TIBBİ LABORATUVARLARDA KALİTE İNDİKATÖRLERİ: ANALİTİK AŞAMA

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Kaliteli ve güvenilir bir laboratuvardan bahsetmek için laboratuvarı bir birim olarak değil bir süreç olarak değerlendirmek gereklidir.

Hatalı laboratuvar sonuçları tıbbi hataların en önemli nedenlerinden biridir.

Bu nedenle, doğru laboratuvar test sonuçları günümüzde tıbbi hataların azaltılmasında çok önemli role sahiptir.

Kohn Linda T, Corrigan Janet M, Donaldson Molla S. To err is human: building a safer health system. Washington, DC: Committee on Quality of Health Care in America. Institute of Medicine. National Academy Press; 2000.

- **KALİTE İNDİKATÖRÜ (CLSI):**

  Kalitenin bir parçası olarak spesifik faaliyetlerin ölçülerek izlenmesi veya kalite sistemi hakkında bilgi almak için sistematik ölçüm sistemi.

quality indicator-measurement (metric) to monitor spesific activities as part of the quality management system

CLSI (Clinical and Laboratory Standards Institute)

Tıbbi hatalar; zaman kaybı,yetersiz tedavi, ek maliyet ve tanı gecikmesine belki de ölüme kadar gidebilecek durumlar yaratmaktadır.

- Bu hataların oluştuktan sonra değil oluşmadan önlenmesi asıl amaç olmalıdır.
- Bunun içinde ölçülebilir, tarafsız ve sürekli geliştirilen prosedürler gereklidir.
- Bu prosedürler kalite indikatörleri olarak sunulabilir. Kalite indikatörlerinin temelinde potansiyel hataların değerlendirilmesi ve gözlenen hataların sıklığı vardır.
- Bunlar tüm kalite yönetim sistemlerinde aslında var olan komponentlerdir. (ISO 9001,ISO 15189 ve ISO 17025)
- CLSI dökümanında tüm bu özellikler tanımlanmıştır.

- **CLSI, kendi kılavuzunu kullanarak laboratuvar içinde ve daha da iyisi ulusal düzeyde kalite indikatörlerinin geliştirilebileceğini ve standardizasyon sağlanabileceğini belirtmektedir.**

- **Bu kılavuzun amacı doğru,etkin,efektif,sürekli kullanılabilecek kalite indikatörleri belirlemeyi sağlayabilmektir.**

CLSI (Clinical and Laboratory Standards Institute)

Pre-Analitik (Ölçüm öncesi) Evre

Analitik (Ölçüm) Evre

- İç kalite kontrolünün, gerekirse kalibrasyonların yapılması
- Kontrol sonuçlarının değerlendirilmesi
- Tetkik/Analiz
- Sonuçların gözden geçirilmesi
- Yorum

Post-Analitik (Ölçüm sonrası) Evre

Pre-Analitik Hatalar ***(%50-%75)***

Analitik Hatalar ***(%7-13)***

- Personel hataları
- Hatalı ölçüm yapan pipet vs.
- Reaktiflerin bozulması
- Cihaz hataları

Post-Analitik Hatalar ***(%18,5-47)***

Biochem Med (Zagreb). Feb 2014; 24(1): 105–113.
Harmonization of pre-analytical quality indicators
Mario Plebani,Laura Sciacovelli,Ada Aita,and Maria Laura Chiozza

International Federation of Clinical Chemistry and Laboratory Medicine(IFCC)

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

Abstract

The identification of reliable quality indicators (QIs) in the total testing process (TTP) represents a crucial step in enabling users to quantify the quality of laboratory services, but the current lack of attention to extra-laboratory factors is in stark contrast with the body of evidence showing the multitude of errors that continue to occur in the pre- and post-analytical phases. Although interesting programs on indicators of the extra-analytical phases have been developed in some countries, there is no consensus on the production of joint recommendations for the adoption of universal QIs and the use of common terminology in the total testing process. In view of the different QIs and terminologies currently used, there an urgent need to harmonize pro-

Introduction

Accurate and efficient clinical laboratory testing is a critical component of high-quality patient care as laboratory test results influence most medical decisions, including diagnosis, prognosis, risk and predictive assessment, and prevention, screening and the monitoring of treatments and therapies. In addition, aggregate test result data are used for public health surveillance, healthcare performance measurement, and quality improvement [1]. The quality of laboratory testing, therefore, may greatly affect the quality and affordability of patient care and any defects or errors impact on the care of each patient as well as the costs incurred by the healthcare system [2]. However, the laboratory testing process is complex

Kalite indikatörleri:

- Mutlaka hasta odaklı olmalı
- Tıbbi laboratuvar akreditasyonunun uluslararası standardizasyonunun gerekliklerine uyumlu olmalı

(ISO 15189:2012)

- İndikatörler tüm test sürecini kapsamalı

- Klinik laboratuvarlar şimdi iç kalite kontrol,dış kalite kontrol /yeterlilik testleri , kalite spesifikasyonları sayesinde objektif olarak kendilerini değerlendirebiliyorlar.

