TECHNOPATH
CLINICAL DIAGNOSTICS

OUALITY CONTROLS FOR OPTIMAL PATIENT CARE

IAMQC
YOUR QUALITY CONTROL SOFTWARE

EXPERT

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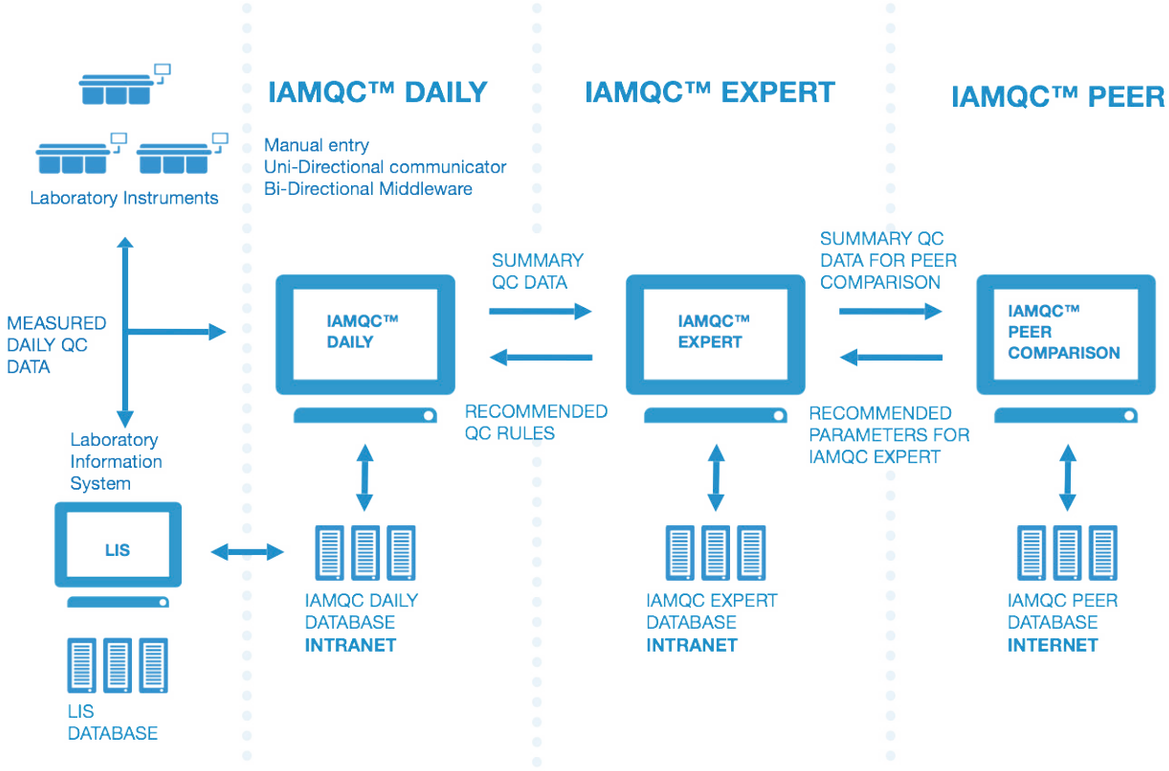
IAMQC

YOUR QUALITY CONTROL SOFTWARE

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.


IAMQC™ DAILY
IAMQC™ EXPERT
IAMQC™ PEER
Manual entry
Uni-Directional communicator
Bi-Directional Middleware
Laboratory Instruments
MEASURED DAILY QC DATA
SUMMARY QC DATA
RECOMMENDED QC RULES
SUMMARY QC DATA FOR PEER COMPARISON
RECOMMENDED PARAMETERS FOR IAMQC EXPERT
IAMQC™ DAILY
IAMQC™ EXPERT
IAMQC™ PEER COMPARISON
Laboratory Information System
LIS
LIS DATABASE
IAMQC DAILY DATABASE INTRANET
IAMQC EXPERT DATABASE INTRANET
IAMQC PEER DATABASE INTERNET

IAMQC
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TECHNOPATH
CLINICAL DIAGNOSTICS

