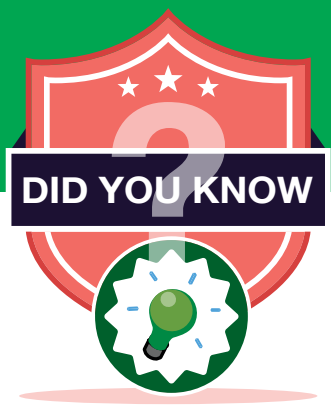
Unity Real Time™ Software

Measure QC Performance with Sigma Metrics

From the **Did You Know** series



Laboratories can use sigma metric analysis in many valuable ways: to assess the efficiency of laboratory practices, to address poor assay performance, and to design a protocol to review internal quality control (QC) with benchmarks. Six Sigma is one of the most popular quality management system tools employed for process improvement. Sigma values are useful for guiding the design of QC strategy, and Six Sigma methods are usually applied when the outcome of the process can be measured.

The Unity Real Time Software Data Analysis Grid can help you calculate sigma metrics for your lab's tests. With the grid, you can configure a total allowable error (TEa), which is conveniently available for many international quality specifications like Biological Variation, CLIA 2024 limits, RCPA limits, etc. The Data Analysis Grid will calculate your sigma metrics based on the lab's coefficient of variation and bias from your selected date range, and it will flag all low sigma values based on your set alert limits.

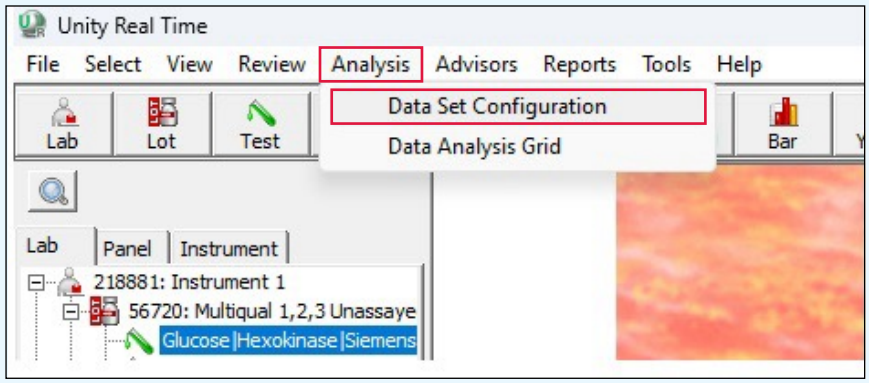
Additional resources about sigma metrics:

- Practical Guide to Six Sigma in the Clinical Lab
- Sigma Metrics, Total Error Budgets & QC

Keep reading to learn how to calculate sigma metrics for your lab with a Data Analysis Grid.

