Store at +2 to +8°C

**PRINCIPLE**

The pancreatic lipase in presence of colipase, desoxycholate and calcium ions, hydrolyses the substrate 1,2-O-dilauryl-rac-glycerol-3-glutaric acid - (6'-methylresorufin)-ester. The sequence of reactions involved in the enzymatic direct lipase determination is the following:

\[
\text{Lipase} \rightarrow 1,2-O\text{-dilauryl-rac-glycerol} + \text{Glutaric acid} + \text{Methylresorufin}
\]

The rate of methylresorufin formation, measured photometrically, is proportional to the catalytic concentration of lipase present in the sample.

**CLINICAL SIGNIFICATION**

Lipase (LPS) is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyzes the hydrolysis of glycerol esters of fatty acids. Determination of LPS is used for diagnosis of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**REAGENTS**

1. **Reagent 1 (buffer)**
   - TRIS pH 8.3 40 mmol/L
   - Colipase ≥ 1 mg/L
   - Desoxycholate ≥ 1.6 mmol/L
   - Taurodesoxycholate 7.2 mmol/L

2. **Reagent 2 (substrate / micro-emulsion)**
   - Tartrate pH 4.0
   - Lipase ≥ 0.7 mmol/L
   - Calcium chloride (CaCl₂) 0.1 mmol/L

**LIPASE CAL**

Lyophilised human serum. Activity see on the vial label.

**PRECAUTIONS**

**LIPASE CAL** Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

**PREPARATION OF REAGENTS**

1. **R1 – R2 Ready to use.** Stability after opening 90 days at +2 to +8°C.
2. **Mix gently before use.** Stability: 7 days at +2 to +8°C or 3 months at -20°C; aliquote into small volumes and freeze.

**STORAGE AND STABILITY:**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2 to +8°C, protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

**REFERENCES**

4. CHRONOLAB has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.
5. In order to avoid contamination it is recommended to use disposable material.
6. CHRONOLAB has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

**QUALITY CONTROL**

Control sera are recommended to monitor the performance of assay procedures: Contro N and Contro P. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE VALUES**

≤ 38 U/L (U/L methylresorufin at 37°C)

These values are for orientation purpose; each laboratory should establish its own reference range.

**PREFORMANCE CHARACTERISTICS**

Accuracy: Results obtained using Chronolab reagents (y) did not show systematic differences when compared with other commercial reagents (x). The results obtained using 100 samples were the following:

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay (n=20)</th>
<th>Inter-assay (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (U/L)</td>
<td>119</td>
<td>215</td>
</tr>
<tr>
<td>SD</td>
<td>4.13</td>
<td>5.97</td>
</tr>
<tr>
<td>CV (%)</td>
<td>3.34</td>
<td>2.78</td>
</tr>
</tbody>
</table>

Regression equation: y = 0.50054x + 3.9443. The performance characteristics depend on the analyzer used.

**INTERFERENCES**

Triglycerides at 300 mg/dL, interfer on determination reducing the activity of enzyme of 6%. Hemoglobin concentration lower than 150 mg/dL and Bilirubin lower than 20 mg/dL do not interfere. A list of drugs and other interfering substances with lipase determination has been reported by Young et al.

**NOTES**

1. In some storage conditions (i.e. storage at a temperature lower that the one indicate) a precipitate may appear in the vial that will not influence that the reagent performance; however, it is recommended to resuspend the product with a slight rotation.
2. In order to avoid contamination it is recommended to use disposable material.
3. CHRONOLAB has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

**REFERENCES**


**PACKAGING**

Ref: 101-0410  Cont. – 4 x 12 ml / 1 x 8 ml