LIPASE (LPS)

COLORIMETRIC
RX DAYTONA PLUS

INTENDED USE

A Lipase test system is a device intended for the quantitative *in vitro* determination of Lipase in human serum and plasma. This product is suitable for use on the RX **daytona plus**, RX **series** analyser.

FOR PRESCRIPTION USE ONLY.

Cat. No.			
LI 8361	R1.	Lipase Buffer	4 x 20 ml
	R2.	Lipase Substrate	4 x 11.2 ml

GTIN: 05055273214284

CLINICAL SIGNIFICANCE [1]

A lipase test system is a device intended to measure the activity of the enzyme lipase in serum and plasma. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

PRINCIPLE [2, 3]

The chromogenic Lipase substrate 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.

SPECIMEN COLLECTION PREPARATION AND STORAGE

Collect serum using standard sampling tubes and plasma using tubes containing Li heparin.
Lipase is stable for 5 days at +2°C to +8°C or 24 hours at +20°C to +25°C.

REAGENT COMPOSITION

Contents		
R1.	**Buffer**	
	TAPS [a]	100 mM
	Sodium hydroxide	40 mM
	Sodium deoxycholate	34 mM
	Sodium azide	7.7 mM
R2.	**Substrate**	
	(+)-Tartaric acid	9.5 mM
	Sodium hydroxide	19 mM
	Colipase	460 IU/ml
	2-Propanol	0.65 M
	DGGMR[b]	0.4 mM

Acronyms: (a) = N-Tris(hydroxymethyl)methyl-3-aminoprpanesulfonic acid.
(b) = 1,2-O-Dilauryl-rac-glycero-3-glutaric acid-(6'—methylresorufin)-ester.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Handle laboratory reagents in accordance with good laboratory practice.

Reagent 1 contains sodium azide. Avoid ingestion or contact with skin and mucous membranes. In case of skin contact, wash affected area with water for 10 minutes. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Health and Safety Data Sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

Suitably qualified laboratory personnel, under appropriate laboratory conditions must use the reagents only for the purpose intended.

STABILITY AND PREPARATION OF REAGENTS

R1. Buffer
Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

R2. Substrate
Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

R1 = Buffer
R2 = Substrate

MATERIALS PROVIDED

Lipase Buffer
Lipase Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

RX **series** Saline (Cat. No. SA 8396)
Randox Assayed Multi-sera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Acid Wash Solution (Cat. No. WS 8397)

PROCEDURE NOTES

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

RX instrument running order should be arranged so that Lipase is before Triglycerides as the last two chemistries. LDL should also not be positioned directly before or after Lipase.

To avoid the potential for reagent carryover, it is recommended that the Randox cholesterol reagent is not run directly before this lipase reagent.

Bile Acids and lipase should not be tested in the same run.

RX DAYTONA PLUS CALIBRATION

The use of Saline and Randox Calibration Serum Level 3 is recommended for calibration. A 2 point calibration is recommended.

STANDARDISATION

Randox Calibration Serum Level 3 is traceable to a lipase internal master reference material.

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

NORMAL VALUES [4]

Normal range: 5.6 – 51.3 U/l

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using a RX **daytona plus** analyser.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for Lipase on the RX **daytona plus** is 2.5 to 759 U/l**.**

In the event of a rerun recovery studies demonstrate that the measuring range can be extended up to 7590 for the RX **daytona plus** analyser within ± 10% of the Lipase concentration.

SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with ≤20% bias and ≤20% imprecision. LoD is the lowest concentration that can be detected to determine the presence or absence of Lipase. LoB is the highest concentration that is likely to be observed in a blank sample.

RX daytona plus

Limit of Blank (U/l)	0.390
Limit of Detection (U/l)	0.674
Limit of Quantitation (U/l)	2.50

PRECISION

Precision was evaluated using 2 unaltered human samples at 2 distinct levels. All samples were tested in singlicate twice a day for 22 days.

WITHIN RUN PRECISION

	Level 1	Level 2
Mean (U/l)	46	93
SD	0.68	0.90
CV (%)	1.5	1.0
n	44	44

TOTAL PRECISION

	Level 1	Level 2
Mean (U/l)	46	93
SD	2.04	1.49
CV (%)	4.5	1.6
n	44	44

REFERENCES

1. Tietz NW *et al.* Lipase in serum-the elusive enzyme: An overview. *Clin Chem* 1993; **39:746**-756.
2. Steinberg WM, Goldstein SS, Davies ND *et al.* Diagnostic assays in acute pancreatitis. (Review). *Ann Intern Med* 1985; **102**:576-580.
3. Leybold A, Junge W. Importance of colipase for the measurement of serum lipase activity. *Adv clin Enzymol* 1986; **4:60**-67.
4. Data on file at Randox.

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