IAMQC™

YOUR QUALITY CONTROL SOFTWARE

USER MANUAL

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1. INTRODUCTION

1.1 *Welcome*

Welcome to TECHNOPATH's IAMQC™ Peer program, designed to compliment and support TECHNOPATH's Multichem™ Quality Control range. (See section 5)

As a participant, you can now access instant peer statistics at the click of a button and receive an assessment of your laboratory performance straight to your email or wherever you can find a web connection.

Simply go to www.IAMQC.com and log in using the credentials provided with this user manual. Upon login you are provided with access to our truly real-time peer system, along with video tutorials to help you get settled. Clicking on the 'Reports' section will allow you to build and view live reports on the spot to analyse your data. Alternatively, these reports are automatically scheduled to the email address(es) you have provided during your installation. Follow the information provided in this user manual to;

- Get ready to participate in IAMQC Peer
- Learn the basic skills to use the system
- Read Reports
- Access support
- Troubleshoot your QC using IAMQC Peer Software

At any time, the recipient list can be updated by clicking on Setup>Laboratory Demographics and editing the email recipient form.

See section 3.1d

1.2 *System Contents*

IAMQC™ Peer facilitates laboratories testing the same lot number of control material to access valuable information from their colleagues through peer comparison. The reports that are generated in IAMQC™ Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can be extremely valuable, indicating the user's performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.

IAMQC™ Peer includes the following information:

1. Customer's mean, SD, CV and N for a month;

2. Customer's cumulative mean, SD, CV and N since it has been reporting a specific control material;

3. The mean, SD and CV, and number of customer sites for a method peer (for sites using the same methodology);

4. The mean, SD and CV, and number of customer sites reporting a specific control for all sites testing all methods;

5. The method peer Standard Deviation Index (SDI): the variance of a customer's mean from the method peer mean, measured by the number of method peer standard deviations that a laboratory's mean varies from the method peer mean;

6. The All Lab SDI: the variance of a laboratory's mean from the All Lab mean, measured in number of All Lab standard deviations that a customer's mean varies from the All Lab mean;

7. Method peer Coefficient of Variation Index (CVI): the ratio of the CV or SD reported by a laboratory to the CV or SD reported by the method peer;

8. All Lab CVI: the ratio of the CV or SD reported by a customer to the CV or SD reported by all laboratories reporting for a specific control.

9. SDI and CVI: indicating how well the Mean and SD of a customer site compares to the data submitted for the peer group.

Traditionally, when the SDI is within +/- 2, the laboratory mean is within 2 standard deviations of the group mean, and therefore laboratories method performance is acceptable. An SDI less than -2 indicates that laboratory mean is lower than the peer group mean and differs from the peer group mean by more than 2 peer standard deviations. An SDI higher than +2 indicates that laboratory mean is higher than the group mean by more than 2 peer group SDs.

10. The %CV (=100%*SD/Mean) or SD within an individual laboratory should be equal to or less than the %CV or SD reported by the overall group, therefore a CVI of less than 1 is normally considered acceptable. The CVI alerts to variation between the precision of laboratory's method and the precision of the peer group: laboratories should be "warned" if the CVI is greater than 1.

2. GETTING STARTED

2.1 *Preparation Check List*

Follow the information provided in this start-up guide to ensure that you are prepared to begin reviewing your QC data. Please ensure that you check off every item in the following list to get started:

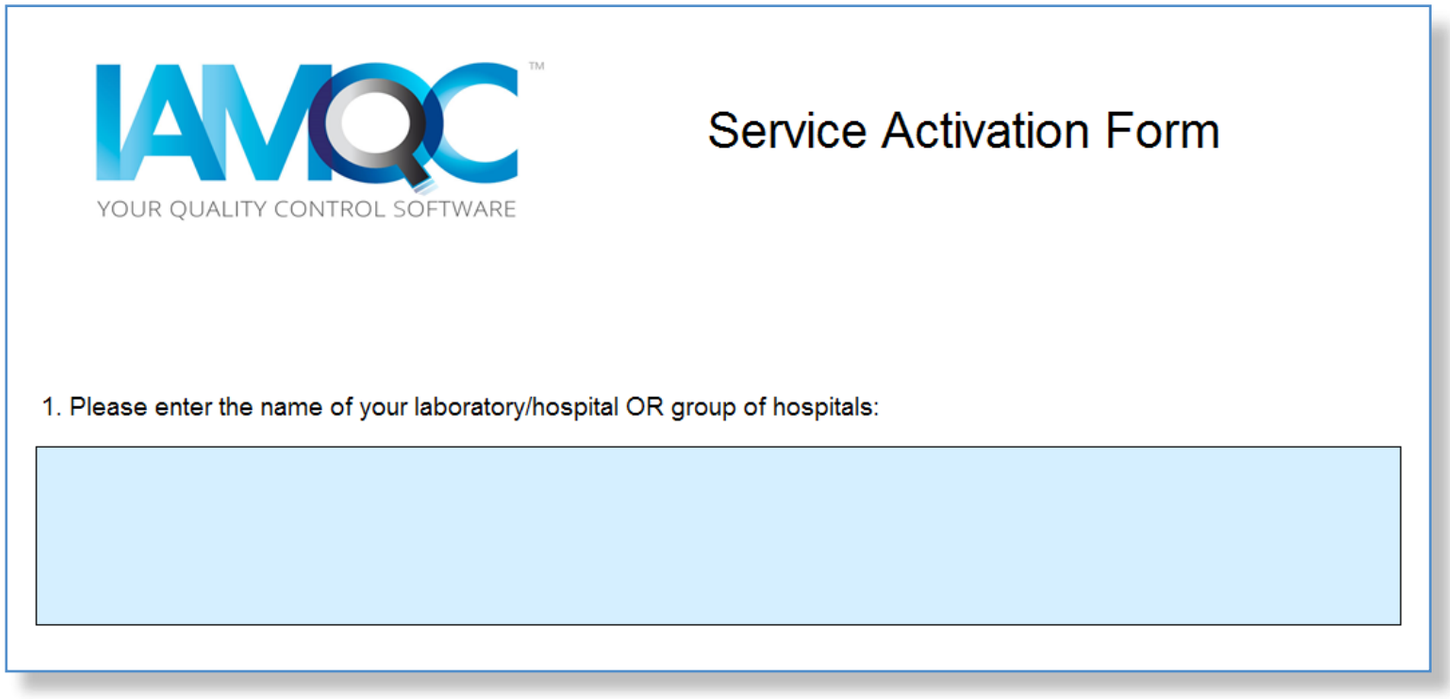
Stage 1

1. Complete Service Activation Form
2. Set Up Barcodes

Stage 2

3. Initial Mapping Step
4. Video Tutorials
5. Verify your Setup
6. Register for the IAMQC™ User Forum

2.1a *Complete Service Activation Form*



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Service Activation Form

1. Please enter the name of your laboratory/hospital OR group of hospitals:

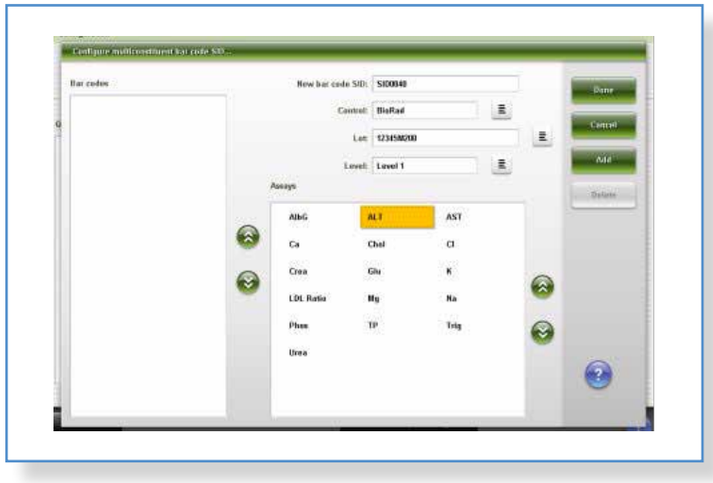
For more information on completing the form, contact your local representative.

The Service Activation Form must be completed and returned to your local representative to ensure a successful installation. Please make sure to complete every section of the form.

Once the form is completed and returned, your local representative will engage the appropriate team member(s) to enable your IAMQC™ Peer license. Once your order has been processed you will receive your login credentials, along with the IAMQC™ User Manual, direct to your email address.

2.1b *ARCHITECT System Configuration*

Utilising the barcode SID function on your Architect System will streamline the process of QC data capture via the released QC file. This will also ensure that all QC is identified correctly and mapped accordingly. Please ensure to complete this step prior to moving on to stage two of the preparation check-list.



Configure a multiconstituent bar code SID on your Architect System

From the Configure multiconstituent bar code SID window, the system administrator can assign the bar code SID (sample identification) for a configured multiconstituent control. Technopath encourages the use of the following logic when assigning a Barcode SID:

{**TP**}{**First 3 digits of Lot Number**}{**Number of Levels**}

FOR EXAMPLE;

TP3271 = Lot Number 32712120 - Level One

TP3272 = Lot Number 32712120 - Level Two

TP3273 = Lot Number 32712120 - Level Three

*Please go to **Section 2 > Installation procedures and special requirements > System Configuration > Configuration screen – QC – Cal settings view** of your Architect Operations Manual for more information on setting up the Multiconstituent bar code SID on your Architect System.*

Prerequisite	Access the Configuration screen - QC - Cal settings view, page 2-147
Module status	Stopped, Warming, or Ready
User access level	System administrator
Supplies	NA

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2.1b *ARCHITECT System Configuration*

PLEASE NOTE: *If the normal procedure in your laboratory is to run QC as 'patient controls', please ensure to use the same 'Barcode SID', as configured in the 'QC- Cal Configuration' section, mentioned above. This will enable the ARCHITECT to recognise the 'patient controls' as QC material and will map the samples accordingly to the QCRELEASED file in the AbbottLink.*

To configure a multiconstituent bar code SID:

1. Select Multiconstituent bar code SID from the QC – Cal categories list on the Configuration screen, and then select F6 - Configure.
2. The Configure multiconstituent bar code SID window displays.
3. Enter the ID to be used for the multiconstituent control level bar code in the New bar code SID data entry box.
4. The bar code SID must be unique for each control level within a lot.
5. Select the Control list button, and then select the desired control.
6. Select the Lot list button, and then select the desired lot.
7. Select the Level list button, and then select the desired level.
8. Select the desired assay(s) from the Assays list, and then select Add.
9. Repeat steps 2 through 6 to configure additional bar code SIDs. (optional)
10. Select Done to save your changes.

Host – Release Mode

To ensure that your QC data is transmitted correctly, please confirm that your 'Host - Release Mode' is configured appropriately. To configure the host – release mode, please refer to the following section in the ARCHITECT Operations Manual:

"Configure host - release mode window (Options - Release/Transmit view), section 2-42 (page 346)."

This setting allows the general operator to select the release mode for QC results. The options are as follows:

- Manual – All results must be manually released. (Default)
- Hold – All results with flags must be manually released.
- Automatic – Results are released automatically.
- Automatic with exceptions – Results and exceptions are automatically released.

It is recommended that customers select either '**Manual**' or '**Automatic**' result release to ensure data is transmitted accordingly to AbbottLink.

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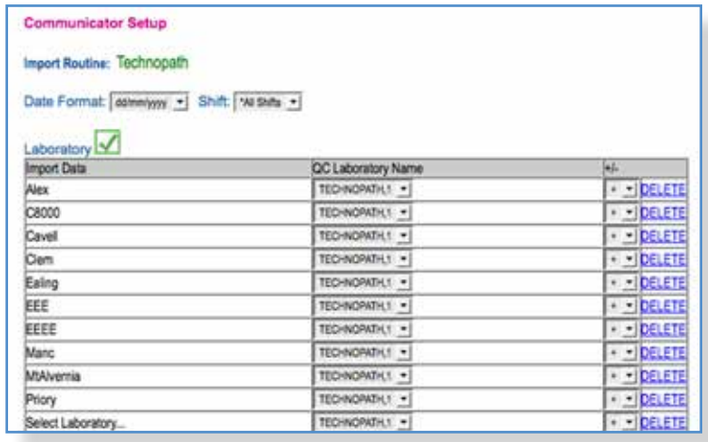
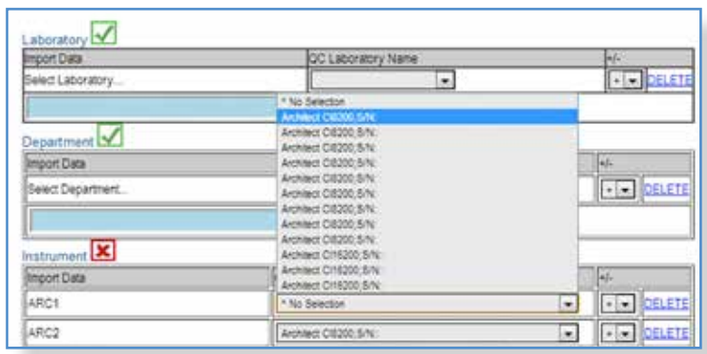
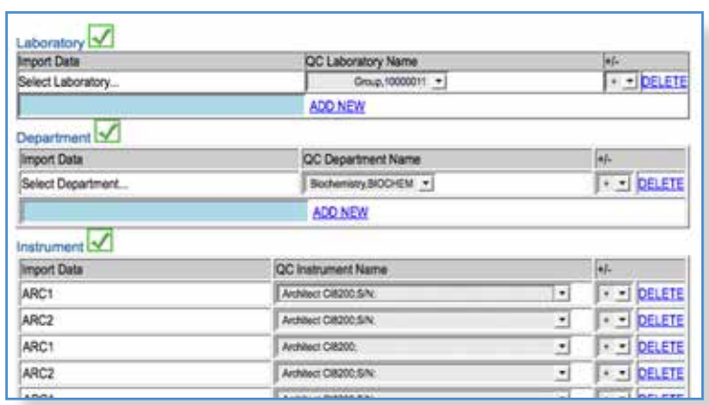




If the system does not display the required information in the drop-down menus to complete your setup, please contact your local representative.



2.1c *Initial Mapping Step*

Upon initial log in, a screen will display some records that need to be mapped to complete your setup. The mapping screen will display all of the information gathered from your setup, including your laboratory name, department, instrument details, test codes and sample/control lot identifiers.

The column on the left represents the information received from the customer's platform and is not editable. The column in the middle provides the customer with a drop-down menu of the options for mapping, already set up in the system by TECHNOPATH. The column on the right provides the option to disable the flow of data for a specific item. If the customer does not want to receive information for a specific item they can simply select the minus (-) from the drop-down option and the item will appear greyed out. The same logic is applied for mapping of all information, i.e instruments, test codes and sample/control lot identifiers. Please go to section 3.1g of the IAMQC™ User Manual for more information.