- IFCC çalışma grubu kalite indikatörü olarak 56 anahtar süreç belirlemiştir.
- Pre-analitik:34
- **Analitik:7**
- Post-analitik:15

Event kept under control: patient identification

Quality indicator (percentages)	Data collection	Time	Note
Number of requests with errors in patient identification/total number of requests	a) count requests with patient identification errors b) count total number of requests c) calculate percentage	Data collection: every day Input data: every month	Errors concerning total (patient identity not assured) and partial (patient identity assured) patient identification has to be included.
Number of requests with errors concerning patient identification, detected before release of results/ total number of requests	a) count requests with errors in patient identification, detected before release of results b) count total number of requests c) calculate percentage	Data collection: every day Input data: every month	Error detected and corrected before release of results. Errors concerning total (patient identity not assured) and partial (patient identity assured) patient identification has to be included.
Number of requests with errors concerning patient identification, detected after release of results/total number of requests	a) count requests with errors in patient identification, detected after release of results b) count total number of requests c) calculate percentage	Data collection: every day Input data: every month	Error detected and corrected after release of results. Errors concerning total (patient identity not assured) and partial (patient identity assured) patient identification has to be included.
Number of misidentified	a) count requests with uncorrected	Data collection:	This indicator must measure the

Appropriateness of test request	Number of requests with clinical question (outpatients)/total number of requests (outpatients) Number of appropriate requests, with respect to clinical question (outpatients)/number of requests reporting clinical question (outpatients)
Patient identification	Number of requests with errors concerning patient identification/total number of requests Number of requests with errors concerning patient identification, detected before release of results/total number of requests Number of requests with errors concerning patient identification, detected after release of results/total number of requests Number of misidentified patients/total number of patients
Request form Order entry	Number of unintelligible outpatient requests/total number of outpatient requests Number of outpatient requests with errors in physician's identification/total number of outpatients requests Number of outpatients requests with errors concerning test input (missing)/total number of outpatient requests Number of outpatient requests with errors concerning input of tests (added)/total number of outpatients requests Number of outpatients requests with errors concerning test input (misinterpreted)/total number of outpatients requests Number of inpatients requests with errors concerning test input (missing)/total number of inpatients requests Number of inpatients requests with errors concerning input of tests (added)/total number of inpatients requests Number of inpatients requests with errors concerning test input (misinterpreted)/total number of inpatients requests
Sample identification	Number of samples improperly labeled/total number of samples

Sample identification	Number of samples improperly labeled/total number of samples
Sample collection	Number of samples collected at inappropriate collection time/total number of samples
	Number of samples collected with inappropriate sample type/total number of samples
	Number of samples collected in inappropriate container/total number of samples
	Number of samples with insufficient sample volume/total number of samples
Sample transportation	Number of samples damaged/total number of samples
	Number of samples transported in inappropriate time/total number of samples for which the transport time is checked
	Number of samples transported under inappropriate temperature conditions/total number of samples for which the transport temperature is checked
	Number of samples improperly stored/total number of samples
	Number of samples lost-not received/total number of samples
Sample acceptance/ rejection	Number of contaminated blood culture/total number of blood cultures
	Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant
	Number of samples hemolyzed (hematology)/total number of samples (hematology)
	Number of samples hemolyzed (chemistry)/total number of samples (chemistry)
	Number of samples clotted (hematology)/total number of samples with anticoagulant (hematology)
	Number of samples clotted (chemistry)/total number of samples with anticoagulant (chemistry)
	Number of samples clotted (immunology)/total number of samples with anticoagulant (immunology)
	Number of samples hemolyzed (immunology)/total number of samples (immunology)
	Number of lipemic samples/total number of samples
	Number of samples unacceptable (microbiology)/total number of samples (microbiology)

Table 2 Indicators for pre-analytical phase (percentages).

Analytical performance	Number of tests kept under control with EQAS-PT per year/total number of tests provided by service, per year Number of unacceptable performances in EQAS-PT Schemes per year/total number of performances in EQA Schemes Number of unacceptable performances in EQAS-PT Schemes per year occurring in previously treated cause/total number of unacceptable performances Number of IQC values that exceed the selected target, per year/total number of IQC values Number of tests with CV% higher than selected target, per year/total number of tests with known CV%
Instrumentation efficiency	Number of reports with delayed delivery for instrumentation failures, per year/total number of reports
Data entry	Number of incorrect results for erroneous transcription and/or manual entry data in computer system/total number of results requiring transcription and/or manual entry in the computer system

Table 3 Indicators for intra-analytical phase (percentage).

İntra analitik fazın İndikatörleri (yüzde olarak)

1) **Yıllık EQAS-PT ile kontrol edilen test sayısı**

   Laboratuvar tarafından çalışılan testlerin toplam sayısı

2) **Yıllık EQAS-PT şemasında kabul edilemeyen toplam test sayısı**

   EQAS-PT şemasındaki toplam test sayısı

3) **Önceden düzeltme çalışması yapıldığı halde EQAS-PT şemasına göre kabul edilemeyen performans sayısı**

   Kabul edilmeyen performansların toplam sayısı

4) **Yıllık hedef değerleri aşan internal kalite kontrol değerlerinin sayısı**

İnternal kalite kontrol değerlerinin toplam sayısı

5) **Hedef değerden daha yüksek % CV li test sayısı**

% CV si bilinen toplam test sayısı

Cihaz etkinliği

6) **Yıllık cihaz arızalarının gecikmiş raporlanma sayısı**

Toplam rapor sayısı

Data girişi

7) **Bilgisayar sisteminde manuel giriş veya veri aktarımı sırasındaki yanlış sonuç sayısı**

