**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:**

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| **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 Reagents  TANGO 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 Form  Package Insert Review Form  NEW 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. | |  |

**References:**

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

Current manufacturer’s package insert instructions.