A scoring system based on the biological variation

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How to assess on a long-term scale the individual laboratory performance based on EQA data?

- **Objective criteria**
- **Evaluation model of long-term analytical performance**

⇨ **Scoring system for individual laboratory performance**

Eur J Clin Chem Clin Biochem 1996; 34:665–678

Characterization and Classification of External Quality Assessment Schemes (EQA) According to Objectives such as Evaluation of Method and Participant Bias and Standard Deviation

Discussion paper from the members of the External Quality Assessment (EQA) Working Group A[1]) on analytical goals in laboratory medicine

Jean Claude Libeer[1], *Henk Baadenhuijsen*[2], *Callum G. Fraser*[3], *Per Hyltoft Petersen*[4], *Carmen Ricós*[5], *Dietmar Stöckl*[6] and *Linda Thienpont*[7]

Our Working Group described in another publication (8) to pros and the cons of different quality specifications and proposed desirable routine analytical goals for quantities assayed in serum. In our opinion, the biological model is the most appropriate for EQA schemes, since this model is the most objective general approach. In

Eur J Clin Chem Clin Biochem 1996; 34: 665 - 678

Eur J Clin Chem Clin Biochem
1995; 33:157–169

Desirable Routine Analytical Goals for Quantities Assayed in Serum

Discussion paper from the members of the External Quality Assessment (EQA) Working Group A[1]) on analytical goals in laboratory medicine

By *Dietmar Stöckl*[1], *Henk Baadenhuijsen*[2], *Callum G. Fraser*[3], *Jean-Claude Libeer*[4], *Per Hyltoft Petersen*[5] and *Carmen Ricós*[6]

for monitoring as:

$s_a \leq 0.5\ s_i$
(in the absence of unidirectional systematic changes), or

$\Delta SE \leq 0.33\ s_i$ (when imprecision is negligible);
see also Annex;

for diagnostic testing as:

$B \leq 0.25\ s_c$ (when the imprecision is negligible),
or
$s_a \leq 0.58\ s_c$ (when bias is negligible);
see also Annex.

Eur J Clin Chem Clin Biochem 1995; 33: 157 - 169

Analytical Quality Specifications (AQS) according to Fraser *et al*

Performance goal	Imprecision (CV_A) (monitoring)	Imprecision (CV_A) (diagnostic testing)
Minimum quality	$CV_A < 0.75\ CV_W$	$CV_A < 0.87\ CV_T$
Desirable quality	$CV_A < 0.50\ CV_W$	$CV_A < 0.58\ CV_T$
Optimum quality	$CV_A < 0.25\ CV_W$	$CV_A < 0.29\ CV_T$

Fraser CG *et al.* Ann Clin Biochem 1997; 34: 8 – 12.

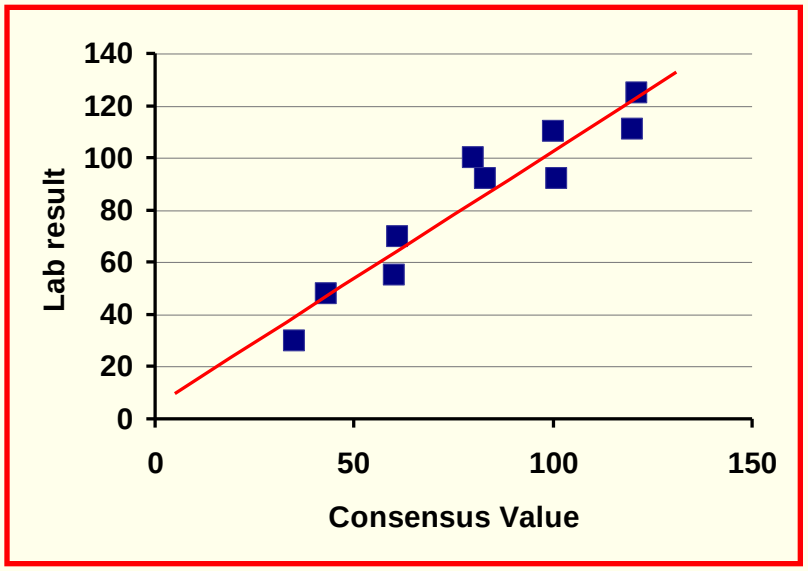
Analytical Quality Specifications (AQS)

Analyte	Biological variation (%)		
	CV_W	CV_B	CV_T
Antithrombin	3.9	7.9	8.8
Protein C chrom	6.6	16.1	17.4
Protein C clot	8.8	15.5	17.8

Analytical Quality Specifications (AQS)

Analyte	Grade	Performance goals based on the biological variation		
		Antithrombin	Protein C chrom	Protein C clot
Optimum	A	2.6	5.0	5.2
Desirable	B	5.1	10.1	10.3
Minimum	C	7.7	15.1	15.5
Unacceptable	D	≥ 7.7	≥ 15.1	≥ 15.5

Long-term evaluation model



IMPRECISION

$$LCV_a = \frac{s_{y|x}/b}{\bar{X}} \bullet 100\%$$

BIAS

$$B = \frac{\sqrt{\frac{n-1}{n} \bullet (b-1)^2 \bullet s_x^2 + (\bar{Y} - \bar{X})^2}}{\bar{X}} \bullet 100\%$$

TOTAL ERROR

$$TE = \frac{\sqrt{s_{y|x}^2 + (b-1)^2 \bullet s_x^2 + (\bar{Y} - \bar{X})^2}}{\bar{X}} \bullet 100\%$$

X = consensus value ; $\bar{X}$ = mean value for X.

s_x = standard error of X

Y = laboratory value ; $\bar{Y}$ = mean value for Y.

b = slope

$s_{y|x}$ = variability of the regression line, which is calculated based on the least-square method.

