**INTENDED USE**
Reagent for quantitative in vitro determination of amylase in biological fluids.

**SUMMARY OF TEST**
Assays of amylase activity in serum and urine are largely used in the diagnosis of diseases of the pancreas and in the investigation of pancreatic function.

**PRINCIPLE OF THE METHOD**
The enzyme α-amylase (EC 3.2.1.1, 1,4-α-D-glucan glucohydrolase) hydrolyzes the EPS to release several different fragments. The fragments so formed are completely hydrolyzed to 4-nitrophenol and glucose by α-glucosidase.
The 4-nitrophenol formed is detected spectrophotometrically at 405 nm to give a measurement of α-amylase activity in the sample. The present method has been made according to IFCC.

**KIT COMPONENTS**
For in vitro diagnostic use only.
The components of the kit are stable until expiration date as indicated on the label. Keep away from direct light sources.

**DO NOT PIPEET BY MOUTH!**
AMY EPS R1 F080: 4 x 16 ml (liquid) blue cap
F245: 12 x 16 ml (liquid) blue cap
AMY EPS R2 F080: 1 x 16 ml (liquid) red cap
F245: 3 x 16 ml (liquid) red cap

Composition in the test: Hepes buffer 50 mM pH 7.10, NaCl 70 mM, calcium acetate 1.0 mM, EPS-G7 5.0 mM, α-glucosidase 6 kU/l.

Store all components at 2-8°C.

**MATERIALS REQUIRED BUT NOT SUPPLIED**

**REAGENT PREPARATION**
Serum as starter procedure: Add 4 ml of reagent R2 to a vial of reagent R1. Stability of working reagent: 60 days at 2-8°C, away from light sources.

Reagent as starter procedure: use separate reagents ready to use. Stability: up to expiration date on labels at 2-8°C; Stability since first opening of vials: preferably within 60 days at 2-8°C.

**PRECAUTIONS**
Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

**SPECIMEN**
Serum, plasma (heparinate only). Urine. Amylase is stable in serum and plasma sample up to 2 months at 2-8°C.

**TEST PROCEDURE (sample as starter)**

<table>
<thead>
<tr>
<th>Wavelength: 405 nm</th>
<th>Lighthpath: 1 cm</th>
<th>Temperature: 37°C</th>
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<tbody>
<tr>
<td>dispense in cuvette working reagent: 1.5 ml</td>
<td>preincubate at 37°C for 5 minutes.</td>
<td>add sample: 50 µl</td>
</tr>
</tbody>
</table>

Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.

**RESULTS CALCULATION**
Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 3480

Calculation in µkat/l: U/l x 0.0167 = µkat/l

**EXPECTED VALUES**

- **Serum - plasma:** 28 - 100 U/l (0.47 - 1.67 µkat/l)
- **Random urine:** ≤ 460 U/l (≤ 7.68 µkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

**QUALITY CONTROL AND CALIBRATION**

The present method has been made according to IFCC. It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

- QUANTINORM CHENA with normal or close to normal control values
- QUANTIPATH CHENA with pathological control values.

If required, a multiparametric, human based calibrator is available:

- AUTOCAL H

Please contact Customer Care for further information.

**TEST PERFORMANCE**

- **Linearity:** the method is linear up to 1500 U/l.
- **Sensitivity/limit of detection (LOD):** the limit of detection is 6 U/l.

- **Interferences:**
  - No interference was observed by the presence of:
    - hemoglobin ≤ 200 mg/dl
    - bilirubin ≤ 48 mg/dl
    - lipids interfere in low values

- **Precision:**
  - Intra-assay (n=10) mean (U/l) SD (U/l) CV%
    - sample 1 77.90 0.74 0.90
    - sample 2 194.80 1.99 1.00
  - Inter-assay (n=20) mean (U/l) SD (U/l) CV%
    - sample 1 75.77 1.90 2.50
    - sample 2 194.15 2.39 1.20

- **Methods comparison:**
  - A comparison between Chema Amylase FL and a commercially available product gave the following results:

    Amylase Chema = x
    Amylase competitor = y
    n = 108
    \[ y = 1.067x + 5.21 \text{ U/l} \]
    \[ r^2 = 0.99 \]

**WASTE DISPOSAL**
This product is made to be used in professional laboratories. P501: Dispose of contents according to national/internaional regulations.

**REFERENCES**


**MANUFACTURER**
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e-mail: mail@chema.com
website: http://www.chema.com

**SYMBOLS**

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