Manuel veya bilgisayar girişli toplam sonuç sayısı

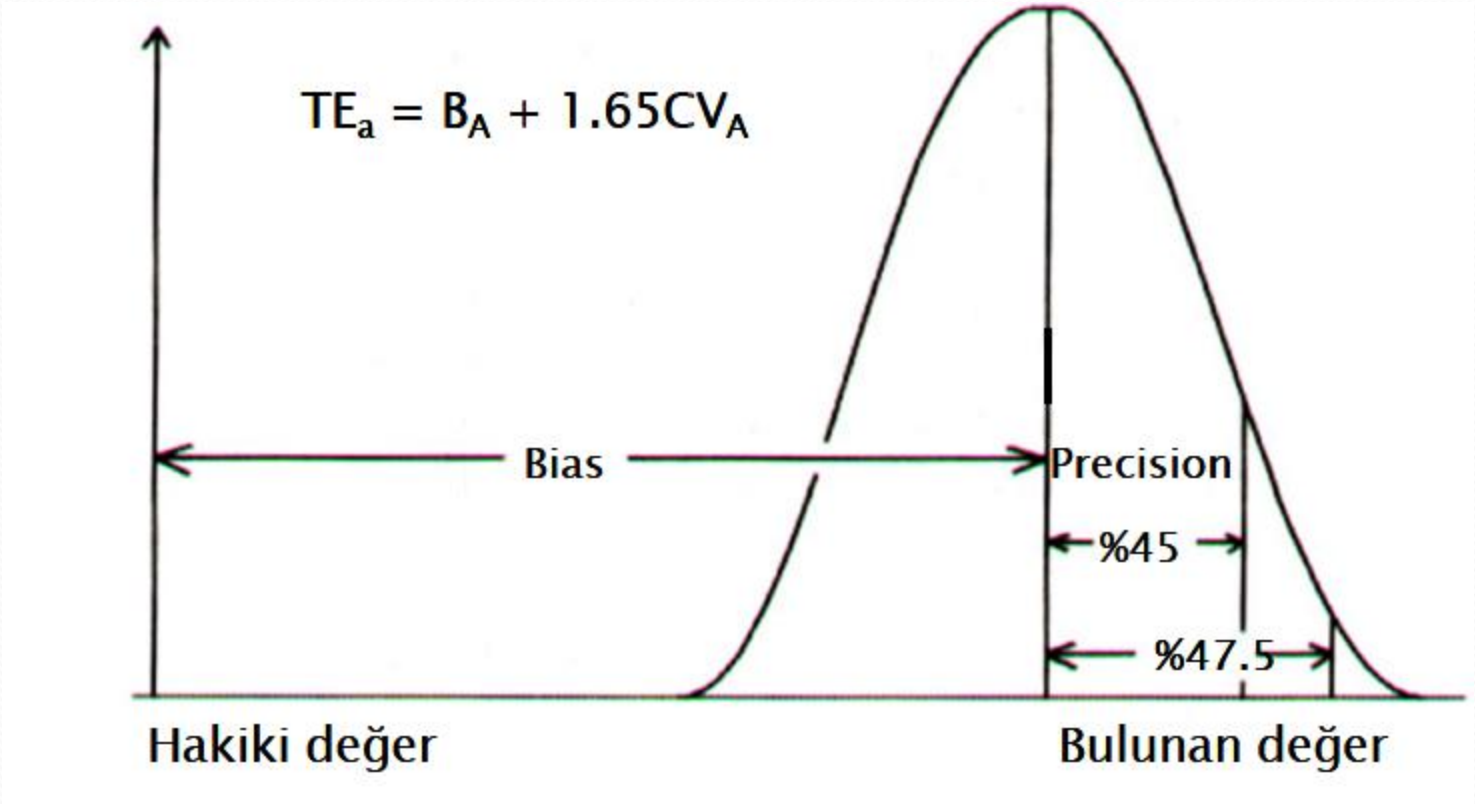
Timeliness of results reporting	Number of reports delivered outside the specified time/total number of reports (percentage) Turn around time (minutes) of potassium at 90th percentile (emergency) Turn around time (minutes) of potassium at 90th percentile (routine) Turn around time (minutes) of International Normalized Ratio value at 90th percentile (routine)" Turn around time (minutes) of C-Reactive Protein at 90th percentile (routine) Turn around time (minutes) of White Blood Cells at 90th percentile (routine) Turn around time (minutes) of Troponin I or Troponin T at 90th percentile (routine)
Accuracy of results reporting	Number of outpatients called back for a blood re-collection due to unsuitable samples or incorrect results/total number of outpatients (percentage) Number of corrected reports/total number of reports (percentage)
Timeliness and effectiveness of critical values reporting	Number of critical values of inpatients communicated within an hour (from result validation to result communication to clinician)/total number of critical inpatients values to communicate (percentage) Number of critical values of outpatients communicated within an hour (from result validation to result communication to clinician)/total number of critical outpatients values to communicate (percentage) Time (from result validation to result communication to clinician) to communicate critical inpatient values (minutes) Time (from result validation to result communication to clinician) to communicate critical outpatient values (minutes)
Effectiveness of interpretative comments	Number of reports with interpretative comments, provided in medical report, impacting positively on patient's outcome/total number of reports with interpretative comments (percentage)
Effectiveness of clinical audit	Number of guidelines issued in co-operation with clinicians per year

Table 4 Indicators of post-analytical phase.

Efficiency of Laboratory Information System	Number of Laboratory Information System downtime episodes, per year
Employee competence	Number of training events organized for all staff, per year
	Percentage "Number of credits obtained by employee, per year/total number of credits to be obtained, per year"

Table 5 Indicators concerning support processes.

Total Hata (Analitik Kavramı)



Toplam hata= Bias+z*precision

% 95 güven aralığı için

Tea=Bias+1.65×precision

DİĞER ANALİTİK KALİTE BELİRLEYİCİLERİ NELER?

