İç Kalite Kontrole Bilimsel Bakış: Etkinlikleri, Sınırlılıkları

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Acıbadem Üniversitesi Tıp Fakültesi
ve ClinLab Laboratuvarı

Tarihçe

- İstatistiksel kalite kontrol (SQC) 1920, Bell Telephone Laboratories.
- Levey ve Jennings kontrol kartı (1950),
- Farklı kontrol düzeyleri Henry ve Segalove (1952),
- Spesifik kontrol serumlarının kullanımı Freier and Rausch (1958) and
- Westgard ve ark kuralları (1981)
- Normallaerin ortalaması, Hoffmann ve Waid (1965),
- Hematolojide hareketli ortalama, Bull (1973),
- Delta kontrol, Nosanchuk, Gottmann (1974),
- Anyon gap, Witte (1975)
- Cembrowski uygulamaları (1988)

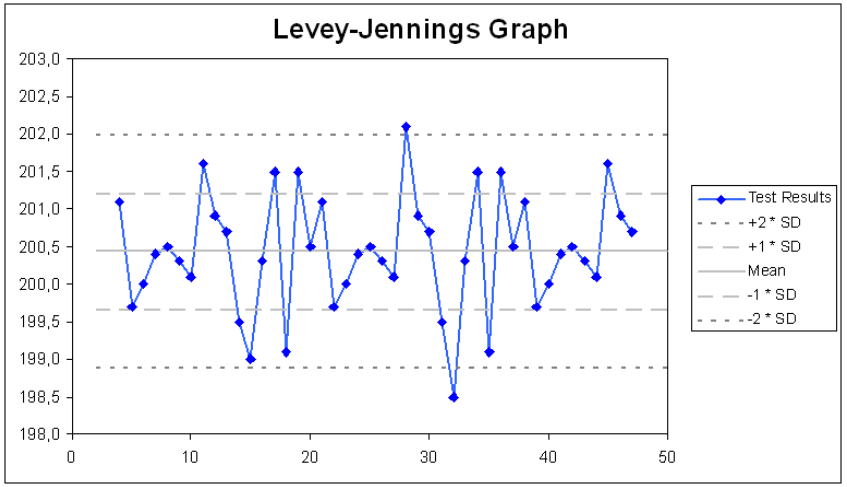


Fig.10 A picture of Prof. George Cembrowski from the web site of the University of Alberta, Canada. Cembrowski is a clinical pathologist and he is specialized in biochemistry, statistics and medical informatics. He has been very effective in the documentation of many statistical quality control methods in collaboration with Westgard and other researchers. He has worked extensively on the moving average theory, as well as the "average of normals", the anion gap, Bull's algorithm and the selection of control methods. He has also worked on external quality assessment, where he suggested specific rules for the detection of systematic errors. He has authored dozens of articles on quality control and other subjects, and he has co-authored (with R. Neill Carey) the book Laboratory Quality Management: Qc and Qa (1989).

Fig.11. A picture of Prof. James Westgard from the web site of the University of Wisconsin, USA. Until he retired, Westgard was a clinical chemist and a professor of clinical pathology at the medical school of the University of Wisconsin. Today he is the most famous researcher on quality control for automated analyzers. He has worked mostly on computer simulations, the Decision Limit Cusum chart, power functions, quality rules for the Levey-Jennings chart (multirule method), the Operational Process Specifications Charts, method validation, and the Six Sigma theory. He has

Fig.13. A picture of Prof. Curtis Parvin from the web site of the University of St. Lewis, USA. Parvin is a biostatistician and specialist in medical informatics and teaches these subjects at the University of Saint Lewis in Washington. He has contributed significantly to the theoretic documentation of power functions and other statistical issues concerning quality control in clinical chemistry.

Fig.14. A picture of Prof. Callum Fraser from the biographical article in Clinical Chemistry. Fraser is a professor of clinical chemistry at the Universities of Saint Andrews and Dundee in Scotland. He has authored papers on many subjects, most of which are about quality control. He is one of the pioneers of the theory of "quality specifications" in the field of clinical chemistry, with significant work on equations and charts which use biological variances as a basic parameter for the selection of the most suitable quality control method.

Figure 16. A picture of Dr. Carmen Ricós from James Westgard's web site. Ricós studied pharmacology at the University of Barcelona and works today in the biochemistry laboratory of the Vall d' Hebron Hospital in Barcelona. She has written many articles on the internal and external quality assessment in clinical laboratories, and is a member of quality committees for many international organizations. She is known especially for her initiative in concentrating biological variances for all substances measured at medical laboratories. These tables are used extensively today in the determination of quality specifications.

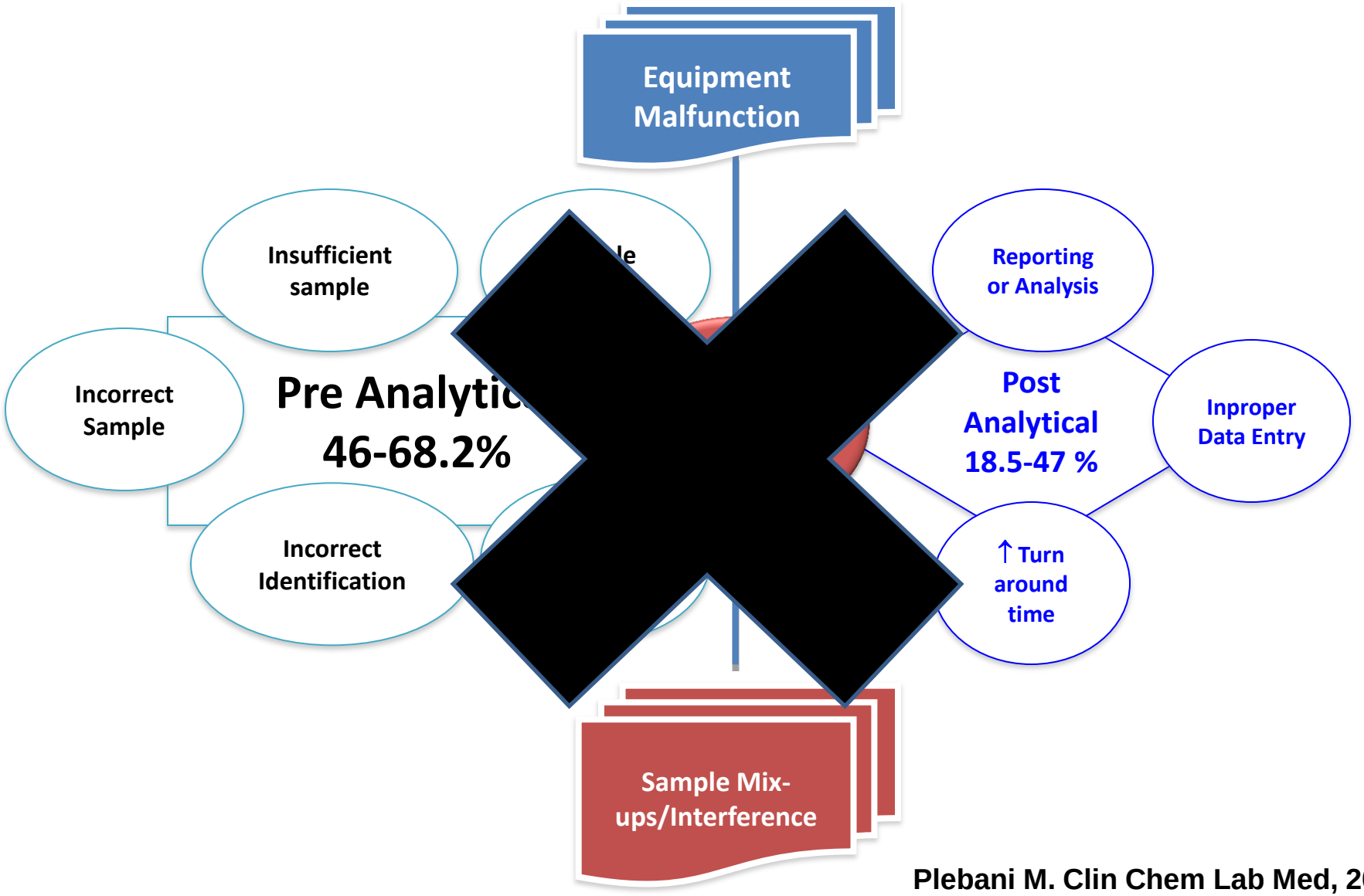
Standardizasyon ..

….. zaman, mekan ve metot farklılıklarına rağmen ölçümler arasında uyumun garanti altına alınmasıdır

Nasıl yapılacak

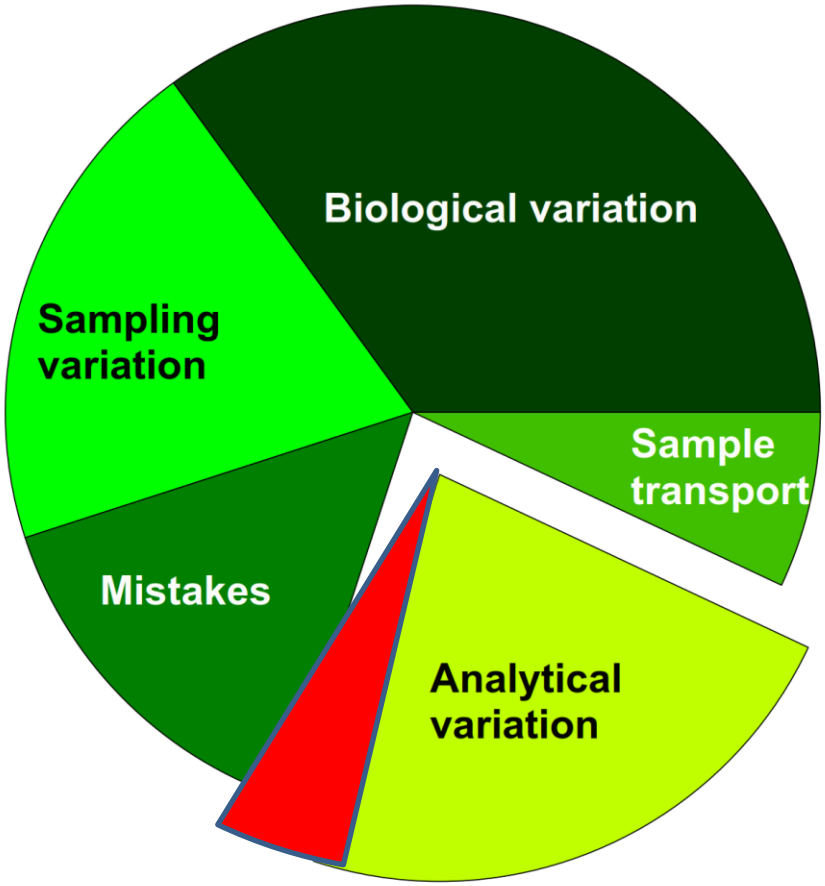
1. **Uygunsuzlukların ve varyasyonların azaltılması**
2. **Uygun bir standarta göre ölçümlerin uygunluğunun sağlanması**

Errors in clinical laboratories



Plebani M. Clin Chem Lab Med, 2006.
Kalra J. Clin Biochem, 2004

Daha Gerçekçi bir yaklaşım ile Test sonuçların değişimleri



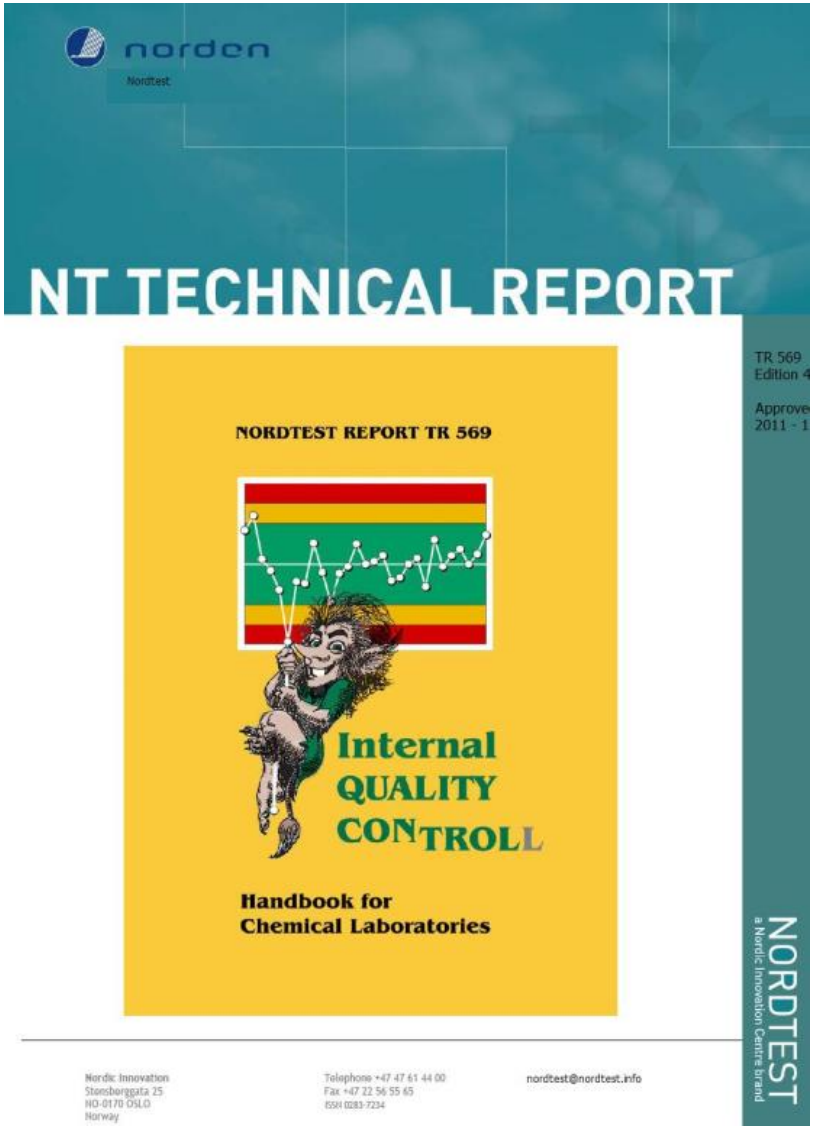
Standardizayonu etkileyen temel problemlerden biriside analitik problemler?

- Kalibrasyon Bias
  farklı ve non-commutable kalibratör, lotlar arası varyasyon
- **Tekrarlanabilirlik problemi**
- Saptama limitleri
  (LOD,LOB,LOQ)
- İnterferanslara yatkınlık
  hemoliz, ilaç, HAMA gibi
- Diğerleri
  Personel, Ekipman, tedarikçi, çevre vs

Elimizde hangi **dökümanlar** var

CLSI

C24-A3	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition
EP18-A2	Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition
EP21-A	Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline
EP23-A™	Laboratory Quality Control Based on Risk Management; Approved Guideline
EP32-R	Metrological Traceability and Its Implementation; A Report
GP27-A2	Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition



Target control limits – estimating the *s* for the control sample

When the control sample encompasses the whole analytical process from the sample entering the laboratory to the analytical report the control values will demonstrate the *within-laboratory reproducibility*, s_{Rw}, and one can compare the obtained s_{Rw} with the requirement. With most other control samples, e.g. standard solutions, blank samples, the obtained standard deviation is just part of the s_{Rw}. Here the analyst has to estimate if the obtained *s* on the control sample is sufficiently low to fulfil the analytical requirement - see Chapter 3.

Recommendations

Start of QC - In order to start the quality control of a new method preliminary control limits and central line can be estimated based on about 25 control values. Only after a longer time period, e.g. one year, can the control limits and the position of the central line be fixed. These first ***preliminary*** warning and action limits can also be based on results from method validation.

Fixed control limits – We do recommend fixed limits and not limits that are constantly changing for stable QC samples. In order to obtain reliable statistical control limits the calculated standard deviation should be based on control values over a one-year period and at least 60 control values. If the time period is shorter usually a too low estimation of the standard deviation is obtained since not all variation is taken into account.

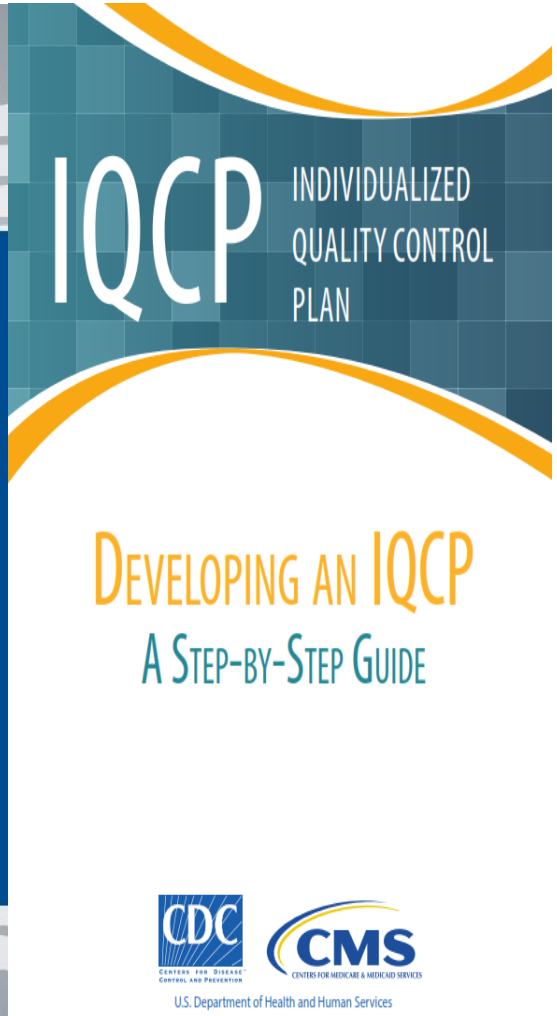
Fixed central line – We recommend fixed central line. In order to obtain a reliable central line a one-year period may be a good time period. If the time period is shorter an unreliable estimate is easily obtained.

Replicate analyses/samples - We also recommend the same number of sub-samples being used both for routine samples and control samples – if we report the mean value of duplicates (e.g. the whole process) for test samples we should also in the X-chart plot the mean value of duplicate analyses for the control sample. If a control sample is analysed several times in the same run, either one or all control values can be plotted in the X-chart.

Multielement analyses – When many analytes are measured in the same analytical run in QC e.g. ICP, XRF, GC, we strongly recommend using target control limits or wider statistical limits for those analytes that are less important. If for example 20 analytes are determined[5] and statistical control limits are used for all analytes, on average one control value (equal to 5 % of the control values) can be expected to be outside the warning limits in each analytical run. Also in about 1 out of 17 analytical runs a control value for one of the analytes is expected to be outside action limit, making ordinary interpretation very unpractical.

http://www.metrologia.cl/medios/NT-Technical%20Report-nordtest%20Report-TR-569.pdf

Kalite kontrol için yeni rehberler



http://www.eurachem.org

Eurachem
A Focus for Analytical Chemistry in Europe

Font

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Key Challenges in Internal Quality Control (2012)

The Eurachem Education and Training Working Group organised an international workshop on internal quality control in Berlin on Wednesday 10 to Thursday 11 October 2012. The event was hosted by the German member of Eurachem, EUROLAB Germany. The workshop covered analytical results from a range of sectors and disciplines including chemical analysis, testing, laboratory medicine and microbiology. The main focus was on internal quality control performed in the laboratory for the continuous monitoring of operations and results of measurements, in order to decide whether results are reliable enough to be released.

The workshop included invited lectures, short communications, posters and break-out sessions.
A training course on internal quality control was held at the same venue the day before the workshop, Tuesday 9 October.

Quick links:

- Training course programme
- Programme and presentations: Day 1
- Programme and presentations: Day 2
- Posters
- Scientific Committee

Workshop

Workshop Day 1 - Wednesday 10 October 2012

- Opening of the workshop
  Bertil Magnusson, SP Swedish Technical Research Institute, Sweden
- Internal quality control in chemical analysis - the big picture
  Michael Thompson, UK
  [View Abstract] [View presentation]
- Internal QC in a production laboratory - large series of automated analyses
  Ulla Lund, Eurofins, Denmark
  [View Abstract] [View presentation]
- The point of view of assessors when reviewing IQC activities
  Ursula Ellerbeck, DAkkS, Department for Analytical Chemistry, Germany
  [View presentation]
- Setting control limits based on demand on measurement quality
  Bertil Magnusson, SP Swedish Technical Research Institute, Sweden
  [View Abstract] [View presentation]
- IQC of DNA analysis
  Ricky Ansell, Swedish National Laboratory of Forensic Science, Linköping, Sweden
  [View Abstract] [View presentation]
- IQC in microbiological testing
  Christina Oscroft, Campden-BRI, UK
  [View Abstract] [View presentation]

Poster session

Breakout sessions offered:

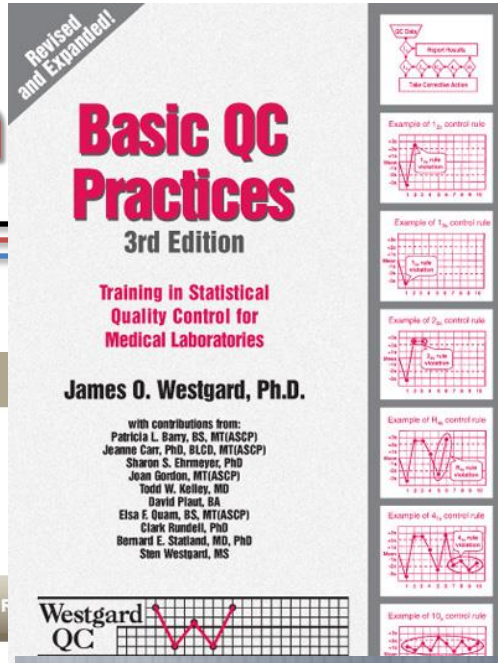
1. Internal QC – Accreditatation body and Laboratory points of view when assessing a laboratory according to the ISO standards 17025, 15189
2. Setting control limits – statistical and target limits
3. QC for laboratories handling many samples
4. Following up QC failures

Summary of breakout sessions (all sessions)

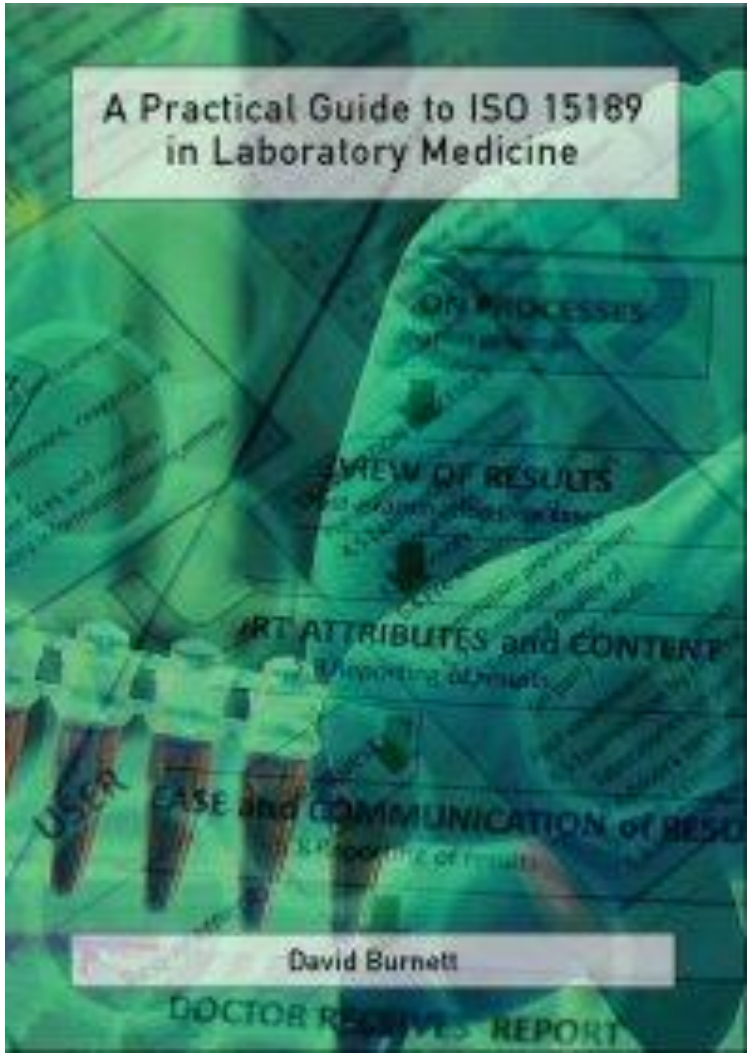
A Practical Guide to Internal Quality Control (IQC) For Quantitative Tests in Medical Laboratories, Version 2.0

February 2015

http://www.westgard.com

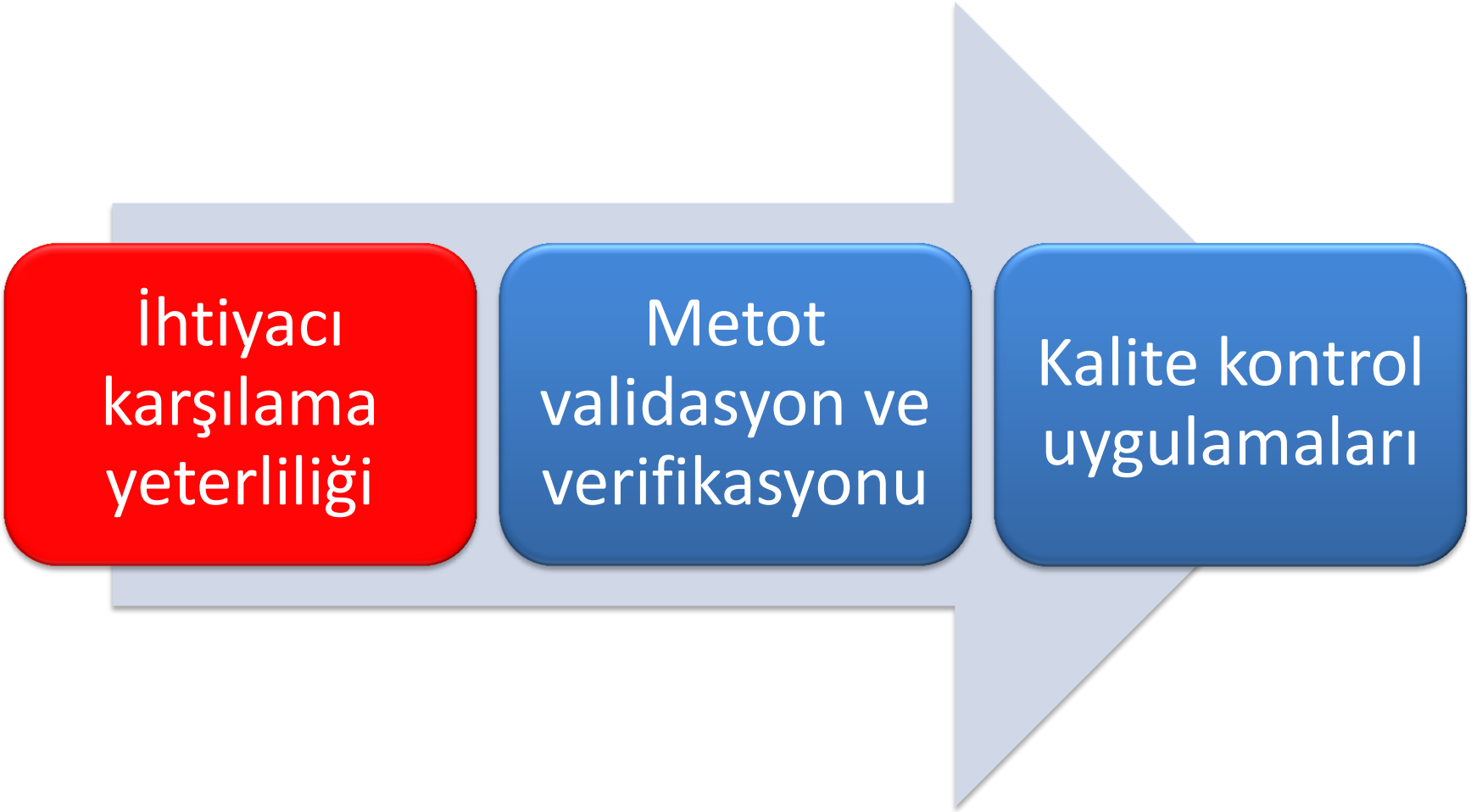


A Practical Guide to ISO 15189 in Laboratory Medicine / 2013



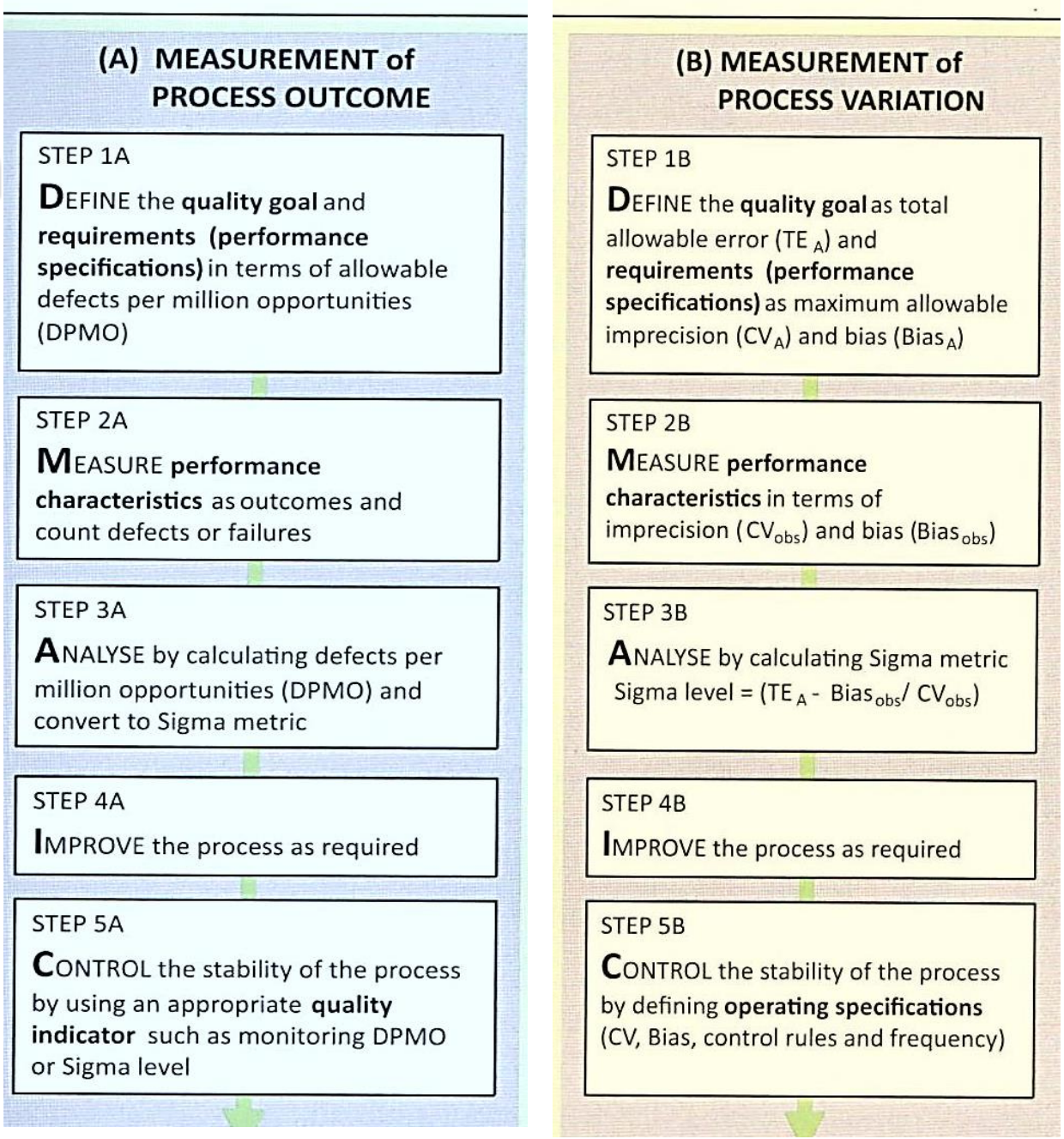
Laboratuvarda Analitik Kalitenin 3 Aşaması

Laboratuvarda Analitik Kalitenin 3 Aşaması



Kalite tanım

İlk ve en önemli, basamak



David Burnett (2013)

Quality Indicators in Laboratory Medicine: from theory to practice

Preliminary data from the IFCC Working Group P
Errors and Patient Safety''

Laura Sciacovelli[1,*], Maurice O'Kane[2], Younis Abdelwahab Skaik[3], Patrizio Caciagli[4], Cristina Pellegrini[4], Giorgio Da Rin[5], Agnes Ivanov[6], Timothy Ghys[7], Mario Plebani[1] and on behalf of the IFCC WG-LEPS

complexity of proce
of knowledge and a
paper is to report
laboratories from F
identify preliminary

DE GRUYTER DOI 10.1515/cclm-2012-0582 — Clin Chem Lab Med 2013; 51(1): 187–195

Mini Review

Mario Plebani*, Maria Laura Chiozza and Laura Sciacovelli

Towards harmonization of quality indicators in laboratory medicine

Analitik dönem Kalite indikatörleri

Table 2 - Quality indicators of the analytical phase: results performances.

