

1999-2011

BOOK OF REFERENCE EXAMPLES

EFFIVALIDATION 3

EffiChem may have patents and/or pending patent applications covering subject matter in this document. The furnishing of this document does not convey any license to these patents.

Copyright 2008 EffiChem. All rights reserved. All EffiValidation products are trademarks or registered trademarks of EffiChem. Other brand and product names are trademarks or registered trademarks of their respective holders.

Content:

FOREWORD	5
OUTLIERS AND NORMALITY TESTS	6
1.1 COCHRAN TEST.....	6
1.2 GRUBBS SINGLE TEST.....	6
1.3 GRUBBS PAIR TEST.....	7
1.4 DIXON TEST.....	7
1.5 NORMALITY TEST.....	8
VALIDATION	9
2.1 REPEATABILITY.....	9
2.1.1 Level by Level from Multiple Measurements.....	9
2.1.2 From Parallel Measurements.....	10
2.2 INTERMEDIATE PRECISION.....	11
2.3 REPRODUCIBILITY.....	11
2.3.1 Data Available.....	11
2.3.2 Results Available.....	12
2.4 ROBUSTNESS.....	12
2.5 ACCURACY.....	13
2.5.1 Limited Concentration Range – Sample Reconstitution Possible.....	13
2.5.2 Limited Concentration Range – Reference Material Available.....	14
2.5.3 Large Concentration Range – Blank Material Available: T-test.....	15
2.5.4 Large Concentration Range – Blank Material Available: Regression.....	16
2.5.5 Large Concentration Range – Blank Material Not Available: T-test.....	16
2.5.6 Large Concentration Range – Blank Material Available: Regression.....	17
2.5.7 Comparison of 2 Methods / Laboratories: T-test Level by Level.....	18
2.5.8 Comparison of 2 Methods / Laboratories: T-test on Difference of Results.....	19
2.6 SELECTIVITY.....	20
2.6.1 Comparison of Calibration Lines.....	20
2.6.2 Comparison of Results with a Standard.....	20
2.6.3 Comparison of Results with Measurements Without the Interference.....	21
2.7 SENSITIVITY.....	22
2.7.1 From Calibration Line.....	22
2.7.2 Minimal Difference in the Validated Property.....	23
2.8 LINEARITY.....	24
2.8.1 Correlation and QC coefficient.....	24
2.8.2 ANOVA for Lack of Fit.....	25
2.8.3 Significance of the Quadratic Term – F-test.....	26
2.8.4 Sign test.....	27
2.9 RANGE.....	28
2.10 LIMIT OF DETECTION AND LIMIT OF QUANTIFICATION.....	28
2.10.1 3s - IUPAC.....	28
2.10.2 3s – Every Sample Corrected for Blank.....	29
2.10.3 3s – Continuously Measured Blank.....	29
2.10.4 From Calibration Line.....	30
2.10.5 From Signal of Blank in Chromatography.....	31
2.11 BLANK.....	31
2.12 REPEATABILITY OF INJECTION – FDA.....	32
2.13 CAPACITY FACTOR - FDA.....	33
2.14 RESOLUTION - FDA.....	34
2.15 TAILING - FDA.....	34
2.16 THEORETICAL PLATE NUMBER – FDA.....	35
INTERLABORATORY COMPARISON	36
3.1 MANDEL STATISTICS H.....	36
3.2 MANDEL STATISTICS K.....	37
3.3 COLLABORATIVE STUDY.....	38

CONTROL CHARTS	39
4.1 INDIVIDUAL MEASUREMENTS – CHARACTERISTICS DETERMINED	39
4.2 INDIVIDUAL MEASUREMENTS – CHARACTERISTICS NOT DETERMINED	41
4.3 REPEATED MEASUREMENTS – CHARACTERISTICS NOT DETERMINED.....	43
4.4 REPEATED MEASUREMENTS – CHARACTERISTICS NOT DETERMINED.....	45
CALIBRATION	48
5.1 LINEAR CALIBRATION.....	48
5.2 QUADRATIC CALIBRATION.....	49
UNCERTAINTIES	51
6.1 FROM PRECISION DATA – MULTIPLE MEASUREMENTS	51
6.2 FROM PRECISION DATA – PARALLEL MEASUREMENTS.....	52
6.3 FROM CONTROL CHART – INDIVIDUAL MEASUREMENTS.....	53
6.4 FROM CONTROL CHART – REPEATED MEASUREMENTS	54
6.5 EXPERT ESTIMATE	55
6.6 FROM PARTIAL UNCERTAINTIES	55

FOREWORD

Book of Reference Examples EffiValidation 3.0 presents all main algorithms of the software. The book aims to prove correct functionality of the software as a part of the software validation life cycle process.

For every important computational method implemented in the software, a reference example is presented, summarizing the data, results, graphical results and the original data source.

The considered original data sources are international standards and other recognized sources, that can be treated as reference sources.

Examples presented in this Book originate from the following literature:

- ISO 8466:1 and 2.
- ISO 8258:1991
- ISO 5725-2, 1997
- EURACHEM/CITAC Guide, Quantifying Uncertainty in Analytical Measurement, Second Edition, June 1999
- D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997
- 19-th edition, Remington: Practice of The Science and Pharmacy, Mack Publishing Company, Easton, 1995

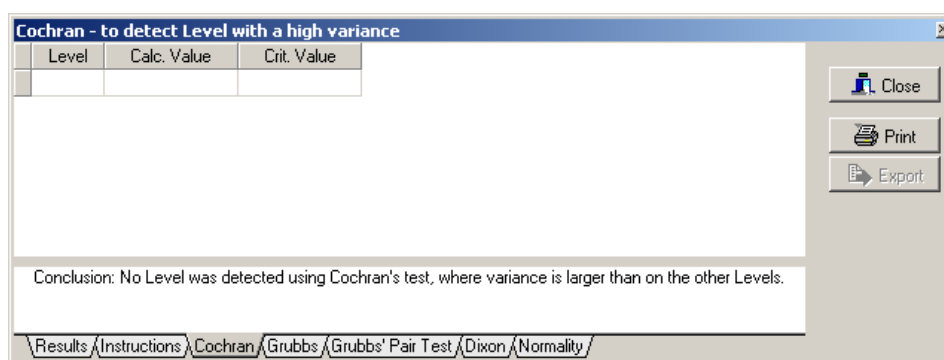
OUTLIERS AND NORMALITY TESTS

1.1 COCHRAN TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 123, tab. 6.1.

Level	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
1	5,59	5,59	5,37	5,54	5,37	5,42
2	5,67	5,67	5,55	5,57	5,43	5,57
3	5,75	5,47	5,43	5,45	5,24	5,47
4	4,74	4,45	4,65	4,94	4,95	5,06
5	5,52	5,47	5,66	5,52	5,62	5,76
6	5,52	5,62	5,47	5,18	5,43	5,33
7	5,43	5,52	5,43	5,43	5,52	5,52

Window Results in EffiValidation 3.0:



1.2 GRUBBS SINGLE TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 112, chapter 5.5.2.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8
22,1	22,4	22,9	23	23,5	23,7	23,9	26,5

Window Results in EffiValidation 3.0:

Level	Number	Value	Calc. Value	Crit. Value
1	8	26,5	2,2031	2,126

Conclusion: Number of Outliers detected using Grubbs' Test is: 1.

Results \ Instructions \ Grubbs \ Grubbs' Pair Test \ Dixon \ Normality

1.3 GRUBBS PAIR TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 446, chapter 14.2.4.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8
22,1	22,4	22,9	23	23,5	23,7	26,0	26,5

Window Results in EffiValidation 3.0:

Level	Measrt 1	Value 1	Measrt 2	Value 2	Calc. Value	Crit. Value

Conclusion: No Pair of Outliers detected using Grubbs' Pair Test.

Results \ Instructions \ Grubbs \ Grubbs' Pair Test \ Dixon \ Normality

1.4 DIXON TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 110, chapter 5.5.1.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8
22,1	22,4	22,9	23	23,5	23,7	23,9	26,5

Window Results in EffiValidation 3.0:

Level	Number	Value	Calc. Value	Crit. Value

Conclusion: No Outlier detected using Dixon's Test.

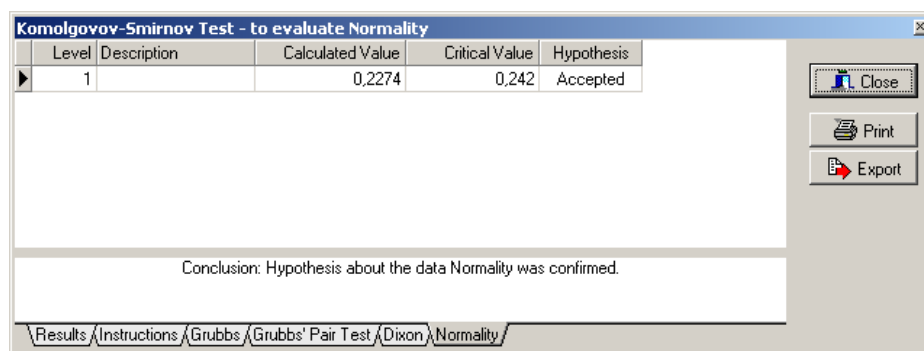
Results \ Instructions \ Grubbs \ Grubbs' Pair Test \ Dixon \ Normality

1.5 NORMALITY TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 118, Table 5.8.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8	Measrt 9	Measrt 10	Measrt 11	Measrt 12
2,104	2,222	2,247	2,286	2,327	2,367	2,388	2,512	2,707	2,751	3,158	3,172

Window Results in EffiValidation 3.0:



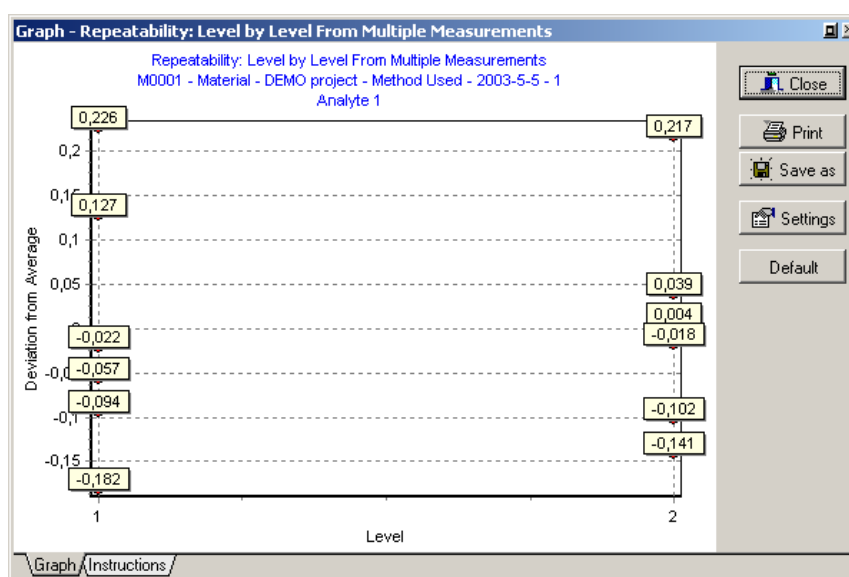
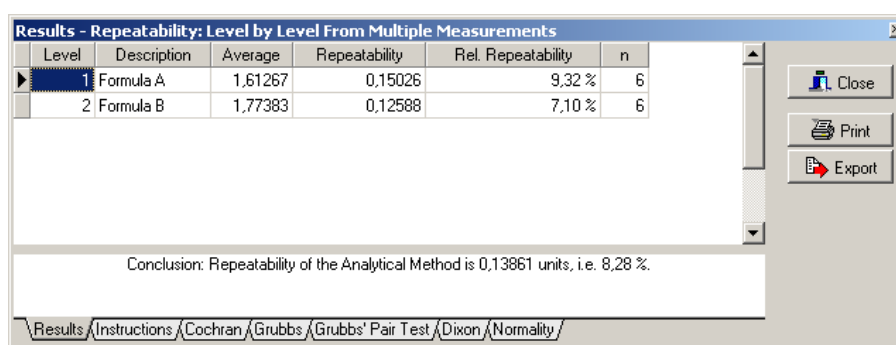
2.1 REPEATABILITY

2.1.1 LEVEL BY LEVEL FROM MULTIPLE MEASUREMENTS

Data source: 19-th edition, Remington: Practice of The Science and Pharmacy, Mack Publishing Company, Easton, 1995, page 126, Table 43:

	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
Table 43, formulation A	1,431	1,74	1,519	1,839	1,556	1,591
Table 43, formulation B	1,813	1,778	1,991	1,672	1,756	1,633

Window Results in EffiValidation 3.0:

