


### CERTIFICATE OF ANALYSIS

<b>Product Name: Prolex™ Streptococcal Grouping Latex Kit</b>		<b>Lot Number: C12936</b>
<b>Product Code: PL.030</b>		<b>Expiration Date: 2016 11</b>
<b>Product Code</b>	<b>Quantity</b>	<b>Components</b>
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
<b>Additional Information</b>		
Storage Conditions:	2-8°C	
Precautions:	Refer to Instructions for Use	
<b>Quality Control Testing</b>		
	<b>Criteria</b>	<b>Result</b>
	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
<b>Release</b>		
2015 08 13		
Date	Quality Control	