



Real-Time Quality Control Analysis

THE QUALITY CONTROL COMPANY

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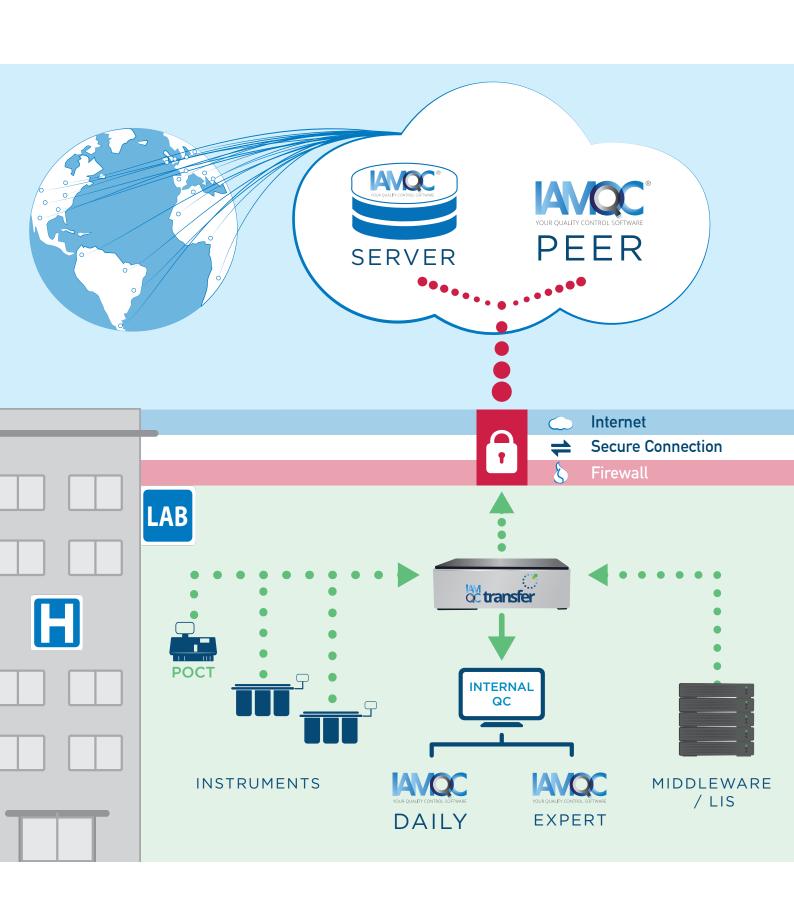


Designed to complement and support Technopath's Multichem® Quality Control (QC) product range, IAMQC® Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time.

IAMQC® Software products allow users to automate, centralise, standardise and improve QC processes in a laboratory setting. Our combination of modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

Technopath's full suite of software products provide clinical laboratories significant cost and time savings, whilst delivering higher confidence in analytical testing methods. Choose from Intranet and/or Internet based statistical quality control and quality assurance software products. IAMQC® software products are practical, graphical, user-definable and easy to use.

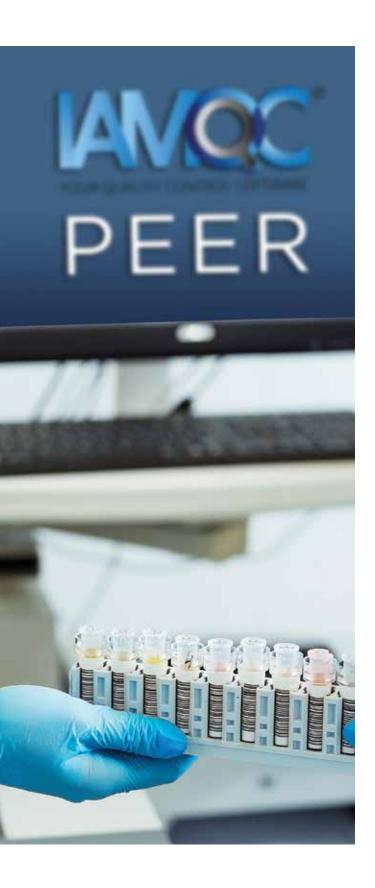












# TECHNOPATH'S SOFTWARE PRODUCTS HELP:

### **BENCH TECHNOLOGISTS:**

- Spend less time on false positive QC flags
- Concentrate on tests, which require their attention
- Spend less time trouble-shooting
- Know how to react when the mean shifts
- Assess the acceptability of new reagent lots and calibrations
- Solve QC problems
- Gain understanding and confidence in the QC process

