

Certificate of Analysis

Product Name: Wellcogen Strep pneumoniae KT/30TST
Product Code: R30859001
Lot Number: 6234303
Expiration Date: 10.06.2026
Date of Manufacture: 02.06.2025

*Date format is DD.MM.YYYY

Item	Description	Lot/Serial	Expire
W74CLUSA6	ZL22 Control Latex Filled Bulk	6183663	30.06.2026
W74NUSA13	ZL26 Negative Control Filled Bulk	6183588	28.02.2027
W74TLUSA5	ZL22 Test Latex Filled Bulk	6183662	10.06.2026
W71UZL26N	ZL26 Positive Control Freeze dried	6234310	02.12.2026

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 at least + agglutination with the Reference Positive Control Antigen at dilutions up to and including 1/32	Conforms
Reactivity with the Controls	The Test Latex must show at least ++ agglutination with the neat Polyvalent Positive Control	Conforms
	The Test Latex must show at least + agglutination with the Polyvalent Positive Control at 1/16	Conforms
	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 the Negative Control although a trace granularity is acceptable	Conforms
Specificity	The Test Latex must not show agglutination with the heterologous Reference Positive Control Antigens although a trace granularity is acceptable	Conforms
	The Control Latex must not react with the Polyvalent Positive Control or the Reference Positive Antigens although a trace granularity is acceptable	Conforms
	There must be no agglutination between the Test or Control Latex and the Buffer although a trace granularity is acceptable	Conforms

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

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Fay Curd
Quality Assurance Manager