**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
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**References:**

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

Current manufacturer’s package insert instructions.