### **LAB MANAGERS:**

- Choose QC rules to maximise true rejects and minimise false rejects
- Quickly see the tests that require their attention
- Skim graphics to quickly review current or historical data by lab, department, instrument or test
- Monitor performance in groups of laboratories
- Review problem tests and QA activities in local and remote labs

## LAB OR HOSPITAL ADMINISTRATORS:

- Save money
- Improve quality
- Improve service
- Review Administrative Summary Reports to ensure quality performance





# PEER

Request IAMQC® PEER Demo: iamqcsupport@technopathcd.com

IAMQC® Peer is an innovative, real-time, Peer Comparison Software. This web based system 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.

To participate in IAMQC® Peer, each individual laboratory submits their individual results or summary statistics (mean, standard deviation, and number of data points) to the central database maintained by Technopath. Laboratories data may be submitted manually on-line or, alternatively, captured by one of our many live interfacing options. The information provided by IAMQC® Peer can be used on a monthly basis to evaluate how well lab's methods are operating relative to the overall peer group. Users can also look at this peer data in real-time interactive tables online, when they are investigating a potential problem with accuracy or precision in an individual method.

# **KEY FEATURES**

- Centralised data management
- Instant comparison data from multiple instruments and locations
- Web based system
- User-friendly navigation
- Easy to read tables and charts
- Facilitates meeting ISO 15189
   requirements
- Significant cost and time savings





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. At any time, the reports are available online and can be downloaded by users using their login name and password.

#### **GROUP COORDINATOR REPORT**

This report provides a test by test listing of statistics for the lab 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.

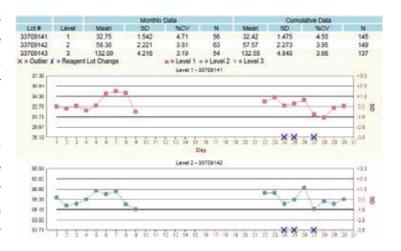
This report provides a centralised review of all instruments from the moment the customer begins to report data and thus facilitates users meeting accreditation requirements, with respect to the storage, retrieval and statistical analysis of quality control data.



## 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 superimposed 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.





#### **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.

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### **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:

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.

Control	Mean	SD	N	LTD Mean	Shift
Level 2 Lot # 33709142 01/02/2016 10:51:00; GR=[28.8-43.2]	28.10LPG	-	1	36.91	All Shifts
Level 2 Lot # 33709142 01/02/2016 12:00:00; GR=[28.8-43.2]	29.00LP	-	1	36.91	All Shifts
Level 2 Lot # 33709142 01/02/2016 11:59:00; GR=[28.8-43.2]	30.30P		1	36.91	All Shifts
.evel 2 Lot # 33709142 /2/02/2016 14:30:00; GR=[28.8-43.2]	26.80LPG		1	36.91	All Shifts
.evel 2 Lot # 33709142 0/02/2016 13:19:00; GR=[28.8-43.2]	26.20LPG	-	1	36.91	All Shifts
Level 3 Lot # 33709143 2202/2016 10:43:00; GR=[60.3-90.4]	57.80LPG		1	76.56	All Shifts
Level 3 Lot # 33709143 02/02/2016 14:34:00; GR=[60.3-90.4]	58.60PG		1	76.56	All Shifts
Level 3 Lot # 33709143	61.10P	-	1	76.56	All Shifts





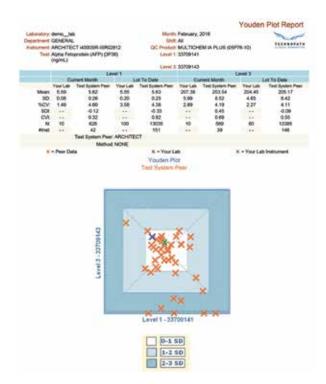
**Flag P -** This value did not pass the Peer Outlier Check, which highlights values more than +/- 3 standard deviations from the peer's mean for the month.