QI-17	Percentage of "Number of unaccepta performances in EQAS/PT"
QI-18	Percentage of "Number of unacceptable corrected, per year/Total number of una
QI-19	Percentage of "Number of tests with CV% higher than selected target, per year/Total number of tests"
QI-20	Percentage of "Number of reports delivered outside the specified time for instrumentation failures, per year/Total number of reports"

Unity
Programa de Comparación entre Laboratorios Organizado por Bio-Rad Laboratories.
BIO-RAD

aQusera 24-7

STRATEGIES TO SET GLOBAL QUALITY SPECIFICATIONS IN LABORATORY MEDICINE

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

International Union of Pure and Applied Chemistry

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

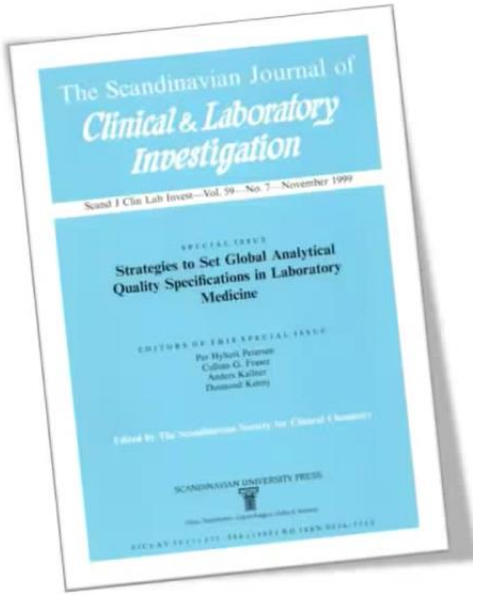
Nobelforum,
Karolinska Institutet
Stockholm April 24-26, 1999

Scand J Clin Lab Invest 1999; 59: 475

FOREWORD

The Stockholm Consensus Conference on Quality Specifications in Laboratory Medicine, 25–26 April 1999

Stockholm konsensusu



27 ülkeden 100'ün üzerinde bilim adamı bir araya geldi

First EFLM Strategic Conference on 'Defining analytical performance goals 15 years after the Stockholm Conference on Quality Specifications in Laboratory Medicine'

Model 1. Based on the effect of analytical performance on clinical outcomes

- a. an Outcome study investigating the impact of analytical performance on clinical outcomes
- b. a Simulation study investigating the impact of analytical performance on the probability of clinical outcomes
- c. a Survey of clinicians' and/or experts' opinion investigating the impact of analytical performance on medical decisions
- These goals will be most realistic since they are based on actual medical decision-making. However, only a few tests have a direct link to medical decisions, so this model is not universally applicable to all tests.

*Model 2. Based on components of biological variation of the measurand ****

- This is familiar territory. The goal here is to make sure the "**analytical noise**" does not drown out the biological signal. This works for tests where the biologic variation is not so small that the analytical specifications for noise are too stringent to be practical. However, in the new DRAFT it was pointed out that there are in fact significant limitations to this approach including the relevance and validity of the biological variation data.

Model 3. Based on state of the art

- This is least desirable model, but it based on the realistic performance "as is" of **the marketplace**. If the best laboratories can only achieve a certain quality, but cannot achieve the quality demanded by models 1 and 2, then the world will have to accept the current performance (for now). While technology is improved and (presumably) manufacturers develop better assays, the laboratory should set its specifications using this third model.

Clinical Chemistry 56:5
714–722 (2010)

Establishment of Outcome-Related Analytic Performance Goals

George G. Klee[1*]

4 grupta performansları toplayabiliriz

Table 1. Performance limits based on CLIA[a] and G-EQUAS[b] proficiency testing limits and biologic variation.

		Based on proficiency testing		Based on biologic variation[c]				
Analyte	Units	CLIA limits[a]	G-EQUAS, %RMSD[b]	CV_I	CV_G	Imprecision	Bias	Total error
Bilirubin	mg/L	±4 (or 20%)	13.0 (>20g/L)	23.8%	39.0%	11.9%	11.4%	31.1%
Calcium	mg/L	±10	6.0	1.9%	2.8%	0.8%	0.8%	2.4%
Cholesterol	mg/L	±10%	7.0	5.4%	15.2%	4.0%	4.0%	8.5%
Cortisol	μg/L	±25%	16.0	20.9%	45.6%	12.5%	12.5%	29.8%
Creatinine	mg/L	±3 (or 15%)	11.5	5.3%	14.2%	3.8%	3.8%	8.2%
Glucose	mg/L	±60 (or 10%)	11.0	5.7%	6.9%	2.9%	2.2%	6.9%
Iron	μg/L	±20%		26.5%	23.2%	13.3%	8.8%	30.7%
Phosphorus	mg/L	±0.3 (or 10.7%)	9.0	8.5%	9.4%	4.3%	3.2%	10.2%
Potassium	mmol/L	±0.5	4.5	4.8%	5.6%	2.4%	1.8%	5.8%
Sodium	mmol/L	±4.0	3.0	0.7%	1.0%	0.4%	0.3%	0.9%
Thyroxine	μg/L	±10 (or 20%)	12.5	4.9%	10.9%	2.5%	3.0%	7.0%
Total protein	g/L	±10%	6.0	2.7%	4.0%	1.4%	1.2%	3.4%
Triglycerides	mg/L	±25%	9.0	20.9%	37.2%	10.5%	10.7%	27.9%
Hematocrit	%	6%	5.0	2.8%	6.4%	1.4%	1.7%	4.1%
Hemoglobin	g/L	7%	4.0	2.8%	6.6%	1.4%	1.8%	4.1%
Leucocytes	10^9/L				19.6%	5.6%	5.6%	14.6%
Erythrocyte mean cell volume	fL				4.8%	0.7%	1.2%	2.3%

[a] CDC *(1)*.
[b] Westgard *(10)*.
[c] http://www.westgard.com/guest17.htm.

$$\%RMSD = \frac{\sqrt{k^2(SD_{cc}{}^2) + Bias^2}}{TV}$$

SD_{cc} = standard deviation
Bias = difference of observed mean from Target Value (TV)
k = statistical "coverage factor" to account for uncertainty (1 for metric, 3 to calculate specification)
TV = Target Value for the control sample (from manufacturer)

Table 2. Performance limits and medical utility[a] based on physicians opinions and analytic bias based on population distributions.[b]

Analyte	Units	Medical utility, % CV			Population analytic bias limits		
		Base value	Change value	Medical CV[a]	Decision limit	Bias limit[b]	Bias, CV
Bilirubin	mg/L	8	14	23.4%	11	±1	9.0%
Calcium	mg/L	90	106	7.0%	102	±1	1.0%
Cholesterol	mg/L	2100	2800	12.3%	2000	±23	1.2%
Creatinine	mg/L	10	15	17.2%	8	±1	12.5%
Glucose	mg/L	100	130	11.2%	1000	±20	2.0%
Iron	μg/L	150	100	17.2%	—	—	—
Phosphate	mg/L	350	250	14.3%	25	±1	4.0%
Potassium	mmol/L	3.8	3.4	4.8%	3.6	±0.1	2.8%
Sodium	mmol/L	125	130	1.7%	134	±1.5	1.1%
Thyroxine	μg/L	60	40	17.2%	50	±4	8.0%
Total protein	g/L	70	85	8.3%	63	±2	3.2%
Triglycerides	mg/L	1300	1900	16.1%	4000	±58	1.5%
Hematocrit	%	42	37	5.4%	35	±0.7	2.0%
Hemoglobin	g/L	150	138	3.6%	119	±3	2.5%
Leucocytes	10^9/L	6.0	3.4	16.4%	3.5	±0.2	5.7%
Erythrocyte mean cell volume	fL	95	100	3.2%	81.5	±0.7	1.0%

[a] Medical CV = 100 × [(change value − base value)/(1.645 × √2)]/[(change value + base value)/2]).
[b] Bias limit = 1 SD of change of population cumulative frequency distribution.

Çok fazla total hata!

Source	Cholesterol (+/- %)	HbA_{1c} (+/- %)	Stockholm level
NECP (USA)	20.0	-	1
NICE (UK except Scotland)	-	7.1	1/2a
Desirable biological goals (2012)	8.5	3.0	2a
NSPG Certification (USA)	-	7.0	3a
CLIA (USA) Rilibak (Germany)	10.0 13.0	- 18.0	4a 4a
CAP-PT (USA)	9.0	7.0	4b

KEY

NECP = National Cholesterol Education Programme
NICE = National Institute for Clinical Excellence
NSPG = National Glycohemoglobin Standardisation Programme
CLIA = Clinical Laboratory Improvement Act
CAP - PT = College of American Pathologists - Proficiency Testing

DE GRUYTER Clin Chem Lab Med 2016; 54(2): 235–239

Opinion Paper

Wytze P. Oosterhuis* and Elvar Theodorsson

Total error vs. measurement uncertainty: revolution or evolution?

Conclusions

The TE and ATE concepts originated by Jim Westgard and co-workers have served clinical chemistry well for decades and still represent a dominating influence on the theory and practice of clinical chemistry. The uncertainty paradigm is widely accepted in other fields of metrology but has suffered from complex mathematics and conceived impracticability. TE is not recognized either in the International Vocabulary of Metrology (4) nor in the GUM (5) which favors MU. The TE and MU paradigms may however appear as two sides of the same coin. Their equations describing variation, e.g. become the same when bias is eliminated and few independent causes of variation are at play. However, their fundamental philosophy is different and has different consequences on practical priorities in clinical chemistry.

Neither the separation proposed by Westgard nor replacing TAE with MU will solve the tensions between TAE and MU within clinical chemistry. In our opinion the TE/ATE models implemented in clinical chemistry can be substantially improved by implementing uncertainty component estimations and methods for uncertainty calculations already applied in other disciplines within metrology. Initial developments in this direction are currently being implemented in clinical chemistry [10, 11, 13].

The pros and cons of the TE and ATE concepts need to be debated, making way for methods that can incorporate all relevant causes of uncertainty when making medical diagnoses and monitoring treatment effects. The calculation of the uncertainty of our results represents an important new opportunity to improve the quality of the services of clinical chemistry to the diagnosis and monitoring the effects of treatment of patients. To be maximally productive this development should preferably proceed not as a revolution but as an evolution of the "total error" concept. However, such evolution depends on freedom from allegiance to all aspects of paradigms that have already served their purpose. This is a fitting lesson to be

Total hata bilimsel değil
Belirsizlik pratik değil

Analitik Standardizasyon ve Harmonizasyon Komitesi

Doç. Dr. Doğan Yücel
Doç. Dr. Tamer İnal
Dr. Murat Öktem
Prof.Dr. Mustafa Serteser
Doç.Dr. Mehmet Şenes
Prof.Dr. Muhittin Serdar
Doç. Dr. Macit Koldaş
Doç. Dr. Turan Turhan
Prof. Dr. Dildar Konukoğlu
Prof. Dr. Özkan Alataş
Prof.Dr. Diler Aslan
Dr. Ferzane Mercan

Analitik standardizasyon ve harmonizasyon komitesi ön çalışma sonuçları

						1. çalışma		2. çalışma	Öneri								Biolojik varyasyon		
	N	75.0	90.0	95.0	97.5	99	95.0	95.0	Türkiye		Spain 1	Spain 2	USA	Germany	Australasia	Switzerland	TE	CVa	Ba
Albumin (Alb)	3736	5	8	10	12	14	11	10	15	Switzerland	13	14	10	20	6	15	3.9	1.6	1.3
Alanin aminotransferase (ALT)	3966	7	13	18	25	36	17	18	20	CLIA	20	23	20	23	12	18	32.1	12.2	2
Alkaline phosphatase (ALP)	3637	10	18	26	34	40	27	26	30	CLIA	28	31	30	21	12	21	11.7	3.2	6.4
Aspartate aminotransferase (AST)	3941	6	11	16	22	30	15	16	20	CLIA	19	21	20	21	12	21	15.2	6	5.4
Chloride (Cl)	3541	3	6	8	10	12	8	8	9	Switzerland	8	9	5	8	3	9	1.5	0.6	0.5
Cholesterol(Cho)	3664	4	8	11	14	19	9	11	11	CLIA	10	11	10	13	6	10	9	3	4.1
Creatinine (Cre)	3883	7	14	19	23	28	20	19	20	Spain	28	20	15	20	8	20	6.9	2.2	3.4
Glucose (Glu)	3899	5	8	11	15	20	13	11	11	spain	10	11	10	15	8	10	7.9	3.3	2.3
HDL cholesterol (HDLC)	3529	10	18	24	29	33	26	24	30	CLIA	34	33	30	No	12	30	11.1	3.6	5.2
Lactate dehydrogenase (LDH)	3563	7	14	21	29	35	22	21	21	Switzerland	25	26	20	18	8	21	11.4	4.3	4.3
Potassium (P)	3624	4	6	9	11	15	8	9	9	Switzerland	7	8	NC	8	5	9	5.8	2.4	1.8
Protein (Prot)	3474	4	7	9	11	13	9	9	10	CLIA	10	12	10	10	5	12	3.4	1.4	1.2
Sodium (Sod)	3588	2	4	6	7	9	5	6	6	Switzerland	5	5	N C	5	2	6	0.9	0.4	0.3
Triglyceride (Tri)	3526	5	9	12	15	18	13	12	15	TÜRKİYE	15	18	25	16	12	20	27.9	10.5	10.7
Urea (Ure)	3748	6	10	14	20	41	13	14	15	TÜRKİYE	17	19	9	20	12	20	15.7	6.2	5.5
HbA1c	722	6	10	13	16	19	13	13	15	TÜRKİYE				18			..	2.8	..

Henüz yeterli sayıda verimiz oluşmamıştır. Buna rağmen veriler önceki çalışmalar ile uyumludur.

Ricos ve ark çalışması incelendiyse Probe error çalışması için laboratuvar sayısının veri olarak verilmesi gerekir. Ancak şu an için gerekli olmadığını düşünüyorum.

Dışlama oranı **%1.55** dir. Bu konuda eğitimlere devam edilmelidir.

Bu verilere göre Mustafa hocanın yaptığı gibi iç kalite kontrol bütcesinin belirleme çalışılmaları yapılmalıdır. Bu konuda bir arkadaşı görevlendirmeliyiz.

Çalışmaya 56926 veri alınmış. Yanlış yazıl olduğu düşünülen 104 veri çıkrılmıştır. Bunlar ekte verilmiştir.

Çalışmaya göre 3SD dışındaki veriler dışlanması apılmıştır. 781 veri çıkarılmıştır.

54 farklı laboratuvar iç kalite kontrol ve dış kalite değerlendirme sonuçları ile tekrar değerlendirme yapıldı

Çalışmanı 2. aşaması
54 laboratuvardan IKK verileri alındı
24'ü değerlendirilmeye alınabildi !

- 4x
- 7x
- 8xx
- 15x
- 16xxxx
- 18xx
- 19xxx
- 20xxxx
- 21x
- 22xxxxx
- 23xxx
- 24x
- 26xxxx
- 27xxxx
- 29xx
- 30x
- 31x
- 32xxx
- 33xxxx
- 34xxxx
- 35xxxx
- 38xx
- 39x
- 41xxx------
- 45xxxx
- 46xxx
- 47x
- 52xxxxx
- 54xxxxx
- Toplu bias
- Toplu EQC bias

		Bias					CV					Total hata	
Analit		total	1	2	3	4	Total	1	2	3	4	TH MEDIAN	TH MEAN
Glikoz	Düzey 1	-2.7	-8.4	-0.9	-1.9	0.7	4.6	3.8	2.8	2.7	1.8	5.9	7.2
mg/dL	Düzey 2	-1.0	-5.9	0.2	-0.1	2.3	4.1	3.0	1.8	1.9	3.4	4.1	5.1
Üre	Düzey 1	2.8	0.9	2.2	2.4	5.7	4.0	4.2	3.4	4.0	3.1	8.4	8.8
mg/dL	Düzey2	-5.0	-6.4	-4.9	-5.2	-3.8	3.2	3.4	3.1	3.2	2.8	10.3	10.2
Kreatinin	Düzey 1	-6.1	-6.2	-5.8	-5.0	-7.9	7.8	9.6	7.2	6.0	8.2	18.7	19.0
mg/dL	Düzey2	6.0	5.4	6.0	7.3	5.3	6.3	8.3	6.0	5.1	5.1	14.8	16.1
Total Protein	Düzey 1	-1.3	0.1	-1.4	-0.4	-3.6	4.9	5.1	4.3	5.1	4.6	8.8	9.2
g/dL	Düzey2	-2.1	-0.9	-2.4	-1.0	-3.9	5.5	6.1	4.8	5.0	5.5	10.4	10.9
Albümin	Düzey 1	4.3	5.2	10.0	-2.7	5.3	5.7	2.1	4.0	5.4	2.3	10.5	10.1
g/dL	Düzey2	1.6	1.8	6.3	-4.6	3.4	5.6	2.6	4.3	5.5	2.8	8.4	8.0
Kolesterol	Düzey 1	0.9	1.8	3.6	-0.5	-1.2	2.9	1.5	2.0	3.7	1.1	3.5	4.3
mg/dL	Düzey2	-17.9	-17.9	-15.6	-19.0	-19.1	2.9	1.2	2.1	3.9	1.7	21.6	21.6
Trigliserit	Düzey 1	-0.6	-2.4	0.1	-2.1	2.2	3.5	2.5	4.2	2.8	2.3	5.4	5.4
mg/dL	Düzey2	1.0	-3.6	0.6	2.6	5.0	7.1	9.1	7.1	5.2	3.3	11.8	11.4
HDL-Kolesterol	Düzey 1	-12.8	-14.3	-12.2	-11.9	-12.5	3.2	2.4	3.8	3.3	2.5	17.1	17.7
mg/dL	Düzey2	1.3	-1.3	5.4	2.0	-0.7	3.8	4.6	2.1	2.2	1.7	4.1	5.7
AST	Düzey 1	-2.1	-5.0	-0.7	-3.3	0.6	4.1	2.8	3.2	4.2	3.2	7.3	7.7
U/L	Düzey2	2.7	2.3	3.1	1.7	3.8	2.6	2.2	2.2	2.2	3.4	6.4	6.9
ALT	Düzey 1	1.5	0.6	3.3	2.9	-0.5	5.5	4.2	4.3	5.6	6.7	10.0	10.2
U/L	Düzey2	-4.8	-4.8	-5.1	-5.0	-4.1	3.3	2.3	2.7	2.7	5.0	9.4	10.0
ALP	Düzey 1	0.5	3.1	-0.1	-1.4	0.8	7.9	6.3	7.7	9.0	8.3	13.5	13.5
U/L	Düzey2	-2.0	-4.0	-4.4	0.7	-0.8	6.9	6.8	6.5	6.7	6.2	13.3	13.0
Sodyum	Düzey 1	-2.3	-2.1	-2.0	-2.5	-2.5	1.5	0.9	1.4	2.3	1.2	4.5	4.7
mmol/L	Düzey2	-2.4	-2.4	-2.2	-2.3	-2.7	1.8	1.3	1.6	2.6	1.5	5.0	5.3
Potasyum	Düzey 1	-1.0	-1.3	-0.7	-1.0	-0.8	2.7	2.5	2.2	3.4	2.6	5.1	5.3
mmol/L	Düzey2	0.9	0.5	1.6	1.1	0.4	2.7	2.6	2.4	2.9	2.9	5.3	5.3
Klorür	Düzey 1	-0.5	0.8	-0.2	-1.4	-1.4	3.0	1.6	2.4	3.5	3.4	5.6	5.0
mmol/L	Düzey2	-1.0	-0.9	-1.6	-1.1	-0.5	3.0	1.7	3.3	3.5	3.1	6.3	5.8
HbA1c	Düzey 1	-0.3	1.9	2.8	-1.8	-4.3	3.8	2.4	3.4	2.7	2.1	4.2	4.7
%	Düzey2	0.3	0.1	3.0	-0.6	-1.0	2.7	2.2	2.6	2.2	1.7	3.9	4.0
LDH	Düzey 1												
U/L	Düzey2												

Çalışma sonuçları

İKK DKD

		Bias			Tekrarlanabilirlik				Total hata						
		Mean	Median	10 - 90 P	Mean	Median	10 - 90 P	CV	Mean	Median	10 - 90 P	N	95	95	Türkiye
1	Albumin (Alb)	5.179	**1.11**	0.248 - 4.590	4.961	4.52	3.086 - 7.186	**8**	10.355*	10.220*	6.613 - 14.978*	3736	10.76078	10.214	15
2	Alanin aminotransferase (ALT	1.596*	**2.07***	0.158 - 4.798*	7.525	7.8	3.822 - 11.772	**10**	15.241	14.09	7.268 - 25.408	3966	16.62208	17.87	20
3	Alkaline phosphatase (ALP)	3.502	**2.51**	0.434 - 9.008	2.726*	2.750*	1.724 - 3.460*	**10**	7.327*	6.660*	4.026 - 16.577*	3637	26.95606	25.97	30
4	Aspartate aminotransferase (	2.568	**1.6**	0.162 - 8.542	4.542*	4.310*	2.818 - 8.937*	**10**	9.950*	9.250*	6.118 - 16.757*	3941	15.2758	16.18	20
5	Chloride (Cl)	0.711*	**0.779***	0.235 - 2.565*	4.676	4.58	2.252 - 7.230	**5**	8.779	8.35	4.734 - 12.842	3541	7.935676	7.818	9
6	Cholesterol(Cho)	1.44	**1.3**	0.0540 - 2.482	4.329	4.25	2.352 - 6.258	**6**	8.582	8.53	4.742 - 12.436	3664	9.160332	10.635	11
7	Creatinine (Cre)	2.39	**1.72**	0.122 - 4.694	5.750*	6.030*	3.011 - 9.884*	**8**	12.749	11.75	7.456 - 19.524	3883	19.87294	19.177	20
8	Glucose (Glu)	1.707	**1.35**	0.0680 - 3.942	4.142*	3.990*	2.566 - 6.572*	**6**	9.019	7.82	4.852 - 14.264	3899	12.99583	11.331	11
9	HDL cholesterol (HDLC)	3.534	**1.8**	0.230 - 8.306	4.606*	4.610*	2.895 - 7.474*	**10**	10.712*	10.560*	6.818 - 19.273*	3529	26.20792	23.606	30
10	Lactate dehydrogenase (LDH)											3563	22.11497	21.4605	21
11	Potassium (P)	1.114	**1.13**	0.134 - 2.266	3.209	2.9	1.586 - 4.126	**4**	5.690*	6.170*	3.222 - 9.188*	3624	7.954546	8.6	9
12	Protein (Prot)	1.768	**1.13**	0.228 - 4.460	4.959	4.78	2.344 - 7.254	**6**	8.771*	8.690*	6.118 - 14.801*	3474	9.413855	9.278	10
13	Sodium (Sod)	0.78	**0.66**	0.0900 - 1.594	3.757*	3.660*	2.304 - 6.815*	**4**	6.946*	6.500*	4.046 - 12.560*	3588	5.18298	5.501	6
14	Triglyceride (Tri)	1.52	**1.43**	0.360 - 3.066	5.643	4.94	2.264 - 9.216	**8**	10.831	9.73	5.688 - 17.898	3526	12.56471	12.352	15
15	Urea (Ure)	1.131*	**1.350***	0.241 - 2.546*	5.353*	4.960*	3.390 - 11.211*	**8**	10.375*	9.450*	6.712 - 19.999*	3748	12.61724	14.094	15

Örnek 1

Kurum Adı:
Tıbbi Biyokimya Sorumlu Uzmanı Ad-Soyad:

												İç Kalite Kontrol	
Analit		4/1/2014	4/2/2014	4/3/2014	4/4/2014	4/7/2014	4/8/2014	4/9/2014	4/10/2014	4/11/2014	4/14/2014	Hedef Değer	Minimum-Maksimum
Glikoz	Düzey 1	102	100	104	98	99	101	102	102	97	100	98.2	90,2-106,2
mg/dL	Düzey 2	*	*	*	*	*	*	*	*	*	*	*	*
Üre	Düzey 1	40	44	36	43	35	38	38	36	38	37	38.4	33,9-42,9
mg/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
Kreatinin	Düzey 1	1.4	1.4	1.3	1.11	1.3	1.2	1.4	1.4	1.3	1.3	1.45	1,11-1,79
mg/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
Total Protein	Düzey 1	5.26	5.47	5.46	4.92	5.86	5.53	5.21	5.24	5.14	5.17	5.38	4,85-5,91
g/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
Albümin	Düzey 1	3.6	3.7	3.6	3.5	3.6	3.5	3.7	3.6	3.6	3.8	3.93	3,43-4,43
g/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
Kolesterol	Düzey 1	153	147	151	149	144	144	145	147	146	152	149	135-163
mg/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
Trigliserit	Düzey 1	91	90	91	86	86	84	87	87	87	90	86.9	77,9-95,9
mg/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
HDL-Kolesterol	Düzey 1	43	45	46	48	43	44	42	44	40	44	43.7	38,2-49,2
mg/dL	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*
AST	Düzey 1	42	43	42	49	47	43	51	47	41	46	46.4	39,9-52,9
U/L	Düzey2	*	*	*	*	*	*	*	*	*	*	*	*