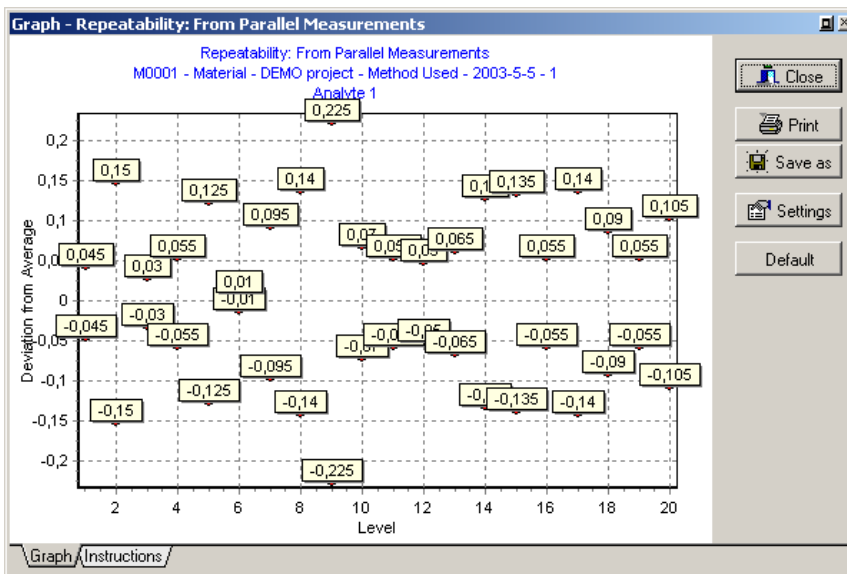
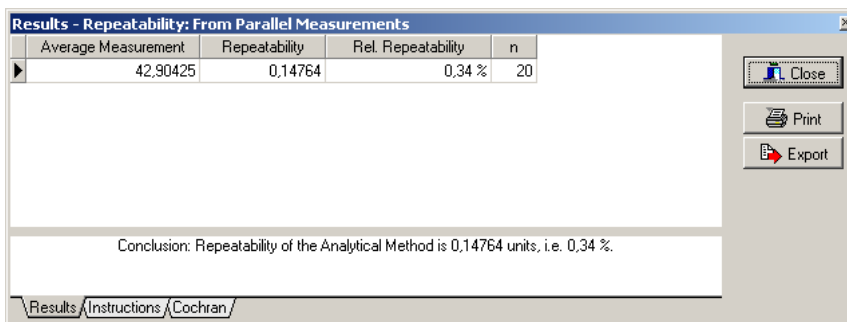


2.1.2 FROM PARALLEL MEASUREMENTS

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 30, Table 2.4:

Experiment	Measrt 1	Measrt 2
1	42,68	42,77
2	42,08	42,38
3	43,39	43,33
4	42,87	42,98
5	42,7	42,95
6	42,93	42,95
7	42,78	42,97
8	42,92	43,2
9	43,34	42,89
10	43,12	43,26
11	42,43	42,54
12	43,05	43,15
13	42,99	42,86
14	43,04	42,78
15	43,41	43,14
16	43,12	43,23
17	42,25	42,53
18	42,96	42,78
19	42,83	42,72
20	42,83	43,04

Window Results in EffiValidation 3.0:

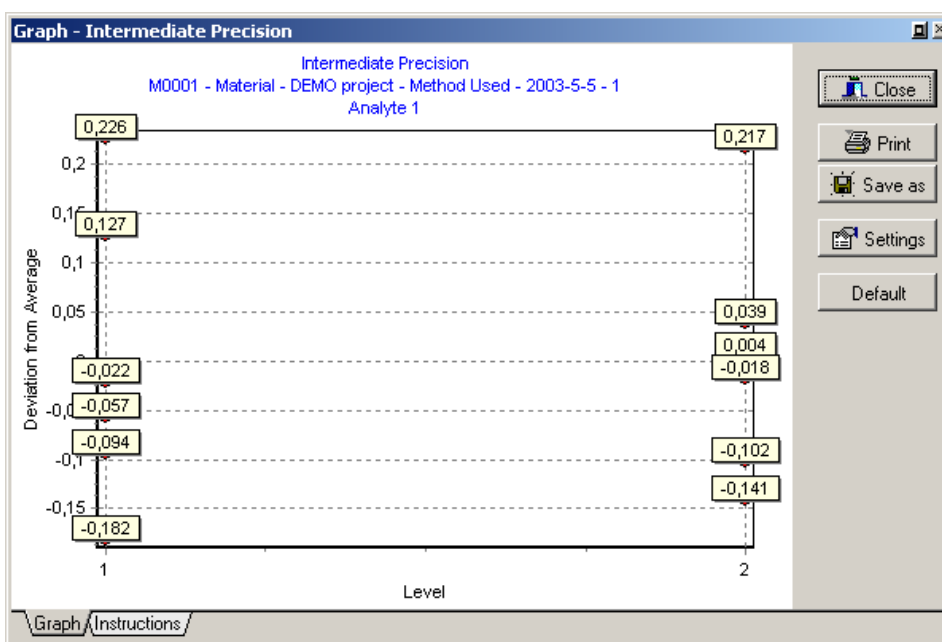
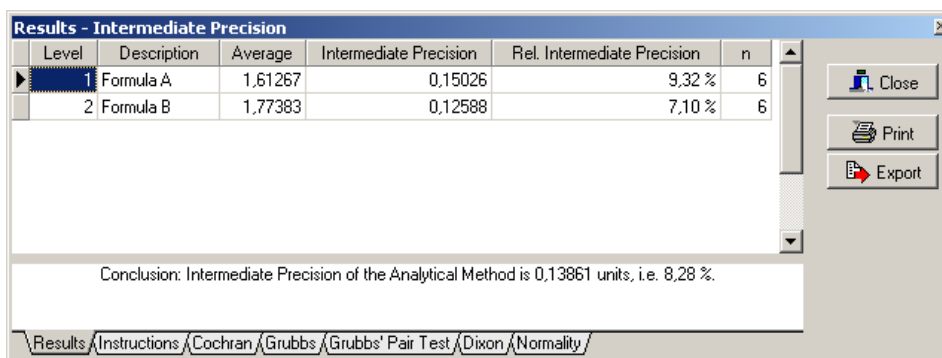


2.2 INTERMEDIATE PRECISION

Data source: 19-th edition, Remington: Practice of The Science and Pharmacy, Mack Publishing Company, Easton, 1995, page 126, Table 43:

	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
Table 43, formulace A	1,431	1,74	1,519	1,839	1,556	1,591
Table 43, formulace B	1,813	1,778	1,991	1,672	1,756	1,633

Window Results in EffiValidation 3.0:



2.3 REPRODUCIBILITY

2.3.1 DATA AVAILABLE

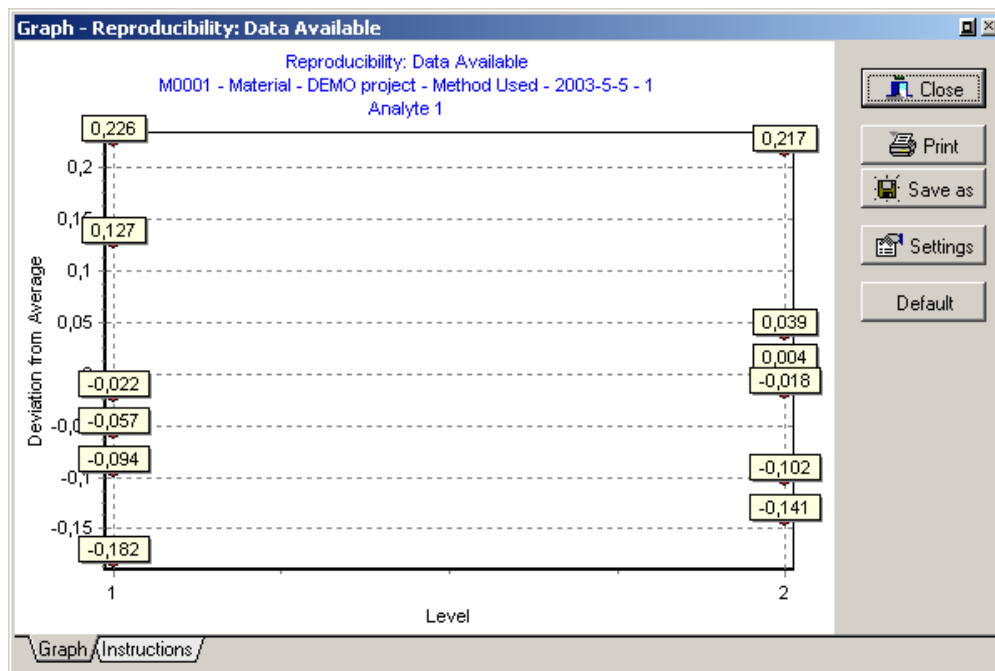
Data source: 19-th edition, Remington: Practice of The Science and Pharmacy, Mack Publishing Company, Easton, 1995, page 126, Table 43:

	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
Table 43, formulace A	1,431	1,74	1,519	1,839	1,556	1,591
Table 43, formulace B	1,813	1,778	1,991	1,672	1,756	1,633

Window Results in EffiValidation 3.0:

Level	Description	Average	Reproducibility	Rel. Repeatability	n
1	Formula A	1,61267	0,15026	9,32 %	6
2	Formula B	1,77383	0,12588	7,10 %	6

Conclusion: Reproducibility of the Analytical Method is 0,13861 units, i.e. 8,28 %.



2.3.2 RESULTS AVAILABLE

Data are not evaluated, but only archived in the database of EffiValidation 3.0.

2.4 ROBUSTNESS

Data source: not found. Data obtained by experimental measurements in a laboratory.

Number of factors: 5

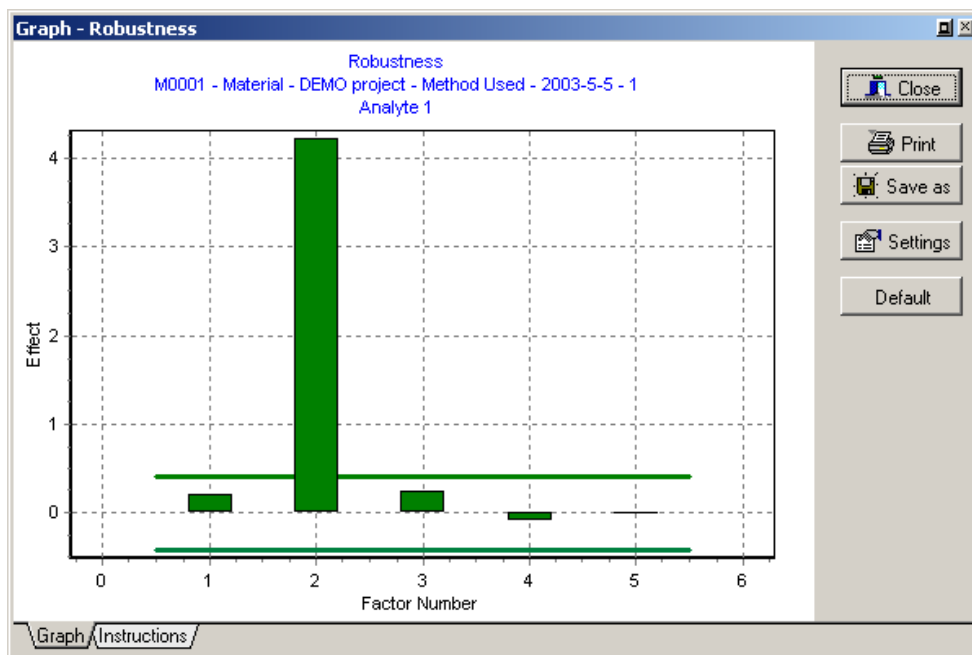
Result	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Dummy 1	Dummy 2
25,01	1	1	1	-1	1	-1	-1
24,92	-1	1	1	1	-1	1	-1
20,33	-1	-1	1	1	1	-1	1
20,64	1	-1	-1	1	1	1	-1
24,58	-1	1	-1	-1	1	1	1
20,83	1	-1	1	-1	-1	1	1
24,53	1	1	-1	1	-1	-1	1
20,34	-1	-1	-1	-1	-1	-1	-1

Dummy factors considered in the calculation:

Window Results in EffiValidation 3.0:

Factor	Factor Effect	Critical Effect	Hypothesis
1	0,21	0,4188	Accepted
2	4,225	0,4188	Rejected
3	0,25	0,4188	Accepted
4	-0,085	0,4188	Accepted
5	-0,015	0,4188	Accepted

Conclusion: the Analytical Method is not robust against all Factors tested.