İzin verilebilir total hata (TEa) ve biyolojik değişkenlik (CV_I : Birey içi ;CV_G :Bireyler arası)

- Clinical Laboratory Improvement Amendments 88 (CLIA'88),
- Rilibak (Alman Kalite Kılavuzu),
- Royal College of Pathologists of Australasia (RCPA) http://www.rcpaqap.com.au/wpcontent/uploads/2013/06/chempath/Allowable%20Limits%20of%20Performance.pdf
- Carmen Ricos (İspanya)
- Callum G. Fraser. Biological Variation. From principles to practise
- Westgard QC (www.westgard.com)

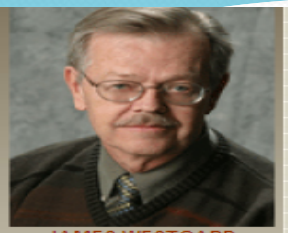
Biyolojik Değişkenliklere göre Analitik Kalite Hedefleri

	Minimum	Optimum	İstenen (desirable)
Biyolojik değişkenlik katsayılarına göre	$CV_A < 0{,}75\ CV_I$ $B_A < 0{,}375\ (CV_I^2 + CV_G^2)^{1/2}$	$CV_A < 0{,}25\ CV_I$ $B_A < 0{,}125\ (CV_I^2 + CV_G^2)^{1/2}$	$CV_A < 0{,}50\ CV_I$ $B_A < 0{,}25\ (CV_I^2 + CV_G^2)^{1/2}$

CV_A: Hedef analitik değişkenlik katsayısı
CV_I: Birey içi biyolojik değişkenlik katsayısı
CV_G: Bireyler arası biyolojik değişkenlik katsayısı
B_A: Hedef bias

Toplam Hataya göre analitik kalite hedefleri

- Bias (yanlılık): Sistematik hata göstergesi: sıfır olmalı veya
- Bias<0,33TEa olmalı
- $S_{analitik\ hedef} < TEa/2;TEa/3;TEa/4$ olmalı



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MINIMUM SPECIFICATIONS FROM BIOLOGICAL VARIATION DATABASE

When the best isn't possible, How low can you go? The Biologic Variation database, compiled by the Spanish CC society and Dr. Carmen Ricos, not only includes desirable and optimal specifications for imprecision, bias and total error, but also *minimum* specifications. For labs unable to achieve the recommended level of quality, here at least is the floor on performance. Updated for 2014.

Minimum Specifications for Total Error, Imprecision, and Bias, derived from intra- and inter-individual biologic variation

This most recent and extensive listing of biologic goals has been provided by Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500. *This database was most recently updated in 2014: see what was updated here.*

See The Reference List
See The References
See The original Guest Essay

Note on abbreviations:
CVw = within-subject biologic variation
CVg = between-subject biologic variation
I = minimum specification for imprecision
B = minimum specification for inaccuracy
TE = minimum specification for allowable total error

	Analyte	Biologic Variation		Minimum Specification		
		CV_I	CV_G	CV(%)	Bias (%)	TE_a
S-	α1-Antitrypsin	5.9	16.3	4.4	6.5	13.8
P-	α2-Antiplasmin	6.2	---	4.7	---	---
S-	α2-Macroglobulin	3.4	18.7	2.6	7.1	11.3
S-	α-Amylase	8.7	28.3	6.5	11.1	21.9
S-	α-Tocopherol	13.8	15.0	10.4	7.6	24.7
S-	Acid phosphatase tartrate-resistant	8.0	13.3	6.0	5.8	15.7
P-	Activate partial thromboplastin, time (APTT)	2.7	8.6	2.0	3.4	6.7
S-	Alanine aminopeptidase	4.1	---	3.1	---	---
S-	Albumin	3.	4.75	2.4	2.1	6.1
S-	Albumin, glycated	5.2	10.3	3.9	4.3	10.8
S-	Alkaline phosphatase, bone isoenzyme	6.2	37.4	4.7	14.2	21.9
P-	Antithrombin III	5.2	15.3	3.9	6.1	12.5
S-	Apolipoprotein B	6.9	22.8	5.2	8.9	17.5
S-	Apolipoprotein A1	6.5	13.4	4.9	5.6	13.6
S-	β2-Microglobulin	5.9	15.5	4.4	6.2	13.5
P-	C Protein	5.8	55.2	4.4	20.8	28.0
S-	Calcium	1.9	2.8	1.4	1.3	3.6
S-	Calcium, ionized	1.7	1.9	1.3	1.0	3.1
S-	Carbohydrate deficient transferrin	7.1	38.7	5.3	14.8	23.5

EQA from an Australian Perspective

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Abstract
Enrolment in external quality assurance programs is part of the accreditation process for medical laboratories in Australia, with the majority of Australian laboratories being enrolled in programs from RCPA Quality Assurance Programs Pty Limited, a company owned by the Royal College of Pathologists of Australasia. An important feature of these programs is that they have been developed with the involvement and contribution of the profession. For example, the Chemical Pathology programs are a joint venture between the company and the Australasian Association of Clinical Biochemists (AACB). Some of the unique features of the programs are the composition of the material, the use of target values, the structure and information in the reports and the use of the internet for data entry and data review. Over the past thirty years, the development of these programs has made a significant contribution to the quality of laboratories in Australia.

Allowable Limits of Performance

Programs, Analytes and Allowable Limits of Performance

ALCOHOL/AMMONIA	Reviewed January 2012
Alcohol	± 2.0 up to 20.0 mmol/L; 10% > 20.0mmol/L
Ammonia	± 5 up to 50 µmol/L; 20% > 50 µmol/L

ANTIBIOTICS	Reviewed April 2013
Amikacin	± 3.4 up to 34.0 µmol/L; 10% > 34.0 µmol/L
Gentamicin	± 0.2 up to 2.0 mg/L; 10% > 5.3 mg/L
Tobramycin	± 0.2 up to 2.0 mg/L; 10% > 5.1 mg/L
Vancomycin	± 2.0 up to 20.3 mg/L; 10% > 20.3 mg/L

BILE ACIDS	Reviewed January 2012
Total Bile Acids	± 4 up to 40 µmol/L; 10% > 40 µmol/L

BIOGENIC AMINES	Reviewed April 2012
Adrenaline	± 30 up to 100 nmol/L; 30% > 100 nmol/L
Dopamine	± 0.20 up to 2.0 µmol/L; 10% > 2.0 µmol/L
5HIAA	± 8 up to 40 µmol/L; 20% > 40 µmol/L
HMMA	± 6 up to 40 µmol/L; 15% > 40 µmol/L
HVA	± 6 up to 40 µmol/L; 15% > 40 µmol/L
Metanephrine	± 0.2 up to 1.0 µmol/L; 20% > 1.0 µmol/L
Noradrenaline	± 75 up to 500 nmol/L; 15% > 500 nmol/L
Normetanephrine	± 0.4 up to 2.0 µmol/L; 20% > 2.0 µmol/L

