diatron

# α-AMYLASE

2°C – 8°C

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0160 **Packaging:** 6 x 18 mL

Σ 450

**INTENDED USE**
Reagents for In Vitro quantitative automated determination of a-Amylase (EC 3.2. 1.1) in samples of human serum, plasma or urine from the general patient population. Measurements of a- Amylase are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis and management of several gastrointestinal, renal and other disorders.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

**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 CNPG3 method is applied. 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.

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

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. This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

**REAGENT COMPOSITION**

| | |
|---|---|
| MES (pH 6,05): | 50 mmol/L |
| Calcium Chloride: | 5 mmol/L |
| NaCl: | 300 mmol/L |
| Potassium thiocyanate: | 900 mmol/L |
| CNPG3: | 2.2 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.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **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 Diatron Pictus® P700 / P500 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 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, heparinized-plasma or urine can be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Centrifuge sample as soon as possible, separate serum from blood cells and store properly if analysis cannot take place right after sample separation. Anti-coagulants other than Li-heparin should not be used because they form complexes with Calcium, inhibiting the enzymatic activity of amylase. Amylase is stable in serum and plasma samples for 1 week at room temperature, and for more than 2 months at 4°C and -20°C. In urine, the enzyme is not stable in acidic environment, so urine samples pH should be regulated at 7.0 before storage.

**CALIBRATION** Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot, for serum calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 2 weeks. 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 offers MEDICON Clinical Chemistry Control levels 1, 2 (1578-0901-12, 1578-0902-12) for serum quality control: Any commercially available quality control can be used for other types of samples. 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 PROVIDED WITH THE KIT**
- Amylase calibrator
- Quality control material
- Diatron Pictus® analyzer
- 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® P700 or P500 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.
**Linearity** Serum: up to 2000 U/L Urine: up to 4000 U/L
**Lowest detection limit** 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® P700 and P500 | | | |
|---|---|---|---|
| **SERUM** | | **URINE** | |
| **Level (U/L)** | **%CV** | **Level (U/L)** | **%CV** |
| 72.8 | 2.80 | 39.5 | 2.4 |
| 194.3 | 1.80 | 605 | 0.8 |
| **Level (U/L)** | **Total %CV** | **Level (U/L)** | **Total %CV** |
| 72.8 | 3.40 | 39.5 | 4.07 |
| 194.3 | 1.20 | 605 | 5.60 |

**INTERFERENCES -** Criterion: recovery within ±10% from target value

| **Serum** | (Insignificant up to) | **Urine** | (Insignificant up to) |
|---|---|---|---|
| Triglycerides | 3000 mg/dL | Bilirubin | 50 mg/dL |
| Hemoglobin | 500 g/dL | Ascorbic Acid | 5 g/L |
| Bilirubin | 20 mg/dL | Glucose | 10 g/L |
| Conj. Bilirubin | 20 mg/dL | Creatinine | 3 g/L |
| Ascorbic acid | 3 mg/dL | Uric Acid | 2.5 g/L |

**Correlation:** A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Serum: Y = 0.999X – 0.903 R=0.9999 N=82 Sample Range = 15 – 689 U/L
Urine: Y = 0.950X – 2.534 R=0.9995 N=86 Sample Range = 23 – 914 U/L

**BIBLIOGRAPHY**

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7. Dupuy, G, Hilaire, G, Aubry, C. Clin. Chem. 1987: 33; 524-528.


**SYMBOLS**

| | |
|---|---|
| Manufacturer | IVD *In vitro* diagnostic medical device |
| Temperature Limit | REF Catalogue Number |
| Caution | Σ Contains sufficient for <n> tests |




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