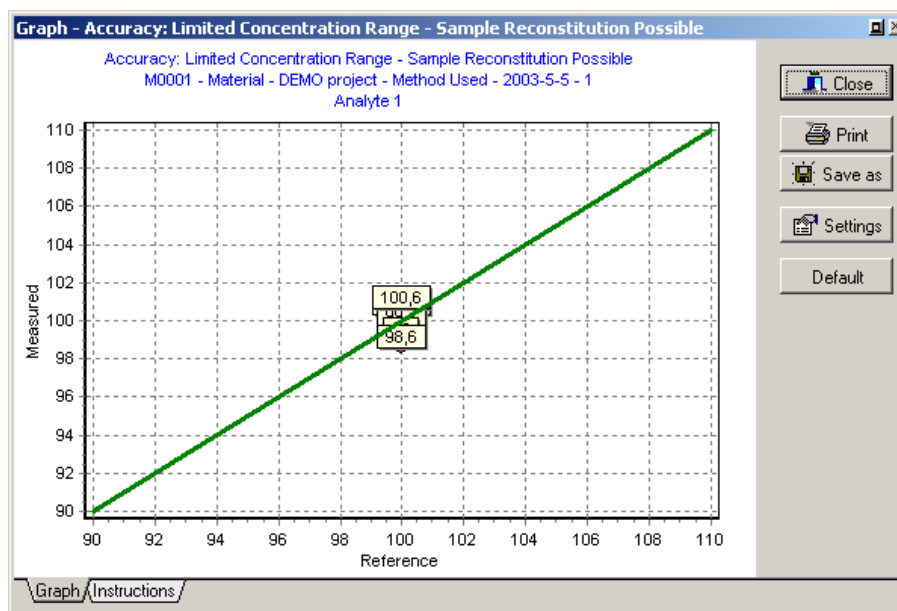
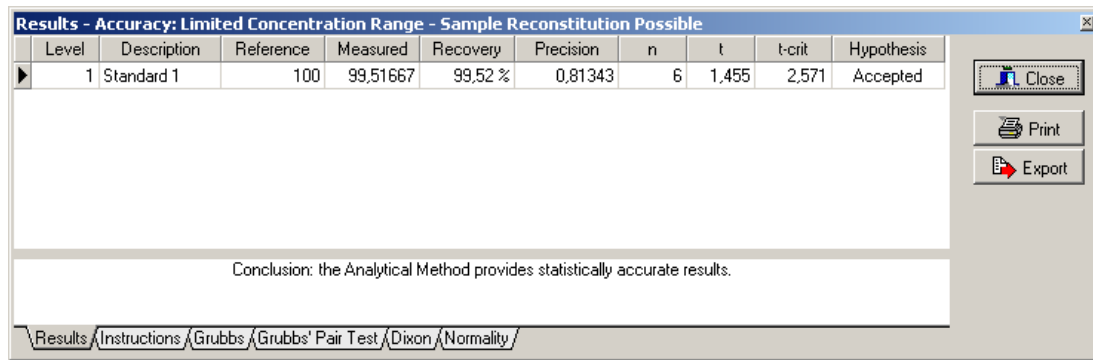
2.5 ACCURACY

2.5.1 LIMITED CONCENTRATION RANGE – SAMPLE RECONSTITUTION POSSIBLE

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 397, chapter 13.5.2.

Reference value	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
100	98,9	100,3	99,7	99	100,6	98,6

Window Results in EffiValidation 3.0:



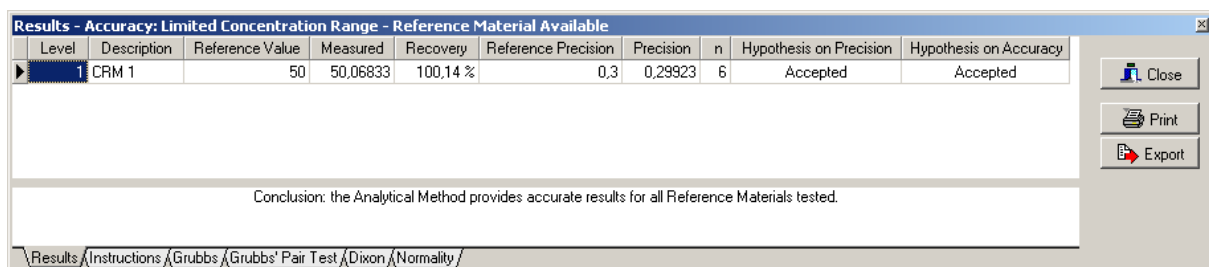
2.5.2 LIMITED CONCENTRATION RANGE – REFERENCE MATERIAL AVAILABLE

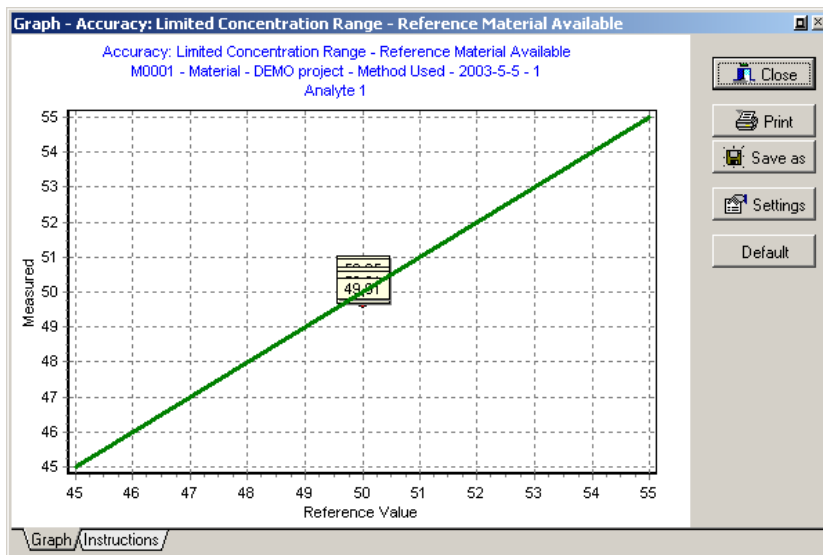
Data source: not found. Data obtained by experimental measurements in a laboratory.

Reference value	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
50	50,45	50,35	50,11	49,68	50,01	49,81

Reference precision: 0,3

Window Results in EffiValidation 3.0:



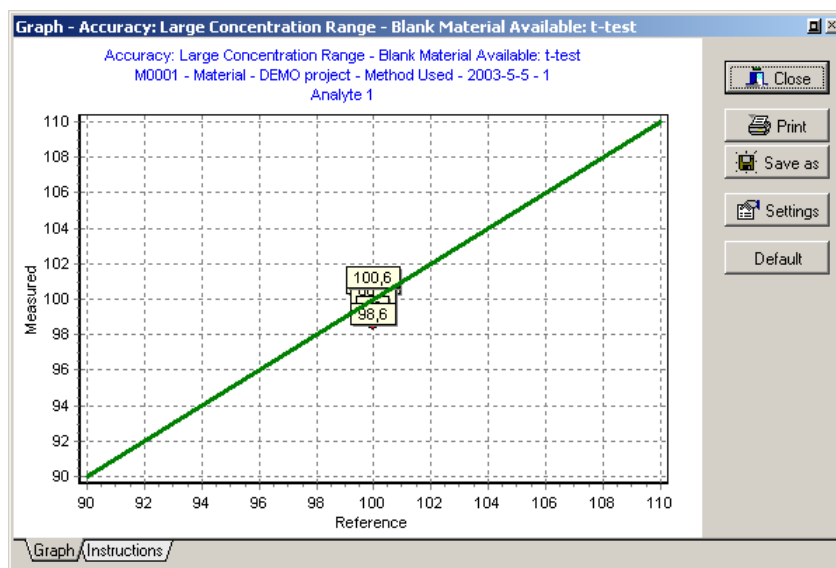
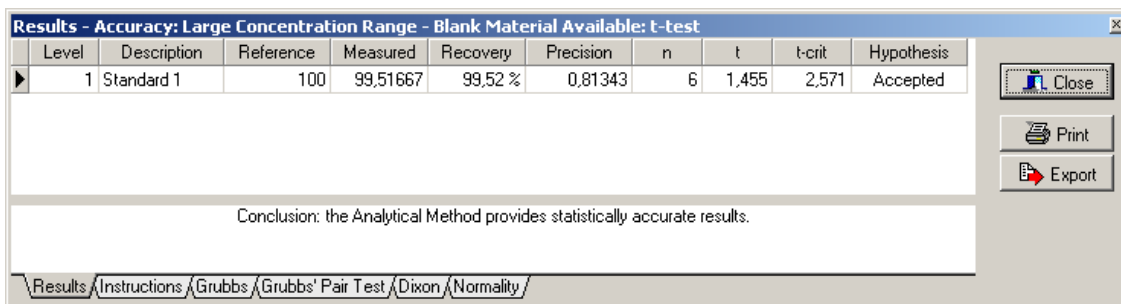


2.5.3 LARGE CONCENTRATION RANGE – BLANK MATERIAL AVAILABLE: T-TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 397, chapter 13.5.2.

Reference	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
100	98,9	100,3	99,7	99	100,6	98,6

Window Results in EffiValidation 3.0:

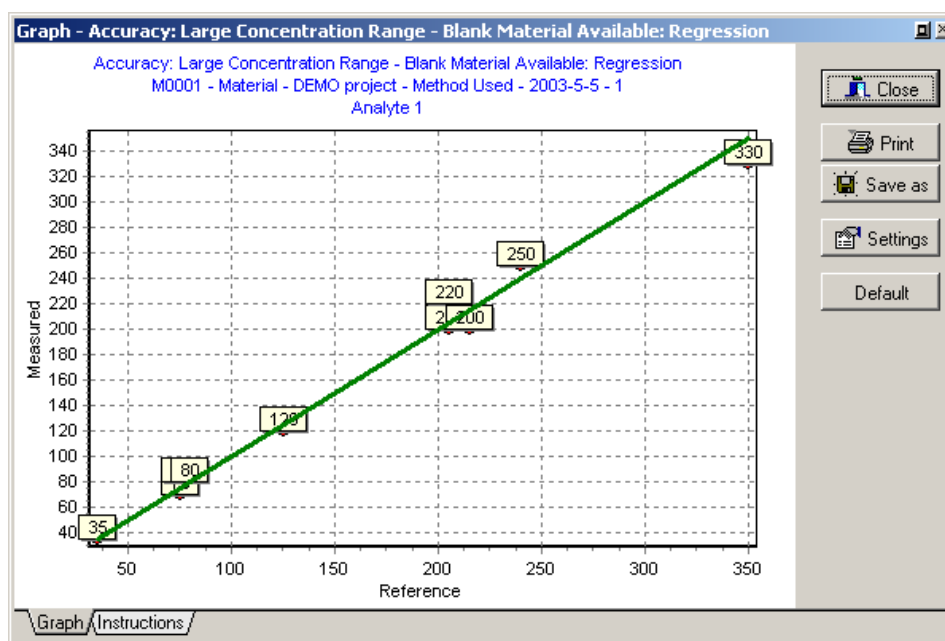
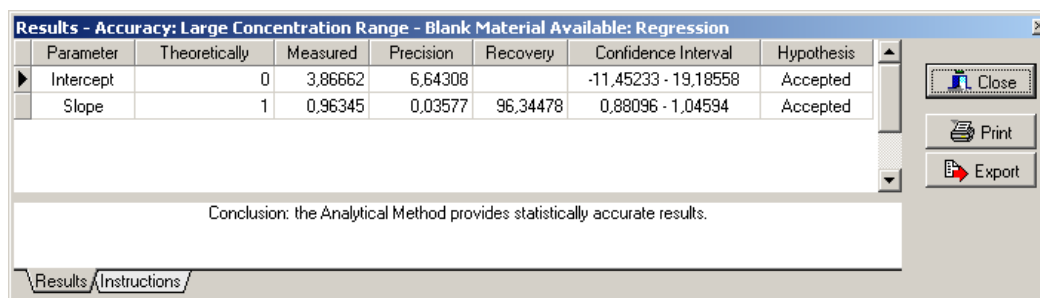


2.5.4 LARGE CONCENTRATION RANGE – BLANK MATERIAL AVAILABLE: REGRESSION

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 193, Table 8.6.

Sample	Measrt 1	Measrt 2
1	35	35
2	75	70
3	75	80
4	80	80
5	125	120
6	205	200
7	205	220
8	215	200
9	240	250
10	350	330

Window Results in EffiValidation 3.0:



2.5.5 LARGE CONCENTRATION RANGE – BLANK MATERIAL NOT AVAILABLE: T-TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 405, chapter 13.5.5.

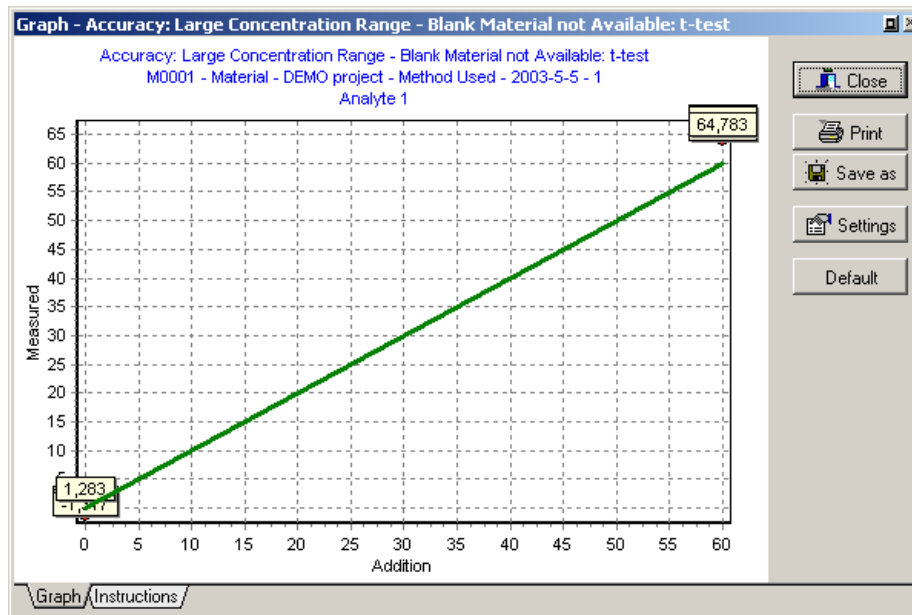
Standard Addition	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
0	90	90,8	89,7	89,2	88,6	91,2
60	156	154,2	155,3	155,6	153,8	154,7

Window Results in EffiValidation 3.0:

Level	Description	Addition	Measured	Recovery	Precision	Confidence Interval	Hypothesis
1	Initial Sample	0	0	0	0,97245	-1,2509 - 1,2509	Accepted
2	Addition 60	60	65,01667	108,36111	0,84774	63,84323 - 66,1901	Rejected

Conclusion: the Analytical Method does not provide statistically accurate results.

