**Purpose:**

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

**Process:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents**  |
| **Receiving reagents** |
| 1 | On arrival:* Retrieve order paperwork from whiteboard clip
* Confirm number, size and description matches order on both the packing list and the TSL order.
 |  |
| 2 | Quarantine reagents that do not match order description, number or size. * + Notify Lab Manager or MLS Lead.
	+ Complete a QIM.
 | QIM |
| 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
* Quantity received
 | 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
* Label legibility
* 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. Complete a QIM. | Inspection and Evaluation of Critical Supplies, Services, and Products |
| **Step** | **Action** | **Related Documents**  |
| **Receiving reagents** |
| 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.
	+ Add NEW LOT card to bundled containers. Complete the following using a sharpie or dry erase marker
		- Reagent Name
		- Lot number
 | NEW LOT cards |
| 7 | Record package insert number. *Note: Ortho Diagnostics stores package inserts on their website. How to obtain instructions for use can be found in each reagent package.* |  |
| 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.
 |  |  |
| * ***NOTE:*** *Package Insert Review column will be completed, if applicable, following review*.
 | Package Insert Review procedure |
| 10 | Record Tech ID |  |
| 11 | Order Forms* Order forms remain on the whiteboard clip until all items are received
* Disposition varies by form:
* Purchase Path printouts: bottom shelf black organizer
* Medical Stores order sheet: dayshift CLT Lead
* TSL Inventory forms: Blanket Orders section of ORDER notebook
* Office supply orders: bottom shelf black organizer
 |  |
| 12 | Process Order Paperwork for Purchasing:* Time Stamp Packing List, Shipping List, etc.
* Print full name
* Make 1 copy
* Place original in an envelope for “Lab Med Purchasing, Box 357110”
* Place copy on the bottom shelf of the black organizer.
 |  |
| 13 | Purchasing Tech: Utilizing the copy and other paperwork from the black organizer* Update Purchase Path, if applicable
* File Packing list/Shipping list and order forms in the Supply Invoice filing drawer by manufacturer
 |  |
| **Putting Reagents into use** |
| 1 | Verify lot number against current QC document. | Daily QC of Manual Testing ReagentsTANGO Daily QC and Maintenance |
| 2 | If new lot:* Reagents
* Remove new lot stickers
* Document open date and tech ID on bottle/box
* QC (if applicable)
* Move all boxes to in use areas
* New Lot card
* Using Sharpie or dry erase marker, document In Use On and Tech ID on card
* Place card on bottom shelf of black organizer for MLS Lead/MLS2 review
* Reagent Receipt Log
	+ Verify package insert review has been performed
	+ Document “in use” date
 | Reagent Receipt FormPackage Insert Review FormNEW LOT cards |
| 3 | If current lot:* Document open date and tech ID on bottle/box
* Document
 |  |
| **Review Cycle** |
| 1 | Annually:* New Reagent Receipt Logs are prepared for each reagent
* Package Inserts no longer in use are archived
* Package inserts in use are confirmed against in house lot numbers
* Review is performed prior to archiving Reagent Receipt Logs.
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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.