

CERTIFICATE OF ANALYSIS (CoA)

Reagent for Serum Lipase Determination (Turbidimetric Method)

Trade name: Bialex Emulsion Lipase – REF: GQ-LL-60

Product: Lipase Reagent Lot No.: 26LL0201

Date of Manufacture: Feb 2026 Expiration Date: 2028.01.10 (YYYY.MM.DD)

Presentation: Kit R1 (Buer) + R2 (Substrate) Storage Conditions: 2 - 8 °C (Refrigerated)

1. PHYSICAL AND CHEMICAL SPECIFICATIONS

Parameter	Specification	Method Result	
Appearance R1 (Buer)	Clear liquid, colorless	As seen	
R2 aspect (Substratum)	Clear liquid (Alcoholic)	As seen	
pH (R1) @ 25°C	8.2-8,8 ± 0.10	8.57	Potentiometry
Initial Absorbance (RT)	0.900 - 1.500 Abs	1.110 Abs Spectrophotometry (340nm)	

2. QUALITY AND PERFORMANCE CONTROL (BIOLOGICAL)

Tests performed at 37°C using serum with known value.

Activity Essay	Expected Value	Value Obtained	Status
Basal Activity (human)	30 - 45 U/L	35.0 U/L	APPROVED

Recovery (Spike)	± 10% of the theoretical	98.2%	APPROVED
Linearity (*)	Up to 1000 U/L	1000 U/L	APPROVED

3. CONFIGURATION OF CALCULATION FACTORS (K)

A comparative study of methods was conducted by processing 50 human serum samples with lipase activities ranging from 30 to 600 U/L. The results obtained with this reagent were compared with a commercial reference method (turbidimetric), yielding a correlation coefficient (r) of 0.992 and a linear regression equation of $y=1.02x-1.5$, demonstrating a high diagnostic equivalence."

Equipment Mode	Reading Time	Factor Type	Factor Value (K)
Semi-automated	5 minutes (300 seconds)	Factor Rate (A/min)	13,460
Semi-automated	5 minutes (300 seconds)	Fixed Time (A1 - A2)	2,692
Manual (37°C)	7 mins (420s)	Manual Multiplier	5,975
Manual (T. Amb.)	7 mins (420s)	Manual Multiplier	49,000

4 . WARNINGS AND LIMITATIONS (INTERFERENCES)

- **Hemolysis:** Samples with visible hemolysis can cause false increases in absorbance (turbidity due to cellular debris). It is recommended to use clear serum.
- **Extreme Lipemia:** Serums with triglycerides > 800 mg/dL require dilution 1:10 premix to avoid saturation of the sample blank.
- **Jaundice:** No significant interference is observed up to levels of bilirubin of 20 mg/dL.
- **RT Stability:** The Working Reagent (Mixture R1+R2) is stable for 8 hours at room temperature or 24 hours in refrigeration.

5. QUALITY CONCLUSION

The above-mentioned batch has been subjected to rigorous downstream enzyme kinetics testing, demonstrating proportionality and optical stability in accordance with the in vitro diagnostic (IVD) standards developed in this protocol.

(*) Dilute samples 1:10 for values greater than 500 IU/L

Released by: _____

Position: Technical Director / Head of Laboratory

Release Date: March 2, 2026

