BIALEX®

717 Ohio Ave, Wichita Falls, TX 76301

CERTIFICATE OF ANALYSIS

Product Name:	PassCheck Multi calibrator for Biochemistry	**Form No / Rev:**	FORM 195 Rev No: New
Item Code:	GQ-CAL-5	**Lot Number:**	26CAL0201
Process:	Lyophilization (HR < 10%)	**Expiration Date:**	2027.07.10
Main Source:	Albumin and preserves	**Application:**	Material Controls for process biochemistry

Quality Control Specifications & Physical Inspections

Parameter / Test Item	Specification / Requirement	Result
Reconstitution Time	Complete dissolution within 30 minutes	**Pass**
Analyte Verification	30 standard biochemistry analytes verified	**Pass**
Container Type	Amber glass vial for light protection	**Pass**
Container Seal	Airtight / Hermetic seal integrity secure	**Pass**
Label Inspection	Correct product data and properly affixed	**Pass**
QR Code Verification	Legible, clear, and successfully scannable	**Pass**

Intended Use & Compatibility Notice

PassCheck Multi calibrator was designed for use with the reagent of the same brand Bialex and is comparable with its specific lot; please check the lot number before use. This is not a universal multi-calibrator; however, due to similar characteristics and values, it may work correctly with many other reagent brands.

Biosafety & Compliance Certifications

All specimens used in the PassCheck Multicalibrator should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, 'Biosafety in Microbiological and Biomedical Laboratories', 2nd edition, 1988 HHS Publication No (CDC)88-8395.
DBA Bialex certifies that all individual human plasma donor units used to manufacture this lot were tested by FDA-approved methods and found to be nonreactive for HBsAg, HIV-1, HIV-2, and HCV.

Approved By:

James Tanaka

Head of Quality Assurance (Jefe de Aseguramiento de la Calidad)