

LIPASE

CATALOGUE NUMBER: 300-50
 300-53

SIZE: 10 x 10 mL + 1 x 35 mL
 5 x 30 mL + 1 x 50 mL

INTENDED USE

For the IN VITRO quantitative measurement of lipase activity in serum.
 Note: For veterinary laboratory use, additional information is available from technical services.

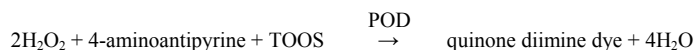
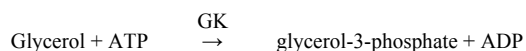
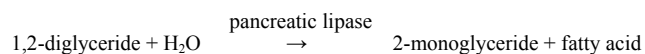
TEST SUMMARY

The measurement of lipase activity in serum and in other fluids is limited, almost without exception, to the evaluation of conditions associated with the pancreas.⁽¹⁾

Lipase activity has been measured with a turbidimetric method using triglyceride as the substrate and a colorimetric method using synthetic substrates.

This assay uses a colorimetric method with a natural substrate, 1,2-diglyceride, and co-lipase and deoxycholate as activators. The method is sensitive and specific for pancreatic lipase.⁽²⁻⁶⁾

TEST PRINCIPLE



MGLP: monoglyceride lipase TOOS: sodium N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine
 POD: peroxidase GPO: glycerol-3-phosphate oxidase
 GK: glycerol kinase

Serum lipase acts on the substrate 1,2-diglyceride to liberate 2-monoglyceride. The 2-monoglyceride is hydrolyzed by monoglyceride lipase into glycerol and fatty acid.

Glycerol kinase acts on glycerol to form glycerol-3-phosphate, which is oxidized by glycerol-3-phosphate oxidase to generate hydrogen peroxide. In the presence of hydrogen peroxide, 4-aminoantipyrine, and TOOS, a quinone dye is produced. The rate of increase in absorbance at 550 nm is proportional to the lipase activity in the sample.

REAGENTS

Enzyme Substrate: A solution (after reconstitution) containing buffer (pH 6.8 at 25°C), > 860 U/L MGLP (microbial) > 1,330 U/L GK (microbial), > 40,000 U/L GPO (microbial), > 1,330 U/L POD (botanical), > 40,000 U/L co-lipase, 634 mg/L 1,2-diglyceride, 2.3 mM TOOS, and 0.73 mM ATP.

Enzyme Substrate Diluent: A solution containing uffer (pH 6.8 at 25°C) and 5.3 mM cholic acid.

Activator Solution: A solution containing buffer (pH 8.7 at 25°C), 36 mM deoxycholate, and 5.9 mM 4-aminoantipyrine.

WARNINGS & PRECAUTIONS FOR USE

S24/25: Avoid contact with skin and eyes.

Avoid ingestion.

See Material Safety Data Sheet for additional information.

REAGENT PREPARATION, STORAGE & STABILITY

Add the required volume of enzyme substrate diluent to the enzyme substrate. See vial label. Mix gently, wait one minute, re-mix.

The activator solution is ready to use.

Supplied reagents stable at 2-8°C until expiry date.

Prepared enzyme substrate stable at 2-8°C for 21 days. Stability claims are based on real time studies.

REAGENT DETERIORATION

The reagent solutions should be clear. Turbidity would indicate deterioration.

DISPOSAL

Reagents must be disposed of in accordance with all Federal, Provincial, State, and local regulations.

SPECIMEN

Fresh, clear, unhemolysed serum. Serum should be separated immediately after collection and the lipase activity assayed promptly.

SAMPLE STORAGE

Samples should be analyzed within 30 minutes. If this is not possible, samples may be tightly stored at 2-8°C for 2 hours or at -20°C for 24 hours.⁽⁵⁾

ANALYTICAL SPECIFICITY

Cross contamination studies have not been performed on automated instruments. Certain reagent/ instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Endogenous glycerol interference is eliminated at concentrations less than 100 mg/dL glycerol (10.86 mmol/L glycerol).