Tek düzey

Her zaman Firmanın önerisi olan aralık kullanımı

Örnek 2

Analit	7/8/2014	7/9/2014	7/10/2014	7/11/2014	7/14/2014	7/15/2014	7/16/2014	7/18/2014	7/21/2014	7/22/2014	7/23/2014	7/24/2014	7/25/2014	7/31/2014	İç Kalite Kontrol	
															Hedef Değer	Minimum-Maksimum
Glikoz	76	76	75		76	74		76		76	75		75	75	73.6	66,1-81,1
mg/dL	281			276			277		287	277		276			283.5	266-301
BUN	19		20	19	19			20		19		20	19	19	20	18,5-21,5
mg/dL		51	52				52		51	51	53		53		53.1	50,1-56,1
Kreatinin	1		1				1	1.1		1		1			1.07	0,95-1,19
mg/dL		5.4		5.4		5.7		5.7		5.2		5.7		5.5	5.59	5,19-5,99
Total Protein	3.8		3.8		3.7		3.6		3.8	3.8			3.8	3.8	3.71	3,21-4,21
g/dL	6.9	6.9		6.9		7		7		6.9	6.9	7			6.89	6,39-7,39
Albümin	2.2		2.2		2.3		2.2		2.3	2.1			2.3	2.2	2.25	1,95-2,55
g/dL	4.3			4.3	4.4		4.3		4.4	4.3	4.4				4.49	3,99-4,99
Kolesterol	137		136		137		136	137		136	137		136		136	123-149
mg/dL		229		223				229	226	223		229			227.8	211,8-243,8
Trigliserit	112		114	116		115			112	116		115		112	121	104-138
mg/dL	242		245	238		248			244	248		247		245	262.5	235,5-289,5
HDL-Kolesterol	47		48	48		47			47	48		48		47	48.3	43,6-53

Bazı günler düzey 1

Bazı günler düzey 2

Örnek 3

													Düzey1;		Düzey2		Düzey3	
7/10/2014	7/11/2014	7/14/2014	7/15/2014	7/16/2014	7/18/2014	7/21/2014	7/22/2014	7/23/2014	7/24/2014	7/25/2014	7/31/2014	Analit	Hedef D	Minimum	Hedef D	Minimum	Hedef	Minimum
213	42	210	43	210	213	42	228	45	228	43	42	**Glikoz**	44	36-52	225	205-245	390	356-424
370	218	374	216	372	382	209	404	226	394		216	mg/dL						
36	8	35	8	36	35	8	34	8	35	7	7	**Üre**	7	(5-9)	34	30-38	61	55-67
62	35	63	34	63	63	34	62	34	62		35	mg/dL						
4.3	1.17	4.44	1.02	4.42	4.45	1.03	4.3	1.04	4.6	1.02	0.94	**Kreatinin**	0.98	0.78-1.18	4.45	4.05-4.85	7.95	4.75-11.15
7.2	4.5	7.76	4.34	7.67	7.76	4.38	7.73	4.4	7.93		4.3	mg/dL						
6	3.7	5.7	3.7	5.6	5.8	3.8	5.8	3.8	5.9	3.7	3.9	**Total Protein**	4	3.6-4.4	6.2	5.6-6.8	8.5	7.5-9.5
8	5.7	7.9	5.7	7.7	7.9	5.8	7.7	5.8	7.8		5.9	g/dL						
3.8	2.3	3.6	2.2	3.5	3.6	2.3	3.6	2.3	3.8	2.3	2.3	**Albümin**	2.4	2.0-2.8	3.7	3.1-4.3	5.2	4.4-6.0
5.3	3.5	4.9	3.7	5	5	3.7	4.9	3.6	5.3		3.7	g/dL						
134	87	135	87	133	136	91	134	89	136	87	88	**Kolesterol**	100	85-115	146	126-166	218	198-238
190	134	185	130	182	183	139	179	137	182		134	mg/dL						
96	83	113	80	105	114	82	108	81	114	74	76	**Trigliserit**	71	56-86	108	88-128	160	135-185
125	107	134	108	135	140	108	133	108	137		109	mg/dL						
28	29	30	30	29	30	30	30	29	29	28	31	**HDL-Kolesterol**	29	23-35		23-35		23-35
												mg/dL						
179	35	173	33	172	173	33	173	32	175	33	33	**AST**	30	25-35	182	157-207	327	287-367
325	175	310	173	305	312	175	308	173	307		176	U/L						

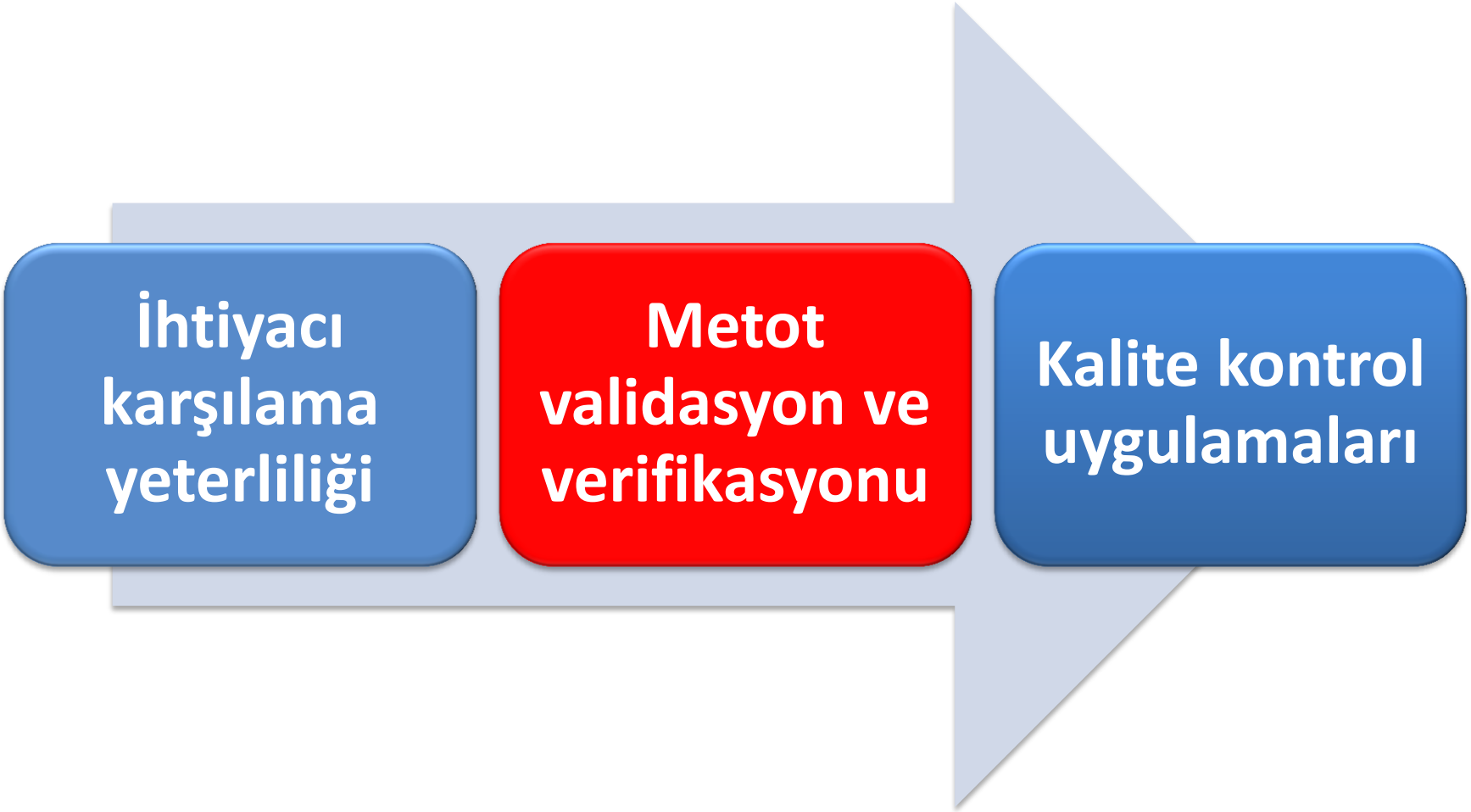
3 düzeyin değişen 2 düzey seçimi

Analitik standardizasyon çalışma sonuçları ve ilgili rehberin hazırlanması

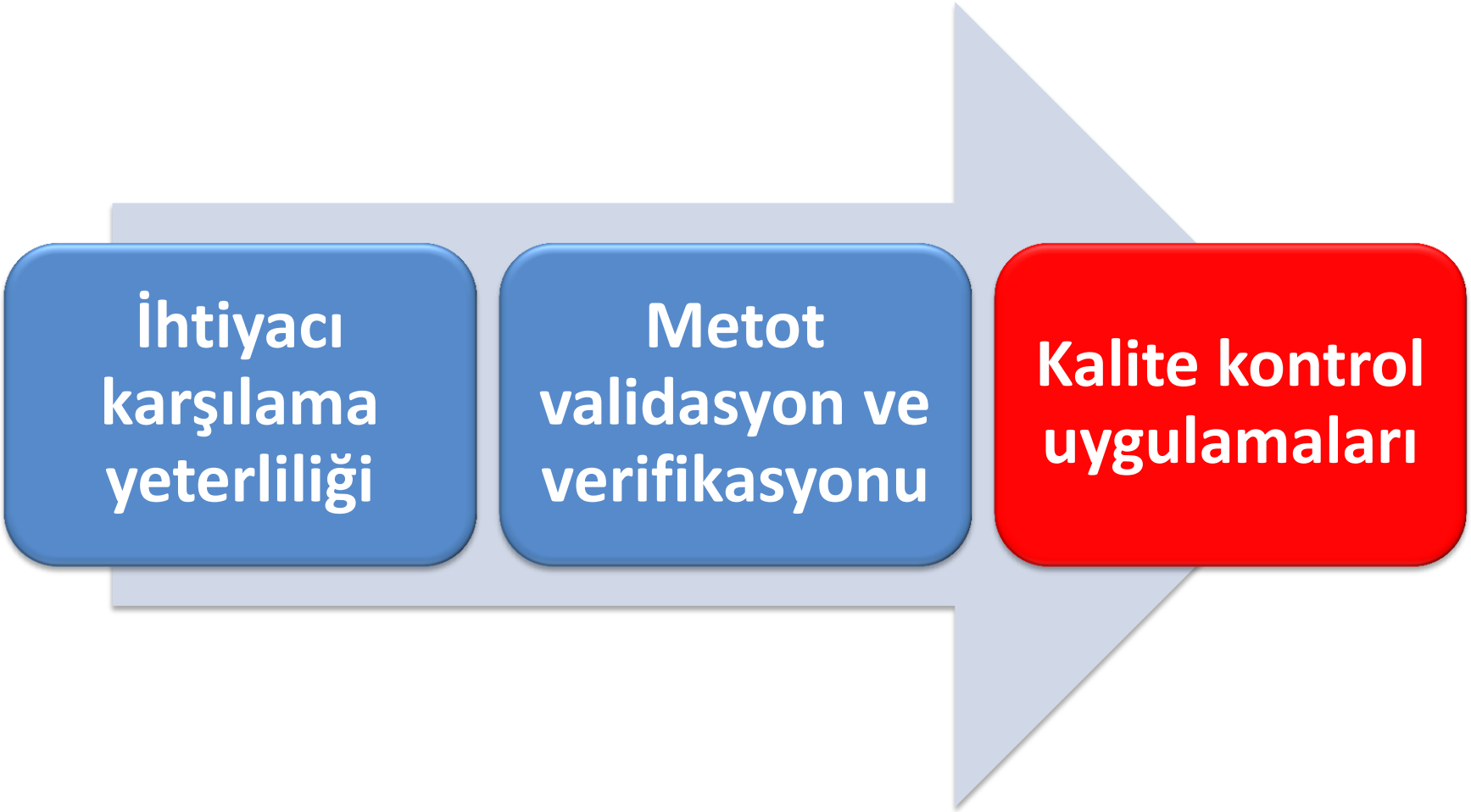
ANALİT	İZİN VERİLEN TOPLAM HATA (%)	ÖNERİLEN TEKRARLANABİLİRLİK (%)
ALBÜMİN	15	7.5
ALANİN AMİNOTRANSFERAZ	20	10
ALKALEN FOSFATAZ	30	10
ASPARTAT AMİNOTRANSFERAZ	20	10
KLORÜR	9	5
KOLESTEROL	11	5
KREATİNİN	20	10
GLİKOZ	11	5
HDL KOLESTEROL	30	10
LAKTAT DEHİDROGENAZ	21	10
POTASYUM	9	5
TOTAL PROTEİN	15	7.5
SODYUM	9	5
TRİGLİSERİT	15	7.5

İZİN VERİLEN TOPLAM HATA HEDEFLERİNE GÖRE LABORATUVAR PERFORMANSI İÇİN KISA REHBER

Laboratuvarda Analitik Kalitenin 3 Aşaması



Laboratuvarda Analitik Kalitenin 3 Aşaması

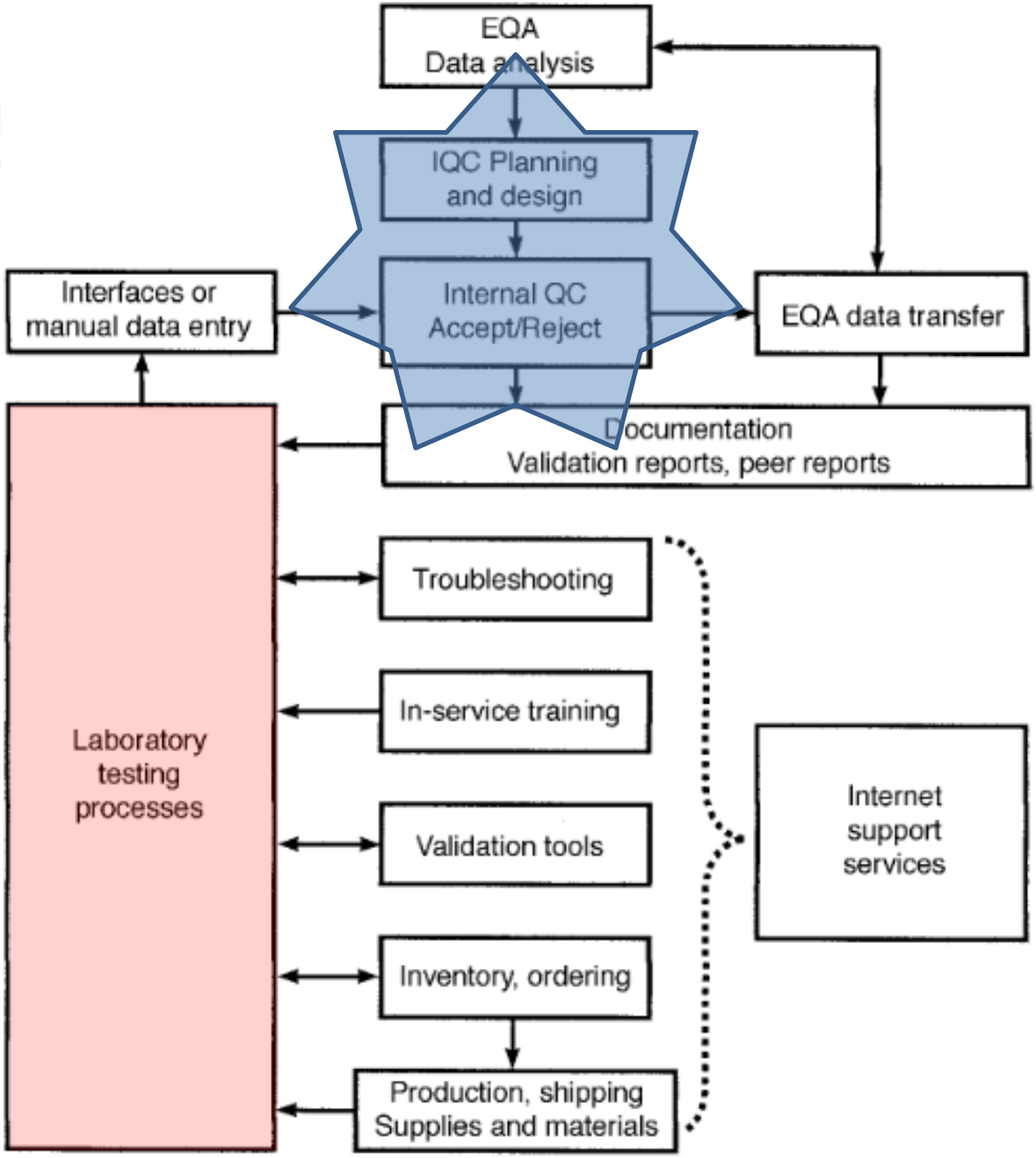


Kalite kontrol prosedürleri

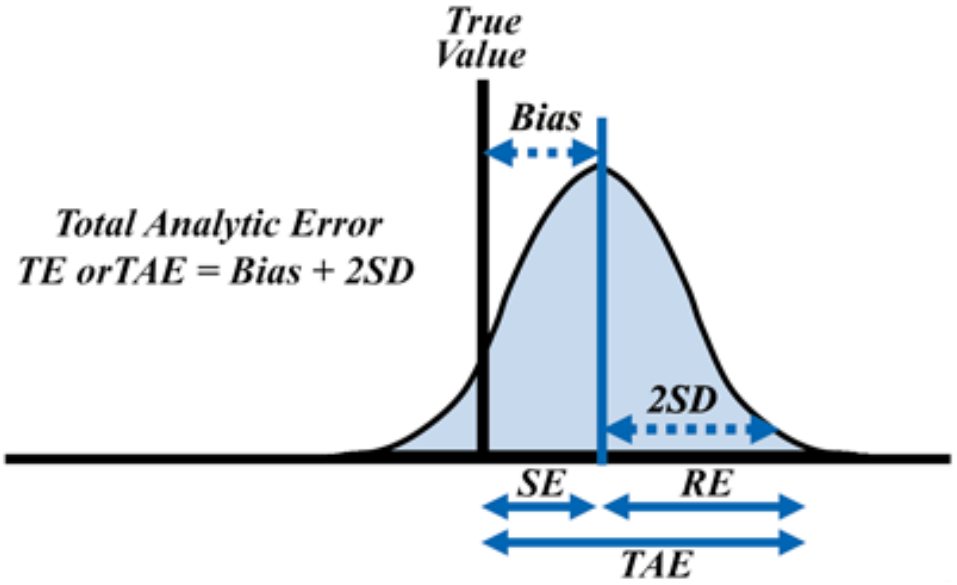
- Analitik döneme ait tekrarlanabilirlik ve doğruluk (?) çalışmaları ile
- sistem problemlerini
- çevre şartlarını
- personel performansını
- değerlendiren **hata tespit** prosedürleridir.

Hizmetin önceden saptanmış özellikleri taşıyıp taşımadığının ve ne ölçüde güvenilir olduğunun incelenmesi için kullanılan yöntemlerdir

Kolay değil !


EQA
Data analysis
IQC Planning
and design
Internal QC
Accept/Reject
Interfaces or
manual data entry
EQA data transfer
Documentation
Validation reports, peer reports
Laboratory
testing
processes
Troubleshooting
In-service training
Validation tools
Inventory, ordering
Production, shipping
Supplies and materials
Internet
support
services

Kabul edilebilir total hata Nasıl Kullanılır?



CLIA

Hata Bütçesi: Total Hatanın

Sistematik Hata **%25-50**,

Rastgele Hata **%25-33**

Biyolojik varyasyon

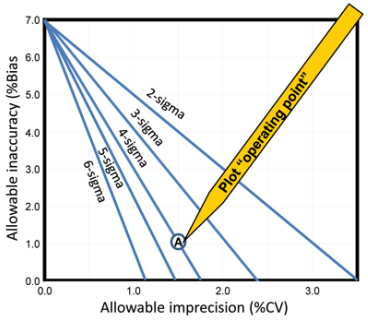
$CV_{w\text{-}day} \leq 0.25$ TE%

$CV_{total} \leq 0.33$ TE%

TE% ≤1.65 ΔRE + ΔSE

Sigma metrik sistem

ATE ≥ bias + 6 SD.



Hasta temelli KK

RMSD

Ehrmeyer, Laessing at al Clin Chem 36, 1736-40, 1990

Westgard and Burnett, Clin Chem 36, 1629-32, 1990

http://www.dgrhoads.com/db2004/ae2004.php

http://www.aacc.org/publications/cln/2013/september/Pages/Total-Analytic-Error.aspx#

QC Asistan 1.2 - [Levy Jennings Tüm Testler]

Giriş Veri Log Pencere Ayar

Test Grubu: Biyokimya

Cihaz: 2700-1

Kontrol: KONTROL 1 OUT

Son 20 Gün için hesapla

Özel tarih yazmaya izin ver

İlk Tarih: 28 Nisan 2009 Salı

Son Tarih: 28 Mayıs 2009 Perşembe

Ölçek: Otomatik 2S 1S 3S

Fosfor (P)

Göster

Yazdır

Kapat

Üre
Lot:26

Kolesterol
Lot:26

Albumin
Lot:26

Kreatinin
Lot:26

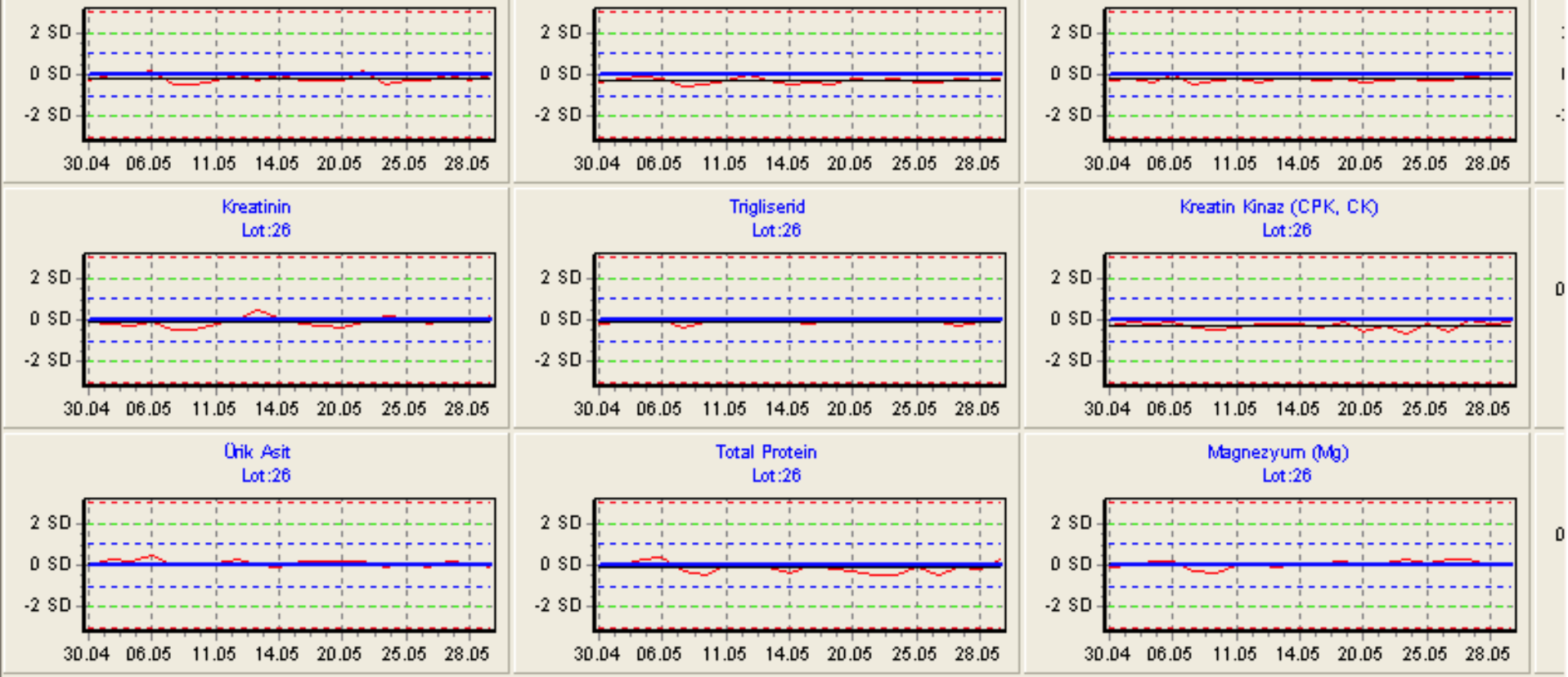
Trigliserid
Lot:26

Kreatin Kinaz (CPK, CK)
Lot:26

Ürik Asit
Lot:26

Total Protein
Lot:26

Magnezyum (Mg)
Lot:26



Başlat -LAB Asistan 2.3 QC Asistan 1.2 Microsoft PowerPoi... 09:52

4 IKK uygulaması önerir

- İstatistiki kalite kontrol uygulaması
- De Fault KK
- Ekivalan KK
- Alternatif KK
  - Risk Temelli KK
  - Hasta verileri ile KK
  - Spesifik (Rilibak gibi)

Kalite Kontrol şekli, sıklığı Ne Olmalıdır ?

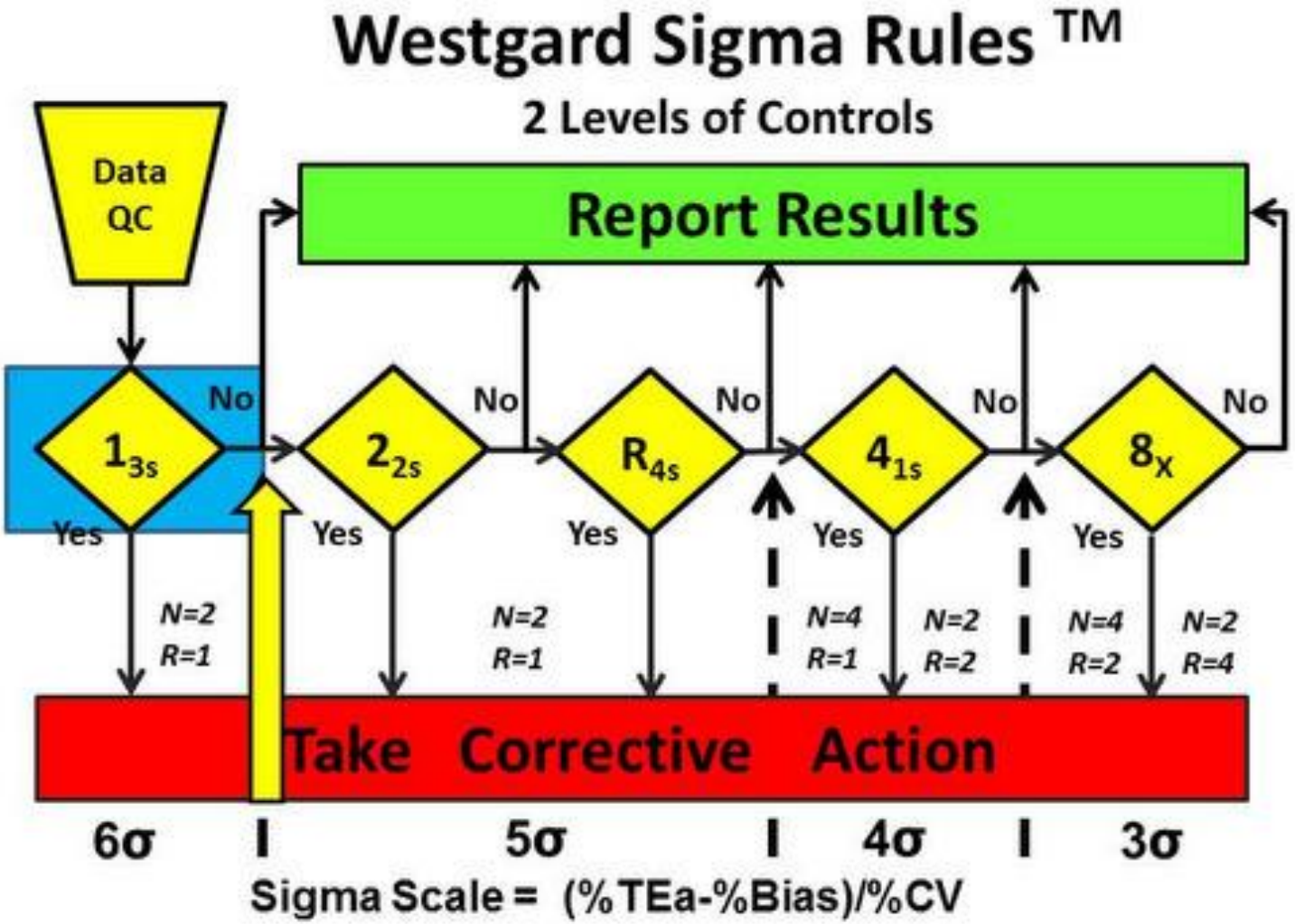
Temel iç Kalite kontrol prosedürü (CLSI C24 A3) (Rilibak ve Chembrowski hariç)

- İlk 20-25 gün analit ölcümü iki düzey yapılır
- Ortalama ve SS Hesaplanır
- L-J kartı üzerinde kurallar oluşturulur
- Yanlış negatif %5, doğru saptama %90 olacak şekilde algoritmalar oluşturulur

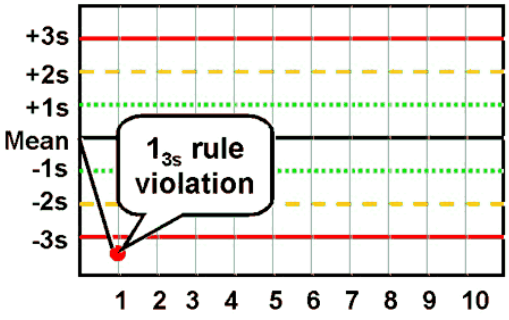
Kurallar :

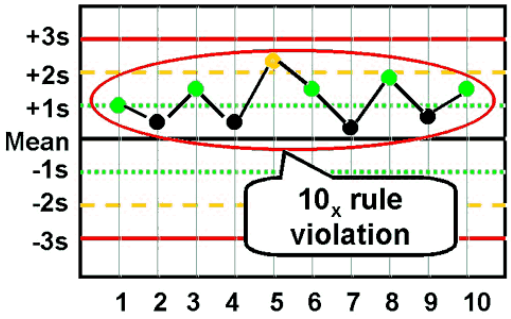
1_{2S}	kontrol et	
1_{3S}	işlemi durdur	rastgele hata
2_{2S}	işlemi durdur	sistematik hata
R_{4S}	işlemi durdur	rastgele hata
4_{1S}	işlemi durdur	sistematik hata
10_{x}	işlemi durdur	sistematik hata

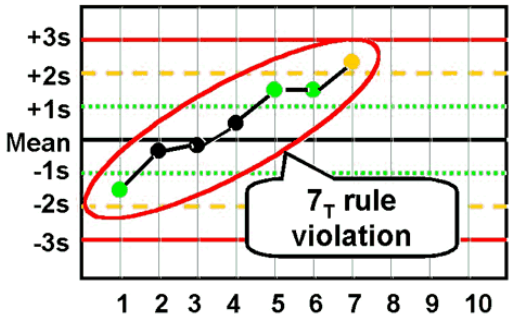
Sigma metrik çoklu kurallar

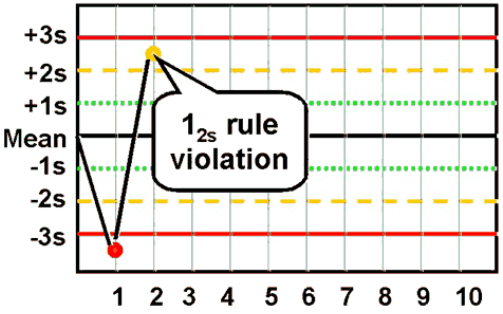


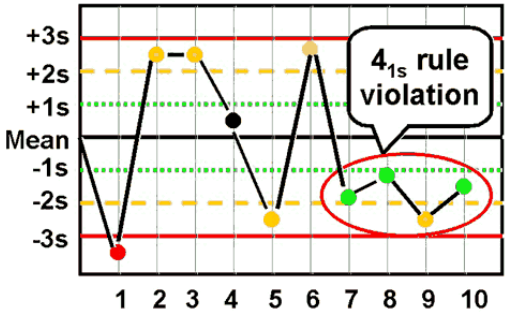
Kurallar


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
1 3s rule violation

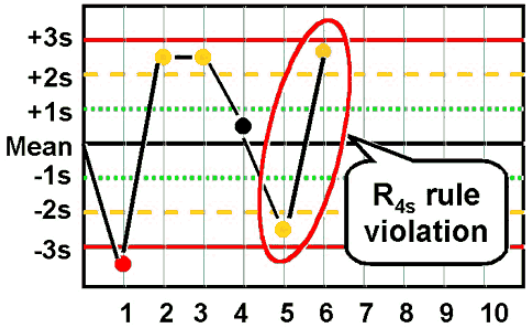

+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
10 x rule violation


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
7 T rule violation


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
1 2s rule violation


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
4 1s rule violation


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
2of3 2s rule violation


+3s
+2s
+1s
Mean
-1s
-2s
-3s
1 2 3 4 5 6 7 8 9 10
R 4s rule violation

- ...
- ....
- ....
- ....
- ....
- .....

