LIPASE

Enzymatic Method

Intended Use:
Lipase Test reagent/kit is a medical device intended for estimation of Lipase in serum or plasma.

Clinical Significance
Determination of Lipase (LPS) activity is used to reflect disorders of pancreas. When acute pancreatitis occurs, the increase of serum LPS activity can last for 10-15 days. Serum LPS helps a lot to the diagnosis of acute pancreatitis. Clinical study has proved that the sensitivity is 80%-100% and the specificity is 84%-96%.

Principle
Lipase hydrolyzes the substrate 6-methyl test halogen spirit ester in microemulsion solution in the presence of Co lipase and bile acid. The presence of lipase and bile acid inhibits the affection of other hydrolases and esterases, so this method can detect the activity of LPS reliably without the affection of serum matrix effect.When 6-methyl test halogen spirit ester was degraded to 6-methylresorufin, the increase of absorbance caused by the red dye is in direct proportion to the lipase activity in the sample

Reagent Composition

R1 Reagent	Glycocoll - 450 mmol/L NaOH – 3.6 mmol/L Colipase – 1 mmol/L NaTDC – 1.6 mmol/L
R2 Reagent	Tartaric Acid Buffer - 19 mmol/L Lipase Chromogenic Substrate-3.4mmol/L

Working Reagent Preparation
Reagent is ready to use.

Stability and Storage
1. Unopened reagent: stable for 12 months at 2～8℃, protect from light.
2. Opened reagent: stable up to 30 days at 2～8℃, protect from light.

Discard if signs of deterioration appear:
- Presence of particles and turbidity.

Materials required
- Photometer or spectrophotometer with a thermostat cell compartment set at 25/30/37ºC, capable of reading at 580 nm.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm path length
- Pipettes to measure reagent and samples.

Sample and Stability
Serum or plasma
Empty stomach serum or heparinized plasma free of hemolysis. Lipase is reported to be stable in serum for 3-4 days at 2-8ºC.

Assay Procedure
Pipette into clean dry test tubes as follows:

Addition Sequence	Calibrator	Test
Sample	-	5µl
Calibrator	5µl	-
R1 Reagent	400µl	400µl
Mix, incubate at 37℃ for 3-5 minutes		
R2 Reagent	100µl	100µl

Mix well and after 60 Sec incubation, measure the change of optical density per 60 sec during 240 sec against distilled water at 580 nm as follows:
A0 - Exactly after 1 minute.
A1, A2 - Exactly after every 60 seconds for 240 seconds.

Calculation
The analyzer automatically calculate the analyte concentration of each sample

Quality Control
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable results.

Linearity
This procedure is linear up to 250 IU/L. If values exceed this limit dilute the sample with distilled water and repeat the assay.

Reference Values

Serum / Plasma	: 13 – 63 IU/L

It is recommended that each laboratory establishes its own normal range representing its patient population.

General System Parameters

Mode	Kinetic
Reaction	Increasing
Wavelength	580 nm
Blank with	Distilled water
Sample Volume	5µl
Reagent Volume	400µl +100µl
Calibrator Conc.	Refer Vial label
Incub. Temp.	37°C
Delay Time	60sec
Read Time	240sec
Interval	60sec
Normal Range	13 - 63 IU/L
Linearity	Up to 250 IU/L
Unit	IU/L

Notes
1. Lipemia (Intralipid): no interference up to 1000mg/dl of intralipid.
2. Hemolysis: no interference up to 50mg/ dl.
3. Bilirubin: no interference up to 50mg/ dl.
4. The result may vary with different analyzers or calibrations.
5. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Reference
1. Ministry of Health of the People's Republic of China. National Clinical Laboratory Operation Instruction (edition 3). Southeast University Press. 2006

For *in vitro* Diagnostic use only.