Bialex®

**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.:** 26LL0401

**Date of Manufacture:** April, 10th **Expiration Date:** 2028.04.01 **(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 |

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## 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) | 11,000 |
| Semi-automated | 5 minutes (300 seconds) | Fixed Time (A1 - A2) | 2,600 |
| Manual (37°C) | 7 mins (420s) | Manual Multiplier | 5,790 |
| 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.

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## 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**