

### CERTIFICATE OF ANALYSIS

|   |                                    |
|---|------------------------------------|
| <b>Product Name:</b> Prolex™ Streptococcal Grouping Latex Kit | <b>Lot Number:</b> C22441          |
| <b>Product Code:</b> PL.030                                   | <b>Expiration Date:</b> 2025-08-31 |

| 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  |
| Instructions for Use: | Refer to pro-lab.com/resources for current version |

#### 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

|            |  |
|------------|--|
| 2024-03-28 |  |
| Date       | Quality Control  |

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