

Certificate of Analysis

Product Name: Wellcogen Strep B KT/30TST
Product Code: R30858701
Lot Number: 3156157
Expiration Date: 30.09.2021
Date of Manufacture: 22.12.2020

*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