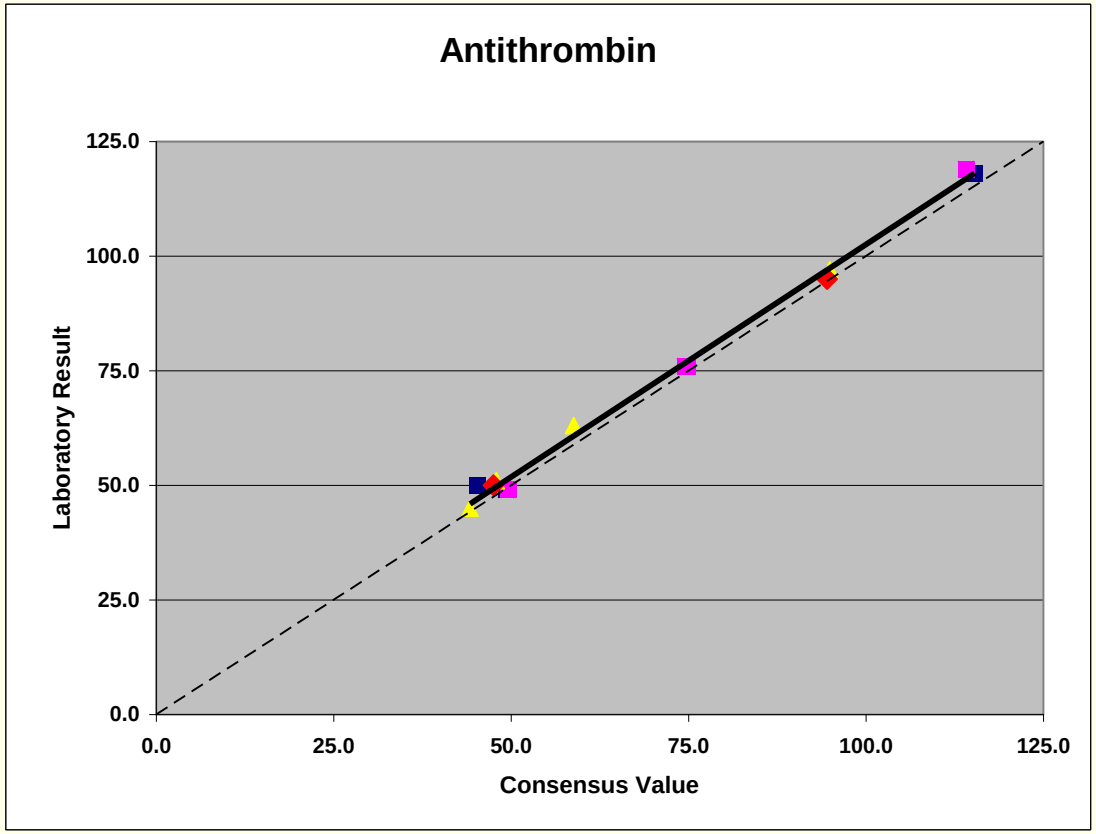
n = number of laboratory results

ANTITHROMBIN

Labcode: **0**

Name
Hospital
Department
City
Country

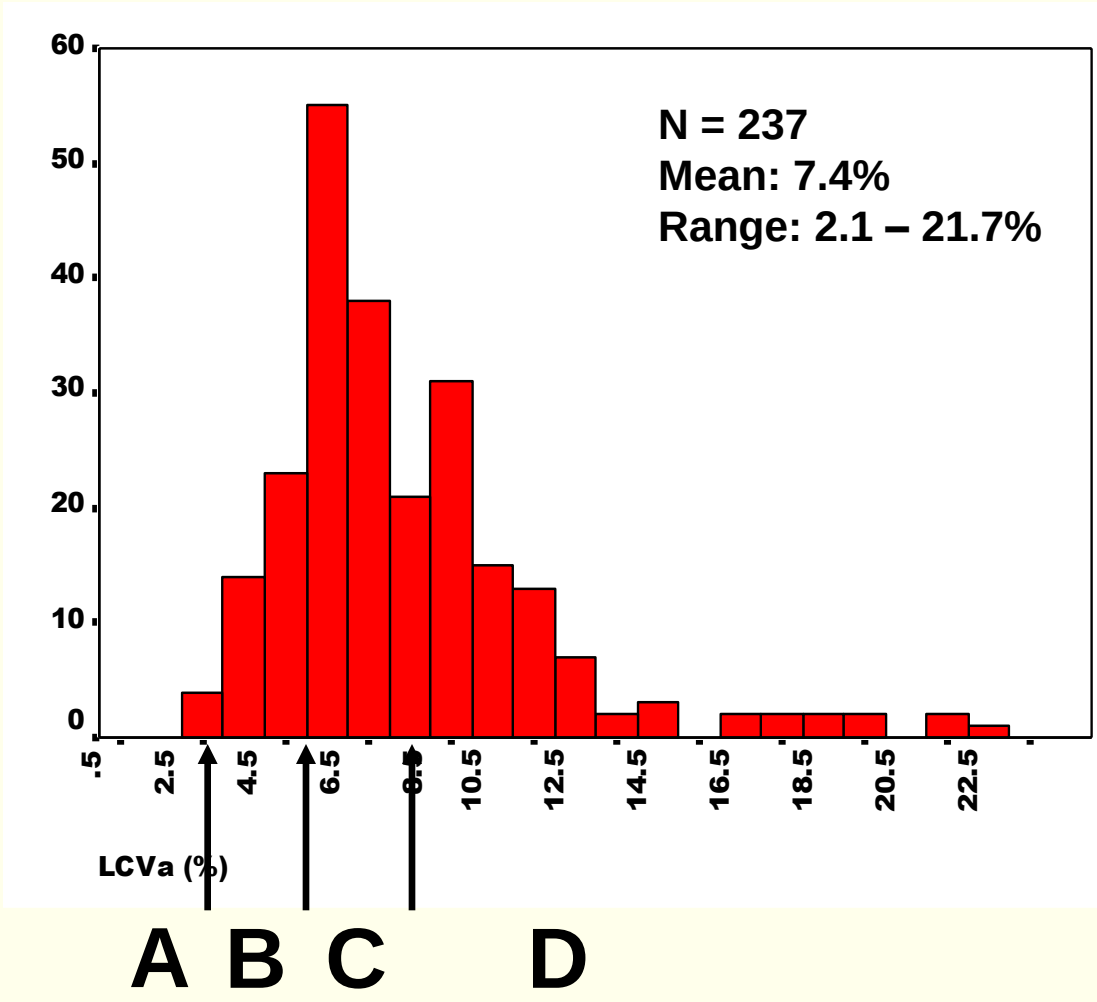
Exercise	Y (Lab Result)	X (Cons. Value)
	0	0
	125	125
2005-1		49.8
2005-2	50.0	45.3
2005-3	118.0	115.3
2005-4	49.0	49.3
2006-1	76.0	74.8
2006-2	119.0	114.1
2006-3	49.0	49.6
2006-4	76.0	74.5
2007-1	97.0	94.9
2007-2	51.0	47.9
2007-3	45.0	44.2
2007-4	63.0	58.8
2008-1	50.0	47.5
2008-2	95.0	94.5
2008-3		
2008-4		
Mean	72.2	68.6
SD		26.1
Number	13.0	

