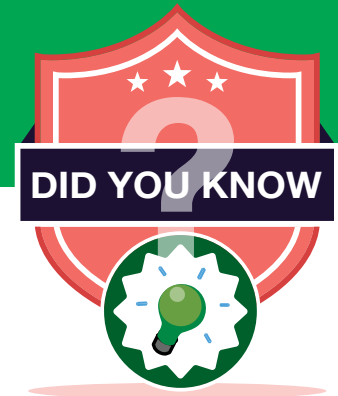


Unity Real Time™ Software

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.

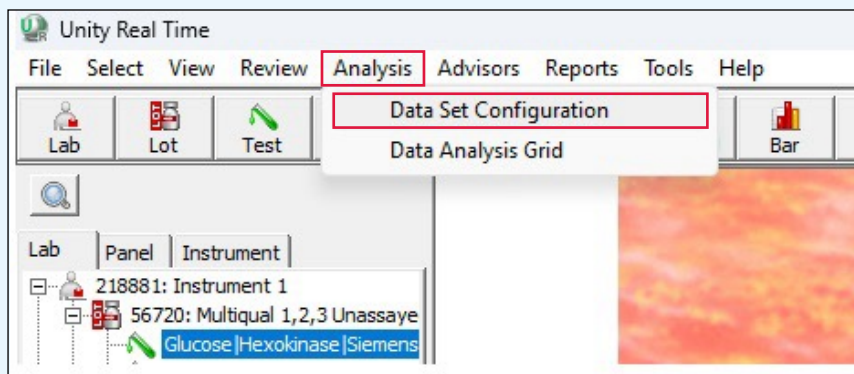
Additional resources about sigma metrics:

- [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**.

Select 'Add' to create a new template or 'Update' to change an existing template.

Add Update

Enter a template name:

Sigma Metrics

Data Set A | Data Set B | General

Your laboratory Consensus group

Current Instrument Peer

Another Instrument Method

1 month

6 months

Cumulative

<input type="checkbox"/>	Instrument	Description	Lab
<input type="checkbox"/>	1drop	Water Quality.temps, cou...	999911
<input type="checkbox"/>	3M Diagnostics	Water Quality.temps, cou...	999911
<input type="checkbox"/>	3v-diagnostic	Water Quality.temps, cou...	999911
<input type="checkbox"/>	Abbott Alinity i	Instrument 1	218881
<input type="checkbox"/>	Abbott Alinity m	Molecular and UA	999901
<input type="checkbox"/>	Beckman Coulter AU680	Instrument 1	218881
<input type="checkbox"/>	Beckman Coulter AU680	Instrument 2	999913
<input type="checkbox"/>	Bio-Rad Banjo ID-Reader	Blood Bank	999991

Evaluation mean/SD

Cumulative

Today

From: 8/ 7/2024 12:00 AM

To: 8/ 7/2024 11:59 PM

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.

Select 'Add' to create a new template or 'Update' to change an existing template.

Add Update

Enter a template name:

Data Set A **Data Set B** General

Select the number of data sets to compare to Data Set A: (Between 1 and 500)

Select the Data Set B to configure below:

Data Set

Your laboratory

- Current Instrument
- Another Instrument

<input type="checkbox"/>	Instrument	Description	Lab
<input type="checkbox"/>	1drop	Water Quality.temps, cou...	999911
<input type="checkbox"/>	3M Diagnostics	Water Quality.temps, cou...	999911
<input type="checkbox"/>	3v-diagnostic	Water Quality.temps, cou...	999911
<input type="checkbox"/>	Abbott Alinity i	Instrument 1	218881
<input type="checkbox"/>	Abbott Alinity m	Molecular and UA	999901
<input type="checkbox"/>	Beckman Coulter AU680	Instrument 1	218881
<input type="checkbox"/>	Beckman Coulter AU680	Instrument 2	999913
<input type="checkbox"/>	Bio-Rad Banjo ID-Reader	Blood Bank	999991

Evaluation mean/SD

Cumulative

Today

From:

To:

Consensus group

- Peer
- Method
- All labs

1 month

6 months

Cumulative

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.

