AGD

CliniPak

LIPASE

(Methyl Resorufin)

Code	Pack Size
AGDSP - LP50	R1 : 2 X 20 mL R2 : 2 X 5 mL
AGDSP -LP36	R1-2x15mL R2-2x3mL

INTENDED USE

This reagent kit is intended for in vitro quantitative determination of Lipase in serum or plasma.

CLINICAL SIGNIFICANCE

Lipases are glycoproteins with a molecular weight of 47000 Daltons. Lipase hydrolyzes the ester linkages. Lipases perform essential roles in digestion, transport and processing of dietary lipids such as triglyc- erides, fats and oils.

Lipase is primarily produced in the pancreas but is also in the mouth and stomach. Most people produce enough pancreatic lipase,but people with cystic fibrosis,Crohn's disease and celiac disease may not have enough lipase to get the nutrition they need from food.

PRINCIPLE

The chromogenic lipase substrate 1,2,-O- dilauryl-rac-glycero-3-glutaric acid-(6- methylresorufin)- ester is cleaved by the catalytic action of alkaline lipase solution to form 1,2-O-dilauryl-rac-glycerol and an unstable intermediate glutaric acid-(6- methylresorufin)-ester.

This decomposes spontaneously in alkaline solution to form glutaric acid and methylresorufin. The colour intensity of the red dye formed is directly proportional to lipase activity and can be determined photometrically.

PROCEDURE

Reagent 1 + Sample + Incubation
(250µL)) (2.5µL) (60Sec)

Reagent 2 ⟶ Measurement
(50µL) (120sec) (578nm)

REAGENT COMPOSITION

REAGENT 1

Tris Buffer pH 8.3	≈ 40 mmol/L
Colipase	≈ 1 mg/L
Deoxicholate	≈ 1.8 mmol/L
Taurodeoxicholate	≈ 7.2 mmol/L

REAGENT 2

Tartrate buffer pH 4.0	≈ 15 mmol/L
Lipase	≈ 0.7 mmol/L
Calcium Chloride	≈ 0.1 mmol/L
Lipase Calibrator	≈Concentration printed on the vial IU/L

STORAGE AND STABILITY

R1 and R2 are ready to use and are stable up to the expiry date.

Lipase Calibrator:
Dissolve with quantity of distilled water as printed on the vial. Cap and mix gently to dissolve the contents. Reconstituted calibrator is stable for 7 days at -20° C Aliquot into small volume and freeze.

The reagents are stable till the expiry date stated on the reagent bottle label when stored at 2-8° C and protected from sunlight.

SAMPLES

Preferably serum samples can be used, heparinised plasma can be used. Do not use hemolysed or grossly contaminated samples.

BASIC PARAMETERS

SHORT NAME	LIPASE
NAME	LIPASE
METHOD	METHYL RESORUFIN
ASSAY	FIXED TIME/TWO POINT
MAIN WAVE	578 nm
SUB WAVE	0
DECIMAL	2
UNIT	IU/L
R1 VOLUME	250µL
INCUBATION	60 Sec
R2 VOLUME	50µL
SAMPLE VOLUME	2.5µL
INCUBATION	60 Sec
MIXING SPEED	1
REACTION TIME (Delay)	60 Sec
CHECK TIME (Read)	60 Sec
LINEAR RANGE	0 - 250IU/L
ABSORBANCE RANGE	2.5
LINEARITY LIMIT	10
SUBSTRATE SHORTAGE	>1.3
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

LINEARITY

Reagent is linear up to 250 IU/L.

Dilute the sample appropriately and re-assay if Lipase concentration exceeds 250 IU/L.Multiply result with dilutionfactor.

REFERENCE NORMAL VALUE

Serum : 13-60 IU/L

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

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