

EQALM Symposium 2009- Berlin

MINIMAL ANALYTICAL QUALITY SPECIFICATIONS



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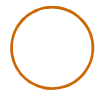


INTRODUCTION

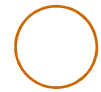
- **CONSENSUS DOCUMENT**
- **MINIMUM QUALITY SPECIFICATIONS**
- **GOVERNMENT & ACCREDITATION**
- **STARTING POINT**



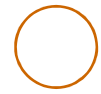
International consensus



Clinical effects



Medical decision effects



Professional recommendations



Law / **EQAS**



State of the art

Kenny D et al. Scan J Clin Lab Invest 1999,59(7)



Common history

Beginning	...	1976	1984	1978
Controls	...	Without assigned values		
Target	...	Method group or overall mean		
Independency		Non profit scientific societies		
Standard	...	Guide ISO/IEC 43-1		
Accreditation ..		In process		



Common actions

- **Promote quality management systems in laboratories**
- **Define quality specifications within each organization**
- **Organize educational sessions on quality items**



Type of laboratories (%)

● Hospital	13	72	59
Public		8	55	45
Private		5	17	14
● Non hospital	..	87	28	41
Public		2	5	5
Private		85	23	36



Datum

- **Common analytes in the various programs**
- **Results from all labs during 2 cycles (years)**
- **Target: consensus or peer group mean**



Calculations (1)

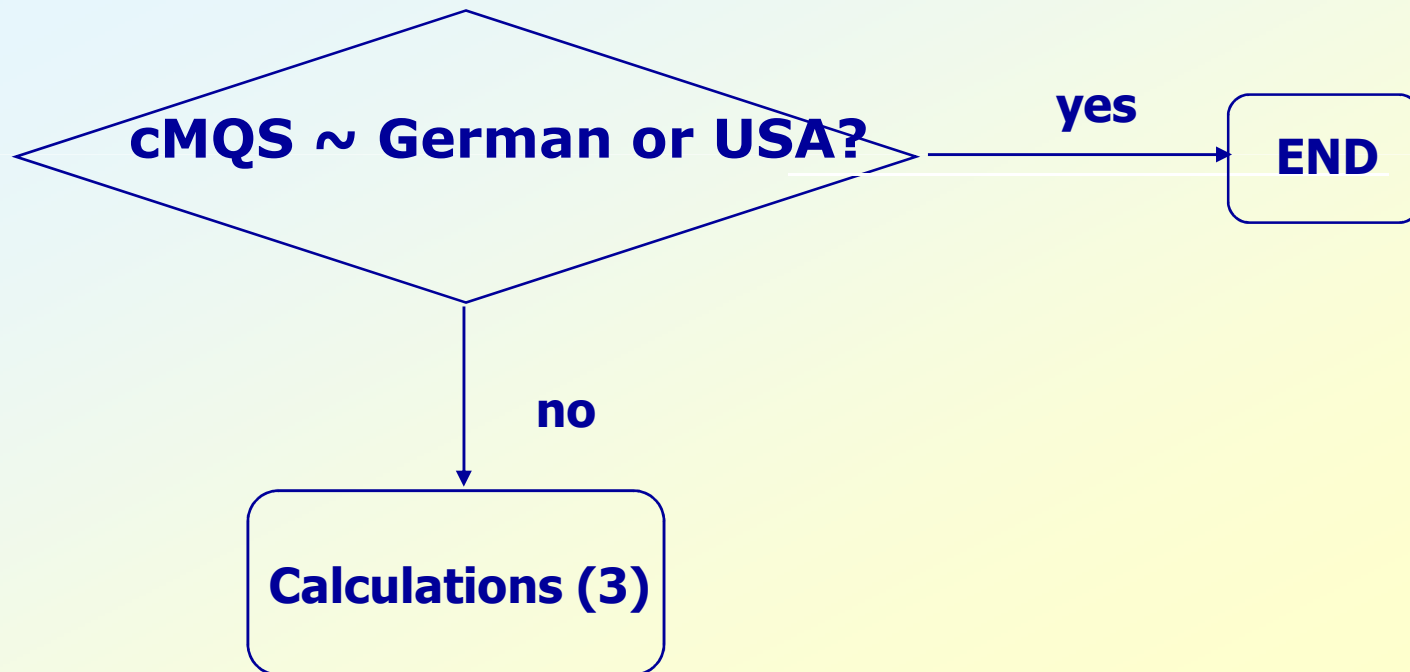
Per analyte

- **% difference vs target (in absolute)**
- **plotting distribution of the differences**
- **elimination of 5% higher differences**
- **defining the 95 percentile as the candidate minimum quality specification (cMQS)**



Calculations (2)

Per analyte





Calculations (3)

Per analyte

- A. Select a value = cMQS**
- B. Count number of labs with 75% or more results within cMQS**
- C. If $\geq 90\%$ of labs satisfy, this value is the Minimum Quality Specification**
- D. If not, go to A selecting a higher cMQS**



Robustness

- ✓ **Years 2005 + 2006**
- ✓ **619.430 results**
- ✓ **1.806 laboratories**
- ✓ **24 rounds**

