


CERTIFICATE OF ANALYSIS

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|---|--|---|
| Product Name: Prolex™ Streptococcal Grouping Latex Kit | | Lot Number: C16971 |
| Product Code: PL.030 | | Expiration Date: 2020-04-30 |
| 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 03 05 |  | |
| Date | Quality Control | |

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