This value was included in the calculation of the peer's mean and SD for this month. **Flag 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.

#### YOUDEN PLOT REPORT

The Youden Report describes internal laboratory performance against the test system peer and method principle peer using the Youden Plot design. Laboratory data is tabularised 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.







# DAILY

Request IAMQC® DAILY Demo: iamqcsupport@technopathcd.com

IAMQC® Daily is a comprehensive Internal Quality Control software that applies Westgard and/or any user-defined QC rules to individual QC results. The software automatically builds interactive Levey-Jennings charts and tables and provides summary and detailed customised reports to the end user. IAMQC® Daily integrates with Microsoft Excel to produce customised electronic reports. The system also allows the import of pre-defined templates, resulting in instant system setups. Users can create audit trails, action logs and summary reports at the click of a button.

IAMQC® Daily comprises a centralised program that facilitates the analysis of multiple QC materials, across numerous departments in a laboratory setting. The system can be configured to submit approved results automatically to IAMQC® Peer via our proprietary driver solutions. This will help to satisfy both Internal and External QC requirements.

# **KEY FEATURES**

- Works with multiple Sites, Departments, Instruments, Tests and Levels.
- Applies Westgard and/or any userdefined QC rules.
- Works with both quantitative and qualitative results.
- Focused troubleshooting for failed QC results via the system Action Log.
- Technologist and Supervisor Reviews and sign-off capabilities.
- Automatic Reverse Levels function.
- QC management at different administrative levels.
- Works on a single PC, LAN, WAN, and/ or over the Internet.
- Runs on a powerful Database
   Management System to support large volumes of data in real time.
- Advanced functions for fast and easy setup.
- Multiple ways to enter data manually.
- Powerful reporting and charting capabilities.

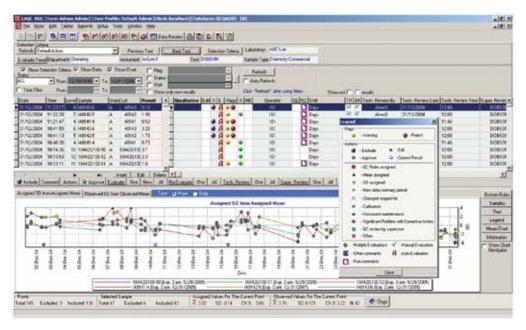




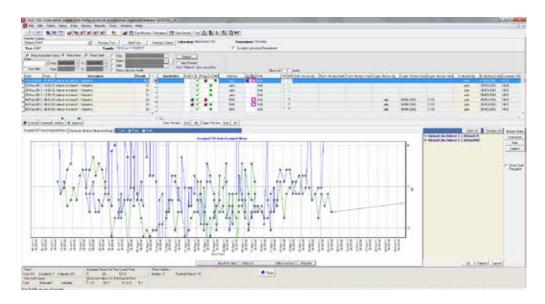
IAMQC® Daily offers a centralised review of all QC data from all laboratories/instruments. Central administrator access facilitates managers to review QC performance at multiple facilities – no need to visit each laboratory site. Closer monitoring of QC from remote locations without additional costs

provides a flexible option for managing the inter and intra-lab performance. The software works on an 'open' platform that allows the end user to add all types of control material from a range of laboratories.

