SCC's Laboratory Information Systems Suite®

SoftTotalQC®

SCC's SoftTotalQC is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process, prior to the release of patient results. This total quality control system helps laboratories improve both the quality of the results reported by the laboratory, and the laboratory's QC operating procedures.

SoftTotalQC is a multisite capable product developed to facilitate and analyze quality control in the clinical laboratory setting. Quality control activities can be defined and documented on controls, reagents, media, panels, drugs, consumables, and maintenance procedures on equipment. Along with quality control, SoftTotalQC provides an inventory control solution allowing each department and site to maintain their supply of controls, reagents, media, panels, drugs, and consumables.

SoftTotalQC is fully integrated with SoftLab®, SoftMic®, SoftBiochemistry®, SoftFlowCytometry®, SoftMolecular®, SoftCytogenetics®, and SoftHLA®, allowing QC results to be posted from instruments or to be manually entered within patient resulting workflows. QC checks can be performed at posting or manually entering patient results and hold patient results from releasing when a QC violation is present. Automatic inventory countdown can also be applied. SoftTotalQC can be used in all other departments of the laboratory as a standalone product.

SoftTotalQC, assuring quality through total quality control management.

FEATURES AND BENEFITS

Feature: Inventory Management

Benefit: SoftTotalQC's Inventory option provides a solution to track and maintain supplies received into the laboratory. This powerful tracking ability allows users to receive new shipments of supplies into the laboratory while documenting their lot numbers, expiration dates, and quantity received. SoftTotalQC provides the ability to perform lot activities such as opening lots when they are ready to be placed into use, closing lots when they are no longer in use or are expired, maintaining supply levels, and preparing batches from stock solutions – all online. Users can place lot records in Testing status when the item must be evaluated and statistics calculated prior to being placed into use. Statistics calculated while in Testing status can be applied to the active parameters prior to placing the lot into use, which means no more number crunching when testing new lots. Lot activities can be performed on individual lot records, or multiple lot records, in the batch mode.

Through setups in SoftLab, SoftMic, SCC's Genetics Information Systems Suite® (Genetics Suite) products, and SoftTotalQC, end users have the ability to count down inventory on a per test basis. The system will notify users when the inventory is low, or ready to expire, based on customized fields in the QC item setups.

Various inventory-related reports are available. These reports can be run ad hoc, or can be scheduled for printing on a specified date and time via Scheduler Setup.

- The Inventory Report provides a list of lot records with their QC item, lot number, expiration, number of units received, and the supply remaining. This report can be grouped by QC item, which provides the ability to view the total supply from all lots of an inventory/QC item.
- The Inventory Workload Report provides a daily, weekly, monthly, or yearly inventory usage report.
- The Lot Parameter Report provides a list of all of the parameters in a lot record with its expected results information. This report can be generated by template or ad hoc from the individual lot record.
- The Parameter Modification Report provides a list of lot records whose Expected values were edited during a specified date range. The report provides the current value, previous value, when the edit was made, and by whom.

FEATURES AND BENEFITS *Cont.*

Users can also print bar code labels to place on received and opened items for scanning, thus creating and/or improving efficiency and accuracy in the QC process.

Feature: Equipment Maintenance Management
Benefit: SoftTotalQC's Equipment Maintenance option enables users to schedule maintenance and view the information for each piece of equipment or instrument used in the laboratory, as well as document unscheduled maintenance and downtime, providing accurate monitoring of equipment. From Equipment Maintenance, users can also keep track of the loading and unloading of reagents to and from the instrument, and expire opened reagents based on the manufacturers' recommended on-board protocol. This monitoring capability assures CLIA compliance, enables equipment stability, and decreases costly repairs, which results in reliable test results.

Feature: Simplified Order Generation
Benefit: QC Orders can be generated automatically in the following situations:

- based on the assigned frequency through SoftTotalQC scheduler.
- when posting QC results from an instrument.
- when a specified SoftLab or SoftMic test is added to a patient order.
- when a specified SoftMic media or panel is added to a patient order.
- when a new lot of a QC item is registered into Inventory.
- when a new lot is opened.

