

## CERTIFICATE OF ANALYSIS

|                                                                                                |                 |                                                                                      |
|------------------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------|
| <b>Product Name:</b> Prolex™ Streptococcal Grouping Latex Kit                                  |                 | <b>Lot Number:</b> C1090                                                             |
| <b>Product Code:</b> PL.030                                                                    |                 | <b>Expiration Date:</b> 2026-07-31                                                   |
| <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                                                                                |
| Instructions for Use:                                                                          |                 | Refer to pro-lab.com/resources for current version                                   |
| <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>                                                                                 |                 |                                                                                      |
| 2025-01-21                                                                                     |                 |  |
| Date                                                                                           |                 | Quality Control                                                                      |

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