

Certificate of Analysis

Product Name: Wellcogen N. menin A,C,Y W135 KT/30TST

Product Code: R30859203 Lot Number: 6246665 Expiration Date: 29.04.2026 Date of Manufacture: 11.06.2025

*Date format is DD.MM.YYYY

Item	Description	Lot/Serial	Expire
W74CLUSA8	ZL23 Control Latex Filled Bulk	6183585	29.04.2026
W74NUSA13	ZL26 Negative Control Filled Bulk	6183588	28.02.2027
W75TLUSA7	ZL23 Test Latex Filled Bulk	6183584	30.04.2026
W71UZL26N	ZL26 Positive Control Freeze dried	6199906	12.10.2026

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 Test Latex must show at least ++

the Controls 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