Results / Instructions / Cochran / Grubbs / Grubbs' Pair Test / Dixon / Normality



2.5.6 LARGE CONCENTRATION RANGE – BLANK MATERIAL AVAILABLE: REGRESSION

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 210, chapter 8.2.9., example 9

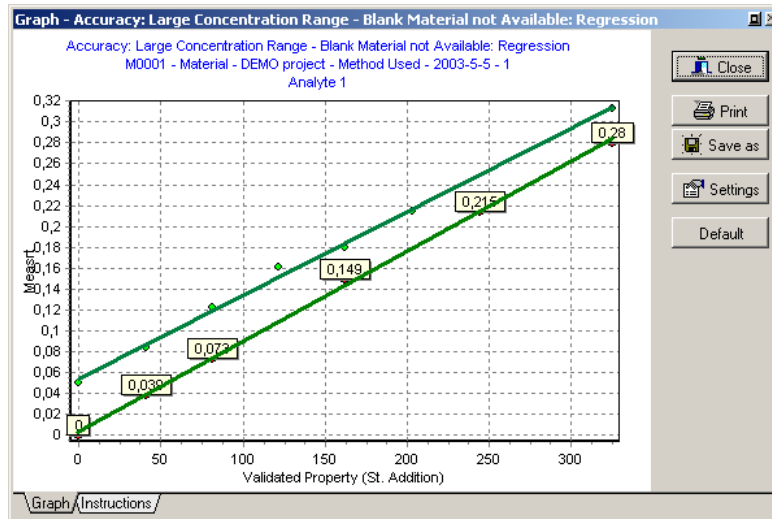
Standard	Calibration		Standard addition	
	ug/l	A*s	ug/l added	A*s
1	0	0	0	0,05
2	41	0,039	41	0,083
3	81	0,073	81	0,122
4	162	0,149	122	0,161
5	244	0,215	162	0,179
6	325	0,28	203	0,215
7			325	0,313

Window Results in EffiValidation 3.0:

Parameter	Calibration	Standard Addition	Recovery	t	t-crit	Hypothesis
Slope	0,00086289	0,00080265	93,02 %	2,394	2,262	Rejected

Conclusion: the Analytical Method does not provide statistically accurate results.

Results / Instructions



2.5.7 COMPARISON OF 2 METHODS / LABORATORIES: T-TEST LEVEL BY LEVEL

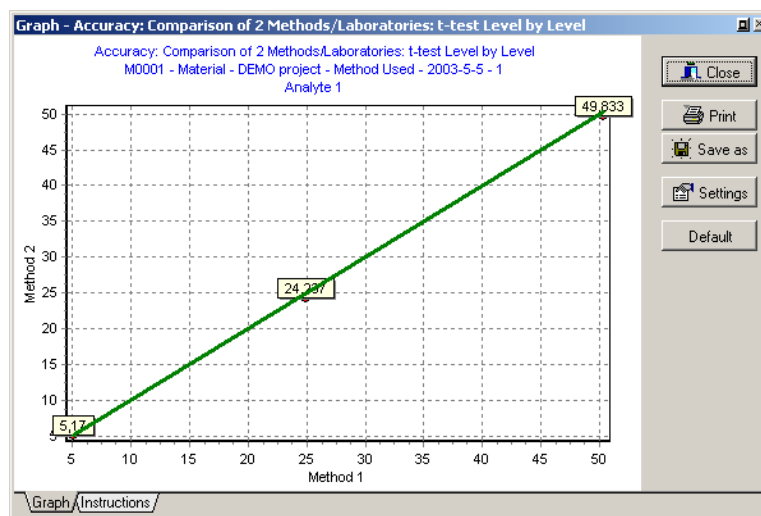
Data source: not found. Data obtained by experimental measurements in a laboratory.

Sample	Method 1 Measrt 1	Method 1 Measrt 2	Method 1 Measrt 3	Method 2 Measrt 1	Method 2 Measrt 2	Method 2 Measrt 3
1	5,33	5,01	4,97	5,31	5,08	5,12
2	25,02	24,95	24,86	24,38	24,22	24,11
3	50,11	50,45	50,35	49,81	49,68	50,01

Window Results in EffiValidation 3.0:

Level	Description	Measured 1	Measured 2	Recovery	Precision 1	Precision 2	t	t-crit	Hypothesis
1	Level 5	5,10333	5,17	101,31 %	0,19732	0,12288	0,497	2,776	Accepted
2	Level 25	24,94333	24,23667	97,17 %	0,08021	0,13577	7,762	2,776	Rejected
3	Level 50	50,30333	49,83333	99,07 %	0,17474	0,16623	3,375	2,776	Rejected

Conclusion: the compared Analytical Methods do not provide statistically the same results.

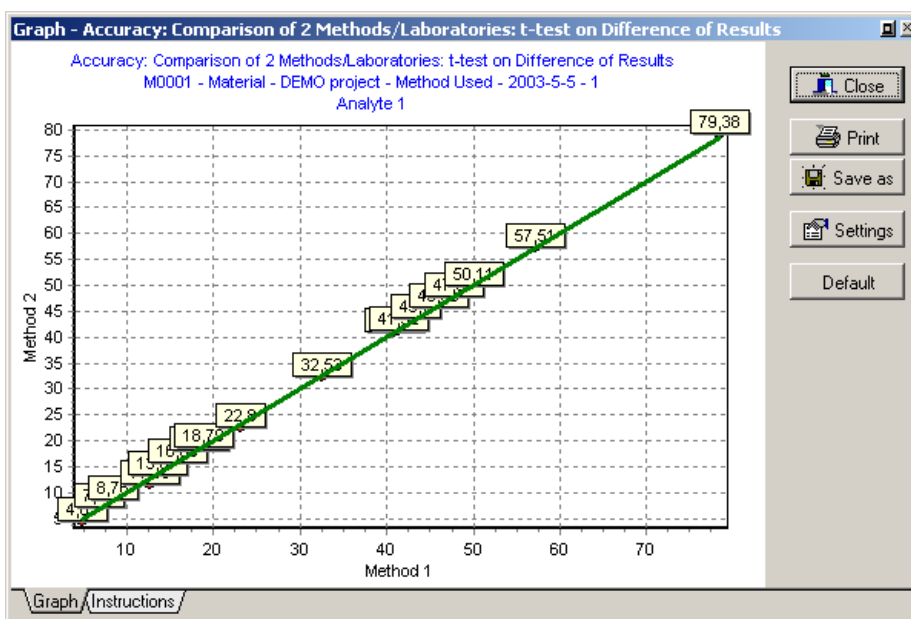
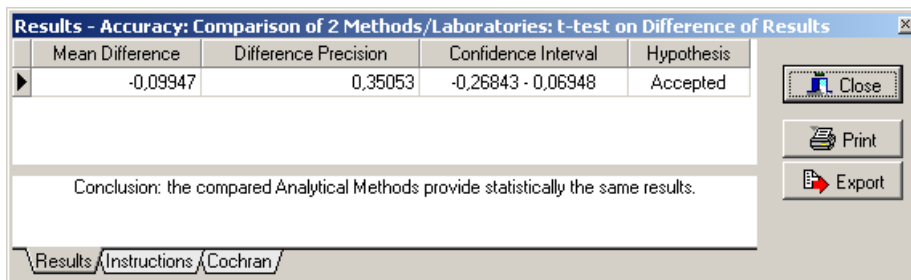


2.5.8 COMPARISON OF 2 METHODS / LABORATORIES: T-TEST ON DIFFERENCE OF RESULTS

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 411, Table 13.7.

Sample	Measrt 1	Measrt 2
1	4,83	4,63
2	6,74	7,39
3	8,46	8,76
4	12,6	11,85
5	13,52	13,67
6	15,72	15,8
7	15,83	16,05
8	18,37	18,22
9	18,9	18,79
10	23,1	22,8
11	32,45	32,53
12	40,89	41,03
13	41,42	41,52
14	43,36	43,7
15	45,96	45,89
16	47,7	47,81
17	50,02	50,11
18	57,2	57,51
19	78,48	79,38

Window Results in EffiValidation 3.0:



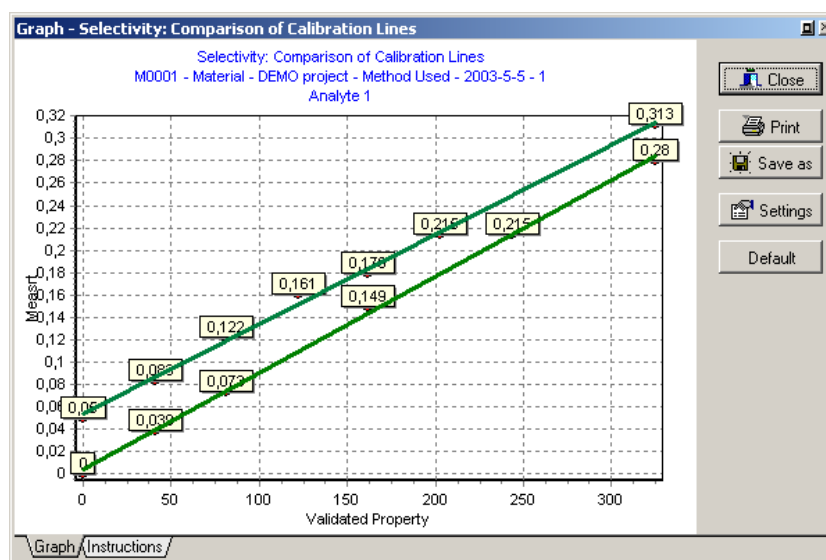
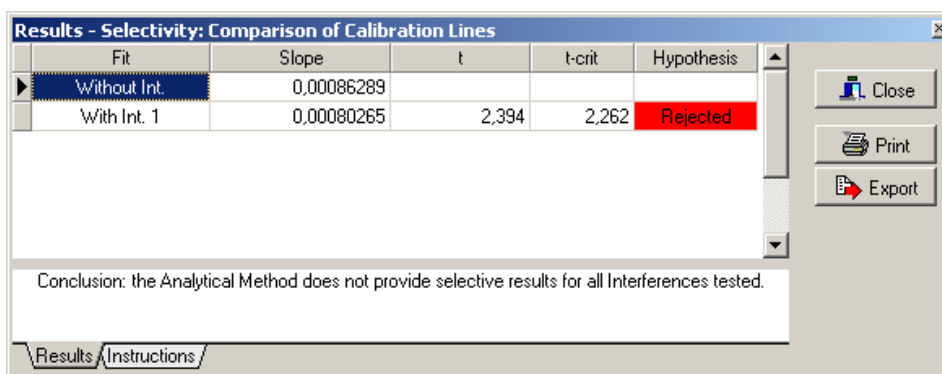
2.6 SELECTIVITY

2.6.1 COMPARISON OF CALIBRATION LINES

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 210, chapter 8.2.9., Example 9

Standard	Calibration without interference		Calibration with interference 1	
	ug/l	A*s	ug/l added	A*s
1	0	0	0	0,05
2	41	0,039	41	0,083
3	81	0,073	81	0,122
4	162	0,149	122	0,161
5	244	0,215	162	0,179
6	325	0,28	203	0,215
7			325	0,313

Window Results in EffiValidation 3.0:

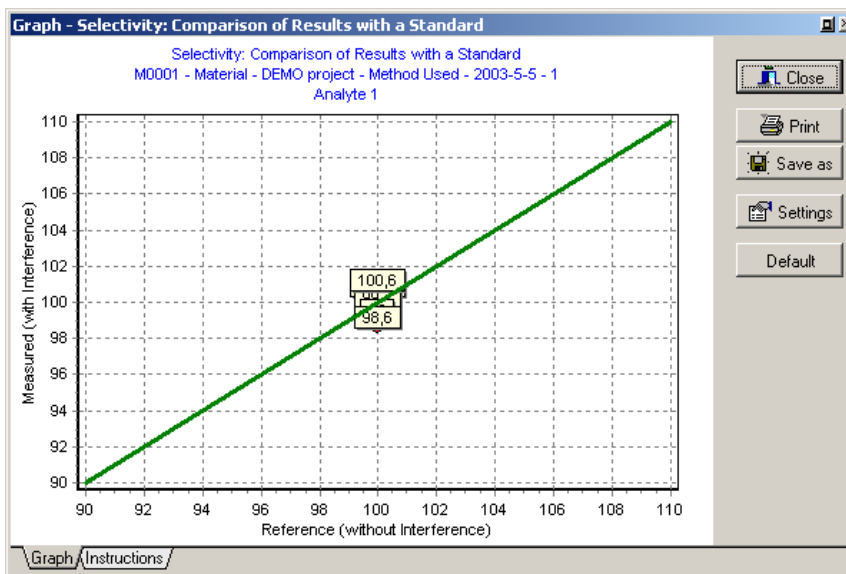
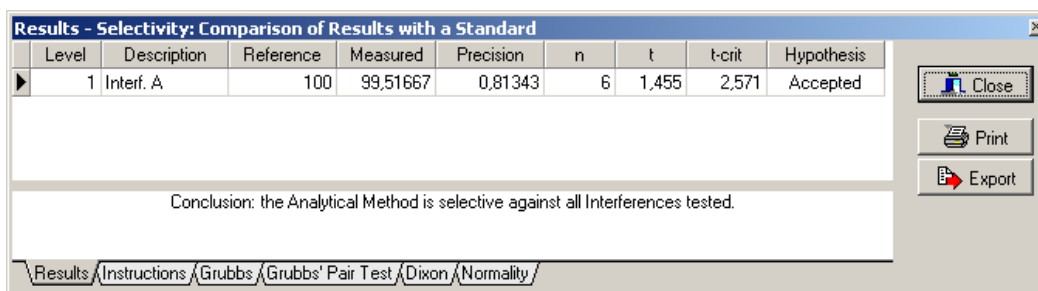


2.6.2 COMPARISON OF RESULTS WITH A STANDARD

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 397, chapter 13.5.2.

