

CERTIFICATE OF ANALYSIS

Product Name:	Prolex™ Streptococcal Grouping Latex Kit			Lot Number:	C19809
Product Code:	PL.030			Expiration Date:	2022-10-31
Product Code	Quantity	Compone			
PL.031	1 x 3.0 ml		cal Group A Latex Reagent		
PL.032	1 x 3.0 ml	•	cal Group B Latex Reagent		
PL.033	1 x 3.0 ml	•	cal Group C Latex Reagent		
PL.034	1 x 3.0 ml		cal Group D Latex Reagent		
PL.035	1 x 3.0 ml	•	cal Group F Latex Reagent		
PL.036	1 x 3.0 ml		cal Group G Latex Reagent		
PL.037	1 x 3.2 ml	•	cal Extraction Reagent 1		
PL.038	1 x 3.2 ml		cal Extraction Reagent 2		
PL.039	2 x 8.0 ml		cal Extraction Reagent 3		
PL.040	1 x 2.0 ml	•	Positive Control (A,B,C,D,F,	G)	
	300	Mixing Stic			
PL.092-48	48 cards	Test Cards			
Additional Information					
Storage Conditions: 2-8°C					
Precautions: Refer to Instructions for Use					
Quality Control Testing					
Criteria					Result
Chemical extraction of Strep group specific antigens.					PASS
Strong agglutination of the test isolate when tested against the corresponding latex reagent.					PASS
No agglutination reaction of the test isolate when tested against heterologous latex reagents. PASS					PASS
Strong agglutination of the Positive Control when tested against the latex reagents.					PASS
Release					
2021-09-09			Vaux	fang	
Date			C	Quality Control	