

**DIAGNOSTIC KIT  
FOR DETERMINATION OF  
LIPASE ACTIVITY**



**II GENERATION**

**OS – LIPASE**

**INTRODUCTION**

Lipase is a digestive enzyme released into the intestine from the pancreas where it breaks down triglycerides into fatty acids and glycerol prior to absorption. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis, obstruction of the pancreatic duct and pancreatic tumours.

**METHOD PRINCIPLE**

The colorimetric, enzymatic method is based on a lipase specific degradation of a chromogenic substrate. The specific lipase substrate-DGGMR [1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester] is cleaved by the catalytic action of lipase to form 1,2-o-dilauryl-rac-glycerol and an unstable intermediate, glutaric acid-(6-methyl resorufin) ester. This decomposes spontaneously in alkaline solution to form glutaric acid and methylresorufin. The lipase activity in the specimen is proportional to the production of methylresorufin in the reaction and can be determined photometrically.

**REAGENTS**

**Package**  
1-Reagent 2 x 34 ml  
2-Reagent 2 x 21.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

**Concentrations in the test**

**1-Reagent**  
BICIN buffer pH 8.0 50 mmol/l  
BICIN = [N,N-bis(2-hydroxyethyl)-glycine  
colipase (porcine pancreas) ≥ 0.9 mg/l  
sodium deoxycholate 1.6 mmol/l  
calcium chloride 10 mmol/l  
detergent  
preservative

**2-Reagent**  
Tartrate buffer pH 4.16 10 mmol/l  
taurodeoxycholate 8.8 mmol/l  
DGGMR [1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin)-ester] 0.27 mmol/l  
detergent  
preservative

**Warnings and notes**

- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

**SPECIMEN**

Serum.  
Heparinized plasma (recommended: heparine lithium, sodium or ammonium salt). Do not use anticoagulants: EDTA, fluorides, citrates and oxalates as they inhibit lipase activity.  
Centrifuge samples containing precipitates before performing the assay.  
Sample may be stored for up to 7 days at 15-25°C or up to 7 days at 2-8°C or one year at -15(-25)°C.  
Nevertheless it is recommended to perform the assay with freshly collected samples!

**PROCEDURE**

These reagents may be used in automatic analysers Olympus AU400/AU640.

1-Reagent and 2-Reagent are ready to use.  
For reagent blank 0.9% NaCl is recommended.

**APPLICATION**

Reagent ID: 030

| Specific Test Parameters |     |             |          |       |    |                            |         |         |                |        |
|--------------------------|-----|-------------|----------|-------|----|----------------------------|---------|---------|----------------|--------|
| General                  |     | LIH         | ISE      | Range |    |                            |         |         |                |        |
| Test name:               |     | LIPA II GEN |          |       |    | Type:                      | Serum   |         | Operation: Yes |        |
| Sample: Volume           | 3   | μL          | Dilution | 10    | μL | Pre-Dilution Rate:         | 1       |         |                |        |
| Reagents: R1 Volume      | 180 | μL          | Dilution | 0     | μL | Min OD                     |         |         | Max OD         |        |
| R2 Volume                | 110 | μL          | Dilution | 0     | μL | L                          | -2.0000 | H       | 2.5000         |        |
| Wavelength: Pri. 570     |     |             |          |       |    | Sec. 700                   | First L | -1.0000 | First H        | 2.5000 |
| Method: RATE             |     |             |          |       |    |                            | Last L  | -1.0000 | Last H         | 2.5000 |
| Reaction Slope: +        |     |             |          |       |    | Dynamic Range:             |         |         |                |        |
| Measuring Point 1: First |     | 16          | Last     | 26    |    | L                          | 1.3     | H       | 400            |        |
| Measuring Point 2: First |     |             | Last     |       |    | Correlation Factor:        |         |         |                |        |
| Linearity:               |     | 15          |          |       |    | A                          | 1.000   | B       | 0.000          |        |
| No-Lag-Time:             |     |             |          |       |    | On-board Stability Period: |         | 49      |                |        |

