



T E C H N O P A T H
C L I N I C A L D I A G N O S T I C S

QUALITY CONTROLS FOR OPTIMAL PATIENT CARE

IAVQC

YOUR QUALITY CONTROL SOFTWARE

PEER

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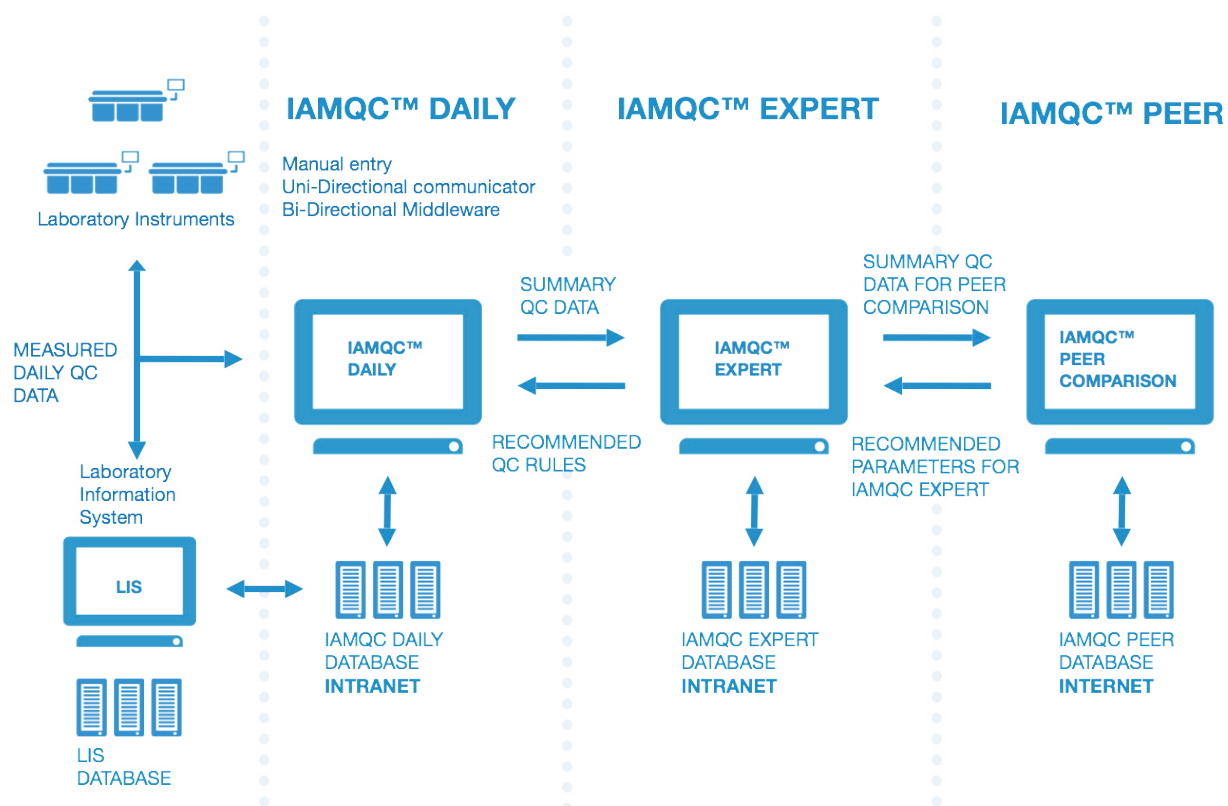




Designed to complement and support TECHNOPATH's Multichem™ Quality Control (QC) product range, IAMQC™ Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time.

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.





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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



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PEER

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.

 **Group Coordinator Report**
MULTICHEM IA PLUS (05P76-10) January, 2015

Alpha Fetusprotein (AFP) (2P36) in U/mL - All Shifts; Instrument Class Name: ARCHITECT; Reagent: ABBOTT; Method: NONE												
QC Product: MICHEM IA-Lot # 33301141												
World Peer												
Lab ID-Name	SN	Shift	Mean	SD	%CV	N	SD	%CV	N	SD	%CV	N
World Peer			5.58	0.295	5.31	568			62.39	2.321	3.72	568

CA 125 (2K45) in U/mL - All Shifts; Instrument Class Name: ARCHITECT; Reagent: ABBOTT; Method: NONE												
QC Product: MICHEM IA-Lot # 33301141												
World Peer												
Lab ID-Name	SN	Shift	Mean	SD	%CV	N	SD	%CV	N	SD	%CV	N
World Peer			15.6	1.16	7.40	475			37.5	2.71	7.22	448

