

## **CERTIFICATE OF ANALYSIS**

Product Name:	Prolex™ Stre	eptococcal Grouping Latex Kit	Lot Number:	C18806
Product Code:	PL.030SJ		Expiration Date:	2022-01-31
Product Code	Quantity	Components	•	
PL.031S	1 x 3.0 ml	Streptococcal Group A Lat	tex Reagent	
PL.032S	1 x 3.0 ml	Streptococcal Group B Lat	tex Reagent	
PL.033S	1 x 3.0 ml	Streptococcal Group C La	reptococcal Group C Latex Reagent	
PL.034S	1 x 3.0 ml	Streptococcal Group D La	treptococcal Group D Latex Reagent	
PL.035S	1 x 3.0 ml	Streptococcal Group F Lat	tex Reagent	
PL.036S	1 x 3.0 ml	Streptococcal Group G La	tex Reagent	
PL.037	1 x 3.2 ml	Streptococcal Extraction R	Reagent 1	
PL.038	1 x 3.2 ml	Streptococcal Extraction R	Reagent 2	
PL.039	2 x 8.0 ml	Streptococcal Extraction R	Reagent 3	
PL.040S	1 x 2.0 ml	Polyvalent Positive Contro	I (A,B,C,D,F,G)	
	300	Mixing Sticks		
PL.092-48J	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
				5400
Strong agglutination of the test isolate when tested against the corresponding latex reagent. PAS				PASS
No agglutination reaction of the test isolate when tested against heterologous latex reagents.				PASS
Strong agglutination of the Positive Control when tested against the latex reagents. PASS				PASS
Release				
			S. A.	
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Date			Quality Control	

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