CO-OXIMETRY	Reviewed January 2012
Haemoglobin Concentration	± 3 up to 100 g/L; 3% > 100 g/L
Fractional Oxyhaemoglobin	± 3 up to 75.0%; 4% > 75.0%
Fractional Carboxyhaemoglobin	± 2.0%
Fractional Methaemoglobin	± 1.0 up to 10.0%; 10% > 10%

BNP	Reviewed January 2012
NT-Pro BNP	± 25 up to 125 ng/L; 20% > 125 ng/L
BNP	± 20 up to 100 ng/L; 20% > 100 ng/L

CSF	Reviewed April 2013
Albumin	± 0.02 up to 0.45 g/L; 5% > 0.45 g/L
Glucose	± 0.2 up to 2.0 mmol/L; 10% > 2.0 mmol/L
Immunoglobulin G	± 0.02 up to 0.10 g/L; 20% > 0.10 g/L
Lactate	± 0.3 up to 3.0 mmol/L; 10% > 3.0 mmol/L
Total Protein	± 0.02 up to 0.45 g/L; 5% > 0.45 g/L
Bilirubin Concentration	± 0.12 up to 0.60 µmol/L; 20% >0.60 µmol/L
Xanthochromia-Bilirubin screen	± 0.002 up to 0.007 AU; 20% >0.007 AU
Xanthochromia – Haemoglobin screen	± 0.02 up to 0.10 AU; 20% >0.10 AU

ENDOCRINE	Reviewed January 2012
AFP	± 2 up to 17 kIU/L; 12% > 17 kIU/L

Allowable limits of performance for the Royal College of Pathologists of Australasia Quality Assurance Program. available at: http://www.rcpaqap.com.au/wp-content/uploads/2013/06/chempath/Allowable%20Limits%20of%20Performance.pdf.

Westgard QC

There are two types of target values listed for the interlaboratory test specifications. RMW means that a Reference Method Value was used to set the guideline. SW means that a target value specific for the test method

(more like a peer group median) was used to set the guideline.

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RILIBAK - GERMAN GUIDELINES FOR QUALITY

An *unofficial* English translation of the RiliBÄK (Richtlinien der Bundesärztekammer). The term 'RiliBÄK' is an abbreviation meaning literally the Guidelines ("Rili") of the German Federal Medical Council (BÄK).

POSTED OCTOBER 2009

- Analytes in Plasma, Serum or Whole Blood
- Analytes in Urine
- Analytes in Cerebrospinal Fluid

These guidelines include specifications for Acceptable % Root Mean Standard Deviation (RMSD) and Acceptable relative deviation for interlaboratory tests.

Analytes in Plasma, Serum, and Whole Blood

#	Analyte	Acceptable % RMSD	Validity range of columns 3 and 5			Acceptable relative deviation in interlab tests	Type of target value in interlab tests
			lower limit	upper limit	units		
1	Activated partial thromboplastin time (aPTT)	10.5%	20	120	s	18.0%	SW
2	Alanine aminotransferase (ALT)	11.5%	20	300	U/L	21.0%	RMW
			0.33	5.0	ukat/L		
3	Albumin	12.5%	20	70	g/L	20.0%	SW