Reference (without interference)	With interf. 1	With interf. 2	With interf. 3	With interf. 4	With interf. 5	With interf. 6
100	98,9	100,3	99,7	99	100,6	98,6

Window Results in EffiValidation 3.0:

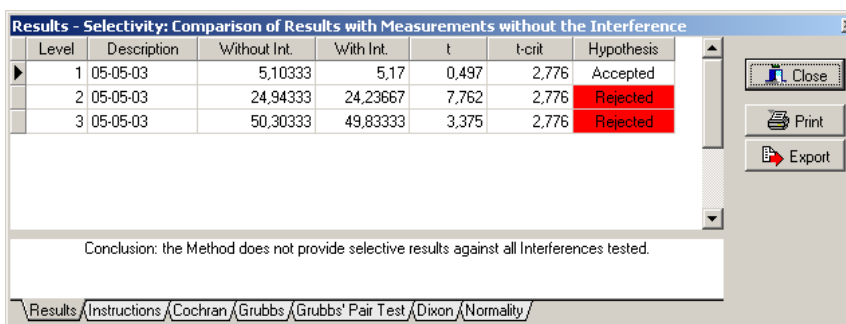


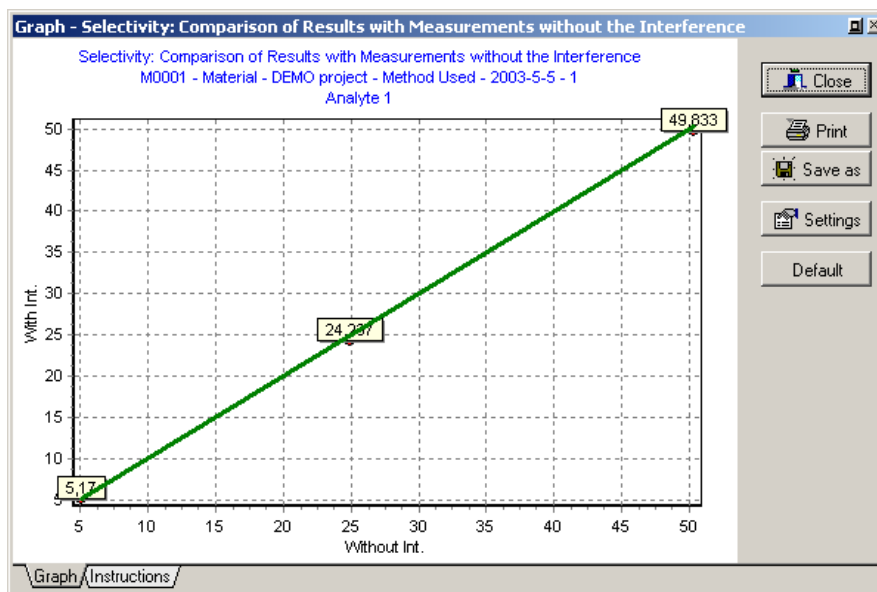
2.6.3 COMPARISON OF RESULTS WITH MEASUREMENTS WITHOUT THE INTERFERENCE

Data source: not found. Data obtained by experimental measurements in a laboratory.

Sample	Without interf. Measrt 1	Without interf. Measrt 2	Without interf. Measrt 3	With interf. Measrt 1	With interf. Measrt 2	With interf. Measrt 3
1	5,33	5,01	4,97	5,31	5,08	5,12
2	25,02	24,95	24,86	24,38	24,22	24,11
3	50,11	50,45	50,35	49,81	49,68	50,01

Window Results in EffiValidation 3.0:





2.7 SENSITIVITY

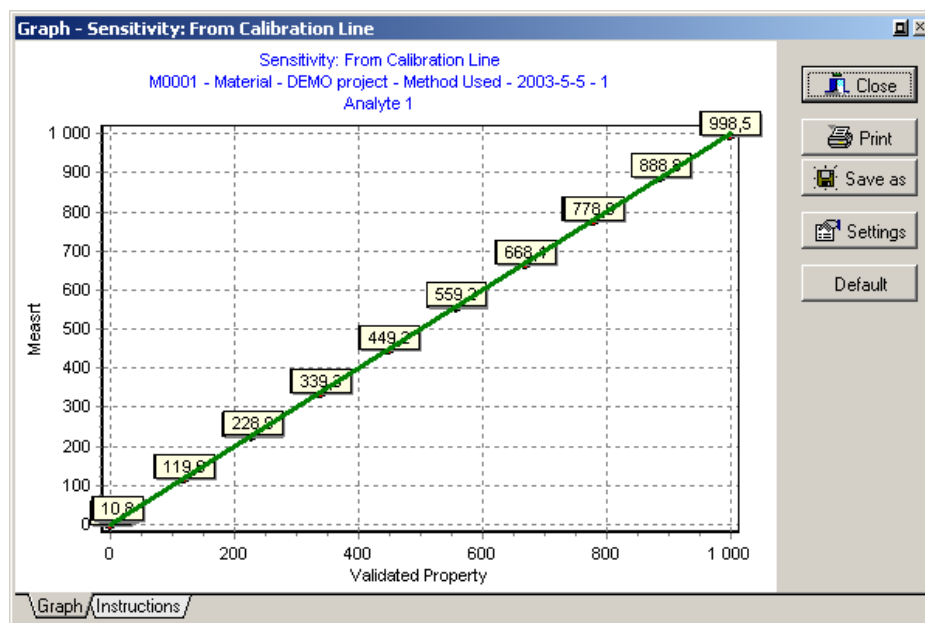
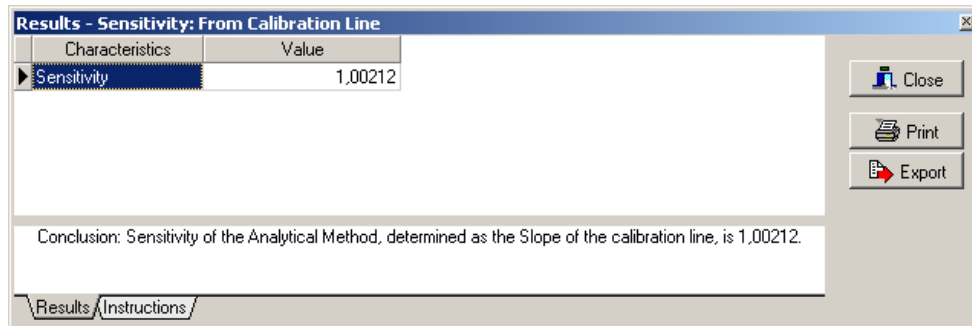
2.7.1 FROM CALIBRATION LINE

Data source: NIST, Norris, J, <http://www.itl.nist.gov/div898/strd/lls/data/LINKS/DATA/Norris.dat>

Sample	Measrt 1	Measrt 2
1	0,2	0,1
2	337,4	338,8
3	118,2	118,1
4	884,6	888
5	10,1	9,2
6	226,5	228,1
7	666,3	668,5
8	996,3	998,5
9	448,6	449,1
10	777	778,9
11	558,2	559,2
12	0,4	0,3
13	0,6	0,1
14	775,5	778,1
15	666,9	668,8
16	338	339,3
17	447,5	448,9
18	11,6	10,8
19	556	557,7
20	228,1	228,3
21	995,8	998
22	887,6	888,8
23	120,2	119,6
24	0,3	0,3
25	0,3	0,6
26	556,8	557,6
27	339,1	339,3
28	887,2	888
29	999	998,5
30	779	778,9

31	11,1	10,2
32	118,3	117,6
33	229,2	228,9
34	669,1	668,4
35	448,9	449,2
36	0,5	0,2

Window Results in EffiValidation 3.0:



2.7.2 MINIMAL DIFFERENCE IN THE VALIDATED PROPERTY

Data source: not found. Data obtained by experimental measurements in a laboratory.

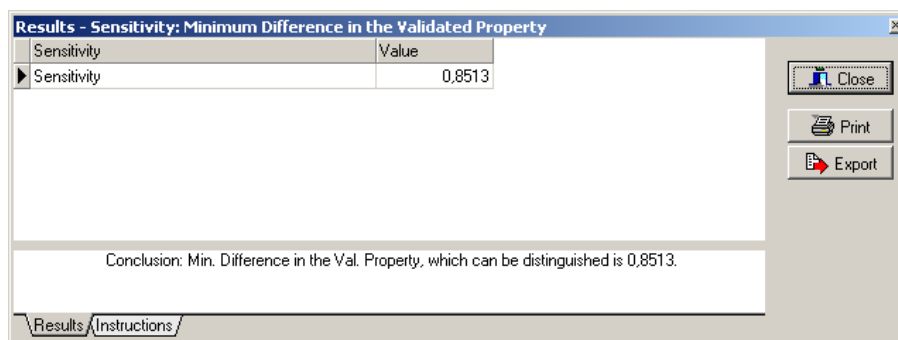
Sensitivity: Minimum Difference in the Validated Property

Repeatability of the Validated Property : 0,1230

Number of Repetitions for Repeatability: 6

Confidence Level 100*(1-alfa) : 95,00

Window Results in EffiValidation 3.0:



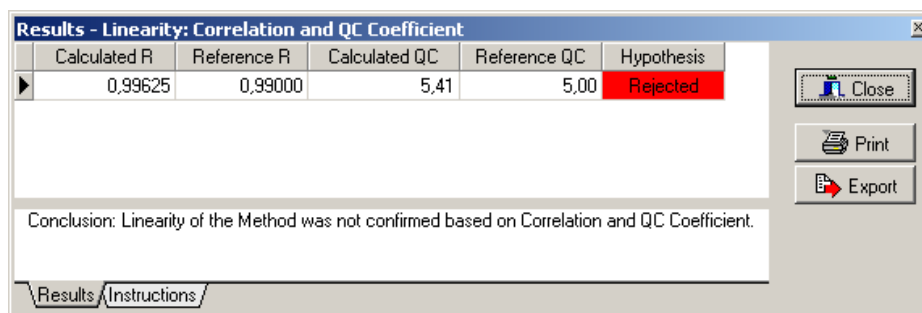
2.8 LINEARITY

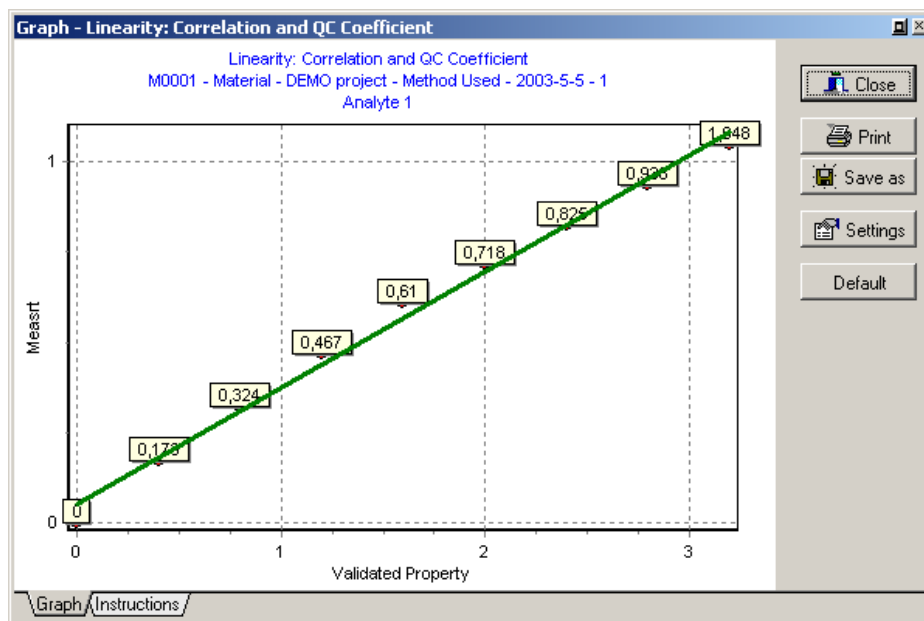
2.8.1 CORRELATION AND QC COEFFICIENT

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 420, chapter 13.6.2., Table 13.9 and 13.10.

