Bioway Chemistry Reagent Series
Lipase Test Kit

Detection of Lipase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R043K11 ***Lipase Test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

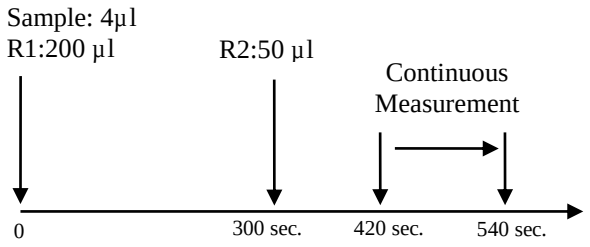

Table 1: Instrument Parameters*

Calibration method	2 point linear	Slope of reaction	increase
Wavelength	580 nm	Sample volume	4 µl
Test method	rate	R1 volume	200 µl
Reaction temperature	37℃	R2 volume	50 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Lipase Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Lipase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Lipase is a glycoprotein that catalyses the hydrolysis of ester chemical bonds in water-insoluble lipid substrates. Serum lipase levels can be useful for the diagnosis and therapeutic monitoring of pancreatic diseases. Elevated levels of lipase are found in acute pancreatitis, calculus or carcinoma that obstructs of the pancreatic duct, chronic or acute renal disease and after endoscopic retrograde pancreatography.

TEST PRINCIPLES

The Kit utilizes a two-part, liquid stable reagent enzymatic method for measuring lipase levels in human serum or plasma. The reagents use a clear substrate solution of 1,2-diglyceride, a natural lipase substrate derived from egg lecithin. It is a highly specific method for pancreatic lipase, using co-lipase and deoxycholate as activators. The colorimetric measurement of the rate of formation of the quinone dye from TOOS provides a highly sensitive reaction with excellent reproducibility and stability.

1,2-diglyceride + H2O $\xrightarrow{\text{Lipase}}$ 2-monoglyceride + fatty acid

2-monoglyceride + H_2O $\xrightarrow{\text{MGLP}}$ glycerol + fatty acid

Glycerol + ATP $\xrightarrow{\text{GK}}$ glycerol-3-phosphate + ADP

Glycerol-3-phosphate + O_2 $\xrightarrow{\text{GPO}}$ dihydroxyacetone phosphate + H2O2

$2H_2O_2$ + 4-aminoantipyrine + TOOS $\xrightarrow{\text{MDH}}$ quinone dye + $4H_2O_2$.

The rate of increase in absorbance at 570 nm is directly proportional to the Lipase concentration in the sample.

MATERIALS PROVIDED

Reagents:

R1	Colipase; surfactant; buffer
R2	Lipase substrate; buffer; Cholic acid; stabilizer

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. Lipase calibrator set (available for purchase) and control set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Other clinical test reagents may contain lipase, avoid cross-contamination by setting analyzers accordingly.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum or Heprin plasma samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens are stable at room temperature for 1 day, or store specimens at 2-8 ℃ for up to 5 days or frozen at -20℃ for up to 1 year. Avoid repeated freeze-thaw cycle.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using Bioway calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 4 µl of sample and 200 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Add 50 µl of R2, mix well and incubate at 37℃ for 120 seconds.
3. Take continuous optical density measurement for another 120 seconds.
4. Calculate average Δ A/min

RESULT

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The Lipase concentration in U/L can be obtained the following calculation:

$$\text{Lipase (U/L)} = \text{Concentration of standard} \times \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Standard}}$$

EXPECTED VALUES

< 60 U/L

It is recommended for each laboratory to establish its own expected values

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with Lipase exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 300 U/L (R≥0.995)

Precision: Within Run: CV≤6%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Bilirubin (60 mg/dL), ascorbic acid (30 mg/dL), and hemoglobin (500 mg/dL)

Reagent Blank Absorbance: at 580nm wavelength and 10 mm optical diameter, O.D. ≤ 0.30

REFERENCES

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4. Tietz N.W. and Shuey D.F., Lipase in Serum - the Elusive Enzyme : An verview. Clin Chem 1993; 39:746-56.
5. Ziegenhorn J. et al, Clin. Chem. 1979; 25:1067.

Not Intended for Sale in the United States.

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