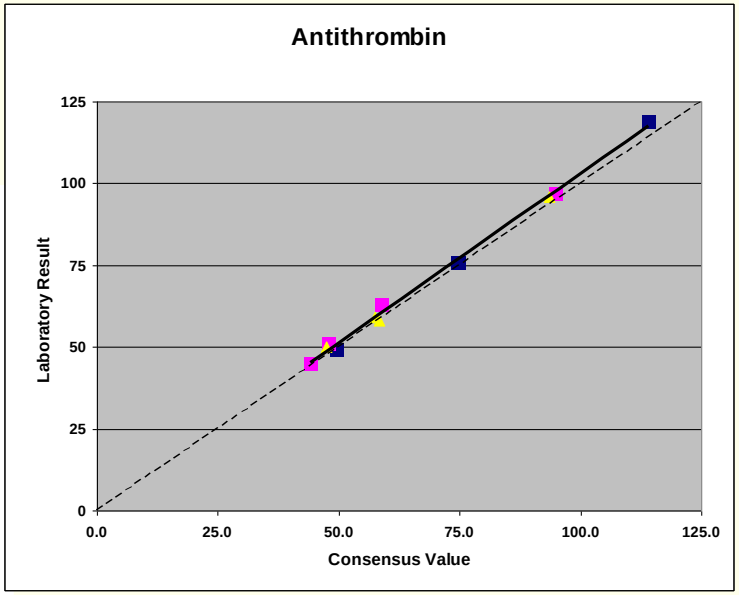


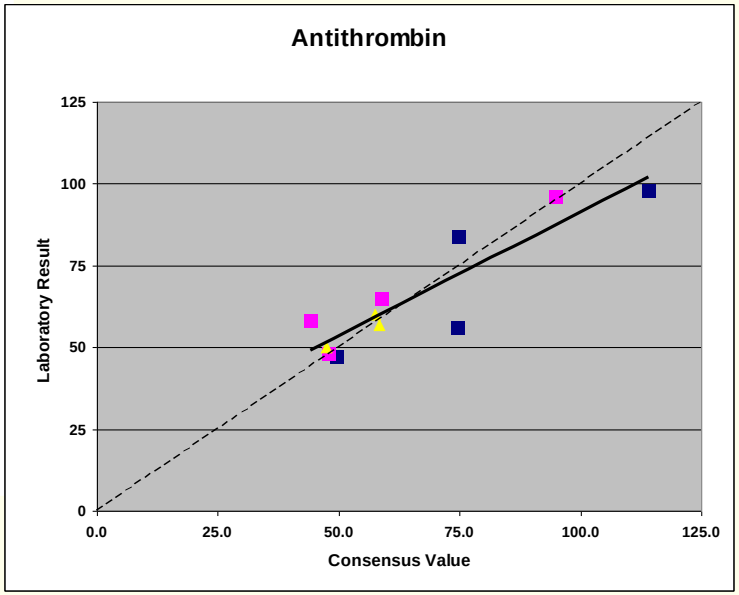
Intercept	1.08	**Variability**	1.84
Slope	1.01	**Corr. Coeff**	0.9958

