

Pancreatic Amylase CC* FS**

Diagnostic reagent for quantitative in vitro determination of pancreatic amylase in serum or plasma on DiaSys respons[®]920

Order Information

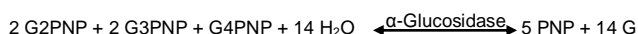
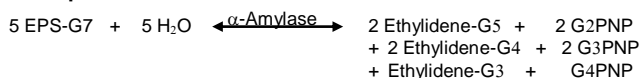
Cat. No. 1 0551 99 10 921

4 twin containers for 120 determinations each

Method

Enzymatic photometric test, in which the substrate 4,6-ethylidene-(G7)-p-nitrophenyl-(G1)-α-D-maltoheptaoside (EPS-G7) is cleaved by α-amylases into various fragments. These are further hydrolyzed in a second step by α-glucosidase producing glucose and p-nitrophenol [1,2]. As the salivary isoenzyme is inhibited selectively by a combination of two monoclonal antibodies during the preincubation phase, the increase in absorbance represents the pancreatic amylase activity in the sample [3-5].

Principle



(PNP = p-Nitrophenol, G =Glucose)

Reagents

Components and Concentrations

| | | | |
|------------|--|---------|-------------|
| R1: | Good's buffer | pH 7.15 | 0.1 mol/L |
| | NaCl | | 62.5 mmol/L |
| | MgCl ₂ | | 12.5 mmol/L |
| | α-Glucosidase | | ≥ 2,5 kU/L |
| | Monoclonal antibodies against salivary amylase (mouse) | | ≥ 31 mg/L |
| R2: | Good's buffer | pH 7.15 | 0.1 mol/L |
| | EPS-G7 | | 8.5 mmol/L |

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

- The remaining activity of salivary α-amylase is up to 3%. Very rarely, extremely high activities of salivary α-amylase may lead to increased readings of pancreatic α-amylase. However saliva and skin do contain α-amylase, therefore, avoid contact with the reagents.
- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- In very rare cases, samples of patients with gammopathy might give falsified results [10].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [6]:

7 days at 20 – 25°C

7 days at 4 – 8°C

1 year at –20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. This method is traceable to the molar extinction coefficient. For internal quality control, DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|----------|------------------|-----------|
| TruCal U | 5 9100 99 10 063 | 20 x 3 mL |
| | 5 9100 99 10 064 | 6 x 3 mL |
| TruLab N | 5 9000 99 10 062 | 20 x 5 mL |
| | 5 9000 99 10 061 | 6 x 5 mL |
| TruLab P | 5 9050 99 10 062 | 20 x 5 mL |
| | 5 9050 99 10 061 | 6 x 5 mL |

Performance Characteristics

| | |
|--|-----------------|
| Measuring range up to 2000 U/L P-amylase (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function). | |
| Limit of detection*** | 2 U/L P-amylase |
| On-board stability | 4 weeks |
| Calibration stability | 4 weeks |

| |
|--|
| Interferences < 10% by |
| Ascorbate up to 30 mg/dL |
| Bilirubin up to 60 mg/dL |
| Lipemia (triglycerides) up to 1800 mg/dL |
| Hemoglobin interferes at low concentrations |
| For further information on interfering substances refer to Young DS [7]. |

| Precision | | | |
|------------------------------|----------|----------|----------|
| Within run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [U/L] | 39.5 | 149 | 234 |
| Coefficient of variation [%] | 2.19 | 2.18 | 1.35 |
| Between run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [U/L] | 39.0 | 145 | 218 |
| Coefficient of variation [%] | 2.86 | 2.47 | 3.73 |

| Method comparison (n=115) | |
|----------------------------|---|
| Test x | DiaSys P-Amylase CC FS (Hitachi 917) |
| Test y | DiaSys P-Amylase CC FS (respons [®] 920) |
| Slope | 1.01 |
| Intercept | -0.652 U/L |
| Coefficient of correlation | 0.999 |

*** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

Pancreatic amylase [U/L] x 0.0167= Pancreatic amylase [μkat/L]

Reference Range [8]

| | | |
|--------------|---------------|---------------|
| | Women | Men |
| Serum/plasma | < 53 U/L | < 53 U/L |
| | < 0.88 μkat/L | < 0.88 μkat/L |

