

**Laboratory Incident Report**

**CONFIDENTIAL**

**Date of Report: Reported by:**

**Date/Time of Discovery: Dept.:**

**Date/Time of Incident: Location:**

**Name (s) of Involved Parties:**

**Description:**

**Investigation, immediate actions taken, and resolution**:

**Which steps will be taken to avoid the type of occurrence in the future?**

**Occurrence Classification: Class I\_\_\_\_ Class II\_\_\_\_\_ Class III\_\_\_\_ Class IV\_\_\_\_\_\_\_\_**

Review: Supervisor: Date: Print Signature

Laboratory Manager: Date:

 Print Signature

Laboratory Director: Date: Print Signature

**FDA reportable: Yes ‬, No Date reported:**

 **‬**

**Complete this form for significant events that occur regarding Laboratory processes. This includes equipment, environment, and materials as well as procedures.**

**Reported by:** Name of individual completing the report. Anyone who adds to the initial report should also date and sign by the added information.

**Statement of Incident:** Bottom line statement of what occurred and its consequences.

**Description:** Elaboration of the event relevant factors. Includes where in the process that the event occurred and where in the process that the event was detected.

**Investigation, immediate action taken, and conclusions:** What investigation was conducted and how. Conclusion of why/how the` event occurred and contributing factors. What was done about the event and date of action. Action taken should include review as appropriate with personnel.

**Which steps will be taken to avoid the type of occurrence in the future?**

Action not yet taken, but recommended to be taken. Frequently involves system or process changes that need to be evaluated to assure that they do not adversely affect other aspects of the operations. Requires approval before implementation.

**Reviewed:** The supervisors of all departments where the event originated, was further compounded, or will participate in additional recommended action must see and sign the form.

**Class IV:** Major occurrence, immediate harm, life threatening to patient, donor, employee, or potential harm without intervention, i.e. sentinel event.

**Class III:** Major occurrence, potential harm to patient, donor employee, or bigfinancial impact, i.e. near miss of a sentinel event.

**Class II:** Medium level occurrence, no serious harm to patient, donor, employee. Involvement of a non-lab department or customer complaint, i.e. patient complaints, physician office complaints, donor complaints, reporting errors.

**Class I:** Internal occurrence, no harm to anyone, i.e. lack of documentation of an event, typographical errors that do not incur above consequences.