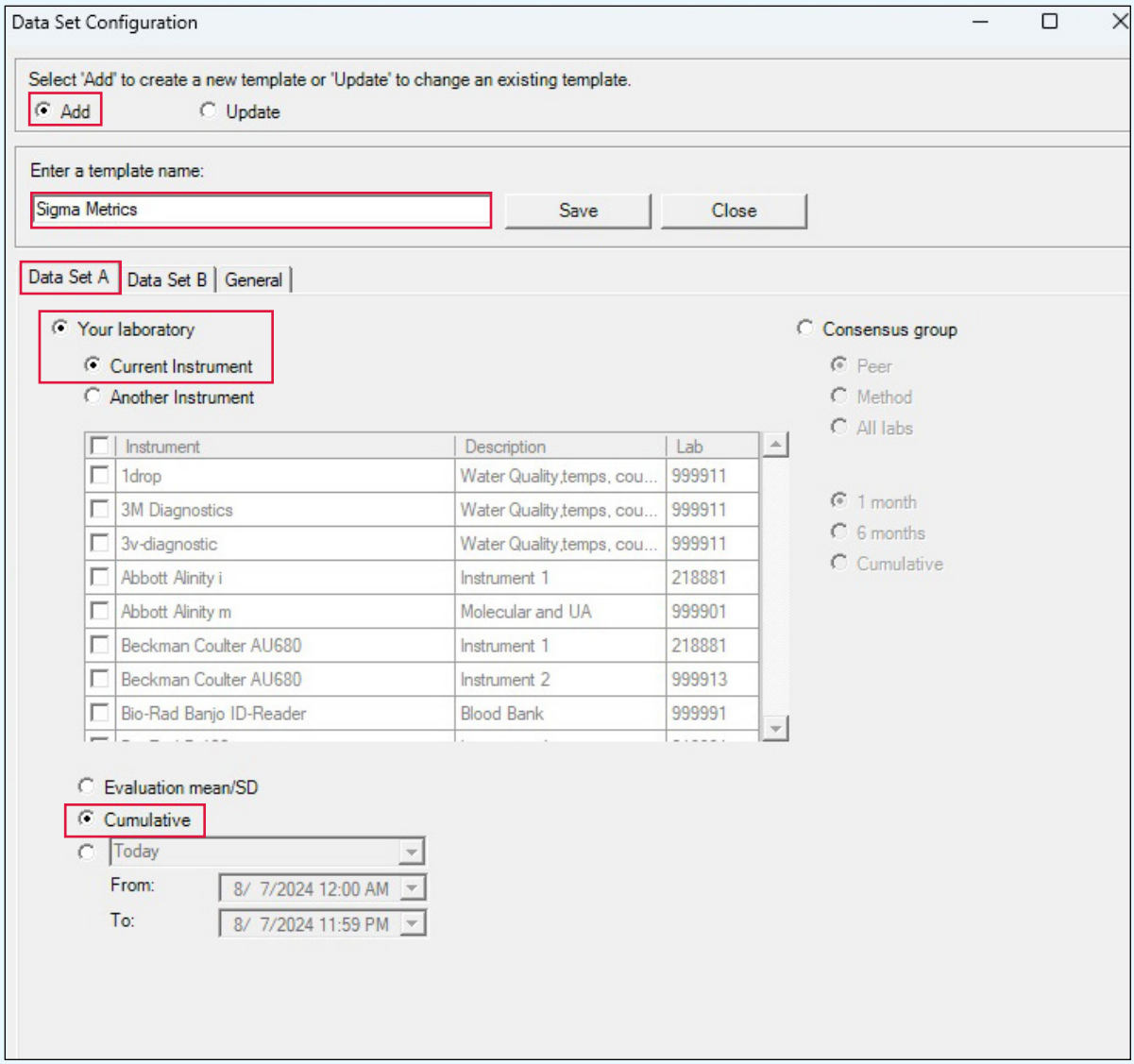
Configure the Data Analysis Grid Template

1. Select **Analysis > Data Set Configuration.**



2. Select **Add** and enter a template name. For this example, the template name is "Sigma Metrics."

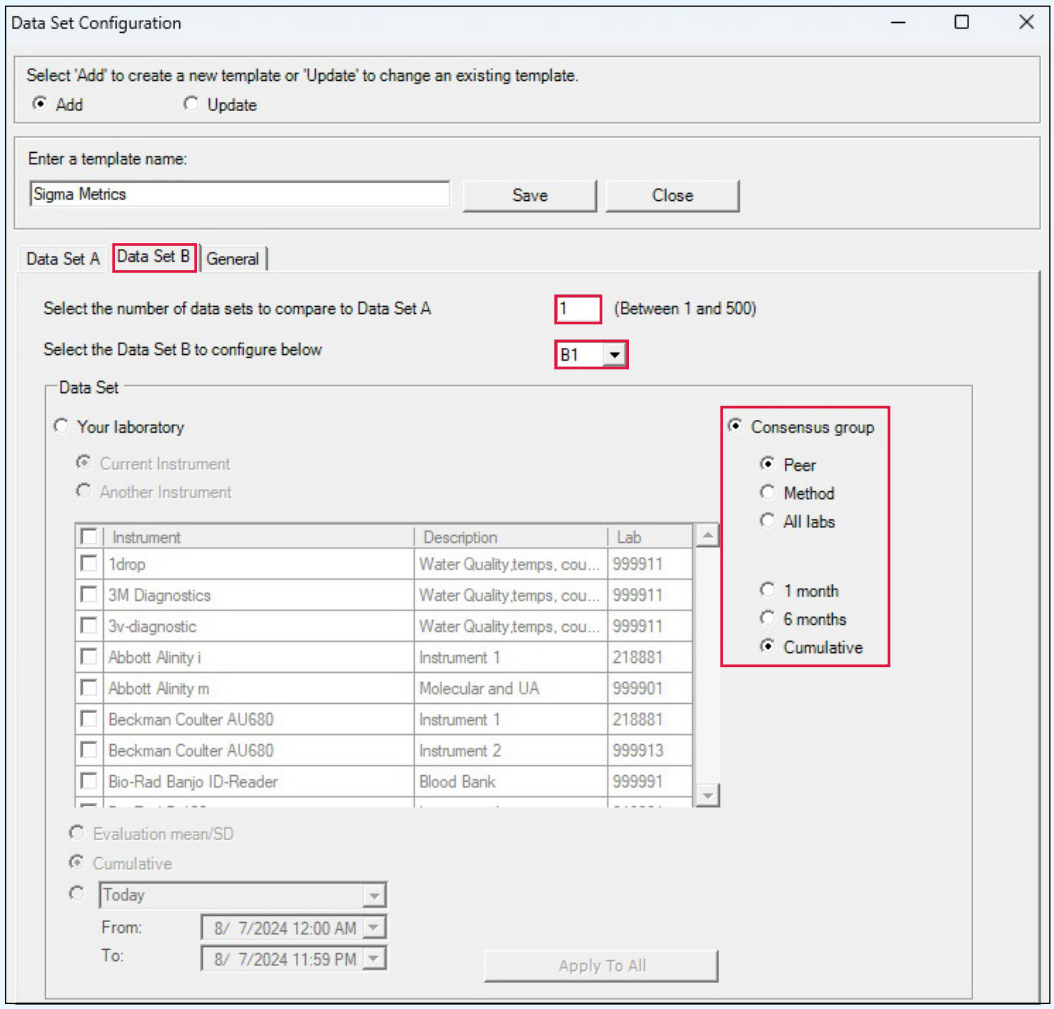
3. On the tab **Data Set A,** select **Your laboratory**. Then select your instrument as **Current Instrument** and your date range as **Cumulative.**



