## New Certificate of Analysis Format

***Please note this is a sample intended for illustrative purposes only.***

CERTIFICATE OF ANALYSIS
**Standardization of CSE against RSE**
**Pyrotell® Gel-Clot Method**

**ACC Internal Control Number: XXXXXX**
**Test date: YY/YY/YYYY**

| Reagent | Catalog No. | Lot No. | Exp. Date |
|---|---|---|---|
| **Pyrotell®** | **G5006** | **123-45-678** | **30 MAR 2012** |
| **Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)** | **E0005** | **987** | **01 DEC 2011** |
| **Reference Standard Endotoxin (RSE)** | **N/A** | **EC-6-3** | **N/A** |

| | |
|---|---|
| Potency of CSE (per ng) | 10 EU/ng<br>**or 10 IU/ng** |
| Potency of CSE (per vial) | **10 EU/ng x 500 ng/vial =** 5,000 EU/vial<br>**or 5,000 IU/vial** |

**If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 1,000 EU/mL.**

Product information has been tabulated, making it easier to check your reagent lots and expiration dates.

Potency information is easier to find, in boldface, and converted to EU/vial.

Users can instantly determine the volume of LRW to use for the reconstitution of the 0.5 ug/vial CSE to obtain an initial concentration of 1000 EU/mL or in the case of the 10ng/vial CSE for the chromogenic method, 50 EU/mL.

**Quality Assurance** **Date**

Notes:

1. **The stated potency applies only to the combination of CSE and LAL lots specified on this certificate.**
2. **The equivalence of the EU and IU is stated in the USP Bacterial Endotoxins Test chapter, <85>, and in the EP Bacterial Endotoxins chapter, 2.6.14.**
3. **Potency is subject to change within the error of the test at any time.**