

Certificate of Analysis

Product Name: PathoDx Strep B Latex KT/60TST

Product Code: R62031 Lot Number: 6211154 **Expiration Date:** 05.10.2026 Date of Manufacture: 15.04.2025

*Date format is DD.MM.YYYY

Description Lot/Serial **Expire** Item W75PDX06G Strep B Group Latex Filled Bulk 6209743 05.10.2026

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

Test **Anticipated Result Actual Result**

Latex Efficacy/ The Latex must show obvious agglutination

Specificity using with its homologous extract

Conforms

The Latex must not show agglutination with the heterologous extracts but a trace reaction

Conforms is acceptable

Reactivity of Latex

Extraction Reagents

with Control Antigens ABC and FG The Latex must show strong positive agglutination with its homologous positive control antigen extract

Conforms

The Latex must show no agglutination with its

heterologous positive control antigen extract Conforms

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Quality Assurance Manager