QC Orders can be generated manually from Order Entry within SoftTotalQC and from the SoftLab and SoftMic applications. Manual orders can be created on individual lot records or on multiple lots at the same time.

Feature: Scheduled order generation and reports
Benefit: SoftTotalQC enables users to schedule routine orders and reports through a scheduling tool. Orders are generated based on a parameter's assigned frequency: Daily, Weekly, Monthly, Quarterly, or Yearly. These orders help ensure that routine quality control is performed. Report Scheduler tasks provide the ability to select a predefined report template created in Reports Setup, and define when and where that report should run. At the selected time, the system will run the report based on the search criteria defined in the template, and print it to its designated printer.

Feature: Individual result entry and resulting worklist
Benefit: Results can be entered for an individual order, or through a resulting worklist. The system will check each result against its expected result. If the results are acceptable, the data is entered into the database. If the results are not acceptable, users will have the opportunity to view previous numerical results in an interactive graph and enter a required corrective action. A variety of resources that include graphs, QC item information, control information, component information, lot information, and result information including expected values or ranges, are available to assist users in making confident decisions concerning the acceptability of QC results. Resulting Worklists help organize and assign quality control activities, which helps streamline lab processes and procedures.

Feature: Result entry through Instrument Interface
Benefit: QC results can be manually posted from the SoftLab Instrument menu, or they can be autoposted from an instrument into the SoftTotalQC database. When QC results are posted, the system validates the results against its Expected results. If the results are deemed out of control, or flagged as a warning, the Corrective Action window will open requiring the user to enter his or her plan of action.

Patient results can be held from posting if the QC results are pending, out of control, or have expired. This feature ensures patient results are reported with confidence and quality. The Instrument Menu allows the user to view QC results that have not yet been posted or those that have already been autoposted or manually posted.

SPOTLIGHT FEATURE

PDA capabilities

Benefits:

Enter QC results via a mobile handheld device. Equipment readings such as temperatures and CO_2 can be entered using this method. Results are entered into the PDA, and the results are downloaded into the SoftTotalQC database. For Inventory Management, the use of mobile handheld devices enables users to receive, open, close, and reconcile supplies in a remote location, which streamlines the process and allows for a more patient-focused environment.

SPOTLIGHT FEATURE

Integration with SCC's SoftLab®, SoftMic®, SoftMedia®, and Genetics Suite.

SoftTotalQC's integration with core SCC laboratory and genetics information management systems enables users to do the following:

- Post and verify either manually, or through Autoposting/Autoverification, from the SoftLab Instrument menu.
- Enter QC results directly from SoftLab/SoftMic Resulting.
- Include QC details when building SoftLab Tasklists.
- Scan package inserts, field service reports, and other important documents into SoftMedia, and add and view documents throughout SoftTotalQC.
- Check QC, Order QC, and Result QC from Resulting Tasklist/Worksheet of SCC's Genetics Suite.
- View the QC results linked to a patient result.

FEATURES AND BENEFITS *Cont.*

Feature: QC Result Review
Benefit: SoftTotalQC provides the ability to perform three different levels of review on the entire order or individual results. The Review Worklist allows users to access a list of orders ready for their level of review and review those orders in batch mode or individually in Result Entry. The interactive Graph Report provides the ability to view the results in a graphical representation and review those results directly from the graph.

Feature: User notifications using rules-based system (RBS)
Benefit: RBS Setup provides the ability to notify specified users when a variety of events occur such as a result is out of control, orders are overdue, a lot is about to expire, or the minimum supply of a QC item has been reached. Notifications can be sent to a user's My Notifications tab, e-mail address, a specified printer, or via text message to the user's phone.

Feature: Advanced reporting capabilities
Benefit: SoftTotalQC enables users to create various reports, based on a variety of search criteria, delivering data that is easily understood and is available on demand. SoftTotalQC produces quality control information that meets pre-defined objectives, providing routine assessment while providing the ability to detect trends and shifts in established mean values.
These reports can be scheduled to print on a specified date and time, automating the process in an efficient manner. Print and view a wide variety of reports from various areas in SoftTotalQC, including Resulting and Review Worklists and an instant report for on screen QC orders.