Both IAMQC® Daily and Expert can run using an internet OR intranet connection. Each PC



Interactive Data Review Screen



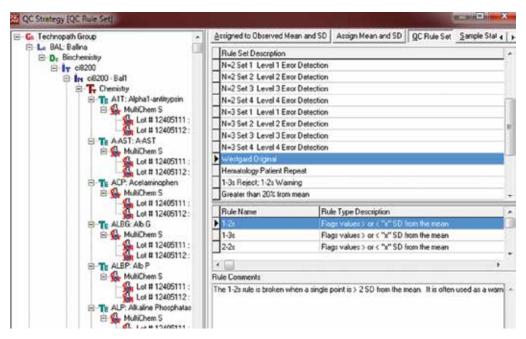
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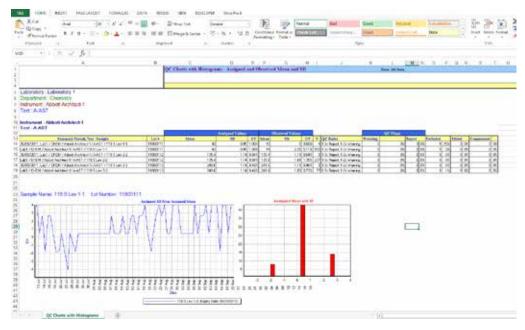
DAILY



license allows the user to manage an unlimited number of departments, control materials (not limited to Technopath materials) and instruments. An unlimited number of user logins can be added to the system at any stage. An administrator module can also manage user logins, customising the functionality that is available to each user. All data can also be filtered using the same logic to apply a user-friendly atmosphere and save time scrolling through data.



Custom Rule Sets



Customisable Reports in Microsoft Excel





# **EXPERT**

Request IAMQC® EXPERT Demo: iamqcsupport@technopathcd.com

IAMQC® Expert is an interactive system that helps front-line laboratory staff select QC rules, reduce unnecessary repeats and make meaningful QC decisions. IAMQC® Expert creates graphical color-coded representations of accuracy and precision, illustrating performance relative to target values and error limits. Interactive modules such as 'Reagent Verification', 'Calibration Check' and 'Mean Shift Analysis' assist with problem solving and decision-making.

IAMQC® Expert allows the end-user to monitor method performance relative to clinical requirements and focus on the tests that require their attention. The system can also be integrated with IAMQC® Daily to automatically capture summary data for analysis. Upon entering the IAMQC® Expert database, the software automatically analyses the data and suggests QC rules to maximise true rejects and minimise false rejects.

# **KEY FEATURES**

- Works with multiple Sites, Departments, Instruments, Tests and Levels.
- Recommends QC rules for IAMQC® Daily software.
- Powerful QC troubleshooting tools.
- Integrates with various Laboratory Information Systems and/or instruments.
- Works on a single PC, LAN, WAN, and over the Internet.
- Runs on a powerful Database Management System.
- Powerful reporting and charting capabilities





## **EXPERT ANALYSIS**

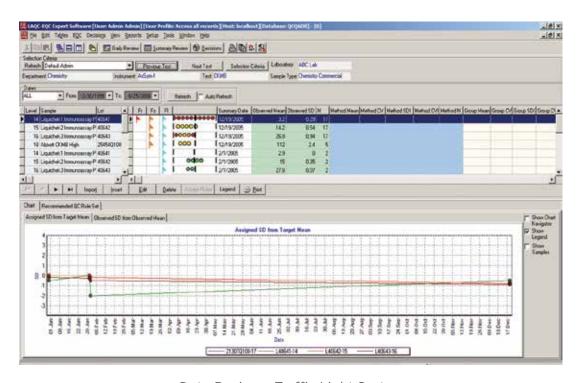
Times and technologies are changing rapidly. Instruments and methodologies are more accurate, precise and stable than they were a decade ago. Most laboratories have adopted these new technical advances, but few have modified their QC processes to match. Many laboratories are still using a 1-2S rule as recommended by Levey and Jennings in 1951.

