Emulsion Lipase

CLINICAL SIGNIFICANCE

Physiological Distribution and Specificity

The exocrine function of the pancreas involves the production of enzymes in small amounts, which are secreted into the digestive tract. Among these, pancreatic lipase plays a key role by cleaving **glycerol esters from long-chain fatty acids**. This enzyme is highly specific to pancreatic tissue, as it is synthesized and stored within the acinar cells. Under normal physiological conditions, only minimal concentrations of lipase are present in the bloodstream.

Diagnostic Utility in Acute Pancreatitis

This **Emulsion Lipase** method is intended for the quantitative determination of lipase in serum or plasma. It is a critical diagnostic tool for the clinical management of pathologies such as **Acute Pancreatitis**.

METHOD PRINCIPLE

This method is based on the turbidimetric determination of pancreatic lipase activity through the enzymatic hydrolysis of a stabilized oil-in-water triglyceride emulsion in a Tris buffered medium. As the lipase in the sample cleaves the triglycerides into monoglycerides and fatty acids, a progressive clearing of the emulsion occurs. This reduction in turbidity is measured photometrically as a decrease in absorbance at 340 nm, where the rate of decline is directly proportional to the lipase catalytic activity present in the specimen.

Reagents Composition

Name	Qty	Values
Tris Buffer,	16 mMol/L	pH 8-8.9
Triolein	0.3mMol/L	NRD
Sodium deoxycholate	19mMol/L	NRD
Calcio Cloride 0.01mMol/L	0.01mMol/L	NRD

Reagents Provided: One vial reagent - Ready to Use. **(Ref: GQ-LL-60, GQ-LL-2X30)**

Materials Required but not provided

- Clinical Chemistry Analyzer (Semi-automated) with 37°C temperature control and filter of 340nm
- Deionized water and Class A glassware.
- Automatic Pipettes
- Assayed Human Control serum (Optional, for validation)

Sample Collection	Interference	Storage and Stability of Reagent	ASSAY PRECAUTIONS
• Fresh Serum or refrigerated for up to 3 weeks with 2 to 8°C • Avoid samples with marked hemolysis. • Stability: up to 1 year at -20°C.	• **Hemoglobin:** Negative interference at high concentrations. • **Bilirubin:** No significant interference up to 20 mg/dL. • **Lipemia:** As this is a turbidimetric method, extremely lipemic samples may require a 1:5 dilution with saline solution.	• Store at **2-8°C** protected from light. • The reagent is stable until the expiration date indicated if uncontaminated.	1. For *in vitro* diagnostic use only. 2. Reagent contains Sodium Azide (0.09%) as a preservative. 3. Avoid detergent contamination; lipase is highly sensitive to surface tension changes.

Work Reagent Preparation:

Dilute 25 µL of substrate into 1 mL of buffer. Homogenize gently and allow to stand for 10 to 15 minutes before use. The working reagent is stable for up to 7 days at room temperature.

Instrument Assay Procedure

Semi Automatic	Automatic
• **Method:** Rate Method • **Calibration Type:** Factor Method • **Calibration Point 1:** Please refer to the Lot-specific Certificate of Analysis for the appropiate calibration factor. • **Wavelength:** 340 nm. • **Temperature:** 37°C. • **Blank Setting:** DI Water • **Reagent Volume:** 400 µL. • **Sample Volume:** 20 µL. • **Lag Time:** 20 seconds. • **Read Time:** 300 seconds • Bring reagent and samples to Room Temperature 25°C	• **Reaction Type:** Decreasing • **Wavelength:** 340 nm. • **Temperature:** 37°C. • **Blank Setting:** DI Water • **Reagent Volume:** 200 µL. • **Sample Volume:** 10 µL. • **Lag Time:** 20 seconds. • **Read Time:** 300 seconds. • **Factor:** Please refer to the Lot-specific Certificate of Analysis for the appropiate calibration factor. • **Reagent Onbord:** 3 Weeks - Refrigerated

OTHER REFERENCES

Performance	Reference Values	Common errors	BIBLIOGRAPHY
• **Limit of Detection:** 3U/L (Instrument dependent). • **Linearity:** Up to 1000 U/L (Dilute 1:10 for higher samples). • **Precision:** Intra-assay C.V. < 0.99%.	• < 200 U/L (*) • **Reference Ranges:** Lipase levels are typically very low in children. In adults, values vary by methodology; for instance, **colorimetric methods often show normal levels below 60 U/L**, while other techniques may reach up to 200 U/L.(*) • **Atlanta Criteria for Diagnosis:** According to the **Revised Atlanta Classification**, a diagnosis of acute pancreatitis requires serum lipase activity at least **three times (3x) the upper limit of normal (ULN)**. • **Kinetics (Diagnostic Window):** In acute pancreatitis, lipase rises within 3 to 6 hours of onset. It remains elevated for a longer period, typically **8 to 14 days**, whereas amylase normalizes sooner. • **Severity Correlation:** The magnitude of serum lipase elevation is not proportional to the clinical severity of the attack. • **Sample Stability:** For accurate results, use **fresh serum** or store **refrigerated at 2–8°C for up to 3 weeks**.	**Check List:** 1. **Bubbles in the cuvette:** As this is a light-scattering method, bubbles will falsely elevate results. 2. **Cuvettes Opaque or dirty :** Residues from other reagents containing detergents will inhibit colipase activity. 3. **Unstable temperature:** Enzymatic kinetics vary by approximately 7% per degree Celsius. 4. **Electronic Noise:** Faulty electrical impedance or poor grounding can destabilize absorbance readings at 340 nm, leading to erratic kinetic signals and inaccurate activity results.	1. **Shihabi, Z. K., & Bishop, C. (1971).** *Simplified turbidimetric assay for lipase activity.* **Clinical Chemistry**, 17(12), 1150–1153. 2. Tietz, N.W., Textbook of Clinical Chemistry, 3rd Ed. 3. **Vogel, W. C., & Zieve, L. (1963).** *A rapid and sensitive turbidimetric method for serum lipase based upon differences between the lipolysis of human serum and a purified pancreatic lipase.* **Clinical Chemistry**, 9(2), 168–181.

QUALITY CONTROL

In-House Performance Validation:

Internal verification was conducted using 50 known reference controls, achieving a **99.1% correlation** with the predicate methodology. The regression analysis yielded a **Slope of 1.02** (Range: 0.98 – 1.05), demonstrating excellent recovery and clinical accuracy across the entire analytical range.

System Validation and Calibration:

It is mandatory for the laboratory to validate the assay before routine use. This specific method utilizes a **lot-specific factor** provided in the Certificate of Analysis (CoA) and is designed **without the use of colipase**.

IMPORTANT: Due to the absence of colipase in this formulation, **standard commercial control serums may not be compatible** and could yield inaccurate results. System integrity and factor accuracy must be verified exclusively using **Assayed Human Serum** with known lipase values established by equivalent emulsion-based methods.

Intra-Laboratory Quality Program:

- Each laboratory must establish an internal quality control program specifically adapted for this **colipase-free** method.
- **Source of Control Material:** It is highly recommended that the **reagent provider supplies Assayed Human Serum** rather than standard commercial controls. Due to the emulsion-based principle of this assay, only human-derived samples with known values are suitable for validating the lot-specific factor.

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