- ✓ **75% of labs answer more than 75% of samples**
- ✓ **Between 5128 & 34088 results per analyte (25810 average)**



Spanish consensus specification (basic biochemistry)

Analyte	%
Sodium	5
Potassium	7
Chloride	8
Calcium	10
Cholesterol	10
Glucose	10

Analyte	%
Protein	10
Albumin	13
Urate	14
Triglyceride	15
Phosphate	15
Urea	17

Overall mean, Peer group mean



Spanish consensus specification (basic biochemistry)

Analyte	%
AST	19
ALT	20
CK	20
γ GT	22
Iron	22
Bilirubin	23

Analyte	%
LDH	25
ALP	28
Creatinine	28
Amylase	33
HDL cholesterol	34
Total ACP	63

Overall mean, Peer group mean



Spanish consensus specification (special biochemistry)

Analyte	%
Phenytoin	13
Theophylline	15
FSH	16
TSH	17
Total PSA	17
Phenobarbital	18

Analyte	%
LH	19
Lithium	19
IgG	20
AFP	22
Free T4	23
IgA	24

Overall mean, Peer group mean



Spanish consensus specification (special biochemistry)

Analyte	%
Total T4	20
CEA	21
Ferritin	22
IgM	23
Total T3	24
Estradiol	25

Analyte	%
Cortisol	25
Digoxin	27
Prolactin	28
Progesterone	29
Testosterone	35

Overall mean, Peer group mean



Spanish consensus specification (basic hematology)

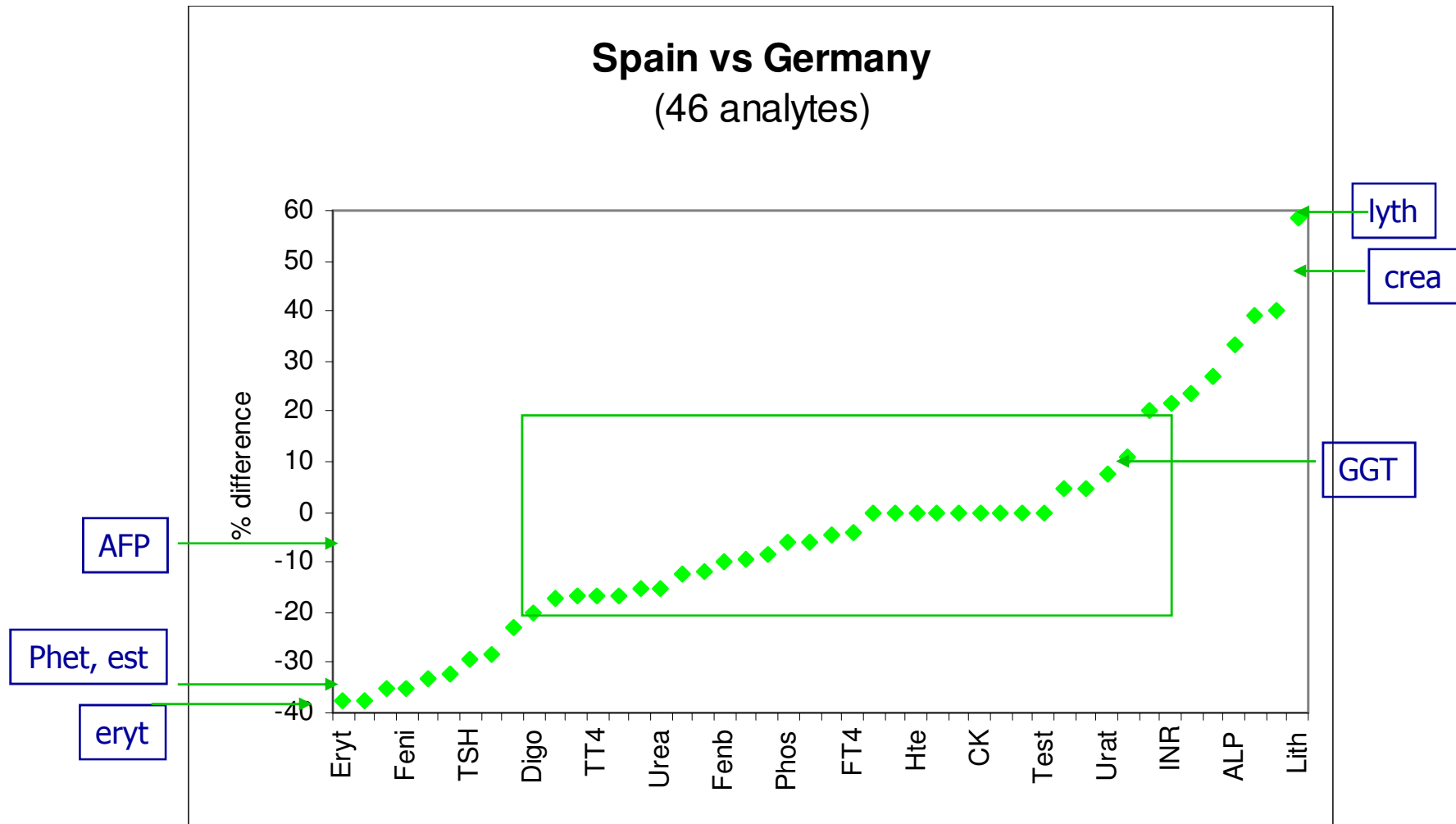
Analyte	%
Erythrocyte	5
Hemoglobin	5
MCH	6
MVC	7
MCHC	9
Hematocrit	9
Leucocyte	11

