**Package Insert Review Form**

**Reagent Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date Received** | **Lot Number** | **Expiration Date** | **Package Insert Number** | **New Package Insert?****(Y or N)** | **Tech ID** |
|  |  |  |  |  |  |

**Review Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tech ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Review Checklist:**

* Comparison of package insert number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ against new package insert number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ completed.
* SOPs reviewed: € NA € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Changes consist of: (check all that apply)**

* Significant procedural changes that will require SOP revision.
* Insignificant changes (i.e., terminology or format) that do not require SOP revision.
* Changes to specimen requirements that will require notification of nursing service, or phlebotomy, or other affected department \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Changes to Material Safety Data Sheet (MSDS)

**Corrective Action: (enter date of performance and tech ID as applicable)**

 Document Change Control Form Complete. SOP pulled for revision. Revision completed \_\_\_\_\_\_\_\_\_\_ Implementation date \_\_\_\_\_\_\_\_\_

 Nursing Service/Phlebotomy/Other affected department notified.

\_\_\_\_\_\_\_\_\_\_ Lot number removed from quarantine.

\_\_\_\_\_\_\_\_\_\_ Forwarded for review to TS Manager.

\_\_\_\_\_\_\_\_\_\_ Review of Package Insert form filed in Reagent Package Insert book.

\_\_\_\_\_\_\_\_\_\_ New MSDS filed or existing MSDS revised

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

**Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**