4. Click on the tab **Data Set B** to configure the next data set. You can technically have up to 500 Data Set B's, but for this instance you'll just need one. Make sure the number of data sets is set to **1**, and the data set is **B1**.

5. Select **Consensus group, Peer** and **Cumulative**.

Note: Consensus group values are not available for non Bio-Rad controls.



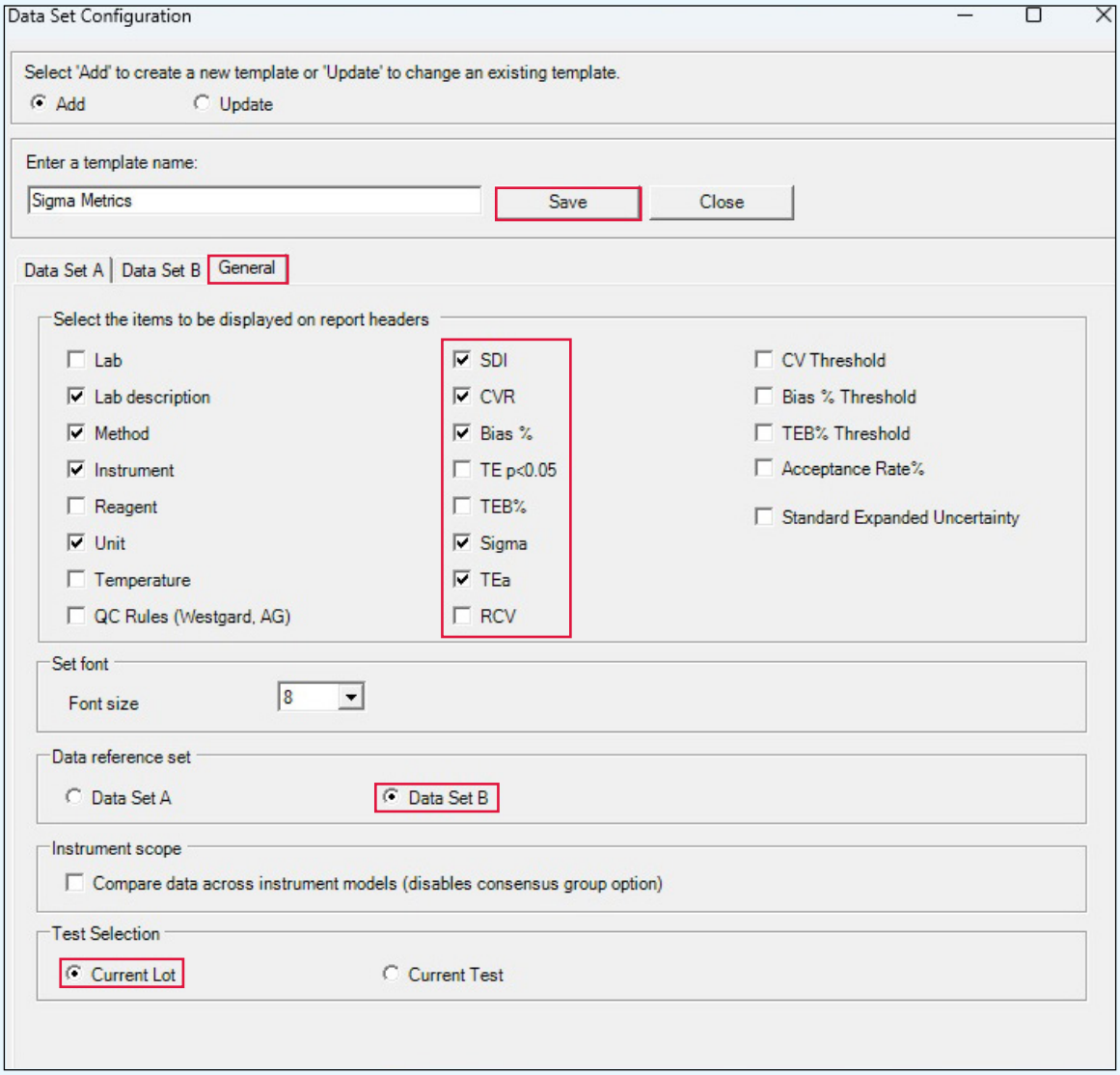
6. Click on the **General** tab. The **General** tab allows further customization for the report.