- The Result Action Log provides a report that will include only those orders that have attached actions.
- Vendor Reports provide end users a printed report that can be faxed, mailed, or attached to an e-mail and sent to the appropriate vendor.
- A Bio-Rad FTP Report is provided, enabling facilities to upload their data to Bio-Rad for peer comparison.

Feature: Interactive reports
Benefit: Interactive graphs enable users to view result points for selected QC items in a graphical representation. Users can view results for a single control level, multiple control levels, and across instruments. Interactive graphs also enable users to look at different datasets for comparison, look for shifts and trends, add comments to specific points, include previously excluded points in the statistics (or exclude previously included points from the statistics), or set the reviewed flag for a group of results. This user-friendly visual documentation feature automates the plotting of control values and provides immediate information for decision making about QC performance, and enables users to maintain the stability of the analytical measuring system. The system also provides interactive Instrument-to-Instrument and Lot-to-Lot comparisons, Calibrations, Patient Correlation Studies, and Lot statistics.

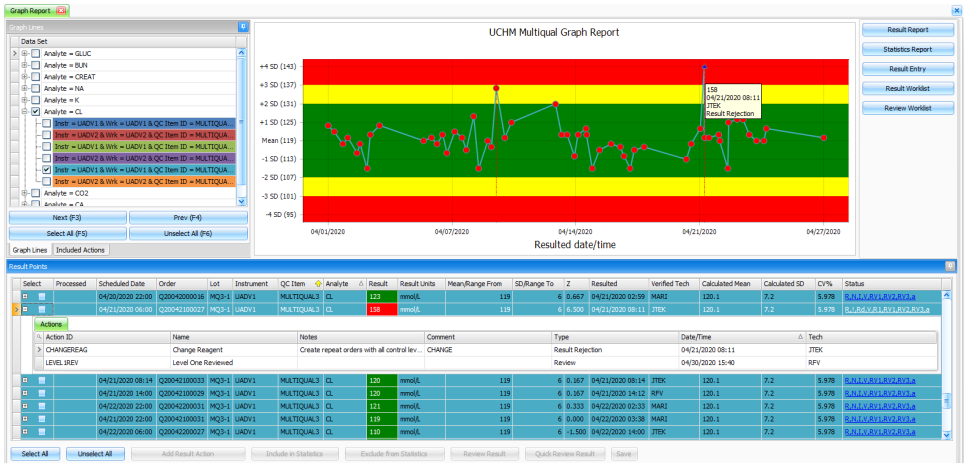
Feature: Statistical Data
Benefit: SoftTotalQC simplifies statistical interpretation by providing tools to better evaluate QC results, enabling better decision making, delivering higher confidence in results, and increasing the quality of patient care.
This powerful tool has the ability to calculate the Mean, Standard Deviation, and Coefficient of Variation for each parameter run on QC material. These statistics can be calculated for the life of the lot, current month only, each of the previous months, and for a specific date range for the lot-parameter combination. These statistics can also be calculated across lots, for active and testing parameters, separately, or in combination. The Standard Deviation Index is calculated for a group of results of the same test and QC item against the assigned mean. The Measurement of Uncertainty category of the Statistics Report enables users to assess the reliability of QC results and determine the imprecision of the analytical methods used in the laboratory.