Long-term $CV_{analytical}$	**2.6%**
Bias	**5.2%**

ANTITHROMBIN 2005 - 2007



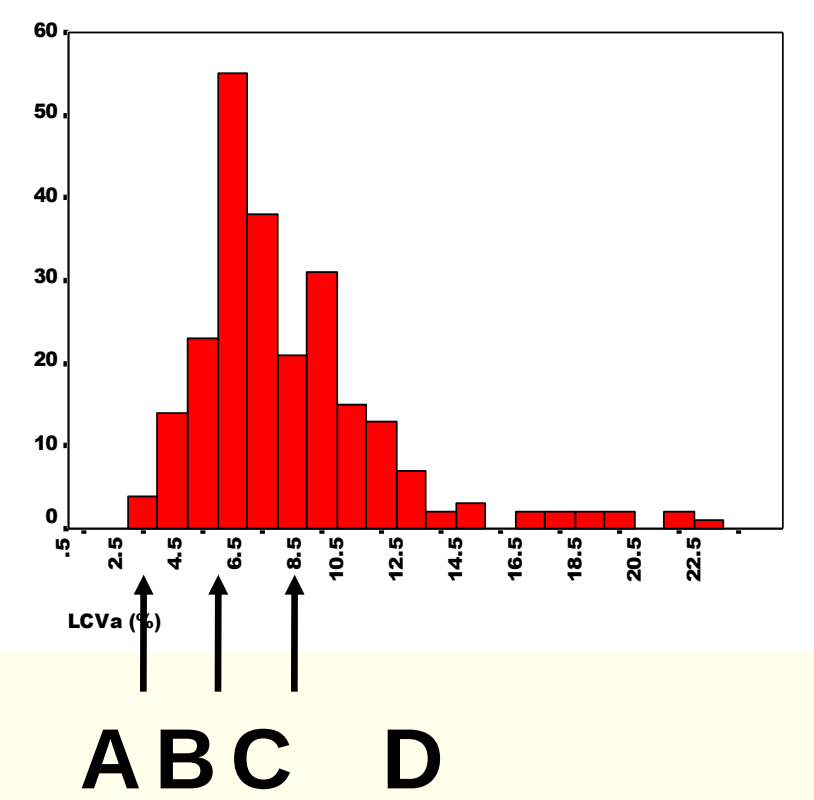


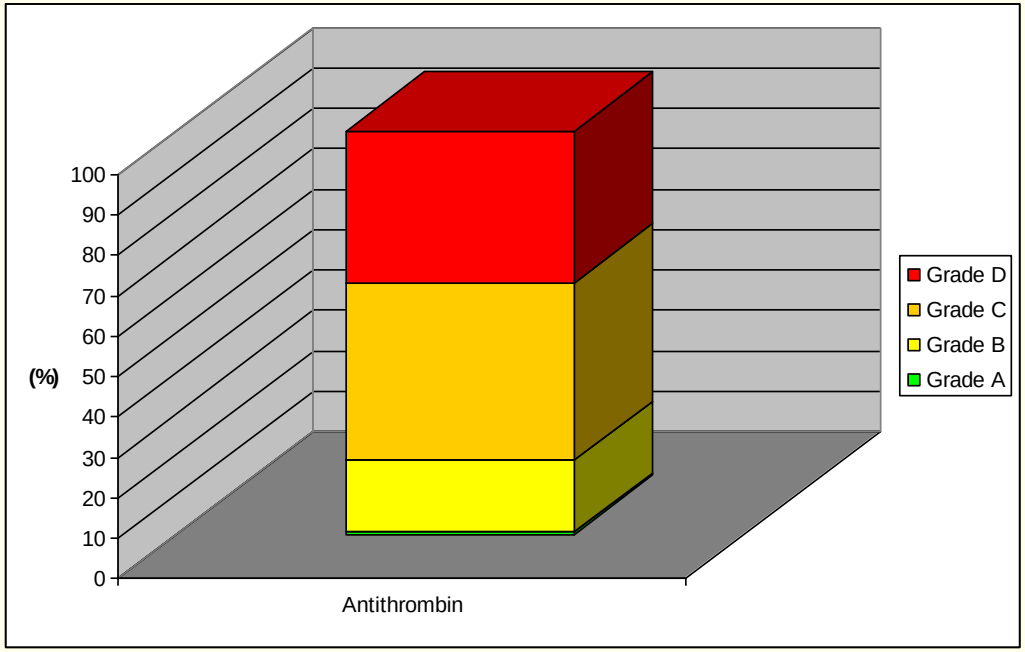


ANTITHROMBIN

2005 - 2007

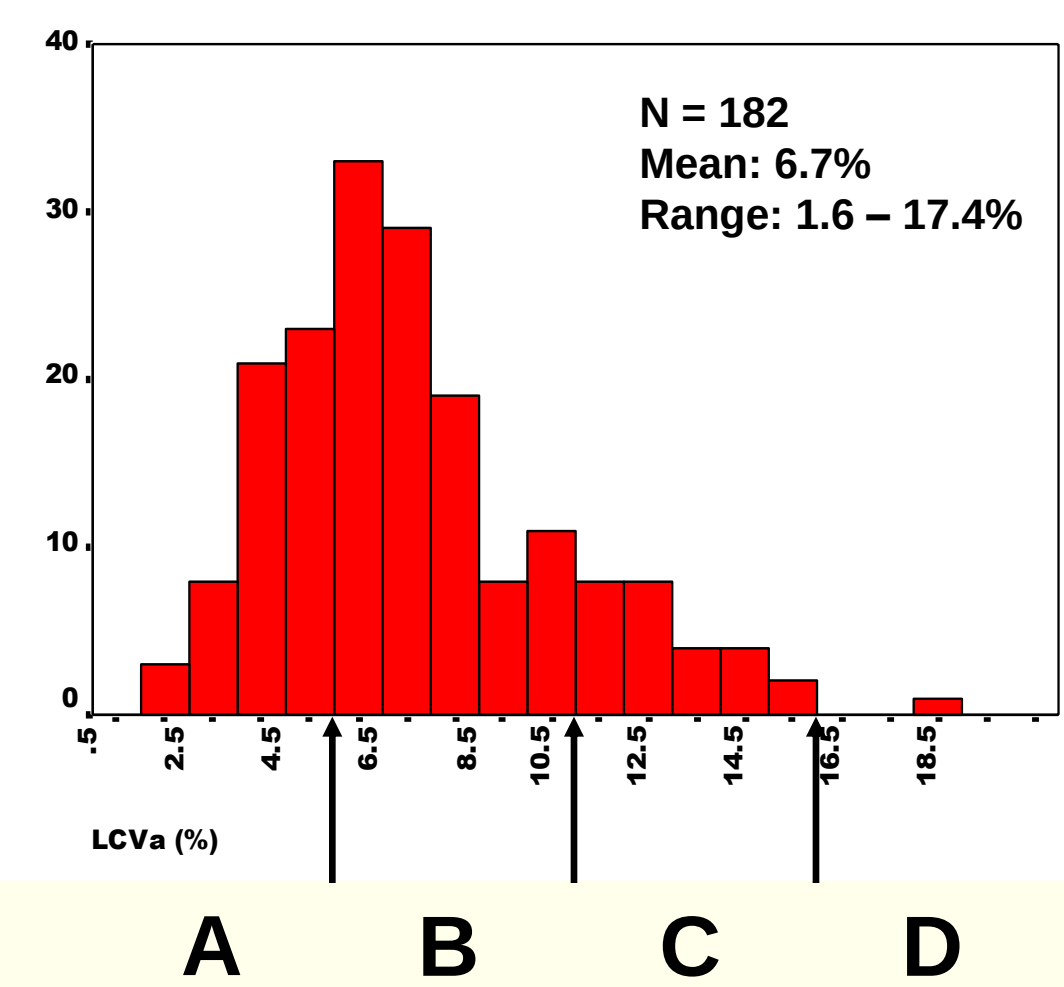
Grade A	0.8%
Grade B	17.7%
Grade C	43.9%
Grade D	37.6%