7. Checkmark the following items: **SDI, CVR, Bias %, Sigma, TEa,** and any other items you'd like to see.

8. For the **Data reference set,** select **Data Set B**. This will allow Data Set B to be the reference set for the current lot.

9. For the **Test Selection,** select **Current Lot**.

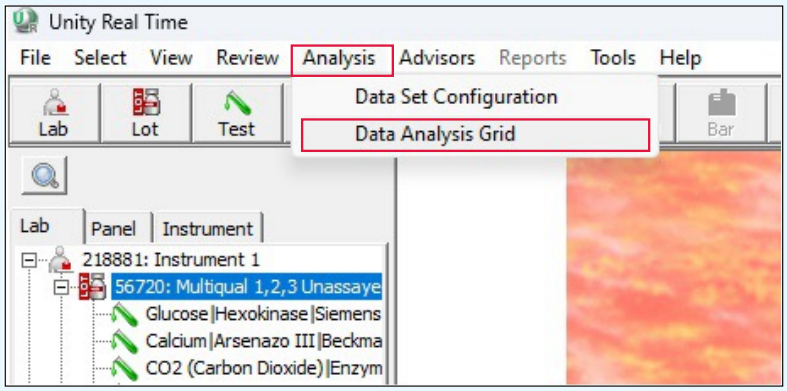
10. Click **Save** next to the template name to save the template.



View the Data Analysis Grid

1. After a template for the Data Analysis Grid has been created, you can open the grid.

Select your lot of interest in the navigation tree. Then navigate to the menu bar and select **Analysis > Data Analysis Grid**.