To complete any outstanding mapping:

1. Select 'SETUP,' > 'LABORATORY DEMOGRAPHICS' from the 'Home' page.
2. The Laboratory Demographics Home Page will now be displayed.
3. Click on the grey Communicator Icon next to the button.
4. The system will displays options for setting up new communicators, click 'NEXT'.
5. The Communicator Setup displays, click 'NEXT'.
6. The system now displays all mapping associated with your account.
7. Mapping that is incomplete displays a red icon beside the section header.
8. Un-mapped items display "No Selection" in the middle column.
9. Click on the 'NO SELECTION' window to view all available items in a drop-down menu.
10. Click on the relevant item to map it to the information shown on the left column.
11. Once all of the mapping is complete, the system should display a green check mark beside each section header.
12. **It is recommended that you ensure every item on the list is mapped appropriately.**
13. Click 'EXIT' to return to the Home Screen.

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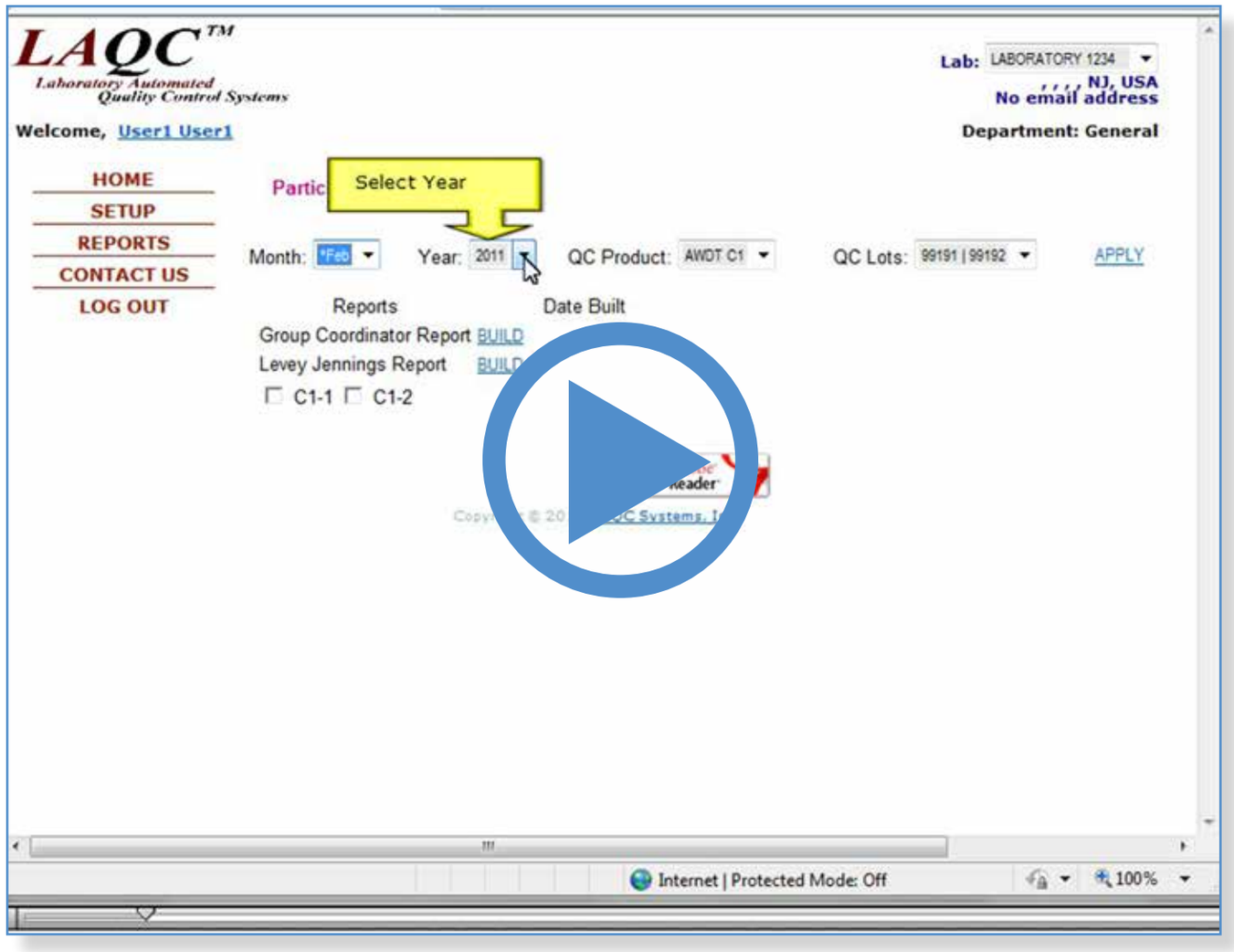
2.1d *Video Tutorials*

For more information on accessing video tutorials, please go to section 3.3c of the IAMQC™ User Manual.

Once you have completed the initial mapping step, you are ready to begin using the system. Begin by clicking on the 'Tutorial' section in the menu bar on the left side of the screen. A drop-down menu will list all of the available video tutorials. Click on the selected topic to open the video tutorial in a new window. Technopath strongly recommends you watch each video tutorial in the list upon initial login.



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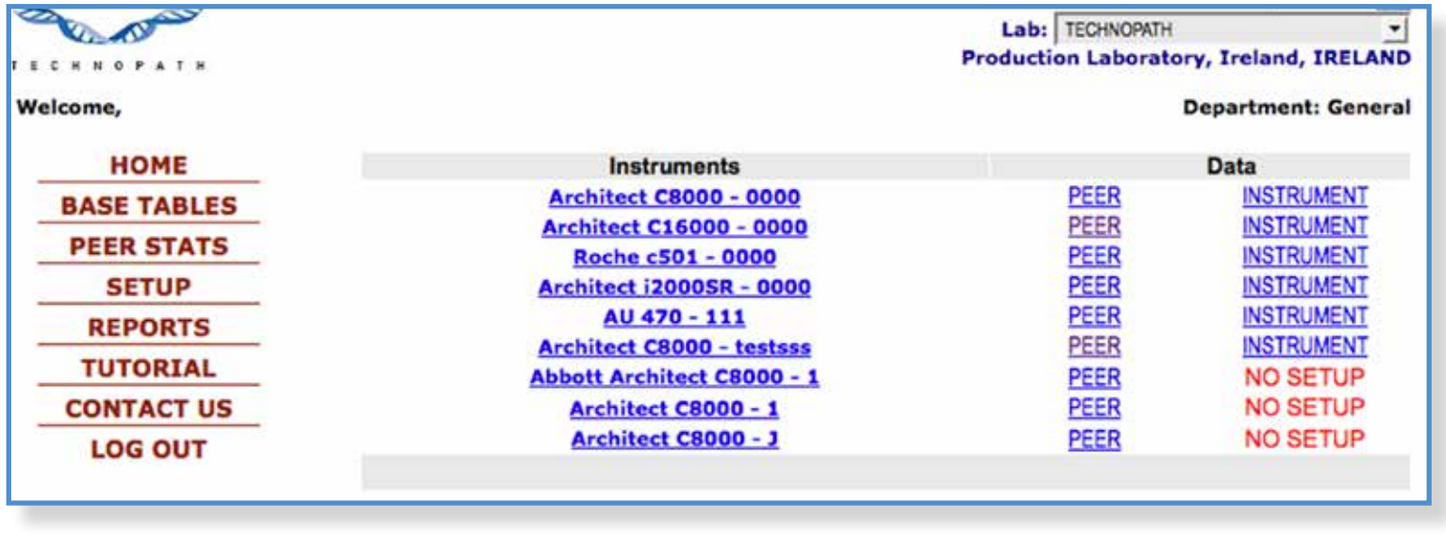
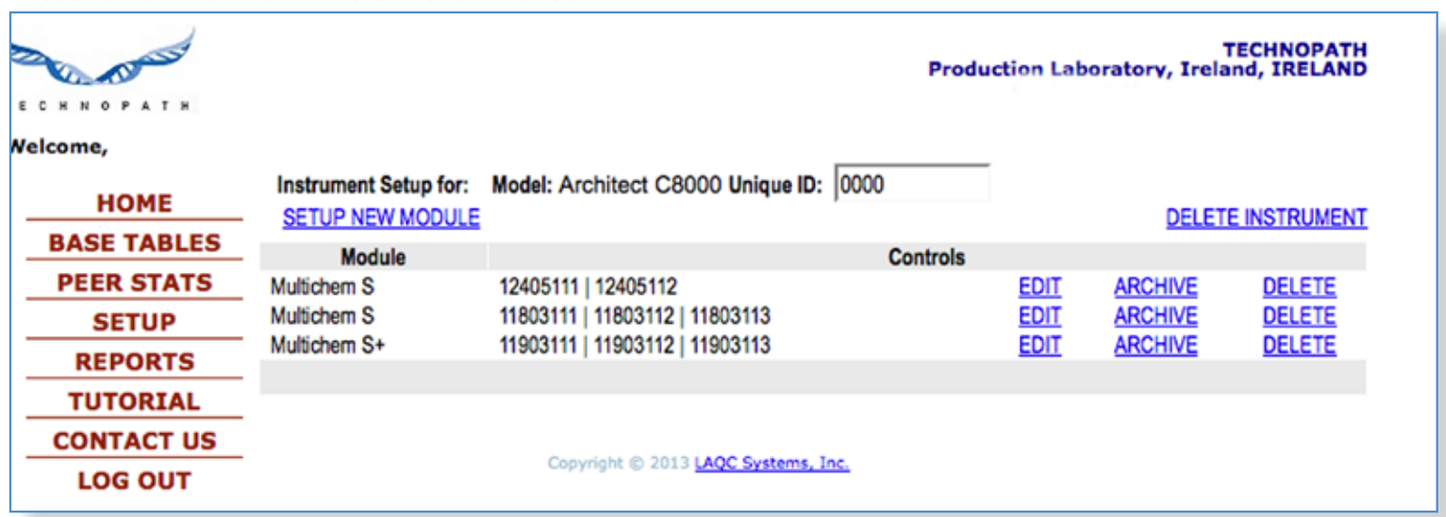
2.1e *Verify your setup*



Upon login, you will be presented with your home page. To ensure your setup is accurate please log in to the system and verify that all of your instruments and control lots are present. The system will display all of the instruments included in your setup, along with a serial identifier for each instrument. Click the individual instrument name to view the control lots that have been associated with your instrumentation. If the setup is incorrect or you are missing certain components please edit your setup by following the instructions provided in section 3.1f of the IAMQC™ User Manual.



For more information on editing your setup, please go to Section 3.1f of the IAMQC™ User Manual

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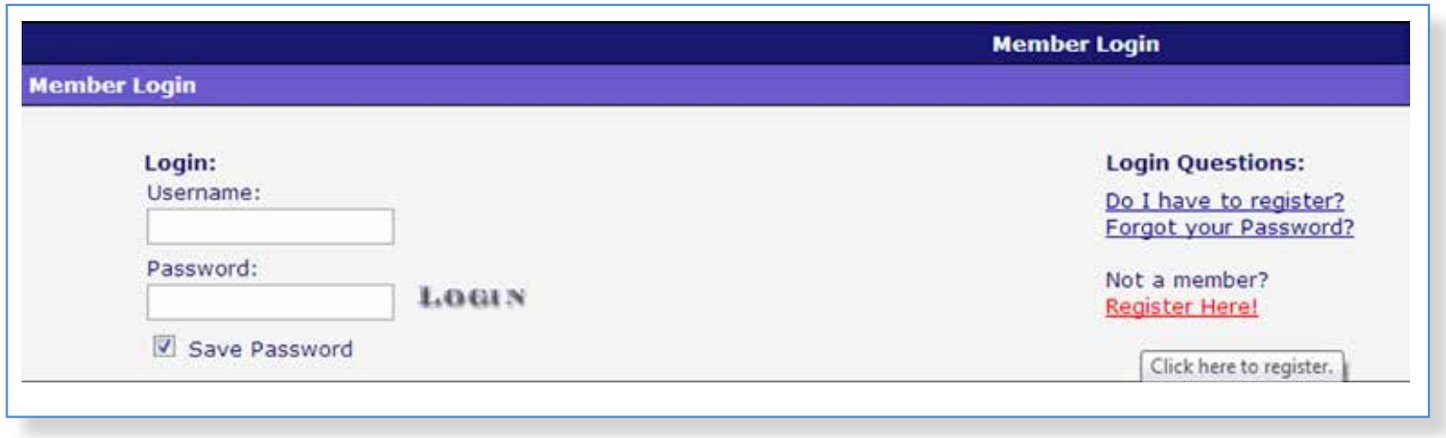
2.1f *Register for the IAMQC™ User Forum*



The steps to register for the IAMQC™ User Forum are as follows:

- Go to http://www.iamqc.com/userforum
- Click on Register Here!
- If you agree to the terms and conditions stated, click on the 'Agree' button.
- Fill out all of the required details and click on submit

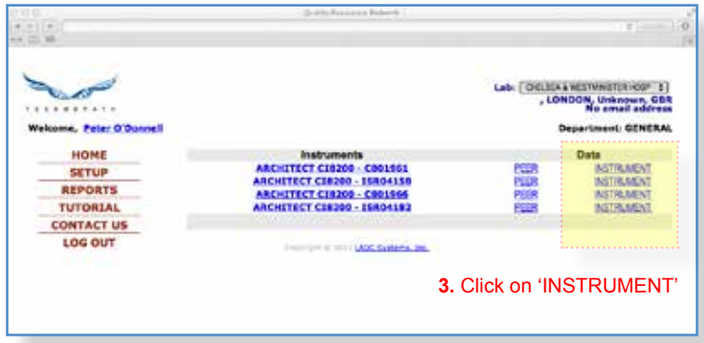
Once you submit your form your registration will be processed within 3-5 working days and you will receive confirmation via the email address you have submitted.

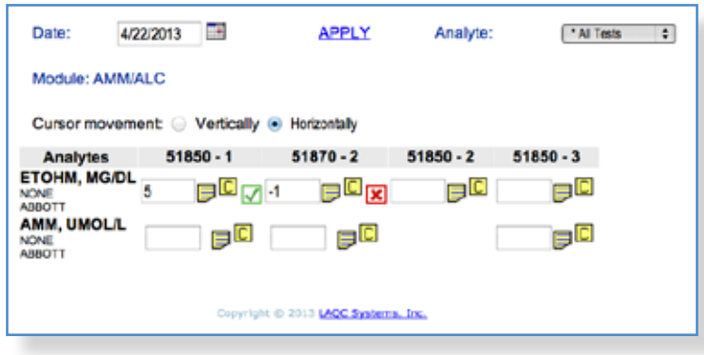
To complete your registration you must have a valid email address.

3. SYSTEM GUIDE

Basic Skills

3.1a *Enter Data Manually*





1. Login to IAMQC™ using your username and password.
2. When the home screen is presented, all of your available instruments are listed.
3. Each instrument listed will allow you to enter data manually by clicking on 'INSTRUMENT', located to the right of the screen.
4. Before data can be entered, you need to set your preferences. Select the Date, then choose your Lot Number from the drop down menu and finally select your cursor movement option.
5. To enter data, click within the first entry cell. Once you have typed your result for the specific analyte, simply hit enter and the cursor will automatically move to the next cell.

   Data can be entered for all tests by default or you can enter data for individual tests by selecting the relevant analyte from the drop down menu.

   The IAMQC™ system gives the user a visual confirmation as to whether the data entered is within the acceptable range by displaying a green check mark for an acceptable entry and a red for an unacceptable entry. To delete a previously entered or an incorrect result, simply clear the cell value(s) and click on 'SAVE' at the bottom of the screen.