Table B 1 b: Analytes in urine

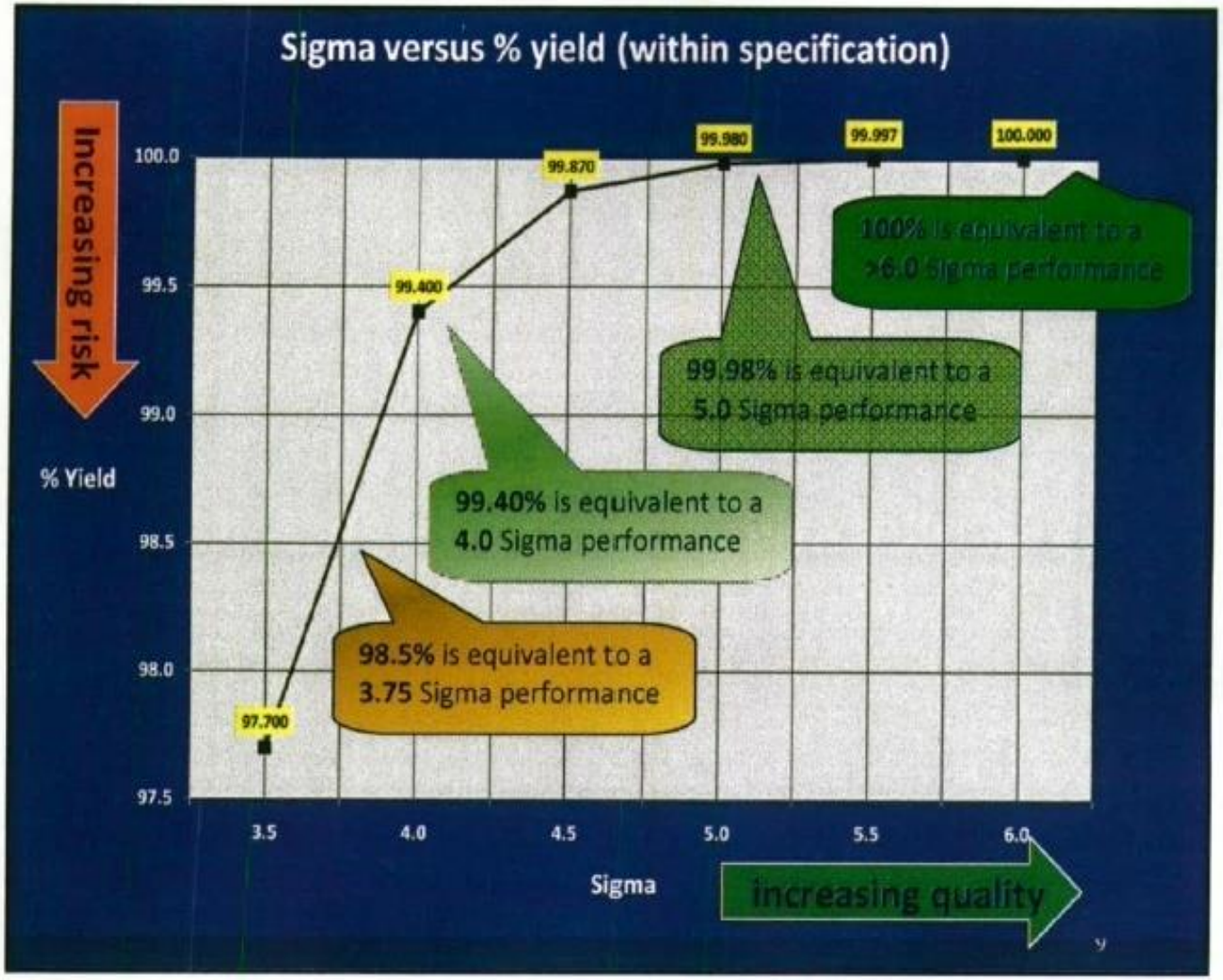
#	Analyte	Acceptable % RMSD	Validity range of columns 3 and 5			Acceptable relative deviation in interlaboratory tests	type of target value in interlaboratory tests
			lower limit	upper limit	units		
1	Albumin	15.0%	1	500	mg/L	26.0%	SW
2	Calcium	8.5%	0.5	6	mmol/L	17.0%	SW
3	Glucose	11.0%	100	4000	mg/L	22.0%	RMW
			0.6	22	mmol/L		
4	Uric acid	13.5%	5	300	mg/L	23.0%	RMW
			30	1784	umol/L		
5	Urea	13.5%	0.1	20	g/L	21.0%	RMW
			1.7	333	mmol/L		
6	Potassium	8.5%	2	140	mmol/L	15.0%	RMW
7	Creatinin	12.0%	0.01	3	g/L	21.0%	RMW
			0.1	27	mmol/L		
8	Sodium	6.5%	50	200	mmol/L	12.0%	RMW
9	Phosphate (anorganic)	11.5%	30	900	mg/L	20.0%	SW
			1	29	mmol/L		
10	Protein (total)	11.5%	5	10000	mg/L	24.0%	SW

Analyte	Acceptance criteria / quality requirements				
	CLIA	Desirable Biologic Goal	RCPA	Rilibak	Spanish Minimum Consensus
GLUCOSE	± 10%	± 6.9%	± 0.4 mmol/L ≤ 5.0 mmol/L; ± 8% > 5.0 mmol/L;	± 15.0%	± 11%

Altı Sigma Yöntemi

=(TEa-bias)/SD veya (%TEa-%bias)/%CV

- Kısaca sürecin iyileştirilmesidir.Sonuçta sigma değeri arttıkça hata sayısı azalırken sürecin güvenirliği artmakta, gereksiz harcamalar azalmakta ve işletme bütçesine pozitif katkı sağlanmaktadır.


Sigma versus % yield (within specification)
Increasing risk
% Yield
100.0
99.5
99.0
98.5
98.0
97.5
99.980
99.997
100.000
99.870
99.400
97.700
100% is equivalent to a
>6.0 Sigma performance
99.98% is equivalent to a
5.0 Sigma performance
99.40% is equivalent to a
4.0 Sigma performance
98.5% is equivalent to a
3.75 Sigma performance
3.5
4.0
4.5
5.0
5.5
6.0
Sigma
increasing quality

