**Purpose:**

This procedure provides instruction for the review of package inserts when the version number indicates insert changes have been made by the manufacturer.

**Procedure:**

|  |  |  |
| --- | --- | --- |
|  | **Action** | **Related Documents**  |
| **1** | * Complete the top grid of the Package Insert Review Form:
* Date Received
* Lot Number
* Appearance evaluation: Y or N
* Package Insert Number
* New Package Insert? Y or N
* Tech ID
 | Reagent Receipt ProcessReagent Receipt FormPackage Insert Review Form |
| **2** | * Attach package insert to the form and route to the CT Lead or TS Manager.
 | Package Insert Review Form |
| **3** | * Record review date and tech ID.
 |  |
| **4** | * Compare for changes:
* Former version number
* New version number
* Procedure(s) utilizing this reagent
	+ NA = Not applicable
	+ List applicable SOPs
 |  |
| **5** | * + - Determine the extent of the changes and mark 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, phlebotomy, or other affected department.
	+ - Quarantine Lot number until Management review of Significant procedural changes.
 |  |
| **6** | * Record a summary of changes in the Comments section and highlight the changes on the new version.
 |  |
| **Step** | **Action** | **Related Docuements** |
| **7** | * Implement corrective action indicated by the extent of the changes.
 |  |
| **8** | * Record corrective actions on the form. Utilize the back of form for additional comments and progress reports.
 |  |
| **Once all correct actions have been completed:** |
| **9** | * Forward to TS Manager for final review.
 |  |
| **10** | * Remove reagents from quarantine once the final review is complete.
 |  |
| **11** | * File all paperwork in the Package Insert notebook.
 |  |
| **12** | * Place new version into the plastic sleeve.
 |  |

**References:**

Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks. AABB Press, Bethesda, MD.

Current manufacturer’s package insert instructions.