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Lorentz K. α -Amylase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 192-202.
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4. Kruse-Jarres JD, Kaiser C, Hafkenscheid JC, Hohenwallner W, Stein W., Bohner J et al. Evaluation of a new alpha-amylase assay using 4,6-ethylidene-(G7)-1-4-nitrophenyl-(G1)-alpha,D-maltoheptaoside as substrate. J Clin Chem Biochem 1989; 27: 103-13.
5. Tietz NW, Burlina A, Gerhardt W, Junge W, Maffertheimer P, Mural T et al. Multicenter evaluation of a specific pancreatic isoamylase assay based on a double monoclonal-antibody technique. Clin Chem 1988; 34: 2096-102.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 16-17.
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8. Junge W, Wortmann W, Wilke B, Waldenstroem J et al. Development and evaluation of assays for determination of total and pancreatic amylase at 37 °C according to the principle recommended by the IFCC. Clin Biochem 2001; 34: 607-15.
9. Junge W, Troge B, Klein G, Poppe W, Gerber M. Evaluation of a new assay for pancreatic amylase: Performance characteristics and estimation of reference interval. Clin Biochem 1989; 22: 109-14.
10. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
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Pancreatic Amylase CC FS

Application for serum and plasma

| Test Details | | Test Volumes | | Reference Ranges | |
|--------------------|----------------------|---------------------|-----------|--------------------------|--------------------------|
| Test | : PAMY | | | Auto Rerun | <input type="checkbox"/> |
| Report Name | : Pancreatic Amylase | | | Online Calibration | <input type="checkbox"/> |
| Unit | : U/L | Decimal Places | : 1 | Cuvette Wash | <input type="checkbox"/> |
| Wavelength-Primary | : 405 | Secondary | : 700 | Total Reagents | : 2 |
| Assay Type | : RATE - A | Curve Type | : Linear | Reagent R1 | : PAMY R1 |
| M1 Start | : 0 | M1 End | : 0 | Reagent R2 | : PAMY R2 |
| M2 Start | : 26 | M2 End | : 33 | | |
| Sample Replicates | : 1 | Standard Replicates | : 3 | Consumables/Calibrators: | |
| Control Replicates | : 1 | Control Interval | : 0 | Blank/Level 0 | : 0 |
| Reaction Direction | : Increasing | React. Abs. Limit | : 2.50 | Calibrator 1 | : * |
| Prozone Limit % | : 0 | Prozone Check | : Lower | | |
| Linearity Limit % | : 0 | Delta Abs./Min. | : 0.00 | | |
| Technical Minimum | : 2.00 | Technical Maximum | : 2000.00 | | |
| Y = aX + b | a= : 1.00 | b= | : 0.00 | | |

* Enter calibrator value.

| Test Details | | Test Volumes | | Reference Ranges | |
|--|----------------|------------------|----------|---|--|
| Test | : PAMY | | | | |
| Sample Type | : Serum | | | | |
| Sample Volumes | | | | Sample Types | |
| Normal | : 4.00 μ L | Dilution Ratio | : 1 X | <input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other | |
| Increase | : 8.00 μ L | Dilution Ratio | : 1 X | | |
| Decrease | : 2.00 μ L | Dilution Ratio | : 1 X | | |
| Standard Volume | : 4.00 μ L | | | | |
| | | | | | |
| Reagent Volumes and Stirrer Speed | | | | | |
| RGT-1 Volume | : 160 μ L | R1 Stirrer Speed | : Medium | | |
| RGT-2 Volume | : 40 μ L | R2 Stirrer Speed | : High | | |

| Test Details | | Test Volumes | | Reference Ranges | |
|------------------------|-----------|--------------|--|---------------------|---|
| Test | : PAMY | | | | |
| Sample Type | : Serum | | | | |
| Reference Range | : DEFAULT | | | | |
| Category | : Male | | | | |
| Reference Range | | | | Sample Types | |
| | | Lower Limit | | Upper Limit | |
| | | (U/L) | | (U/L) | |
| Normal | : 0.00 | | | 53.00 | <input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other |
| Panic | : 0.00 | | | 0.00 | |