Hata belirleme ve düzeltme süreci

Error Condition	High P_{fr}	High P_{ed}
No errors	1_{2s}	
Random error		$1_{2.5s}$, 1_{3s}, $1_{3.5s}$, R_{4s},
Systematic error		2_{2s}, 4_{1s}, $2of3_{2s}$, 3_{1s}, 6_{x}, 8_{x}, 9_{x}, 10_{x}, 12_{x}, cusum

RASTGELE HATA

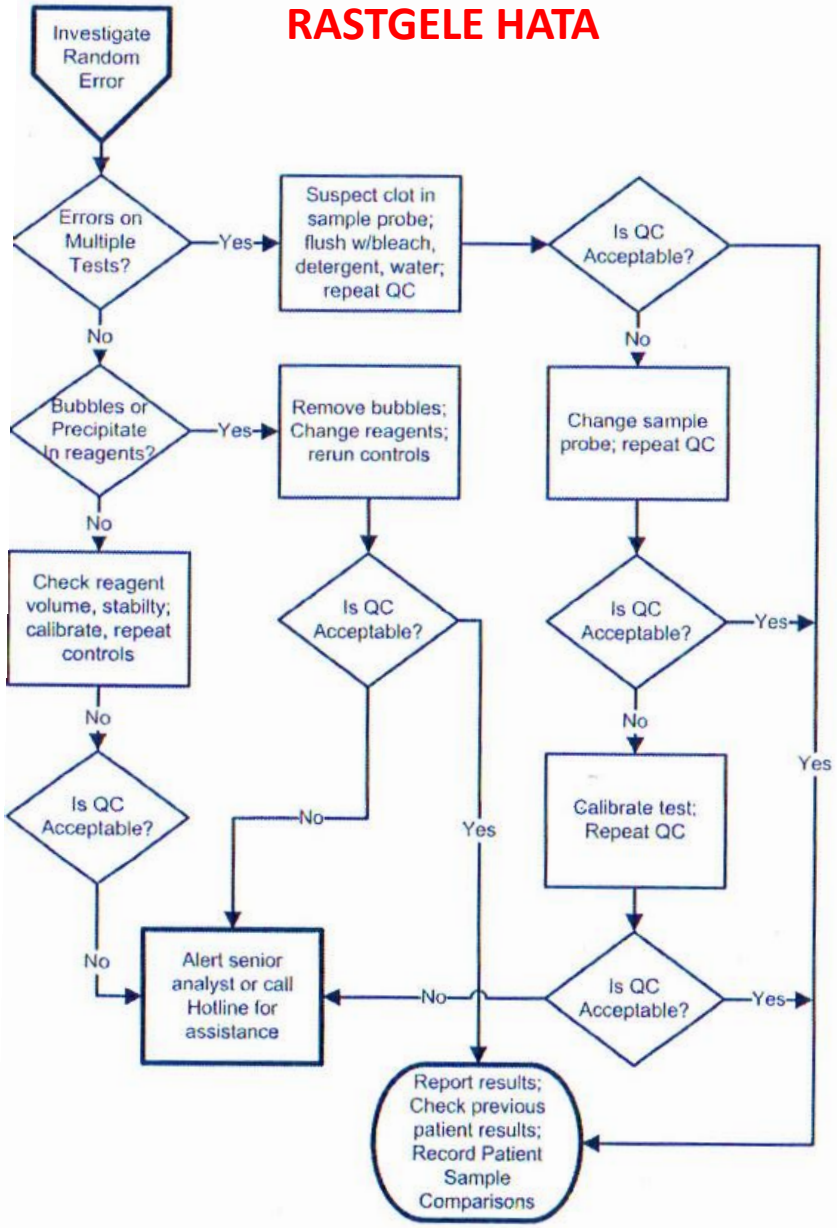


Figure 8-5. Troubleshooting Guide: Investigate Random Error

SİSTEMATİK HATA

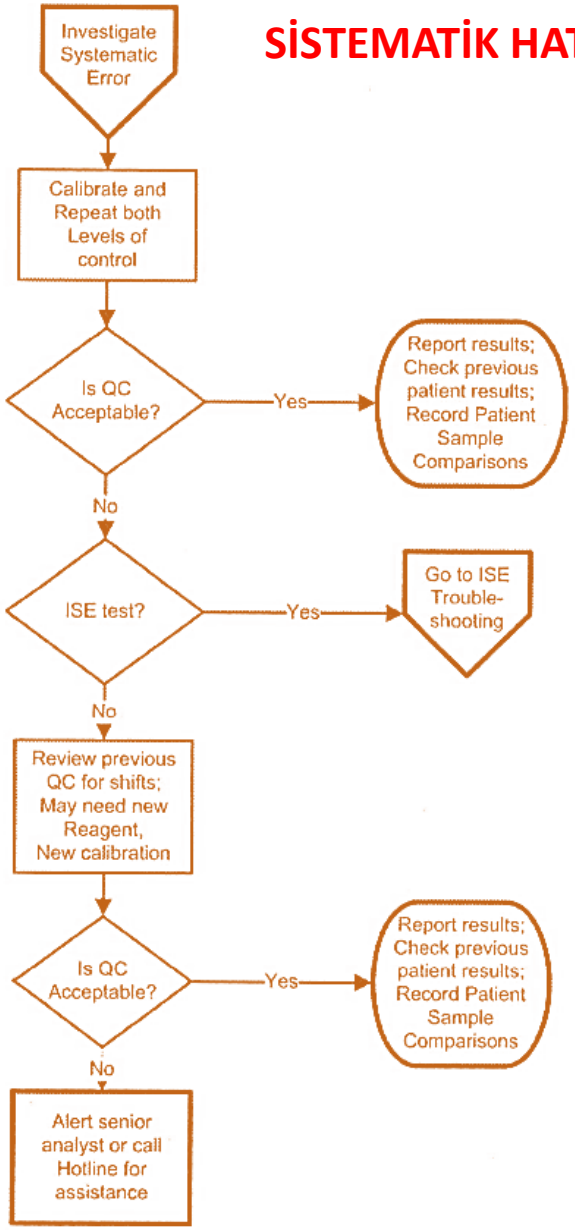
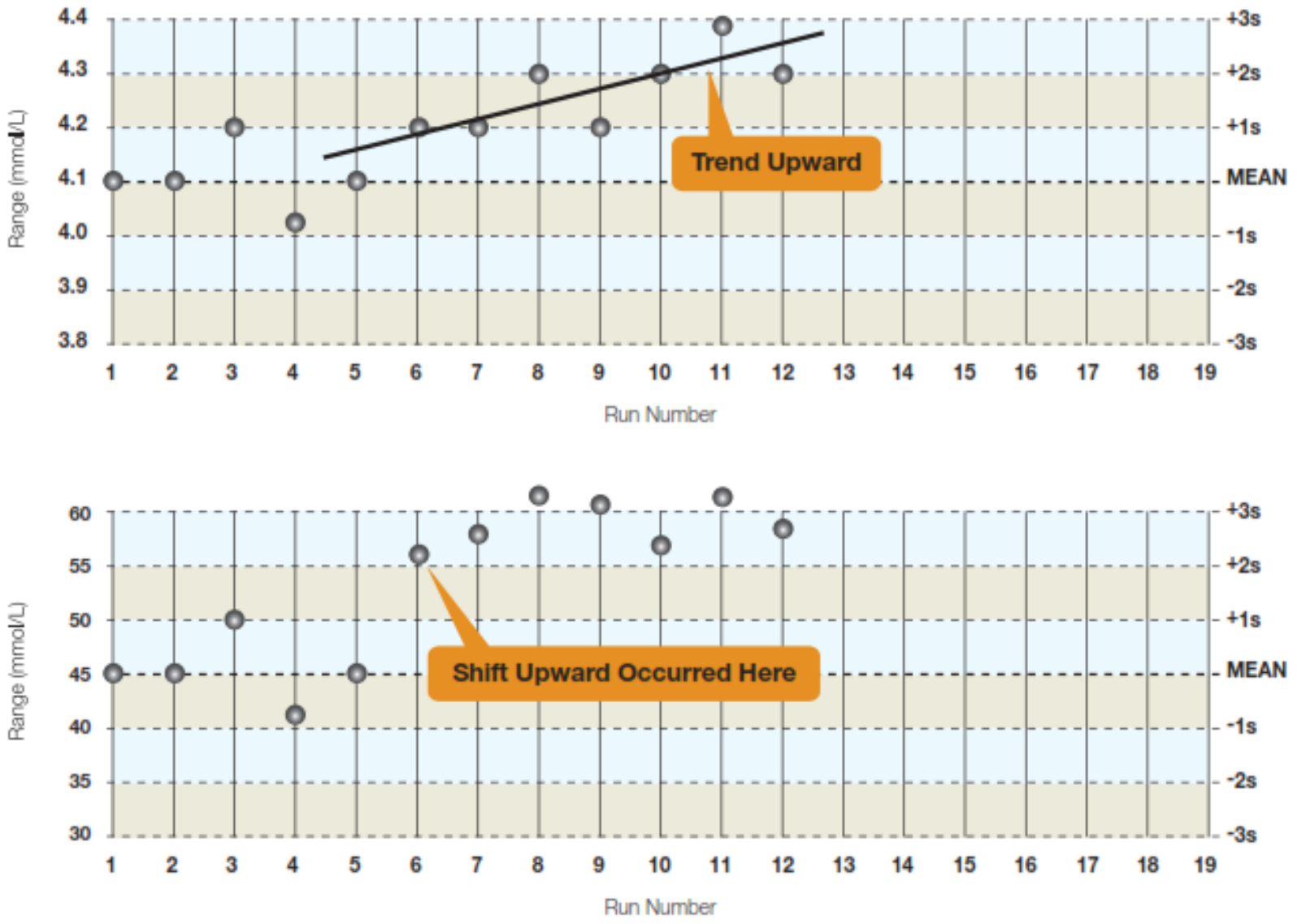


Figure 8-4. Troubleshooting Guide: Investigate Systematic Error

Figure 5: Trend Upward and Shift Upward



Systematic Error

Systematic error is evidenced by a change in the mean of the control values. The change in the mean may be gradual and demonstrated as a **trend** in control values or it may be abrupt and demonstrated as a **shift** in control values.

Trend

A trend indicates a gradual loss of reliability in the test system. Trends are usually subtle. Causes of trending may include:

- Deterioration of the instrument light source
- Gradual accumulation of debris in sample/reagent tubing
- Gradual accumulation of debris on electrode surfaces
- Aging of reagents
- Gradual deterioration of control materials
- Gradual deterioration of incubation chamber temperature (enzymes only)
- Gradual deterioration of light filter integrity
- Gradual deterioration of calibration

An example of trending on a Levey-Jennings chart is provided in Figure 5.

Shift

Abrupt changes in the control mean are defined as shifts. Shifts in QC data represent a sudden and dramatic positive or negative change in test system performance. Shifts may be caused by:

- Sudden failure or change in the light source
- Change in reagent formulation
- Change of reagent lot
- Major instrument maintenance
- Sudden change in incubation temperature (enzymes only)
- Change in room temperature or humidity
- Failure in the sampling system
- Failure in reagent dispense system
- Inaccurate calibration/recalibration

An example of a shift in test system performance is provided in Figure 5.

C24-A3
Vol. 26 No. 25
Replaces C24-A2
Vol. 19 No. 5

Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition

Kaliteyi tanımla

↓

%CV ve Bias ölç

↓

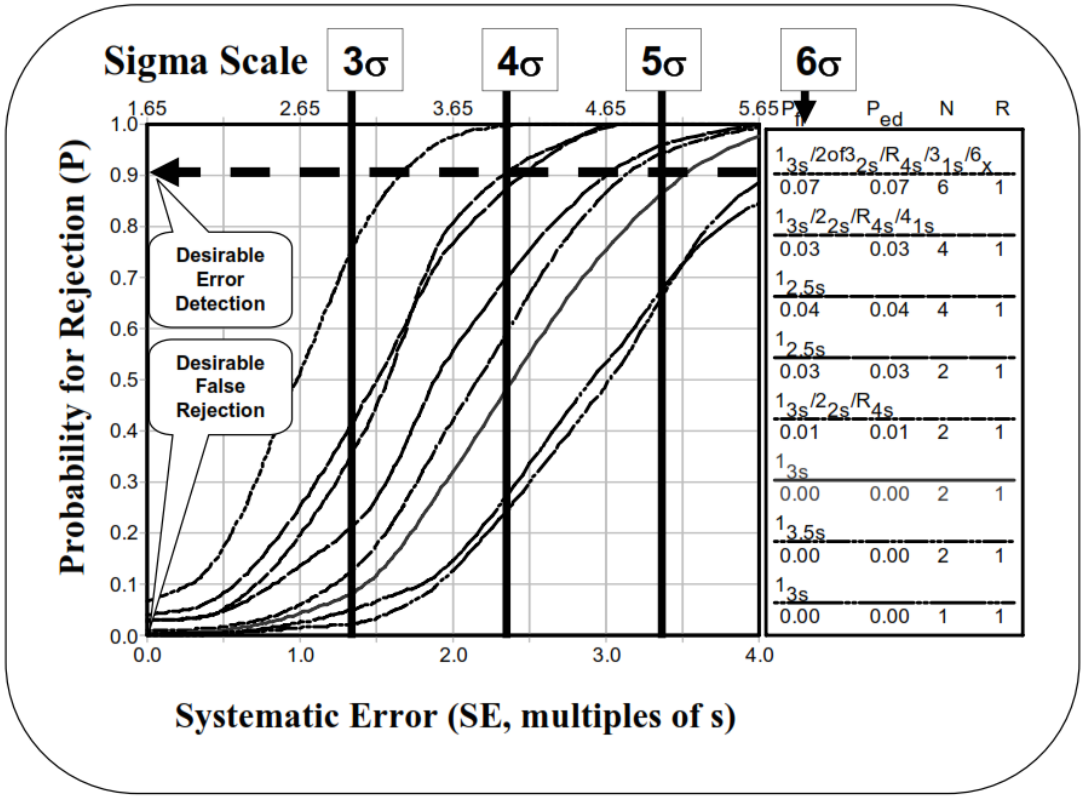
Kural berirle, N

↓

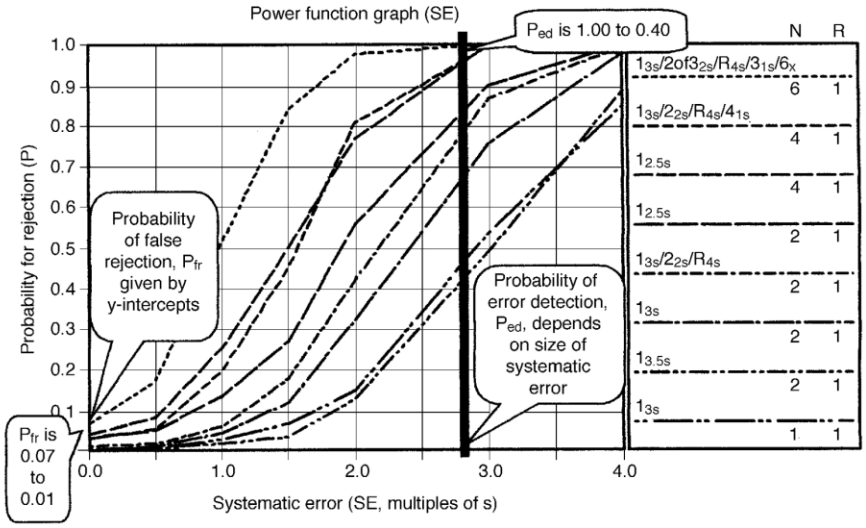
Kural uygulması belirle

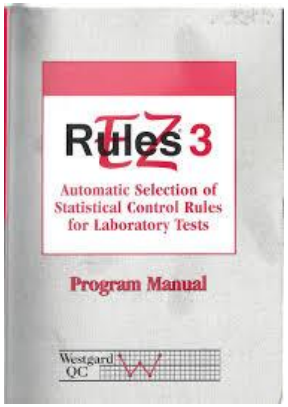
↓

Doğru KK uygula

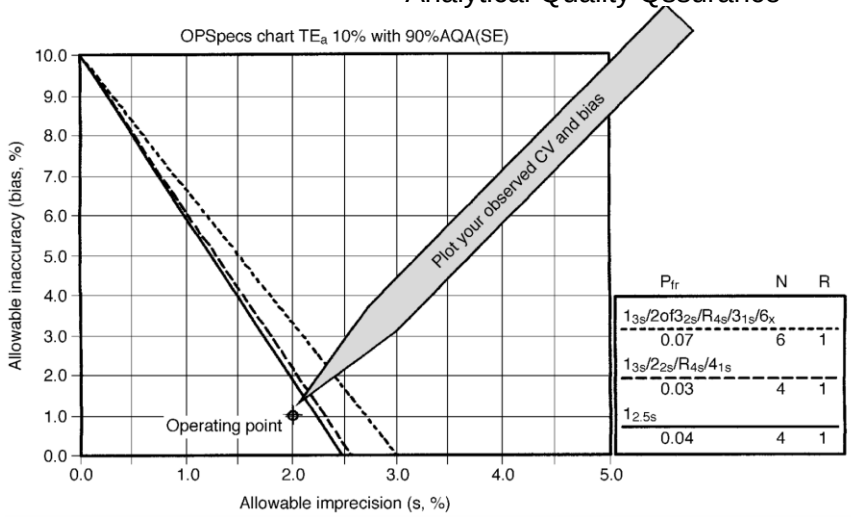


Westgard temelli İKK anlamak için OP Spect anlamak zorundayız

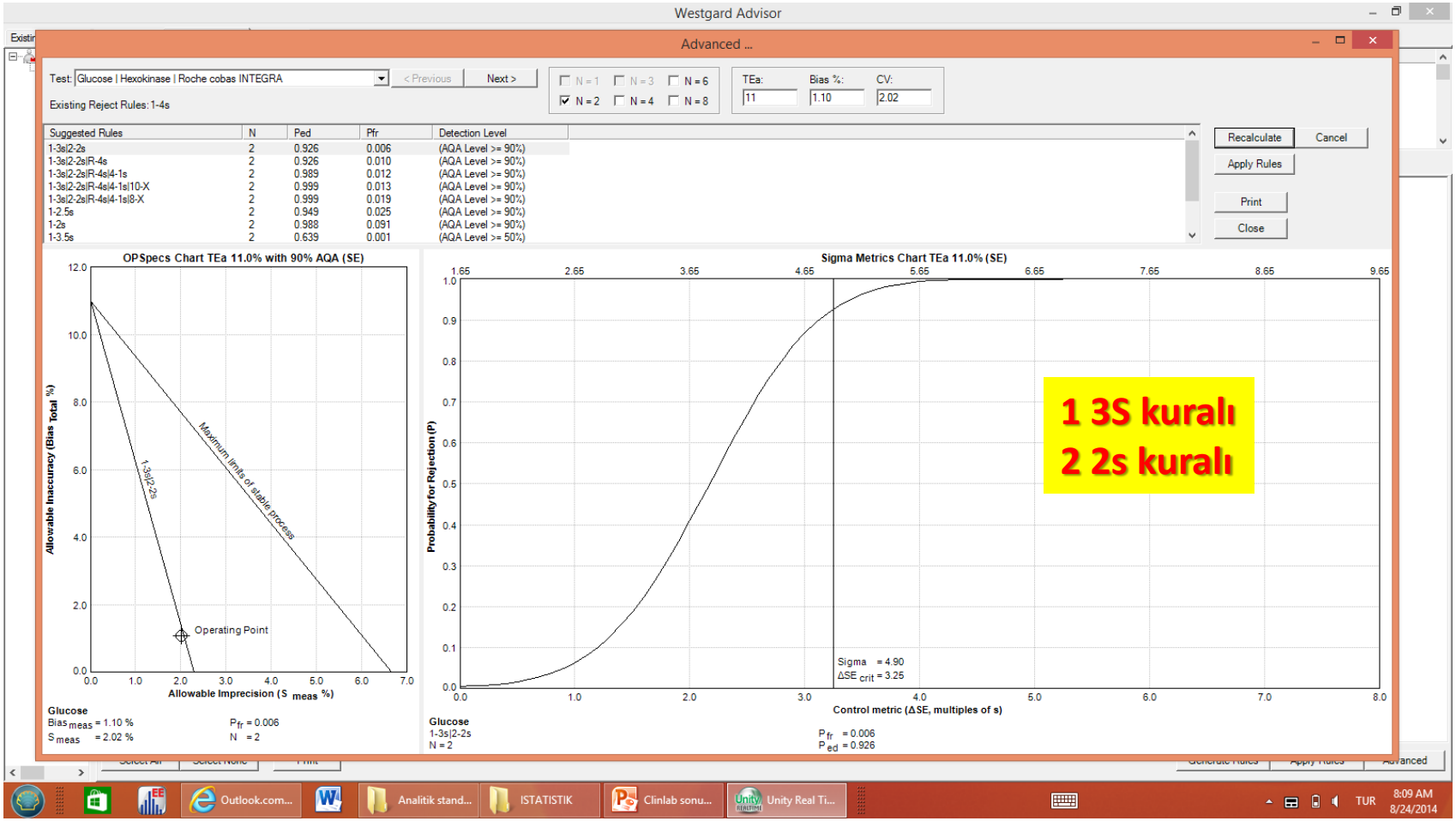




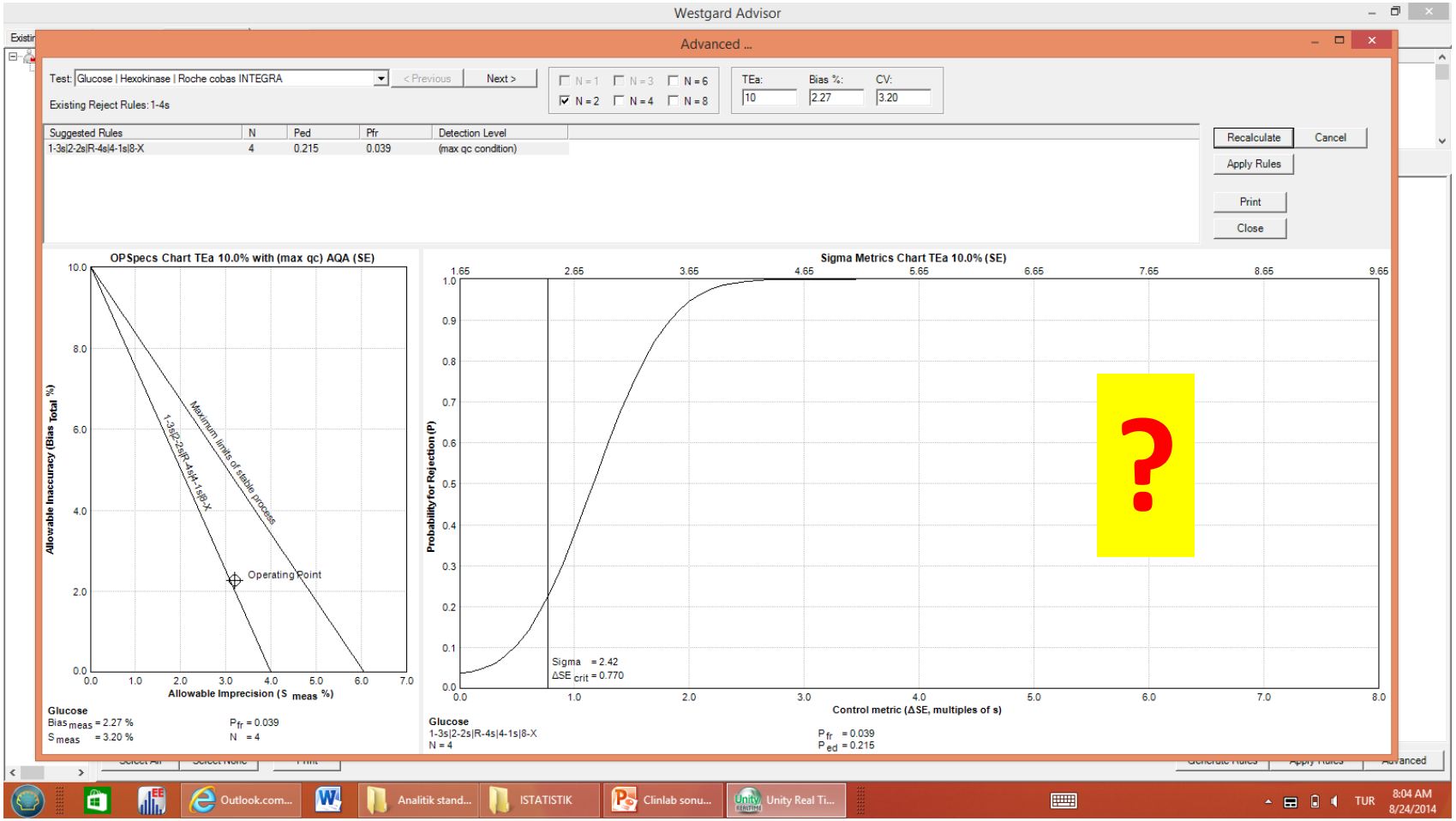
Analytical Quality Qssurance



Kolesterol TE:11, Bias:1.10, Pre:2.02



Albumin TE:10, Bias:2.27, Pre:3.20



Kontrol kurallarının YP etkileri

False Rejection Rates of Common Control Rules

Control Rule	# Controls per Run			
	1	2	3	4
1_{2s}	5%	9%	14%	18%
$1_{2.5s}$	1%	3%	3%	4%
1_{3s}	0%	0%	1%	1%
$1_{3.5s}$	0%	0%	0%	0%
$1_{3s}/2_{2s}/R_{4s}$	-	1%	2%	2%
$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	-	-	-	3%
$1_{3s}/2of3_{2s}/R_{4s}$	-	-	1%	-
$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}$	-	-	2%	-

