**TITLE: Assigning Statistics in Inventory for New Lots in Lot Records**

1. QC Item (for example Control) Setup record has already been created and saved.
   * The example uses the result values from the Testing Parameters to calculate statistics, then applying these values to the Active Parameters for the corresponding Tests.
   * Follow the same steps when using result values from the Active Parameters to calculate statistics, apply the values to update the expected results for the Active Parameters.
   * If posting QC results from an instrument, define both Active and Testing QC Identifiers.
2. Action Setup
   * Find or create an Action Setup record with the Type “Assign statistics”
     + This will be used with the Lot Record when defining, or updating the Expected Results using the Apply Statistics functionality.
3. Inventory > Batch Receiving
   * Receive the QC Item by registering a lot record. Place the lot in Testing status in order to generate QC orders for the new lot validation.
   * Result orders generated for the Testing lot until the number of orders required by our SOP is reached
   * For mean value tests, the Scheduler is is programmed to fire 2 orders per day for 10 days(a total of 20 orders) once the first result is entered on “Testing” lot. Since no time limit is programmed, these orders will not be considered overdue if not run on that day and the Westgard rules do not apply. Statistics can be calculated once there are at least 2 result entered for a test..
   * Review results for the new lot to ensure no obvious outliers or erroneous results will be included when establishing the new statistics. Exclude these values from statistics before calculating data.
4. Assign Statistics
   * From Inventory > Lot Record, select the appropriate lot record
   * Place the Lot Record in Edit mode
     + Open the Testing Parameters tab
     + Select the Tests on which you want the statistics performed
     + Click the Statistics button at the bottom right corner of the window
   * The Lot Statistics window opens
     + The Mean, SD, CV, and total number of results available displays in the grid for each selected Test/Parameter.
       - Assigned (ASG) - the current expected results.
       - Lot to Date (LTD) – statistics based on result values for the lot up to the current date
       - Previous Months (LMT) – statistics based on result values for the previous month up to the current date
         * The number of months defaults to 2, this field can be edited, and the statistics recalculated as needed.
       - Month to Date (MTD) – statistics based on result values entered from the first of the current month to the current date.
       - Across Lots (AML) – statistics based on result values entered within the number of months entered in the “Number of months for Across Lots calculation”, regardless of the lot used to generate the results
         * The number of months defaults to 2, this field can be edited, and the statistics recalculated as needed.
     + Focus on the Lot to Date statistics when deciding to apply the statistics
     + To select the Mean and/or SD values to apply, press the CTRL key and click on the value to be selected
     + The field turns pink
     + Click the Apply Statistics button
   * In the Apply Statistics window
     + Verify the “Copy Statistics to” field displays the appropriate option. (Active or Testing)
     + Verify the values to be changed in the New Mean, New SD, and/or New CV% fields
     + Select the Test(s)/Parameter(s) to be updates by placing a check in the Select column checkbox
     + Enter a predefined Action with the Type Assign Statistics
     + Click OK
   * Statistics from Testing are now applied to the Expected Result fields for the Active Lot Record.
   * For chemistry test some assays are only used as back up testing on the alternate analyzer. New lot correlations are not necessarily performed on the back-up analyzer. The new lot statistics are taken from the correlations performed on the primary analyzer and applied to the back-up analyzer in expected ranges.

* Go to the Testing lot number and select the “Active Parameters” tab.
* Check the EDIT and enter the new expected values and SD’s from the primary testing assays into the back-up testing assays.
* Press “SAVE” and enter the ‘ACTION” for new lot of control testing for the entire lot.

5, To run QC on the “Testing Lot” after applying statistics and use the new ACTIVE PARAMETERS.

* + Change the “Testing Lot” from Testing to Active Status.
  + Order/Generate QC.
  + Run with Active QC identifier barcodes.
  + When the results cross to SOFT, choose the correct “ACTIVE” lot to Post results.
  + In TQC, change the lot status back to “Testing”.
  + Open the Lot Record when you are ready to place the lot into production.

**Reference :**

SOFT Total QC Module.