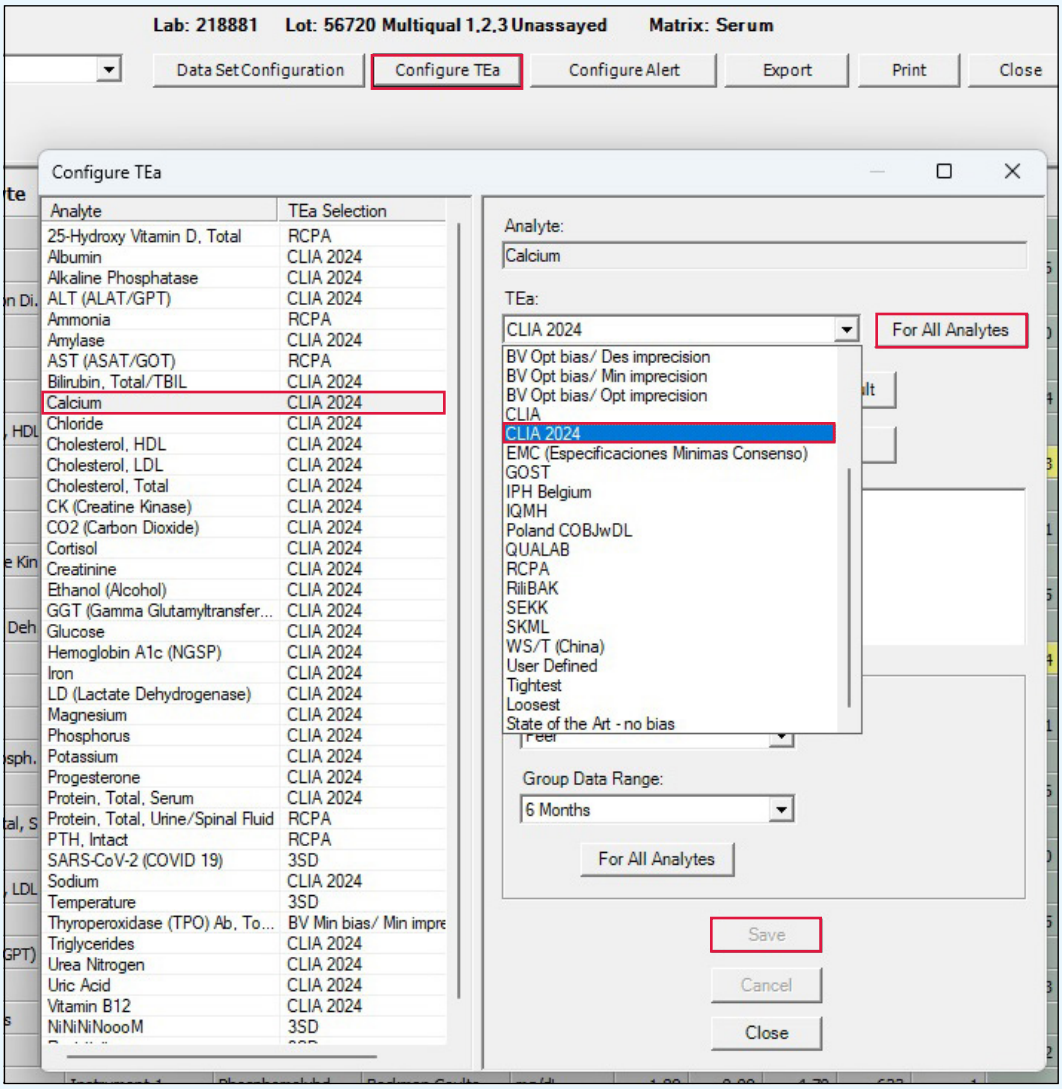


2. The Data Analysis Grid will open. You will need to configure the TEa value to calculate the sigma metrics value. Click on the button **Configure TEa**.

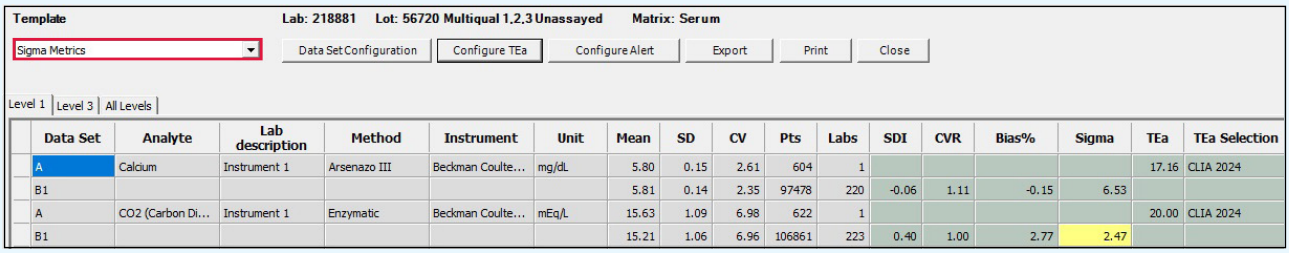
3. When the **Configure TEa** window appears, select the analyte on the left side and then select the TEa of your choice. If you want to use **CLIA 2024** for all analytes, select **CLIA 2024** and then click the button **For All Analytes**.

You will notice not all analytes have a **CLIA 2024** recommendation, so for those you can pick any other option or enter a manual value by selecting **User Defined** (not shown in the image).