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

EXPERT

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

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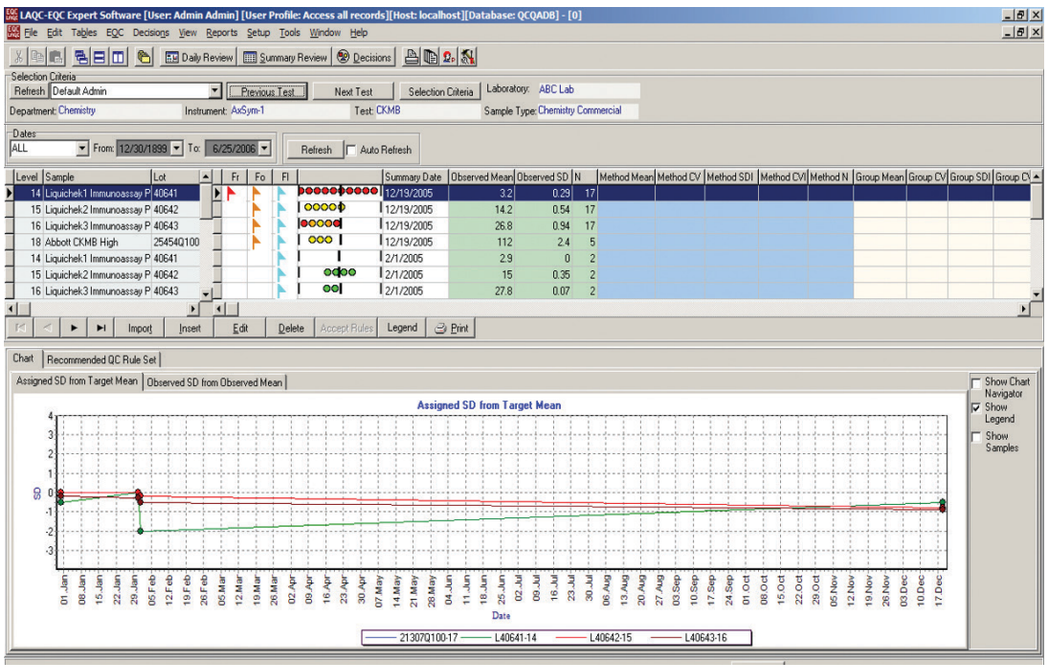
EXPERT ANALYSIS

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



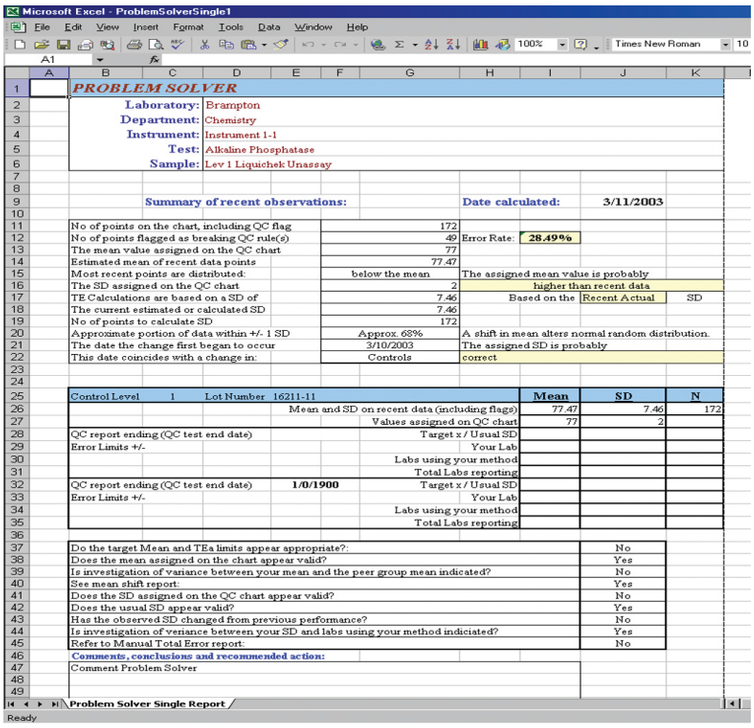
Data Review - Traffic Light System

EXPERT

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 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.



Microsoft Excel - ProblemSolverSingle1

File Edit View Insert Format Tools Data Window Help

1	**PROBLEM SOLVER**									
2		**Laboratory:**	Brampton							
3		**Department:**	Chemistry							
4		**Instrument:**	Instrument 1-1							
5		**Test:**	Alkaline Phosphatase							
6		**Sample:**	Lev 1 Liquichek Unassay							
7										
8										
9		**Summary of recent observations:**					**Date calculated:**		**3/11/2003**	
10										
11		No of points on the chart, including QC flag			172					
12		No of points flagged as breaking QC rule(s)			49	Error Rate:	**28.49%**			
13		The mean value assigned on the QC chart			77					
14		Estimated mean of recent data points			77.47					
15		Most recent points are distributed:			below the mean	The assigned mean value is probably				
16		The SD assigned on the QC chart			2	higher than recent data				
17		TE Calculations are based on a SD of			7.46	Based on the	Recent Actual	SD		
18		The current estimated or calculated SD			7.46					
19		No of points to calculate SD			172					
20		Approximate portion of data within +/- 1 SD			Approx. 68%	A shift in mean alters normal random distribution.				
21		The date the change first began to occur			3/10/2003	The assigned SD is probably				
22		This date coincides with a change in:			Controls	correct				
23										
24										
25		Control Level	1	Lot Number	16211-11			**Mean**	**SD**	**N**
26						Mean and SD on recent data (including flags)		77.47	7.46	172
27						Values assigned on QC chart		77	2	
28		QC report ending (QC test end date)				Target x / Usual SD				
29		Error Limits +/-				Your Lab				
30						Labs using your method				
31						Total Labs reporting				
32		QC report ending (QC test end date)		**1/0/1900**		Target x / Usual SD				
33		Error Limits +/-				Your Lab				
34						Labs using your method				
35						Total Labs reporting				
36										
37		Do the target Mean and TEa limits appear appropriate?:						No		
38		Does the mean assigned on the chart appear valid?						Yes		
39		Is investigation of variance between your mean and the peer group mean indicated?						No		
40		See mean shift report:						Yes		
41		Does the SD assigned on the QC chart appear valid?						No		
42		Does the usual SD appear valid?						Yes		
43		Has the observed SD changed from previous performance?						No		
44		Is investigation of variance between your SD and labs using your method indicated?						Yes		
45		Refer to Manual Total Error report:						No		
46		**Comments, conclusions and recommended action:**								
47		Comment Problem Solver								
48										
49										

