

CERTIFICATE OF ANALYSIS (CoA)

Product: Lipase Reagent (Turbidimetric Method) | **REF:** GQ-LL-60 Lot No.:

26LL0601 | **DOM:** JUN 03, 2026 | **EXP:** 2028.06.01

Presentation: Kit R1 (Buffer) + R2 (Substrate) | **Storage:** 2-8 °C

1. PHYSICAL & CHEMICAL SPECIFICATIONS

R1 Appearance: Clear liquid, colorless

R2 Appearance: Clear liquid (Alcoholic) **pH (R1) @ 25°C:** 8.57

(Specification: 8.2 - 8.8)

Initial Absorbance (340nm): 1.110 Abs (Specification: 0.900 - 1.500 Abs)

2. QUALITY & PERFORMANCE CONTROL (37°C)

3. **Basal Activity (Human):** 35.0 U/L (Expected: 30 - 45 U/L) **APPROVED**

- **High Serum Value (Human):** 270 U/L (Expected: 200 - 300 U/L) **APPROVED**

- **Recovery (Spike):** 98.2% (Expected: 10% of theoretical) **APPROVED**

- **Linearity:** Up to 1000 U/L **APPROVED** (Dilute 1:10 if > 500 IU/L) (26LL0601)

4. CONFIGURATION OF CALCULATION FACTORS (K = 3900)

Equipment Mode: Semi-automated

- **Reading Time:** 5 minutes (300 seconds)

- **Factor Type:** Factor Rate (A/min)

- **Factor Value (K):** 3900

5. WARNINGS & INTERFERENCES

Hemolysis: False increases in absorbance; use clear serum **Lipemia:**

Triglycerides > 800 mg/dL require 1:10 premix dilution.

- **Jaundice:** No significant interference up to 20 mg/dL bilirubin

- **Stability:** Working Reagent (R1+R2) is stable for 8h at RT / 24h refrigerated

5. QUALITY CONCLUSION

Batch meets all downstream enzyme kinetics, proportionality, and optical stability IVD standards

Released by: Technical Director / Head of Laboratory

Status: BATCH RELEASED