Sample	Measrt 1	Measrt 2
1	0	0
2	0,4	0,173
3	0,8	0,324
4	1,2	0,467
5	1,6	0,61
6	2	0,718
7	2,4	0,825
8	2,8	0,938
9	3,2	1,048

Window Results in EffiValidation 3.0:





2.8.2 ANOVA FOR LACK OF FIT

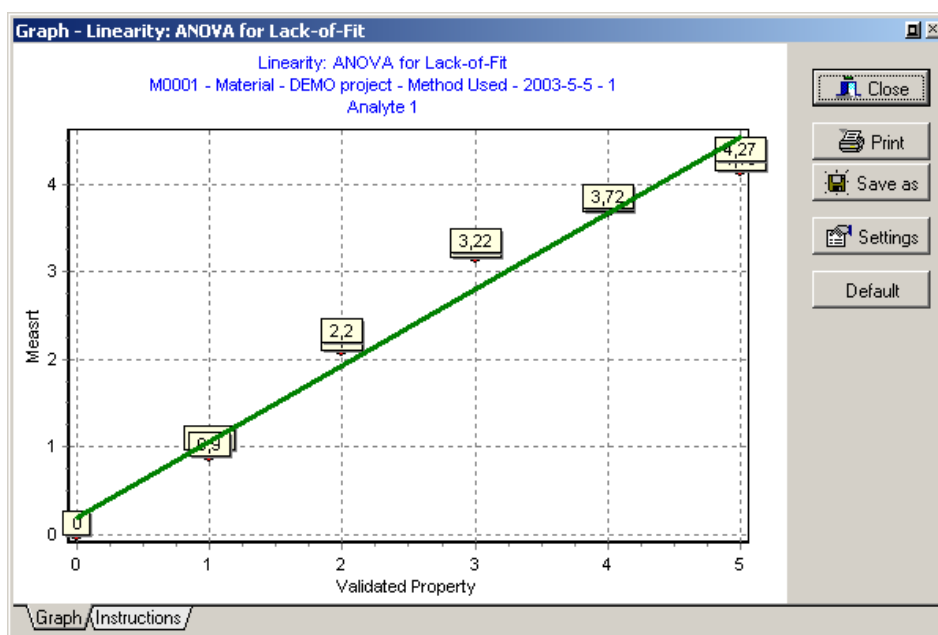
Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 185, chapter 8.2.2.2., Example 2, Table 8.3.

Sample	Val. property	Measrt 1	Measrt 2
1	0	0	0
2	1	0,98	0,9
3	2	2,1	2,2
4	3	3,16	3,22
5	4	3,68	3,72
6	5	4,15	4,27

Window Results in EffiValidation 3.0:

Source	Sum of Squares	Degrees of Freedom	Average Sum of Squares	F	F - crit	Hypothesis
Fit	0,72141714	4	0,18035429	60,12	7,15	Rejected
Pure Error	0,018	6	0,003			

Conclusion: Linearity was not statistically confirmed.

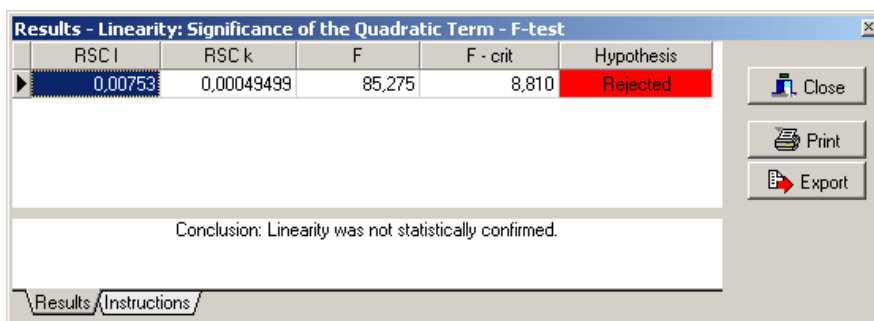


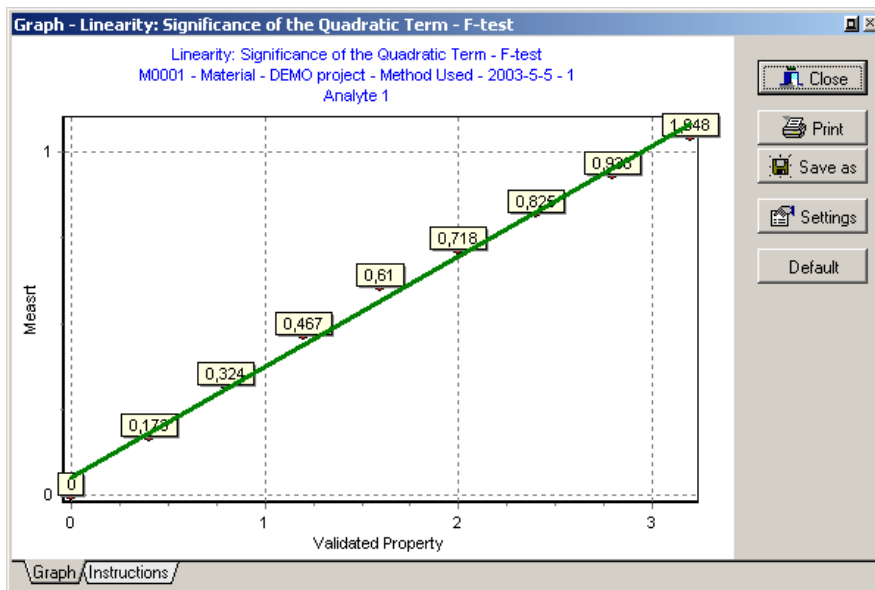
2.8.3 SIGNIFICANCE OF THE QUADRATIC TERM – F-TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 420, chapter 13.6.2., Table 13.9 and 13.10.

Sample	Measrt 1	Measrt 2
1	0	0
2	0,4	0,173
3	0,8	0,324
4	1,2	0,467
5	1,6	0,61
6	2	0,718
7	2,4	0,825
8	2,8	0,938
9	3,2	1,048

Window Results in EffiValidation 3.0:



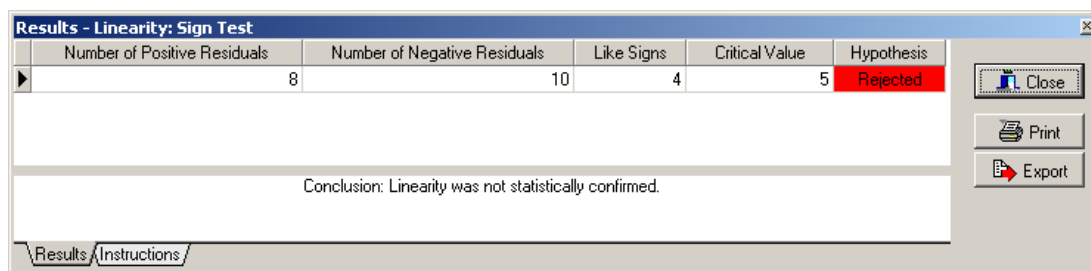


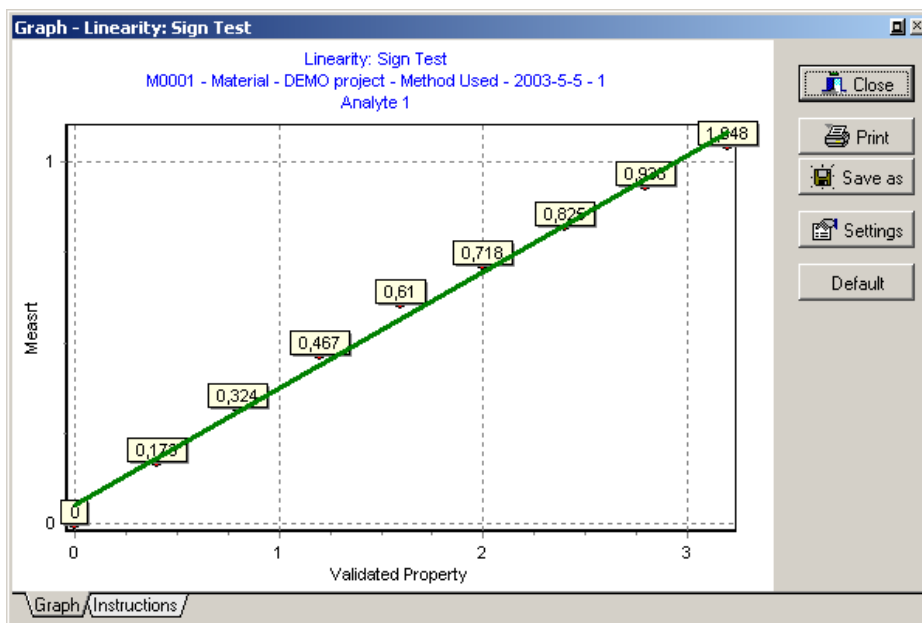
2.8.4 SIGN TEST

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 420, chapter 13.6.2., Table 13.9 and 13.10. – repeated twice

Sample	Measrt 1	Measrt 2
1	0	0
2	0,4	0,173
3	0,8	0,324
4	1,2	0,467
5	1,6	0,61
6	2	0,718
7	2,4	0,825
8	2,8	0,938
9	3,2	1,048
10	0	0
11	0,4	0,173
12	0,8	0,324
13	1,2	0,467
14	1,6	0,61
15	2	0,718
16	2,4	0,825
17	2,8	0,938
18	3,2	1,048

Window Results in EffiValidation 3.0:





2.9 RANGE

Range is not accessed but only archived in the database of EffiValidation 3.0:

2.10 LIMIT OF DETECTION AND LIMIT OF QUANTIFICATION

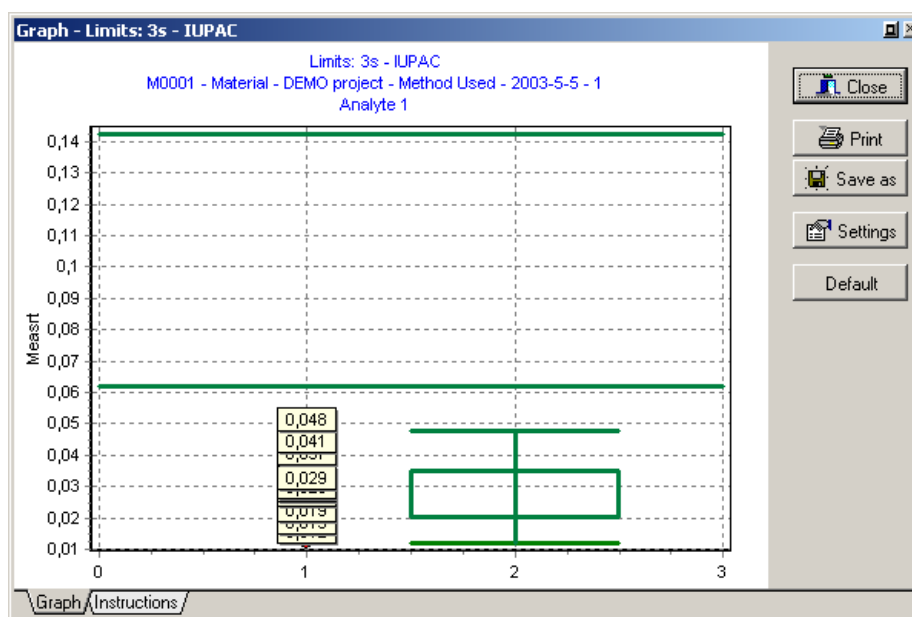
2.10.1 3s - IUPAC

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 430, chapter 13.7.6.

Slope: 1

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8	Measrt 9	Measrt 10
0,025	0,037	0,012	0,029	0,048	0,026	0,024	0,015	0,041	0,019

Window Results in EffiValidation 3.0:



2.10.2 3s – EVERY SAMPLE CORRECTED FOR BLANK

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 430, chapter 13.7.6.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8	Measrt 9	Measrt 10
0,025	0,037	0,012	0,029	0,048	0,026	0,024	0,015	0,041	0,019

Window Results in EffiValidation 3.0:

Measurement on the Limit of Detection	Measurement on the Limit of Quantification	Validated Property on the Limit of Detection	Validated Property on the Limit of Quantification
0,03609	0,12032	0,03609	0,12032

Conclusion: Limit of Detection/Quantification is 0,03609 and 0,12032. Val. Property on the Limit of Detection/Quantification is 0,03609 and 0,12032.