Global Analytical Goal Survey Results

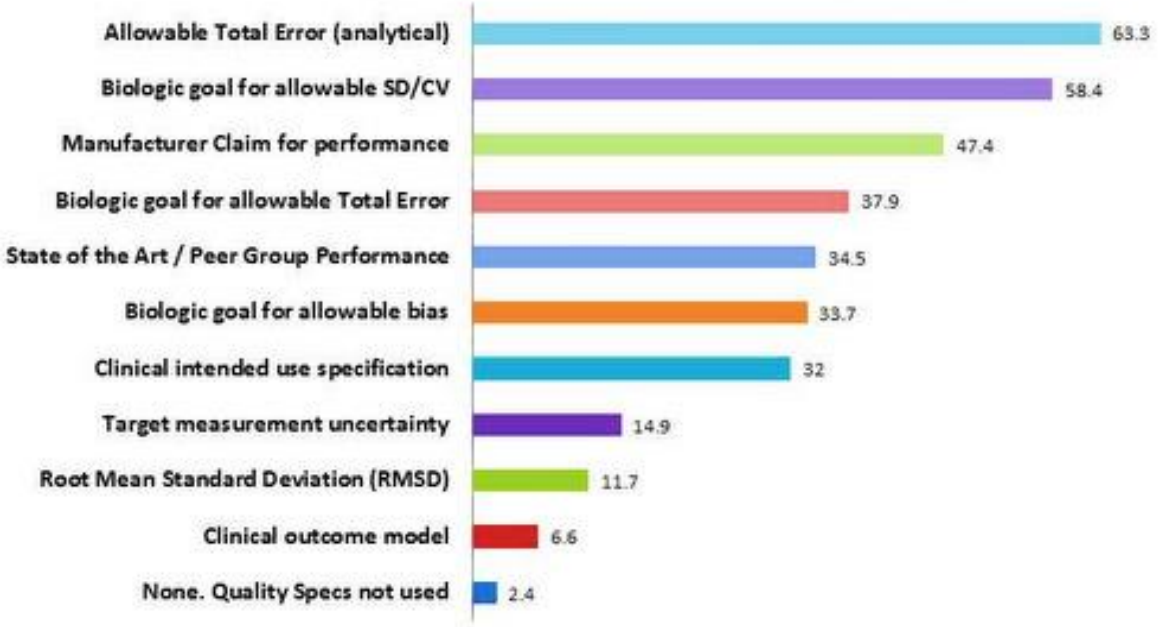
More than 450 responses were received from more than 80 different countries

In December 2014 and January 2015

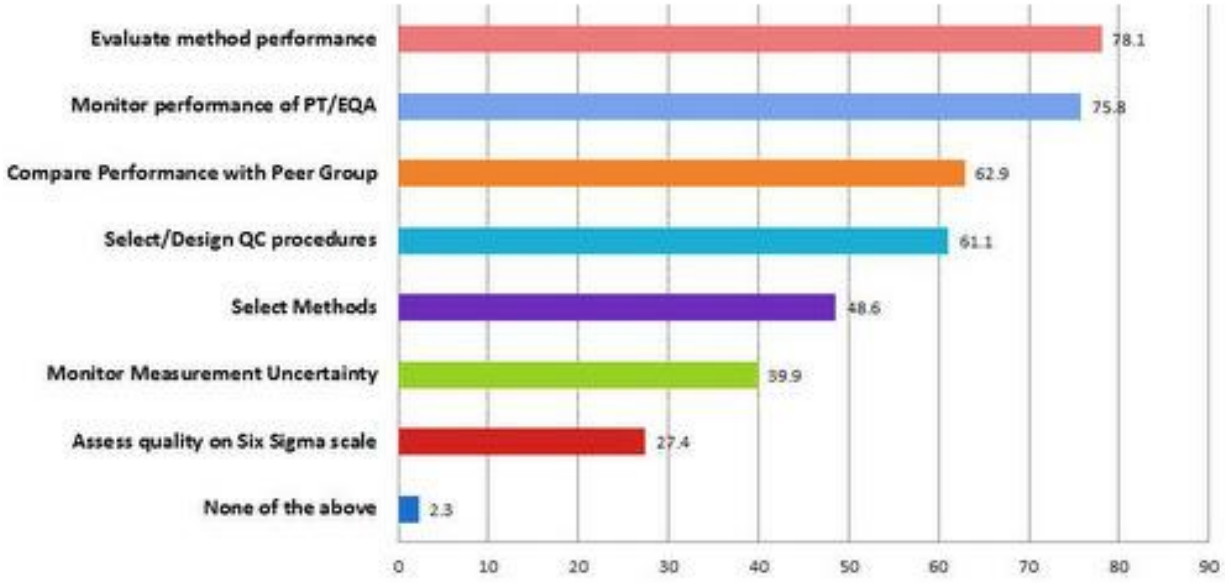
- Andorra
- Armenia
- Argentina
- Austria
- Australia
- Belgium
- Bulgaria
- Bahrain
- Brazil
- Botswana
- Belarus
- Cambodia
- Canada
- Cote d'Ivoire
- Chile
- Cameroon
- China
- Costa Rica
- Croatia
- Denmark
- Ecuador
- Estonia
- Egypt
- Ethiopia
- Federated States of Micronesia
- Finland
- France
- Greece
- Hong Kong
- Indonesia
- Ireland
- India
- Iran
- Italy
- Jordan
- Japan
- Kazakhstan
- Kenya
- Kuwait
- Lebanon
- Lithuania
- Macedonia
- Malaysia
- Mauritius
- Mongolia
- Mozambique
- Mexico
- Nepal
- Netherlands
- Nigeria
- Norway
- Oman
- Philippines
- Poland
- Portugal
- Qatar
- Romania
- Russia
- Saudi Arabia
- Serbia
- Singapore
- Slovenia
- South Africa
- Spain
- Sudan
- Sweden
- Switzerland
- Thailand
- Turkey
- Uganda
- Ukraine
- United Kingdom
- United States
- Uzbekistan
- Vietnam
- Zambia

http://www.westgard.com/global-goal-results.htm

Types of Goals used in the Lab (N=409)



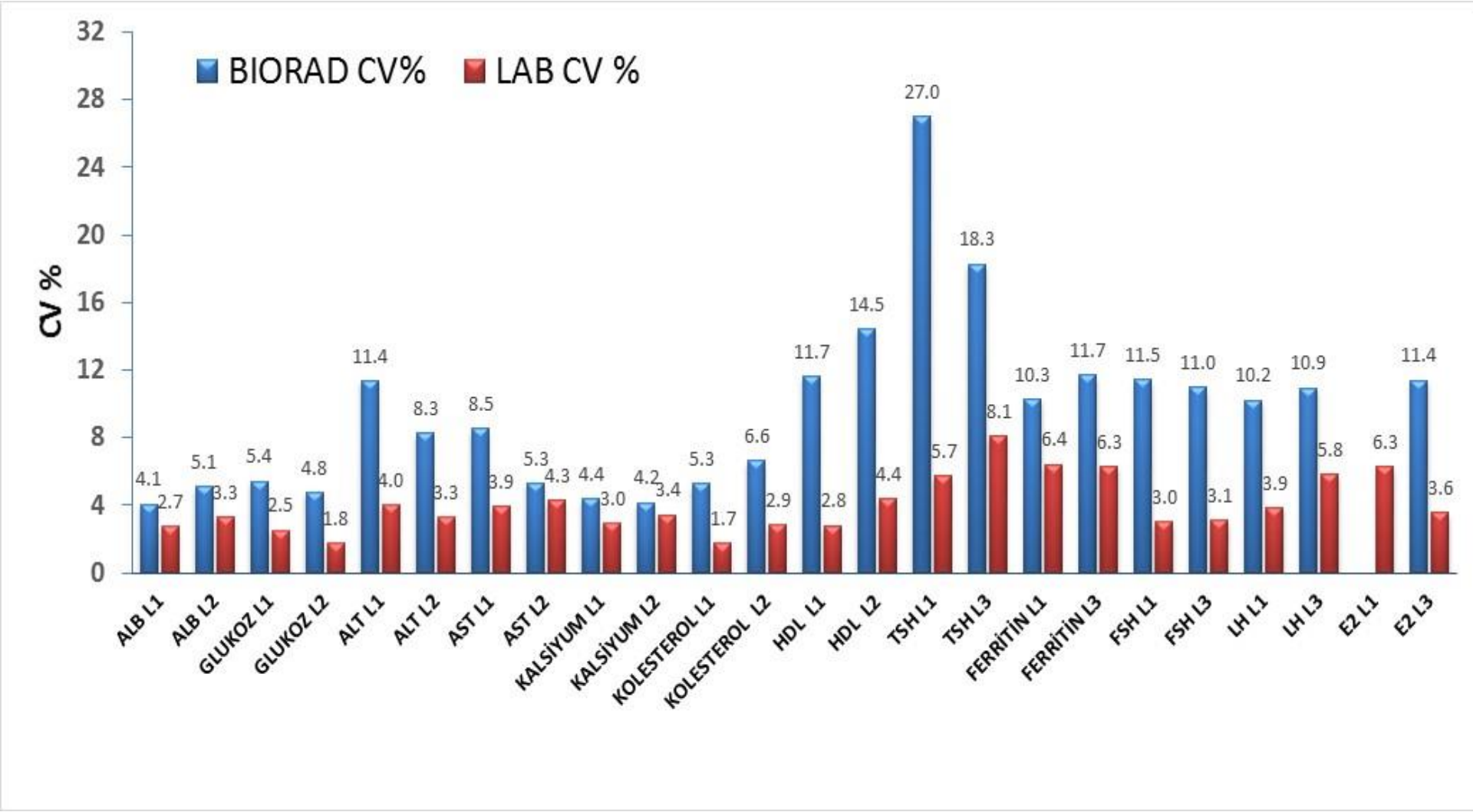
How do you use your Quality Goals?



A survey of qc practices of 86 labs in the UK

- 89.5% use the *same* QC procedure for *all* analytes
- 55.3% use single 2 SD rules
- 56% use manufacturer derived ranges to set control limits
- 81.3% use peer group or EQA data to set control limits
- 82.6% **repeat the control** on failed QC flag
- 84.9% **run a new control**
- 93.7% re-calibrate, then re-run the control

Üretici önerisi kullanılabilir mi?



http://www.westgard.com/guest4.htm

- **Manufacturer's Control Ranges Vs User's Calculated Limits**
- Some instrument manufacturers market analyte-specific control products. These materials are useful after calibration to verify the calibration and to provide more control replicates when they are needed for effective control of the method. Some manufacturers produce these controls with relatively wide target ranges rather than assaying them and providing lot-specific mean concentrations or peer data comparison. To set up initial quality control ranges with these materials, the manufacturer's assigned range must be divided by 6 to estimate the standard deviation. Otherwise the ranges are too wide

Rutin Biyokimya için 6

Hormonlar için yaklaşık 7-8

Üretici ortalama kullanmak çok zor

deFault KK

- **Her 24 saatte bir 2 düzey kontrol çalışmayı yap**

Ekivalan KK

- Ürticilerin reaktif ve kalibratör stabiliteleri artmıştır.
- Çevre şartları, lot to lot değişimleri, personel değişimleri çok test için minimaldir
- Internal monitoring systems (electronik, internal veya prosedural kontroller) ile tespid edildiğinde
- Kalite kontrol çalışmaları haftalık (veya aylık)bile olabilir

Feature

Received 7.11.05 | Revisions Received 8.24.05 | Accepted 8.24.05

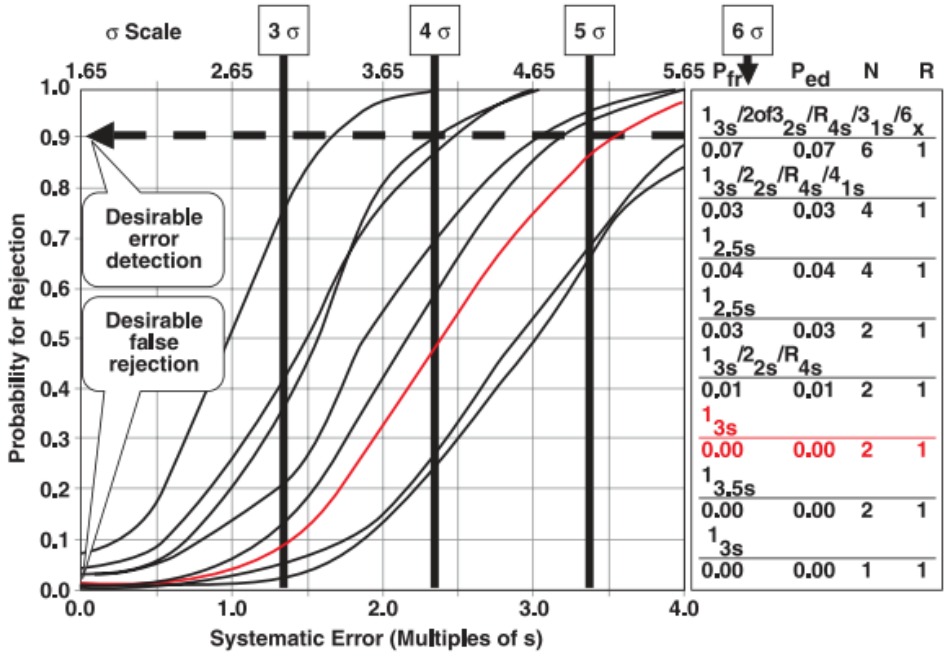
CLIA and Equivalent Quality Control: Options For The Future

Judy Yost, MA, MT(ASCP), Penny Mattingly, MA, MT(ASCP)SBB
(Centers for Medicare and Medicaid Services, Baltimore, MD)

CLSI C24

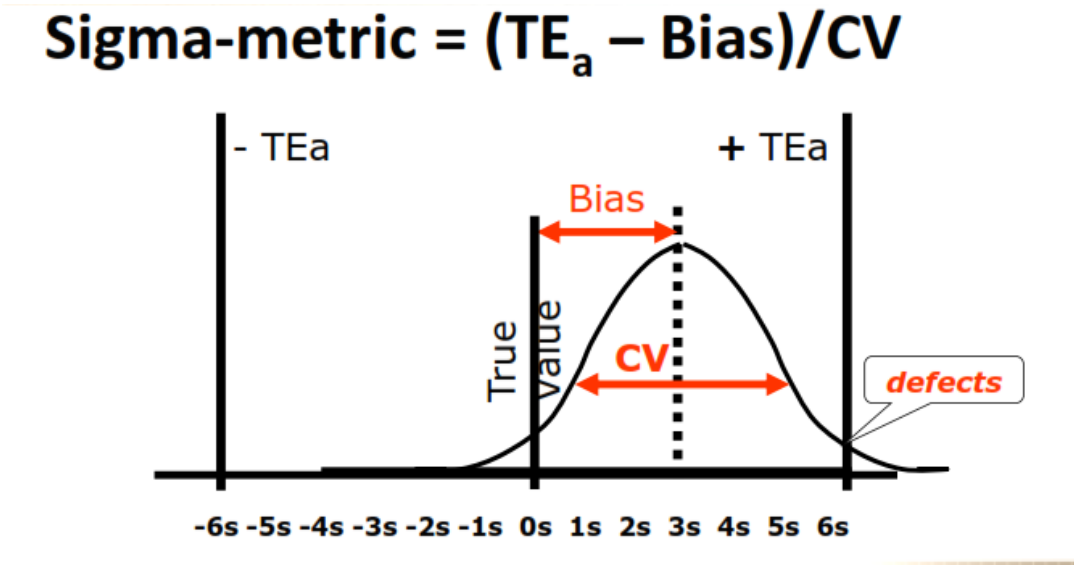
CLSI C24-A3 on Analytical Run (2)

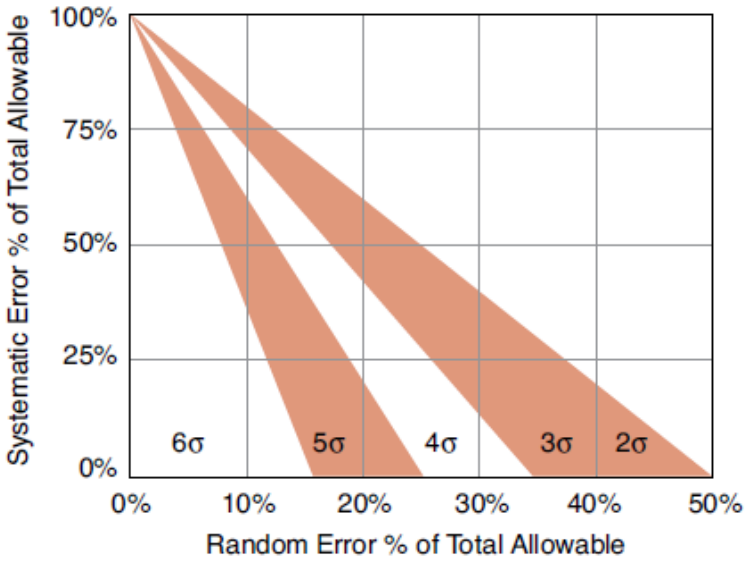
- "The length of an analytical run must be defined appropriately for the specific analytical system and specific measurement procedure…"
  - Laboratory should consider
    - expected stability,
    - number of patient samples,
    - cost of re-analysis,
    - workflow patterns,
    - operator competency,
    - criticality of tests and
    - impact of errors



- **6 sigma**: tek kontrol kuralı 1 3.5S veya 1 3S, 2 kontrol
- **5 sigma**: tek kontrol kuralı 1 3S veya 1 2.5S, 2/3 kontr
- **4 sigma**: çoklu kural (Westgard), 3 / 4 kontrol
- **3.5 sigma**: çoklu kural, 6 kontrol

İKK de Six Sigma değerlendirmesi





- Dramatic impact of **world class** performance

  – *Less* QC Effort Needed?

  – Fewer, maybe NO, repeated controls
  – Fewer Service Visits or Tech Support Calls
  – Fewer recalibrations, trouble-shooting episodes
  – Better compliance for PT, EQA, etc.

Choosing QC Rules Based on Risk Management (Error Rates)

Critical Systematic Error (SEc) reaches zero when 5% of results exceed the TEa limit.

- SEc uses a z-value of 1.65
- **SEc = [(TEa-bias)/s] – z**

Error Rate Categories

Low= method that experiences <3% QC flags/year

Moderate= method that experiences 3-10% QC flags/year

High= method that experiences >10% QC flags/year**as)/s] - z**

D: Examine QC chart **D**aily
+: Increase control frequency
I: **I**nitiate corrective action

ΔSE_c	Low	Moderate	High
>3	1-3.5s	1-3s	1-2.5s (D,I)
2-3	1-3s	1-2.5s	1-2s (D,I)
1-2	1-2.5s (D)	1-2s (D,+)	1-2s (D,+,I)
<1	1-2s (D,I)	1-2s (D,+,I)	1-2s (D,+,I)

A Practical Guide to Internal Quality Control (IQC) For Quantitative Tests in Medical Laboratories, 2015

Appendix 3: Precision goals derived from CLIA criteria

Chemistry

Test or Analyte	CLIA	Five-Sigma Precision	Six-Sigma Precision
ALT	20%	4.0%	3.3%
Albumin	10%	2.0%	1.7%
Alkaline Phosphatase	30%	6.0%	5.0%
Amylase	30%	6.0%	5.0%
Bilirubin, total	0.4 mg/dL or 20% (greater)	0.08 mg/dL or 4%	0.067 mg/dL or 3.3%
Blood gas pCO_2	5 mm Hg or 8% (greater)	1 mm Hg or 1.6%	0.8 mm Hg or 1.3%
Blood gas pH	0.04 pH units	0.008 pH units	0.00067 pH
Calcium, total	1.0 mg/dL	0.2 mg/dL	0.17 mg/dL
Chloride	5%	1.0%	0.83%
Cholesterol, total	10%	2.0%	1.7%
Cholesterol, HDL	30%	6.0%	5.0%
Creatine kinase	30%	6.0%	5.0%
Creatinine	0.3 mg/dl or 15% (greater)	0.06 mg/dL or 3.0%	0.05 mg/dL or 2.5%
Glucose	6 mg/dL or 10% (greater)	1.2 mg/dL or 2.0%	1.0 mg/dL or 1.7%
Iron, total	20%	4.0%	3.3%
LDH	20%	4.0%	3.3%
Magnesium	25%	5.0%	4.2%
Potassium	0.5 mmol/L	0.1 mmol/L	0.08 mmol/L
Sodium	4 mmol/L	0.8 mmol/L	0.67 mmol/L
Total protein	10%	2.0%	1.7%
Urea Nitrogen	2 mg/dL or 9% (greater)	0.4 mg/dL or 1.8%	0.33 mg/dL or 1.5%
Uric acid	17%	3.4%	2.8%

İKK uygulamalrının maliyete etkisi

Quality Cost Worksheet, Part I: Waste & Rework

Test	Cholesterol Example
Method	ABC Inc.
System	DEF Analyzer

1. Runs/Day	2
2. Days/Year	365
3. Control Rule in use	1:2s
3a. False Rejection (Pfr) - use table	0.09
4. Number of Controls per Run	2
5. Estimated Cost per Control	$0.50
6. Number of tests in each test group	20
7. Cost per test	$0.50
False Rejection test cost: If you repeat the *entire* test group Multiply 1 x 2 x 3a x 6 x 7.	$657.00
False Rejection control cost: If you only repeat controls Multiply 1 x 2 x 3a x 4 x 5.	$65.70
8. Average hourly rate of employees who perform the rework ("repeat run")	$20
9. Average amount of time consumed when one run of this test must be redone.	1.0 hours
Rework labor cost: Multiply 1 x 2 x 3a x 8 x 9.	$1,314
TOTAL COST OF WASTE & REWORK: Add Control cost + Test cost + Rework labor cost	$2,036.70

This is the cost of rework if the test performs *perfectly*. If any real problems occur, the cost of rework is more!

Quality Cost Worksheet, Part I: Waste & Rework

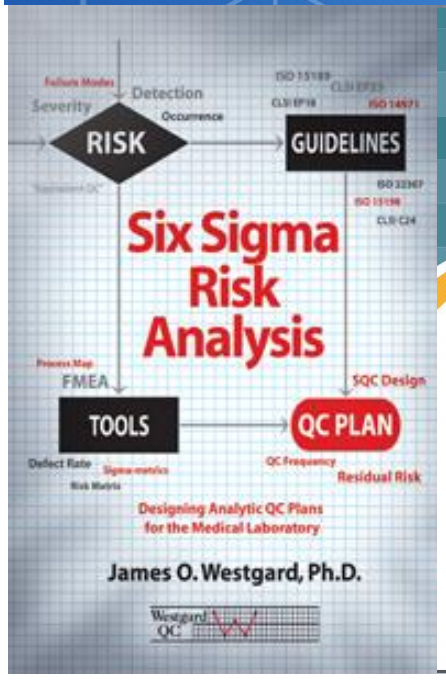
Test	Cholesterol Example
Method	ABC Inc.
System	DEF Analyzer

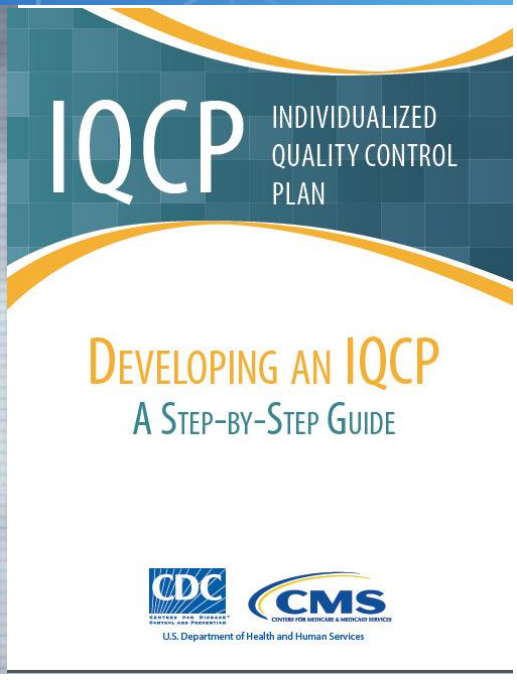
1. Runs/Day	2
2. Days/Year	365
3. Control Rule in use	1:3s/2:2s/R:4s
3a. False Rejection (Pfr) - use table	0.01
4. Number of Controls per Run	2
5. Estimated Cost per Control	$0.50
6. Number of tests in each test group	20
7. Cost per test	$0.50
False Rejection test cost: If you repeat the *entire* test group Multiply 1 x 2 x 3a x 6 x 7.	$73.00
False Rejection control cost: If you only repeat controls Multiply 1 x 2 x 3a x 4 x 5.	$7.30
8. Average hourly rate of employees who perform the rework ("repeat run")	$20
9. Average amount of time consumed when one run of this test must be redone.	1.0 hours
Rework labor cost: Multiply 1 x 2 x 3a x 8 x 9.	$146.00
TOTAL COST OF WASTE & REWORK: Add Control cost + Test cost + Rework labor cost	$226.30

Note for this example, switching from the 1$_{2s}$ rule to a "Westgard Rule" provides immediate reduction in waste.

Risk ve Risk Analizleri temelli kalite kontrol

ISO 15198:2004
Clinical laboratory medicine. In vitro diagnostic medical devices. Validation of user quality control procedures by the manufacture





Bütün süreçte olduğu gibi kalite kontrol sürecindede risk analizi yapılabilir

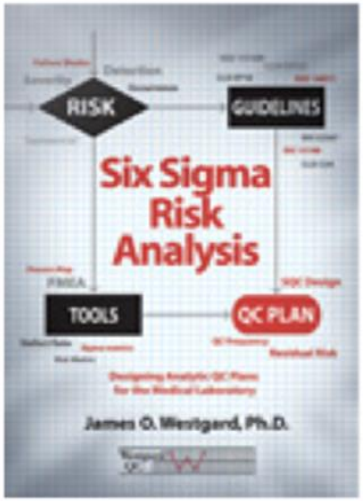
Alternatif KK- Risk temelli KK

Risk Management

Recommended by ISO, adopted by manufacturers

- Accepted by CLSI & CMS for "Alternate QC"
  - **EP18** "Risk management techniques to identify and control laboratory error sources"
  - **EP22** "Presentation of manufacturer's risk mitigation information"
  - **EP23** "Laboratory QC based on risk management"
    - Includes "QC toolbox" for monitoring residual risks
    - "Surrogate" QC, instrument checks, performance checks, patient comparisons, patient data QC (Delta checks, consistency checks, AoN), PT/EQA

New Book: Six Sigma Risk Analysis



DO THE RIGHT QC WITH SIX SIGMA RISK ANALYSIS.

Risk nedir?

"Bir laboratuvar hatasının riski belli bir ihtimaldedir"i hesaplayarak ölçebiliriz

istenmeyen bir olaydır vb

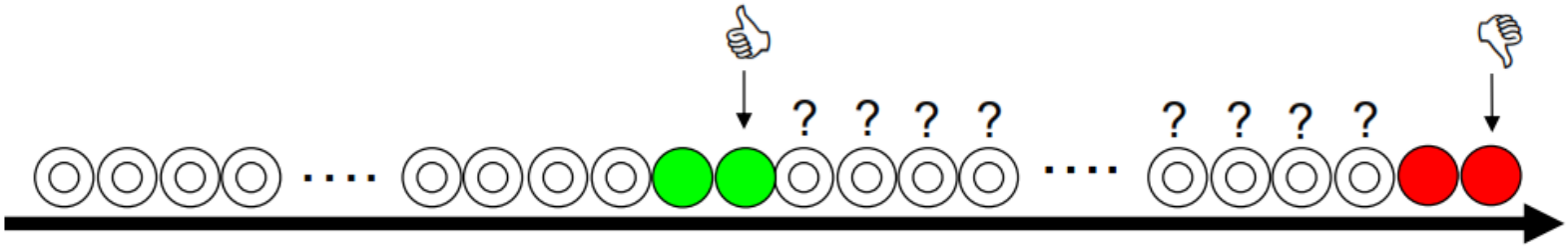
Tanımlar (ISO 14971)

- **Risk:** **Zararın varlığının ihtimali ile zararın ciddiyetinin kombinasyonudur (O x S)**
- **Zarar:** İnsan sağlığı için fiziksel hasar veya zarar, veya çevre veya özelliğinin hasarı
- **Ciddiyet:** Bir tehlikenin muhtemel sonucunun ölçüsü
- **Tehlike**: Zararın potansiyel kaynağı

ISO tanımına göre: risk kantitatiftir, varlığın ihtimalinin ölçüsüdür ve zararın ciddiyetidir

Nasıl ve Ne sıklıkla IKK uygulaması yapılır ?

CLIA hasta sonuçlarını riske atmamak için minimum 24 saat (veya her çalışmada) iki düzey kontrolü zorunlu kılar (in section 493.1253 (3) on page 3707-12)
(koagülasyon, kan gazı gibi testler hariç)

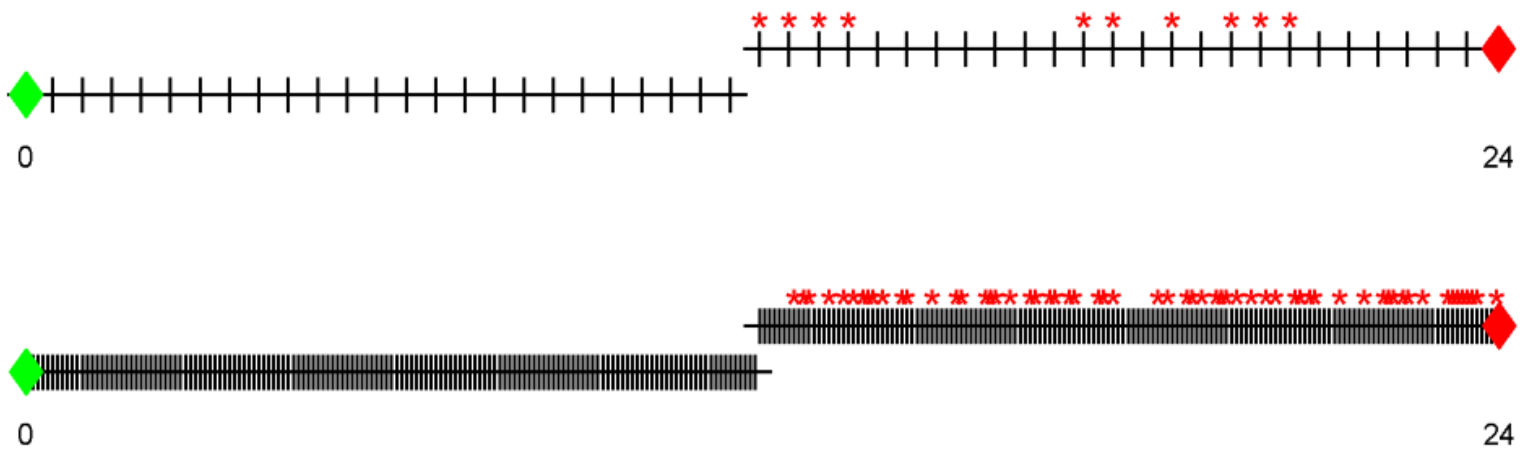


? ? ? ? ?

