Lipase Kinetic

CLINICAL SIGNIFICANCE

Physiological Distribution and Specificity

Pancreatic Lipase is an enzyme primarily synthesized and secreted by the pancreatic acinar cells into the duodenum for the hydrolysis of long-chain triglycerides. Unlike amylase, which is present in various tissues like the salivary glands, lipase is highly specific to pancreatic tissue, making its serum determination a more reliable indicaror of pancreatic cell injury.

Diagnostic Utility in Acute Pancreatitis

Lipase determination is fundamental in the diagnosis of acute pancreatitis, where serum levels may rise from 2 to 50 times the upper limit of normal. Compared to other biomarkers, lipase remains elevated for longer periods (up to 14 days), providing a broader diagnostic window that is crucial for evaluating patients who present several days after the onset of clinical symptoms

METHOD PRINCIPLE

Unlike traditional clearing turbidimetric methods, this assay utilizes a stabilized emulsion that, upon reaction with the lipase in the sample, generates an **increase in turbidity**.
Lipase, in the presence of **colipase** and bile salts (activators), hydrolyzes the fatty acid substrate. The hydrolysis products (free fatty acids) interact with the buffer components and the antiprecipitant to form micellar aggregates that increase light scattering. The increase in absorbance at **340 nm** is directly proportional to the lipase activity in the sample.

Reagents Composition

Name	Qty	Values
Tris Buffer,	26 mMol/L	pH 8-9.2
Triolein	0.3mMol/L	NRD
Sodio deoxicolate	19mMol/L	NRD
Calcio Cloride 0.01mMol/L	0.01mMol/L	NRD
Colipase1	0.3mMol/L	NRD

Reagents Provided: One vial reagent - Ready to Use. (Ref: GQ-LK-2x15, GQ-LK-30, GQ-LK-60)

Materials Required but not provided

- Clinical Chemistry Analyzer (Automated or Semi-automated) with 37°C temperature control and filter of 340nm
- Protein-based Calibrator and Controls.
- Deionized water and Class A glassware.
- Automatic Pipettes
- Passcheck Calibrator (GQ-CAL-5)
- Passcheck Universal Assayed Serum Control Level I & II

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. • **Note:** Do not freeze. Slight sedimentation is normal; swirl gently before use.	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.

Instrument Assay Procedure

Semi Automatic	Automatic
• **Method:** Rate Method • **Calibration Type:** One Point Linear • **Calibration Concentration 1:** Use PassCheck Calibrator • **Wavelength:** 340 nm. • **Temperature:** 37°C. • **Blank Setting:** DI Water • **Reagent Volume:** 500 µL. • **Sample Volume:** 50 µL. • **Lag Time:** 60 seconds. • **Read Time:** 180 seconds • Bring reagent and instrument to Room Temperature 25°C	• **Reaction Type:** Increasing Kinetic. • **Wavelength:** 340 nm. • **Temperature:** 37°C. • **Blank Setting:** DI Water • **Reagent Volume:** 200 µL. • **Sample Volume:** 20 µL. • **Lag Time:** 60 seconds. • **Read Time:** 150 seconds. • **Factor:** Use PassCheck Calibrator • **Reagent Onbord:** 3 Weeks - Refrigerated • Bring reagent and instrument to Room Temperature 25°C

Instrument-Dependent Optimization (Two-Point Protocol)

Due to variations in optical system linearity, lamp intensity degradation, or restrictive kinetic protective algorithms common in certain semi-automated chemistry analyzers, high-activity samples may undergo premature signal clipping when using standard Rate settings. If Quality Control Level II recovers below the established target range, the instrument must be programs under the following validated fixed-time parameters to bypass hardware-specific photometric limitations:

- **Method:** Two Point (Fixed Time)
- **Calibration Type:** Two Point Linear
- **Calibration Concentration 1:** 0 (DI Water)
- **Calibration Concentration 2:** Use PassCheck Calibrator Value (e.g., 55 U/L)
- **Lag Time:** 60 seconds
- **Read Time:** 180 seconds

OTHER REFERENCES

Performance	Reference Values	Common errors	BIBLIOGRAPHY
• **Limit of Detection:** 10U/L (Instrument dependent). • **Linearity:** Up to 1275 U/L (Dilute 1:10 for higher samples). • **Precision:** Intra-assay C.V. < 0.8%.	• < 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. **US Patent 5,378,6...:** "Single system reagent for the determination of lipase", 2. Tietz, N.W., Textbook of Clinical Chemistry, 3rd Ed.

QUALITY CONTROL

See on next page

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 Calibratio :

It is mandatory for the laboratory to validate the assay before routine use. It is recommended to use **PassCheck controls** and PassCheck Calibrator to ensure system integrity. The calibration frequency must be performed **every 2 weeks** or whenever a new lot of reagent is used, or if quality control results fall outside established limits.

- **Intra-Laboratory Quality Program:** Each laboratory should establish its own internal quality control program. At least two levels of control (Normal and Pathological) should be analyzed daily. Results must be plotted on Levey-Jennings charts to monitor precision and detect systematic shifts or trends in accordance with Good Laboratory Practices (GLP).

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