2.10.3 3s – CONTINUOUSLY MEASURED BLANK

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 430, chapter 13.7.6.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8	Measrt 9	Measrt 10
0,025	0,037	0,012	0,029	0,048	0,026	0,024	0,015	0,041	0,019

Window Results in EffiValidation 3.0:

Measurement on the Limit of Detection	Measurement on the Limit of Quantification	Validated Property on the Limit of Detection	Validated Property on the Limit of Quantification
0,04867	0,16223	0,04867	0,16223

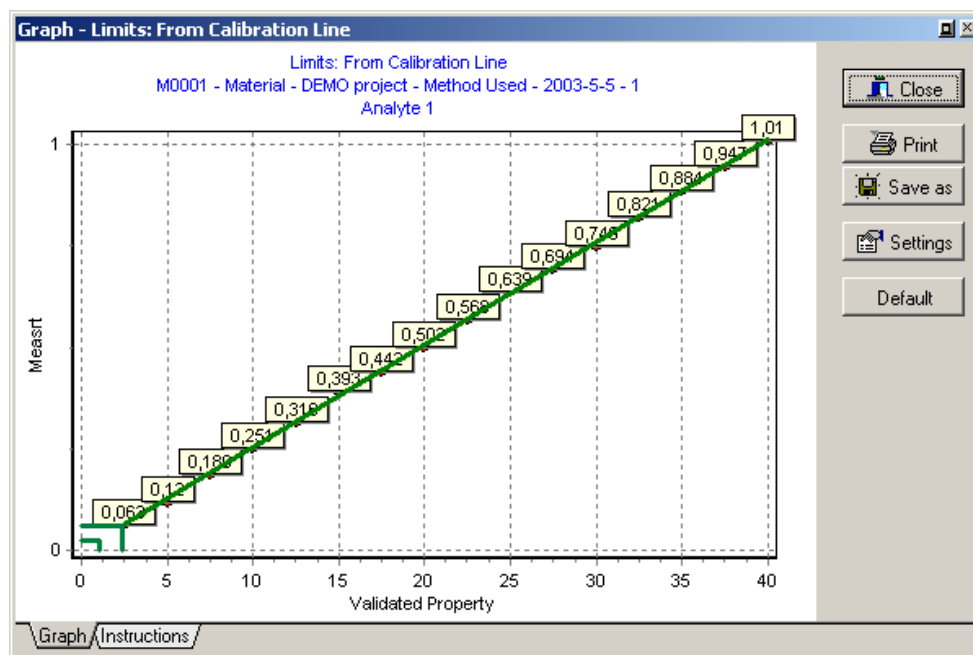
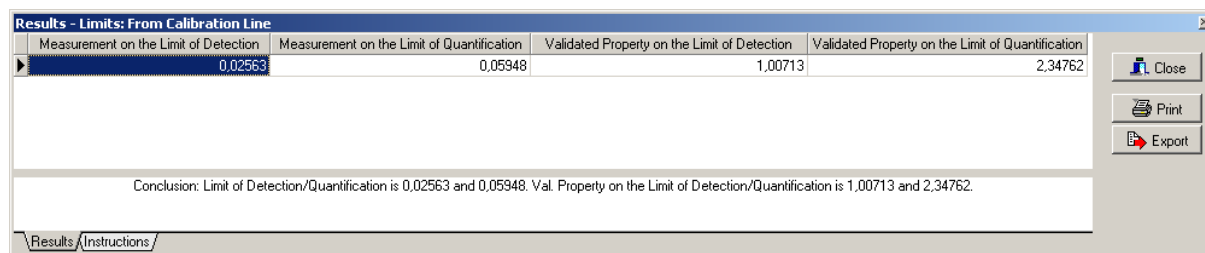
Conclusion: Limit of Detection/Quantification is 0,04867 and 0,16223. Val. Property on the Limit of Detection/Quantification is 0,04867 and 0,16223.

2.10.4 FROM CALIBRATION LINE

Data source: M. Meloun, J. Militký, Statistical evaluation of experimental data, Edice PLUS, Praha, 1994, page 498, chapter 6.7.2., Example 6.53

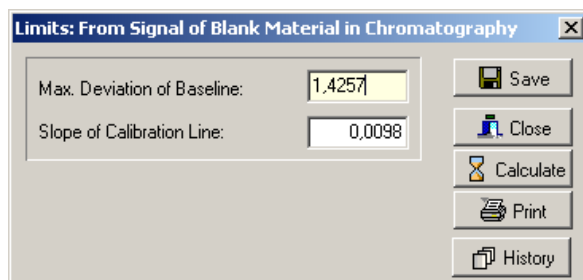
Sample	Measrt 1	Measrt 2
1	2,5	0,063
2	5	0,12
3	7,5	0,189
4	10	0,251
5	12,5	0,316
6	15	0,393
7	17,5	0,442
8	20	0,502
9	22,5	0,568
10	25	0,639
11	27,5	0,694
12	30	0,749
13	32,5	0,821
14	35	0,884
15	37,5	0,947
16	40	1,01

Window Results in EffiValidation 3.0:

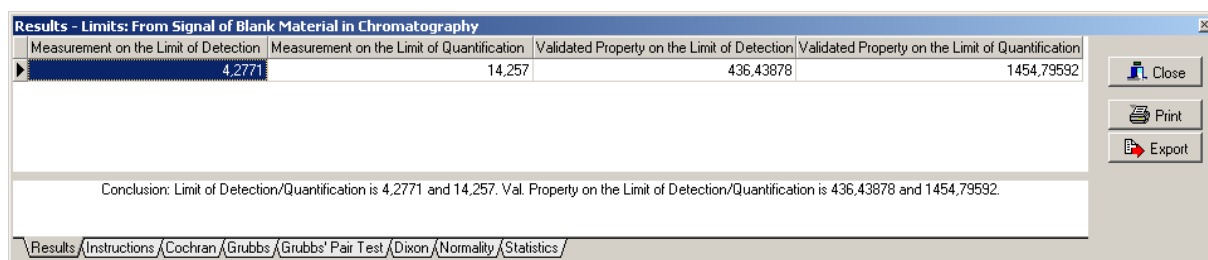


2.10.5 FROM SIGNAL OF BLANK IN CHROMATOGRAPHY

Data source: not found. Data obtained by experimental measurements in a laboratory.



Window Results in EffiValidation 3.0:

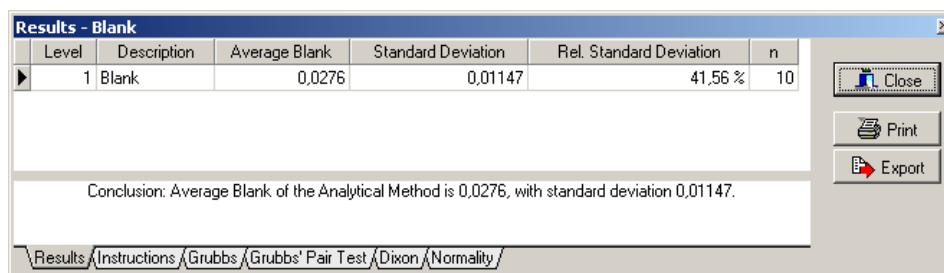


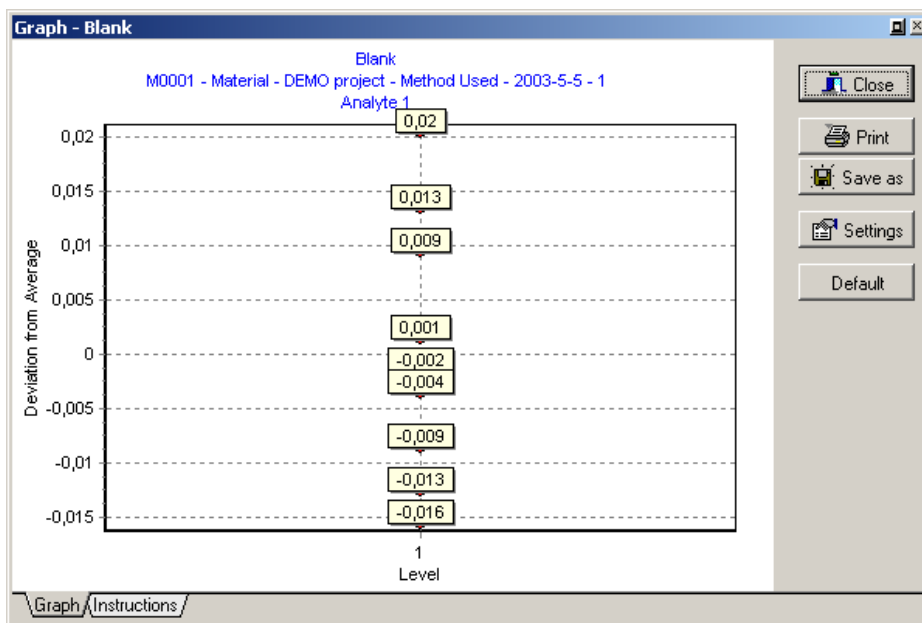
2.11 BLANK

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 430, chapter 13.7.6.

Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6	Measrt 7	Measrt 8	Measrt 9	Measrt 10
0,025	0,037	0,012	0,029	0,048	0,026	0,024	0,015	0,041	0,019

Window Results in EffiValidation 3.0:



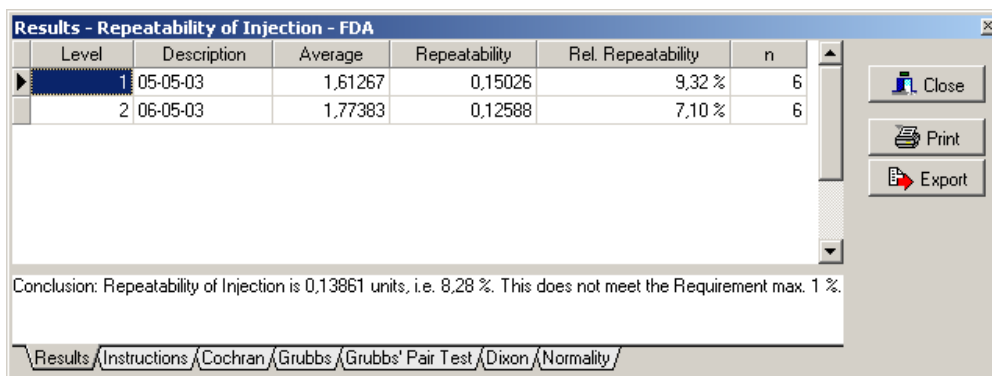


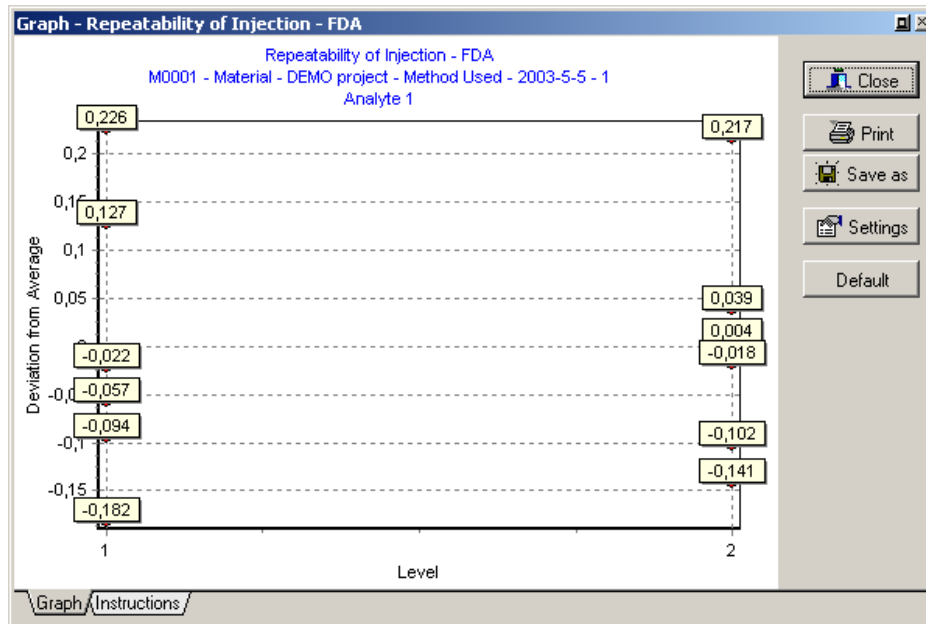
2.12 REPEATABILITY OF INJECTION – FDA

Data source: 19-th edition, Remington: Practice of The Science and Pharmacy, Mack Publishing Company, Easton, 1995, page 125 and 126, Table 42 and 43:

	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
Table 43, formulation A	1,431	1,74	1,519	1,839	1,556	1,591
Table 43, formulation B	1,813	1,778	1,991	1,672	1,756	1,633

Window Results in EffiValidation 3.0:





2.13 CAPACITY FACTOR - FDA

Data obtained by experimental measurements in a laboratory.

Data Table - Capacity Factor - FDA

Sheet Edit Data Transformation Results

Units: min. min.

	Descriptio	Ret. Time	Dead Vol.
1	Injection 1	3,1	0,2
2	Injection 2	3,2	0,15
3	Injection 3	3,2	0,18

Analyte 1 / Analyte 2 /

Instructions:
Enter data to evaluate **Capacity Factor - FDA**: enter Retention Time and Dead Volume. Rows in the **Data Table** correspond to repeated injections of the sample/standard.
In column **Description**, a user note can be entered, e.g. "Injection 1" (optional).
In the **Units** boxes above the Table, type in the units for the considered Retention Time and Dead Volume.
Click on the **Save** icon or **Sheet** and **Save** in the menu.
To create a **New** sheet (for another analyte), **Open**, **Save** or specify **Sheet Properties** go to the **Sheet** menu. Click on **Edit Print Report** to edit the print report, **Preview** to view the report and **Print** to start printing.
Click on the **Calculate** icon or **Results** and **Calculate** to start the calculation of Capacity Factor and to show results.

Time: 200ms 3

Window Results in EffiValidation 3.0:

Results - Capacity Factor - FDA

Level	Description	Capacity Factor
1	Injection 1	14,5
2	Injection 2	20,33
3	Injection 3	16,78

Conclusion: calculated Capacity Factor is 17,20, which meets the Requirement $k > 2$.

Results / Instructions

2.14 RESOLUTION - FDA

Data obtained by experimental measurements in a laboratory.

	Description	Ret. Time 1	Ret. Time 2	Half-W. 1	Half-W. 2
1	Injection 1	2,5	2,9	0,1	0,12
2	Injection 2	2,4	2,85	0,12	0,11
3	Injection 3	2,6	2,95	0,1	0,1

Time: 160ms 3

Window Results in EffiValidation 3.0:

Level	Description	Resolution
1	Injection 1	0,91
2	Injection 2	0,98
3	Injection 3	0,88

Conclusion: Resolution is 0,92, which does not meet the Requirement $R > 1,5$.

2.15 TAILING - FDA

Data obtained by experimental measurements in a laboratory.

