

PANCREAS-AMYLASE liquicolor

Enzymatic Colorimetric Test for the Quantitative Determination of Pancreas-Amylase

Package Size

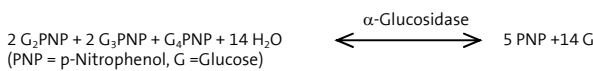
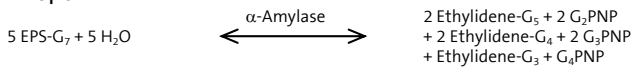
| | | | |
|-----|-------|-----------|-------------------|
| REF | 12009 | 4 x 10 ml | Complete Test Kit |
| | 12029 | 6 x 20 ml | Complete Test Kit |

IVD

Method

α -Amylases are hydrolytic enzymes which break down starch into maltose. The pancreatic amylase (p-amylase) is produced solely by the pancreas and released into the intestinal tract. As pancreatic and salivary amylase show a structural homology of 97%, the only method to distinguish both sufficiently is to use an assay based on monoclonal antibodies to inhibit the salivary enzyme. The amylase present in the blood is eliminated through the kidney and excreted into the urine. Therefore, elevation of serum activity is reflected in the rise of urinary amylase activity. Measurement of pancreatic amylase in serum and urine is mainly applied for the diagnosis of pancreatic disorders as well as for detecting the development of complications. In acute pancreatitis the blood amylase activity increases within few hours and returns to values within the reference range at the latest after 5 days. Although the pancreatic amylase is much more specific for detection of pancreatic disorders than the total amylase, for confirmation of an acute pancreatitis an additional measurement of lipase is recommended.

Principle



Contents

| | | | |
|-----|--|-----------|---|
| REF | 12009 | 12029 | |
| BUF | 4 x 10 ml | 6 x 20 ml | |
| SUB | 2 x 5 ml | 6 x 5 ml | |
| BUF | Buffer Good's Buffer NaCl MgCl ₂ α -Glucosidase Monoclonal antibodies against salivary amylase Sodium azide | | pH 7.15 0.1 mol/l 62.5 mmol/l 12.5 mmol/l ≥ 2.5 kU/l ≥ 31 mg/l 0.95 g/l |
| SUB | Substrate reagent Good's Buffer EPS-G7 Sodium azide | | pH 7.15 0.1 mol/l 8.5 mmol/l 0.95 g/l |

Additional Material not Supplied with the Kit

| | |
|-----|---|
| REF | 13160 |
| CAL | 4 x for 5 ml AUTOCAL lyophilised Calibrator for HUMAN Clinical Chemistry Systems |

Reagent Preparation and Stability

Reagents are ready for use and stable until the expiration date stated on the label, when stored at 2...8°C. Avoid freezing and contamination.

Specimen

Serum or heparin or EDTA plasma, urine

Stability in serum/plasma:
7 days at 20...25°C
7 days at 2...8°C
1 year at -20°C

Stability in urine:
2 days at 20...25°C
10 days at 2...8°C
3 weeks at -20°C

Discard contaminated specimens.

Interferences

Bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl and ascorbic acid up to 30 mg/dl do not interfere with the results. Hemoglobin interferes even at low concentrations and therefore hemolytic samples should be avoided.

Assay

Wavelength: 405 nm (reference wavelength 660 nm)
Optical path: 1 cm
Temperature: 37°C
Measurement: against reagent blank

Pipetting Scheme

| | | | |
|--|--------------|--------------|--------------|
| Pipette into cuvettes: | | | |
| | Blank | Sample | Urine |
| Calibrator/sample | - | 20 μ l | 10 μ l |
| BUF | 1000 μ l | 1000 μ l | 1000 μ l |
| Mix carefully, incubate for 3 minutes. Start reaction by adding SUB. | | | |
| SUB | 250 μ l | 250 μ l | 250 μ l |
| Mix, incubate 2 min at 37°C, read absorbance and start stop watch. After exactly 1, 2 and 3 min read absorbance again and then calculate $\Delta A/\text{min}$. | | | |

Calculation

$$\Delta A/\text{min} = [\Delta A/\text{min}_{\text{sample or calibrator}}] - [\Delta A/\text{min}_{\text{blank}}]$$

$$\text{p-amylase activity [U/l]} = \frac{\Delta A/\text{min (sample)}}{\Delta A/\text{min (calibrator)}} \times \text{activity calibrator [U/l]}$$

$$\text{Or: p-amylase activity [U/l]} = \Delta A/\text{min} \times 5670$$

Performance Characteristics

Linearity: 5 - 2000 U/l

No prozone phenomenon observed.

Linearity and potential prozone limit depend on the analyzer in use.

Typical performance data can be found in the Verification Report, accessible via

www.human.de/data/gb/vr/en-pamy.pdf or
www.human-de.com/data/gb/vr/en-pamy.pdf

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

Reference Values

| | Females | Men |
|--------------|-------------------------------|-------------------------------|
| Serum/plasma | < 53 U/l; < 0.88 μ kat/l | < 53 U/l; < 0.88 μ kat/l |
| Urine | < 319 U/l; < 5.32 μ kat/l | < 356 U/l; < 5.93 μ kat/l |

These ranges are given for orientation only. Each laboratory should establish its own reference values.

Automation

Proposals to apply the reagents on analyzers are available on request. Each laboratory has to validate the application in its own responsibility.

Quality Control

All control sera with pancreatic amylase activities determined by this method can be employed.

Notes

- 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 amylase. Saliva and skin do contain α -amylase and can therefore cause contamination. Contact of reagents with skin and saliva should be carefully avoided.
- Simultaneous determination of pancreatic amylase and alpha-amylase can lead to reagent carryover and erroneous alpha-amylase results. Additional wash steps should be performed to avoid reagent carryover.
- SUB may turn yellowish during shelf life. This does not affect the test performance as long as the reagent blank is < 0.300 A. Otherwise SUB should no longer be used.
- In rare cases false results can be observed in patients with gammopathy.

Safety Notes

BUF SUB

Precautionary statements

P234 Keep only in original container.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

References

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Human