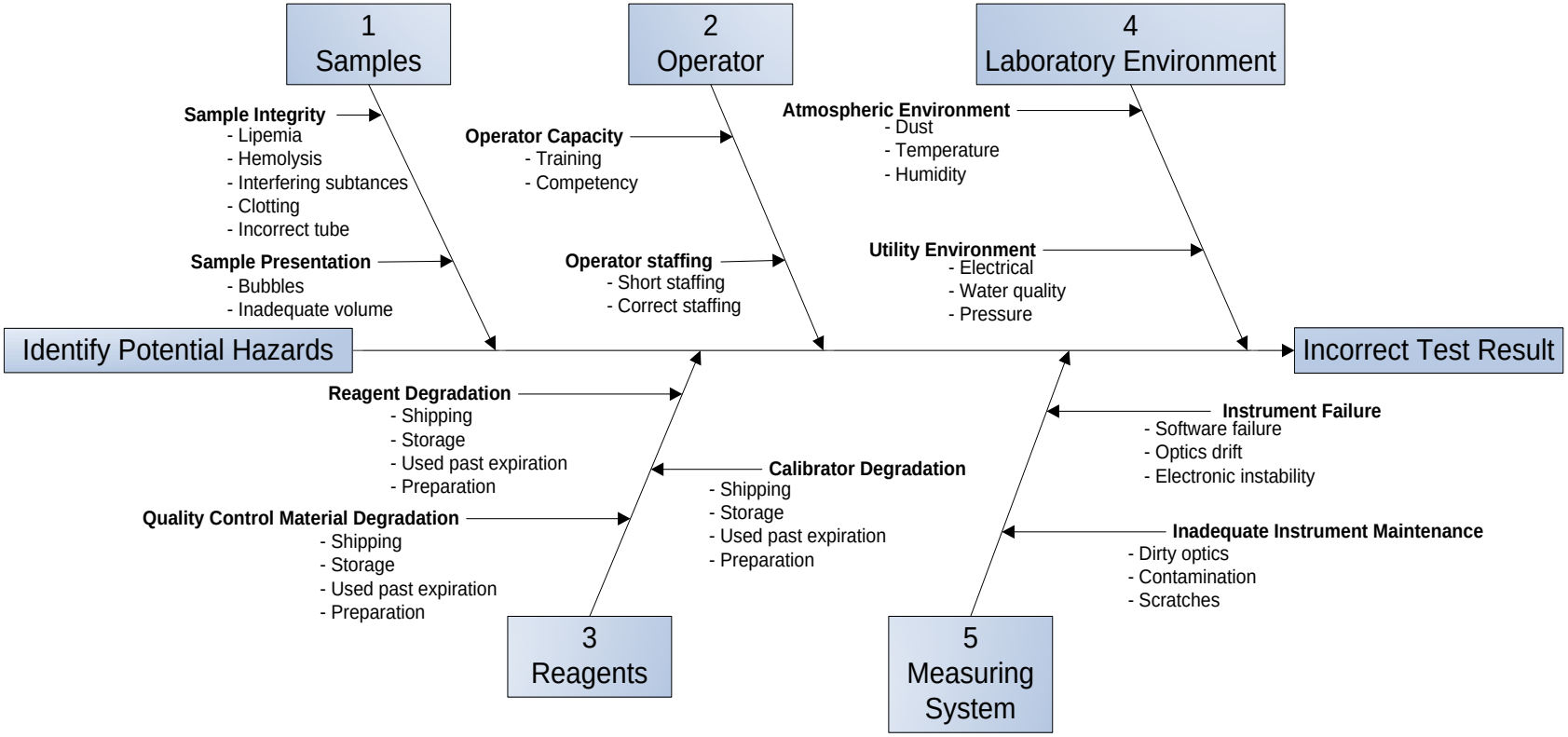
Hasta sonuçlarına ait düzeltme yapılacak mıdır?

Risk nedir

Bu durumda risk çalışılan hasta sayısı ile ilgilidir.



Identify the Risks



Hedefler ve risk ilişkisi

Recommended QC Tool	Sigma >5.5	Sigma 3.5-5.5	Sigma <3.5
Analyst/operator controls			
Standard Operating Procedure	Essential	Essential	Essential
Operator training	High	High	High
Operator checklists	High	High	High
System maintenance	High	High	High
Operator competency	High	High	High
Built-in analyzer controls			
Electronic checks	Low	Moderate	High
Function tests	Low	Moderate	High
Process tests	Low	Moderate	High
Calibration checks	Low	Moderate	High
Integrated controls	Low	Moderate	High
Stable control materials			
Statistical QC	Essential	Essential+	Essential++
Frequency of QC	Low	Moderate	High
SQC with peer comparison	Low	Low	Low
Periodic EQA, PT	Regulatory	Regulatory	Regulatory
Trueness controls	Low	Low	Low
Patient data analysis			
Implausible values	High	High	High
Delta checks	Low	Moderate	High
Correlation algorithms	Low	Moderate	High
Repeat patient testing	Low	Moderate	High
Population statistics	Low	Moderate	High

Table 14-3. Priority of different QC tools in relation to the Sigma performance of the testing process.

Recommended QC Tool	Practicality	Reliability	Effort
Analyst/operator controls			
Standard Operating Procedure	Man/computer	Low	Moderate
Operator training	Manual	Low	Moderate
Operator checklists	Man/computer	Moderate	Low
System maintenance	Manual	Low	Low
Operator competency	Man/computer	Low	Moderate
Built-in analyzer controls			
Electronic checks	Man/computer	High	Low
Function tests	Man/computer	High	Low
Process tests	Computer	High	Low
Calibration checks	Man/computer	High	Low
Integrated controls	Computer	High	Low
Stable control materials			
Statistical QC	Man/computer	High	Moderate
SQC with peer comparison	Computer	Moderate	Moderate
Periodic EQA, PT	Manual	Moderate	Low
Trueness controls	Man/computer	Low	Low
Patient data analysis			
Implausible values	Man/computer	Moderate	High/Low
Delta checks	Computer	Low	Moderate
Correlation algorithms	Computer	Low	Moderate
Repeat patient testing	Man/computer	Low	Moderate
Population statistics	Computer	Moderate	High

Table 14-4. Example assessment of feasibility of different QC tools on basis of practicality, reliability, and effort to implement.

Failure Reporting, Analysis, and Corrective Action Systems (FRACAS)

Manufacturer-Completed Section				Clinical Laboratory–Completed Section							
Step or Component in Which Failure Occurs	**Failure**	**Cause**	**Effect**	**Severity**	**Probability**	**Criticality**	**Recommended Action From Manufacturer**	**Prevention**	**Detection**	**Recovery**	**Outcome Measure**
Operator	Sample not collected correctly	Sample clotted or incorrect tube type	Incorrect result	1	1	1	Training, instructions	Operator training on proper sample collection, monitor sample conditions on arrival to laboratory	Sample arrives in wrong container or clotted	Request new sample	Audit operator training; monitor for frequency of failure
Operator	Sample contaminated with target/analyte carryover	Improper sample handling	Incorrect result	4	1	4	Change gloves when handling different samples	Operator training; clean work area; maintain sterile technique	QC or proficiency test failure	Repeat analysis	Audit frequency of QC; monitor frequency of failure.
Operator	Wrong assay system used for test	Operator interrupted, selected wrong test	Result on a different test	1	1	1	Verify test system matches what is entered in computer	Operator training; locate analyzer where technologists are not interrupted	Wrong test after analysis	Repeat analysis with correct test	Audit operator training; monitor for frequency of failure
Operator	Sample added to wrong place in assay system	Operator failure	No result	1	1	1	Assay designed so sample, if collected properly, does not fit anywhere but proper insertion point	Operator training	Analyzer failure	Reinsert sample and start analysis	Audit operator training and competency

6 Sigma

Control Rule	*Analytes*
For 5.0 Sigma values and above:	Triglycerides, ALP, Magnesium, Uric Acid, Creatinine, CPK, Glucose, Total Protein, Amylase, Potassium, Calcium
13s with N=2	
For 4.0 to 5.0 Sigma values:	LDH, BUN, ALT
12.5s with N=2	
For Sigma values below 4.0:	Cholesterol, Chloride, Albumin, AST, T. Bilirubin, Sodium
"Westgard Rules" with N=2	

Türk Biyokimya Dergisi [Turkish Journal of Biochemistry - Turk J Biochem] 2005; 30 (4); 296-305.

Araştırma Makalesi [Research Article] Yayın tarihi Aralık, 2005 © TurkJBiochem.com

[Published online December, 2005]

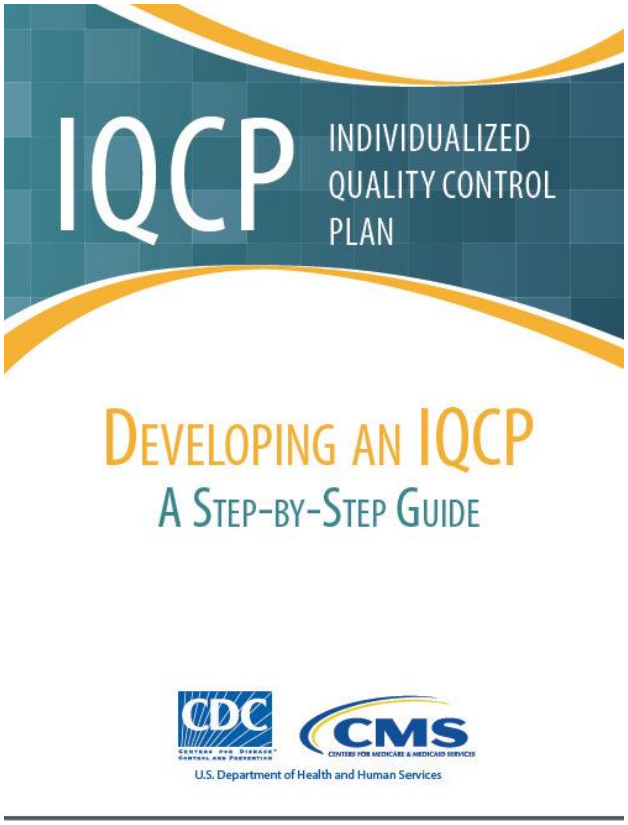
Klinik Laboratuvarlarda Toplam Laboratuvar Performansının Değerlendirilmesi: Normalize OPSpec Grafikleri, Altı Sigma ve Hasta Test Sonuçları

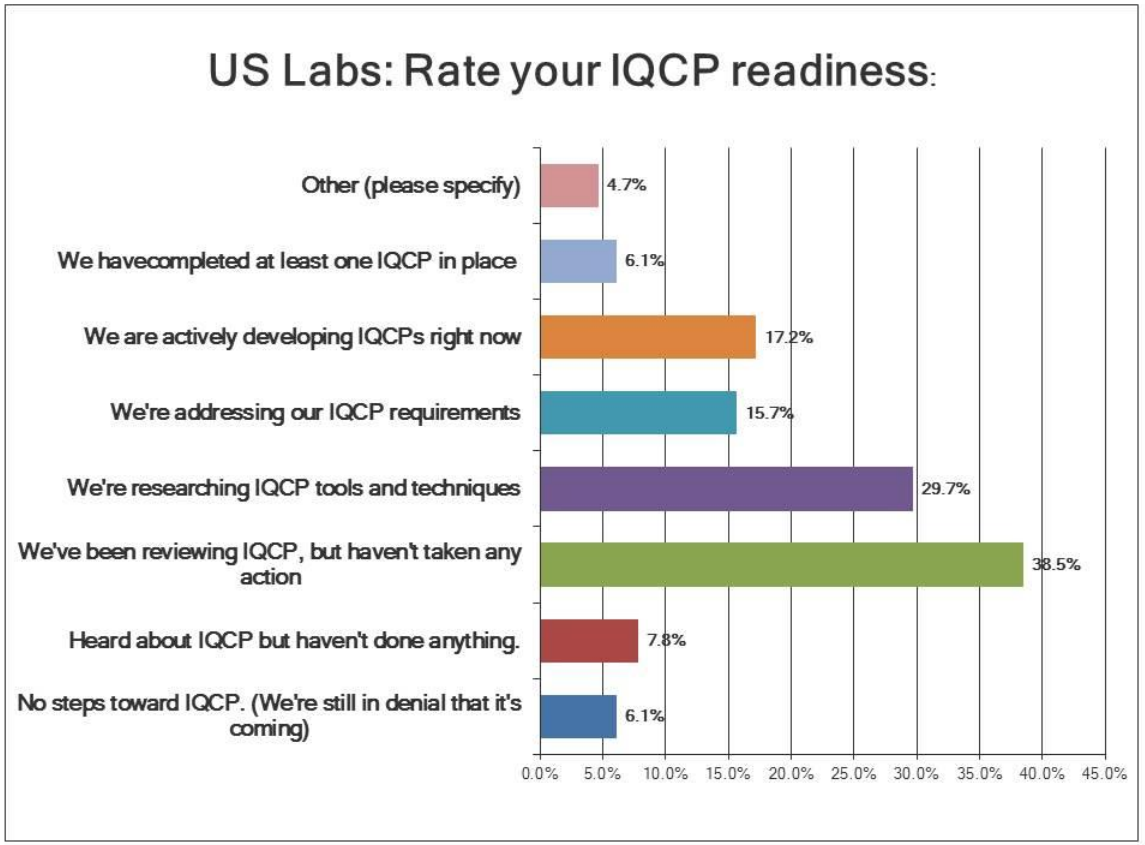
[Assessment of Total Clinical Laboratory Process Perfromance: Normalized OPSpecs Charts, Six Sigma and Patient Test Results]

Klinik Yararlılık, (CVO Grupları)	S / CV Oranı		ARALIK 2003 Test süreci performansı (Sigma düzeyi-S)								
			S-3			S-2			S-1		
			≤4			4-6			≥6		
			L1	L2	L3	L1	L2	L3	L1	L2	L3
	CVO-3	≥2		*TProt*	*Glu LD Na*					*Kreat*	*Alb Kreat*
	CVO-2	1-2	*Cl İnP*	*BUN Na Glu LD*	*GGT*	*Alb*	*BUN*	*Cl*	*AST Ca K Mg*	ALP *AST Ca TKol*	ALP *K İnP TKol Mg ÜA*
	CVO-1	<1	*CK*	*TBil*	*GGT*		*GGT TG*			*ALT*	*ALT TG*

Turk J Biochem 2005; 30 (4); 296-305.

Kullanılıyor mu?

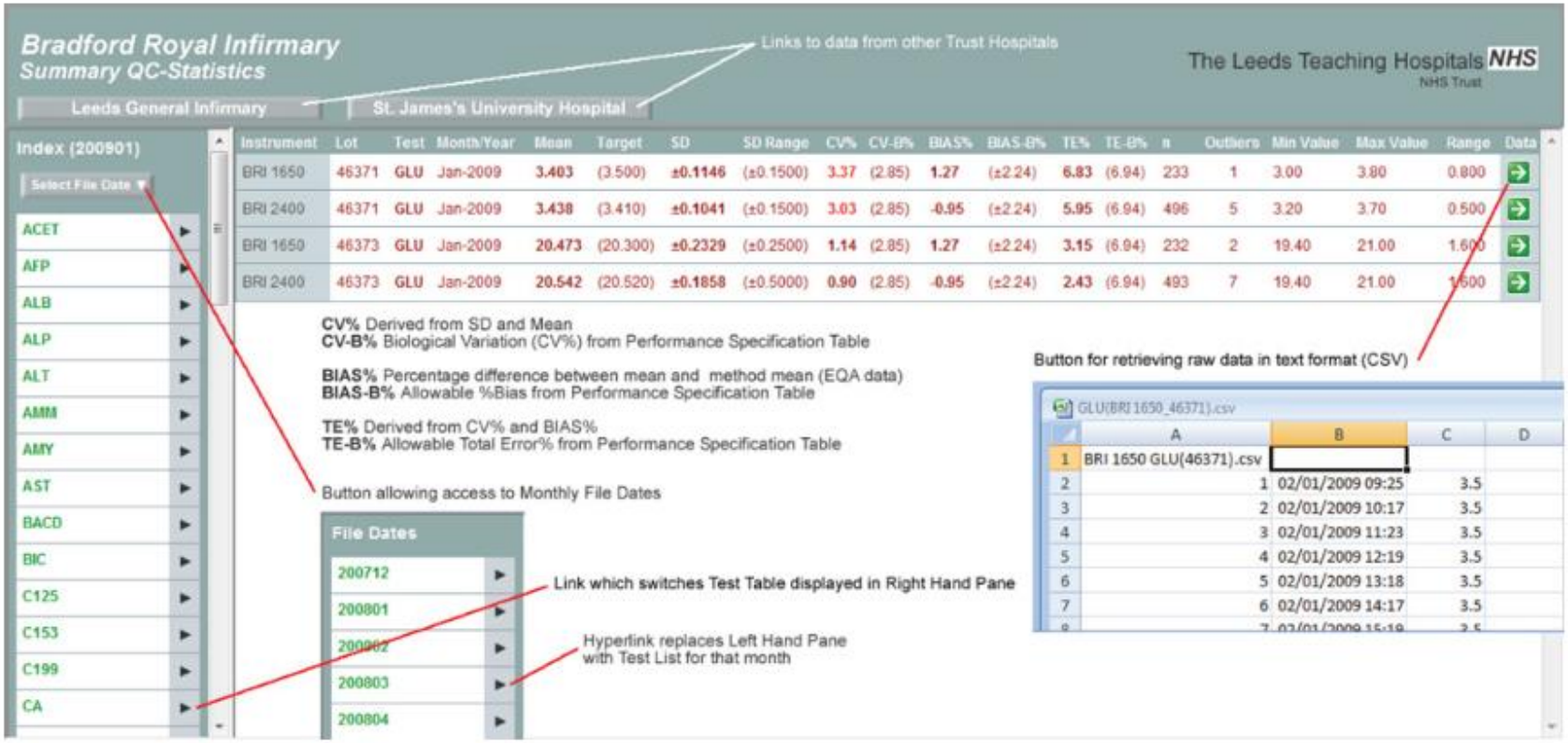


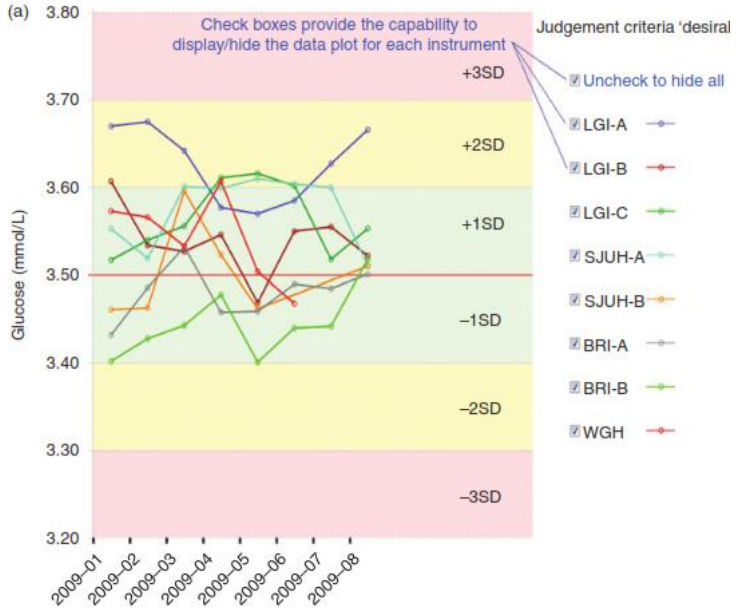


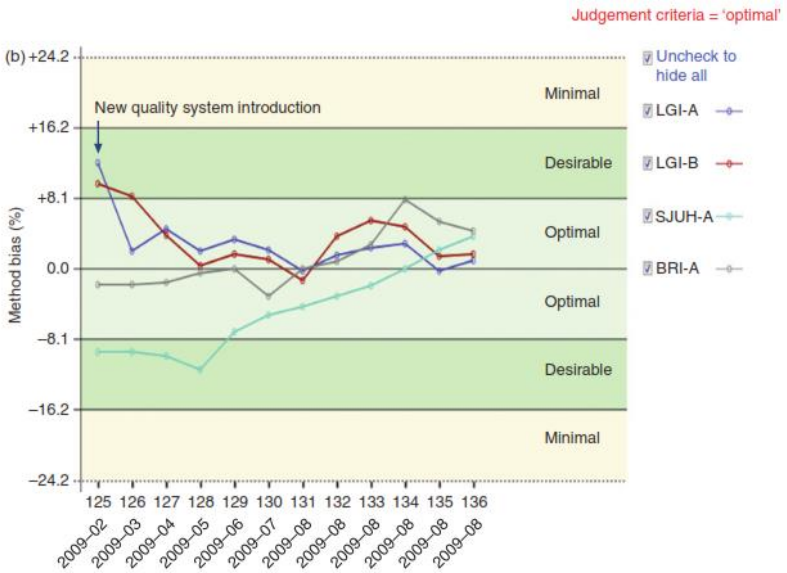
The implementation of a system for managing analytical quality in networked laboratories

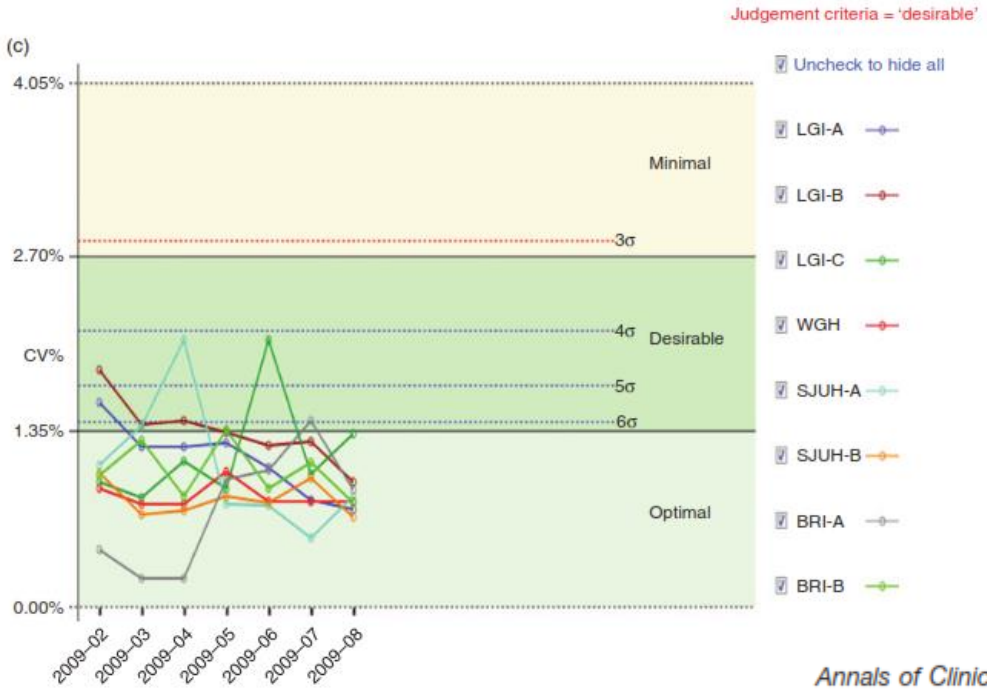
Nuthar Jassam[1], Chris Lindsay[2], Kevin Harrison[1], Douglas Thompson[1], Mike P Bosomworth[1] and Julian H Barth[1]

[1]Department of Clinical Biochemistry, Leeds General Infirmary, Leeds LS1 3EX; [2]Siemens Healthcare Diagnostics, Sir William Siemens Square, Surrey, UK




(a)
Check boxes provide the capability to display/hide the data plot for each instrument
Judgement criteria 'desiral
Uncheck to hide all
LGI-A
LGI-B
LGI-C
SJUH-A
SJUH-B
BRI-A
BRI-B
WGH
+3SD
+2SD
+1SD
–1SD
–2SD
–3SD
Glucose (mmol/L)
3.80
3.70
3.60
3.50
3.40
3.30
3.20
2009–01
2009–02
2009–03
2009–04
2009–05
2009–06
2009–07
2009–08


Judgement criteria = 'optimal'
(b)
New quality system introduction
Uncheck to hide all
LGI-A
LGI-B
SJUH-A
BRI-A
Minimal
Desirable
Optimal
Optimal
Desirable
Minimal
Method bias (%)
+24.2
+16.2
+8.1
0.0
–8.1
–16.2
–24.2
125 126 127 128 129 130 131 132 133 134 135 136
2009–02
2009–03
2009–04
2009–05
2009–06
2009–07
2009–08
2009–08
2009–08
2009–08
2009–08
2009–08


Judgement criteria = 'desirable'
(c)
Uncheck to hide all
LGI-A
LGI-B
LGI-C
WGH
SJUH-A
SJUH-B
BRI-A
BRI-B
Minimal
3σ
Desirable
4σ
5σ
6σ
Optimal
CV%
4.05%
2.70%
1.35%
0.00%
2009–02
2009–03
2009–04
2009–05
2009–06
2009–07
2009–08

Hasta sonuçlarına göre kalite kontrol

- 1965 Hofmann AON önerdi
- 1974 Bull hemotoloji analizörleri için geliştirdi
- 1984 Cembrowski hasta temelli KK kuralları oluşturdu
  - Normallerin ortalaması (AON)
  - Hareketli ortalama-Moving Avarage (MA)
  - Exponantially weighted moving avarage (EWMA)
  - Diğerleri