   - You can enter more than one result per day by clicking on the Multiple Line icon.
   - You can enter comments for each result by clicking on the Comments icon.

6. When data entry is complete, Click 'SAVE' at the bottom of the screen. Clicking 'SAVE' posts all changes and results to the database. Once you have successfully saved your results, a confirmation message will appear at the bottom of the screen stating 'Your data has been entered successfully'.

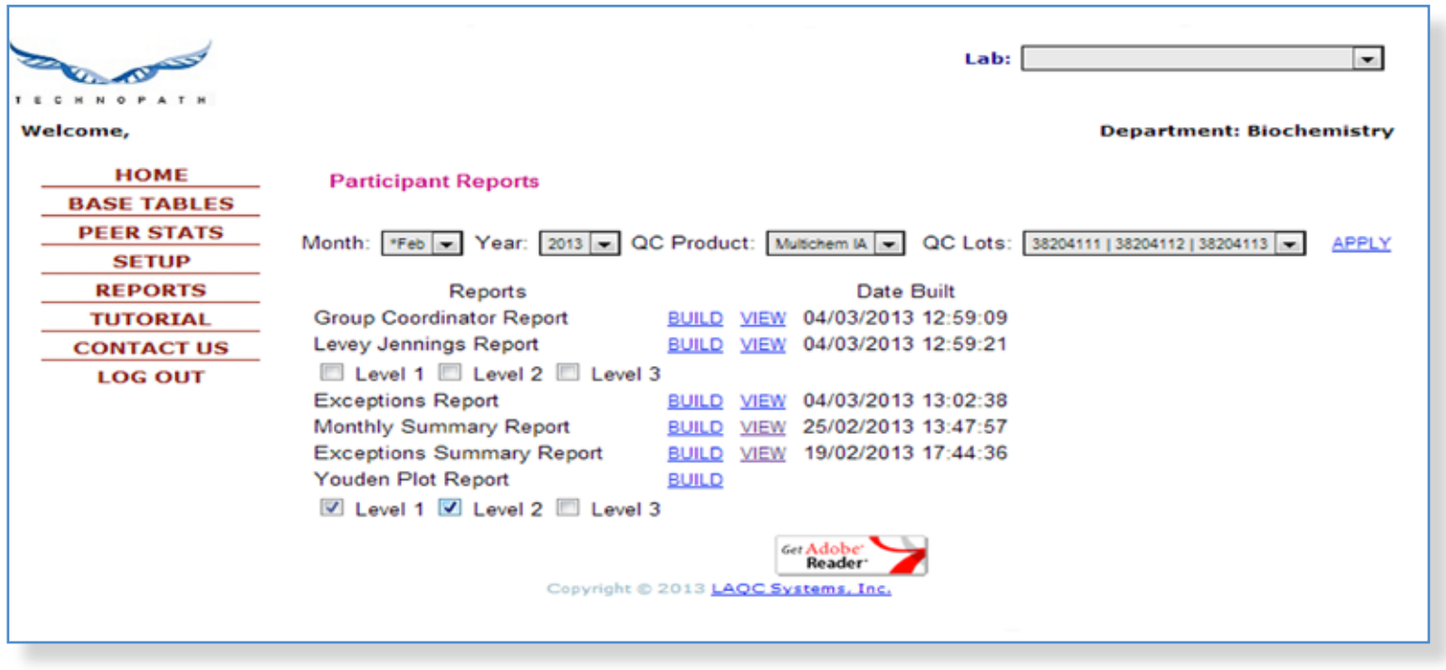
RETURN

Basic Skills

3.1b *Build Reports*

1. From the 'HOME' page, click the 'REPORTS' button on the left side of the screen.
2. Before you build your IAMQC™ report set your preferences by choosing the relevant Product and Lot Number and entering the time period of interest in the Date section. Click 'APPLY' to set your preferences.
3. Click on 'BUILD' beside the report you wish to view. This will create a report in PDF format. All reports are calculated and built in real-time to give you the most up-to-date information available. Once the report is built it will be displayed on the screen. You can then print, save or close the report

   Previously built reports can be accessed online by clicking the 'VIEW' button. The date and time the most recent report was built is displayed next to each individual report. Certain reports provide the option of selecting the QC levels to be included in the report. Simply check-mark the box beside each level you want to include and click 'BUILD'.

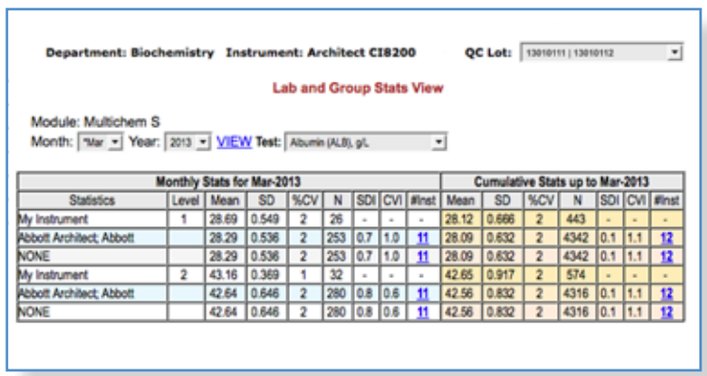


RETURN

Basic Skills

3.1c *View Interactive Peer Stats*

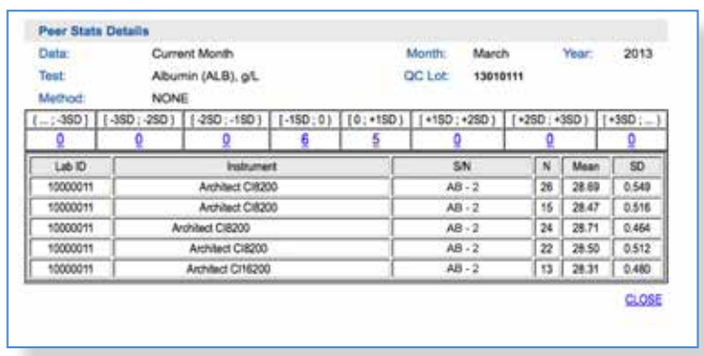
1. Login to IAMQC™ using your username and password.
2. When the home screen is presented, Click on the 'PEER' button next to your chosen instrument to view peer statistics for the selected instrument.



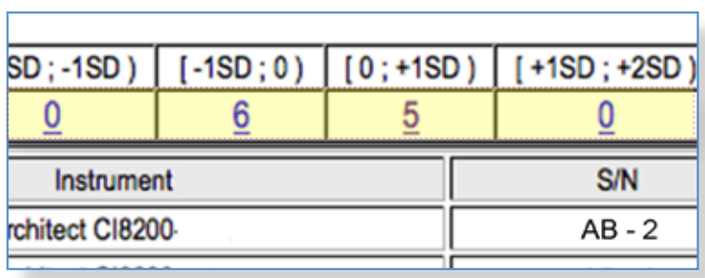
3. In the case that multiple lot numbers of control material are set up on the one instrument, select the lot number you wish to view from the drop-down menu in the top right corner of the screen.

   Set the time period you wish to view from the date section and select the test from the drop-down menu. Click the 'VIEW' button to apply your selections.

   All statistics displayed are calculated in real-time for the preferences previously selected.



4. The interactive table shown displays live results for the selected month, along with cumulative peer statistics for this particular lot of control material. The first row of the table outlines the performance of your selected instrument, the second row contains statistics for the 'Test System Peer Group' (all participants using the same Instrument Class, Method and Reagent for the same test/lot of control material), and the third row displays statistics for the 'Method Principle Peer Group' (all participants using the same methodology for the same test/lot of control material).



   Users can also view the distribution of participants' results in the selected peer group, displayed in an SD range, by clicking on the blue number in the 'number of instruments' column (for the selected month or cumulative results).

   A new window opens displaying a Standard Deviation (SD) range table outlining all instruments in the peer group. Click on the number in each SD range to view individual submissions.

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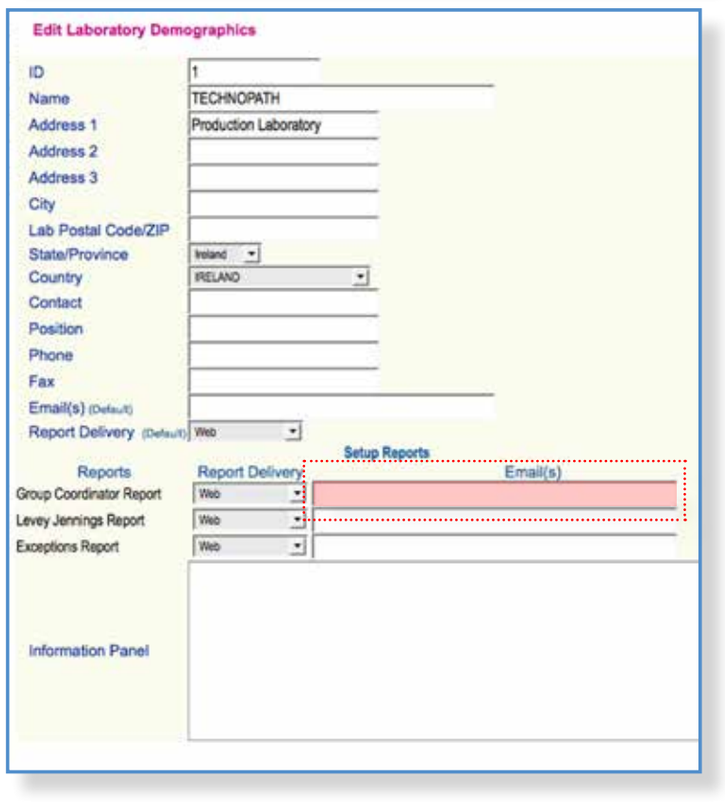
Basic Skills

3.1d *Edit Laboratory Demographics*



1. From the 'Home' page, click the 'SETUP' button on the left side of the screen. Select 'LABORATORY DEMOGRAPHICS' from the drop-down menu displayed.
2. On the 'Laboratory Demographics' screen, click on the 'EDIT' button to make changes. The system will now display all of the previously saved laboratory demographic information. Make changes as necessary.

   The customer can also change the email recipients that receive the IAMQC™ reports. Using the drop-down options for report delivery, the customer can choose between making the reports available only by logging in to the website, by email attachment to specified users or by email notification containing a link to specified users.
3. Once the options are chosen, the user types in the relevant email addresses into the form and clicks on save to post changes to the database.

Account administrator privileges are required to edit the email recipient. Contact your local administrator if you do not have the required privileges.

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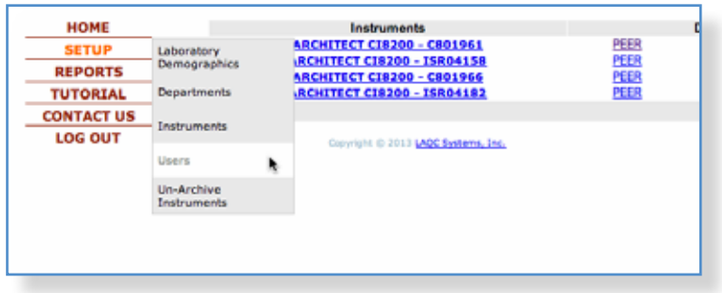
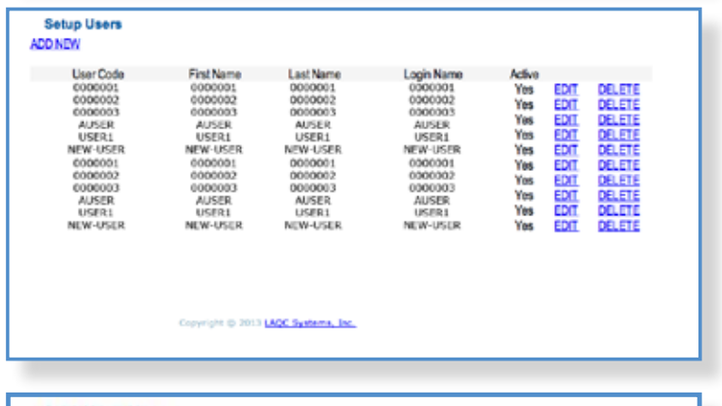
Basic Skills

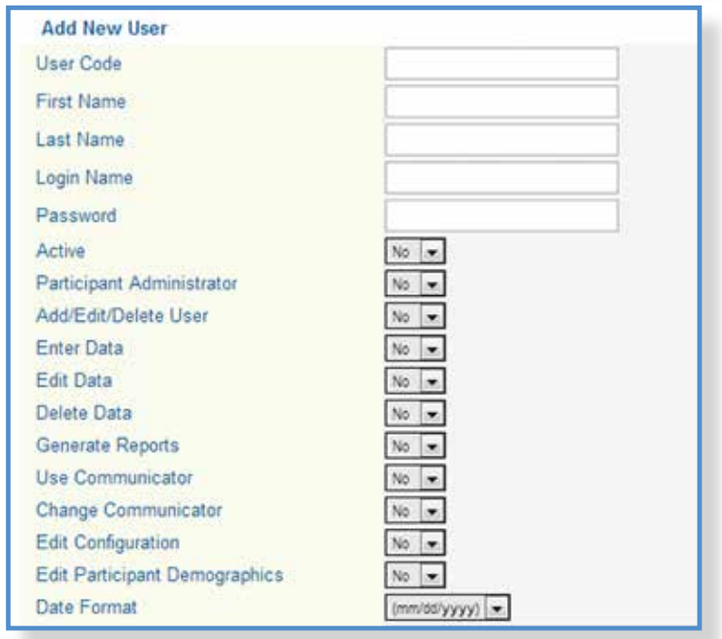
3.1e *Setup Users*



1. From the 'Home' page, click the 'SETUP' button on the left side of the screen. Select 'USERS' from the drop-down menu displayed.



Users that have already been setup for your account are displayed on the screen. Click on the 'ADD NEW' button to setup new users.



2. Enter user information and set the user access rights.
3. Click save to post changes to the database.

All updated information will now be displayed on the 'Setup Users' page.

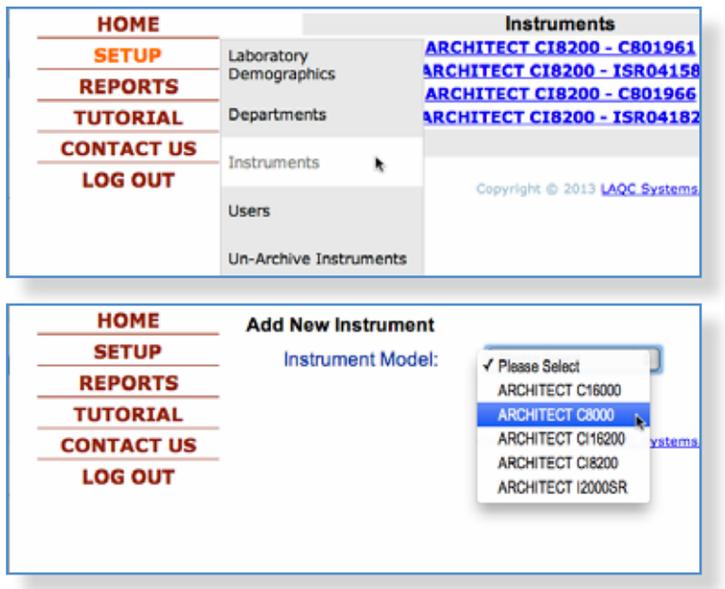
If you wish to make changes to an existing account, simply click on 'EDIT' next to the selected user and make changes as necessary.

