**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 Process  Reagent Receipt Form  Package 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.