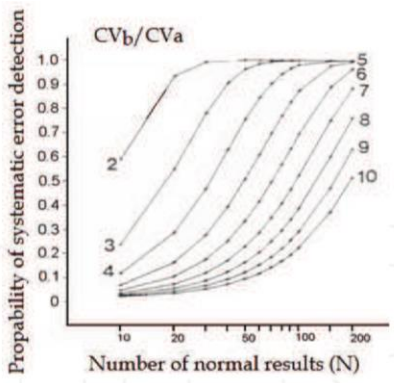
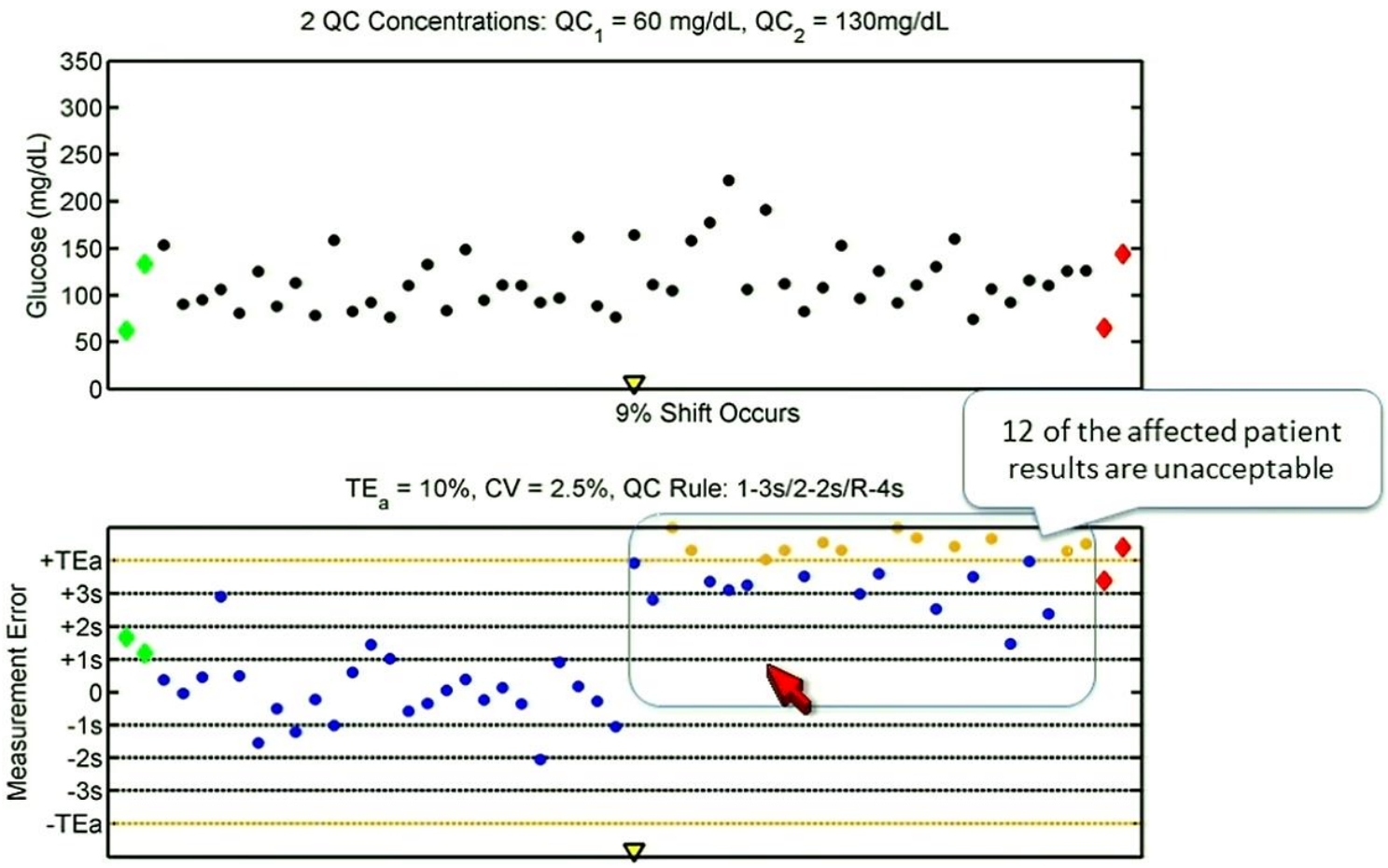
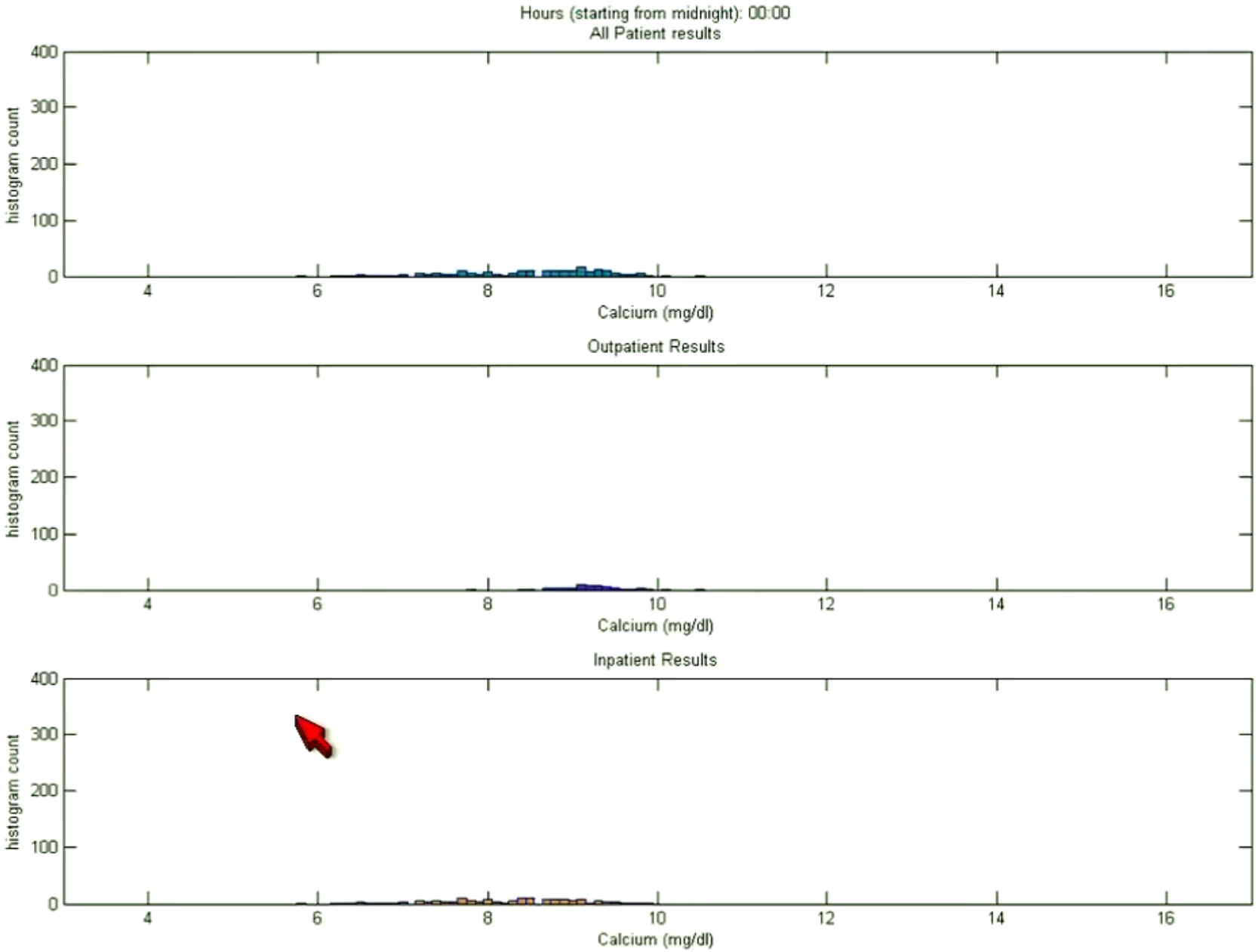


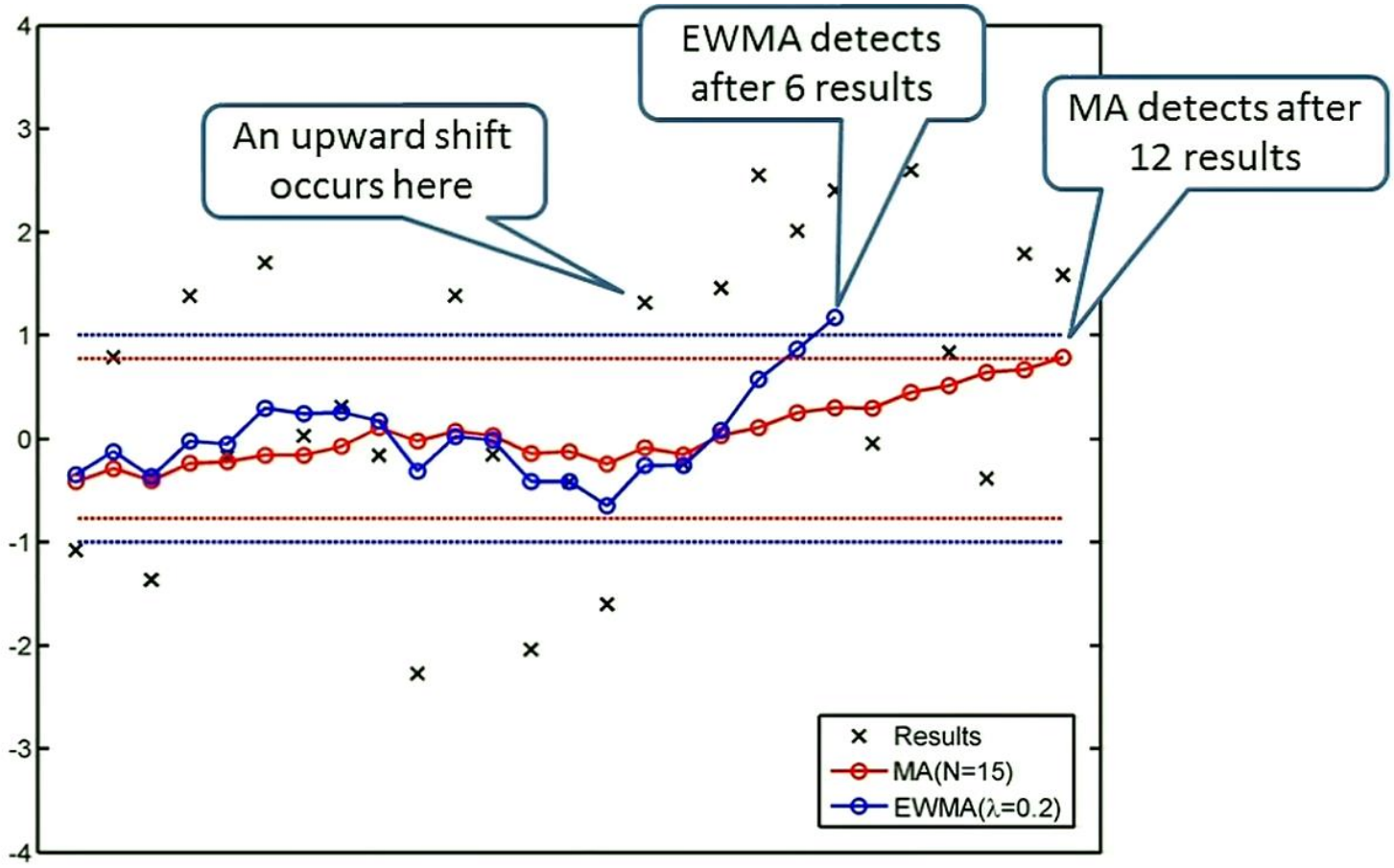
Fig. 13. Cembrowski nomogram which correlates the ratio CV_b/CV_a with the number of normals (N). The normogram detects systematic errors with $\Delta SE = 2s$ with probability of false alarm 1%

Unacceptable Patient Results

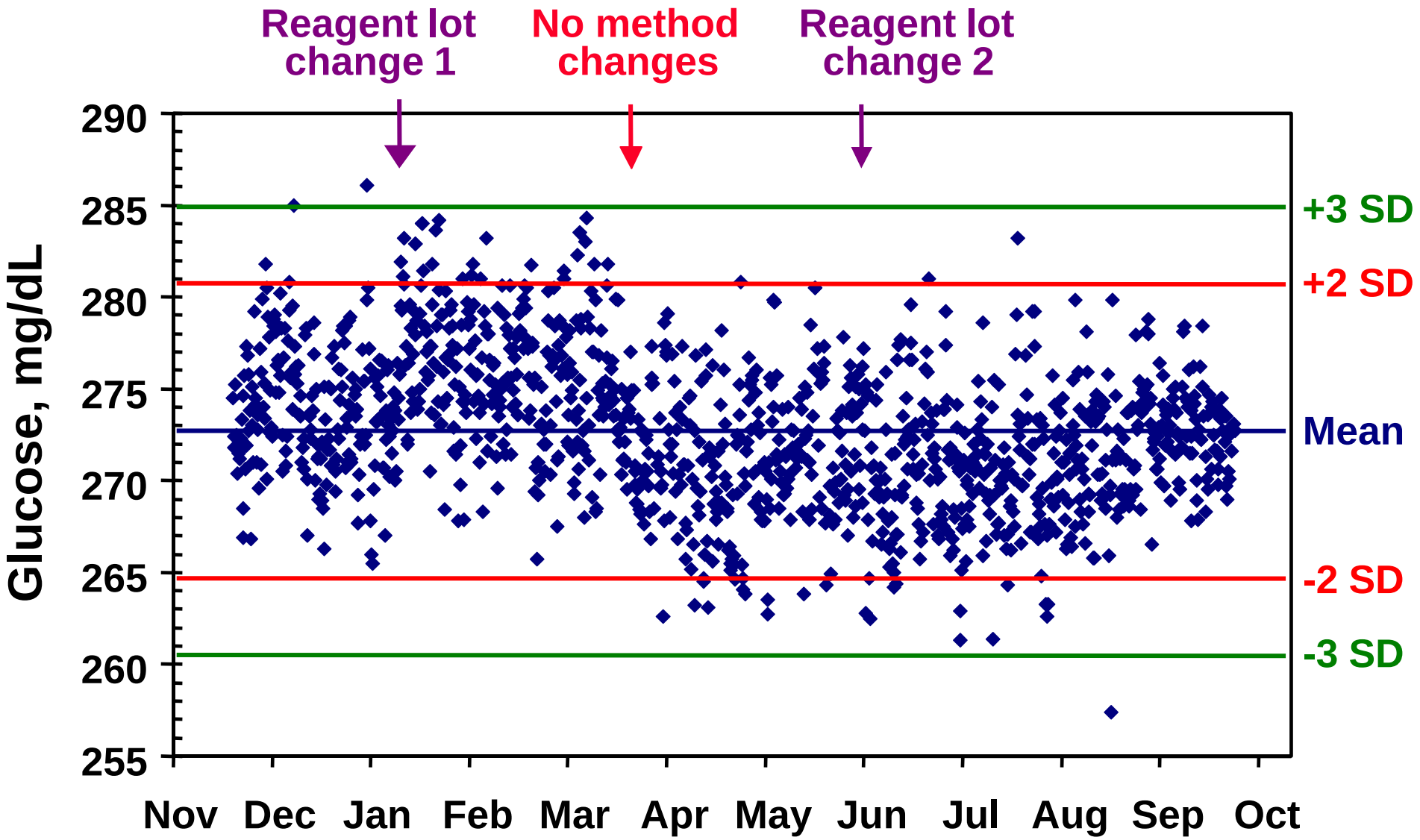



Hours (starting from midnight): 00:00
All Patient results
histogram count
400
300
200
100
0
4
6
8
10
12
14
16
Calcium (mg/dl)
Outpatient Results
histogram count
400
300
200
100
0
4
6
8
10
12
14
16
Calcium (mg/dl)
Inpatient Results
histogram count
400
300
200
100
0
4
6
8
10
12
14
16
Calcium (mg/dl)

Hareketli ortalama-Moving Avarage (MA)
Exponantially weighted moving avarage (EWMA)



Variability must include all sources



Thoughts on quality-control systems: a laboratorian's perspective

George S. Cembrowski*

Table 3. Comparison of numbers of patient results to be averaged for average of patient quality control for nine representative clinical chemistry tests.

Analyte	s_p/s_a	$N_{Westgard}$	$N_{Douville}$ $(4\times s_p^2/s_a^2)$
ALP	13.8	450	762
AST	2.2	40	19
Bilirubin	8.6	120	296
Calcium	1.8	60	13
Cholesterol	10.3	450	424
Potassium	2.8	100	31
T_4, free	2.5	100	25
T_4, total	6.1	60	149
TSH	8.9	300	317

The s_p/S_a and $N_{Westgard}$ are taken from the Westgard, Smith, Mountain and Boss paper with N being derived from Westgard's OPSpecs analysis of power functions of averages of patient data.

ALP, alkaline phosphatase; AST, aspartate aminotransferase; T_4, thyroxine; TSH, thyrotropin.

Clinical Chemistry 43:5
886–892 (1997)

Unity verilerini ile bizim verilerimizin karşılaştırılması
Farklı amaçlar için kullanımı

Unity™ Worldwide Report
Assayed Chemistry • Lot 14480 • Exp 31–May–2017

Creatinine Alkaline picrate–kinetic mg/dL

Siemens Dimension Series

	Level	Mon	Cum	Level	Mon	Cum
Mean	1	2.80	2.73	2	6.26	6.17
SD		0.141	0.140		0.222	0.247
CV		5.0	5.1		3.5	4.0
# Points		1058	23427		997	22373
# Labs		33	135		33	131

Unity % 5.1 % 4

Bu değerlerin yaklaşık 3SD ile aralıklar belirleniyor

Bizim verilerimiz

% 2.59 % 2.84

Creatinine Alkaline picrate–kinetic, IFCC–IDMS Standardized mg/dL

Abbott AEROSET/ARCHITECT (c, i, ci models)

	Level	Mon	Cum	Level	Mon	Cum
Mean	1	2.77	2.78	2	6.31	6.30
SD		0.109	0.116		0.139	0.188
CV		3.9	4.2		2.2	3.0
# Points		2918	38205		2812	37799
# Labs		69	146		69	146

Beckman Coulter AU 400/480/600/640/680/2700/5400/5800

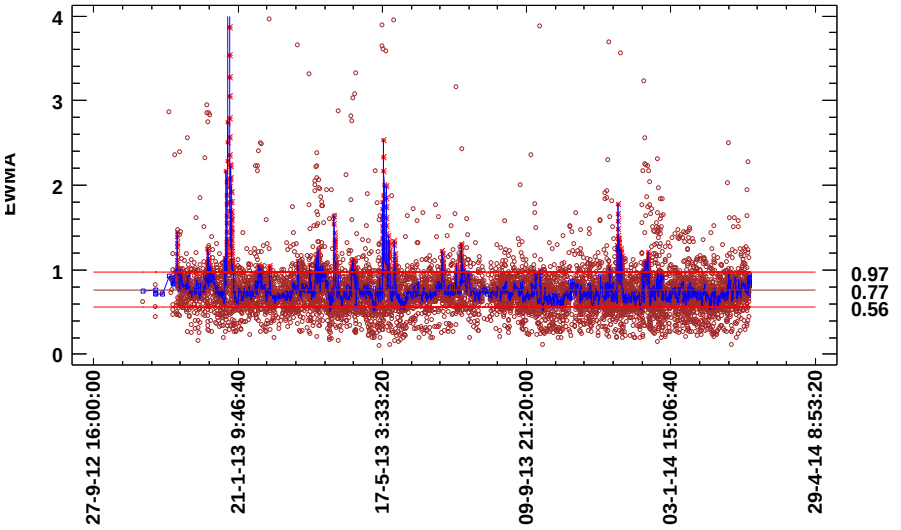
	Level	Mon	Cum	Level	Mon	Cum
Mean	1	2.22	2.21	2	5.53	5.49
SD		0.071	0.086		0.149	0.182
CV		3.2	3.9		2.7	3.3
# Points		1282	15825		1269	15504
# Labs		37	68		37	69

Roche cobas 6000/8000/c 311

	Level	Mon	Cum	Level	Mon	Cum
Mean	1	2.19	2.18	2	5.37	5.36
SD		0.112	0.129		0.178	0.194
CV		5.1	5.9		3.3	3.6
# Points		2039	27246		1970	26635
# Labs		75	111		72	110

EWMA Uygulamalarımız

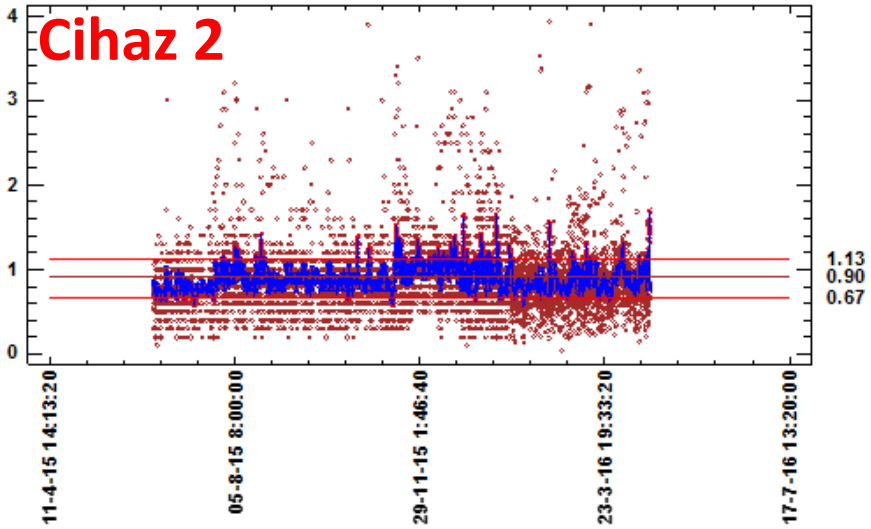
Cihaz 1



Referans Aralıklar (Erişkin)

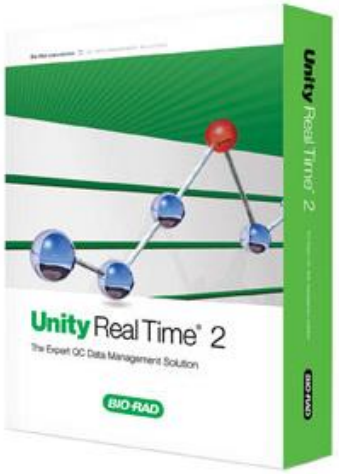
0.5-0.9 mg/dl
0.7-1.2 mg/dl

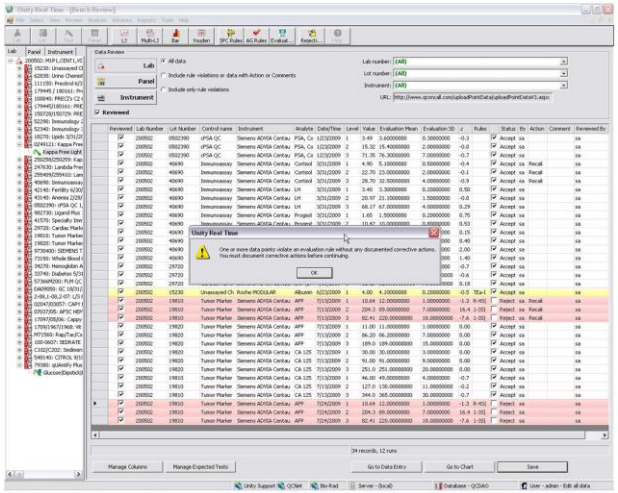
Cihaz 2

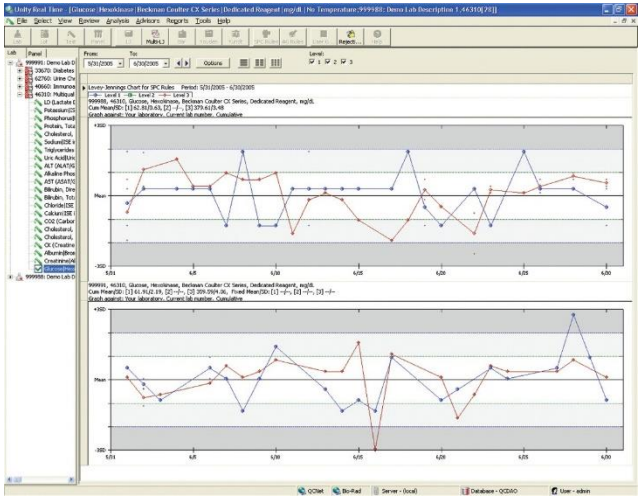


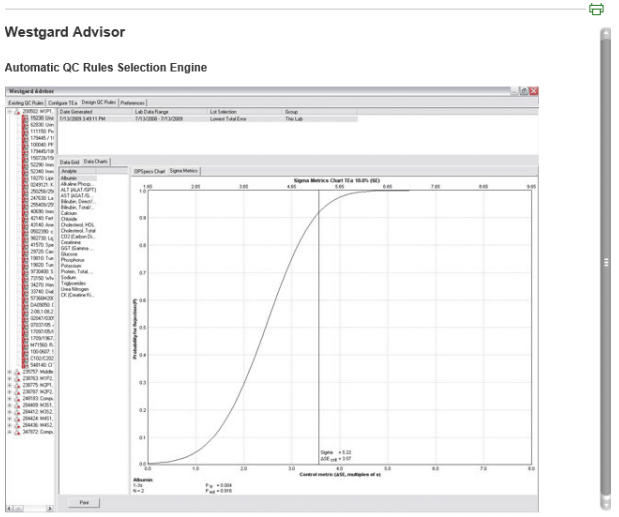
0.6-1.0 mg/dl
0.8-1.3 mg/dl

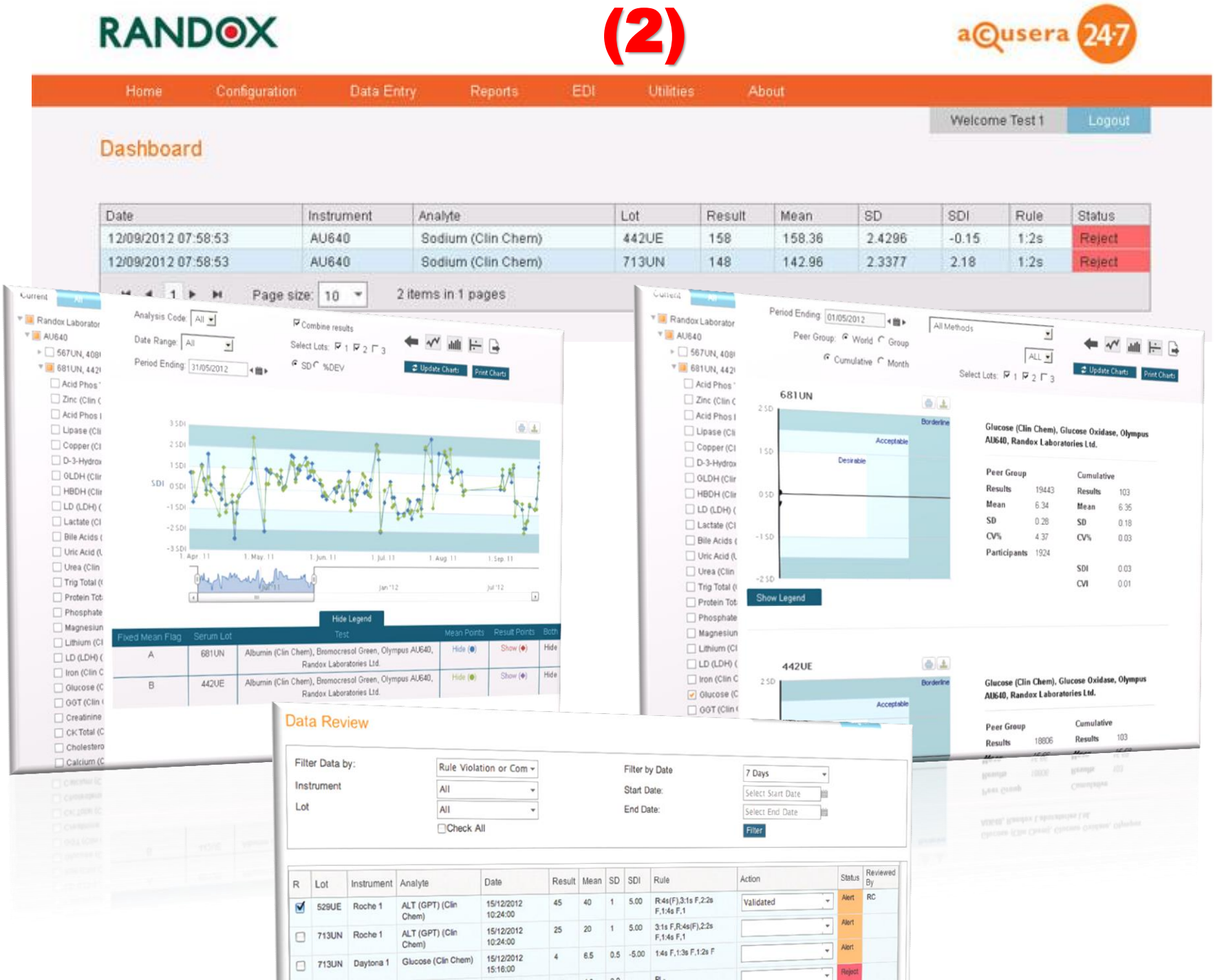
Farklı İKK yaklaşımları (1)










RANDOX
(2)
aQusera 24·7
Home
Configuration
Data Entry
Reports
EDI
Utilities
About
Welcome Test 1
Logout
Dashboard
Date
Instrument
Analyte
Lot
Result
Mean
SD
SDI
Rule
Status
12/09/2012 07:58:53
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442UE
158
158.36
2.4296
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1:2s
Reject
12/09/2012 07:58:53
AU640
Sodium (Clin Chem)
713UN
148
142.96
2.3377
2.18
1:2s
Reject
Page size: 10
2 items in 1 pages
Data Review
Filter Data by:
Rule Violation or Com
Instrument
All
Lot
All
Check All
Filter by Date
7 Days
Start Date:
Select Start Date
End Date:
Select End Date
Filter
681UN
442UE
Glucose (Clin Chem), Glucose Oxidase, Olympus AU640, Randox Laboratories Ltd.
Show Legend
Hide Legend

Analit ve Analize göre kalite uygulamaları

Kolesterol

- CLIA sets a criterion for acceptable performance as 10% of the target value (TV) in proficiency testing surveys [6].
- NCEP sets the maximum specifications for method CV at 3.0% and method bias at 3.0% [*].
- NCEP sets a clinical decision interval of 20% based on a desirable cholesterol level of 200 mg/dL or less and an undesirable level of 240 mg/dL or greater, i.e., 40 mg/dL at a level of 200 mg/dL [*].

[*] National Cholesterol Education Program Laboratory Standardization Panel. Current status of blood cholesterol measusrements in clinical laboratories in the United States. Clin Chem 1988;34:193-201.

