


CERTIFICATE OF ANALYSIS

Product Name: Prolex™ Streptococcal Grouping Latex Kit		Lot Number: C12799
Product Code: PL.030		Expiration Date: 2016 09
Product Code	Quantity	Components
PL.031	1 x 3.0 ml	Streptococcal Group A Latex Reagent
PL.032	1 x 3.0 ml	Streptococcal Group B Latex Reagent
PL.033	1 x 3.0 ml	Streptococcal Group C Latex Reagent
PL.034	1 x 3.0 ml	Streptococcal Group D Latex Reagent
PL.035	1 x 3.0 ml	Streptococcal Group F Latex Reagent
PL.036	1 x 3.0 ml	Streptococcal Group G Latex Reagent
PL.037	1 x 3.2 ml	Streptococcal Extraction Reagent 1
PL.038	1 x 3.2 ml	Streptococcal Extraction Reagent 2
PL.039	2 x 8.0 ml	Streptococcal Extraction Reagent 3
PL.040	1 x 2.0 ml	Polyvalent Positive Control (A,B,C,D,F,G)
	300	Mixing Sticks
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
	Strong agglutination of the Positive Control when tested against the latex reagents.	PASS
Release		
2015 06 18		
Date	Quality Control	

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