Data Set Configuration

Select 'Add' to create a new template or 'Update' to change an existing template.

Add Update

Enter a template name:

Sigma Metrics

Data Set A | Data Set B | **General**

Select the items to be displayed on report headers

<input type="checkbox"/> Lab	<input checked="" type="checkbox"/> SDI	<input type="checkbox"/> CV Threshold
<input checked="" type="checkbox"/> Lab description	<input checked="" type="checkbox"/> CVR	<input type="checkbox"/> Bias % Threshold
<input checked="" type="checkbox"/> Method	<input checked="" type="checkbox"/> Bias %	<input type="checkbox"/> TEB% Threshold
<input checked="" type="checkbox"/> Instrument	<input type="checkbox"/> TE p<0.05	<input type="checkbox"/> Acceptance Rate%
<input type="checkbox"/> Reagent	<input type="checkbox"/> TEB%	<input type="checkbox"/> Standard Expanded Uncertainty
<input checked="" type="checkbox"/> Unit	<input checked="" type="checkbox"/> Sigma	
<input type="checkbox"/> Temperature	<input checked="" type="checkbox"/> TEa	
<input type="checkbox"/> QC Rules (Westgard, AG)	<input type="checkbox"/> RCV	

Set font

Font size: 8

Data reference set

Data Set A **Data Set B**

Instrument scope

Compare data across instrument models (disables consensus group option)

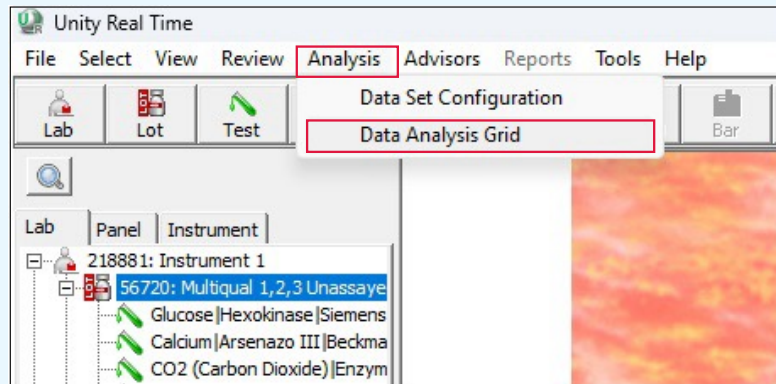
Test Selection

Current Lot Current Test

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**.

