

[Size]

Liquid

R1: 30 mL×1, R2: 10 mL×1

【Intended Use】

In vitro test for the quantitative determination of lipase (LPS) activity in human serum .

Determination of LPS activity is used to reflect disorders of pancreas. When acute pancreatitis occurs, the increase of serum LPS activity can last for 10-15 days. Serum LPS helps a lot to the diagnosis of acute pancreatitis. Clinical study has proved that the sensitivity is 80%-100% and the specificity is 84%-96%.

【Principle】

Lipase hydrolyzes the substrate 6-methyl test halogen spirit ester in microemulsion solution in the presence of Co lipase and bile acid. The presence of lipase and bile acid inhibits the affection of other hydrolases and esterases, so this method can detect the activity of LPS reliably without the affection of serum matrix effect. When 6-methyl test halogen spirit ester was degraded to 6- methylresorufin, the increase of absorbance caused by the red dye is in direct proportion to the lipase activity in the sample

【Components】

	Components	Concentration
R1	Sodium deoxycholate	58.0 mmol/L
R2	DGGMR Cholinesterase	0.35 mmol/L 300 IU/mL
CAL	Lyophilized	Mentioned on Vial Label

[Storage and Stability]

- Unopened reagent: stable for 18 months at 2~8℃, protect from light.
- Opened reagent: stable up to 30 days at 2~8℃, protect from light.

[Specimen Collection and Handling]

Only the specimens listed below were tested and found acceptable.

For specimen collection and preparation, only use suitable tubes or collection containers.

Specimen: Serum samples on an empty stomach are the recommended specimens.

Serum: Collect fresh serum using standard sampling tubes. When processing samples in primary tubes, follow the instructions of the tube manufacturer.

For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended.

Stability : Store serum less than 4 days at 2 ~ 8℃, 1 month at -25℃ ~ -15℃. Protected from light and avoid repeated freeze thaw cycles.

[Procedure]

Reagent preparation: 3R1:1R2

Pri Wavelength: 570nm **Sec Wavelength:** 700nm

Temperature: 37℃

Cuvette: 1cm

	Blank Tube	Calibration Tube	Sample Tube
Sample	—	—	3 μL
Calibrator	—	3μL	—
Deionized water	3μL	—	—
R1	225μL	225μL	225μL
Mix, incubate at 37°C for 5 minutes.			
R2	75μL	75μL	75μL
Mix, incubate at 37°C for 6 to 8.5 minutes, calibrate with blank tube calculate change rate of absorbance per minute (ΔA/min(sample)) .			

Calibration

Calibration frequency :30 days

Recalibration is recommended:

- after reagent bottle change
- after reagent lot change
- if required following quality control

- if key component of analyzer is changed

Quality control

It is recommended to use Lipase Controls for daily quality control.

Two levels of controls should be assayed at least once a day.

Values obtained should fall within a specified range.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Calculation :

The analyzer automatically calculate the analyte concentration of each sample.

[Expected Value]

13 U/L~63U/L

The reference range should be determined by each hospital to confirm with the characteristics of the region being tested.

【Limitations and Interference】

- Lipemia (Intralipid): no interference up to 1000mg/dl of intralipid.
- Hemolysis: no interference up to 50mg/ dl.
- Bilirubin: no interference up to 50mg/ dl.
- VC: no interference up to 30mg/ dl.

The result may vary with different analyzers or calibrations.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

【Performance characteristics】

Blank Absorbance

A ≤0.3000, ΔA/min≤0.005

Accuracy ≤±10%

Analytical sensitivity ΔA>0.01 at 100U/L LPS

CV ≤5%。


Batch Error R≤6%。








Measuring range: 0~300U/L



【Precautions and warnings】

- For in vitro diagnostic use.
- Avoid skin and eye contact. Avoid ingestion.
- Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.
- Do not use the product if interior package is damaged during shipment.
- The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth, calibration results do not meet the appropriate standard specification, or control values out of range.
- Exercise the normal precautions required for handling all laboratory reagents.
- Wear protective clothing and disposable gloves while handling the kit reagents.
- Wash hands thoroughly after performing the test.
- Use in ventilated area.
- For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician".
- For biological spills, indicate appropriate disinfectants and disinfection procedure.
- Dispose of all specimens and components of the kit as potentially infectious agents.
- Do not use the kit or any kit component past the indicated expiry date.
- Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
- Avoid microbial contamination of reagents.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

【Definition of Symbols】

USE BY (LAST DAY OF THE MONTH)	
BATCH CODE	LOT

DATE OF MANUFACTURE	
TEMPERATURE LIMITS	
CONSULT INSTRUCTIONS FOR USE	
HANDLE WITH CARE	
UPWARDS LAY	
KEEP DRY	
KEEP AWAY FROM SUNLIGHT	
IN VITRO DIAGNOSTIC MEDICAL DEVICE	IVD

CATALOGUE NUMBER	REF
SUFFICIENT FOR	
MANUFACTURER	

【Bibliography】

1.Ministry of Health of the People's Republic of China. National Clinical Laboratory Operation Instruction (edition 3). Southeast University Press. 2006.

【Manufacturer】



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