

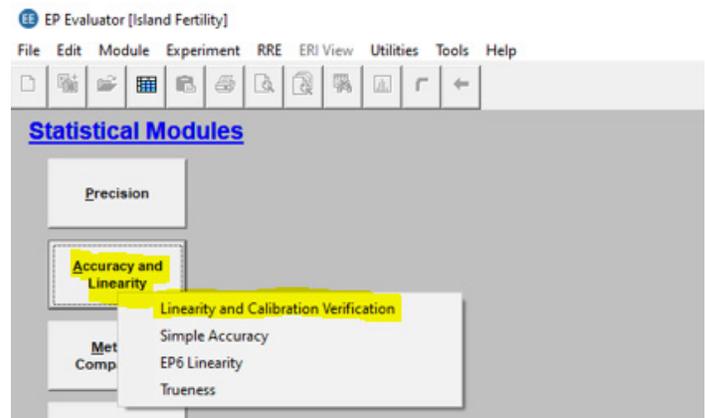
Roche Diagnostics announced the replacement of various Elecsys CalChecks with LGC Clinical Diagnostics | Maine Standards VALIDATE kits in July 2022. To assist with the adoption of these new materials, we are defining key differences between VALIDATE and Elecsys CalChecks below:

| VALIDATE | Elecsys CalChecks |
|--|--|
| VALIDATE Calibration Verification / Linearity Test Kit solutions are intended for <i>in vitro</i> diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems. | CalChecks are assayed controls for use in calibration verification and for use in verification of assay range. |
| Single or Multi-Analyte | Single-Analyte |
| Liquid, ready-to-use | Lyophilized |
| Multiple uses and extended open-vial stability | Single Use |
| Prepared in a manner such that an equal distance (delta) exists between Levels 1 through 5, consistent with the CLSI EP6 recommendation for preparing linearity sets. | Levels are prepared separately and are not linked through equal distances (deltas). |
| Data reduction/calculations are performed using levels 1 and 3 (delta). Maine Standards utilizes MSDRx™ as their free data reduction/linearity software. | Data reduction/calculations are performed using targets from each lot of CalCheck. |

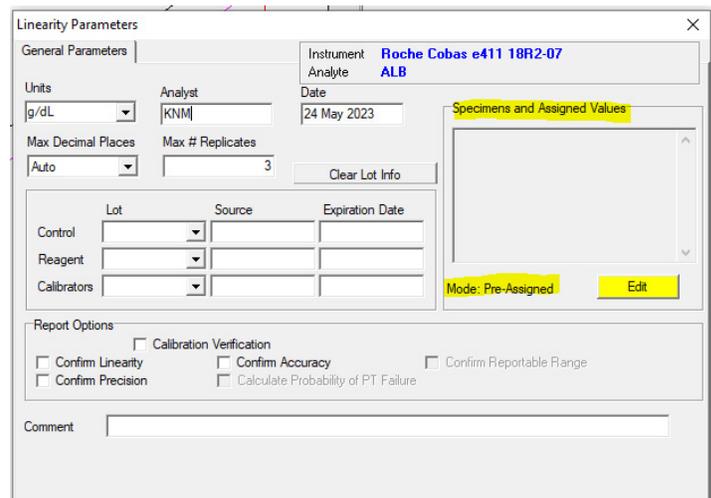
Processing VALIDATE Data in EP Evaluator

The following is the recommended module to use that best aligns with the VALIDATE MSDRx Calibration Verification software.

- Under **Statistical Modules**, select **Accuracy and Linearity** and then **Linearity and Calibration Verification**

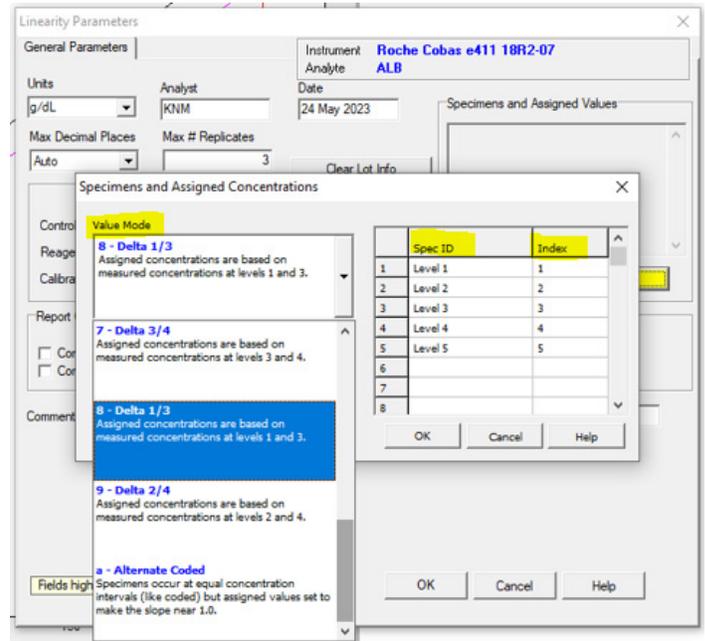


- Next, select the instrument and analyte that was tested and enter the units of measure, lot numbers, expiration date, etc. Then in the **Specimens and Assigned Values** section click the **Edit** button to change the mode.



3. In the pop-up screen that appears, click the **Edit** button and then select the dropdown for **Value Mode**. Scroll, locate and select **Option 8, Delta 1/3**. Then fill in the **Spec ID** and **Index** to align with the below image (Spec ID L1 = Index 1, etc.) and select **OK**. This will allow EP Evaluator to automatically calculate the mean and target values based on the recovered values entered in future steps.

NOTE: VALIDATE products do not have assigned values.

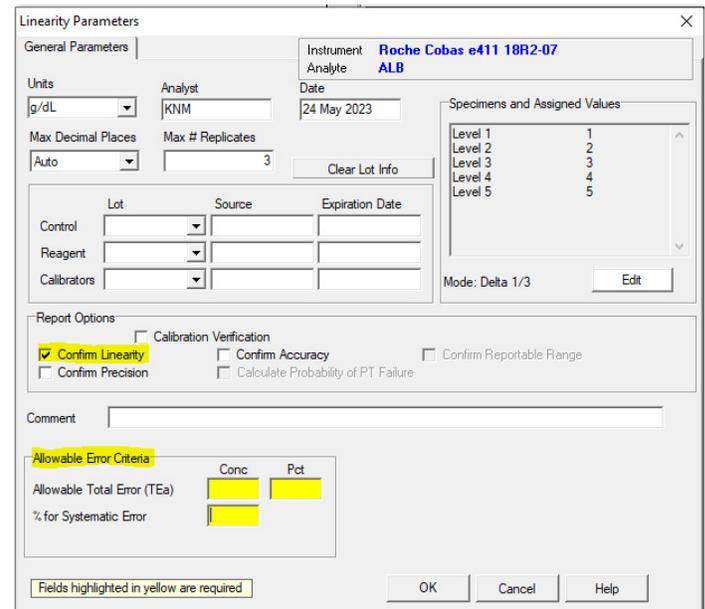


4. Select the **Confirm Linearity** option, complete the **Allowable Error** section and then click **OK**.

NOTE: Facilities must determine what % Systemic Error they should use but 50% is the value typically used.

Allowable Total Error and the **% for Systematic Error** should be determined by the laboratory with guidance from CLIA and Westgard listed below for reference:

- CLIA [▶](#)
- Westgard [▶](#)



5. Enter only your results/data into the chart and the Delta 1/3 value mode will calculate the **Mean** and **Assigned** values automatically for each level. Review the populated data to determine the pass/fail of the testing event..