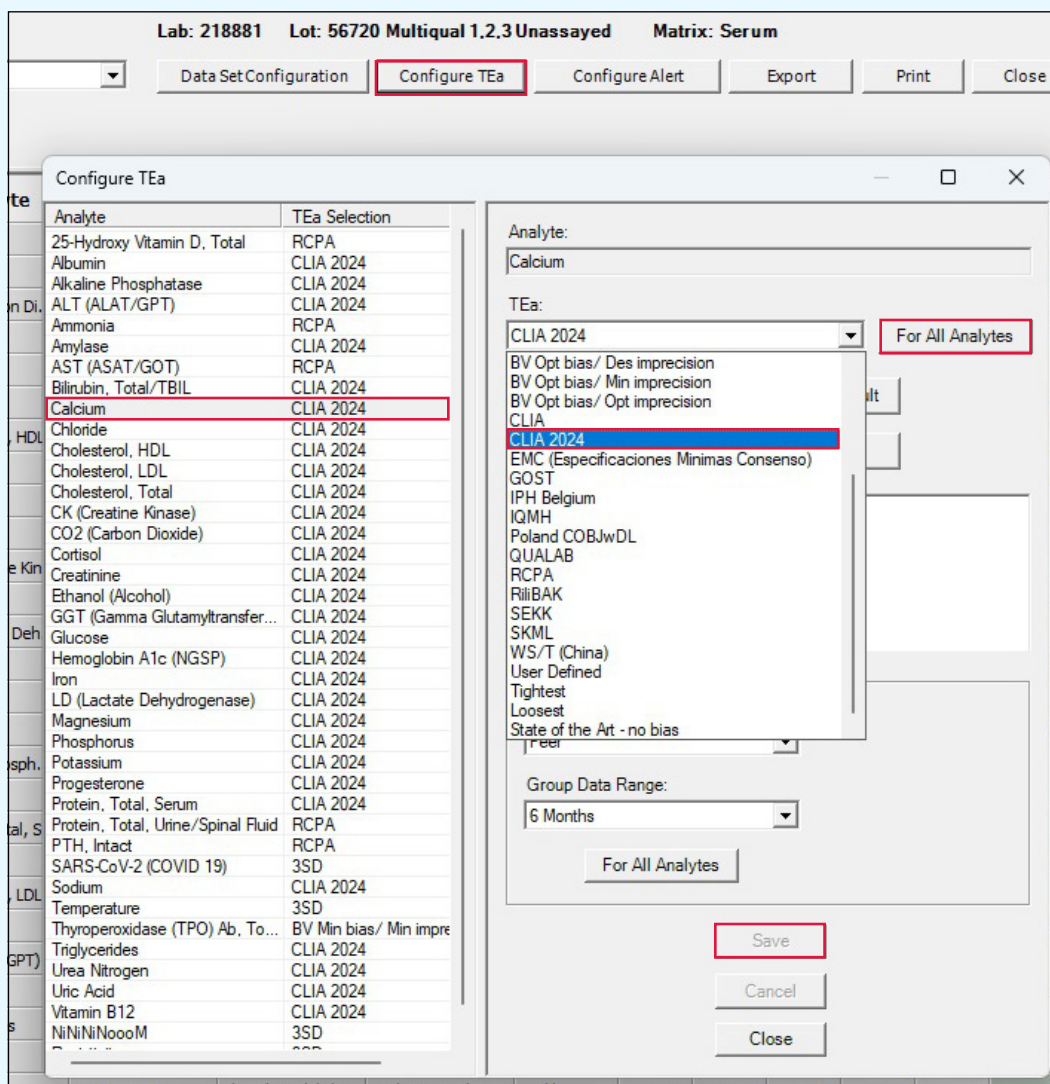


2. The Data Analysis Grid will open. You will need to configure the TEa value to calculate the sigma metrics value. Click on the button **Configure TEa**.

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.”

Template Lab: 218881 Lot: 56720 Multiquial 1,2,3 Unassayed Matrix: Serum

Sigma Metrics Data Set Configuration Configure TEa Configure Alert Export Print Close

Level 1 | Level 3 | All Levels

	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.

0 Multiquial 1,2,3 Unassayed Matrix: Serum

Configure TEa **Configure Alert** Export

Configure Alerts Thresholds Of Data Analysis

Alerts Thresholds

SDI ±

CVR

Sigma

Acceptance Rate%

CV

Bias%

TEB%

Set Color...

OK Cancel

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.

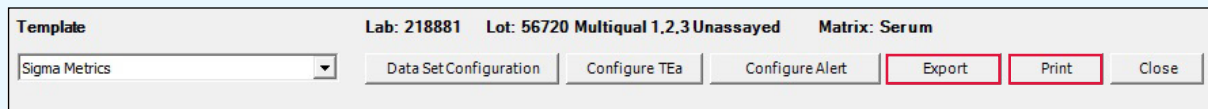
Template Lab: 218881 Lot: 56720 Multiqual 1,2,3 Unassayed Matrix: Serum

Sigma Metrics Data Set Configuration Configure TEa Configure Alert Export Print Close

Level 1 | Level 3 | All Levels

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
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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		

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





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