

LGGS, Inc.

LGGS, Inc. is an independently owned contract laboratory specializing in U.S.P. and ANSI/AAMI/ISO microbiological testing. We are dedicated to providing safe and reliable product testing. We proudly produce accurate results with the utmost efficiency for every client. Our commitment is to developing ongoing business relationships with our customers.

Bacterial Endotoxin in Medical Devices

Pyrogens are fever inducing substances. They can be classified into two groups: microbial and non-microbial. The endotoxins from Gram-negative bacteria are considered the most significant pyrogens. LGGS, Inc. offers Bacterial Endotoxin (LAL) Validation and routine testing services by Kinetic Turbidimetric Assay as outlined in ANSI/AAMI ST72, *Bacterial Endotoxins-Testing methodologies, routine monitoring and alternatives to batch testing* and the FDA's Guideline on Validation of the Limulus Aemocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices, December, 1987.

Sample Selection:

"The sampling criteria for selection of product units for endotoxin testing is based on the premise that the manufacturing process is controlled and in compliance with quality system requirements." (ANSI/AAMI ST72)

| Selection of Number of Samples | |
|--------------------------------|----------------------------------|
| Lot size | Number of samples |
| <30 | 2 |
| 30-100 | 3 |
| >101 | 3% of lot, up to a maximum of 10 |

LAL by Kinetic Turbidimetric Assay:

Product Validation

Validation Summary Report

Routine Testing



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