Click 'DELETE' next to a specific user to delete this user account and all associated information.

RETURN

Basic Skills

3.1f *Edit Your Setup - Setting up a new Instrument*

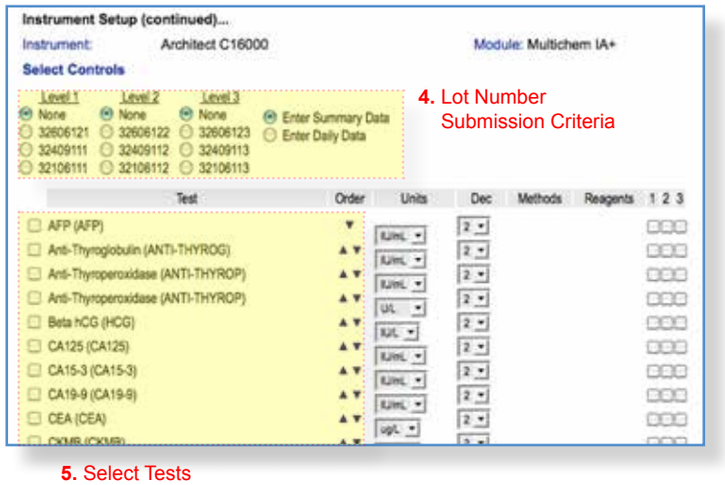


Follow these steps to setup a new instrument:

1. From the 'HOME' page, click the 'SETUP' button on the left side of the screen. Select 'INSTRUMENTS' from the drop-down menu displayed.

2. Select an instrument model from the dropdown menu and enter the serial number of the instrument (or any unique identifier) and click 'CONTINUE'.

3. Select a module (MULTICHEM product) to associate to your instrument from the dropdown menu. The system will now display all of the available lot numbers for this product/instrument association.



5. Select Tests

4. Select your lot number by clicking on the button next to it and choose your submission criteria, i.e Daily/Summary submission. Users should choose 'Enter Daily Data' as the default option. Summary data submission is only relevant when submitting monthly data.

5. Check mark each relevant test for data submission and click 'SAVE' (located at the bottom of the screen).

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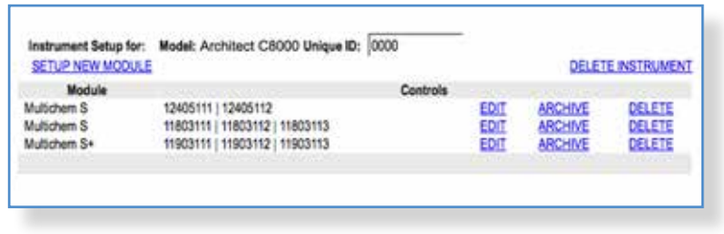
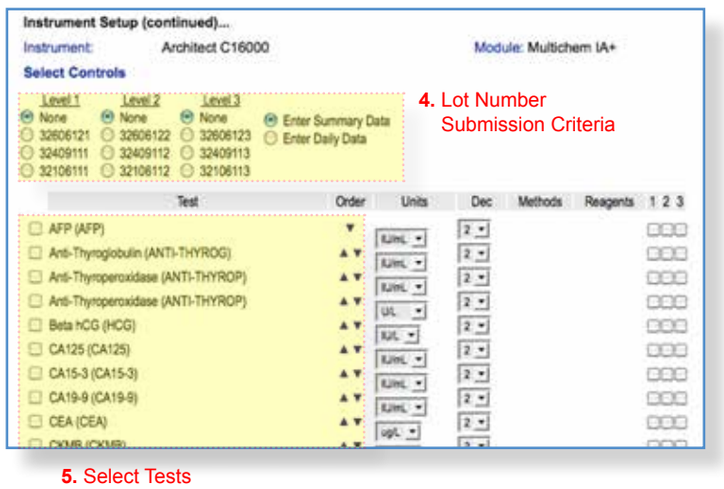
Basic Skills

Edit Your Setup - Setting up a new control on your instrument





Follow these steps to setup a new control on your instrument:

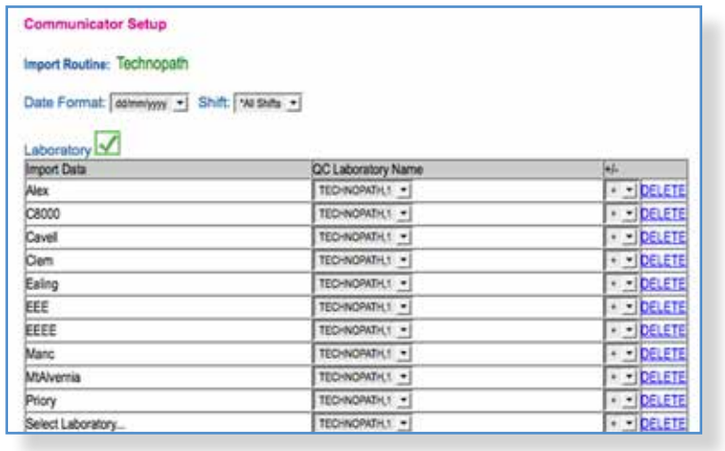
1. Click on your chosen instrument model on the HOME page.
2. Click on 'SETUP NEW MODULE'.
3. Select a module (MULTICHEM product) to associate to your instrument from the dropdown menu. The system will now display all of the available lot numbers for this product/instrument association.
4. Select your lot number by clicking on the button next to it and choose your submission criteria, i.e Daily/Summary submission.
5. Check mark each relevant test for data submission and click 'SAVE' (located at the bottom of the screen).

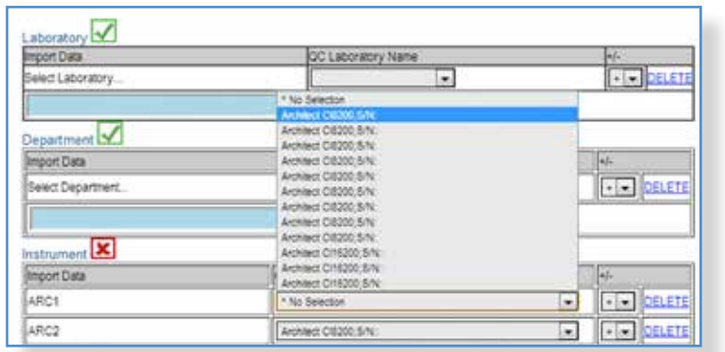
Users should choose 'Enter Daily Data' as the default option. Summary data submission is only relevant when submitting monthly data.

RETURN

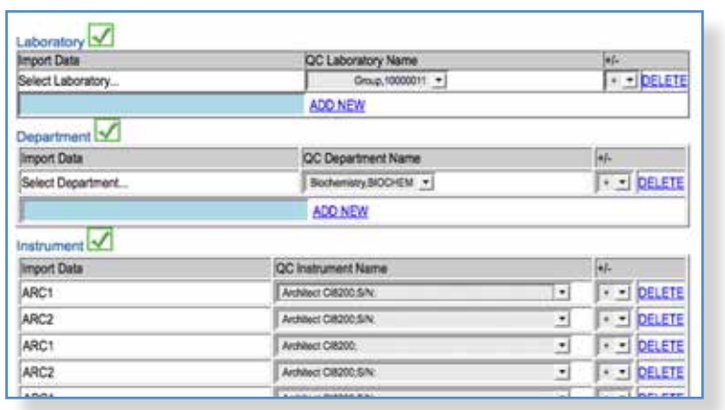
Basic Skills

3.1g *Mapping*





If the system does not display the required information in the drop-down menus to complete your setup, please contact your local representative.



Upon initial log in, a screen will display some records that need to be mapped to complete your setup. The mapping screen will display all of the information gathered from your setup, including your laboratory name, department, instrument details, test codes and sample/control lot identifiers.

The column on the left represents the information received from the customer's platform and is not editable. The column in the middle provides the customer with a drop-down menu of the options for mapping, already set up in the system by TECHNOPATH. The column on the right provides the option to disable the flow of data for a specific item. If the customer does not want to receive information for a specific item they can simply select the minus (-) from the drop-down option and the item will appear greyed out. The same logic is applied for mapping of all information, i.e instruments, test codes and sample/control lot identifiers. Please go to section 3.1g of the IAMQC™ User Manual for more information.

To complete any outstanding mapping:

1. Select 'SETUP,' > 'LABORATORY DEMOGRAPHICS' from the 'Home' page.
2. The Laboratory Demographics Home Page will now be displayed.
3. Click on the grey Communicator Icon next to the button.
4. The system will displays options for setting up new communicators, click 'NEXT'.
5. The Communicator Setup displays, click 'NEXT'.
6. The system now displays all mapping associated with your account.
7. Mapping that is incomplete displays a red icon beside the section header.
8. Un-mapped items display "No Selection" in the middle column.
9. Click on the 'NO SELECTION' window to view all available items in a drop-down menu.
10. Click on the relevant item to map it to the information shown on the left column.
11. Once all of the mapping is complete, the system should display a green check mark beside each section header.
12. **It is recommended that you ensure every item on the list is mapped appropriately.**
13. Click 'EXIT' to return to the Home Screen.

3.2 *Report Guide*

The delivery of your reports can be customized depending on the user preferences.

Each one of the IAMQC™ peer comparison reports are generated in PDF format and are available on the web. These reports can be generated by the user or automatically on a user defined schedule. The generated reports can be emailed automatically as well as printed and mailed. At any time, the reports are available online and can be downloaded by users using their login name and password.

Standard Reports

Group Coordinator Report

Levey Jennings Report

Exception Notes Report

Monthly Summary

Youden Report

Group Coordinator Report

This report is a test-by-test listing of statistics for the laboratory and its peer groups for up to 3 levels of control material. A peer group is a group of labs using the same control material and the same analytical method. The Group Coordinator Report documents all of the relevant data points submitted to IAMQC™ and automatically provides a statistical analysis in table format. This report provides a centralized review of all instruments from the moment the customer begins to report data and thus facilitates users meeting accreditation requirements, with respect to the storage, retrieval and statistical analysis of quality control data.

Group Coordinator Report

TECHNOPATH

Immunoglobulin A (IgA) in g/L - All Shift ; Instrument Class Name: Abbott Architect; Reagent: Abbott; Method: NONE

Product: Multichem S			ETECHCHEM 1-LOT # 13010111						LOT # 13010112						LOT # 13010113					
Instrument Model: Architect CI8200							World Peer						World Peer						World Peer	
Lab ID - Name	S/N	Shift	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI
LOCA	AB1	All	1.39	0.032	2.33	37	0.00	1.00												
Group Peer			1.39	0.032	2.33	37	0.00	1.00					-	-					-	-
World Peer			1.39	0.032	2.33	37	0.00	1.00					-	-					-	-

Immunoglobulin G (IgG) in g/L - All Shift ; Instrument Class Name: Abbott Architect; Reagent: Abbott; Method: NONE

Product: Multichem S			ETECHCHEM 1-LOT # 13010111						LOT # 13010112						LOT # 13010113					
Instrument Model: Architect CI8200							World Peer						World Peer						World Peer	
Lab ID - Name	S/N	Shift	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI
LOCA	AB1	All	7.04	0.135	1.92	35	0.00	1.00												
Group Peer			7.04	0.135	1.92	35	0.00	1.00					-	-					-	-
World Peer			7.04	0.135	1.92	35	0.00	1.00					-	-					-	-

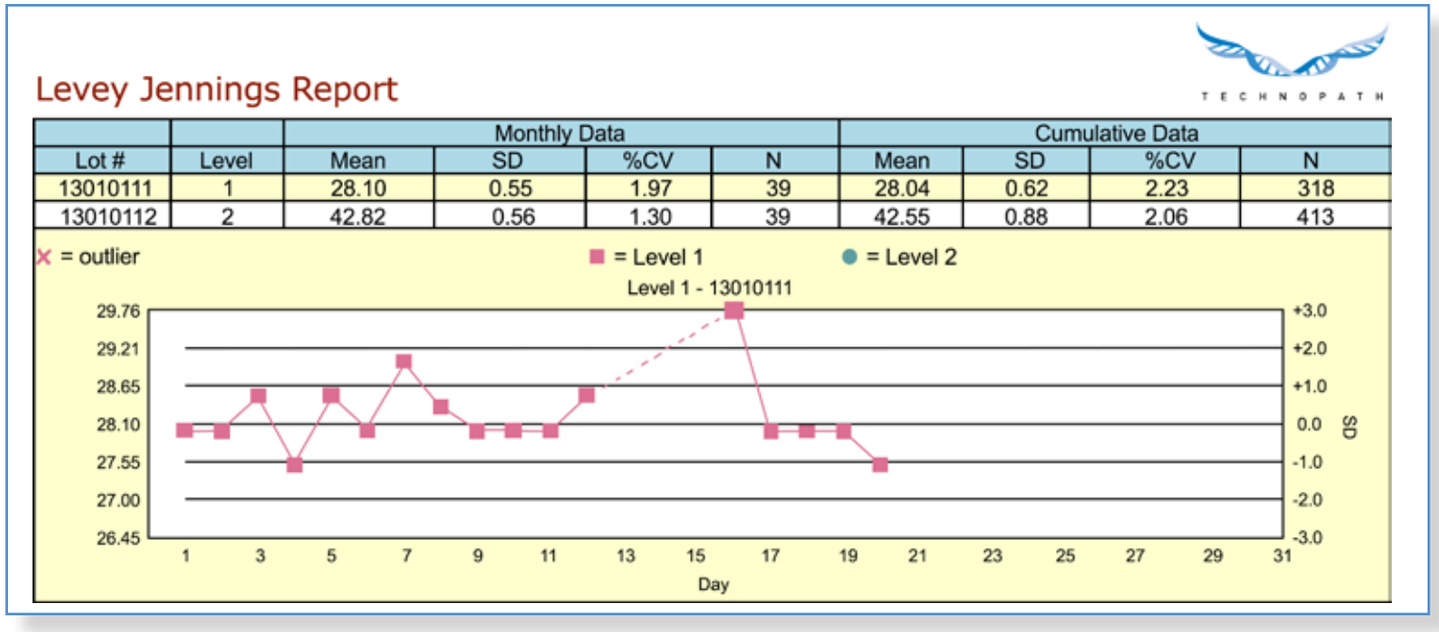
Immunoglobulin M (IgM) in g/L - All Shift ; Instrument Class Name: Abbott Architect; Reagent: Abbott; Method: NONE

Product: Multichem S			ETECHCHEM 1-LOT # 13010111						LOT # 13010112						LOT # 13010113					
Instrument Model: Architect CI8200							World Peer						World Peer						World Peer	
Lab ID - Name	S/N	Shift	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI	Mean	SD	%CV	N	SDI	CVI
LOCA	AB1	All	0.62	0.039	6.26	40	0.00	1.00												
Group Peer			0.62	0.039	6.26	40	0.00	1.00					-	-					-	-
World Peer			0.62	0.039	6.26	40	0.00	1.00					-	-					-	-

