

## **Endotoxin Quantitative Kinetic Turbidimetric Assay Report of Analysis**

### **Product Information**

**Client:** Novatide

**Product Tested:** Thymosin Alpha-1 5mg

**Lot Number:** 8201947365

**Vials Tested:** 2

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

**Test Date:** 01/21/2026

### **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**

| <b>Solution</b>                | <b>Endotoxin<br/>Concentration/Added to</b> | <b>Concentration (EU/ml) /<br/>% Recovery</b>                  |
|--------------------------------|---------------------------------------------|----------------------------------------------------------------|
| Sample/Product Solution        | None (EU/mL)                                | <b>A: &lt;0.079, B: &lt;0.079</b><br><b>Average: &lt;0.079</b> |
| Positive Product Control (PPC) | 1.0 EU/mL in Product                        | <b>A: 0.870, B: 0.814</b><br><b>Percent Recovery: 84.193%</b>  |
| Negative Control               | None (EU/mL)                                | <b>A: &lt;0.079, B: &lt;0.079</b>                              |

**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:** \_\_\_\_\_

