Enzymatic, Kinetic insufficiency or macroamylasemia (presence of a complex amylase-IgG not filtered by the glomerulus).

intra-abdominal pathologies, renal insufficiency, ovary cancers, salivary gland lesions, acute alcoholism, renal activity returning to the normal after 3 to 5 days. However, a serum amylase increase is also observed in other pancreatitis and their complications, carcinoma). During acute pancreatitis, a transitory increase of serum amylase digestion. Analysis of serum amylase is mainly used in the diagnosis of the pancreatic diseases (acute or chronic

Method

The rate of increase in absorbance is measured at 405 nm and is directly proportional to the activity

Substrate: CNP-G₂ (2-chloro-4-nitrophenyl-α-maltoside)
Enzymatic, Kinetic

PRINCIPLE

Substrate CNP-G₃ is hydrolyzed by catalytic action of α-amylase to produce CNP (2-chloro-4-nitrophenol), Enzymatic, Kinetic

The rate of increase in absorbance is measured at 405 nm and is directly proportional to the activity u-amylase in the sample.

Reagents Composition

Reagent: R
MIES buffer, pH 6.15 50 mmol/L
Sodium chloride 70 mmol/L
Calcium chloride 6 mmol/L
Potassium thiocyanate 900 mmol/L
CNP-G₂ 2.27 mmol/L
Sodium azide < 0.1 %

Material Required but Not Provided

- ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
- ELITROL I, control serum, ref.CONT-0080, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0180, 10 x 5 mL.
- General Laboratory equipment.

Precautions and Warning

- This reagent kit is for professional in vitro diagnostic use only.
- Contact with acids liberates toxic gas.
- Saliva and sweat contain amylase. It is therefore recommended to wear gloves and a mask to avoid the contamination of the reagent.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The reagent contains less than 0.1 % sodium azide. Sodium azide can react with copper and lead to form explosive metal azides. If discharged in the plumbing system, rinse with plenty of water.
- For more information, Safety Data Sheet (SDS) is available on request for professional users.

Waste Management

Disposal of all waste material should be in accordance with local, state, and Federal regulatory requirements.

Stability of Reagents

Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label. On board stability: Refer to § PERFORMANCE DATA.

Preparation

The reagent is ready to use.

Reagent Deterioration

The reagent solution should be clear. Cloudiness would indicate deterioration. Any reagent showing evidence of contamination should be discarded.

Samples

- Specimen
- Serum
- Lithium heparinized plasma
- Storage

Serum and plasma are stable 1 week at room temperature, 1 week at 2-8 °C and 1 year at -20 °C.

References

- AMSL-0230 6 x 20 mL
- R: 6 x 20 mL

AMYLASE SL

Kit composition:

Enzymatic, Kinetic

Calculation

See application included in the barcode indicated at the end of the insert.

Quality Control

To ensure accurate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) should be used. These controls should be assayed together with patient samples, at least once a day and after each calibration. The control frequency should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined range, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

Performance Data at 37 °C

A) On ELITech Clinical Systems Selectra ProM Analyzers

- Measuring range
  Determined according to CLSI EP6-A protocol(10), the measuring range is from 20 to 1500 U/L (0.33 to 25.0 μkat/L). Samples exceeding 1500 U/L should be diluted 1:10 with NaCl 9 g/L, solution (neutral saline) and re-assayed. Use of this procedure extends the measuring range from 1500 to 15000 U/L (25.00 to 250.00 μkat/L). This extended measuring range was confirmed in a study where a high concentration of amylase was spiked into native serum samples. The recovery observed did not exceed the expected recovery by > ± 10 %.
  The « rerun dilution » function performs the sample dilution automatically. Results take the dilution into account.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
  Determined according to CLSI EP17-A protocol(12).
  LoD = 6 U/L (0.10 μkat/L)
  LoQ = 13 U/L (0.22 μkat/L)

- Precision
  Determined according to CLSI EP5-A protocol(12).

