diatron

α-AMYLASE

For use on Diatron Pictus® series analyzers

Method: CNPG3
Product code: 1419-0162, 1419-0160
Package: 6 x 36 ml, 6 x 18 ml
Store at: 2° – 8°C
For *in vitro* use only

INTENDED USE

Reagent for the determination of a-amylase activity in human serum, plasma or urine specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE

The concentration of a-amylase is low in infants and rises to adult levels at the end of the first year of life.
Serum amylase is increased in parotitis, pancreatitis, intestinal obstruction, strangulated bowel, ectopic pregnancy, diabetic ketoacidosis, peritonitis, pancreatic cyst or pseudocyst, macroamylasemia, renal failure, head injury, viral infections, biliary tract diseases, post-operational patients, some lung and ovarian tumors, intestinal trauma. a-Amylase levels are decreased in cases of pancreatic insufficiency, advanced cystic fibrosis, and in severe liver diseases.
Amylase in urine is increased in all the cases mentioned for serum, except in renal failure and macroamylasemia. In these cases, urine amylase levels appear normal or even decreased. Amylase levels may remain increased in urine up to 2 weeks after an acute pancreatitis episode and may be related to the formation of a pseudocyst.

METHOD PRINCIPLE

The chromatometric method of a-amylase determination uses 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) as substrate, causing the release of 2-chloro-4-nitrophenol (CNP). The enzyme reacts directly with the substrate and does not require the presence of other auxiliary enzymes. The resulting rate of increase of absorbance at 405/490 nm is directly proportional to the concentration of a-amylase in the sample.

$$10\text{CNPG3} \xrightarrow{\text{a-Amylase}} 9\text{CNP}+\text{CNPG2}+9\text{G3}+\text{G}$$

CNPG3: 2-chloro-4-nitrophenyl-α-D-maltotrioside
CNP: 2-chloro-4-nitrophenol
CNPG2: 2-chloro-4-nitrophenyl-α-D-maltoside
G3:maltotrioside
G:glucose

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".

The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION

MES (pH 6,05):	36.1 mmol/L
Calcium acetate:	3.60 mmol/L
NaCl:	37.2 mmol/L
Potassium thiocyanate:	253 mmol/L
CNPG3:	1.63 mmol/L

WARNINGS - PRECAUTIONS

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION

The reagent is liquid and ready-to-use when placed in the corresponding position of the analyzer. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

REAGENT DETERIORATION

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE

Unopened, the reagent is stable at 2 – 8°C up to the expiry date stated on the label. After opening, it remains stable for 56 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE

Serum or heparinized plasma should only be used. Other commonly used anticoagulants form complexes with Ca(II) ions, inhibiting amylase activity. Citrate, oxalate and EDTA may reduce the enzymatic activity up to 15%. Enzymatic activity loss in serum is negligible for 7 days at room temperature and for more than 60 days at 4°C.

In urine, amylase may be less stable at acidic pH. Therefore the adjustment of pH at 7 is recommended before storage.

CALIBRATION

Diatron provides MEDI-CAL (1578-0891) for serum calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 14 days. Calibration should be repeated when a new lot of reagent is used, after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

QUALITY CONTROL

Diatron provides the Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT SUPPLIED WITH THE KIT

- Amylase calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS

Serum or plasma: 24-90 U/L **Urine:** up to 410 U/L **24h Urine:** up to 370 U/L
For laboratories using serum reference intervals up to 220U/L, urine reference intervals are modified as follows: **Urine:** up to 1000 U/L **24h Urine:** up to 900 U/L
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

WASTE DISPOSAL

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® series analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

	Pictus® P400	Pictus® P700/P500 series
Linearity	Serum: up to 2000 U/L Urine: up to 4000 U/L	Serum: up to 2000 U/L Urine: up to 4000 U/L
Lowest detection limit	Serum: 1.1 U/L Urine: 1.3 U/L	Serum: 1.2 U/L Urine: 0.6 U/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

	Pictus® P400			Pictus® P700/P500 series		
Serum	Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
	80.6	3.30	3.64	78.4	2.42	2.91
	213	2.93	3.30	215	1.94	2.39
Urine	46.7	3.33	3.53	45.9	1.92	3.33
	207	3.15	3.41	206	1.88	3.34

Interferences: Criterion: recovery within ±20% from target value

Serum	Pictus® P400	Pictus® P700/P500 series
Lipemia	No interference up to 1000 mg/dL Intralipid®	No interference up to 3000 mg/dL Intralipid®
Heamoglobin	No interference up to 500 mg/dL	No interference up to 500 mg/dL
Non conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Ascorbate	No interference up to 3 mg/dL	No interference up to 3 mg/dL
Urine	**Pictus® P400**	**Pictus® P700/P500 series**
Non conj. Bilirubin	No interference up to 50 mg/dL	No interference up to 15 mg/dL
Conj. Bilirubin	No interference up to 5 mg/dL	No interference up to 50 mg/dL
Ascorbate	No interference up to 5 g/L	No interference up to 5 g/L
Glucose	No interference up to 1 g/L	No interference up to 10 g/dL
Creatinine	No interference up to 3 g/L	No interference up to 3 g/L
Uric Acid	No interference up to 2.5 mg/dL	No interference up to 2.5 mg/dL
Urea		No interference up to 5 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

CE IVD

Pictus® P400			
Serum: Y = 1.118X – 5.847	R=0.9955	N=60	Sample range = 30.7 – 583 U/L
Urine: Y = 0.927X + 10.8	R=0.9959	N=43	Sample range = 0.1 – 267 U/L
Pictus® P700/P500 series			
Serum: Y = 0.997X + 0.645	R=0.9984	N=37	Sample range = 19.8 – 177 U/L
Urine: Y = 1.160X – 4.475	R=0.9870	N=26	Sample range = 0.9 – 217 U/L

BIBLIOGRAPHY

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3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
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SYMBOLS