**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 also describes the receipt of labels and verifying for acceptability prior to 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. | Quality Improvement Monitor Form |
| 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  Quality Improvement Monitor Form |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 and is currently in use, no action is required. * Lot number or expiration date does NOT match previous entry or matches previous entry but is not currently in use, 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: Immucor and Ortho Diagnostics store package inserts on their websites. How to obtain instructions for use can be found in each reagent package.* | | Reagent Receipt Form |
| 8 | Compare package insert number to previous entries and answer ‘*New Package Insert?’* on Reagent Receipt Form.   * **Y** = package insert number has not been previously recorded on the form. * **N** = package insert number is previously recorded on the form. | | Reagent Receipt Form |
| 9 | If you answer **Y**es, compare changes and determine whether changes are significant. | | Package Insert Review Form |
| **If** | **Then** |
| Changes affect the MSDS or will cause significant changes in any SOPs | * Quarantine lot number. * Complete Package Insert Review Form. | Package Insert Review Form |
| Changes do NOT affect the MSDS or current SOPs | * Complete Package Insert Review Form. | Package Insert Review Form |
| * ***NOTE:*** *Package Insert Review column will be completed, if applicable, following review*. | | | Package Insert Review procedure |
| 10 | Record Tech ID   * If lot received is same and currently in use, document CIU on the “Date in use & Tech ID line | | Reagent Receipt Form |
| 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  Additional Manual Reagent QC Form |
| 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 new expiration date (if applicable) | |  |
| **Receiving Labels** | | | |
| 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 labels that do not match order description, number or size.   * + Notify Lab Manager or MLS Lead.   + Complete a QIM. | | Quality Improvement Monitor Form |
| 3 | For labels that match order description, complete Label Receipt Form. Start a new form if necessary.   * Date Received * Catalog number * Quantity received- # of rolls or labels * Appearance ok? Y or N * Batch/MFG date- some labels have a batch and/or manufacture date * Tech ID | | Label Receipt Form |
| 4 | Labels must be verified for acceptability by matching the new labels with the labels in the Master Label Binder   * If acceptable- then labels can be used as intended * If not acceptable- let Lead or Manager know. Do not use label | |  |
| 5 | Labels that require review and approval before use are:   * New labels that has not been used before * Changes to label content | |  |
| **Quarantine of Reagents and Labels** | | | |
| 1 | Reagents and Labels must be placed in quarantine pending investigation for the following;   * New reagents that require package insert review due to changes to the MSDS or HMC TSL SOPs. * Reagents and Labels that do not meet the acceptability criteria | |  |
| 2 | Reagents and Labels must be quarantined at the appropriate storage temperature   * All refrigerated reagents must be placed on the quarantine shelf in the Reagent Refrigerator * All room temperature reagents and labels must be placed in the quarantine bucket at the back of the lab | |  |
| 3 | Notify Manager or MLS Lead for appropriate follow up. Complete QIM | | Quality Improvement Monitor Form |
| **Review Cycle** | | | |
| 1 | Annually:   * New Reagent and Label Receipt Forms are prepared for each reagent and label * 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 and Label Receipt Forms. | |  |

**References:**

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

Current manufacturer’s package insert instructions.