

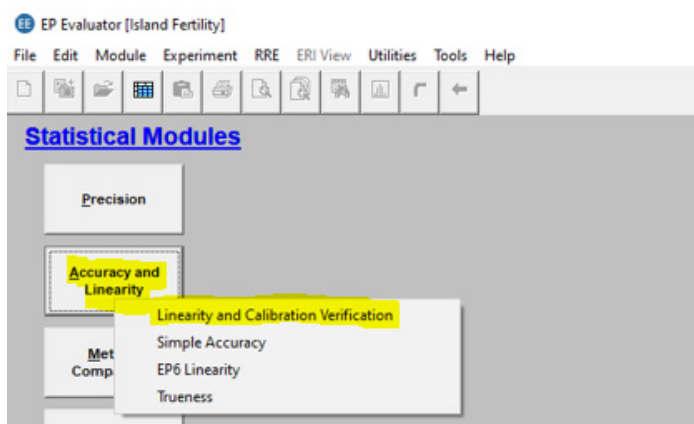
Roche Diagnostics announced the replacement of various Elecsys CalChecks with LGC Clinical Diagnostics | Maine Standards VALIDATE kits in July 2022. To assist with the adoption of these new materials, we are defining key differences between VALIDATE and Elecsys CalChecks below:

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.

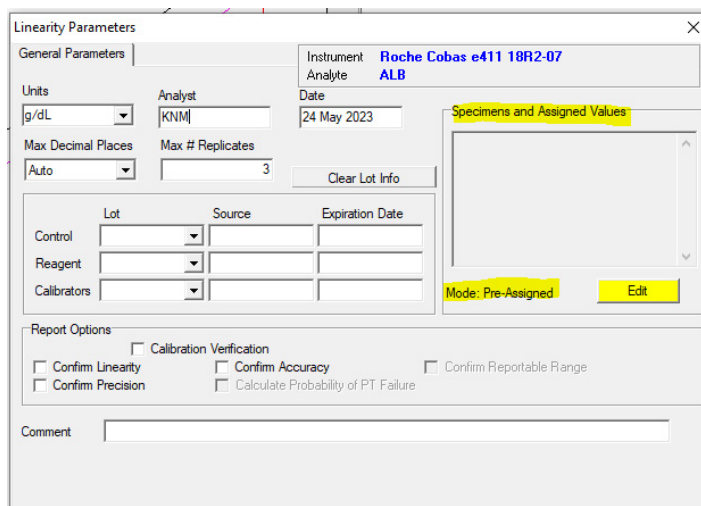
Processing VALIDATE Data in EP Evaluator

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

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



2. 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.



- 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.

Linearity Parameters

General Parameters | Instrument: Roche Cobas e411 18R2-07 | Analyte: ALB

Units: g/dL | Analyst: KNM | Date: 24 May 2023

Max Decimal Places: Auto | Max # Replicates: 3

Value Mode: 8 - Delta 1/3
Assigned concentrations are based on measured concentrations at levels 1 and 3.

Specimens and Assigned Concentrations:

Spec ID	Index
1	Level 1
2	Level 2
3	Level 3
4	Level 4
5	Level 5
6	
7	
8	

OK Cancel Help

- 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 [▶](#)

Linearity Parameters

General Parameters | Instrument: Roche Cobas e411 18R2-07 | Analyte: ALB

Units: g/dL | Analyst: KNM | Date: 24 May 2023

Max Decimal Places: Auto | Max # Replicates: 3

Specimens and Assigned Values:

Level 1	1
Level 2	2
Level 3	3
Level 4	4
Level 5	5

Mode: Delta 1/3 Edit

Report Options:

☒ Confirm Linearity ☐ Calibration Verification ☐ Confirm Accuracy ☐ Confirm Reportable Range

☐ Confirm Precision ☐ Calculate Probability of PT Failure

Allowable Error Criteria:

	Conc	Pct
Allowable Total Error (TEa)		
% for Systematic Error		

Fields highlighted in yellow are required

OK Cancel Help

- 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..

Specimens and Assigned Values:

Spec ID	Assigned	Mean	Rep 1	Rep 2	Rep 3
1	Level 1	--	x		
2	Level 2	--	x		
3	Level 3	--	x		
4	Level 4	--	x		
5	Level 5	--	x		

F4: Excl. Spec F5: Exclude F6: Clear Flags F7: Parameters F9: History