

Certificate of Analysis

Product Name: PathoDx Strep B Latex KT/60TST

Product Code: R62031 6275429 Lot Number: **Expiration Date:** 19.01.2027 **Date of Manufacture:** 20.08.2025

*Date format is DD.MM.YYYY

Extraction Reagents

Antigens ABC and FG

Description Lot/Serial **Expire** Item W75PDX06G Strep B Group Latex Filled Bulk 6239301 19.01.2027

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 The Latex must show strong positive agglutination with Control

with its homologous positive control antigen extract Conforms

The Latex must show no agglutination with its

heterologous positive control antigen extract Conforms

Fay Curd

Quality Assurance Manager