**INTENDED USE**
Diagnostic reagent for quantitative in vitro determination of alpha-Amylase in human serum and plasma.

**CLINICAL SIGNIFICANCE**
α-Amylase is derived mainly from the salivary glands and the exocrine pancreas. α-Amylase catalyses the hydrolysis of α-1,4 glucosidic linkages of starch and other related polysaccharides to produce maltose and other oligosaccharides. The enzyme is a relatively small molecule which is rapidly cleared by the kidneys and excreted in the urine.

α-Amylase is most frequently measured in the diagnosis of acute pancreatitis when serum levels may be grossly elevated. In acute pancreatitis α-amylase starts to rise approximately 4 hours after the onset of pain, reaches a peak at 24 hours and remains elevated for 3-7 days. Hyperamylasemia is also associated with other acute abdominal disorders, biliary dysfunction, salivary gland disorders, ruptured ectopic pregnancy and macroamylasemia.

**PRINCIPLE**
2-Chloro-4-nitrophenol-β -1- 4 galactopyranosylmaltotrioside (CNP-G) is a direct substrate for determination of α-amylase activity, which does not require the presence of ancillary enzymes. The rate of 2-chloro-4-nitrophenol formation can be monitored at (400-420) nm and is proportional to the α-amylase activity.

**REAGENT COMPOSITION**
- MES buffer 0.91 mmol/l
- Sodium Azide 13.85 mmol/l
- Potassium Thiocyanate 450 mmol/l
- Sodium Chloride 300 mmol/l
- Calcium Chloride 3.81 mmol/l
- CNPG 0.91 mmol/l

**REAGENT PREPARATION**
Reagent is liquid, ready to use.

**STABILITY AND STORAGE**
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

**SPECIMEN COLLECTION AND HANDLING**
Use serum, plasma (heparin, EDTA), urine. It is recommended to follow NCCLS procedures (or similar standardized conditions).

**STABILITY**
- in serum/plasma: 7 days at 20–25°C
- in urine: 2 days at 20–25°C

Discard contaminated specimens.

**CALIBRATION**
Calibration with calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

**EXPECTED VALUES**
- at 37°C
  - Serum: up to 80 U/I
  - Urine: up to 500 U/I

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

**PERFORMANCE DATA**
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

**STABILITY**
- Serum: 7 days at 2-8°C
- Urine: 7 days at 20–25°C

**EXPECTED VALUES IN VITRO**
- Measured in urine: 1 year at -20°C
- Measured in serum: 3 weeks at -20°C

It is recommended to follow NCCLS procedures (or similar standardized conditions).

**INTERFERENCES**
- Following substances do not interfere: haemoglobin up to 2.5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.
- Note: Saliva and skin contain alpha-amylase therefore never pipette reagents by mouth and avoid contamination of samples and reagents. Even trace contamination can affect results.

**WARNING AND PRECAUTIONS**
For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

**REFERENCE RANGE**
- Serum: 0-10 U/I
- Urine: 0-50 U/I

**OTHER**
- Applications for automatic analysers are available on request.

**WASTE MANAGEMENT**
Please refer to local legal requirements.

**ASSAY PROCEDURE**

**Wavelength:** 405 (400 – 420) nm

**Cuvette:** 1 cm

| Working solution | 1000 µl |
| Sample | 20 µl |

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (DA/min).

2. Using factor:

Amylase activity (UI) = f x DA/min

C_cal = calibrator concentration

f = factor

f = 3128 (at 405 nm)

**APPLICATIONS FOR AUTOMATICAL ANALYSERS**

**ASSAY PARAMETERS FOR PHOTOMETERS**

<table>
<thead>
<tr>
<th>Mode</th>
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<tbody>
<tr>
<td>Wavelength (nm)</td>
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<tr>
<td>Sample Volume (µl)</td>
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<tr>
<td>Working Reagent Volume (µl)</td>
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<tr>
<td>Units</td>
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REFERENCES