

# AGD CliniPak LIPASE

## (METHYL RESORUFIN)



| Code       | Pack Size                 |
|------------|---------------------------|
| AGDSP-LP15 | R1:1x12.5 ml, R2:1x2.5 ml |



### INTENDED USE

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

### CLINICAL SIGNIFICANCE

Lipase belong to the class of enzymes that catalyzes the hydrolysis of fats. They play an important role in the digestion, transport and processing of dietary lipids. Lipase are secreted by pancreas, intestine, gastric juice, adipose tissues, lysosomes and blood.

Very high levels of lipase indicates acute pancreatitis. High than normal levels are observed in chronic kidney diseases, peptic ulcer, gall bladder diseases, pancreatic cancer, intestinal problems, diabetes, salivary gland disorders and use of alcohol.

Decreased levels are observed in permanent damage to the cells of pancreas (damage caused by cystic fibrosis, chronic pancreatitis).

### PRINCIPLE

The chromogen lipase substrate 1,2-O-dilauryl-rac-glycerol-3-glutaric acid-(6-methylresorufin)-ester is cleaved by the catalytic action of alkaline lipase solution to form 1,2-Odilauryl-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 photo metrically.

### WORKING REAGENT

Reagents are ready to use.

### REAGENT COMPOSITION

#### REAGENT 1

|                    |              |
|--------------------|--------------|
| Tris Buffer pH 8.3 | ≈ 40mmol/L   |
| Cholipase          | ≈ 1mg/L      |
| Deoxycholate       | ≈ 1.8 mmol/L |
| Taurodeoxycholate  | ≈ 7.2 mmol/L |

#### REAGENT 2

|                         |             |
|-------------------------|-------------|
| Tartarate Buffer pH 4.0 | ≈ 15mmol/L  |
| Lipase                  | ≈ 0.7mmol/L |
| Calcium Chloride        | ≈ 0.1mmol/L |

**Lipase Calibrator** :Dissolve with distilled water(QTY printed on label). Cap and mix gently to dissolve contents. Reconstituted calibrator is stable for 7 days at -20°C.

|                   |                                    |
|-------------------|------------------------------------|
| Lipase Calibrator | Concentration printed on the label |
|-------------------|------------------------------------|

### REAGENT PREPARATION, STORAGE & STABILITY

**STABILITY** : up to expiration date on labels at 2-8°C.

#### REAGENT DETERIORATION :

Turbidity or precipitation in any kit or change in color of the reagent component indicates deterioration and the component must be discarded.Reagent blank absorbance value should be below 0.1 Abs.

### SPECIMEN COLLECTION AND HANDLING

Unheamolytic serum and plasma (heparin) to be used. It is recommended to follow NCCLS procedures (or similar standardized conditions).

#### Stability in serum / plasma:

7 days at 20-25°C

7 days at 4-8°C

1 year at -20°C

Do not use Hemolysed or grossly contaminated samples.

### QUALITY CONTROL

Randox controls Normal and Pathological levels are recommended for establishing instrument performance.

### NORMAL RANGE

Serum : 13 - 60 IU/L

### PERFORMANCE DATA

**Linearity:** 250 U/L

## BASIC PARAMETERS

|                    |                        |
|--------------------|------------------------|
| Short Name         | Lipase                 |
| Name               | Lipase                 |
| Method             | Two Point / Fixed Time |
| Reagent Blank      | Reagent                |
| Main Wave          | 578 nm                 |
| Sub Wave           | 0                      |
| Decimal            | 2                      |
| Unit               | IU/L                   |
| R1 Volume          | 260 µL                 |
| R2 Volume          | 40 µL                  |
| Sample Volume      | 4 µL                   |
| Assistant Start    | 6 (Point)              |
| Assistant End      | 14 (Point)             |
| Test Point - Start | 16 (Point)             |
| Test Point - End   | 24 (Point)             |
| Linearity          | 250 U/L                |

## ASSAY PROCEDURE

The samples and reagent should be brought to room temperature prior to use.

|                                       | Calibrator | Sample |
|---------------------------------------|------------|--------|
| Reagent 1                             | 260 µL     | 260 µL |
| Calibrator                            | 4 µL       | ---    |
| Sample                                | ---        | 4 µL   |
| Mix and incubate for 60 secs at 37°C. |            |        |
| Reagent 2                             | 40 µL      | 40 µL  |

Mix and read the absorbance immediately.

**NOTE** :- Application for Fully automatic instruments are available on request.










## WARNINGS AND PRECAUTIONS

1. Reagent may contain some Non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
4. Waste management: Please refer to disposal guidelines as per local authority.

## REFERENCES

1. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 689-708.
2. Tietz N, Shuey DF. Lipase in serum - the elusive enzyme: an overview. Clin Chem 1993; 39:746- 56.
3. Lorentz K Lipase. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH- Books Verlagsgesellschaft; 1998. p. 95-7.
4. Lott J, Patel ST, Sawhney AK, Kazmierczak SC, LoveJE. Assays of serum lipase: analytical and clinical considerations. Clin Chem 1986;32:1290-1302.
5. Borgström B. The action of bile salts and other detergents on pancreatic lipase and the interaction with colipase. Biochimica et Biophysica Acta 1977;488:381-91.

## SYMBOLS

| Sr. No. | Symbol   | Instruction  |
|---------|--|--|
| 1       |          | Trademark of AGD Biomedicals P Ltd                                     |
| 2       |  Caution | Note : Misoperation may result in injury to the user or property loss. |
| 3       |          | Manufacturer   |
| 4       |          | Date of Manufacture  |
| 5       |          | Consult Instructions for Use   |
| 6       |          | Unique Device Identification   |
| 7       |          | Limit of Temperature   |
| 8       |          | Catalogue Number   |
| 9       |          | Authorized representative in the European community                    |



### AGD Biomedical Pvt. Ltd.

Site 2 : Plot No. W-29 E, TTC Industrial Area, MIDC, Thane Belapur Road, Rabale, Navi Mumbai, Thane, Maharashtra, (India)- 400701.  
E : [indiasales@agdbio.com](mailto:indiasales@agdbio.com)  
W : [www.agdbio.com](http://www.agdbio.com)

ISO 13485:2016 ISO 9001:2015



Obelis s. a.  
Bd General Wahis  
53 1030 Brussels Belgium  
Phone : +32 2 732 59 54