Thermo Fisher
S C I E N T I F I C

Certificate of Analysis

Product Name: Wellcogen Bacterial Antigen KT/30TST
Product Code: R30859602
Lot Number: 6208580
Expiration Date: 11.02.2026
Date of Manufacture: 29.04.2025
*Date format is DD.MM.YYYY

Item	Description	Lot/Serial	Expire
W71UZL26N	ZL26 Positive Control Freeze dried	6199906	12.10.2026
W74CLUSA2	ZL20 Control Latex Filled Bulk	6175817	11.03.2026
W74CLUSA4	ZL21 Control Latex Filled Bulk	6175819	11.02.2026
W74CLUSA6	ZL22 Control Latex Filled Bulk	6183663	30.06.2026
W74CLUSA8	ZL23 Control Latex Filled Bulk	6183585	29.04.2026
W74NUSA13	ZL26 Negative Control Filled Bulk	6149406	30.11.2026
W74TLUSA1	ZL20 Test Latex Filled Bulk	6175816	11.03.2026
W74TLUSA3	ZL21 Test Latex Filled Bulk	6175818	11.02.2026
W74TLUSA5	ZL22 Test Latex Filled Bulk	6183662	10.06.2026
W74US10CL	ZL24 Control Latex Filled Bulk	6232640	05.05.2026
W75TLUSA7	ZL23 Test Latex Filled Bulk	6183584	30.04.2026
W75TLUSA9	ZL24 Test Latex Filled Bulk	6183586	05.05.2026

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

Test	Anticipated Result	Actual Result
Sensitivity and Specificity	Each Test latex must show:	
	At least ++ agglutination with the Neat Polyvalent Positive Control (3.6ml)	Conforms
	At least + agglutination with the Polyvalent Positive Control (1.2ml) at 1/16	Conforms
	At least + agglutination with the appropriate Reference Antigen	Conforms
	No agglutination with the heterologous Reference Antigen although trace granularity is acceptable	Conforms
	No agglutination with the Negative Control although a trace is acceptable	Conforms
	The Control Latexes must not show any agglutination with any of the samples, although a trace granularity is acceptable	Conforms
Efficacy of Polyvalent Control	The Test Latexes with the overlay Polyvalent Positive Control must show at least + agglutination at one minute and at least ++ agglutination at three minutes	Conforms

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

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Fay Curd
Quality Assurance Manager