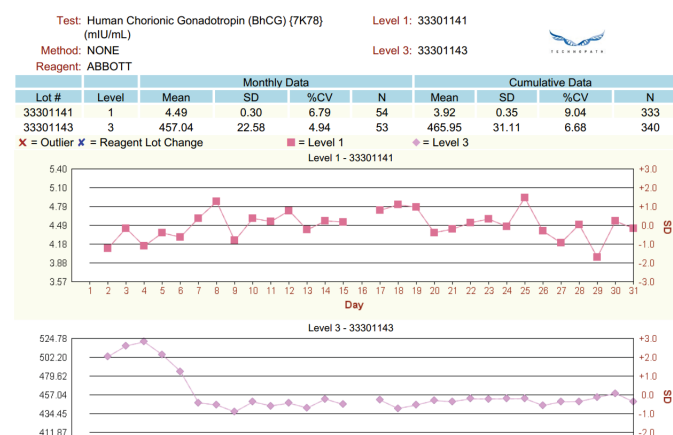
CA 19-9 (2K44) in U/mL - All Shifts; Instrument Class Name: ARCHITECT; Reagent: ABBOTT; Method: NONE												
QC Product: MICHEM IA-Lot # 33301141												
World Peer												
Lab ID-Name	SN	Shift	Mean	SD	%CV	N	SD	%CV	N	SD	%CV	N
World Peer			13.4	0.85	6.33	459						

CA 15-3 (2K45) in U/mL - All Shifts; Instrument Class Name: ARCHITECT; Reagent: ABBOTT; Method: NONE												
QC Product: MICHEM IA-Lot # 33301141												
World Peer												
Lab ID-Name	SN	Shift	Mean	SD	%CV	N	SD	%CV	N	SD	%CV	N
World Peer			13.5	0.62	4.53	29			0.36	0.78		

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.



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.

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.

This report provides the customer with an indication of



Monthly Summary Report January, 2015

MULTICHEM IA PLUS (05P76-10)

Affiliation: NO AFFILIATION

Alpha Fetoprotein (AFP) (3P36) (IU/mL) - All Shifts													
	LTD	Jan 2015	Dec 2014	Nov 2014	Oct 2014	Sep 2014	Aug 2014	Jul 2014	Jun 2014	May 2014	Apr 2014	Mar 2014	Feb 2014
MCHEM IA+Lot # 33301141													
Your Lab	ARCHITECT c8200 - ISIRI, NONE, ABBOTT												
Mean	5.62	4.98	5.36	5.28	5.78	5.93	5.77	5.78	5.78	5.93	5.77	5.78	5.77
SD	0.415	0.174	0.112	0.138	0.282	0.190	0.138	0.117	0.282	0.190	0.138	0.117	0.138
%CV	7.39	3.49	2.09	2.62	4.88	3.21	2.40	2.02	4.88	3.21	2.40	2.02	2.40
N	115	27	25	24	28	28	26	6	28	28	26	6	26
Test System Peer	ARCHITECT, NONE, ABBOTT												
Mean	5.65	5.57	5.62	5.65	5.72	5.68	5.64	5.63	5.62	5.65	5.72	5.68	5.64
#Inst	76	41	49	53	58	46	30	20	49	53	58	46	30
SDI	-0.10	-2.02	-1.15	-1.38	0.23	0.97	0.45	0.83	-1.15	-1.38	0.23	0.97	0.45
CVI	1.61	0.67	0.51	0.55	1.15	0.71	0.50	0.61	0.51	0.55	1.15	0.71	0.50
MCHEM IA+Lot # 33301142													
Your Lab	ARCHITECT c8200 - ISIRI, NONE, ABBOTT												
Mean	62.54	59.70	65.96	66.99	64.70	63.09	62.89	61.60	66.99	64.70	63.09	62.89	61.60
SD	2.831	2.688	1.148	2.016	1.832	1.420	2.842	1.859	2.016	1.832	1.420	2.842	1.859
%CV	4.53	4.50	1.74	3.01	2.83	2.25	4.52	3.02	3.01	2.83	2.25	4.52	3.02
N	115	27	25	24	27	28	26	7	24	27	28	26	7
Test System Peer	ARCHITECT, NONE, ABBOTT												
Mean	62.90	62.42	63.00	63.34	63.02	63.10	62.51	62.19	63.34	63.02	63.10	62.51	62.19
#Inst	75	45	50	54	56	46	31	20	54	56	46	31	20
SDI	-0.15	-1.18	1.32	1.38	0.67	-0.01	0.13	-0.25	1.38	0.67	-0.01	0.13	-0.25
CVI	1.13	1.22	0.49	0.72	0.71	0.54	0.99	0.81	0.72	0.71	0.54	0.99	0.81

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.

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.



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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.

