ELITechGroup
CLINICAL SYSTEMS

ELITech Clinical Systems
Selectra Pro Series Analyzers

AMYLASE SL

***In vitro* diagnostic reagent, for professional use only**

☛***References :***
AMSL-0230 6 x 20 mL

Kit composition :
***R**: 6 x 20 mL*

☛**CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)**

INTENDED USE
ELITech Clinical Systems AMYLASE SL is intended for the quantitative *in vitro* determination of amylase in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers.
Measurements of amylase are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).
It is not intended for use in Point of Care settings*.

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 corresponding to of 4 to 6-fold elevation being reached in 12 to 72h after the beginning, the activity returning to the normal after 3 to 5 days. However, a serum amylase increase is also observed in other intra-abdominal pathologies, renal insufficiency, ovary cancers, salivary gland lesions, acute alcoholism, renal insufficiency or macroamylasemia (presence of a complex amylase-IgG not filtered by the glomerulus).

METHOD [3]
Substrate: CNP-G_3 (2-chloro-4-nitrophenyl-α-maltotrioside)
Enzymatic, Kinetic

PRINCIPLE [3]
Substrate CNP-G3 is hydrolyzed by catalitic action of α-amylase to produce CNP (2-chloro-4-nitrophenol).

$$5\ \text{CNP-G}_3 \xrightarrow{\alpha\text{-Amylase}} 3\text{CNP} + 2\text{CNP-G}_2 + 3\ \text{Maltotriose} + 2\ \text{Glucose}$$

CNP-G_2 = 2-Chloro-4-nitrophenyl-α-maltoside

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

REAGENTS 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-G_3	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 plumbing 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 user.

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 [4]
- 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.

REFERENCE VALUES [5]
Serum, plasma (37 °C): 31-107 U/L

Note : *It is recommended that each laboratory establishes and maintains its own reference values. The data given here are only for information.*

Conversion factor: U/L x 0.0167 = µkat/L

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

CALIBRATION
For calibration, multiparametric calibrator Elical 2 must be used. Its value is traceable to IFCC method[5]
Calibration frequency : Refer to § PERFORMANCE DATA.

QUALITY CONTROL
To ensure adequate 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 ranges, 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[6], 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].

LoD = 6 U/L (0.10 µkat/L)
LoQ = 13 U/L (0.22 µkat/L)

- Precision
Determined according to CLSI EP5-A2 protocol[8].

		Mean		Within-run	Total
	n	U/L	µkat/L	CV (%)	
Low level	80	82	1.37	1.3	2.7
Medium level	80	204	3.40	0.9	2.2
High level	80	992	16.53	1.5	2.6

- 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-A2 protocol[9].
The sample concentrations were between 21 and 1439 U/L (0.35 and 23.98 µkat/L).
The parameters of the linear regressions are as follows:
Correlation coefficient: (r) = 0.999
Linear regression: y = 0.976 x - 1 U/L (0.02 µkat/L)

- Interferences
Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol[10]. 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).
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (504 µmol/L).
Hemoglobin: No significant interference up to 500 mg/dL.
Ascorbic acid: No significant interference up to 20.0 mg/dL (1136 µmol/L).
Acetylsalicylic acid: No significant interference up to 200 mg/dL (11.1 mmol/L).
Acetaminophen : No significant interference up to 30 mg/dL (2.0 mmol/L).

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom'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.

.../...

* : US FDA only
☛: Modification from previous version

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AMSL-0230 6 x 20 mL

Kit composition :
R: *6 x 20 mL*

B) On ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range

Determined according to CLSI EP6-A protocol[6], 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].

LoD = 4 U/L (0.07 µkat/L)
LoQ = 13 U/L (0.22 µkat/L)

- Precision

Determined according to CLSI EP5-A2 protocol[8].

		Mean		Within-run	Total
	n	U/L	µkat/L	CV (%)	
Low level	80	81	1.35	1.9	2.6
Medium level	80	204	3.40	1.1	1.7
High level	80	988	16.47	1.2	1.5

- 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 EP9-A2 protocol[9].

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 = 0.954 x + 5 U/L (0.08 µkat/L)

- Interferences

Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2 protocol[10]. 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).
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Conjugated bilirubin: No significant interference up to 29.5 mg/dL (504 µmol/L).
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Ascorbic acid: No significant interference up to 20.0 mg/dL (1136 µmol/L).
Acetylsalicylic acid: No significant interference up to 200 mg/dL (11.1 mmol/L).
Acetaminophen : No significant interference up to 30 mg/dL (2.0 mmol/L).

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macro-globulinemia) 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

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☛SYMBOLS

IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instruction for use	LOT Batch code
Manufacturer	Use by
REF Catalogue number	CE European Conformity

Amylase IFCC 0
165 FTNA-AMSL

☛: Modification from previous version

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