RETURN

Levey Jennings Report

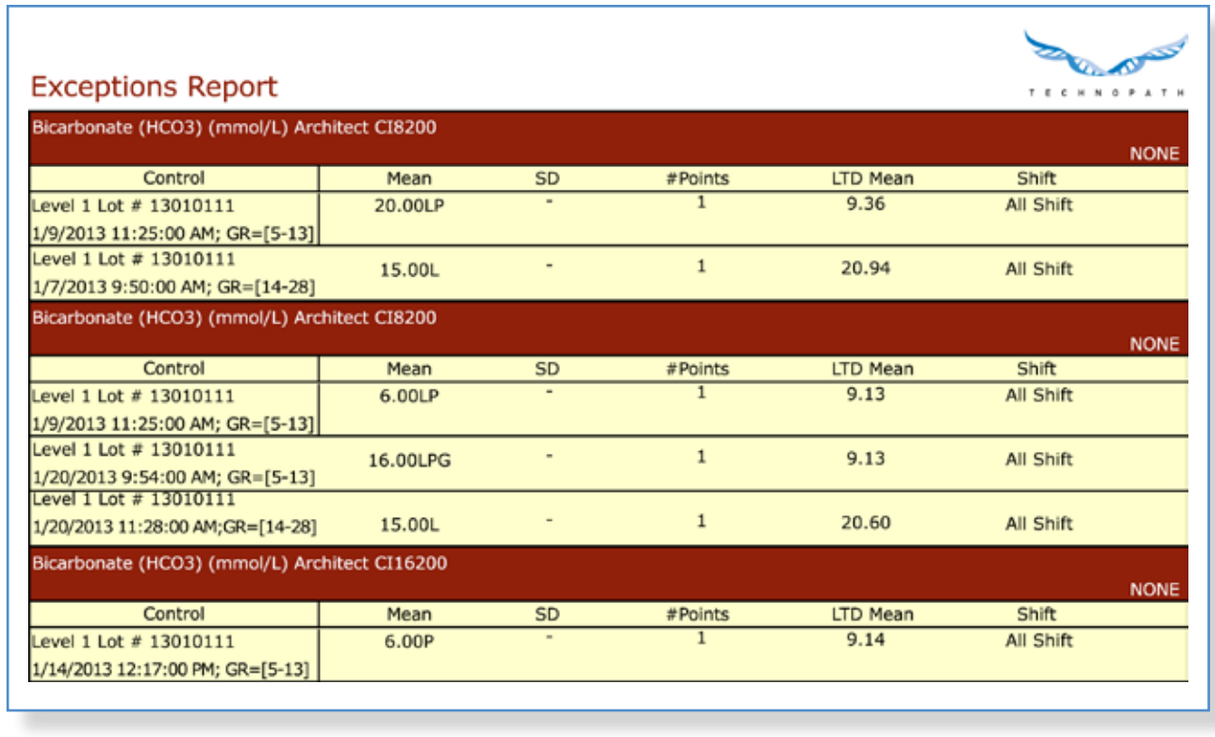
The Levey Jennings report displays individual daily QC means for the selected month for a specific analyte. The report can be generated for two or three levels of QC material. This report also provides a super-imposed version of all QC levels at the bottom of each sheet, highlighting any level specific bias. The top of the graph displays a summary of both monthly and cumulative data, including all of the relevant statistics for the laboratory.



RETURN

Exception Notes Report

This report summarizes the laboratory's tests and analytical methods which differ in performance from its peer group using SDI, CVI, and Total Error performance criteria. If a specific assay does not meet specific performance criteria the information is highlighted to the user as an exception. The Exception Notes Report indicates the following flags: (see next page)



Exceptions Report

TECHNOPATH

Bicarbonate (HCO3) (mmol/L) Architect CI8200					NONE
Control	Mean	SD	#Points	LTD Mean	Shift
Level 1 Lot # 13010111 1/9/2013 11:25:00 AM; GR=[5-13]	20.00LP	-	1	9.36	All Shift
Level 1 Lot # 13010111 1/7/2013 9:50:00 AM; GR=[14-28]	15.00L	-	1	20.94	All Shift

Bicarbonate (HCO3) (mmol/L) Architect CI8200					NONE
Control	Mean	SD	#Points	LTD Mean	Shift
Level 1 Lot # 13010111 1/9/2013 11:25:00 AM; GR=[5-13]	6.00LP	-	1	9.13	All Shift
Level 1 Lot # 13010111 1/20/2013 9:54:00 AM; GR=[5-13]	16.00LPG	-	1	9.13	All Shift
Level 1 Lot # 13010111 1/20/2013 11:28:00 AM;GR=[14-28]	15.00L	-	1	20.60	All Shift

Bicarbonate (HCO3) (mmol/L) Architect CI16200					NONE
Control	Mean	SD	#Points	LTD Mean	Shift
Level 1 Lot # 13010111 1/14/2013 12:17:00 PM; GR=[5-13]	6.00P	-	1	9.14	All Shift

RETURN

Exception Notes Report

The flags indicated are based on the statistical analysis of your data compared to your test system peer and do not necessarily indicate a quality control problem. Decisions regarding these flags should be based both on analytical significance and also medical significance of your quality control data compared to test system peer data.

Flag L - This Value did not pass the Laboratory Outlier Check, which highlights values more than +/- 3 standard deviations from the lab's mean for the month. This value was included in the calculation of the lab's mean and SD for this month.

Flag P - This Value did not pass the Peer Outlier Check, which highlights values more than +/- 3 standard deviations from the peer's mean for the month. This value was included in the calculation of the peer's mean and SD for this month.

Flag S - This Value did not pass the ALL-SHIFT Peer Outlier Check, which highlights values more than +/- 3 standard deviations from the peer's mean for the month. This value was included in the calculation of the peer's mean and SD for this month.

Flag G - This value did not pass the Gross Outlier Check, which excludes extremely discrepant data that falls outside of present limits for each test. This data was not processed and is not included in IAMQC™ Reports and was excluded from the calculation of the peer stats.

Monthly Summary Report

For each test, and control level, this report displays summary statistics for the last twelve individual months and Lot-to-Date period for the laboratory and its peer groups. This data is useful for long-term Intra-laboratory and Inter-laboratory comparisons. This report provides the customer with an indication of the 'usual' method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. (The report also displays the customer's monthly SDI and CVI, indicating any shifts from the peer group.) The 'monthly summary' report facilitates the user investigating changes in performance over time.

Monthly Summary Report

TECHNOPATH

Albumin (ALB) (g/L) - All Shift

		LTD	Jan	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr	Mar	Feb
ETECHEM1-LOT#13010111			*2013*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*
Your Lab	Architect C18200 - ABC, NONE Abbott													
	Mean	28.03	28.17	28.49	27.66	27.86	28.07							
	SD	0.631	0.577	0.782	0.478	0.391	0.371							
	%CV	2.25	2.05	2.75	1.73	1.41	1.37							
	N	291	12	79	73	70	57							
Test System Peer	Abbott Architect, NONE Abbott													
	Mean	27.98	28.38	28.27	27.70	27.780.	28.02							
	Peers	12	12	12	12	11	2							
	SDI	0.09	-0.38	0.35	-0.38	0.17	0.14							
	CVI	0.99	1.05	1.23	0.85	0.80	1.01							

Albumin (ALB) (g/L) - All Shift

		LTD	Jan	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr	Mar	Feb
ETECHEM1-LOT#13010112			*2013*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*	*2012*
Your Lab	Architect C18200 - ABC, NONE Abbott													
	Mean	42.53	42.79	43.21	42.16	42.24	42.44							
	SD	0.896	0.535	1.321	0.471	0.501	0.499							
	%CV	2.11	1.25	3.13	1.12	1.19	1.18							
	N	381	19	94	94	94	80							
Test System Peer	Abbott Architect, NONE Abbott													
	Mean	42.39	43.02	42.77	42.03	42.06	42.42							
	Peers	12	12	12	11	10	2							
	SDI	0.18	-0.36	0.49	0.24	0.30	0.04							
	CVI	1.11	0.84	1.46	0.87	0.82	1.01							

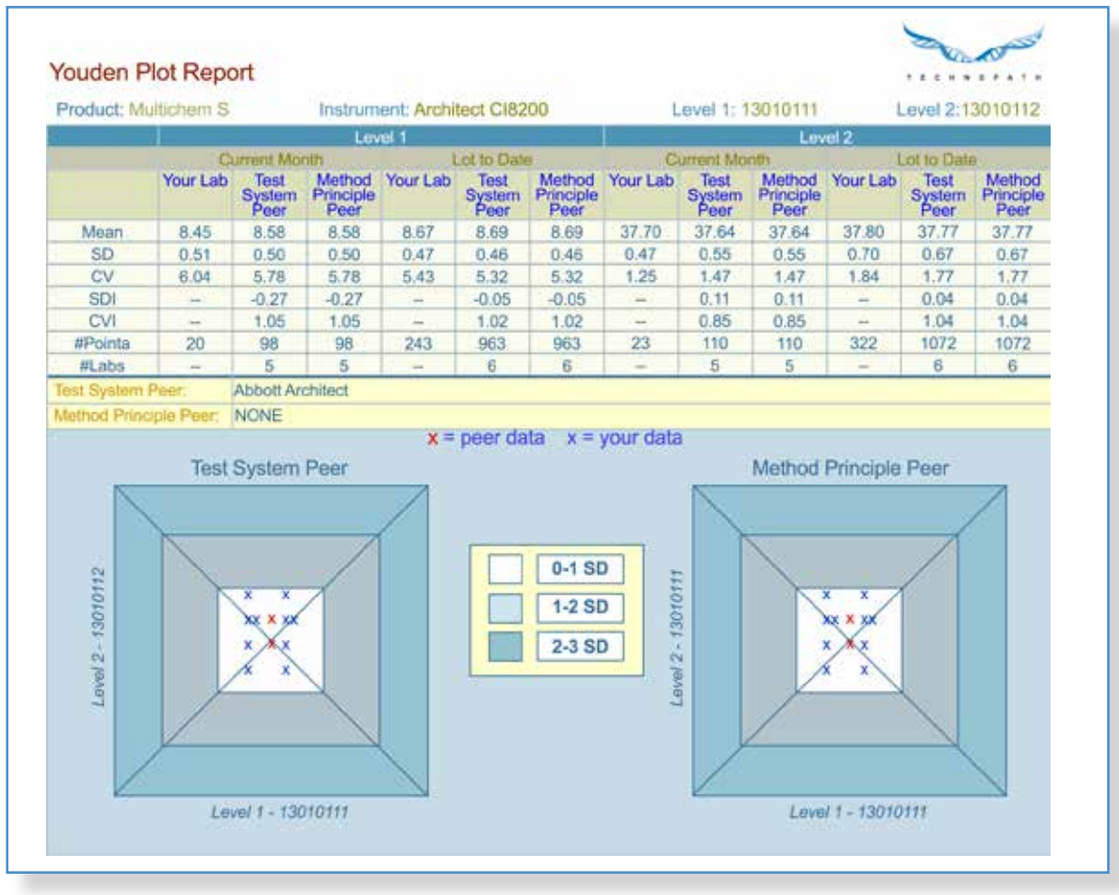
RETURN

Youden Report

Identifying where your results fall in the shaded regions of the graph provides an indication of your analytical performance relative to your peer group. Please note that a maximum of two levels can be plotted on the Youden report. Level selection is required.

The Youden report describes internal laboratory performance against the test system peer and method principle peer using the Youden Plot design. Laboratory data is tabularized at the top of the page by individual analyte. The lower half of the page provides a laboratory vs. peer comparison in the form of a Youden plot. The centre of each Youden plot represents the mean of the associated peer group.

It is appropriate to assume that each laboratory has its own systematic error. A user that has good precision could unknowingly have an error within their laboratory that is operating to displace their results from the values achieved by the rest of the peer group. The Youden plot visualizes both bias and imprecision and can be used to evaluate systematic and/or random error.



Youden Plot Report

Product: Multichem S | Instrument: Architect CI8200 | Level 1: 13010111 | Level 2:13010112

	Level 1						Level 2					
	Current Month			Lot to Date			Current Month			Lot to Date		
	Your Lab	Test System Peer	Method Principle Peer	Your Lab	Test System Peer	Method Principle Peer	Your Lab	Test System Peer	Method Principle Peer	Your Lab	Test System Peer	Method Principle Peer
Mean	8.45	8.58	8.58	8.67	8.69	8.69	37.70	37.64	37.64	37.80	37.77	37.77
SD	0.51	0.50	0.50	0.47	0.46	0.46	0.47	0.55	0.55	0.70	0.67	0.67
CV	6.04	5.78	5.78	5.43	5.32	5.32	1.25	1.47	1.47	1.84	1.77	1.77
SDI	--	-0.27	-0.27	--	-0.05	-0.05	--	0.11	0.11	--	0.04	0.04
CVI	--	1.05	1.05	--	1.02	1.02	--	0.85	0.85	--	1.04	1.04
#Pointa	20	98	98	243	963	963	23	110	110	322	1072	1072
#Labs	--	5	5	--	6	6	--	5	5	--	6	6

Test System Peer: Abbott Architect

Method Principle Peer: NONE

x = peer data x = your data

Test System Peer

Level 2 - 13010112

Level 1 - 13010111

0-1 SD

1-2 SD

2-3 SD

Method Principle Peer

Level 2 - 13010111

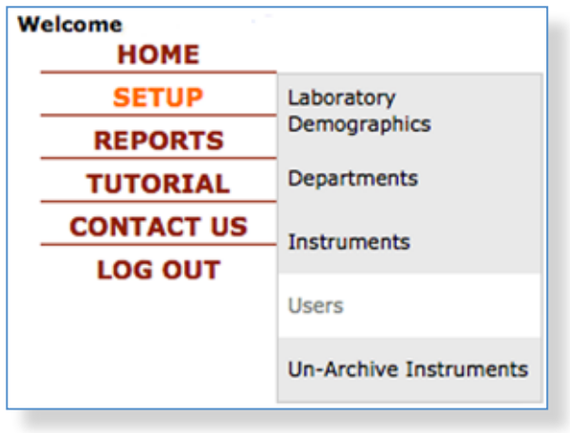
Level 1 - 13010111

RETURN

3.3 *System Menus*

3.3a *Setup*

See section 3.1d



1. Laboratory Demographics
2. Departments – *The steps to set up a new Department are as follows:*

    Click on Setup on the menu on the left side of the screen

    Click on Departments

    Click on 'Add New'

    Select the type of department you wish to set up from the drop-down menu

    Click Save

See section 3.1f

3. Instruments

See section 3.1e

4. Users
5. Un-Archive Instruments - *The steps to un-Archive instruments are as follows:*

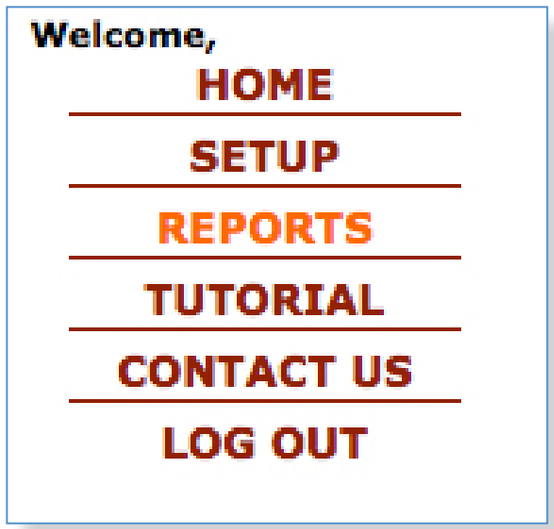
    Click on Setup on the menu on the left side of the screen

    Click on 'Un-Archive' Instruments

    Choose the instrument you wish to un-archive from the drop-down menu in the top right of the screen

    Select the control lot numbers you wish to un-archive on this instrument and click 'Un-Archive'

See section 3.1b



3.3b *Reports*

To view the various reports select this option.