Interferences from icterus, lipemia, and hemolysis were evaluated for this lipase method on a Roche/Hitachi® 704 analyzer using a significance criterion of >10% variance from control. Interference data was collected in serum.

Activity of Analyte	Substance Tested	Concentration of Interferent Where Interference is Insignificant	
510.5 U/L	Hemoglobin	1000 mg/dL	155 µmol/L
514.0 U/L	Bilirubin	20 mg/dL	342 µmol/L
510.0 U/L	Intralipid	1000 mg/dL	3000 mg/dL (34 µmol/L) Simulated Triglycerides

The information presented above is based on results from Genzyme Diagnostics' studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.⁽⁷⁾

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

Genzyme Diagnostics' Lipase reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED)

1. Automated analyzer capable of accurately measuring absorbance at 550 nm.
2. Calibration material (Lipase Calibrator, Cat. No. SE-050 is appropriate for use).
3. Quality Control materials.

TEST CONDITION

For the data presented in this insert, studies using this reagent were performed using a rate test mode, with a sample to reagent ratio of 1:80 and a primary wavelength reading of 550 nm. For assistance with applications on automated analyzers within Canada and the U.S., please contact Genzyme Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

Calibration material should be used to calibrate the procedure. Cat. No. SE-050 is available from Genzyme Diagnostics for this purpose. The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required in accordance with local, state and federal guidelines. The results should fall within the acceptable ranges established by the laboratory.

CALCULATIONS

The analyzer automatically calculates the lipase activity of each sample.

TEST LIMITATIONS

A sample with lipase activity exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS⁽⁷⁾

7.2-59.3 U/L (37°C)

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

PERFORMANCE CHARACTERISTICS

RESULTS

Lipase activity is reported as U/L.

REPORTABLE RANGE

The generic procedure is linear to 600.0 U/L. Linearity using automated procedures will depend on the sample/reagent ratio used.

PRECISION STUDIES

Total precision was established by assaying two control sera six separate times.

Activity (U/L)	Total SD (U/L)	Total CV %	Activity (U/L)	Within Run SD (U/L)	Within Run CV %
42	1.8	4.2	43	0.8	1.8
252	6.0	2.4	269	4.2	1.6

Within run precision was established by assaying two control sera twenty times.

ACCURACY








A comparison was made between this method and Ektachem 700 using 99 samples ranging from 0-600 U/L. The correlation coefficient was 0.9945. Linear regression analysis gave the following equation:

This method = 0.2815 (reference method) - 8.73 U/L.

The information presented above is based on results from Genzyme Diagnostics' studies and is current at the date of publication.

REFERENCES

1. Tietz, N.W. (Ed.), Fundamentals of Clinical Chemistry, W.B. Saunders Co., Toronto, 635 (1982).
2. Imamura, S. and Misaki, H.: "A sensitive method for assay of lipase activity by coupling with β -oxidation enzymes of fatty acid." Selected Topics in Clinical Enzymology 2:73, 1984.
3. Imamura, S. et al.: "A method using 1,2-diglyceride as substrate for assay of lipase activity by coupling with β -oxidation enzymes of fatty acid" Collection of summaries of lectures in the 126th general meeting of Kinki Branch, Analytical Section, Japan Society of Clinical Chemistry, p.11-31, 1986.
4. Hayashi, C. and et al.: "Assay methods for human lipases" Clinical Examination, Instrument and Reagent, 2:225, 1986.
5. Kitaura, S. et al.: "Properties of monoglyceride lipase produced by thermophilic bacteria" Collection of summaries of lectures in the 61th general meeting of The Japanese Biochemical Society, 848, 1988.
6. Imamura, S. et al., Clin., Chem., Abstract Issue in the 41st National Meeting, 1120, 1989.
7. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, Third Edition, 1990.

Definitions for Symbols	
 LOT Batch code	 Use by YYYY-MM-DD or YYYY-MM
 Manufacturer	 REF Catalog number
 Consult instructions for use	 Temperature limitation
 IVD <i>in vitro</i> diagnostic medical device	

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IN30050-15

April 2, 2009