Template Provided By:

# Cancer Imaging Program

National Cancer Institute

## GEL-CLOT ASSAY: Bacterial Endotoxins LAL Test Form

(Refer to GEN-Q114)

**Manufacturing Batch Number:** _____ **Date Performed:** _____

**MATERIALS:**

| Description | ITC | Quantity | Amount Used | ITN/Lot |
|---|---|---|---|---|
| **Final Product** | | 0.1 mL | | |
| **LAL Reagent Water or Sterile Water for Injection (SWFI)** | **SS-LRW** or **SS-WFI** | QS | | SS- |
| **Limulus Amebocyte Lysate (LAL)** | **SS-LAL** | 1 | | SS-LAL |
| **Control Standard Endotoxin (CSE)** | **SS-CSE** | 1 | | SS-CSE |

**Depyrogenation Log Number:** _____ **CSE Standard Number:** _____

**LAL Reconstitution Date:** _____ **LAL Sensitivity (λ):** _____ **EU/mL**

**CSE Reconstitution Date:** _____ **Initial Block Temperature:** _____ **°C**

**CSE Dilution Prep Date:** _____ **Final Block Temperature:** _____ **°C**

**Test Start Time:** _____ **Test End Time:** _____

**Results with CSE Standard Series** (+ = gel clot formed, - = no gel clot formed)

| Tube | Sample | Dilution | 20 Minutes | One Hour Duplicate Test | |
|---|---|---|---|---|---|
| 1 | Negative Water Control | | | | |
| 2 | Positive Water Control (0.25λ) | | | | |
| 3 | Positive Water Control (0.5λ) | | | | |
| 4 | Positive Water Control (λ) | | | | |
| 5 | Positive Water Control (2λ) | | | | |
| 6 | Positive Product Control at NIC (2λ) | | | | |
| 7 | Product at NIC | | | | |
| 8 | Positive Product Control at NIC (80λ) | | | | |

**OR**

**Limit Test** (+ = gel clot formed, - = no gel clot formed)

| Tube | Sample | Dilution | 20 Minutes | One Hour Duplicate Test | |
|---|---|---|---|---|---|
| 1 | Negative Water Control | | | | |
| 5 | Positive Water Control (2λ) | | | | |
| 6 | Positive Product Control at NIC (2λ) | | | | |
| 7 | Product at NIC | | | | |
| 8 | Positive Product Control at NIC (80λ) | | | | |

**20-Minute In-Process Test:** **Pass** ___ **Fail** ___

____ **Gel Clot Test with CSE Standard Series:** **Pass** ___ **Fail** ___

**OR**

____ **Gel-Clot Limit Test:** **Pass** ___ **Fail** ___

**Performed By:** _____ **Date:** _____

**QC Review:** _____ **Date:** _____



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