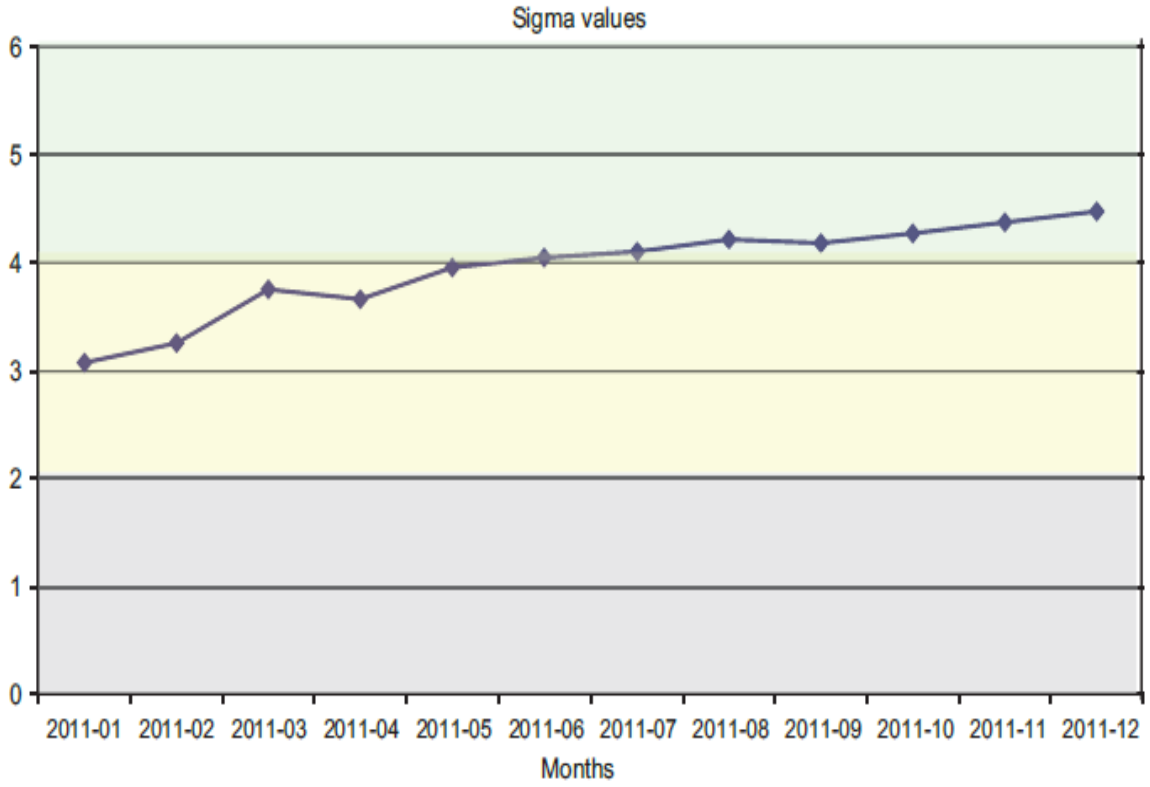


Figure 1 Laboratory report showing the sigma trend concerning the samples with inadequate sample-anticoagulant volume ratios.

Panik değer Raporlama (ISO/DIS 15189)

- Panik değer uyarı verdiği an derhal bildirilmeli ve kayıt altına alınmalıdır.
- Panik değer sonuçları yaşamsal sonuçlardır ve klinisyenler tarafından hemen değerlendirilmelidir. Belli bir zaman diliminde bildirilmeli (15 dakika içinde) ve ayrıntılı kayıt alınmalıdır.
- İndikatör olarak değerlendirilebilinir.Panik değer eksiksiz olarak bildirilmeli ve belirli peryotlarda % olarak değerlendirilmelidir.

Metod performansını gösteren parametreler

- 1. Dogruluk (Accuracy)
- 2. Gerçeklik (trueness)
- 3. Kesinlik (Precision)
- 4. Girişim(interferans)
- 5. Saptama Sınırı (Limit of detection = LoD)
- 6. Kantitatif Sınırı (Limit of Quantitation=LoQ)
- 7.Doğrusallık (Linearite)
- 8. Ölçüm /Ölçme Belirsizligi
- 9.Tekrar üretilebilirlik (Reproducibility)
- 10.Yöntemin kararlılığı,güçlülüğü (Robustness)

EKSTERNAL KALİTE KONTROL (EQAS)/ YETERLİLİK TESTİ (PROFİCENCY TESTİNG)

- Akredite olmuş dış kalite kontrol proğramındaki değerlendirmeler, IFCC ve ISO tarafından klinik laboratuvarlar için belirlenen eksternal kalite kontrol sonuçları değerlendirme kurallarına göre yapılmalıdır.
- TS EN ISO/IEC 17043 "Yeterlilik Testleri için Genel Şartlar" Standardı laboratuvarlar arası karşılaştırma ölçümü/yeterlilik testlerinin gerçekleşmesi aşamasında tüm yönetimsel ve teknik faaliyetleri kapsamaktadır .
- ILAC (The International Laboratory Accreditation Cooperation) Kılavuzu (ILAC-G:08/2007)

  (Biorad,RIQAS,DigitalPT,CAP (College of American Pathologists) v.b)

Z skor :SDI:Standard Deviation Index

$$z = \frac{(x - X)}{\hat{\sigma}}$$

where:

x = result reported by participant

X = assigned value

$\hat{\sigma}$ = standard deviation for proficiency assessment

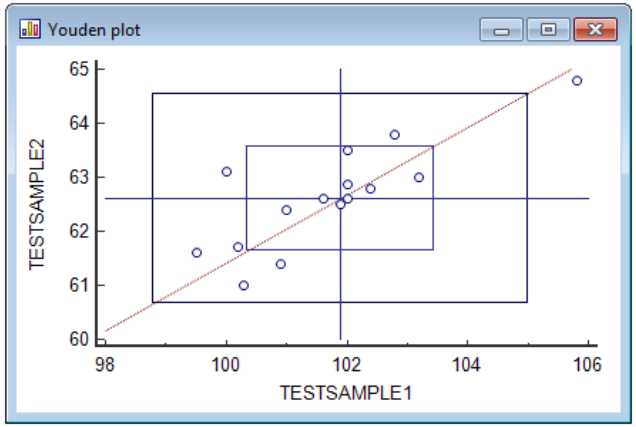
- $|z| \leq 2.0$ güvenli performans
- $2.0 < |z| < 3.0$ sorgulanması gereken performans
- $|z| \geq 3.0$ yetersiz

İÇ KALİTE KONTROL PERFORMANSI NASIL DEĞERLENDİRİLİR?

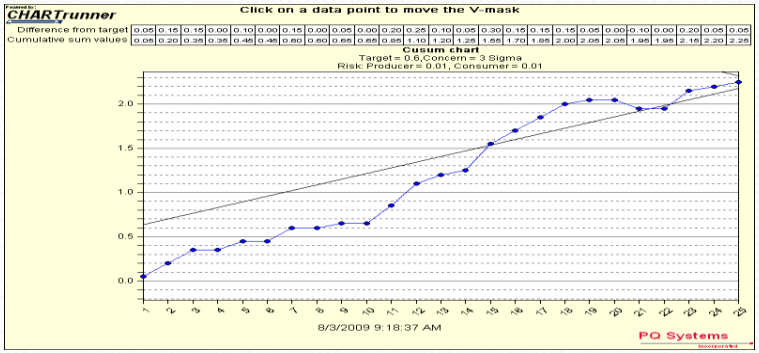
- İç kalite kontrol grafikleri (Levey Jennings grafikleri)

