

Certificate of Analysis

Product Name	Urea (UREA) Test Kit (Urease-GLDH)			Material Code	71324
Lot No.	50305024H	Package	R1:18ml×1 R2:6ml×1;	Manufacture Date	2025.3.7
Lot Size	R1:18ml×1 R2:6ml×1;	Market Area	BIALEX FORMULATION	Expiry Date	2026.3.6
Sample Amount	1盒	Sampling Date	2025.3.7	Analysis Date	2025.3.7
Inspection Basis	Inspection procedures				
Test Items	Quality Standard		Result		Comment
Appearance and properties	Reagent componets are complete.Labels are clear and correct.		Reagent componets are complete.Labels are clear and correct.		Qualified
Appearance and Character	R1 is colorless clear liquid		R1 is colorless clear liquid		
	R2 is colorless or light yellow clarifying liquid		R2 is colorless liquid		
Volume	R1≥18 mL, R2≥6 mL R1≥18 mL, R2≥6 mL		R1 18.5 ml R2 6.2ml		Qualified
Blank Absorbance	Reagent blank absorbance≥1.2, (340nm, 1cm optical path)		1.5622		Qualified
Accuracy	Whether the quality control results are within the target range		Yes		Qualified
Linear Range	range: [0.9,35.7]mmol /L,r≥0.990		0.9994		Qualified
Reproducibility	repeatability CV≤5%		2.15%		Qualified
Conclusion	合格/Pass				
Remarks					
QC	Zhen	Checked By	Jim	Approved By	D. Klein
Signature / Date	2025.3.7	Signature / Date	2025.3.7	Signature / Date	2025.3.7