AMYLASE
For discrete analyzers
Method: IFCC
Product Code: 1418-0160
4 x 8 mL (R1) + 4 x 2 mL (R2)
1418-0161
4 x 32 mL (R1) + 4 x 8 mL (R2)
Store at 2 – 8 °C
For in vitro use

INTENDED USE
MEDICON Amylase is a set of reagents for the enzymatic determination of amylase in human serum, plasma and urine, with BECKMAN COULTER AU400/600/6000-IVD/6402/6700/5400 and other discrete analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
The concentration of α-Amylase in infants is low and rises to adult levels at the end of the first year of life. Serum amylase is increased in pancreatitis, pancreatic ulcer, strangulated bowel, ectopic pregnancy, diabetic ketoacidosis, perforated, pancreatic cyst or pseudocyst, macroamylasemia, renal failure, head injury, viral infections, biliary tract diseases, post-operative patients, some lung and ovarian tumors, intestinal trauma. α-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 macromyelasma. In these last cases, urine amylase levels are normal or 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 pseudocyst.

METHOD PRINCIPLE
The IFCC method is used. The kinetic determination of α-Amylase is based on the hydrolytic action of the enzyme on a synthetic substrate of deactivated p-nitrophenyl maltosaccharide (mNP-AT), during which glucose polymers and p-nitrophenol oligosaccharides are produced. Further hydrolysis of the p-nitrophenyl oligosaccharides with the α-glucosidase enzyme action leads to the release of p-nitrophenol. Increase of absorbance at 410 nm is proportional to the concentration of α-Amylase in the sample. The reaction is zero point kinetic.

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 for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes, skin and mucous membranes.

WARNINGS - PRECAUTIONS
- The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes, skin and mucous membranes.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN₃ < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Reagents should be disposed according to national rules.
- MSDS is available by MEDICON upon request.

PREPARATION* Reagents are liquid, ready to use, and placed at their corresponding places on the analyzer. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- When it is turbid.
- After prolonged exposure to high temperature.

SHELF LIFE Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8 °C. Once opened, reagents are stable for up to 1 month when stored refrigerated on the analyzer.

SAMPLE Use serum, or heparinized-plasma as specimen. Other anti-coagulants should not be used as they form complexes with Ca²⁺, inhibiting the enzymatic activity of amylase. Citric and osac acid salts and EDTA circumvent enzymatic activity by 10%. Loss of enzymatic activity in serum is insignificant for 1 week at room temperature, and for more than 2 months at 4°C.

In urine, the enzyme is less stable in acidic environments, so urine pH should be regulated at 7.0 before storage.

CALIBRATION Determination takes place in MB Calibration Mode. The calibration factor is derived by the mean of at least 3 separate analyses series, on different days, in single point calibration mode (AB). MEDICON provides MEDI-CAL 1578-01891), or BECKMAN COULTER Control for Clinical Chemistry Analyzers Cat. No 66300 (MEDICON code: 4477-0891) for serum calibration, and MEDI-CAL-U (1579-0185) or BECKMAN COULTER Urine Calibrator Cat. ODC0025 (MEDICON code: 4478-0950) for urine calibration. A new calibration vial should be used for each series of series of analyses. Recalibration should be repeated after major maintenance is performed on the analyzer or after a critical part is replaced or when a significant shift in control values occurs. Use of reagent blank when changing reagent lot is suggested.

QUALITY CONTROL MEDICON provides the following products for quality control: MEDICON Clinical Chemistry Control levels 1.2 (1578-01901, 1579-01902), BECKMAN COULTER Control Serum ODC0003 and ODC0004 (MEDICON code: 4478-0941 & 4478-0942 respectively) for serum, and MEDITROL-U 1.2 (1579-0181) or BIORAD Lyphochek Qualitative Urine Control Normal Cat no 397 and Abnormal Cat no 398 (MEDICON code: 1778-0181 & 1778-0182 respectively) for urine.

Control values and limits shall fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Amylase should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unstable 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
- Automated biochemistry analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum, plasma:
- Serum: up to 60 U/L
- Plasma: up to 100 U/L

For urine:
- Urine: up to 220 U/L

For laboratories using reference intervals of serum or plasma up to 220 U/L, urine values are as follows:
- Urine: up to 100 U/L

WASTE DISPOSAL
This product contains sodium azide (NaN₃), 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 pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
Linerarity
The assay is linear up to 2000 U/L for serum and 4900 U/L for urine. When values exceed this range samples should be diluted accordingly.

Sensitivity
The lowest detectable level of Amylase is estimated at 0 U/L for serum and 1.2 U/L for urine.

The lowest detection limit (L DL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times in the assay and the LSD is calculated as the absolute mean plus three standard deviations.

Precision

<table>
<thead>
<tr>
<th>Level (U/L)</th>
<th>Within Run CV%</th>
<th>Between Run CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>109</td>
<td>2.9</td>
<td>2.86</td>
</tr>
<tr>
<td>308</td>
<td>2.33</td>
<td>2.56</td>
</tr>
</tbody>
</table>

Precision is estimated on two concentrations of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference

<table>
<thead>
<tr>
<th>Interference</th>
<th>Serum</th>
<th>Urine</th>
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</thead>
<tbody>
<tr>
<td>Lipemic</td>
<td>insignificantly up to 1000 mg/dL</td>
<td>insignificantly up to 250 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>insignificantly up to 250 mg/dL</td>
<td>insignificantly up to 20 mg/dL</td>
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<tr>
<td>Non-Con. Bilirubin</td>
<td>insignificantly up to 20 mg/dL</td>
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</tr>
<tr>
<td>Bilirubin</td>
<td>insignificantly up to 20 mg/dL</td>
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<tr>
<td>Ascorbic acid</td>
<td>insignificantly up to 3.5 g/L</td>
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<tr>
<td>Creatinine</td>
<td>insignificantly up to 300 mg/dL</td>
<td>insignificantly up to 300 mg/dL</td>
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<tr>
<td>Glucose</td>
<td>insignificantly up to 50 g/L</td>
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<tr>
<td>Ascorbic acid</td>
<td>insignificantly up to 50 g/L</td>
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</tr>
<tr>
<td>Creatinine</td>
<td>insignificantly up to 10 mg/dL</td>
<td>insignificantly up to 15 mg/dL</td>
</tr>
<tr>
<td>Ammonia</td>
<td>insignificantly up to 2.5 g/L</td>
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<tr>
<td>Gentamycin</td>
<td>insignificantly up to 10 mg/dL</td>
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A comparison was performed between this reagent and another commercially available product. The results were as follows:

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BIBLIOGRAPHY

SYMBOLS

*For RA analyzers, mix reagent R1 with reagent R2 in a 4 : 1 ratio.

MEDICON HELLAS S.A - Melitonta 5-7, 153 44 Gerakas, Greece. Tel: +302106060600 - Fax: +302106812966 - www.mediconsa.com

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