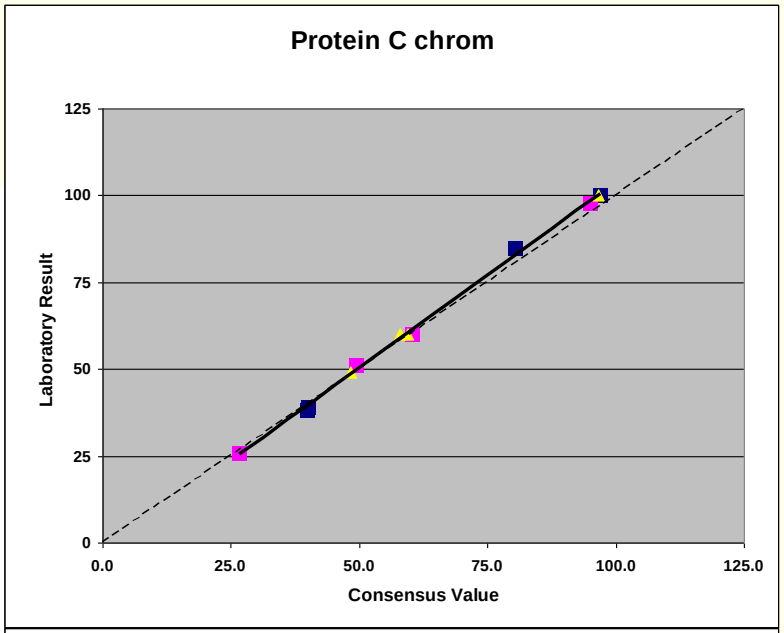


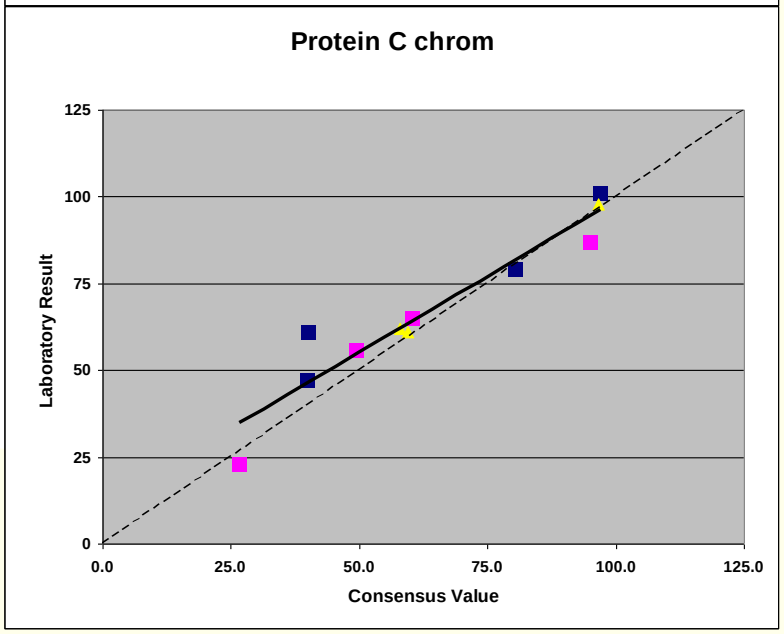


PROTEIN C CHROM

2005 - 2007



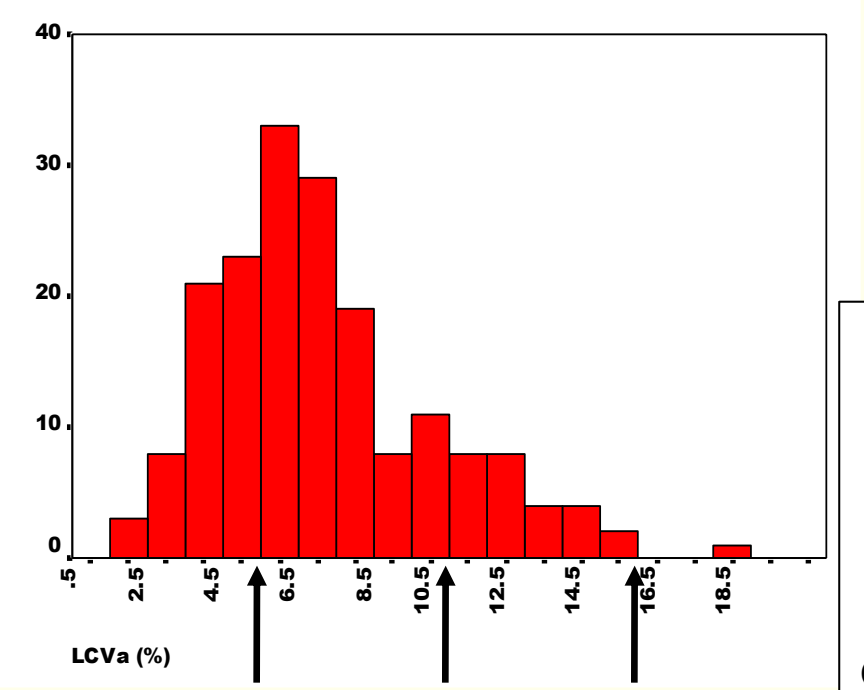




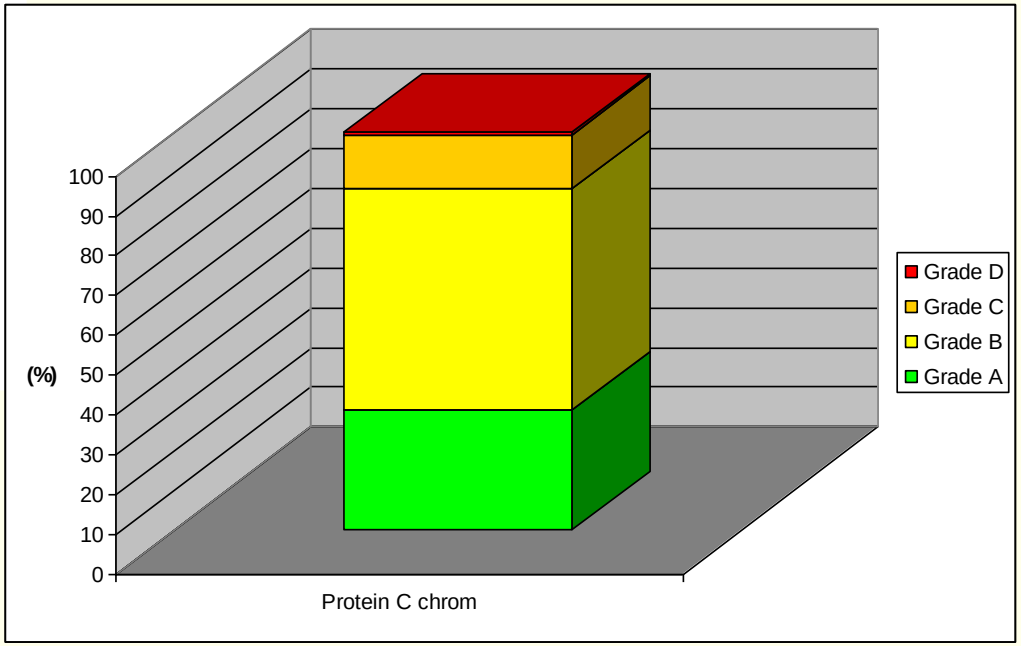
PROTEIN C CHROM

2005 - 2007

Grade A	30.2%
Grade B	55.5%