Analyte	%
Platelet	16
PTTA ratio	20
Prothrombin rat	23
PTTA (sec)	26
INR	28
Fibrinogen	28
Prothrombin (%)	33

Overall mean, Peer group mean

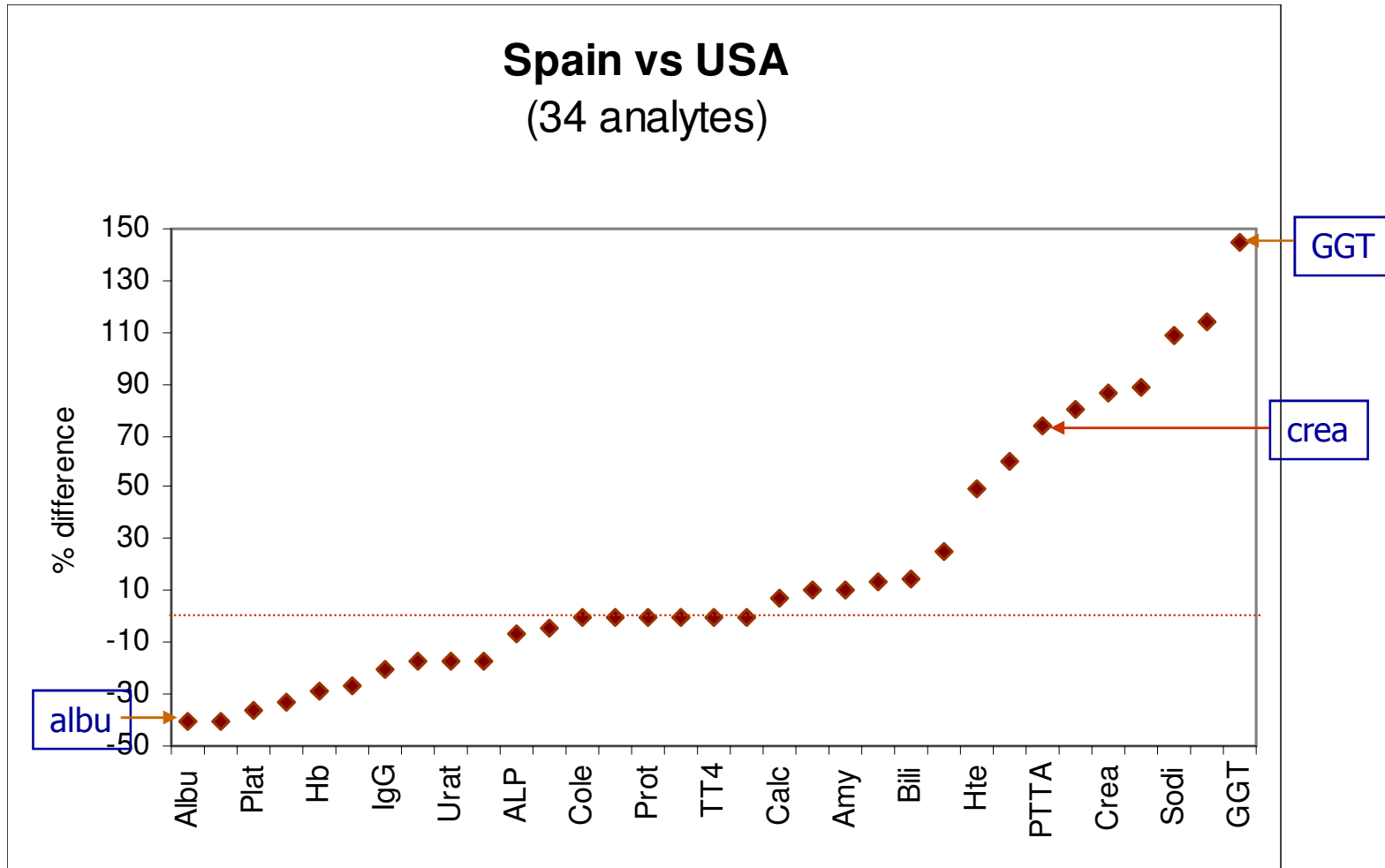


- **Comparison between countries**





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Discussion

61 analytes studied

- **29 of 61: specification = P₉₅ results**
- **32 of 61: specification widened
to assure less than 90% labs failing**



Conclusions (1)

- **The model has a scientific basis**
- **The model can be applied to other data
(new programs, different rounds, etc)**



Conclusions (2)

- **It is assured that only less than 90% laboratories could fail**
- **These are MINIMUM quality specifications, implying immediate corrective actions**