

**Job Aid 2: Parallel Testing 607**

**New lot numbers of control materials are analyzed in parallel with the currently in-use control material.**

* **Step 1**: Using the package insert information:
  + Set the initial control limits, usually a ±2 SD range, for the new lot # of control.
  + Use this range as a guideline only to ensure that the control material is acceptable (shipped and stored correctly).
* **Step 2**: For each day of parallel testing:
  + Test current lot number of control to confirm that the instrument/method is performing within quality specifications.
  + Analyze the new control material and ensure that the data point falls between the ±2 SD range.
  + Handle the new lot number material in the same manner to encompass the normal day-to-day sources of variability (inherent randomness) routinely encountered, such as:
    - In-use expiration date – if an opened bottle of control material is used for more than 1 day routinely at your site, then this practice should be done with the new lot number so that control stability is reflected in your data.
    - Technical staff routinely assigned to that workstation
    - Instrument maintenance performed as per schedule
* **Step 3**: Serial testing of new lot number of control material
  + Collect a minimum of 20 data points from the new lot number
    - Preferably over a 20 day period
    - If a shorter time frame must be used, then collect 20 data points over a 10 day period by analyzing the new lot number twice a day
  + Record your data points and keep instrument printouts if applicable
* **Step 4**:Calculate your observed mean and SD for the new lot number
* **Step 5**: Calculate your control limits (± 1 sd, ±2 sd, ± 3 sd, and ± 4 sd)
* **Step 6**: Create your L-J chart
* **Step 7**: When your current lot number expires or is consumed,
  + Replace the L-J charts with the new-to-be current charts
  + Retain the old charts according to your record retention schedule