In 1981 Westgard recommended using a multirule algorithm to avoid the false positive flags inherent in using only a 1-2S rule. Technology has come a long way since 1981, and for the past ten years industry leaders such as James Westgard, Per Hyltoft Petersen and Callum Fraser have advised the use of a variety of QC rules to match the analytical capability and stability of each test. With the dramatically improved precision of today's methods, we now see shifts of several SD for the same control on the same test from time to time within a single laboratory. We have designed

a QC system that will alert users to significant changes and not generate QC flags when the system is operating safely within acceptable limits.

The system compares method performance to defined quality requirements (rather than to last month's data) and recommends QC strategies that will warn users when QC data points exceed acceptable performance - with a minimal number of false flags. In the design of our QC system we "balance" the quality control system to meet the changing performance and stability of the analytical system.

Our analytical processes also vary in their susceptibility to the occurrence of significant errors. Error rates vary from low to moderate to high, depending on the frequency of significant errors that occur in a specific test system. Some methods seldom encounter significant problems. Others are susceptible



Data Review - Traffic Light System





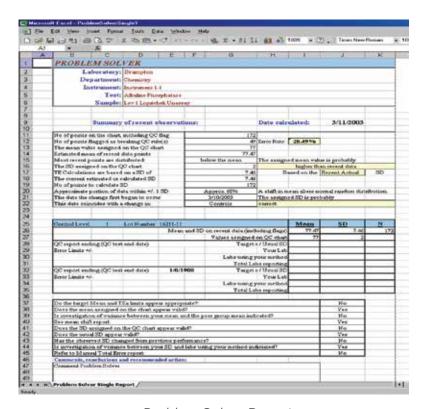
to relatively frequent sources of significant error. Methods with high error rates frequently see significant shifts in the mean or have ongoing precision problems; these methods may also be susceptible to frequent instrument breakdowns or problems.

We monitor method performance (accuracy and precision) relative to a quality requirement by calculating critical systematic error (^SEc). Critical systematic error is an extremely powerful and useful statistic. ^SEc indicates in one number how method accuracy and precision compare to the target and TEa limit set for each control. ^SEc indicates the number of standard deviations the mean can shift before the results will exceed error limits. Therefore changes in either the mean or SD will be reflected in a change in critical systematic error.

Our QC system has an improved error detection process when methods are close to the error limit (have a low ^SEc) or when methods have poor stability and are prone

to errors. In this case we will select a higher number of controls or run our existing controls more frequently and we will select QC rules that are more powerful when assessing small changes in method performance. When the ^SEc is high (method performance is well within quality requirements) and the analytical system is stable, we will run fewer controls or run controls less frequently and we will select QC rules to minimise false QC flags.

Critical systematic error is a valuable indicator of the size of the shift in the mean that we must detect. We can easily visualize how it would be appropriate to use "tighter" QC rules when the method is closer to the error limit and to use "looser" QC rules when a method can shift many standard deviations before exceeding the quality requirement. When we run more levels of controls or run the same controls more frequently, we increase our probability of detecting errors. Unfortunately, we also increase the probability of false rejection. Remember, if we are using a 1-2S rule, we will see 5% of our "good" data falling between



Problem Solver Report





2 and 3 SD. Therefore, the more controls we run, the higher the probability in any given run that one of them will fall outside two standard deviations. When it is necessary to design a QC process to detect a very small change in the analytical system, one of the strategies we can use is to increase the number and frequency of the controls.

IAMQC® Expert is a user-friendly interactive expert system that helps front-line laboratory staff select QC rules, reduce unnecessary repeats and make meaningful QC decisions. The software creates graphical colour-coded representations of accuracy and precision illustrating performance relative to target values and error limits for several departments or groups of affiliated laboratories. Interactive modules assist with problem solving and decision-making.