SAMPLE SCREENSHOTS

Interactive L-J graph report

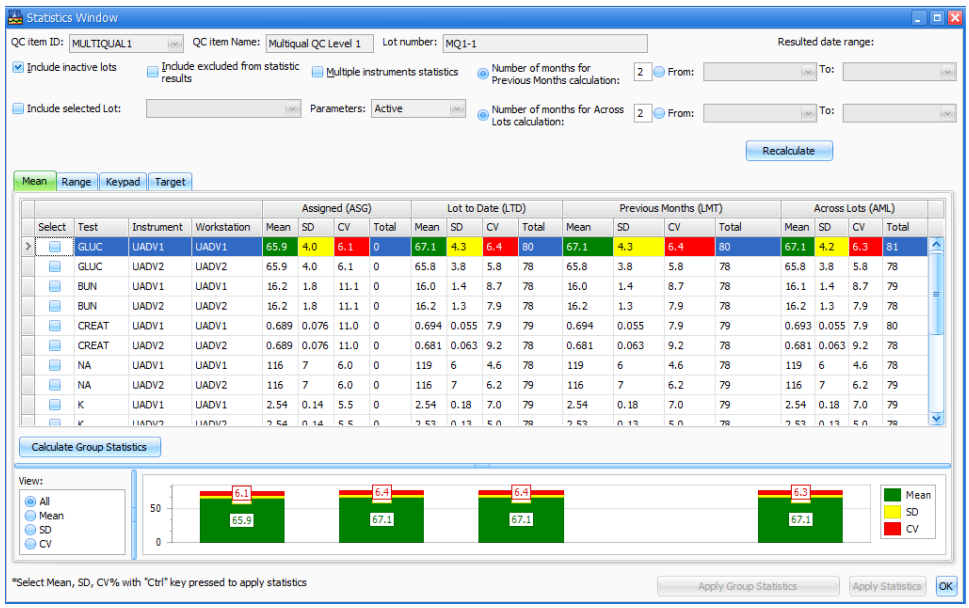
Enables users to view and evaluate results in a graphical and interactive format. Data sets can be created to view results for a specific analyte, QC item, and Instrument/Workstation or grouped together to compare results from multiple QC items, analytes, Instruments/Workstations in one graph. Result points are represented in different shapes or colors when they exceed their upper or lower limits (arrows), are converted (star), or excluded from statistics (gray). Vertical action lines represent actions performed on the result itself, its lot or equipment record, helping to troubleshoot trends, shifts, or outliers.

Placing the mouse pointer over a result point in the graph allows users to view the result value, resulted date, time, and tech and action type, if present. Clicking the point opens the result's detailed information in the Result Points grid.



Statistics Window

Users can open the Statistics window for selected parameters from Lot Record. From the Statistics window, users can select their mean and standard deviation (SD), or range, and apply them to their active parameters.



Select	Test	Instrument	Workstation	Assigned (ASG) Mean	SD	CV	Total	Lot to Date (LTD) Mean	SD	CV	Total	Previous Months (LMT) Mean	SD	CV	Total	Across Lots (AML) Mean	SD	CV	Total
	GLUC	UADV1	UADV1	65.9	4.0	6.1	0	67.1	4.3	6.4	80	67.1	4.3	6.4	80	67.1	4.2	6.3	81
	GLUC	UADV2	UADV2	65.9	4.0	6.1	0	65.8	3.8	5.8	78	65.8	3.8	5.8	78	65.8	3.8	5.8	78
	BUN	UADV1	UADV1	16.2	1.8	11.1	0	16.0	1.4	8.7	78	16.0	1.4	8.7	78	16.1	1.4	8.7	79
	BUN	UADV2	UADV2	16.2	1.8	11.1	0	16.2	1.3	7.9	78	16.2	1.3	7.9	78	16.2	1.3	7.9	78
	CREAT	UADV1	UADV1	0.689	0.076	11.0	0	0.694	0.055	7.9	79	0.694	0.055	7.9	79	0.693	0.055	7.9	80
	CREAT	UADV2	UADV2	0.689	0.076	11.0	0	0.681	0.063	9.2	78	0.681	0.063	9.2	78	0.681	0.063	9.2	78
	NA	UADV1	UADV1	116	7	6.0	0	119	6	4.6	78	119	6	4.6	78	119	6	4.6	78
	NA	UADV2	UADV2	116	7	6.0	0	116	7	6.2	79	116	7	6.2	79	116	7	6.2	79
	K	UADV1	UADV1	2.54	0.14	5.5	0	2.54	0.18	7.0	79	2.54	0.18	7.0	79	2.54	0.18	7.0	79
	K	UADV2	UADV2	2.54	0.14	5.5	0	2.53	0.13	5.0	78	2.53	0.13	5.0	78	2.53	0.13	5.0	78

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