LIPASE SYSTEM PACK

(Methyl Resorufin Method)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI26	Lipase System Pack	2x40 + 2x10 ml

BEACON

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Lipase in human serum and Plasma.

CLINICAL SIGNIFICANCE

Lipases are enzymes which hydrolyze glycerol ester of long fatty acids. The enzyme and its cofactor colipase is produced in the pancreas, lipase being also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate / water interface. Determination of lipase is used for investigation of pancreatic disorders. In acute pancreatitis the lipase concentrations rise to 2-50 fold to upper reference limit within 4-8 hours after begin of abdominal pain peaking at 24 hours and decreasing within 8 to 14 days. Elevated lipase values can also be observed in chronic pancreatitis and obstruction of the pancreatic duct.

PRINCIPLE

Enzymatic color test.

The colorimetric substrate 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin)-ester is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the alkaline test condition to yield the chromophore methylresorufi. The kinetic of color formation at 580 nm is monitored and it is proprtional to lipase activity in sample.

REAGENT COMPOSITION

Reagent 1 : Lipase Reagent 1

Bicine Buffer	>40 mmol/l
Colipase	>0.98 mg/l
Na-Deoxycholate	>1 mmol/l
Calcium Chloride	>8 mmol/l

Reagent 2 : Lipase Reagent 2

Buffer	>8 mmol/l
Taurodeoxyl-Cholate	>8 mmol/l

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

Reagent R2 is a microemulsion. Therefore, a slight apparent precipitation could occur, showing a light red deposit on the bottom of vial. It is a normal behavious and it is recommended to resuspend solution before analysis with a mild shaking.

On board stability: Min 30 days if refrigerated (+8-+14°C) and not contaminated.

SPECIMEN COLLECTION & HANDLING

Use serum, Plasma (hepairin, EDTA).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

in serum / plasma:	7 days	at +4 - +8°C
	1 year	at -20°C

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

U/l x 0.017 = µkat/l

EXPECTED VALUES

Serum

at 37°C = Up to 60 U/L (=1.0 µkat/l)

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon System. Data obtained in your laboratory may differ from these values.

Limit of quantification: 3 U/L
Linearity: 300 U/L
Measuring range: 3 - 300 U/L

PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	44	1.34	3.07
Sample 2	73	1.50	2.04

Intra-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	38.73	1.11	2.87

COMPARISON

A comparison between Lipase System Pack (y) and a commercially available test (x) using 20 samples gave following results:

y = 1.044x - 0.604 U/L
r = 0.995

INTERFERENCES

Following substances do not interfere:
Hemoglobin upto 4.5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 1000 mg/dl.

NOTE:

Reagents such as Triglyrides,Cholesterol,LDL,HDL,Albumin contain high concentration of detergent and hydrolysing enzymes,cross contamination from such reagent should be avoided.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagents 1 is not classified as dangerous. It contains less than 0.1% sodium azide, which is classified as very toxic and dangerous substance for environment.

Reagent 2 of the kit contains less than 5% propan-1-ol.

WASTE MENAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 , Beaconic Chem 400 &
(Fully Auto Biochemistry Analyzer)

TEST NAME	LIPASE
FULL NAME	LIPASE
PRI WAVE	578 nm
SEC WAVE	-
ASSAY/POINT	FIXED TIME
START	10
END	23
DECIMAL	2
UNIT	U/L
LINEARITY RANGE LOW	3
LINEARITY RANGE HIGH	300
SAMPLE VOLUME	4 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	50 µl
SUBSTRATE DEPLETED	-
LINEARITY	300
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTRATION STD	Refer calibrator label.

REFERENCES

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SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics