REAGENT PREPARATION

Serum as starter procedure:
Add 4 ml of reagent B to a vial of reagent A. Stability of working reagent: 60 days at 2-8°C, away from light sources.

Reagent as starter procedure:
use separate reagents ready to use. Stability: up to expiration date on labels at 2-8°C; Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

SPECIMEN

Serum, plasma (heparinized only). Urine. Amylase is stable in serum and plasma sample up to 2 months at 2-8°C.

TEST PROCEDURE (sample as starter)

Wavelength: 405 nm
Lightpath: 1 cm
Temperature: 37°C
dispense in cuvette working reagent: 1.5 ml
preincubate at 37°C for 5 minutes.
add sample: 50 μl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.

TEST PROCEDURE (reagent as starter)

Wavelength: 405 nm
Lightpath: 1 cm
Temperature: 37°C
dispense in cuvette reagent A: 1.2 ml
add sample: 50 μl
incubate at 37°C for 5 minutes.
dispense in cuvette reagent B: 300 μl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Mix, calculate the ΔA/min.

RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 1460
Calculation in μkat/l: U/l x 0.0167 = μkat/l

EXPECTED VALUES

Serum - plasma: 28 - 100 U/l (0.47 - 1.67 μkat/l)
Random urine: ≤ 460 U/l (≤ 7.68 μkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QN 0050 CH QUANTINORM CHEMA 10 x 5 ml with normal or close to normal control values
QP 0050 CH QUANTIPATH CHEMA 10 x 5 ml with pathological control values
If required, a multiparametric, human based calibrator is available
AT 0030 CH AUTOCAL H 10 x 3 ml

Please contact Customer Care for further information.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

REFERENCES


MATERIALS REQUIRED BUT NOT SUPPLIED


SUMMARY OF TEST

Assays of amylase activity in serum and urine are largely of use in the diagnosis of diseases of the pancreas, and in the investigation of pancreatic function. In acute pancreatitis, a transient rise in serum amylase activity occurs within 2 to 12 h of the onset; levels return to normal by the third or fourth day. A four- to six-fold elevation in amylase activity above the reference limit is usual, with maximal levels attained in 12 to 72 h. In acute pancreatitis associated with hyperlipemia, serum amylase activity may be normal; the spuriously normal amylasemia may be unmasked either by serial dilution of the serum. A significant amount of the serum amylase is excruted in the urine, and therefore elevation of serum activity is reflected in the rise of urinary amylase activity. Urine amylase, as compared with serum amylase, appears to be more frequently elevated, reaches higher levels, and persists for longer periods. The urinary clearance of amylase is markedly increased in acute pancreatitis; in quiescent chronic pancreatitis, both serum and urine activities are usually subnormal. In some important groups of nonpancreatic disorders, reasons for hyperamylasemia are known. Although about 25% of the serum amylase is normally eliminated in the urine, in renal insufficiency the serum amylase activity is increased up to two- fold of the upper reference limit and in proportion to the extent of renal impairment. Neoplastic hyperamylasemia is an increasingly recognized entity for which clinical chemists must be constantly alert. Additionally, tumors of the lung and serous tumors of the ovary can produce hyperamylasemia with elevations as high as 50 times the upper reference limit. Both kinds of tumor can produce pleural effusion. The amylase activities in these effusions can be greater than 200 times the upper reference limit for serum. Salivary gland lesions caused by infection, irradiation, obstruction, surgery, and tumor have all been reported as producing a significant S-type hyperamylasemia. Mumps (infective parotitis) and maxillofacial surgery can cause a two-fold elevation, and salivary gland irradiation can produce a transient 9- to 18-fold elevation of serum amylase activity. Biliary tract diseases such as cholecystitis can cause up to four-fold elevation of the serum amylase activity as a result of either primary or secondary pancreatic involvement. It has been estimated that some 200 methods for the assay of amylase have been described. The present method is based on the chromogenic substrate 4,6-ethylidene(G1)-4-nitrophenyl(G7)-β-D-glucosidase (EC 3.2.1.1, 1,4-β-D-glucosidase as ancillary enzyme in optimized conditions (IFCC).

α-amylase (EC 3.2.1.1, 1,4-β-D-glucanohydrolase) hydrolizes the EPS to release several different fragments. The fragments so formed are completely hydrolyzed to 4-nitrophenol and glucose by α-glucosidase (EC 3.2.1.2, 4-β-D-glucosidase) hydrolase 6 kU/l.

MANUFACTURER

Chema Diagnostica
Via Campania 214
60030 Monsano (AN) - ITALY - EU
phone +39 0731 605064
fax +39 0731 605672
e-mail: mail@chema.com
website: http://www.chema.com

SYMBOLS

© 1998 Chema Diagnostica

© IUS-7.5 UK rev. 23/05/2011