Grade C	13.7%
Grade D	0.5%

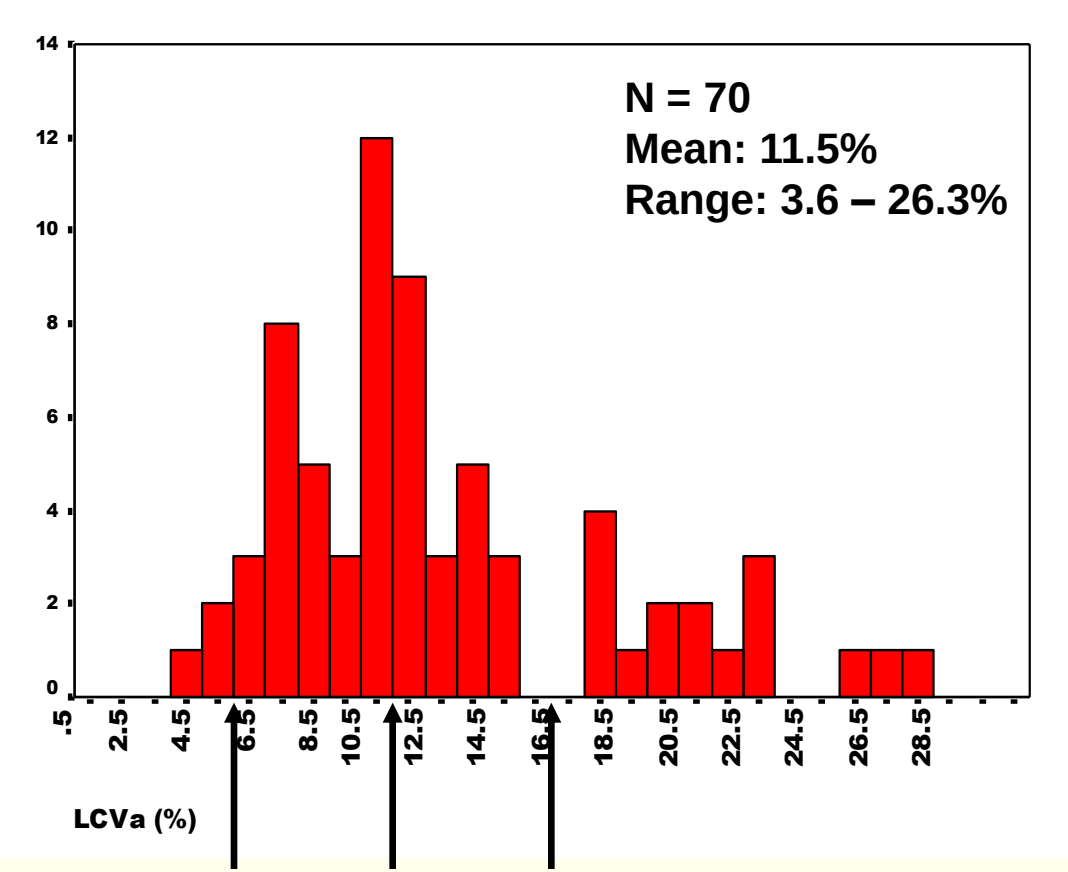


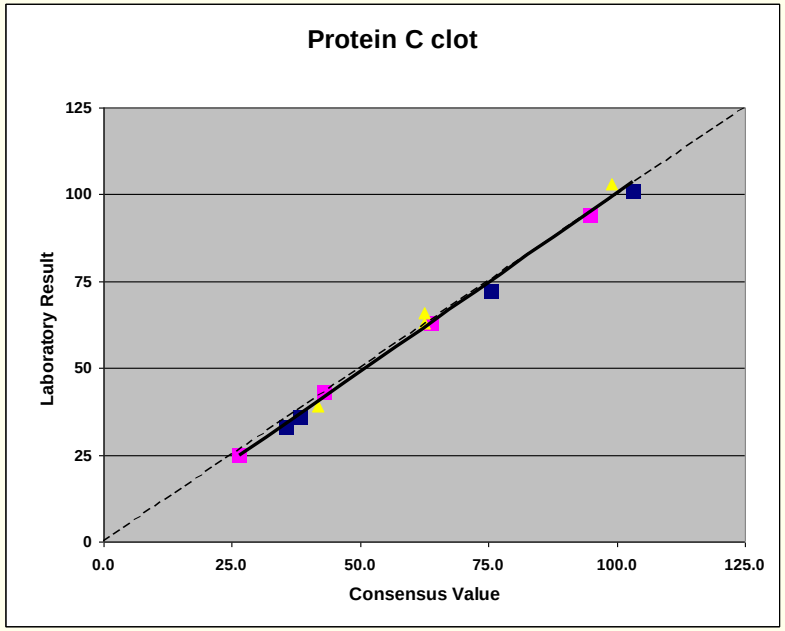
A B C D

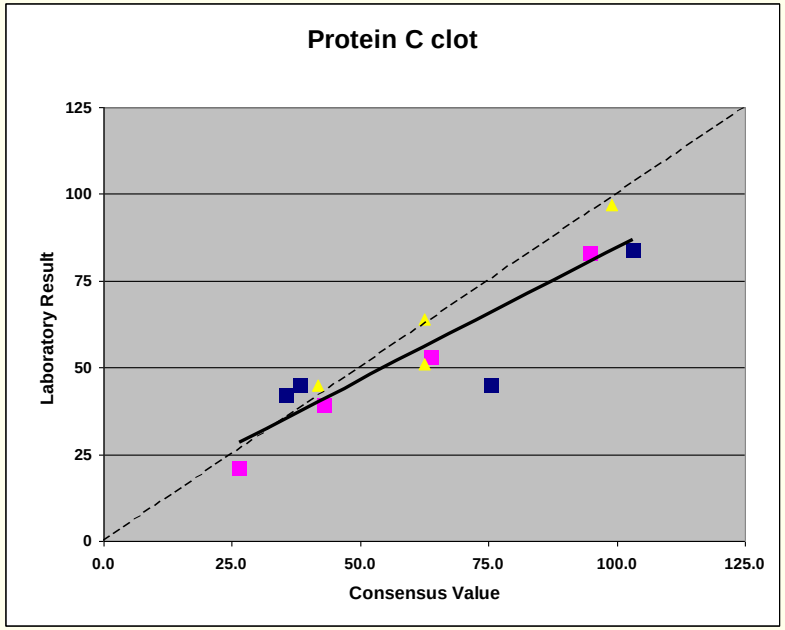


PROTEIN C CLOT

2005 - 2007



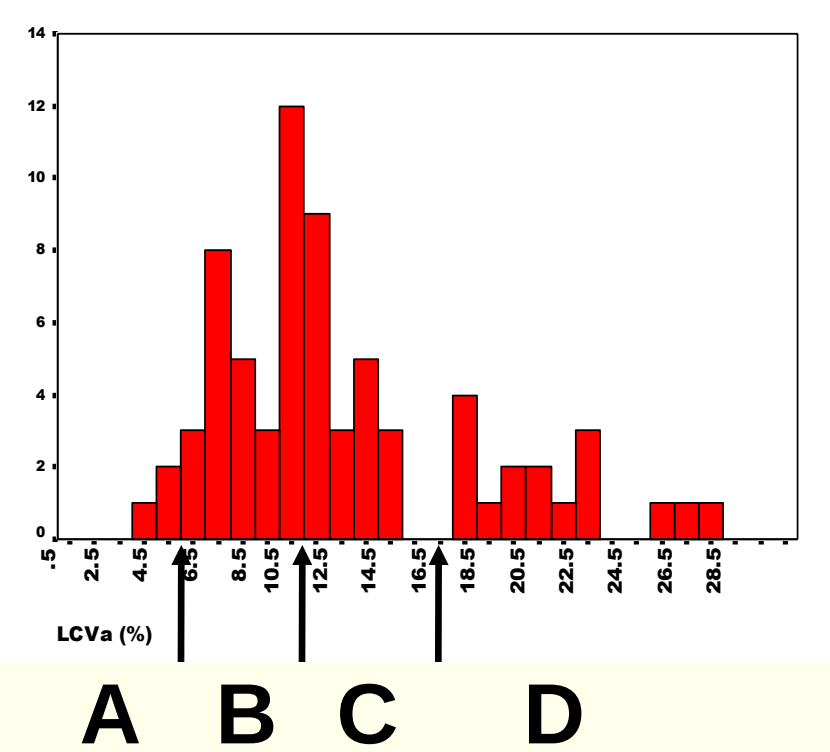


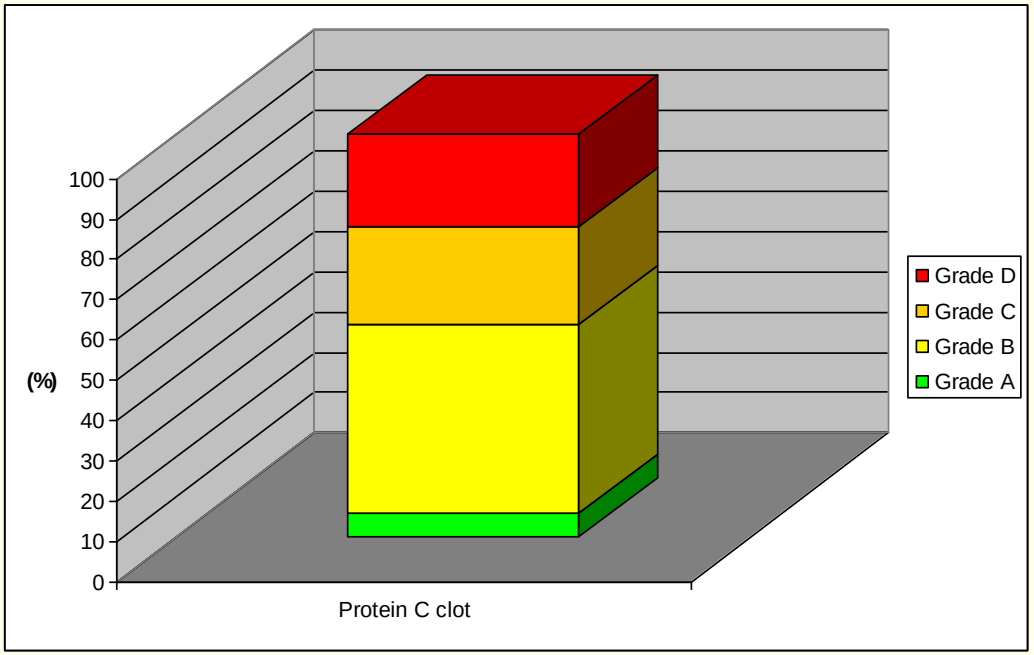


