

CERTIFICATE OF ANALYSIS

| Product Name: | Prolex™ Streptococcal Grouping Latex Kit | | | Lot Number: | C20086 |
|--|--|-------------|------------------------------|-------------------------|------------|
| Product Code: | PL.030 | | | Expiration Date: | 2023-01-31 |
| Product Code | Quantity | Compone | | | |
| PL.031 | 1 x 3.0 ml | | cal Group A Latex Reagent | | |
| PL.032 | 1 x 3.0 ml | • | cal Group B Latex Reagent | | |
| PL.033 | 1 x 3.0 ml | • | cal Group C Latex Reagent | | |
| PL.034 | 1 x 3.0 ml | | cal Group D Latex Reagent | | |
| PL.035 | 1 x 3.0 ml | • | cal Group F Latex Reagent | | |
| PL.036 | 1 x 3.0 ml | | cal Group G Latex Reagent | | |
| PL.037 | 1 x 3.2 ml | • | cal Extraction Reagent 1 | | |
| PL.038 | 1 x 3.2 ml | | cal Extraction Reagent 2 | | |
| PL.039 | 2 x 8.0 ml | | cal Extraction Reagent 3 | | |
| PL.040 | 1 x 2.0 ml | | Positive Control (A,B,C,D,F, | G) | |
| | 300 | Mixing Stic | | | |
| 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 | | | | | PASS |
| Strong agglutination of the Positive Control when tested against the latex reagents. | | | | | PASS |
| Release | | | | | |
| 2021-12-06 | | | Vour | fang | |
| Date | | | C | uality Control | |