

Certificate of Analysis

Product Name: PathoDx Strep B Latex KT/60TST

Product Code: R62031 Lot Number: 2379312 **Expiration Date:** 29.02.2020 Date of Manufacture: 30.08.2018

*Date format is DD.MM.YYYY

Extraction Reagents

Antigens ABC and FG

Description Lot/Serial **Expire** Item W75PDX06G Strep B Group Latex Filled Bulk 2355441 29.02.2020

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

> 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

Conforms