4. Click **Save** to save your selection. Then close the **Configure TEa** screen.

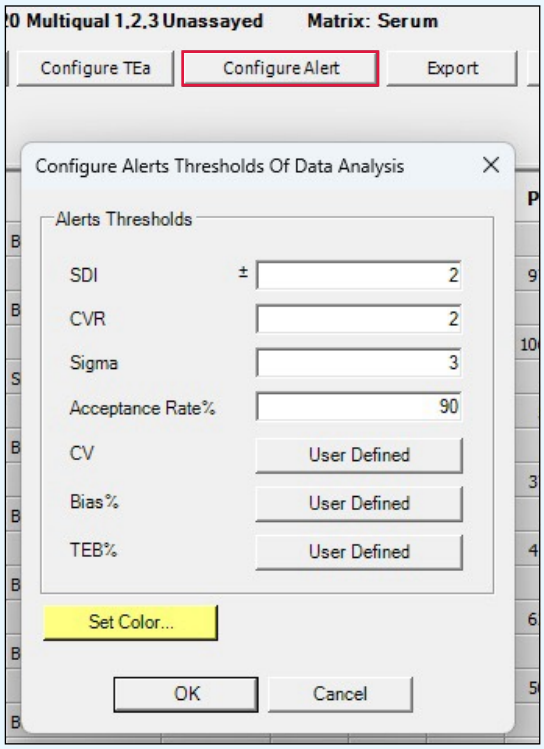


5. Select your template from the dropdown to view your calculations. The template in this example was named “Sigma Metrics.”



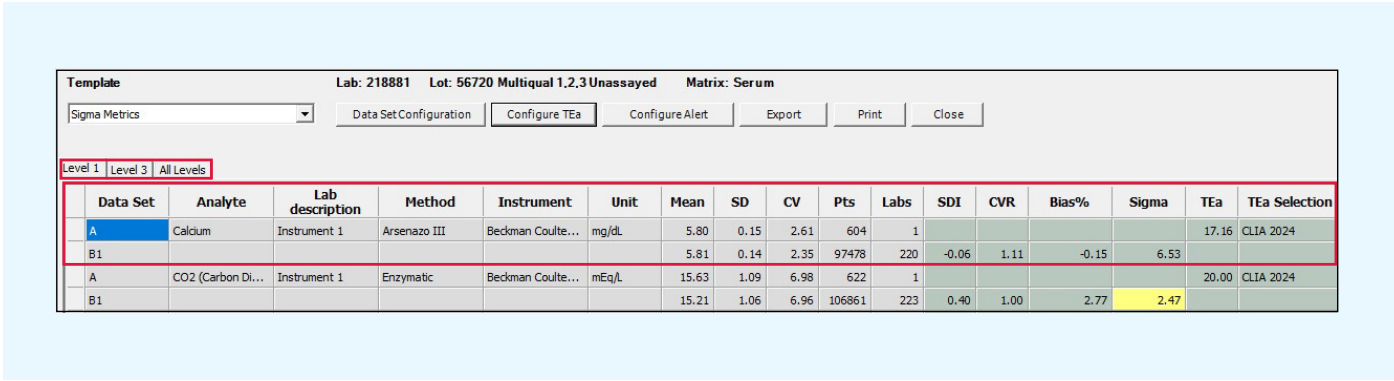
Data Set	Analyte	Lab description	Method	Instrument	Unit	Mean	SD	CV	Pts	Labs	SDI	CVR	Bias%	Sigma	TEa	TEa Selection
A	Calcium	Instrument 1	Arsenazo III	Beckman Coulte…	mg/dL	5.80	0.15	2.61	604	1					17.16	CLIA 2024
B1						5.81	0.14	2.35	97478	220	-0.06	1.11	-0.15	6.53		
A	CO2 (Carbon Di…	Instrument 1	Enzymatic	Beckman Coulte…	mEq/L	15.63	1.09	6.98	622	1					20.00	CLIA 2024
B1						15.21	1.06	6.96	106861	223	0.40	1.00	2.77	2.47		

6. To set alerts, click **Configure Alert**. This will allow you to highlight results if they fall outside a specific range. In this example, all sigma values below 3 will be highlighted yellow.



7. You can now view different levels by clicking their respective tabs or by clicking **All Levels**.

The row for **Data Set A** includes your lab's cumulative data and the TEa selection you made. The row for **Data Set B1** includes your peer group's data for that level and the calculated SDI, CVR, bias, and sigma value. Sigma values falling outside the specific range you selected are highlighted.



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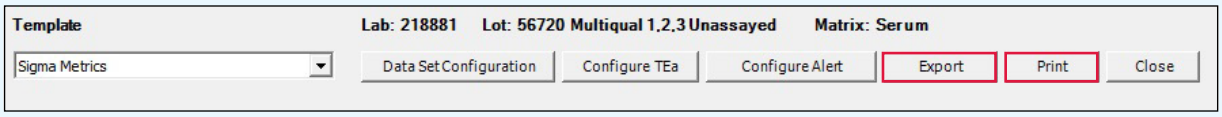
8. These tables can be saved and printed as PDFs or exported as .xlsx files, as needed.



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