

CERTIFICATE OF ANALYSIS

Product Name: Prolex™ Streptococcal Grouping Latex Kit	Lot Number: C18121
Product Code: PL.030	Expiration Date: 2021-03-31

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

2019 12 20	
Date	Quality Control