3.3c *Tutorial*

To view video tutorials on using IAMQC™ Peer:

Click on Tutorial

Select the video you wish to view

Click on the 'play video' button at the bottom of the pop-up window

Click on the close window button at the top of the pop-up window to return to the Home page

3.3d *Contact Us*

To contact Technopath regarding your IAMQC™ Peer software:

Click on Contact Us

Enter your contact details into the relevant fields

Enter your comments/query into the comments box

Click submit

3.3e *Log Out*

Select the button "LOG OUT" to log out of IAMQC™ Peer

RETURN

Workflow

3.4a *IAMQC™ Reports via Email*

There are two suggested methods to use the IAMQC™ Peer system;

- Scheduled Reports
  or
- Login and Review

All peer comparison reports are generated in PDF format and can be generated by the user or automatically on a user defined schedule. The generated reports can be emailed automatically as well as printed. The user defined schedule is fully customisable and can be scheduled on a daily, weekly or monthly basis (default). PDF reports will be emailed to all recipients included in the laboratory demographics section of individual customer logins.

Workflow

3.4b *IAMQC™ Reports via Web*

Login and Review

At any time, users can login to the web-based system to view and download reports or alternatively utilise the various interactive reports built into the system. This instant access to live peer statistics is particularly useful when troubleshooting issues with performance. Click on any of the interactive peer statistic options to instantly calculate real-time statistics. Compare monthly data to cumulative values and build an instant 'SD range' chart, illustrating instrument bias relative to the group peer. Video tutorials explain all of the functions available in the system and a simple 'contact us' option allows for instant communication to TECHNOPATH's support team.

See section 3.1c

3.5 *Help Section*

Frequently Asked Questions

General

Q: What is IAMQC™?

Q: How do customers participate in IAMQC™?

Q: How do I read the IAMQC™ reports?

Q: What precautions do I need to make before using IAMQC™

Q: Does IAMQC™ provide live statistics?

Q: Where can I find my login credentials?

Q: How should I access my QC performance using IAMQC™ Peer?

Q: My IAMQC™ report is missing some data, what can I do?

Q: What is the importance of comparing my analytical method and how can I do it in IAMQC™?

Q: Do I need to log in to the system to access reports?

Q: I'm not receiving any reports to my email inbox, how can I correct this?

Q: I've forgotten my username/password, what can I do?

Reports

Q: How do I read the IAMQC™ Reports?

Q: Can I troubleshoot historical data with IAMQC™?

Q: How do I change the email recipients that are designated to receive reports?

Q: What reports are available?

Support

Q: Who do I contact for support?

Q: Where can I find additional support/tips on using the software?

Q: Are there any tutorials available?

Q: What MULTICHEM products does IAMQC™ Peer support?

Q: Where can I go to get more information on the software?

Q: Where can I find information on basic QC terminology and statistics related to IAMQC™

System

Q: How does the system handle sensitive data?

Q: What languages are available?

Q: How do I move my instruments?

Q: How do I register for IAMQC™?

Q: I've got a new instrument, how do I update my setup?

RETURN

Q: What is IAMQC™?

A: IAMQC™ is a real-time laboratory quality control (QC) software administered and maintained by TECHNOPATH. This software is a proprietary QC data management system that provides inter-laboratory comparison reports based on data collected from laboratories worldwide.

Q: How do customers participate in IAMQC™?

A: Customers with a working AbbottLink connection may choose to use the automated version of the software. This software enables individual laboratories to evaluate their performance relative to the peer group. Laboratories can manually submit individual results and monthly summary statistics to a central computer that compares the data from many sites analysing the same material. The software includes Group Coordinator, Levey-Jennings, Exceptions Summary, Monthly Summary and Youden Plot reports. These reports indicate how an individual laboratory's mean value compares to the average mean value obtained by other sites, which are testing the same material with the same methodology. Predefined QC reports may be built instantly and sent electronically to all preselected recipients. Charts and reports can be generated by the user or automatically on a user defined schedule. Reports are available on-line and can be downloaded using pre-assigned login names and passwords. The system also provides comparison for a laboratory's SD or CV relative to the SD or CV of the method peer and the group peer. Automating the data capturing process via the AbbottLink connection increases the laboratory's productivity. Automation transforms the quality control process, making it easier, faster and better by avoiding manual entry errors.

Q: What precautions do I need to make before using IAMQC™

A: Ensure to check off every item in the preparation check-list before you get started. The preparation check-list consists of completing the service activation form, setting up the Architect platform to use barcodes, an initial mapping step to map any outstanding data, watching the video tutorials, verifying the setup online and registering for the IAMQC™ User Forum. More information on this list can be found in the IAMQC™ User Manual and IAMQC™ Startup Guide.

Q: Does IAMQC™ provide live statistics?

A: IAMQC™ provides a truly real-time peer comparison program. The system builds live statistics as soon as reports are generated or as soon as you log-in and click on 'view peer stats'. This is very important when looking at quality control material over the shelf-life of the product, as it is necessary to look at the most up to date data available to view an accurate representation of performance.

Q: Where can I find my login credentials?

A: Your login credentials are supplied via email along with the IAMQC™ User Manual. If you can no longer locate them please contact your local account administrator.

Q: How should I assess my QC performance using IAMQC™ Peer?

A: The IAMQC™ User Manual contains a section on assessing your performance. Please see the following extract:

Method Comparison

It is expected that laboratories using the same analytical method and testing the same batch of control material will generate similar mean values and standard deviations.

Compare your mean value to that of the average value generated by the entire peer group to analyse your overall accuracy.

The peer group mean can also be very useful for setting the target mean for control material.

If your laboratory's mean differs significantly from the method peer mean, check the following:

- calibration history
- reagent lot changes
- instrument settings
- any other parts of the analytical process.

Historical Data

IAMQC™ Peer provides a 'monthly summary' report outlining a laboratory's performance over an extended period of time. This report provides the customer with an indication of the 'usual' method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. The report also displays the customer's monthly SDI and CVI, indicating any shifts from the peer group.

continued

If the mean for a specific analyte is decreasing/increasing significantly over a number of months in your laboratory, use the 'monthly summary' report to compare your data to the peer group mean. If the peer group mean remains constant over the same period of time, then the problem most likely resides in your laboratory.

Trending and Shifts

The most important aspect of troubleshooting any issues that may arise regarding your analytical performance is to find out when the problem started. Issues that develop over an extended period of time can be caused by a deteriorating lot of reagents or by a growing instrumentation problem. Issues that arise all of a sudden are more likely due to a recent change in reagents, calibration or instrumentation. It is important to differentiate between gradual changes (trending) and sudden changes (shifts), as different causes have different solutions. If your laboratory experiences a gradual or sudden change in performance, make sure to document the following changes, to assist in your troubleshooting process;

- A new reagent lot
- A new reagent package
- A new calibrator lot
- A new calibrator package
- A new package of controls
- A new vial of controls
- Instrumentation maintenance
- New software
- New processes in the analytical method

Q: What is the importance of comparing my analytical method and how can I do it in IAMQC™?

A: It is expected that laboratories using the same analytical method and testing the same batch of control material will generate similar mean values and standard deviations. When a laboratory compares their own mean value to the average value generated by the entire peer group, they can tell if their overall analytical process, or individual instrument, is accurate. The system automatically generates and displays a method peer mean. This is also very useful for setting the target mean for control material.

Compare the statistics listed for your instrumentation to the values achieved by other peer group members.

If your laboratory's mean differs significantly from the method peer mean, you may want to check your calibration history, reagent lot changes, instrument settings, or other parts of the analytical process.

Q: Do I need to log in to the system to access reports?

A: All reports can be scheduled on a user-defined basis and sent to specified email recipients. However, users can log in to the web system at any stage to view peer stats and generate live reports.

Q: My IAMQC™ report is missing some data, what can I do?

A: Missing information indicates that TECHNOPATH has not received any information for the specific assay(s).

Customers can troubleshoot by checking the following:

1. Customers utilising the AbbottLink interface can check that the AbbottLink connection to each individual analyser is active by following the instructions provided in Section 10-570 of the ARCHITECT Systems Operations Manual. If the Abbotlink is disconnected, please contact your Local Area Customer Support to resolve the issue.

2. Customers utilising the AbbottLink interface that have confirmed that the connection is fine can check their mapping screen, located on their IAMQC™ web page, to ensure all of the mapping has been completed correctly. Upon log in, click on 'SETUP' and a drop-down menu will appear. Click on 'LABORATORY DEMOGRAPHICS' from the drop-down menu. On the 'Laboratory Demographics' screen click on the 'SETUP COMMUNICATORS' icon - . Click on 'NEXT' and then 'NEXT' again to gain access to the mapping screen. Please see INDEX B for instructions on how to complete any outstanding mapping. When mapping is not completed for specific information, a red '' will be displayed. Once the mapping is completed and saved, the red '' will change to a green check mark ''. Please see section 3.1g of the IAMQC™ User Manual for more information on mapping.

3. Customers are encouraged to ensure they set up their Lot Number correctly and accurately in order to avoid any potential issues with data capture. If an error has occurred during the setup of a new lot of control material on the instrument and the Lot Number does not match the exact lot information, customers will receive a notification from Technopath to their email.. Customers can check their mapping screen (see point 2) or alternatively correct the setup on the instrument to resolve the issue.

4. Changing the method for running QC on your instrument (i.e. natively → as a patient sample / patient sample → natively) can affect the flow of data. If a customer plans to, or has recently changed their process for running QC, they should contact their local support.

continued

5. Customers who plan to or have recently changed instrumentation must update their setup online and inform their local representative of the change. Failure to do so can lead to inconsistencies in QC data due to the connection updates. Please see Page 10 of this guide for more information on updating your setup.
6. If the problem persists after checking the above items, the customer may engage their local representative to investigate.

Q: I'm not receiving any reports to my email inbox, how can I correct this?

A: All reports can be scheduled on a user-defined basis and sent to specified email recipients. Check that the correct email address has been entered in the laboratory demographics section. If all email addresses are correct, contact your local IT team to ensure that your server and email client will allow you to receive emails from webmaster@iamqc.com. If the problem persists contact your local representative.

Q: I've forgotten my username/password, what can I do?

A: Click on the forgotten password link located on the login screen. This will bring you through the process of submitting your details to request your password.

Q: How do I read the IAMQC™ Reports?

A: PDF reports are emailed to recipients on a defined schedule. Alternatively the reports can be generated online by clicking on 'REPORTS' on the Home page of the system and selecting 'BUILD' beside your selected report. Once you have opened your selected report, follow these steps to complete your review;

1. Check the date printed on the report to ensure you are using the most current report.
2. Check that the Lot Number displayed on your report matches the Lot Number of control material that you are using.
3. Find an analyte of interest by scrolling down (electronic report) or clicking on 'CTRL + F' to search for your analyte by typing the name into the find window.
4. Once you have found the analyte of interest you can review all of your instruments for this analyte versus peer statistics.
5. Assay information is included in the IAMQC™ reports when values are reported that fall within the TECHNOPATH outlier range. Missing information indicates that TECHNOPATH has not received any information for the specific assay(s) OR the values that were received were outside the acceptable range. Values received that fall outside the acceptable range will be highlighted in the Exceptions report.

Q: Can I troubleshoot historical data with IAMQC™?

A: IAMQC™ Peer provides a 'monthly summary' report outlining a laboratory's performance over an extended period of time. This report provides the customer with an indication of the 'usual' method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. The report also displays the customer's monthly SDI and CVI, indicating any shifts from the peer group. The 'monthly summary' report facilitates the user investigating changes in performance over time.

If, the mean for a specific analyte is decreasing/increasing significantly over a number of months in your laboratory, use the 'monthly summary' report to compare your mean each month to the peer group mean. If the peer group mean remains constant over the same period of time, then the problem most likely resides in your laboratory. Check for any changes in your analytical method and investigate the performance of your reagents and calibrators.

Q: How do I change the email recipients that are designated to receive reports?

A: The customer can change the email recipients that receive the IAMQC™ reports at any stage by logging in to the system using their specified login credentials. Upon log in, click on 'SETUP' on the left hand side of the screen and a drop-down menu will appear. Click on 'LABORATORY DEMOGRAPHICS' from the drop-down menu. On the 'Laboratory Demographics' screen click on the 'EDIT' button. The 'Edit Laboratory Demographics' screen allows the user to update and edit their demographics including; customer name, address, contacts and email recipient list.

Using the drop-down options for report delivery, the customer may choose between making the reports available only by logging in to the website, by email attachment to specified users or by email notification containing a link to specified users. Once the options are chosen, the user types in the relevant email addresses into the form and clicks on save.

Q: What reports are available?

A: Five reports are included in the web system; Group Coordinator, Levey-Jennings, Exceptions Notes, Monthly Summary and Youden Plot, with others available upon request. Please see the INDEX to view a description and screen shot of each report.

NOTE
Account administrator privileges are required to complete this step.

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Q: Who do I contact for support?

A: For queries regarding the software please contact your local Abbott representative.

Q: Where can I find additional support/tips on using the software?

A: Ask questions or share ideas with other customers on our User-Friendly Forum. Discussions ranging from web log-in to creating reports are available at the click of a button. Customers must register before they can post.

Q: Are there any tutorials available?

A: Once you receive your login credentials you can view online video tutorials on using the system.

Q: What MULTICHEM products does IAMQC™ Peer support?

A: IAMQC™ compliments the full range of MULTICHEM products including: IA Plus, S Plus (Assayed), S Plus (Unassayed), P, U & WBT.

Q: Where can I go to get more information on the software?

A: You can find more information on all of the available software products at:

http://clinicaldiagnostic.techno-path.com/QcSoftware.aspx

Q: Where can I find information on basic QC terminology and statistics related to IAMQC™?

A: The IAMQC™ User Manual contains a glossary with information on terms associated with QC analysis and statistics. Please see section 6 - 'IAMQC™ Glossary' in the IAMQC™ User Manual.

Q: How does the system handle sensitive data?

A: IAMQC™ Peer only accepts quality control (QC) data and does not accept any patient demographics. A secure connection is established to receive all QC data. Information on data transmission, HIPAA compliance, can be obtained from specific AbbottLink documents. Contact your local AbbottLink representative for more information.

Q: What languages are available?

A: The system is available in English, French, German, Italian and Spanish, with many other languages to follow in 2013 - 2014.

Q: How do I name my instruments?