## IAMQC® Expert Helps Bench Technologists:

- Spend less time on false positive QC flags
- Concentrate on tests which require their attention
- · Spend less time trouble-shooting
- Know how to react when the mean shifts

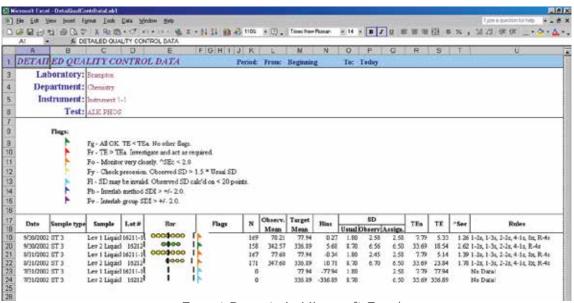
- Assess the acceptability of new reagent lots and calibrations
- · Solve QC problems
- Gain understanding & confidence in the QC process

## **IAMQC®** Expert Helps Lab Managers:

- Monitor method performance relative to CLIA or clinical requirements
- Choose QC rules to maximise true rejects and minimise false rejects
- Quickly see the tests that require their attention
- Skim graphics to quickly review current or historical data by lab, department, instrument or test
- Monitor performance in groups of laboratories
- Review problem tests and QA activities in local and remote labs

# IAMQC® Expert Helps Lab Or Hospital Administrators:

- Save money
- Improve quality
- Improve service
- Review Administrative Summary Reports to ensure quality performance



Expert Reports in Microsoft Excel





# **TRANSFER**

The most advanced connectivity solution available for laboratory instrumentation.



IAMQC® Transfer is a connectivity device that can communicate with Laboratory Information Systems (LIS), Middleware, automated instrumentation and Point Of Care platforms. Through the use of our proprietary drivers and a single board computer device, IAMQC Transfer processes and communicates data from your system to any one of our powerful IAMQC software packages; IAMQC Peer, IAMQC Daily, IAMQC Expert or IAMQC

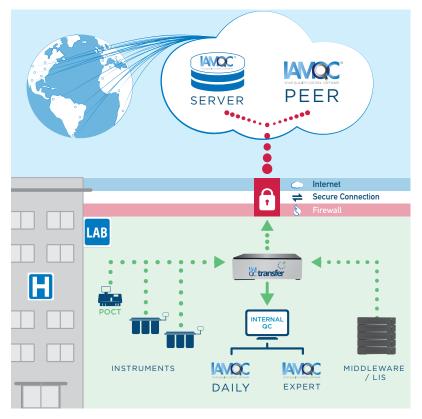
Proficiency Testing module. By combining software and hardware elements, we can eliminate the requirement for additional PCs or servers. A plug-and-play set up, combined with over 200 available connectivity options ensure an un-matched level of flexibility – all within an incredibly small, seamless enclosure.

Automated data collection. Easy to Implement. Introducing IAMQC Transfer in to your laboratory will drive efficiency through automation, whilst increasing quality by transitioning away from manual entry programs. IAMQC Transfer can function as a uni-

Request IAMQC® TRANSFER Demo: iamqcsupport@technopathcd.com

directional interface to process QC files and data streams of all formats. However, in addition to receiving the results, IAMQC Transfer can also work as a bi-directional interface, where it will communicate back to the instrument, LIS or middleware. To satisfy the requirements of laboratories of all sizes and configurations, Technopath Clinical Diagnostics introduces IAMQC Transfer, a next-generation informatic solution.

More than just an interface to IAMQC Software, IAMQC Transfer is available to purchase as a stand-alone connectivity device for your software program. By providing a comprehensive solution that can work with multiple information systems, Technopath Clinical Diagnostics' IAMQC Transfer can automate your data collection process. Contact us at qcsoftware@technopathcd.com for more information.







# CONNECTIVITY

Providing the flexibility for an internet OR intranet connection facilitates the customer in choosing their preference with regards to connectivity. The system can run locally behind a firewall, or alternatively, over the web should access be required outside of the local network.

