BIALEX®

CERTIFICATE OF ANALYSIS / PROTOCOLO DE ANÁLISIS

Product Name / Producto: Bialex AST	**REF. #:** GQ-AST-100
Box Lot/Lote Caja: 26AST0901	**Qty Manufacture / Cantidad:** 680 Kits
MFG Date / F. Fab: 2026-09-22	**Storage / Almacenamiento:** 2-8°C
EXP. Date / F. Cad: 2028-07-10 (YYYY-MM-DD)	**Quality Status:** GMP Quality Certified

1. Physical Inspection / Inspección Física

Component/Componente	Status/ Estado	Component/Componente	Status/ Estado
Labels / Etiquetas	Acceptable / Aceptable	HPDE Bottle / Botella HDPE	Acceptable / Aceptable
QR Code / Código QR	Acceptable / Aceptable	Box / Caja	Acceptable / Aceptable

2. Performance Characteristics / Características de Rendimiento

Parameter/ Parámetro	Specification / Especificación	Observed Result / Resultado Observado
Reagent AST Aspect / Aspecto	Liquid Translucid clear, non-visible particles	Pass/Conforme
Reagent AST Values @ 340nm	> 900	1.370

3. Quality Control (PassCheck Results @ 340nm, Constant Temp @ 37°C)

Control/Control	Specification / Especificación (n)	Target Value / Valor Objetivo	Observed Result / Resultado	Precision / Desviación
Control 1 (26PCK0171)	n=20	80.00 U/L	79.00 U/L	SD < 1.0% (Pass)
Control 2 (26PCK0172)	n=20	248.00 U/L	241.00 U/L	SD < 1.0% (Pass)

4. Technical Parameters & Instrumentation Factors / Parámetros Técnicos

- **Linearity / Linealidad:** Up to 600 U/L (999 U/L) - Pass
- **PassCheck Calibrator (REF: GQ-CAL-5/Lot 26CAL0101):** Value: 80.60 U/L (Using lag time 60s, 180s of reader)
- **Instrument Factors / Factores por Instrumento:** Biolis 24i: 6000 | I-L100: 2060 | Most semi-automatic (Run: 180s, Lag: 60s): 2060 | Cuvetta x 1cm: 2000

5. Release and Authorization / Conclusión y Autorización

Conclusion/Conclusión: Release for sale / Aprobado para venta	**Liable Person:** QC
Quality Assurance: Jean Tanaka	
Biosecurity Note: Vector must not be considered pathogenic; kit does not contain genes of livestock disease. No animal derived additives.	

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