A: Unique identifiers can be applied for each individual instrument in the system. From the 'Home' page click on the instrument you would like to name. The system will display all of the associated information for the selected instrument. At the top of the screen you will find a 'Unique ID' box. Create your unique identifier by entering your specific information (alpha-numeric) in the box. Click anywhere on the screen to save your information.

Q: I've got a new instrument how to I update my setup?

A: Upon login, you will be presented with your home page. The system will display all of the instruments included in your setup, along with a serial identifier for each instrument. Click on each instrument to view the control lots that have been associated with your instrumentation. The unique instrument identifier can be changed by updating the 'Unique ID' box (located at the top of the screen).

Follow these steps to setup a new instrument:

1. Click on Setup>Instruments
2. Select an instrument model from the dropdown menu and enter the serial number of the instrument (or any unique identifier) and click 'CONTINUE'.
3. Select a module (MULTICHEM product) to associate to your instrument from the dropdown menu. The system will now display all of the available Lot Numbers for this product/ instrument association.
4. Select your Lot Number by clicking on the button next to it and choose your submission criteria, i.e Daily/Summary submission.
5. Check mark each relevant test for data submission and click 'SAVE' (located at the bottom of the screen).

Follow these steps to setup a new control on your instrument:

1. Click on your chosen instrument model on the Home page
2. Click on 'SETUP NEW MODULE'.
3. Select a module (MULTICHEM product) to associate to your instrument from the dropdown menu. The system will now display all of the available Lot Numbers for this product/ instrument association.
4. Select your Lot Number by clicking on the button next to it and choose your submission criteria, i.e Daily/Summary submission.
5. Check mark each relevant test for data submission and click 'SAVE' (located at the bottom of the screen).

NOTE
Users should choose 'Enter Daily Data' as the default option. Summary data submission is only relevant when submitting monthly data.

RETURN

4. TROUBLESHOOTING

Troubleshooting your QC using IAMQC Peer Software

IAMQC™ Peer facilitates laboratories testing the same lot number of control material to access valuable information from their colleagues through peer comparison. The reports that are generated in IAMQC™ Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can be extremely valuable, indicating the user's performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.

Useful Statistics

4.1a Coefficient of Variation Index (CVI)

IAMQC™ Peer automatically checks your statistics for the following:

CVI - The coefficient of variation index (CVI) compares the laboratories CV to the peer group average CV for evaluating precision.

The CVI calculation is:

$$\frac{\text{Lab CV}}{\text{Peer Median CV}}$$

- A CVI value > 2.0 indicates that the laboratories CV is significantly greater than (by at least 100%) the average CV of the test system peer.

- A CVI value > 1.5 indicates that the laboratories CV is significantly greater than (by at least 50%) the average CV of the test system peer.

- It may be necessary to investigate for sources of imprecision or random error.

4.1b Standard Deviation Index (SDI)

SDI - The standard deviation index (SDI) compares the laboratories mean to the peer group average mean for evaluating accuracy.

The SDI calculation is:

$$\frac{\text{Lab Mean - Peer Avg. Mean}}{\text{Peer SD}}$$

- An SDI value outside of the range; -2.0 to +2.0, indicates that the laboratory mean is in the outer distribution of means in the Test System Peer.
- In a normally distributed population, 5% of the peer will be in this range.
- An SDI value outside of this range: -1.5 to +1.5, may be used as an early warning signal by the laboratory.
- In a normally distributed population, 14% of the peer will be in this range. It may be necessary to investigate for sources of inaccuracy or systematic error.

Assessing Your Performance

4.2a Method Comparison

It is expected that laboratories using the same analytical method and testing the same batch of control material will generate similar mean values and standard deviations.

ALT (ALT) in U/L - All Shift ; Instrument Class Name: Abbott Architect C8000; Reagent: Abbott; Method: NONE													
10000011	All	52.84	1.589	3.01	20	0.70	0.65	62.00	1.338	2.16	20	-0.05	0.37
10000011	All	51.88	1.586	3.06	16	0.30	0.66	62.12	1.364	2.20	17	-0.02	0.38
Group Peer		51.17	2.373	4.64	81	-	-	62.19	3.610	5.80	81	-	-
World Peer		51.17	2.373	4.64	81	-	-	62.19	3.610	5.80	81	-	-

Compare your mean value to that of the average value generated by the entire peer group to analyse your overall accuracy.

The peer group mean can also be very useful for setting the target mean for control material.

If your laboratory's mean differs significantly from the method peer mean, check the following:

- calibration history
- reagent lot changes
- instrument settings
- any other parts of the analytical process.

Assessing Your Performance

4.2b Historical Data

IAMQC™ Peer provides a 'monthly summary' report outlining a laboratory's performance over an extended period of time.

This report provides the customer with an indication of the 'usual' method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. The report also displays the customer's monthly SDI and CVI, indicating any shifts from the peer group.

Monthly Summary Report

Albumin (ALB) (g/L) - All Shift

		LTD	Jan	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr	Mar	Feb
ETECHEM1-LOT#13010111			2013	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012
Your Lab	Architect C18200 - ABC, NONE Abbott													
	Mean		28.03	28.17	28.49	27.66	27.86	28.07						
	SD		0.631	0.577	0.782	0.478	0.391	0.371						
	%CV		2.25	2.05	2.75	1.73	1.41	1.37						
	N		291	12	79	73	70	57						
Test System Peer	Abbott Architect, NONE Abbott													
	Mean		27.98	28.38	28.27	27.70	27.780.	28.02						
	Peers		12	12	12	12	11	2						
	SDI		0.09	-0.38	0.35	-0.38	0.17	0.14						
	CVI		0.99	1.05	1.23	0.85	0.80	1.01						

Albumin (ALB) (g/L) - All Shift

		LTD	Jan	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr	Mar	Feb
ETECHEM1-LOT#13010112			2013	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012
Your Lab	Architect C18200 - ABC, NONE Abbott													
	Mean		42.53	42.79	43.21	42.16	42.24	42.44						
	SD		0.896	0.535	1.321	0.471	0.501	0.499						
	%CV		2.11	1.25	3.13	1.12	1.19	1.18						
	N		381	19	94	94	94	80						
Test System Peer	Abbott Architect, NONE Abbott													
	Mean		42.39	43.02	42.77	42.03	42.06	42.42						
	Peers		12	12	12	11	10	2						
	SDI		0.18	-0.36	0.49	0.24	0.30	0.04						
	CVI		1.11	0.84	1.46	0.87	0.82	1.01						

Check for any changes in your analytical method and investigate the performance of your reagents and calibrators.

If the mean for a specific analyte is decreasing/increasing significantly over a number of months in your laboratory, use the 'monthly summary' report to compare your data to the peer group mean. If the peer group mean remains constant over the same period of time, then the problem most likely resides in your laboratory.

Assessing Your Performance

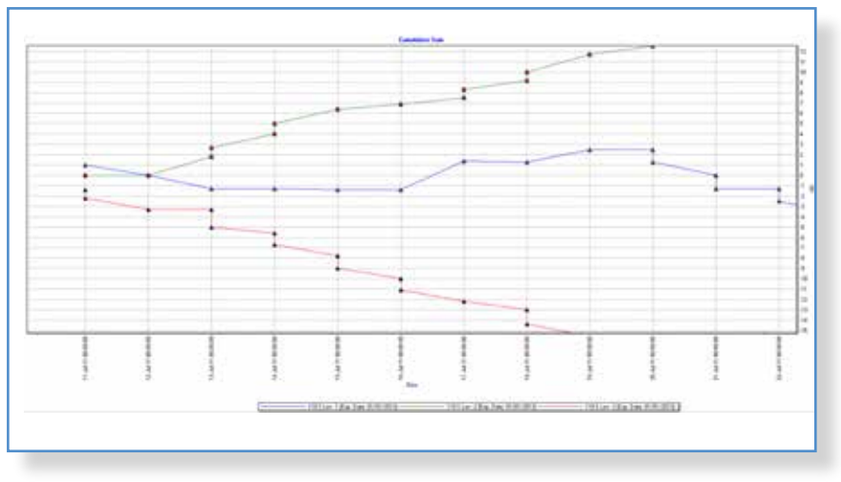
4.2c Trending and Shifts

The most important aspect of troubleshooting any issues that may arise regarding your analytical performance is to find out when the problem started.

> Issues that develop over an extended period of time can be caused by a deteriorating lot of reagents or by a growing instrumentation problem.
>
> Issues that arise all of a sudden are more likely due to a recent change in reagents, calibration or instrumentation.

It is important to differentiate between gradual changes (trending) and sudden changes (shifts), as different causes have different solutions. If your laboratory experiences a gradual or sudden change in performance, make sure to document the following changes, to assist in your troubleshooting process;

- A new reagent lot
- A new reagent package
- A new calibrator lot
- A new calibrator package
- A new package of controls
- A new vial of controls
- Instrumentation maintenance
- New software
- New processes in the analytical method



Assessing Your Performance

4.2d Reacting to Standard Deviation Index (SDI) flags

See Section 4.3b

An SDI flag indicates a value outside of the range; -2.0 to +2.0. This indicates that the laboratory mean is in the outer distribution of means in the Test System Peer. In a normally distributed population, 5% of the peer will be in this range. An SDI value outside of this range: -1.5 to +1.5, may be used as an early warning signal by the laboratory. In a normally distributed population, 14% of the peer group will be in this range. It may be necessary to investigate for sources of inaccuracy or systematic error.

SDI is calculated by the following:

$$SDI = \frac{\text{Laboratory Mean} - \text{Peer Group Mean}}{\text{Peer Group Standard Deviation}}$$

The most important thing to check when reacting to an SDI flag is the validity of the numbers used in the calculation. Make sure to check the following:

- the laboratory mean value reported reflects your current performance
- the values are calculated from a valid number of laboratories
- any significant changes in values from the previous month

If your mean varies significantly from the peer group mean, the significance of that variation can be assessed by calculating Total Error and comparing it to your Total Allowable Error.

Significant variance from the peer group mean is generally linked to bias or systematic error. As previously mentioned, systematic error is usually associated with the following:

- changes in reagent lot numbers
- changes in calibration
- changes to instrumentation
- consistent changes in the analytical process

4.2e Reacting to CVI flags

A CVI value > 2.0 indicates that the laboratories CV is significantly greater than (by at least 100%) the average CV of the test system peer. A CVI value > 1.5 indicates that the lab's CV is significantly greater than (by at least 50%) the average CV of the test system peer.

CVI is calculated by the following:

$$\text{CVI} = \frac{\text{Laboratory CV}}{\text{Peer Group CV}}$$

If your CVI indicates a value > 1.0, it may be necessary to investigate for sources of imprecision or random error. Random error increases with inconsistent changes such as:

- handling errors
- fluctuations in temperature
- fluctuations in volume

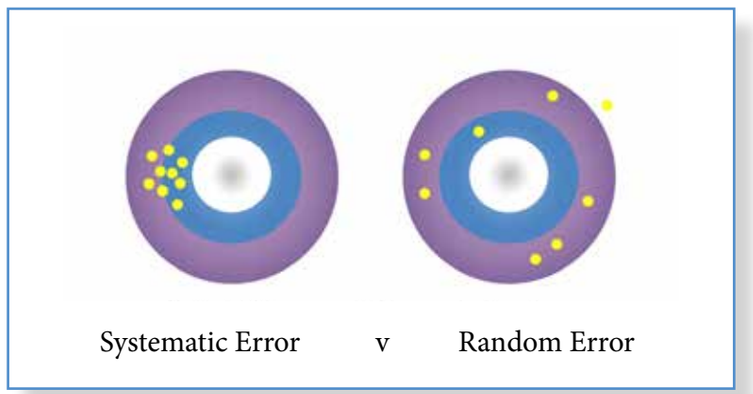
Basic Concepts of QC Analysis

4.3a Random Error

Random errors are always present within an analytical method and can result in values falling on either side of the mean. An increased level of inconsistencies in handling of reagents, calibrators or controls, as well as instrument sample measurement, temperature or wavelength, will produce increased random error.

This is reflected by an increased standard deviation and co-efficient of variation. Random error increases when the system experiences inconsistent changes such as:

- fluctuations in temperature;
- fluctuations in volume;
- inconsistent environmental conditions;
- electrical interferences;
- inconsistent handling of materials from technologist to technologist.

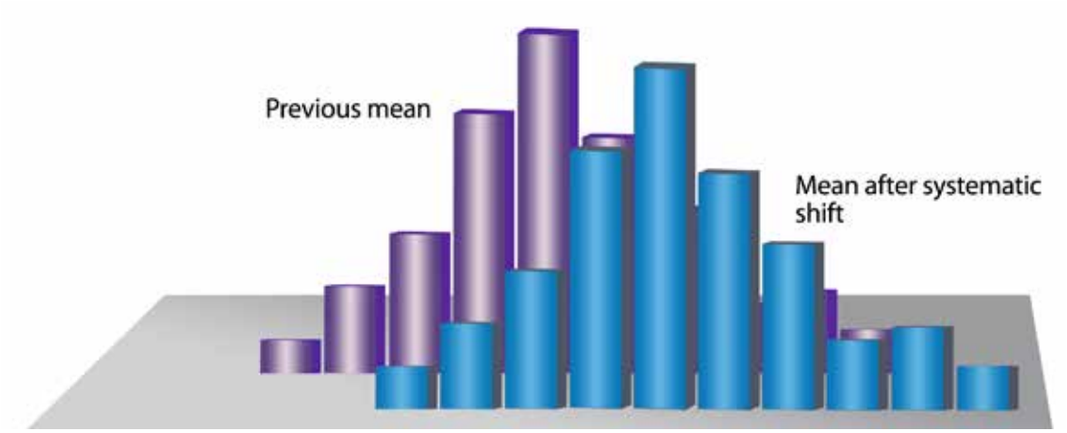


Basic Concepts of QC Analysis

4.3b Systematic Error

Systematic error can be described as a change that is always in one direction and will cause a shift in the mean value. When the observed mean value changes for an assay, the bias (measured value minus true value) will also change. Consistent variations in an instrument, reagent or calibrator can result in systematic error. Systematic error is also linked with a change in accuracy.

In a laboratory, accuracy is the agreement between the measured value for an analyte on a specific specimen and the true value for that analyte on that specimen.



- Systematic error is associated with a change in accuracy.
- Random error is associated with a change in precision.
- Because random and systematic errors do not occur independently, it is necessary to calculate Total Error (TE) to reflect the total variation from the true value.

Total Error can be used to compare a laboratory with another laboratory. However knowing just the total error does NOT provide an answer to the question "Is Laboratory A or Laboratory B meeting the quality requirements for that test?" TE tells us how far results are reported from the desired, target or "true" value. TE on its own does not tell us if that is good enough to meet clinical and proficiency needs.

Basic Concepts of QC Analysis

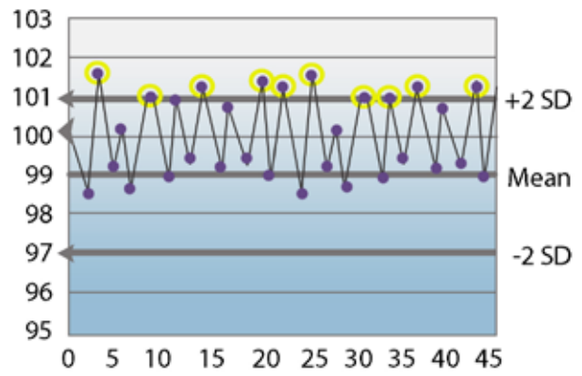
4.3c Assigning your Mean

One of the most common errors in laboratory quality control is the failure to assign the correct mean and SD on quality control charts. This may be caused by erroneous calculations or by assigning the mean and SD from sources of information other than observed method performance.