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean μkat/L</th>
<th>Within-run CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>80</td>
<td>1.37</td>
</tr>
<tr>
<td>Medium</td>
<td>204</td>
<td>0.9</td>
</tr>
<tr>
<td>High</td>
<td>992</td>
<td>1.63</td>
</tr>
</tbody>
</table>

- Correlation
  A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (IFCC method) on 100 human serum samples according to CLSI EP9-A protocol(9). The sample concentrations were between 21 and 1439 U/L (0.35 and 23.96 μkat/L). The parameters of the linear regressions are as follows:
  Correlation coefficient: (r) = 0.999
  Linear regression: y = 0.976 x + 1.0 U/L (0.02 μkat/L)

- Interferences
  Studies have been performed to determine the level of interference from different compounds according to CLSI EPT-2 protocol(12). Recovery within ± 10% of initial value of amylase activity of 80 and 1000 U/L.
  Triglycerides: No significant interference up to 3000 mg/dL (33.9 mmol/L).
  Conjugated bilirubin: No significant interference up to 30 mg/dL (2.0 μmol/L).
  Copper: No significant interference up to 29.5 mg/dL (504 μmol/L).
  Hemoglobin: No significant interference up to 5.0 g/dL (113 μmol/L).
  Aspartate aminotransferase: No significant interference up to 20.0 mg/dL (111 μmol/L).
  Acetaminophen: No significant interference up to 30 mg/dL (2.0 mmol/L).
  Other compounds may interfere(12,13).

- On board stability / calibration frequency
  On-board stability: 28 days.
  Calibration frequency: 28 days.
  Make a new calibration when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.
B) On ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range
  Determined according to CLSI EP6-A2 protocol(10), the measuring range is from 20 to 1500 U/L (0.33 to 25.00 μkat/L). Samples exceeding 1500 U/L should be diluted 1:10 with NaCl 9 g/L solution (normal saline) and re-assayed. Use of this procedure extends the measuring range from 1500 to 15000 U/L (25.00 to 250.00 μkat/L). This extended measuring range was confirmed in a study where a high concentration of amylase was spiked into native serum samples. The recovery observed did not exceed the expected recovery by ± 10%.

  The « rerun dilution » function performs the sample dilution automatically. Results take the dilution into account.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)
  Determined according to CLSI EP17-A protocol(7).

  Low level: 4 U/L (0.07 μkat/L)
  Medium level: 20 U/L (0.33 μkat/L)
  High level: 13 U/L (0.22 μkat/L)

- Precision
  Determined according to CLSI EP6-A2 protocol(10).

<table>
<thead>
<tr>
<th>Mean Within-run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n U/L</td>
<td>μkat/L</td>
</tr>
<tr>
<td>Low level</td>
<td>80</td>
</tr>
<tr>
<td>Medium level</td>
<td>80</td>
</tr>
<tr>
<td>High level</td>
<td>80</td>
</tr>
</tbody>
</table>

- Correlation
  A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (IFCC method) on 100 human serum samples according to CLSI EP6-A2 protocol(10).

  The sample concentrations were between 23 and 1426 U/L (0.38 and 23.77 μkat/L).

  The parameters of the linear regressions are as follows:
  Correlation coefficient: \( r = 0.999 \)
  Linear regression: \( y = 0.954x + 5 \text{μkat/L} \)

- Interferences
  Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol(10).

  - Triglycerides: No significant interference up to 3000 mg/dL (33.9 mmol/L).
  - Conjugated bilirubin: No significant interference up to 30.0 mg/dL (504 μkat/L).
  - Hemoglobin: No significant interference up to 500 mg/dL.
  - Acetaminophen: No significant interference up to 30 mg/dL (2.0 mmol/L).
  - Acetylsalicylic acid: No significant interference up to 200 mg/dL (11.1 mmol/L).
  - Ascorbic acid: No significant interference up to 20.0 mg/dL (1136 μmol/L).
  - Hemodialysis: No significant interference up to 170 mg/dL (29.5 μkat/L).
  - Protein precipitation: No significant interference up to 100mg/dL (1.9 mmol/L).
  - In very rare cases, monoclonal gammapathies (multiple myeloma), in particular IgM type (Waldenström’s macroglobulinemia) can cause unreliable results(11).
  - Other compounds may interfere(12,13).

- On board stability / calibration frequency
  On-board stability: 28 days.
  Calibration frequency: 28 days.

  Make a new calibration when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

BIBLIOGRAPHY