

Certificate of Analysis

Product Name: Wellcogen Strep B KT/30TST
Product Code: R30858701
Lot Number: 3181675
Expiration Date: 30.09.2021
Date of Manufacture: 08.02.2021

*Date format is DD.MM.YYYY

| Item | Description | Lot/Serial | Expire |
|-----------|------------------------------------|------------|------------|
| W74CLUSA2 | ZL20 Control Latex Filled Bulk | 2973508 | 30.09.2021 |
| W74NUSA13 | ZL26 Negative Control Filled Bulk | 2952488 | 31.05.2022 |
| W74TLUSA1 | ZL20 Test Latex Filled Bulk | 2973507 | 30.09.2021 |
| W71UZL26N | ZL26 Positive Control Freeze dried | 3146482 | 31.07.2022 |

Test Results carried out according to the Quality Assurance Product Release and Test Specification

| Test | Anticipated Result | Actual Result |
|---|--|---------------|
| Sensitivity | The Test latex must show obvious agglutination at least + with the Reference Strep B Antigen with dilutions up to and including 1/8000 | Conforms |
| Specificity | The Test Latex must show strong agglutination at least ++ with the Polyvalent Positive Control | Conforms |
| | The Test Latex must not show agglutination with the heterologous Reference Positive Control Antigens although trace granularity is acceptable | Conforms |
| Efficacy of the polyvalent positive control | The Test Latex (Negative Control) with the overlay Polyvalent Positive Control must show at least + agglutination at one minute and at least ++ agglutination at three minutes | Conforms |
| | The Test Latex must not show any agglutination with buffer A although trace granularity is acceptable | Conforms |

All testing performed at Rotator speeds of 100rpm and 150rpm



Fay Curd
Quality Assurance Manager