Built-in real-time and semi-real time interface solutions are available to capture data from all

Cerner Millennium LIS

Citation LIS

types of instruments, middleware systems and LIS across all departments. To date, we have developed over 200 types of drivers for data capturing purposes. IAMQC® Daily can also capture QC results from diagnostic instruments that are not interfaced to the DMS and from manual result entry programs on a daily basis. IAMQC® Drivers include, but are not limited to, the following list:

Siemens Immulite (DPC)

Siemens Novius LIS

Abbott Architect **RCM** Beziers Datalink Abbott AXSYM EPIC LIS SDF 1.0 Quadramed LIS Abbott CELL DYN Roche COBAS FRMA ABX Fletcher Flora Roche FLECSYS **AVL OMNI 5 HMS LIS** Roche HITACHI 747 Hutt No 2 QC Roche Integra 4.1.ARC Bayer Atlas **Bayer CLINITEK** IL ELECTRA 1000 Roche Modular Beckman AU Roche PSM **IL Synthesis** Beckman DxC Immucor Galileo RT Communicator Beckman DXI ACCESS 2 LabDag LIS Schuvlab LIS Beckman Remisol McKesson LIS Siemens ADVIA Centaur Beckman SYNCHRON CX9 Meditech LIS Siemens CentraLink Cerner LIS Menarini Siemens Dimension 2.0

**CLARIS LIS** Microscan SOFT LIS Coag-A-Mate MTX II **MOLIS LIS** StaRRsed ConcurTrak SDF Stat Profile M Mysis LIS **CPSI LIS NEMO Middleware** Sunquest 1 **NOVA ELECTROLYTE 5** Dade Behring BN II Nephelometer SYSMEX Dade Dimension **NUCLEUS** TOSOH A1c 2.2

Microplate

Dairyland LISOmnilab AMSUF100Data Innovations IMOrchard LISUriScan-S300Dawning UCOrtho Vitros ECiViper



MGC 240 Qualitative 1.0



# BENEFITS

- 1. Centralised review of all QC data from all laboratories/instruments. Central administrator access to review QC performance at multiple facilities no need to visit each laboratory site
- 2. Closer monitoring of QC from remote locations without additional costs
- 3. Built-in real-time and semi-real time interface solutions. Integrate with various Laboratory Information Systems and/or instruments
- **4. Capture QC results** from diagnostic instruments and manual result entry programs on a daily basis
- Compare each result to Assigned Mean & SD
- 6. Assess QC results against a set mean and standard deviation using QC rules (Westgard and/or User-defined): single or multiple QC rules
- 7. Auto-approval protocol
- 8. Troubleshoot problematic daily QC
- 9. Manage multiple Sites, Departments, Instruments, Tests and QC Levels on one central database
- Manage both quantitative and qualitative results
- **11. Manage different departments** (Chemistry, Haematology, Microbiology, etc.) on one software system
- 12. Focused troubleshooting for failed QC results
- 13. Technologist and Supervisor Reviews / Sign-off
- 14. "Reverse Levels" automatic function
- **15. QC management at different levels:** administrative and bench technologists

- 16. Document all activities regarding daily QC
- 17. Tracking of proficiency testing performance and problem resolution
- Documentation of new reagent/calibrator/ QC lot numbers and studies
- 19. Monthly reporting on-line for management
- 20. Document activities and administrative comments for summarized QC data
- **21. Transfer detail and summary data** between a Laboratory and a single QC database in real time over the Internet
- 22. Internal/External peer QC review capability.
  Collect, analyse and compare individual
  laboratory data immediately with a worldwide peer group at the touch of a button
  over the Internet
- 23. Works on a single PC, LAN, WAN, and over the Internet
- **24.** Runs on a powerful Database Management System to support large volumes of data in real time
- **25.** Multiple Assign and Advanced Setup/
  Copy functions for fast and easy setup and ongoing maintenance
- **26.** Multiple ways to enter data manually (by Level, Test or Instrument; one at a time or many at a time)
- 27. Monthly Supervisor Review
- **28. Powerful reporting and charting capabilities.** Includes User-definable reports
- 29. Multi-user environment
- **30. Audit trail/Admin module** for setting up users with different security profiles





