Lipase (LPS) diagnostic reagent Kit (Enzymatic colorimetric method)
Product Instruction

Product name
Generic Name: Lipase (LPS) Diagnostic Reagent Kit (Enzymatic colorimetric method)
Abbreviation: LPS

Package Specifications
Calibrator (lyophilized):
Specification 1 (0.5mL×1; 1 level);
Quality Control (lyophilized):
Specification 1 (0.5mL×1; 1 level);

Intended use
Lipase (LPS) diagnostic reagent is used for quantitative in vitro determination of lipase in human serum and plasma on photometric systems.

Clinical significance
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
The chromogenic Lipase substrate 1, 2-o-dilauryl-rac- glycero-3-glutaric acid-(6 ' -methylresorufin)-ester (DGGMR) 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.

Main ingredient

Composition	Main ingredients
R1	Buffer pH7.5 100mmol/L, Taurodeoxycholic acid 34mmol/L
R2	Tartaric acid buffer, co-lipase 50KU/L, 1,2-o-dilauryl-rac- glycero-3-glutaric acid-(6'-methylresorufin)-ester.
Calibration	PBS buffer 50mM, sucrose 5%, BSA 8%, Lipase 5%.
Quality control	PBS buffer 50mM, sucrose 5%, BSA 8%, Lipase 1%.

Storage and stability
This kit stays stable for 12 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
-20℃, stable for 7 days.

Assay procedure
1. Operation steps
This reagent is liquid and can be used directly.
For 2:1 reagent

Main wavelength	570 nm	Sample(S)	3 μl
Subwavelength	700nm	Reagent 1	200 μl
Reation temperature	37℃	Reagent 2	100 μl
Reaction type	Rate method	reaction direction	Ascending (+)
Incubate for 300 seconds, zero setting for the reagent + water, and measure the absorbance change rate within 2 minutes.			

For 3:1 reagent

Main wavelength	570 nm	Sample(S)	3 μl
Subwavelength	700nm	Reagent 1	225 μl
Reation temperature	37℃	Reagent 2	75 μl
Reaction type	Rate method	reaction direction	Ascending (+)
Incubate for 300 seconds, zero setting for the reagent + water, and measure the absorbance change rate within 2 minutes.			

For 4:1 reagent

Main wavelength	570 nm	Sample(S)	4 μl
Subwavelength	700nm	Reagent 1	200 μl
Reation temperature	37℃	Reagent 2	50 μl
Reaction type	Rate method	reaction direction	Ascending (+)
Incubate for 300 seconds, zero setting for the reagent + water, and measure the absorbance change rate within 2 minutes.			

Reference interval
6～60U/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
Measuring range
For 2:1 reagent:
6U/L - 600U/L;

For 3:1 reagent:
6U/L - 400U/L;
For 4:1 reagent:
6U/L - 300U/L.
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference
The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	40mg/dl
Haemoglobin	200mg/dl
VC	30mg/dl
Triglyceride	1000mg/dl

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

Analyzer parameters
For 2:1 Reagent

HITACHI	
Model	7180
Assay Code	Rate A
Reaction Time	10
Assay Point	21-29
Wave Length Sec	700
Wave Length Prim	570
ABS. Limit	32000
Sample Volume（uL）	3
R1 Volume（uL）	200
R2 Volume（uL）	0
R3 Volume（uL）	100
Calibration Type	LINER
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	3
Sample DIL. VOL.	/
R1 Volume（uL）	200
R2 Volume（uL）	100
Reagent DIL. VOL.	/
Measure Wave 1	570
Measure Wave 2	700
METHOD	RATE
SLOPE	-
Method Point	16-22
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	LINER
STD(1) Conc.#	*
Unit	U/L

For 3:1 Reagent

HITACHI	
Model	7180
Assay Code	Rate A
Reaction Time	10
Assay Point	21-29
Wave Length Sec	700
Wave Length Prim	570
ABS. Limit	32000
Sample Volume（uL）	3
R1 Volume（uL）	225
R2 Volume（uL）	0
R3 Volume（uL）	75
Calibration Type	LINER
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	3
Sample DIL. VOL.	/
R1 Volume（uL）	225
R2 Volume（uL）	75
Reagent DIL. VOL.	/
Measure Wave 1	570
Measure Wave 2	700
METHOD	RATE
SLOPE	-
Method Point	16-22
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	LINER
STD(1) Conc.#	*
Unit	U/L

For 4:1 reagent

HITACHI	
Model	7180
Assay Code	Rate A
Reaction Time	10
Assay Point	21-29
Wave Length Sec	700
Wave Length Prim	570
ABS. Limit	32000
Sample Volume（uL）	4
R1 Volume（uL）	200
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	LINER
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or(0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	4
Sample DIL. VOL.	/
R1 Volume（uL）	200
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	570
Measure Wave 2	700
METHOD	RATE
SLOPE	-
Method Point	16-22
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	

FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	LINER
STD(1) Conc.#	*
Unit	U/L

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