

CERTIFICATE OF ANALYSIS

Name	HbA1c Calibrator	Lot No.(Product)	51026162T	Material Code	91032
Specifications	1mL×5	Expiry Date	2026.11.01	Date of Manufacture	2025.11.02
Lot No. (Quality Control)	50407162L			Lot No.(Reagent)	50827097F
Appearance	red			Content	1.0mL

Sampling volume	S: 6μL; R1: 225μL; R2: 75μL			Analytical method	end-point method	
Primarily	31-33	Secondary	12-13			
Accuracy						
Target value	1	2	3	Average value		Target range
5.20	5.15	5.15	5.20	5.17		4.70-5.70
10.10	10.00	10.30	10.40	10.23		9.10-11.10
Homogeneity						
Box	Results	Repeated test results				
1	0.00	0.00	0.00	0.00	0.00	
2	0.00	0.00	0.00	0.00	CV between the bottles	0.00%
3	0.00	0.00	0.00	0.00		
Box	Results	Repeated test results				
1	5.40	5.24	5.45	5.40	5.51	
2	5.51	5.29	5.35	5.51	CV between the bottles	5.01%
3	5.29	5.51	5.29	5.51		
Box	Results	Repeated test results				
1	8.70	8.79	8.61	8.61	8.53	
2	8.70	8.44	8.96	8.96	CV between the bottles	0.00%
3	8.70	8.70	8.53	8.70		
Box	Results	Repeated test results				
1	10.10	10.40	10.40	10.10	10.40	
2	9.80	10.00	9.90	10.40	CV between the bottles	0.00%
3	9.90	10.00	9.90	10.30		
Box	Results	Repeated test results				
1	14.30	13.87	14.59	13.87	14.44	
2	13.87	14.16	13.87	14.01	CV between the bottles	0.00%
3	14.44	14.01	14.73	14.73		

