**Purpose:**

This process describes the steps for the receipt, record, physical appearance evaluation, package insert review and quarantine of reagents.

**Process:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Action** | | **Related Documents** |
| **1** | * Receive reagents. | |  |
| **2** | * On arrival: * Update Purchase Path, if applicable * Confirm number, size and description matches order | |  |
| **3** | * + Quarantine reagents that do not match order description, number or size.   + Notify Lab Manager or CT Lead. | |  |
| **3** | * For reagents that match order description, log onto Reagent Receipt Record for reagent and manufacturer. Start a new form if necessary. * Date Received * Lot number (use a separate line for each lot number) * Expiration Date | | * + Reagent Receipt Form |
| **4** | * Inspect and evaluate all containers for breakage and leakage. * Inspect and evaluate a random sampling of containers in each lot number for reagent appearance: * Examine for color and clarity of antisera. * Examine for hemolysis and turbidity of reagent cells * Note package integrity that might cause damage to reagents | | Inspection and Evaluation of Critical Supplies, Services, and Products |
| **5** | * + Record appearance evaluation: (Appearance OK?)     - Y = acceptable appearance and condition of reagents and packaging     - N = unacceptable or questionable appearance or condition   + Quarantine and mark DO NOT USE, any unacceptable reagents for return to Manufacturer | | Inspection and Evaluation of Critical Supplies, Services, and Products |
|  | **Action** | | **Related Documents** |
| **6** | * + - * Compare lot number to previous entry on the Reagent Receipt Record. * Lot number and expiration date matches last entry, no action is required. * Lot number or expiration date does NOT match previous entry, attach NEW LOT DO NOT USE sticker to each reagent container. | |  |
| **7** | * + - * Record package insert number. | |  |
| **8** | * + - * Compare package insert number to previous entries. | |  |
| **9** | * + Record package insert review status in the *New Package Insert* column. | | Package Insert Review Form |
| **If** | **Then** |
| * **Y** = package insert number has not been previously recorded on the form | * Quarantine lot number. * Complete Package Insert Review Form. | Package Insert Review Form |
| * **N** = package insert number is recorded on the form. |  |  |
| **10** | * + - * Record Tech ID | |  |
| * ***NOTE:*** *Package Insert Review column will be completed, if applicable, following review*. | | | * + - * Package Insert Review procedure |

**References:**

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

Current manufacturer’s package insert instructions.