

Endotoxin Quantitative Kinetic Turbidimetric Assay Report of Analysis

Product Information

Client: Novatide

Product Tested: TB-500 5mg

Lot Number: 4185039276

Vials Tested: 2

Test Performed: PYROSTAR ES-F/Plate Kinetic Turbidimetric Assay

Test Date: 01/15/2026

Reagent Information

Lysate Product #: WPEPK4-50015

Lysate Lot #: 122412A

Lysate Exp: 12/01/2026

Lysate Sensitivity: 0.01 – 10 EU/mL

Control Standard Endotoxin (CSE) Product #: WPEPK4-50015

CSE Lot #: G-07USA

CSE Exp: 09/01/2029

KTA Test Results

Solution	Endotoxin Concentration/Added to	Concentration (EU/ml) / % Recovery
Sample/Product Solution	None (EU/mL)	A: <0.079, B: <0.079 Average: <0.079
Positive Product Control (PPC)	1.0 EU/mL in Product	A: 0.889, B: 0.935 Percent Recovery: 91.201%
Negative Control	None (EU/mL)	A: <0.079, B: <0.079

Interpretation: This test is considered valid when: the positive product control % recovery is between 50% and 200%, and both negative control concentrations do not exceed the limit of the blank value required by the lysate reagent employed (0.079 EU/ml). When sample concentrations match the negative control, samples are considered free of endotoxin.

Sample resuspended in 2 ml endotoxin free water for testing. **Average EU/ml in test solution: <0.079**

TOTAL Average Endotoxin EU in Sample: NEGATIVE

Analyst Signature:

