lipase and compares well with turbidimetric method, at the is rapid and very sensitive, highly specific for pancreatic colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3-glu immunological techniques. In the present method, the new tric, turbidimetric, spectrophotometric, fluorometric, and released in a 24-h incubation at 37°C and estimated by lipase activity was defined by the amount of free fatty acids activity. Thus, care should be exercised in the interpre activity increases, although this elevation is neither as usual in this disease. Obstruction of the pancreatic duct by a calculus or by carcinoma of the pancreas may cause an no increase of serum lipase activity is therefore not unu marginal or subnormal serum activities. Marginal or acinar tissue in the later stages of the disease results in Serum lipase assays may also be of value in the diagno

**SUMMARY OF TEST**

Human lipase is a glycoprotein with a molecular weight of 48000 and an isoelectric point of about 5.8. For full catalytic activity and greatest specificity, the presence of bile salts and a cofactor, called colipase, is required. Lipases are defined as enzymes that hydrolyze glycerol esters of long-chain fatty acids. Both lipase and colipase are synthesized in the pancreatic acinar cells and secreted by the pancreas in roughly equimolar quantities. Lipase measurements on serum, plasma, and ascitic and pleural fluid are used exclusively to investigate pancreatic disorders, usually pancreatitis. The complete absence of lipase and colipase has been reported. Such congenital absence results in severe steatorrhea. After an attack of acute pancreatitis, the serum lipase activity increases within 4 to 8 h, peaks at about 24 h, and decreases within 8 to 14 days; levels remain elevated longer than those of amy lase. Lipase elevations usually parallel those of amylase, but increases in lipase activity may occur sooner or later than increases in amylase activity, and lipase may rise to a greater extent. In acute pancreatitis, normoamylasemia may occur in up to 20% of such patients. Likewise, the extinction of activity of a spurious normo-amy lase. Serum lipase activity is probably a more specific dia gnosis finding in cases where amylase activity is decreased, because many of these conditions are less likely to cause increases in lipase activity than in amylase activity. It must be emphasized, however, that these foregoing comments apply to results obtained with a specific lipase assay. Serum lipase assays may also be of value in the diagnos is of chronic pancreatitis, but severe destruction of the acinar tissue in the later stages of the disease results in a reduction of the amount of enzyme that can enter the circulation and in subnormal serum activities. Marginal or no increase of serum lipase activity is therefore not unu sual in this disease. Obstruction of the pancreatic duct by a calculus or by carcinoma of the pancreas may cause an increase in serum lipase activity, depending on the location of the obstruction and the amount of remaining functioning tissue. In acute and chronic renal disease, serum lipase activity is increased, although this elevation is neither as frequent nor as pronounced as that with serum amylase activity. Thus, care should be exercised in the interpre tation of elevated serum lipase values in the presence of renal disease. In contrast to amylase, which is present in both the pancreas and the parotid glands, lipase is not pre sent in the parotid gland. Therefore, in mumps (acute paro titis) without pancreatic involvement, serum lipase activity is usually not elevated but serum amylase activity is. In 1932, Cherry and Crandall first recognized the clinical value of blood lipase measurement in monitoring pan creatic injury. The method involved their names used a buf fered, stabilized 50% emulsion of olive oil as substrate; lipase activity was defined by the amount of free fatty acids released in a 24-h incubation at 37°C and estimated by titration to 0.5 mEq/ml of alkali. Since 1932, many lipase methods have been described; they have used both triglyceride and nontriglyceride substrates in titri metric, turbidimetric, spectrophotometric, fluorometric, and immunoturbidimetric techniques. In the present method, the new colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3-glu taric acid-(6methyl-resorufin)-ester is used. The method is rapid and very sensitive. It is highly specific for pancreatic lipase synthesis and compares well with turbidimetric method, at the same time avoiding some its drawbacks.

**PRINCIPLE OF THE METHOD**

The colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3- glutaric acid-(6methyl-resorufin)-ester is cleaved by pan creatic lipase and the resulting dicarboxylic acid ester is hydrolysed under the alkaline test conditions to yield the characteristic color of methyresufin. The kinetic of colour forma tion at 580 nm is monitored and it is proportional to lipase activity in sample.

**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 0500 CH QUANTINORM CHEMA 10 x 5 ml with normal or close to normal control values
- QP 0500 CH QUANTIPATH CHEMA 10 x 5 ml with pathological control values.

If required, a multiparametric, human based calibration is available:

- AT 0030 CH AUTOCL H 10 x 3 ml

Please contact Customer Care for further information.

**TEST PERFORMANCE**

**Linearity**

The method is linear up to 300 U/l. If the limit value is exceeded, it is suggested to dilute sample 1+1 with saline solution (9 g/l) and to repeat the test, multiplying the result by 2.

**Sensitivity/limit of detection (LOD)**

The limit of detection is 1 U/l.

**Interferences**

No interference was observed by the presence of: ascorbic acid ≤ 50 mg/dl, hemoglobin ≤ 400 mg/dl, bilirubin ≤ 50 mg/dl, and lipids ≤ 1000 mg/dl.

**Precision**

Intra-assay (n=10) mean (U/L) SD (U/L) CV%

| Sample 1 | 60.6 | 0.54 | 0.89 |
| Sample 2 | 90.4 | 0.70 | 0.77 |

Inter-assay (n=20) mean (U/L) SD (U/L) CV%

| Sample 1 | 59.9 | 1.76 | 2.94 |
| Sample 2 | 90.3 | 1.80 | 1.99 |

**METHODS COMPARISON**

A comparison between Chema and a commercially available product gave the following results:

- Lipase Chema = y
- Lipase competitor = x

n = 89

\[ y = 0.93x + 0.50U/I \]

\[ r^2 = 0.99 \]

**REFERENCES**


**QUALITATIVE COMPONENTS**

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label. Keep away from direct light sources.

**REAGENT PREPARATION**

Use separate reagents ready to use. Do not shake! Stability: up to opening of vials: use preferably within 90 days at 2-8°C.

**CAUTION**

Reagent B is a microemulsion. Therefore, a slight apparent precipitation could occur showing a light red deposit on the bottom of vial. It is a normal behaviour and it is recommended to resuspend solution before analysis, with a mild shaking.

**PRECAUTIONS**

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully, avoiding contact with skin and swallow.

Some commercial reagents for triglycerides, HDL and LDL determination could contain microbial lipases, whose could stick on surface of instrument plastic cuvettes. It is recommended to program a "wash" procedure before lipase determination, if a contamination is suspected. Perform the test according to the general "Good Labora tory Practice" (GLP) guidelines.

**SPECIMEN**

Serum, plasma heparinate. Samples are stable 7 days at 2-8°C.

**TEST PROCEDURE**

Wavelength: 580 nm

Lightpath: 1 cm

Temperature: 37°C

dispense: blank calibrator sample

reactant A 1 ml 1 ml 1 ml

water 20 µl

- 20 µl -

- 20 µl -

- 20 µl -

Mix carefully (do not shake), incubate at 37°C for 5 minutes.

dispense: blank calibrator sample

reactant B 250 µl 250 µl 250 µl

Mix, execute a first reading of absorbance after 2 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the ΔA/min.

**RESULTS CALCULATION**

ΔA/min = ΔA/min (calibrator or sample) - ΔA/min (blank)

serum/plasma sample:

UI (methyleneresolfin 37°C) = x Calibrator value

**EXPECTED VALUES**

Normal subjects: ≤ 60 UI (methyleneresolfin 37°C)

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