PROTEIN C CLOT

2005 - 2007

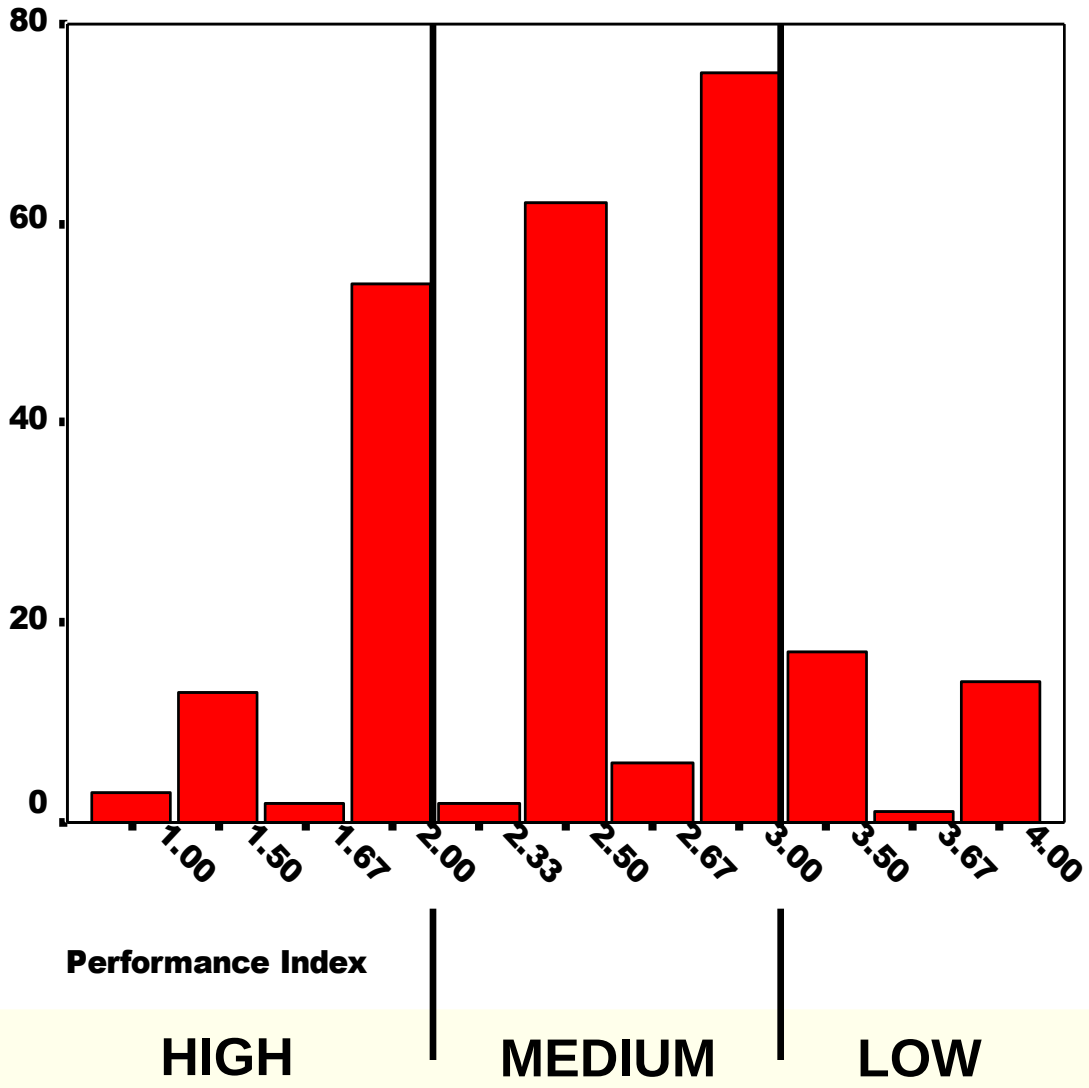
Grade A	5.7%
Grade B	47.1%
Grade C	24.3%
Grade D	22.9%





Performance Index

2005 - 2007



High	29%
Medium	58%
Low	13%

Conclusions

1) Appropriate tools for objective performance assessment of an individual laboratory based on EQA data are available.

2) Grading of long-term analytical performance differs per laboratory test.

3) Overall 29% of the laboratories have an good Performance Index, while 13% show a bad Performance Index.