

CERTIFICATE OF ANALYSIS

Product Name:	Prolex™ Streptococcal Grouping Latex Kit		Kit Lot Number:	C18243
Product Code:	PL.030SJ		Expiration Date:	2021-05-31
Product Code	Quantity	Components		
PL.031S	1 x 3.0 ml	Streptococcal Group	A Latex Reagent	
PL.032S	1 x 3.0 ml	Streptococcal Group	B Latex Reagent	
PL.033S	1 x 3.0 ml	Streptococcal Group	C Latex Reagent	
PL.034S	1 x 3.0 ml	Streptococcal Group	D Latex Reagent	
PL.035S	1 x 3.0 ml	Streptococcal Group	F Latex Reagent	
PL.036S	1 x 3.0 ml	Streptococcal Group	G Latex Reagent	
PL.037	1 x 3.2 ml	Streptococcal Extrac	ction Reagent 1	
PL.038	1 x 3.2 ml	Streptococcal Extrac	ction Reagent 2	
PL.039	2 x 8.0 ml	Streptococcal Extrac	ction Reagent 3	
PL.040S	1 x 2.0 ml	Polyvalent Positive C	Control (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
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
Strong agglutination of the Positive Control when tested against the latex reagents. PASS				
Release				
2020 01 03			S.	
Date			Quality Control	

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