AMYLASE SL

In vitro diagnostic reagent, for professional use only

CLINICAL SIGNIFICANCE (1,2)

α-Amylase is an enzyme from pancreatic or salivary origin that hydrolyses 1,4-α-glucosidic bonds, thus helping for starch digestion. Analysis of serum amylase is mainly used in the diagnosis of the pancreatic diseases (acute or chronic pancreatitis and their complications, carcinoma). During acute pancreatitis, a transitory increase of serum amylase is observed, a peak being reached approximately 12h after the beginning, the activity returning to the normal after 3 or 4 days. However, a serum amylase increase is also observed in other intra-abdominal pathologies, ovary or lung cancers, salivary gland lesions, acute alcoholism, renal insufficiency or macroamylasemia (presence of a complex amylase-IgG not filtered by the glomerulus).

METHODE (3)

Substrate: CNP-G3 (2-chloro-4-nitrophenyl-α-maltotrioside)
Enzymatic, Kinetic

PRINCIPLE (3)

Substrate CNP-G3 is hydrolyzed by catalytic action of α-amylose to produce CNP (2-chloro-4-nitrophenol).

\[
\text{α-Amylase} \quad 5 \text{CNP-G3} \rightarrow 3 \text{CNP} + 2 \text{CNP-G2} + 3 \text{Maltotriose} + 2 \text{Glucose}
\]

CNP-G2 = 2-Chloro-4-nitrophenyl-α-maltoside

REAGENT COMPOSITION

Reagent : R

- MES buffer, pH 6.15 : 50 mmol/L
- Sodium chloride : 70 mmol/L
- Calcium chloride : 6 mmol/L
- Potassium thiocyanate : 900 mmol/L
- CNP-G3 : 2.27 mmol/L

MATÉRIEL REQUIRED BUT NOT PROVIDE

- CONT-0060 ELITROL I 10 x 5 mL
- CONT-0160 ELITROL II 10 x 5 mL

PRECAUTIONS

The reagent contains less than 0.1% sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalisations, rinse with plenty of water.
- It is advisable not to mix this reagent with acids.
- Use clean or single use laboratory equipment only to avoid contaminations.
- Saliva and sweat contain amylase. It is therefore recommended to wear gloves and a mask to avoid the contamination of the reagent.
- Store protected from light.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local and legal requirements.

STABILITY OF REAGENTS

To store at 2-8°C and protected from light.

The reagent is stable until the expiry date stated on the label.

On board stability:

The stability is specific for each analyser (for Selectra refer to § PERFORMANCE DATA)

Preparation and Stability of Working Reagent

The reagent is ready to use.

SAMPLES (1,2,5)

- Specimen
  - Serum
  - Heparinized plasma

- Storage
  Samples are stable 1 week at room temperature and 1 month at 4°C.

REFERENCE VALUES (4)

Serum, plasma (37°C): < 90 U/L

Note:
It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

PROCEDURE

This reagent can be used on most analysers, semi automated analysers and manual method.

The applications are available on request.

Wavelength: 405 nm
Temperature: 37°C
Read against distilled water

Mix and after a 25 seconds incubation, measure the change of absorbance per minute (ΔA/min) during 4 minutes.

CALCULATION (3)

At 405 nm, with a 1 cm light path cuvette:

\[
\text{Activity (U/L)} = \Delta A/\text{min} \times 2949 \text{ at 37°C}
\]

QUALITY CONTROL

To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) are recommended.

PERFORMANCE DATA at 37°C on Selectra

- Analytical range
  The reagent is linear from 25 to 2000 U/L.
- Detection limit (6)
  Determined according to the SFBC, the detection limit is equal to 7 U/L.
- Analytical Sensitivity
  The average variation of the analytical signal is 0.34 mΔA/min per U/L of amylase for a light path of 1 cm.
- Precision
  Within-run reproducibility

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
<th>m</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low level</td>
<td>20</td>
<td>61</td>
<td>1.5 %</td>
</tr>
<tr>
<td>Medium level</td>
<td>20</td>
<td>216</td>
<td>1.8 %</td>
</tr>
<tr>
<td>High level</td>
<td>20</td>
<td>362</td>
<td>0.7 %</td>
</tr>
</tbody>
</table>

References:

AMSL - 0390 1 x 50 mL
AMSL - 0400 6 x 50 mL

Kit composition:

R 1 x 50 mL
R 6 x 50 mL

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**AMYLASE SL**

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**Between-run reproducibility**

- **Low level:**  
  n = 20  
  m = 92 U/L  
  CV = 2.5%

- **Medium level:**  
  n = 20  
  m = 223 U/L  
  CV = 1.7%

- **High level:**  
  n = 20  
  m = 1442 U/L  
  CV = 2.4%

**- Correlation**

A comparative study was performed between ELITech method and another commercial reagent (Enzymatic method – CNP-G7 substrate (blocked p-nitrophenyl-maltoheptaoside)) on 52 human serum samples. The sample concentrations ranged up to 1800 U/L.

The parameters of linear regression are as follows:

- **Correlation coefficient:**  
  (r) = 0.9994

- **Linear regression:**  
  y = 1.11 x - 0.5 U/L

**- Interferences (6,7)**

According to SFBC recommendations, studies were performed to determine the level of interference from different compounds:

- **Hemoglobin:** Negative bias from 145 mg/dL on normal serum (1.45 g/L). Negative bias from 75 mg/dL on pathological serum (0.75 g/L).
- **Triglycerides:** No significant interference up to 1000 mg/dL (10 g/L).
- **Bilirubin:** No significant interference up to 36 mg/dL (360 mg/L; 616 µmol/L).

Other compounds may interfere. (8-10)

**- On board stability (not cooled)**

On board stability: 28 days (capped vials and stored at 2-8 °C during the night).

**BIBLIOGRAPHY**


**SYMBOLS USED ON LABELS**

- **IVD**: In vitro diagnostic medical device
- **R**: Consult Instruction for use
- **REF**: Manufacture’s address
- **LOT**: Catalogue number
- **T**: Temperature limitation
- **E**: Expiration date

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