



Certificate of Analysis

Product Name	Glycohemoglobin A1c (HbA1c) Test Kit (Latex Enhanced Immunoturbidimetric)			REF	71397
Lot No.	50212097MT	Package	R1:30mL×1 R2:10mL×1	Manufacture Date	2025.2.20
Lot Size	R1:30mL×1 R2:10mL×1	Market Area	Bialex Formulation	Expiry Date	2026.2.19
Sample Amount	1盒	Sampling Date	2025.2.20	Analysis Date	2025.2.20
Inspection Basis	Inspection procedures				
Test Items	Quality Standard		Result		Comment
Appearance and Character					Qualified
	Reagent componets are complete.Labels are clear and correct.		Reagent componets are complete.Labels are clear and correct.		
	R1 is Milky white liquid		R1 is Milky white liquid		
	R2 is colorless clear liquid		R2 is colorless clear liquid		
Volume	R1≥30 mL, R2≥10 mL		R1 30.2 ml R2 10.5ml		Qualified
Reagent blank	Reagent blank absorbance ≤1.7,(37℃,660nm, 1cm optical path)		0.5012		Qualified
Accuracy	Whether the quality control results are within the target range		Yes		Qualified
Linear Range	range: 2~14%, r≥0.990		0.9995		Qualified
	Repeatability CV≤10%		1.88%		Qualified
Conclusion	Pass				
Remarks					
QC		Checked By	Jim	Approved By	D, Klein
Signature / Date	2025.2.20	Signature / Date	2025.2.20	Signature / Date	2025.2.20