LIPASE (LPS)

COLORIMETRIC
HITACHI 717

INTENDED USE

For the quantitative *in vitro* determination of Lipase in human serum and plasma. This product is suitable for use on the Hitachi 717.

Cat. No.

LI 7979	R1.	Lipase Buffer	6 x 20 ml
600 tests	R2.	Lipase Substrate	3 x 20 ml

GTIN: 05055273204247

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.

SAMPLE COLLECTION 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 to +8°C.

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

R1 = Buffer
R2 = Substrate

MATERIALS PROVIDED

Lipase Buffer
Lipase Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

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)

PROCEDURE NOTES/ ASSAY LIMITATION

Program analyser with the appropriate instrument settings (see below). Enter values based on those given in the Randox calibration insert sheet.

If running Randox Lipase and Randox Triglycerides or Randox LDL reagent:
Instrument running order should be arranged so that Randox Lipase is before Randox Triglycerides as the last two chemistries. Randox LDL should also not be positioned directly before or after Lipase.

PROCEDURE 1: SMS preceding Lipase determination

Temperature:	+37°C

PROGRAM 2 CHEMISTRY PARAMETERS

TEST	*(SMS)
ASSAY CODE (1 POINT)	1-50-0
SAMPLE VOLUME (µl)	1-1
R 1 VOLUME (µl)	350-100-0
R 2 VOLUME (µl)	350-100-0
WAVELENGTH (nm)	0-800
CALIB METHOD	1-0-0
STD 1 CONC-POS	0-1
STD 2 CONC-POS	0-2
STD 3 CONC-POS	0-0
STD 4 CONC-POS	0-0
STD 5 CONC-POS	0-0
STD 6 CONC-POS	0-0
SD LIMIT	0.1
DUPLICATE LIMIT	100
SENSITIVITY LIMIT	0
ABS. LIMIT (INC/DEC)	0-0
PROZONE LIMIT	0-0
EXPECTED VALUE	0-100000
INSTRUMENT FACTOR	1.0

* Data entered by operator

PROCEDURE 2: LIPASE DETERMINATION

Temperature:	+37°C

PROGRAM 2 CHEMISTRY PARAMETERS

TEST	*(LIPASE)
ASSAY CODE (RATE-A)	5-29-38
SAMPLE VOLUME (µl)	3
R 1 VOLUME (µl)	200-20-0
R 2 VOLUME (µl)	100-20-0
WAVELENGTH (nm)	700-570
CALIB METHOD	1-0-0
STD 1 CONC-POS	0.0-1
STD 2 CONC-POS	assigned value-2
STD 3 CONC-POS	0-0
STD 4 CONC-POS	0-0
STD 5 CONC-POS	0-0
STD 6 CONC-POS	0-0
SD LIMIT	0.1
DUPLICATE LIMIT	50
SENSITIVITY LIMIT	0
ABS. LIMIT (INC/DEC)	32000-0
PROZONE LIMIT	0-0
EXPECTED VALUE	* - *
PANIC VALUE	* - *
INSTRUMENT FACTOR	1.00

* Data entered by operator

CALIBRATION

We recommend that this assay should be calibrated using Randox Calibration Serum Level 3.

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.

INTERFERENCES

Serum analytes other than Lipase were added to normal serum spiked with Lipase. The following analytes were tested up to the following levels and found not to interfere:

Bilirubin	72.7 mg/dl
Haemoglobin	441 mg /dl
Triglyceride	2615 mg/dl

NORMAL RANGE[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.

ASSAY RANGE

The range of this assay is approximately 3.50 - 651 U/l.
If the sample activity exceeds the upper limit, dilute sample 1+1 with 0.9% NaCl Solution and reassay.
Multiply the result by 2.

SENSITIVITY

The minimum level of Lipase detectable with an acceptable level of precision has been determined as 3.50 U/l.

PRECISION (Serum)

Intra Assay Precision

	Level 1	Level 2	Level 3
Mean (U/l)	20.6	39.2	109
SD	0.691	0.581	1.41
CV (%)	3.35	1.48	1.30
n	20	20	20

Inter Assay Precision

	Level 1	Level 2	Level 3
Mean (U/l)	18.6	35.4	75.6
SD	0.369	0.869	1.78
CV (%)	1.98	2.46	2.35
n	20	20	20

METHOD COMPARISON

The Randox method (Y) was compared to another commercially available method (X). Forty patient samples with values spanning the range 9.4 to 344.4 U/l were tested. Linear regression analysis of the data resulted in the following equation:

$$Y = 1.05\ X - 2.00$$

With a correlation coefficient r = 0.99

SERUM/PLASMA CORRELATION

The Randox method was used to compare serum samples (X) to plasma samples (Y) taken from the same donor. Seventeen samples were tested. Linear regression of these data resulted in the following equation:

$$Y = 0.98\ X + 1.15.$$

With a correlation coefficient r = 0.99.

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.

Revised 26 Feb 18 pl
Rev. 004

THIS PAGE IS INTENTIONALLY BLANK