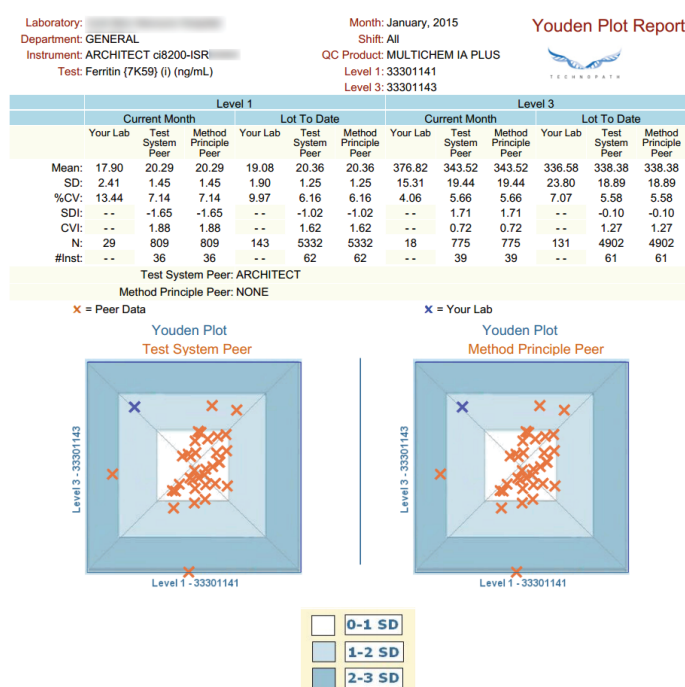
Data Exclusion Flags

Alpha Fetoprotein (AFP) (3P36) (IU/mL) ARCHITECT ci8200 - ISR ABBOTT					
Control	Mean	SD	N	LTD Mean	Shift
Level 3 Lot # 33301143 1/2/2015 1:19:00 PM; GR=[118-177]	174.70P	-	1	155.96	All Shifts
Level 3 Lot # 33301143 1/4/2015 2:08:00 PM; GR=[118-177]	175.20P	-	1	155.96	All Shifts
Level 3 Lot # 33301143 1/5/2015 1:04:00 PM; GR=[118-177]	172.40P	-	1	155.96	All Shifts
CA 125 (2K45) (U/mL) ARCHITECT ci8200 - ISR ABBOTT					
Control	Mean	SD	N	LTD Mean	Shift
Level 3 Lot # 33301143 1/1/2015 1:29:00 PM; GR=[75.4-113]	78.0P	-	1	84.1	All Shifts
Carcinogenic Embryonic Antigen (CEA) (7K68) (ng/mL) ARCHITECT ci8200 - ISR ABBOTT					
Control	Mean	SD	N	LTD Mean	Shift
Level 2 Lot # 33301142 1/9/2015 5:27:00 PM; GR=[13.5-20.2]	19.30P	-	1	16.33	All Shifts
Level 2 Lot # 33301142 1/11/2015 3:29:00 PM; GR=[13.5-20.2]	19.40P	-	1	16.33	All Shifts

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.



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 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:

Abbott Architect	Dawning UC	RCM Beziers
Abbott AXSYM	EPIC LIS SDF 1.0	Roche COBAS
Abbott CELL DYN	ERMA	Roche ELECSYS
ABX	Fletcher Flora	Roche HITACHI 747
AVL OMNI 5	HMS LIS	Roche Integra 4.1.ARC
Bayer Atlas	Hutt No 2 QC	Roche Modular
Bayer CLINITEK	IL ELECTRA 1000	Roche PSM
Beckman AU	IL Synthesis	RT Communicator
Beckman DxC	Immucor Galileo	Schuytlab LIS
Beckman DXI ACCESS 2	LabDaq LIS	Siemens ADVIA Centaur
Beckman Remisol	McKesson LIS	Siemens CentraLink
Beckman SYNCHRON CX9	Meditech LIS	Siemens Dimension 2.0
Cerner LIS	MGC 240 Qualitative 1.0	Siemens Immulite (DPC)
Cerner Millennium LIS	Microplate	Siemens Novius LIS
Citation LIS	Microscan	SOFT LIS
CLARIS LIS	MOLIS LIS	StaRRsed
Coag-A-Mate MTX II	Mysis LIS	Stat Profile M
ConcurTrak SDF	NEMO Middleware	Sunquest 1
CPSI LIS	NOVA ELECTROLYTE 5	SYMEX
Dade Behring BN II Nephelometer	NUCLEUS	TOSOH A1c 2.2
Dade Dimension	Omnilab AMS	UF100
Dairyland LIS	Orchard LIS	UriScan-S300
Data Innovations IM	Ortho Vitros ECi	Viper
Datalink	Quadrated LIS	RCM Beziers

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
- ⑤ 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**
- ⑩ **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**
- ⑱ **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 world-wide 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





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Fort Henry Business Park, Ballina, Co. Tipperary, Ireland.
info@technopathCD.com www.technopathclinicaldiagnostics.com