- Westgard kuralları (1_{2s},1_{3s},2_{2s},R_{4s},4_{1s},10_{x})

Youden grafiği

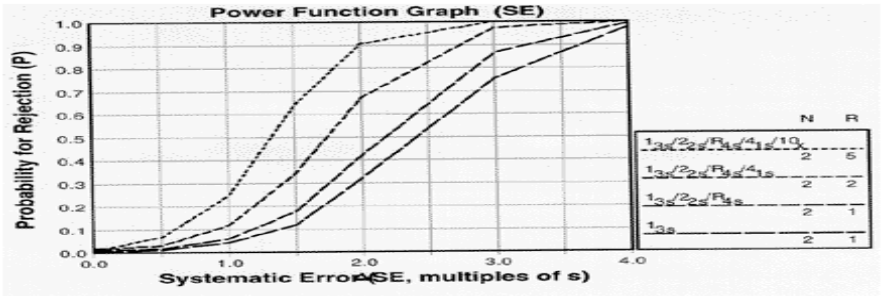


Kümülatif (cusum) toplam grafiği



Kalite Planlama Araçları:
Aylık İKK Sonuçlarından Kontrol Prosedürünü Belirleme

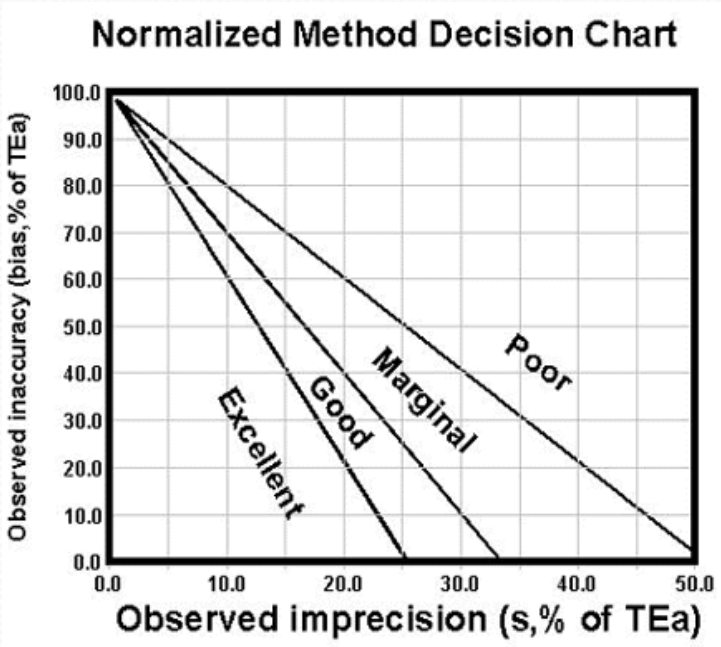
- **Güç fonksiyon grafiği**



- **Kritik hata grafikleri**

  Kritik sistematik Hata (ΔSec)= $[(Te_a-B_A)/CV_A-1,65]$: Method performansı için iyi bir indikatör.Tek rakam.

- **OPSpecs grafikleri:**Kontrol ölçüm ve kontrol kural sayısının saptanmasında en kullanılır. Ölçüm işleminin belirsizliği (imprecision) ve doğrudan uzaklaşma (inaccuracy) derecesidir.



The Normalized OPSpecs Calculator (Javascript)

IMPORTANT: Your browser must support Javascript (Navigator 3.0 or higher). When entering data into this calculator, do not include units, % symbols, etc. Just enter the numbers by themselves. If you get an error message, reload the page and start over.

Step A. Enter the critical medical decision level (Xc): **NOTE: You must enter a decision level for this calculator to work!**	0.0
Step B. Enter your Analytical Quality Requirement in concentration units (TE_a) and calculate %:	0.0 Then Calculate %TEa
The answer will appear on the right. If you know the $\%TE_a$, you can enter it here directly.	0.0 $\%\ TE_a$
Step C. Enter your observed method SD in concentration units:	0.0 Then Calculate %CV
The answer will appear on the right. If you know the %CV, you can enter it here directly.	0.0 $\%\ CV$
Step D. Enter your observed method bias in concentration units:	0.0 Then Calculate %Bias
The answer will appear on the right. If you know the %Bias, you can enter it here directly.	0.0 $\%\ Bias$
Step E. Plot the following normalized operating point on one of the charts listed below:	Calculate X-value Your X-Value Calculate Y-value Your Y-Value

RESET

http://www.westgard.com/normalized-opspecs-calculator.htm

Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures

Brochure #4

What are they, and when can I use them?

Information to assist your laboratory in meeting this CLIA quality control requirement option for nonwaived (moderate and high complexity) test systems!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulations (CLIA) that became effective April 24, 2003. A summary of equivalent quality control options is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at **http://www.phppo.cdc.gov/CLIA/regs/toc.asp.**

CMS Centers for Medicare & Medicaid Services

CDC Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Table 1 Equivalent QC options for eligible test systems

EQUIVALENT QC OPTIONS				
Equivalent QC Option	**Test System Description**	**Evaluation Process:**		**Equivalent QC Procedure Testing Frequency**
		Internal Monitoring Systems*	**Test Two Levels of External Controls**	
Option 1	Test Systems with Internal Monitoring System that Checks ALL Analytic Components	Daily testing with acceptable results	Results acceptable for 10 consecutive testing days	Testing external controls at least once per calendar **month** and **daily** testing by the internal monitoring system*
Option 2	Test Systems with Internal Monitoring System that Checks SOME Analytic Components	Daily testing with acceptable results	Results acceptable for 30 consecutive testing days	Testing external controls at least once per calendar **week** and **daily** testing by the internal monitoring system*
Option 3	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar **week**

* Internal monitoring system checks must be performed in accordance with the manufacturer's instructions, but not less frequently than daily.