Table 1

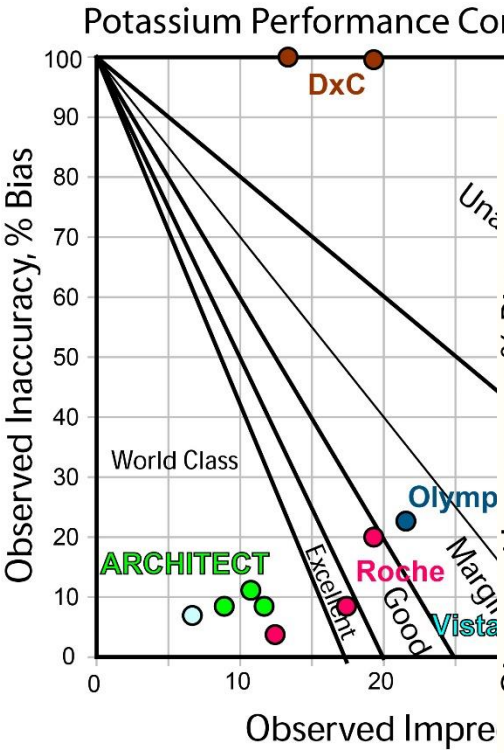
Estimates of Analytic Quality for Cholesterol, Calcium, Glucose, and Glycohemoglobin as Determined From National PT Surveys*

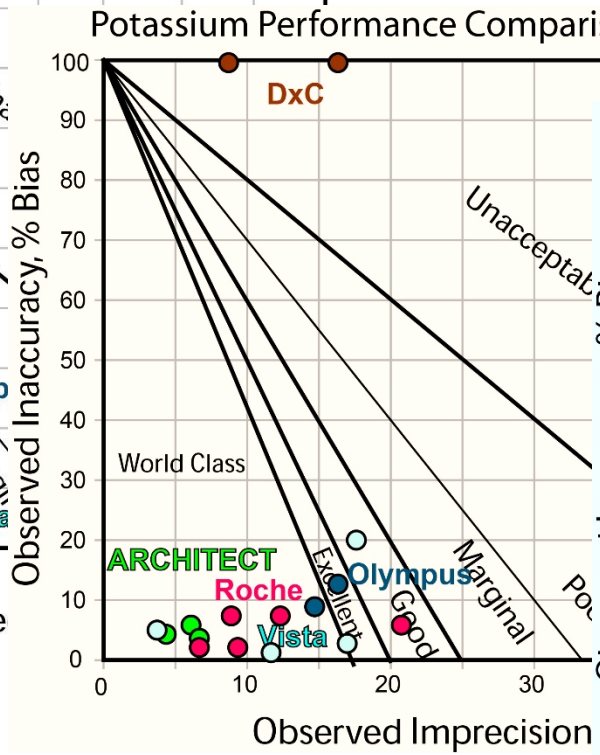
PT Program	No. of Laboratories	Group Mean	NTQ (σ)	NMQ (σ)	LMQ (σ)
Cholesterol with TE_a = 10.0%					
AAFP	296	201.0	2.01	2.01	2.54
MLE	577	224.4	2.27	2.38	2.99
AAB	1,498	223.0	2.37	2.68	3.51
API	2,647	221.3	2.28	2.37	3.19
CAP	4,240	198.7	3.57	3.71	4.19
Summary	**9,258**	**210.8**	**2.88**	**3.02**	**3.67**
Calcium with TE_a = 1.0 mg/dL					
AAFP	164	10.2	2.50	2.35	2.71
MLE	528	10.5	2.44	2.69	3.50
AAB	1,444	11.1	2.78	2.95	3.37
API	2,695	11.1	2.63	2.98	3.45
CAP	4,955	10.4	3.03	3.07	4.30
Summary	**9,786**	**10.7**	**2.84**	**3.00**	**3.86**
Glucose with TE_a = 10.0%					
AAFP	245	134.0	1.91	2.64	3.16
MLE	628	106.1	1.75	2.13	2.99
AAB	1,665	106.4	2.22	2.60	3.20
API	3,038	106.6	2.42	2.70	3.24
CAP	5,146	149.6	3.70	4.14	4.88
Summary	**10,722**	**120.5**	**2.95**	**3.34**	**4.00**
Glycohemoglobin with TE_a = 10.0%					
AAFP	209	9.30	1.82	2.12	2.76
MLE	342	9.03	1.31	1.15	2.33
AAB	885	8.11	1.53	1.82	2.50
API	1,650	9.27	1.69	1.69	2.35
CAP	1,980	9.30	2.43	2.29	2.82
Summary	**5,066**	**9.06**	**1.93**	**1.93**	**2.57**

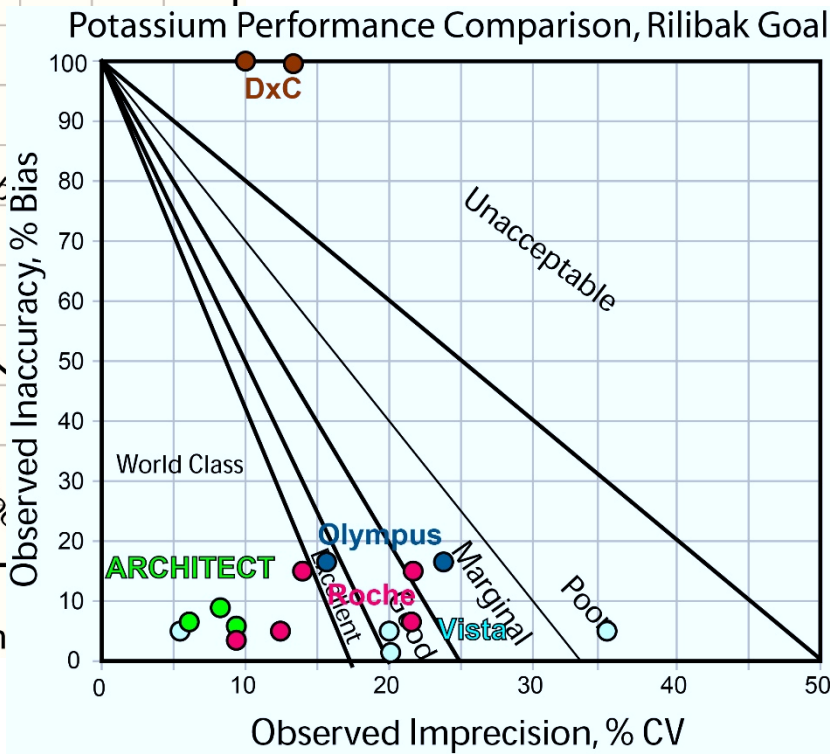
AAB, American Association of Bioanalysts; AAFP, American Academy of Family Physicians; API, American Proficiency Institute; CAP, College of American Pathologists; LMQ, local method quality; MLE, Medical Laboratory Evaluation; NMQ, national method quality; NTQ, national test quality; PT, proficiency testing; TE_a, allowable total errors.

* Presented as σ metrics. The group means for cholesterol, calcium, and glucose are given in conventional units (mg/dL); for glycohemoglobin, as the percentage of hemoglobin. The following are conversion factors for Système International units: cholesterol, multiply by 0.02586 (mmol/L); calcium, multiply by 0.25 (mmol/L); glucose, multiply by 0.05551 (mmol/L). Summary figures, in bold, are weighted averages that account for the relative number of laboratories in the respective PT groups.

Analyte	Acceptance criteria / quality requirements					
	CLIA	Desirable Biologic Goal	RCPA	Rilibak	SEKK	Spanish Minimum Consensus
Potassium	± 0.5 mmol/L	± 5.8%	± 0.2 mmol/L ≤ 4.0 mmol/L ± 5% > 4.0 mmol/L	± 8%	± 8%	± 8%







Quality Control in Coagulation Testing

Semin Thromb Hemost 2008; 34(7): 642-646

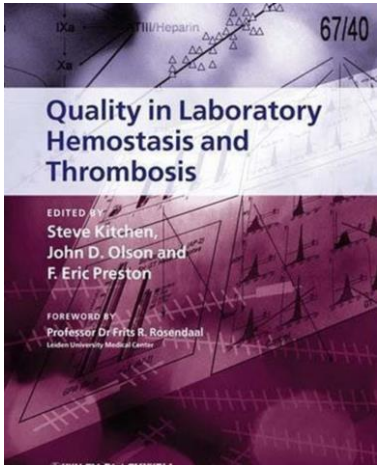


Table 2 Quality of Some Coagulation Testing According to the Six Sigma Metrics

	Mean	NTQ (σ)	NMQ (σ)	LMQ (σ)
PT ($TE_A = 15\%$)	16.8	—	1.77	5.35
INR ($TE_A = 20\%$)	1.57	—	2.39	3.52
Fibrinogen ($TE_A = 20\%$)	260.0	1.78	2.01	3.24

Common goals: minimum acceptable of 3 σ, strive for 6 σ.
Source: From Westgard JO, Westgard SA. The quality of laboratory testing today. Am J Clin Pathol 2006;125:343–354.

Table 1 The Median and Range of the Long-Term Analytical Coefficient of Variation (LCVa, %), Bias (B, %), and Total Error (TE, %) for Antithrombin, Protein C, and Protein S

		LCVa (%)		Bias (%)		Total Error (%)	
Analyte	**Laboratories (Number)**	**Median**	**Range**	**Median**	**Range**	**Median**	**Range**
Antithrombin (activity)	136	7.6	2.6–43.8	3.8	0.3–17.1	9.1	3.4–34.3
Protein C (activity)	132	8.6	3.3–33.3	4.4	0.4–27.3	10.0	4.0–53.3
Protein C (antigen)	48	10.8	4.7–33.4	6.8	1.2–14.9	12.4	6.3–35.8
Protein S (activity)	69	17.2	4.3–88.6	12.8	3.1–34.8	24.5	9.9–87.0
Protein S (total antigen)	79	13.4	5.9–52.1	10.7	1.9–40.5	18.5	8.9–48.1
Protein S (free antigen)	65	14.1	5.4–91.8	9.2	3.3–34.3	17.9	9.4–54.9

Source: Modified from Meijer P, Haverkate F, Kluft C. Performance goals for the laboratory testing of antithrombin, protein C and protein S. Thromb Haemost 2006;96:584–589.

Immunoassay

- Immunoassay methods often have higher CVs than observed for routine chemistry and hematology tests.
- Laboratory QC practices often involve analyzing 3 or 4 different levels of controls and sometimes analyzing these controls in duplicate.
- In planning QC for such applications, it is useful to assess the error detection and false rejections characteristics of higher N multirule QC procedures and see how they compare with the performance from more common QC procedures having Ns of 2 to 4.

Table 2 Suggested acceptable levels of precision

Method	Acceptable precision (between-batch coefficient of variation, %)
Turbidimetry	3–5
Nephelometry	3–5
ELISA	8–12
Radioimmunoassay	8–12
Radial immunodiffusion	10–20
Rocket electrophoresis	10–20

ELISA, enzyme-linked immunosorbent assay.

Take-home messages

- The major objective of quality assurance is to improve the quality of results such that uniformity exists both within and between laboratories.
- Monitoring analytical sensitivity is essential to prevent the reporting of false-negative results.
- For quantitative data, Shewhart/Levey–Jennings charts are useful in monitoring precision.
- "Third-party" controls should be included wherever possible.
- The main benefits of internal quality control are realised with early recognition of problems and swift introduction of corrective action.

1. two consecutive points outside 2 SD;
2. a single point outside 3 SD;
3. five consecutive points either rising or
4. five consecutive points either above or

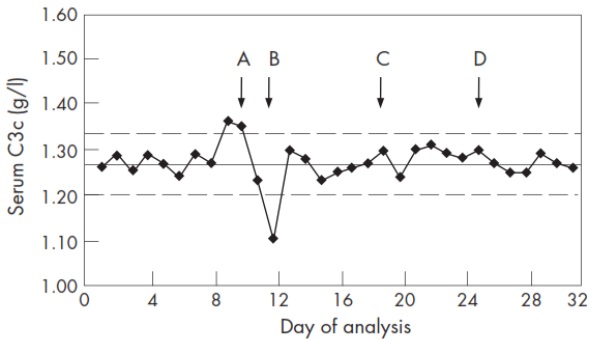


Figure 1 Shewhart chart for serum complement C3c. "Action points" are shown by arrows A–D. These indicate where the assay is potentially out of control (see text) and where remedial action should be considered.

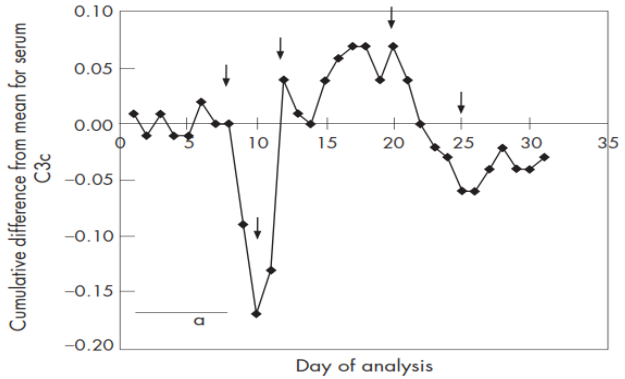


Figure 2 Cusum chart with the same serum complement C3c data as in fig 1. Area "a" shows an accurate assay in good control. Arrows indicate points where a change in accuracy has occurred.

My approach to internal quality control in a clinical immunology laboratory

J Clin Pathol. 2006 Jul; 59(7): 681–684.

Tam kan performansları

Assay	Ricos CV%	Ricos Bias%	Ricos TEa%	CLIA TEa%	Spanish Minimum TEa%	Rilibak TEa%
WBC	5.73%	6.05%	15.44%	15%	9.0%	12.0%
RBC	1.6%	1.7%	4.4%	6.0%	4.0%	8.0%
HGB	1.43%	1.84%	4.19%	7.0%	5.0%	6.0%
HCT	1.35%	1.74%	3.97%	6.0%	8.0%	9.0%
MCV	0.7%	1.26%	2.42%		7.0%	
PLT	4.6%	5.9%	13.4%	25.0%	16.0%	
Neutrophils	8.55%	9.25%	23.35%			
Lymphocytes	5.1%	9.19%	17.6%			
Monocytes	8.9%	13.2%	27.9%			
Eosinophils	10.5%	19.8%	37.1%			
Basophils	14.0%	15.4%	38.5%			

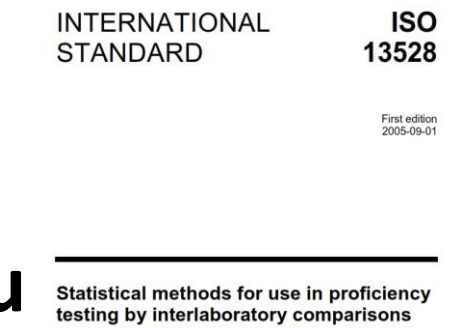
Tam Kan Analizi

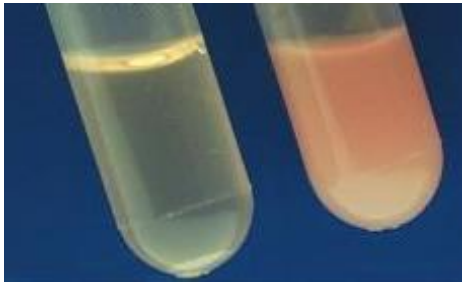
Analyte	Biologic-Based QC procedure recommendation	CLIA-Based QC procedure recommendation
RBC	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}$ with N=3	1_{3s} with N=3
HGB	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}$ with N=6	$1_{3.5s}$ with N=3
HCT	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6_{x}$ with N=6	$1_{2.5s}$ with N=3
PLT	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6_{x}$ with N=6	$1_{3.5s}$ with N=3
WBC	$1_{3.5s}$ with N=3	$1_{3.5s}$ with N=3
%Neutrophil	$1_{3.5s}$ with N=3	---
%Lymphocyte	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6_{x}$ with N=6	---
%Monocyte	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6_{x}$ with N=6	---
%Eosinophile	$1_{3s}/2of3_{2s}/R_{4s}/3_{1s}$ with N=3	---
%Basophile	$1_{3.5s}$ with N=3	---

"Implementation of the process Six Sigma in Haematology's Laboratory" by Recondo C. Grassi C, Blanco M, and Domecq P., Clin Chem Lab Med 2008; 46,

İKK sınırlılıkları

- Commutability
- Materyal farklılıkları
- Stabilite
- Homojenite
- Değerlerinin klinik durumlarla uyumu
- Eş grup değerlendirme problemleri
- Maliyetleri (Unassayed daha uygun)
- Bulunabilirlikleri





Kalite Kontrol materyalleri birbirinden farklıdır

ELSEVIER

Clinica Chimica Acta 327 (2003) 25–37

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Review

Specimen materials, target values and commutability for external quality assessment (proficiency testing) schemes

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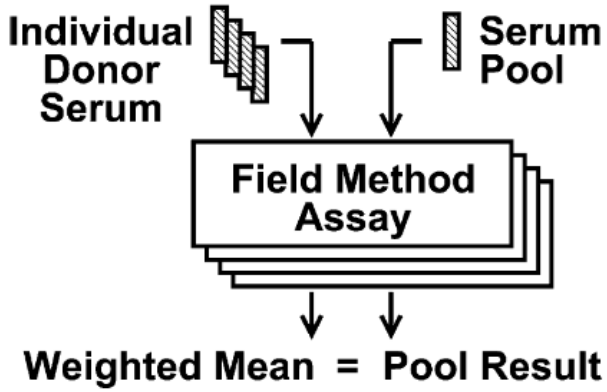
Received 28 June 2002; received in revised form 2 October 2002; accepted 8 October 2002



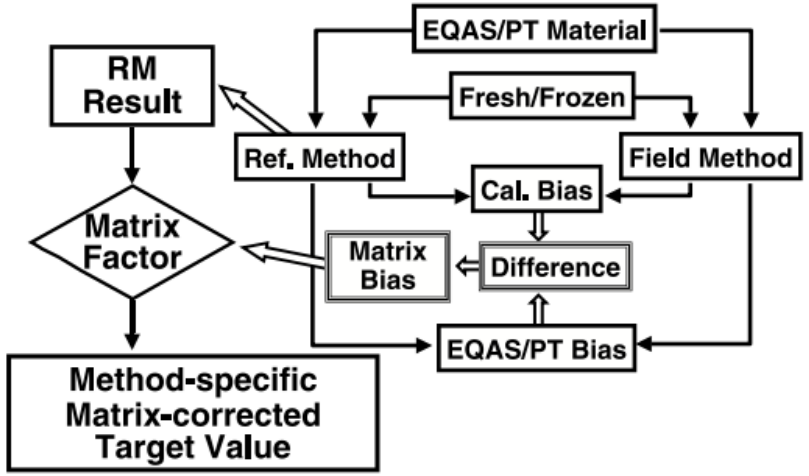


Table 1
Examples of method-specific matrix-corrected target values for cholesterol[a]

Reference method value = 4.40 mmol/l				
Method	PT material result (mmol/l)	Calibration bias from FF[b] result (%)	Matrix bias (%)	Matrix-corrected target value[c] (mmol/l)
Hitachi/Roche	4.23	0.3	−4.2	4.22 ± 0.02
Dimension	3.99	1.2	−10.5	3.94 ± 0.02
Beckman	4.51	3.1	−0.5	4.38 ± 0.02
Vitros	4.35	−2.8	1.8	4.48 ± 0.02

[a] Adapted from Ross et al. [5] for specimen C-02 in the 1994 College of American Pathologists Comprehensive Chemistry Survey.
[b] FF is a fresh-frozen unadulterated off-the-clot pooled serum specimen.
[c] ± 95% confidence interval.

C37-A
Vol. 19 No. 25
Replaces C37-P
Vol. 18 No. 7

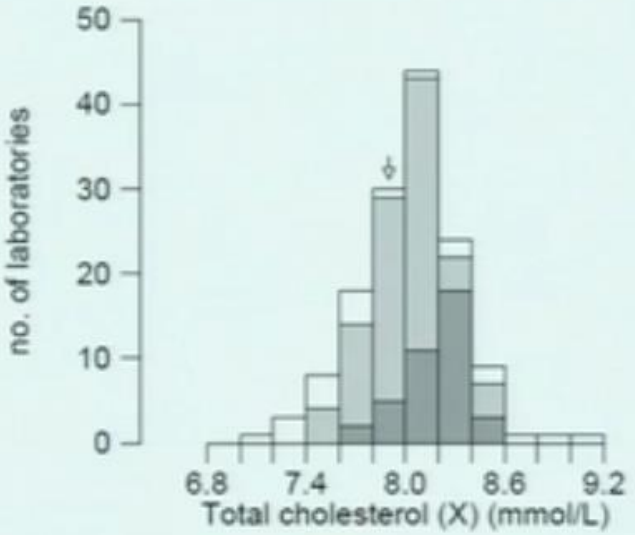
November 1999

Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline

Total cholesterol - fresh single donor serum

Specimen : 115D

	n	Mean	SD	CV(%)
All methods	131	8.04	0.27	3.3
Dry slide	12	7.53	0.24	3.1
OCD (J&J) slides [1JJ]	12	7.53	0.24	3.1
Cholesterol oxidase	119	8.09	0.23	2.8
Abbott reagents [2AB]	27	8.04	0.07	0.9
Beckman reagents [2BK]	11	8.12	0.11	1.3
Dade Behring reagents [2BE]	3	7.83		
Olympus reagents [2OL]	19	8.24	0.21	2.5
Roche reagents [2BO]	39	8.22	0.17	2.1
Siemens (Bayer) reagents [2TE]	20	7.78	0.14	1.8
Point of care	9	8.49	0.43	5.1
Cholestech	9	8.49	0.43	5.1



Reference method value 8.53 mmol/L

		Analyser on y axis						
		Material	E170	AxSYM	OCD	Architect	Beckman	Immulite
Analyser on x-axis	Centaur	Patients	0.907	0.924	0.740	0.732	0.855	0.764
	Centaur	QAP	0.875	0.929	0.907	0.776	0.800	0.993
	Centaur	Liquicheck	0.916	0.858	0.958	0.762	0.967	1.139
	Centaur	Lyphocheck	0.939	0.986	1.012	0.734	0.872	1.228
	E170	Patients		1.015	0.823	0.805	0.940	0.839
	E170	QAP		1.061	1.038	0.888	0.911	1.134
	E170	Liquicheck		0.939	1.043	0.795	1.054	1.240
	E170	Lyphocheck		1.049	1.077	0.782	0.928	1.306
	AxSYM	Patients			0.796	0.791	0.921	0.821
	AxSYM	QAP			0.976	0.835	0.861	1.068
	AxSYM	Liquicheck			1.051	0.567	1.068	1.245
	AxSYM	Lyphocheck			1.025	0.744	0.884	1.245
	OCD	Patients				0.970	1.135	1.015
	OCD	QAP				0.855	0.876	1.091
	OCD	Liquicheck				1.270	1.006	1.191
	OCD	Lyphocheck				0.726	0.862	1.214
	Architect	Patients					1.165	1.038
	Architect	QAP					1.027	1.278
	Architect	Liquicheck					0.923	0.859
	Architect	Lyphocheck					1.187	1.670
	Beckman	Patients						0.892
	Beckman	QAP						1.233
	Beckman	Liquicheck						1.183
	Beckman	Lyphocheck						1.408

Slopes for each material in each set of analyser pairs.

TSH için

Stabilite için örnek

Table 4 Percentage changes in concentration of analytes at the end of 7 months

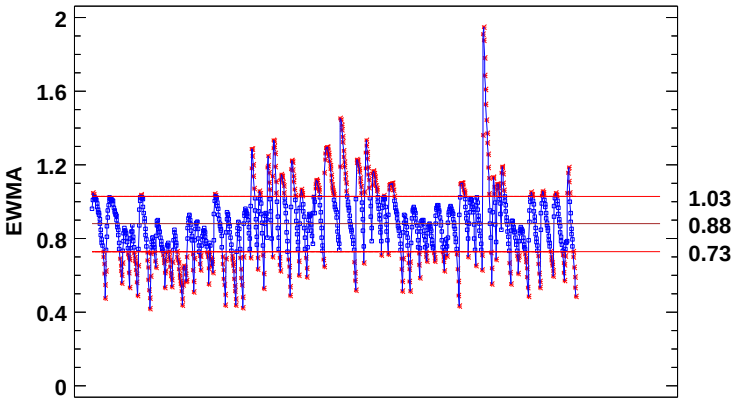
Tests	At 2–8 °C (%)	At −20 °C (%)	RT (%)
Glu	+2	3	−43
BUN	0	0	−18
Creat	−2	−2	−56
AST	−10	0	47
ALT	+11	8	55
ALP	−1	4	12
TB	+4	3	−7
TP	−1	1	4
Alb	−1	0	−1

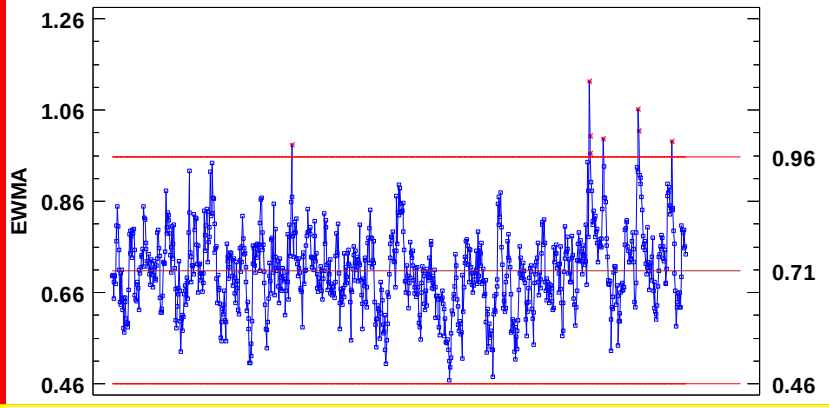
İç kalite kontrol sonuçlarındaki sınırlı oynamalar hasta sonuçlarını etkiliyor mu?

Cihaz 1

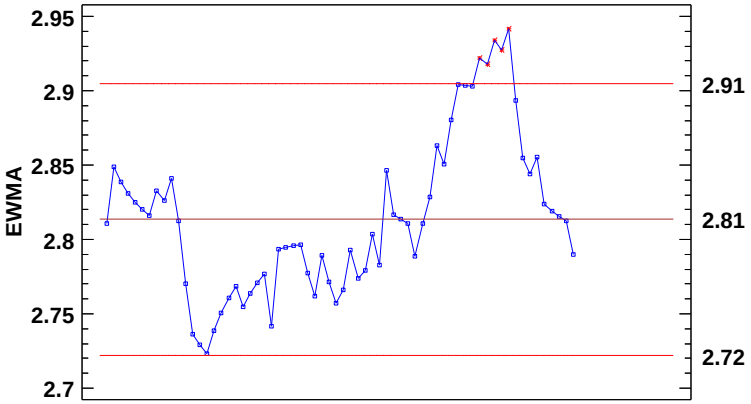
Cihaz 2

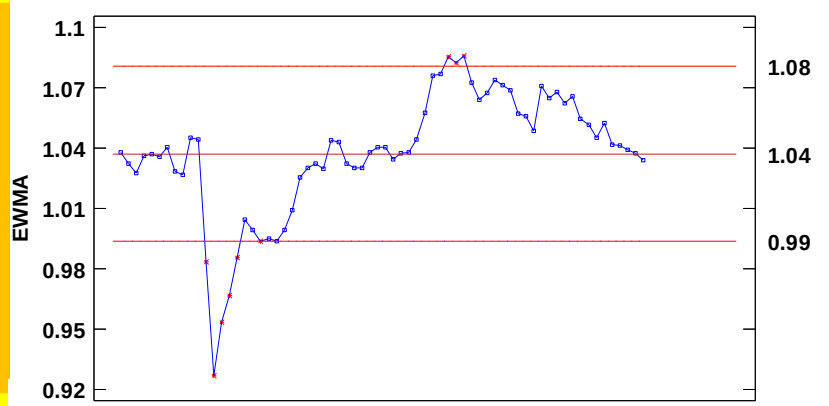
HASTA SONUÇLARI





Düzey 1 Kontrol





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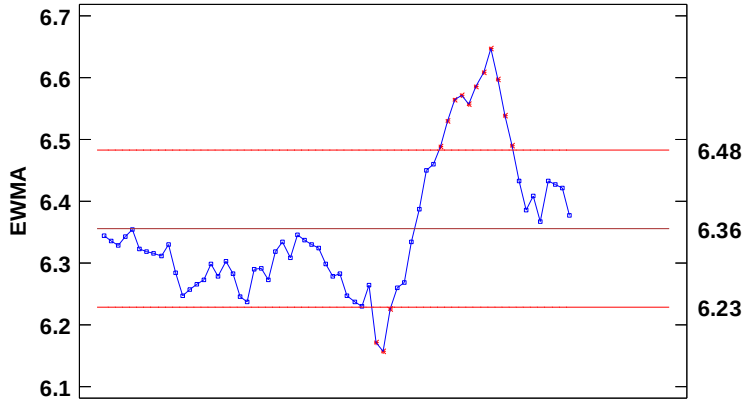

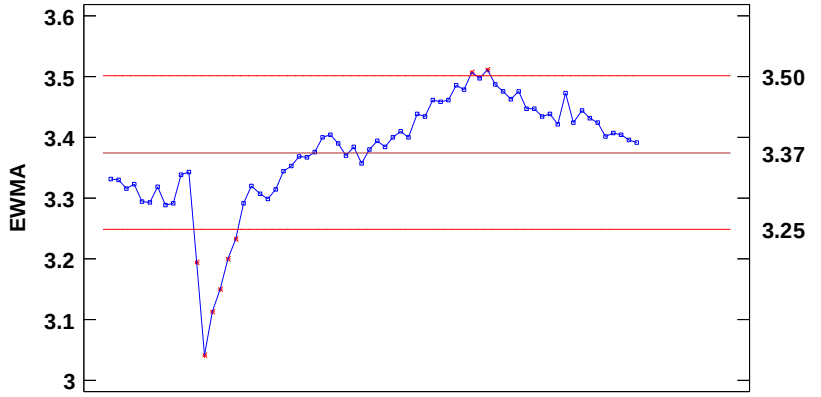

Sonuç

- **LBYS en kritik ekipmanınız.**
- **Standardizasyon ve harmonizasyon çalışmalarının güncel olarak takip edilmesi**
- **Kullanılan metoda ait üreticilerden gerekli bilgilerin alınması ve değerlendirilmesi**
- **Analite, metoda, klinik ihtiyaca ve laboratuvarın yapısına uygun kalite indikatörlerinin seçilerek süreç takip optimizasyon**
- Analitik ihtiyacın belirlenmesi (?)
- Ulusal bir KK programına ihtiyacımız var
- **İhtiyaca ve analite uygun riski minimalize eden kalite kontrol uyulması**
- **Alternatif kalite kontrol uygulamalarında bilgi sahibi olunmalı. Hasta sonuçlarından KK uygulamalarına ağırlık verilmeli**

Bilgilerinden yararlandığım ve verilerini kullandığım bütün bilim insanlarına teşekkür ederim.