Bialex®
CERTIFICATE OF ANALYSIS

GENERAL PRODUCT INFORMATION	
Nombre del Producto / Product Name: UREA TEST KIT (UREASE-GLDH)	**Referencia / Reference (REF #):** 71324
Número de Lote / Lot Number (LOT): 51114024H	**Fecha de Fabricación / Mfg. Date:** 2025-11-17
Fecha de Vencimiento / Exp. Date: 2026-11-16	**Cantidad / Package:** R1: 48mL x 2 / R2: 16mL x 2

PHYSICAL INSPECTION			
Etiquetas / Labels: PASA / PASS	**Código QR / QR Code:** PASA / PASS	**Frasco PEAD / HDPE Bottle:** PASA / PASS	**Caja / Box:** PASA / PASS

ANALYTICAL PERFORMANCE CHARACTERISTICS		
Especificación / Specification	**Valores Esperados / Expected Values**	**Resultados Obtenidos / Obtained Results**
Blanco de Reactivo / Reagent Blank (Absorbancia @ 340nm)	0.500 - 2.000	1.576
Linealidad / Linearity	≤ 35.7 mmol/L	35.7 mmol/L (PASA / PASS)
Repetibilidad / Repeatability (CV %)	< 3.54%	PASA / PASS
Exactitud / Accuracy	Dentro del rango objetivo / Within target range	PASA / PASS

INTERNAL QUALITY CONTROL (LOT: 51114024H)		
Componente / Control	**Control 1**	**Control 2**
Valores de Referencia Asignados / Target Range	Normal / Normal	Patológico / Pathological
Resultados Obtenidos / Obtained Values	PASA / PASS	PASA / PASS
Tiempo de lectura para Absorbancia / Read Time:	5 minutos / 5 minutes (PASA / PASS)	

STORAGE CONDITIONS & CONCLUSION

Temperatura de Almacenamiento / Storage Temp: 2-8°C

Lot Conclusion: Released for Sale / Approved.
Biological and Safety Declaration: The kit does not contain genes nor expresses antigens of livestock or poultry disease-causing agents. The kit contains no animal-derived additives such as albumin or serum.

Responsible Person:
Jean Tanaka
(Quality Assurance / QC)

Electronically Issued

BIALEX LAB
* QC *
QUALITY ASSURANCE

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