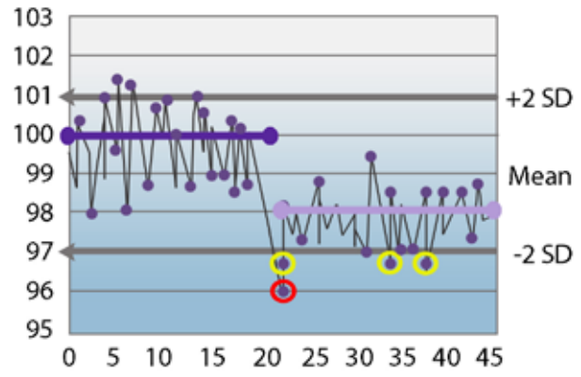
Quality Control rules detect variation from the mean value. If the assigned mean value is not the observed mean value, QC rules cannot function as designed. Only a calculated or estimated value based on recent data points always reflects what the mean is at any specific point in time. The calculated mean/average from all points in the previous month may be invalid if a shift has occurred with a new calibration or new reagent lot. Similarly, the usual mean from a stable time period may not be valid for a new reagent lot or following instrument maintenance or software changes. The value provided in the package insert by the control manufacturer will probably not reflect performance on your laboratory instrument at this specific time.

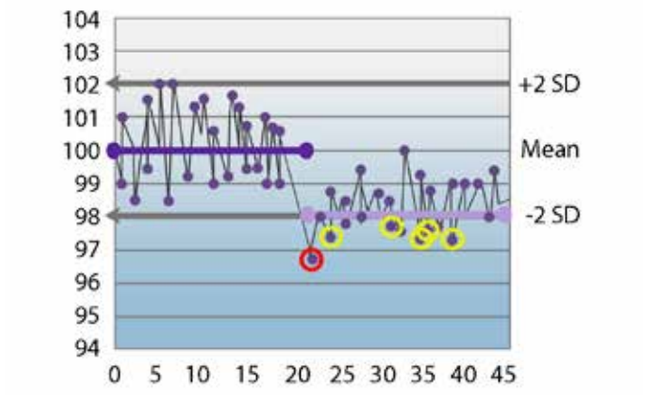
In order for quality control rules to adequately alert us to change in the current performance of a test system, the QC chart must first reflect actual current observed performance for both the mean and SD.

If the mean value assigned on the quality control chart is different from the actual observed mean value, points will fall more than, for example, 2 SD from the Assigned mean when they are within 2 SD of the Actual mean.



Basic Concepts of QC Analysis





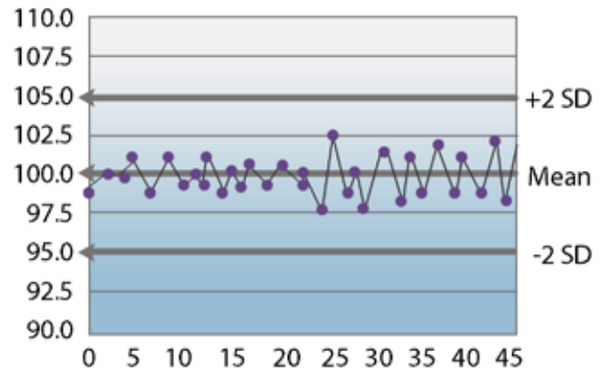
Incorrect assignment of the mean value on quality control charts is a common problem in many of our laboratories. When we see an increased incidence of quality control flags, one of the first items to check is the Assigned mean.

The first 25 points show a true mean of 100 and the second 25 points show a drop of -2 SD's to a true mean of 98. Because the mean was arbitrarily assigned at 99, it took 18 runs to generate a 1-3s reject flag following this shift of -2 SD's. The second graphic illustrates how, if the mean had been assigned at the true value of 100, this shift of -2 SD's would have become apparent much sooner.

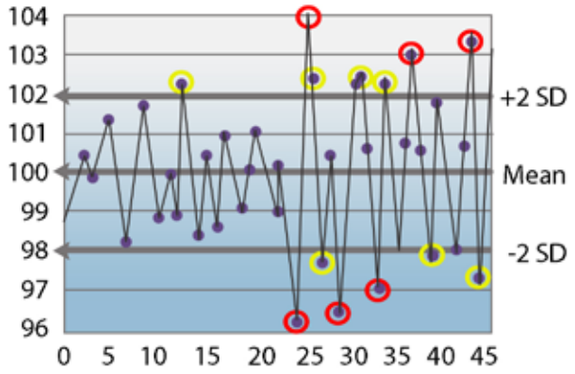
Basic Concepts of QC Analysis

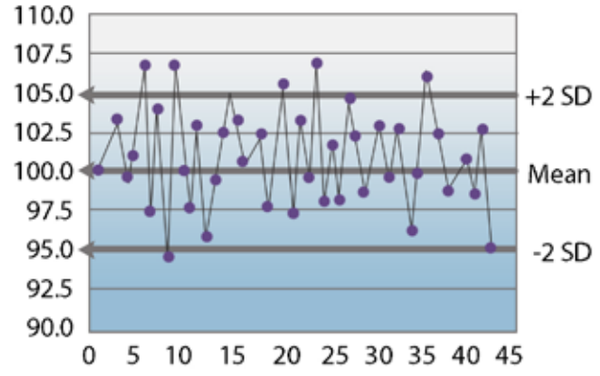
4.3d Assigning your Standard Deviation (SD)

QC charts with an SD assigned higher than the observed SD, will show an increased proportion of data with +/- 1 SD (more than 68%). A better strategy is to assign the observed mean and standard deviation on the quality control chart and choose appropriate QC rules based on method performance and quality requirements.



When the standard deviation is arbitrarily Assigned a value higher than the Actual SD, we see false negative QC flags. Our quality control system is incapable of alerting us to significant change. When the standard deviation on the QC chart is significantly higher than the Actual SD, we will not see QC flags even when significant systematic change occurs.



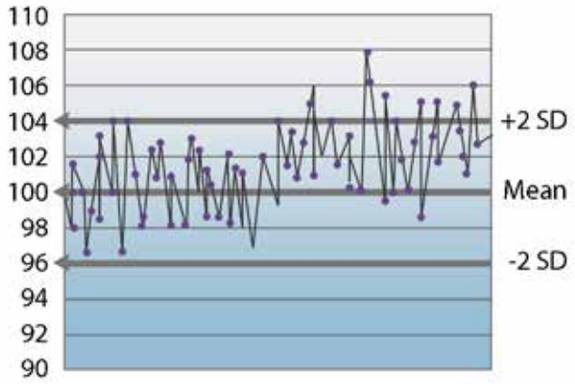


When the SD is assigned at a value lower than the actual SD, more data points will fall outside 2 and 3 SD simply by random distribution. This is shown in the graphic where the SD is arbitrarily assigned at 2.5 while the observed SD is 3.2. Eight of the 50 data points are flagged as exceeding 2 SD. This equates to an error rate of 16%. We expect only 5% of points to fall between 2 and 3 SD, and would therefore conclude that this method has significant problems. We may repeat the flagged controls, increase the frequency of calibration, change our procedures, investigate instrument problems or even send samples out.

Basic Concepts of QC Analysis

4.3e Mixed Populations of Data

Both the mean and the SD will be incorrect if they are calculated on mixed populations of data, or data that do not exhibit normal Gaussian distribution. The graphic illustrates an example we may see after introduction of a new reagent lot, new calibration, or a significant change to the instrument configuration. The first 50 points show a mean of 100 and an SD of 2.0; the next 50 points show a mean of 104 and an SD of 2.0. If data are combined, the calculated mean = 101.7 and SD = 2.9.



5. ADDITIONAL TECHNOPATH PRODUCT INFORMATION

MULTICHEM **IA PLUS**

MULTICHEM **S PLUS ASSAYED**

MULTICHEM **WBT**

MULTICHEM **S PLUS UNASSAYEI**

MULTICHEM **P**

MULTICHEM **U**

TECHNOPATH's Multichem range provides the complete third party quality control solution for today's automated laboratory, where a wide range of analytes are being consolidated onto single platforms.

- Multichem IA Plus (Immunoassay QC)
- Multichem S Plus Assayed (Serum Chemistry, Immunology, and Immunoprotein QC)

We also offer complementary Multichem products for additional Immunochemistry needs:

- Multichem WBT (Whole Blood Transplant QC)
- Multichem S Plus Unassayed (Serum Chemistry, Immunology, and Immunoprotein QC)
- Multichem P (Serum Immunoprotein QC)
- Multichem U (Urine Chemistry QC)

TECHNOPATH's Multichem: The features you need...

- Exceptional level of test consolidation in a third-party laboratory QC
- Liquid stable for ease of use and storage
- Targeted at clinical decision points
- Multichem's human based matrices mimic patient sample performance
- Provides tri-level utility across the analytical range
- Supports accreditation/regulatory requirements, e.g. rilibak, iso 15189, clsi/clia, etc.

...and the benefits you want.

- Improved QC performance
- Improved quality assurance
- Reduced QC packaging, storage and inventory management
- Overall gains in operational efficiencies – less time, less inventory, more analytes

RETURN

6. GLOSSARY

Accuracy

Agreement between the measured value and the true value.

Allowable limits of error

The magnitude of an error than can be tolerated in an analytical system. Total Error Allowed (TEa) can apply to clinical or statistical limits.

Analyte

That which is being measured. Glucose and hemoglobin are analytes.

Analytical method

A procedure for measuring the amount of analyte in a sample. (See analytical system.)

Analytical run

A set of samples (controls and patients) about which a quality control decision is made. A run can last a few minutes or a few hours.

Analytical system

The procedure, reagents, calibrators and instruments for used to measure the amount of analyte in a sample, and the quality control system used to determine if results are acceptable to report.

Average

The midpoint of a set of data, found by summing the data and dividing by the total number of points. The average is the same as the Mean.

Bias

The difference between the true value and the measured value. Bias has the same units of measure as the analyte.

Calibration

The process of analyzing known samples of different concentrations in order to establish a curve against which to relate or "read" unknown samples.

Coefficient of variation

The ratio of the SD to the Mean. Usually CV is expressed as a % using the formula:

% CV = SD/ Mean x 100

Controls

Those samples introduced into an analytical run to monitor the system..

Critical Systematic Error (ΔSEc)

Within a test system, ΔSEc indicates the number of SDs the Mean can shift before more than 5% of the data will exceed the Total Error Allowed (TEa).

ΔSEc is calculated as [(TEa - lBias l))/ SD] - 1.65

Error

Variation from the true value. Errors are random or systematic and can be positive (higher) or negative (lower than the true value).

External quality control

A system in which samples are analyzed by a laboratory and the data compared to data from other laboratories.

Flag

A means of drawing attention to a specific test. Examples of flags include violation of a QC rule, Interlab SDI exceeding " 2.0 or Total Error exceeding TEa.

Frequency of Errors

The frequency with which medically important errors are expected to occur in a test system. Related to method stability.

Gaussian curve

A curve, also referred to as a bell curve which relates the probability of data distribution to the distance from the Mean. It is generally assumed that random errors in analytical systems follow a Gaussian distribution.

Gaussian distribution

Normal random distribution of a single population of data about the mid-point or Mean. 68% of data will fall within +/- 1 SD, 95% within +/- 2 SD and 99.7% within +/- 3 SD of the Mean.

Imprecision

A measure of the random error in a system. The degree of imprecision can be stated in standard deviation measured in units (e.g. mmol/L) or as %CV.

Inaccuracy

The difference between the true value and the measured value.

Matrix

The material in which an analyte is found. The usual matrix for chemistry controls is serum. The matrix is affected by processing and additives, and may cause variation in results from method to method.

Mean

The mid-point of a set of data. Found by summing the data points and dividing by the number of points.

x_1 = data point

N = number of points

$$\text{Mean} = \frac{\Sigma x_1}{N}$$

Medical decision level

That concentration of analyte about which interpretations critical to patient care are made. There can be more than one medical decision level for each analyte.

Method stability

A measure of the frequency with which medically important errors are expected to occur in a test system.

Stability is usually rated by bench workers using the method as either “excellent”, “moderate” or “poor”.

“N” or “n”

Refers to the n(umber) of samples from which a statistic is calculated. “N” also refers to the number of control points in a run.

Non-Gaussian

A distribution of data points which does not follow a bell-shaped curve. If the data are non-Gaussian, the calculated mean and SD will be incorrect.

Outlier

A data point within a set of data that differs from the majority of data in that set. On occasion, such outliers are excluded from calculations.

Precision

The reproducibility of a measurement. Specifically known as the variation about the Mean. Precision is measured by the SD or CV.

Quality control

A system for monitoring and maintaining a level of acceptability of patient data. The QC system usually includes controls, control charts, a set of rules for monitoring each data point and a protocol of corrective action.

Quality Control Rule

The combination of a limit and the number of control values which need to exceed that limit for a run to be judged out of control. For example, the 1 3s rule will require one point to exceed 3 SDs for the run to be labeled “out”. The rule does not include the total number of controls analyzed.

Random error

An inconsistent change in the test system that causes a change in precision, reflected by points showing greater scatter both above and below the mean.

Due to the presence of variables such as small variations in temperature, voltages, pipes, there will be some deviation from the true value in any measurement. These errors are inherent, common and always present.

Range

The difference between high and low values in a set of data. In the set 34, 35, 36, 37, 38, 39, the range is 34-39. Range is often used to calculate values within 1, 2 or 3 SDs of the Mean.

Rule

The combination of the limits that must be exceeded by N controls in a run for the run to be labeled "out" or out of control. For example, in the 1 3s rule should one control in the run exceed either + 3s or - 3s the run is termed out.

Standard deviation

A measure of imprecision or dispersion.

Standard deviation Index (SDI)

An indicator of the variance of a single point from the mean measured in number of SDs. May be used for individual points or to express variance of a single laboratory's mean value from the peer group mean in external QC programs.

Systematic error

A consistent change in the test system that causes a change in accuracy, reflected by all points shifting in the same direction either above or below the mean.

Target value

The best estimate of the amount of analyte in a control sample. (See true value)

Total Error

The combined effect of systematic and random error.

Calculated as: $TE = |Bias| + 1.96\ SD$

For ease of calculation,

2 SD is often substituted for 1.96 SD.

Total Error Allowable (TEa)

The magnitude of an error than can be tolerated in an analytical system. TEa specifies the maximum allowable variation from the true value. TEa can apply to clinical or statistical limits. If a test has a true value of 100 and TEa of 20 units, results are acceptable if the calculated Total Error is less than 20.

True value

The amount of analyte in a sample. The true value is difficult to determine. It may be set based on reference laboratory results, peer data or historical data.

Variable

Any part of a measuring system that can change. These would include temperature, time, volumes, reagents. These variables contribute to systematic error and random errors.