1192 U/L | NSI |
| Bilirubin (unconjugated) | 50 mg/dL (855 µmol/L) | 45 U/L | NSI |
| | 37.5 mg/dL (641 µmol/L) | 52 U/L | NSI |
| | 50 mg/dL (855 µmol/L) | 52 U/L | +19.2% |
| | 50 mg/dL (855 µmol/L) | 1171 U/L | NSI |
| Hemolysis (hemoglobin) | 1000 mg/dL (10.0 g/L) | 44 U/L | NSI |
| | 1000 mg/dL (10.0 g/L) | 52 U/L | NSI |
| | 1000 mg/dL (10.0 g/L) | 1148 U/L | NSI |
| Lipemia[b] (triglycerides from Intralipid) | 800 mg/dL (9.0 mmol/L) | 46 U/L | NSI |
| | 600 mg/dL (6.8 mmol/L) | 53 U/L | NSI |
| | 800 mg/dL (9.0 mmol/L) | 53 U/L | +13.2% |
| | 800 mg/dL (9.0 mmol/L) | 1193 U/L | NSI |

[a] NSI = No significant interference. A percentage effect ≥ 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.[12]

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.

siemens.com/healthcare

## References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7. Clinical and Laboratory Standards Institute (formerly NCCLS). *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Fourth Edition.* CLSI document GP44-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
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10. Clinical and Laboratory Standards Institute (formerly NCCLS). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.* CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

11. Clinical and Laboratory Standards Institute (formerly NCCLS). *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* CLSI document EP05-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.
12. Twomey PJ, Don-Wauchope AC, McCullough D. Unreliability of triglyceride measurement to predict turbidity induced interference. *J Clin Pathol.* 2003 Nov;56(11):861–862.

## Definition of Symbols

The following symbols may appear on the product labeling:

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
| IVD | *In vitro* diagnostic medical device | REF REF | Catalog number |
| | Legal manufacturer | EC REP | Authorized Representative in the European Community |
| CE | CE Mark | CE 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 | Σ (n) | Contains sufficient for (n) tests |
| | Recycle | PRINTED WITH SOY INK | Printed with soy ink |
| **Rev.** | Revision | YYYY-MM-DD | Date format (year-month-day) |
| LOT | 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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