Problem Solver Single Report

Ready

Problem Solver Report

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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
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- Solve QC problems
- Gain understanding & confidence in the QC process

IAMQC™ Expert Helps Lab Managers:

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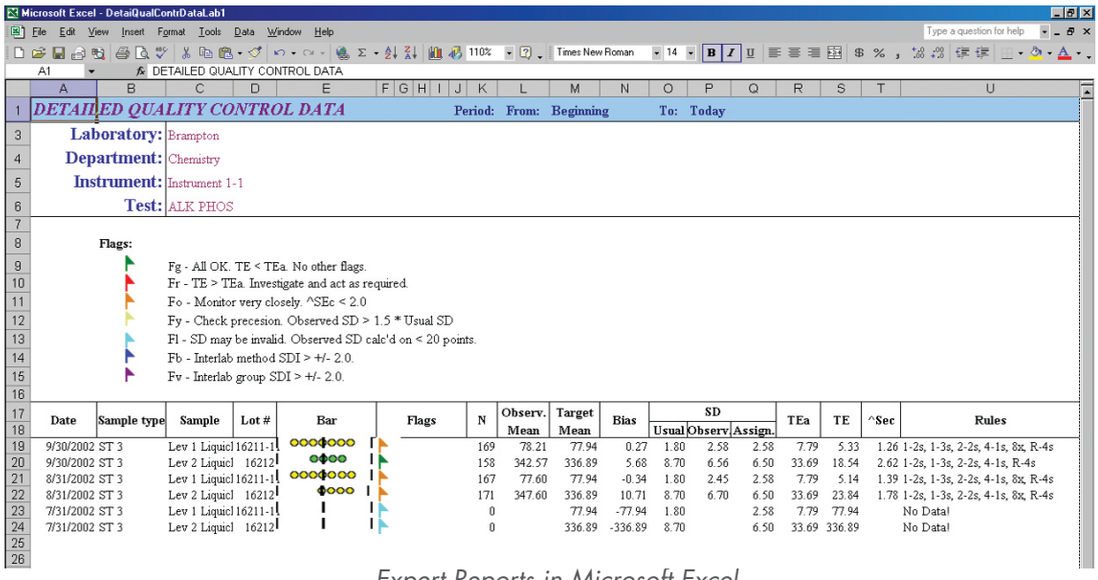

DETAILED QUALITY CONTROL DATA — Period: From: Beginning To: Today

Laboratory: Brampton
Department: Chemistry
Instrument: Instrument 1-1
Test: ALK PHOS

Flags:
Fg - All OK. TE < TEa. No other flags.
Fr - TE > TEa. Investigate and act as required.
Fo - Monitor very closely. ^SEc < 2.0
Fy - Check precesion. Observed SD > 1.5 * Usual SD
Fl - SD may be invalid. Observed SD calc'd on < 20 points.
Fb - Interlab method SDI > +/- 2.0.
Fv - Interlab group SDI > +/- 2.0.

Date	Sample type	Sample	Lot #	Bar	Flags	N	Observ. Mean	Target Mean	Bias	SD Usual	SD Observ	SD Assign.	TEa	TE	^Sec	Rules
9/30/2002	ST 3	Lev 1 Liquicl	16211-1			169	78.21	77.94	0.27	1.80	2.58	2.58	7.79	5.33	1.26	1-2s, 1-3s, 2-2s, 4-1s, 8x, R-4s
9/30/2002	ST 3	Lev 2 Liquicl	16212			158	342.57	336.89	5.68	8.70	6.56	6.50	33.69	18.54	2.62	1-2s, 1-3s, 2-2s, 4-1s, R-4s
8/31/2002	ST 3	Lev 1 Liquicl	16211-1			167	77.60	77.94	-0.34	1.80	2.45	2.58	7.79	5.14	1.39	1-2s, 1-3s, 2-2s, 4-1s, 8x, R-4s
8/31/2002	ST 3	Lev 2 Liquicl	16212			171	347.60	336.89	10.71	8.70	6.70	6.50	33.69	23.84	1.78	1-2s, 1-3s, 2-2s, 4-1s, 8x, R-4s
7/31/2002	ST 3	Lev 1 Liquicl	16211-1			0		77.94	-77.94	1.80		2.58	7.79	77.94		No Data!
7/31/2002	ST 3	Lev 2 Liquicl	16212			0		336.89	-336.89	8.70		6.50	33.69	336.89		No Data!

Expert Reports in Microsoft Excel

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EXPERT

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

TECHNOPATH
CLINICAL DIAGNOSTICS

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