| Specific Test Parameters |     |             |       |          |       |           |       |                   |  |   |  |
|--------------------------|-----|-------------|-------|----------|-------|-----------|-------|-------------------|--|---|--|
| General                  |     | LIH         | ISE   | Range    |       |           |       |                   |  |   |  |
| Test name:               |     | LIPA II GEN |       |          |       | Type:     | Serum |                   |  |   |  |
| Value/Flag:              |     | #           |       | Level L: |       | #         |       | Level H:          |  | # |  |
| Normal Ranges:           |     |             |       |          |       |           |       |                   |  |   |  |
|                          | Sex | Age L       | Age H | L        |       | H         |       |                   |  |   |  |
|                          | #   | Year        | Month | Year     | Month | #         | #     |                   |  |   |  |
| 1.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 2.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 3.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 4.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 5.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 6.                       | #   | #           | #     | #        | #     | #         | #     |                   |  |   |  |
| 7. None Selected         |     |             |       |          |       | #         | #     |                   |  |   |  |
| 8. Out of Range          |     |             |       |          |       | #         | #     |                   |  |   |  |
| Panic Value:             |     | L           |       | H        |       | Unit: U/l |       | Decimal Places: 1 |  |   |  |

| Calibration Specific |          |             |      |                               |             |                         |
|----------------------|----------|-------------|------|-------------------------------|-------------|-------------------------|
| General              |          | ISE         |      |                               |             |                         |
| Test name:           |          | LIPA II GEN |      |                               |             | Type: Serum             |
| Calibration Type:    |          | 3AB         |      | Formula: Polygonal            |             | Counts: 3               |
| Process:             |          | CONC        |      |                               |             |                         |
|                      | Cal. No. | OD          | CONC | Factor/OD-L                   | Factor/OD-H |                         |
| Point 1:             | #        |             | **   | -2.0000                       | 2.5000      |                         |
| Point 2:             | #        |             | *    | -2.0000                       | 2.5000      |                         |
| Point 3:             | #        |             | *    | -2.0000                       | 2.5000      |                         |
| Point 4:             |          |             |      |                               |             |                         |
| Point 5:             |          |             |      |                               |             |                         |
| Point 6:             |          |             |      |                               |             |                         |
| Point 7:             |          |             |      |                               |             |                         |
| 1-Point Cal.Point:   |          |             |      | Slope Check: None             |             | Advanced Calibration: # |
| MB Type Factor:      |          |             |      | Calibration Stability Period: |             | 14                      |

# User defined  
\* Calibrator value  
\*\* 0.9% NaCl

**REFERENCE VALUES<sup>4</sup>**

|              |             |                    |
|--------------|-------------|--------------------|
| Normal range | 13 – 60 U/l | 0.22 – 1.00 μkat/l |
|--------------|-------------|--------------------|

It is recommended for each laboratory to establish its own reference ranges for local population.

**QUALITY CONTROL**

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared every 2 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

#### PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Olympus AU400. Results may vary if a different instrument is used.

- **Sensitivity:** 1.3 U/l (0.022  $\mu$ kat/l).
- **Linearity:** up to 400 U/l (6.67  $\mu$ kat/l).  
For higher activity dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.
- **Specificity / Interferences**  
Haemoglobin up to 0.5 g/dl, bilirubin up to 60 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

#### ▪ Precision

| Repeatability (run to run)<br>n = 10 | Mean<br>[U/l] | SD<br>[U/l] | CV<br>[%] |
|--------------------------------------|---------------|-------------|-----------|
| level 1                              | 40.57         | 0.41        | 1.02      |
| level 2                              | 57.38         | 1.69        | 2.94      |

| Reproducibility (day to day)<br>n = 10 | Mean<br>[U/l] | SD<br>[U/l] | CV<br>[%] |
|--|---------------|-------------|-----------|
| level 1                                | 39.45         | 1.04        | 2.63      |
| level 2                                | 56.08         | 0.89        | 1.59      |

#### ▪ Method comparison

A comparison between lipase activity at Olympus AU400 (y) and at Cobas Integra 400 (x) using 67 samples gave following results:

$$y = 0.988 x + 2.100 \text{ U/l};$$

$$R = 1.000 \quad (R - \text{correlation coefficient})$$

#### WASTE MANAGEMENT

Please refer to local legal requirements.

#### LITERATURE

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