	Description	Peak Width at 5%	Difference Max.-Start
1	Injection 1	4,4	2,6
2	Injection 2	4,6	2,5
3	Injection 3	4,5	2,55

Time: 160ms 3

Window Results in EffiValidation 3.0:

Level	Description	Tailing
1	Injection 1	0,84615
2	Injection 2	0,92
3	Injection 3	0,88235

Conclusion: Tailing is 0,88284, which meets the Requirement for Tailing max. < 2.

2.16 THEORETICAL PLATE NUMBER – FDA

Data obtained by experimental measurements in a laboratory.

Description	Ret. Time	Peak Width at Baseline
1 Injection 1	4.4	0.242
2 Injection 2	4.6	0.251
3 Injection 3	4.5	0.257

Instructions:
Enter data to evaluate **Theoretical Plate Number - FDA**: enter Retention Time and Peak Width on Baseline. Rows in the Data table correspond to repeated injections of the sample/standard. In column Description, a user note can be entered, e.g. "Injection 1" (optional). In the Units boxes above the Table, type in the units for the considered Retention Time and Peak Width on Baseline. Click on the *Save* icon or *Sheet* and *Save* in the menu. To create a *New* sheet (for another analyte), *Open*, *Save* or specify *Sheet Properties* go to the *Sheet* menu. Click on

Time: 181ms 3

Window Results in EffiValidation 3.0:

Level	Description	Theoretical Plate Number
1	Injection 1	5289,3
2	Injection 2	5373,9
3	Injection 3	4905,4

Conclusion: Theoretical Plate Number is 5 190. This meets the Requirement N > 2000.

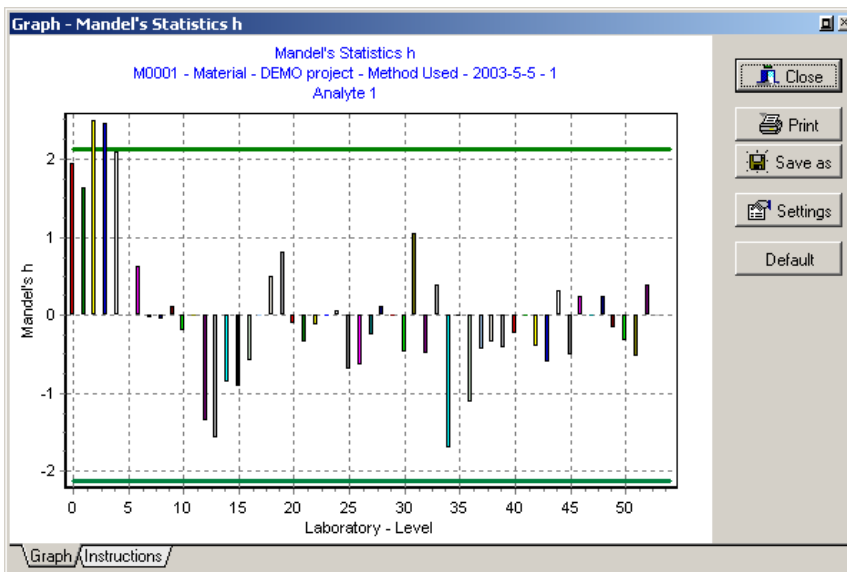
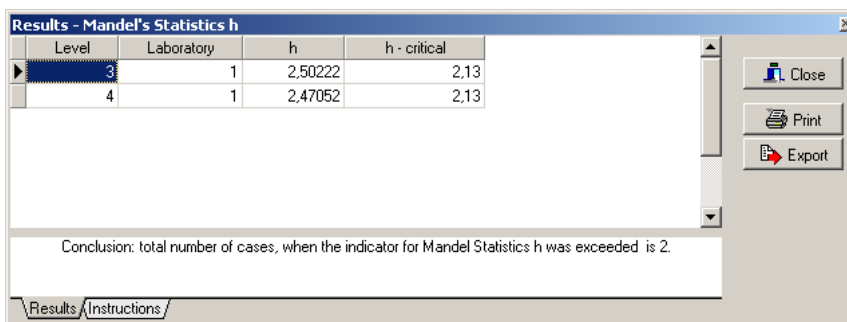
INTERLABORATORY COMPARISON

3.1 MANDEL STATISTICS H

Data source: ISO 5725-2, 1997, page 45, Table B.12:

Level:	1		2		3		4		5	
Laboratory	1	2	1	2	1	2	1	2	1	2
1	4,44	4,39	9,34	9,34	17,4	16,9	19,23	19,23	24,28	24
2	4,03	4,23	8,42	8,33	14,42	14,5	16,06	16,22	20,4	19,91
3	3,7	3,7	7,6	7,4	13,6	13,6	14,5	15,1	19,3	19,7
4	4,1	4,1	8,93	8,8	14,6	14,2	15,6	15,5	20,3	20,3
5	3,97	4,04	7,89	8,12	13,73	13,92	15,54	15,78	20,53	20,88
6	3,75	4,03	8,76	9,24	13,9	14,06	16,42	16,58	18,56	16,58
7	3,7	3,8	8	8,3	14,1	14,2	14,9	16	19,7	20,5
8	3,91	3,9	8,04	8,07	14,84	14,84	15,41	15,22	21,1	20,78
9	4,02	4,07	8,44	8,17	14,24	14,1	15,14	15,44	20,71	21,66

Window Results in EffiValidation 3.0:

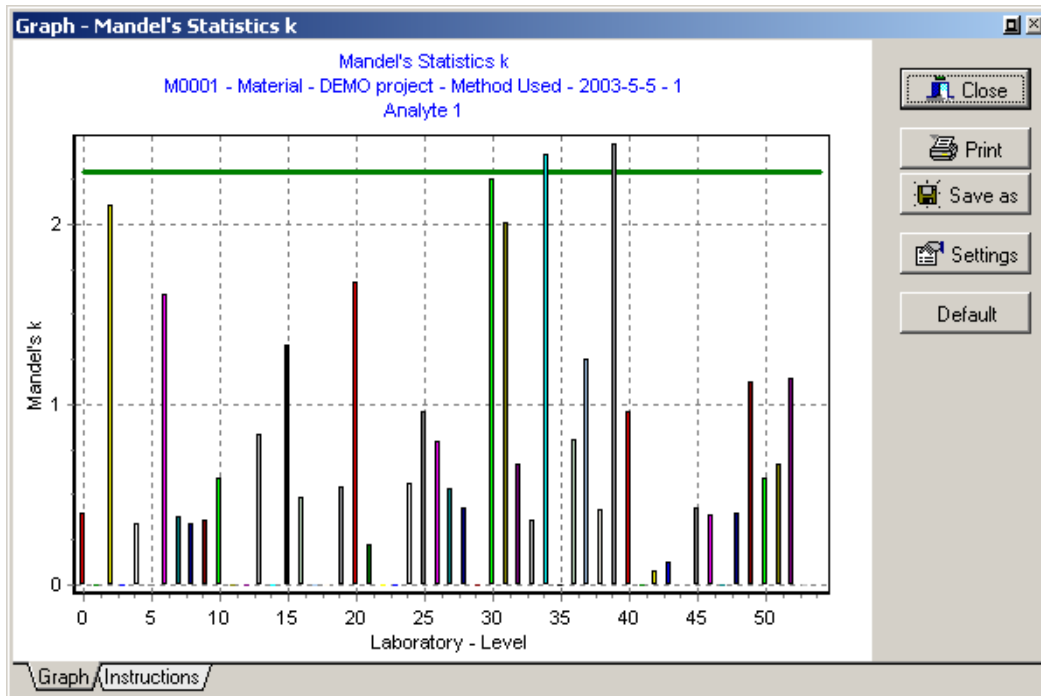
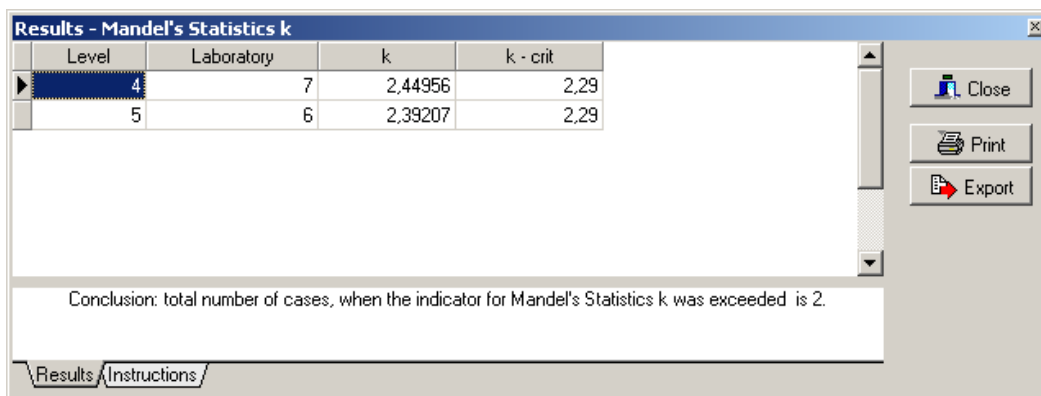


3.2 MANDEL STATISTICS K

Data source: ISO 5725-2, 1997, page 45, Table B.12:

Level:	1		2		3		4		5	
Laboratory	1	2	1	2	1	2	1	2	1	2
1	4,44	4,39	9,34	9,34	17,4	16,9	19,23	19,23	24,28	24
2	4,03	4,23	8,42	8,33	14,42	14,5	16,06	16,22	20,4	19,91
3	3,7	3,7	7,6	7,4	13,6	13,6	14,5	15,1	19,3	19,7
4	4,1	4,1	8,93	8,8	14,6	14,2	15,6	15,5	20,3	20,3
5	3,97	4,04	7,89	8,12	13,73	13,92	15,54	15,78	20,53	20,88
6	3,75	4,03	8,76	9,24	13,9	14,06	16,42	16,58	18,56	16,58
7	3,7	3,8	8	8,3	14,1	14,2	14,9	16	19,7	20,5
8	3,91	3,9	8,04	8,07	14,84	14,84	15,41	15,22	21,1	20,78
9	4,02	4,07	8,44	8,17	14,24	14,1	15,14	15,44	20,71	21,66

Window Results in EffiValidation 3.0:



3.3 COLLABORATIVE STUDY

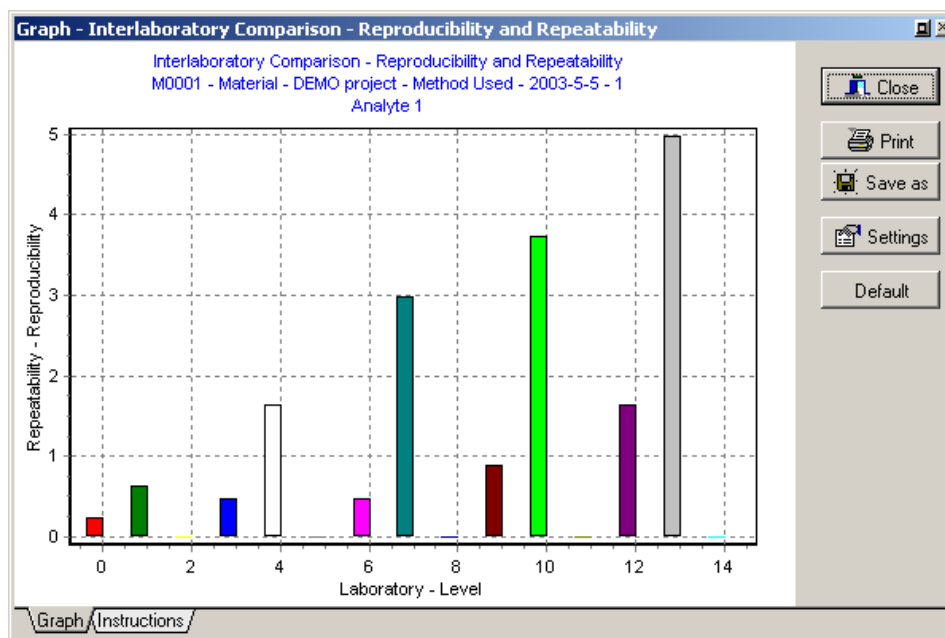
Data source: ISO 5725-2, 1997, page 45, Table B.12:

Level:	1		2		3		4		5	
Laboratory	1	2	1	2	1	2	1	2	1	2
1	4,44	4,39	9,34	9,34	17,4	16,9	19,23	19,23	24,28	24
2	4,03	4,23	8,42	8,33	14,42	14,5	16,06	16,22	20,4	19,91
3	3,7	3,7	7,6	7,4	13,6	13,6	14,5	15,1	19,3	19,7
4	4,1	4,1	8,93	8,8	14,6	14,2	15,6	15,5	20,3	20,3
5	3,97	4,04	7,89	8,12	13,73	13,92	15,54	15,78	20,53	20,88
6	3,75	4,03	8,76	9,24	13,9	14,06	16,42	16,58	18,56	16,58
7	3,7	3,8	8	8,3	14,1	14,2	14,9	16	19,7	20,5
8	3,91	3,9	8,04	8,07	14,84	14,84	15,41	15,22	21,1	20,78
9	4,02	4,07	8,44	8,17	14,24	14,1	15,14	15,44	20,71	21,66

Window Results in EffiValidation 3.0:

Level	Average on Level	Repeatability (r)	Rel. Repeatability (%)	Reproducibility (R)	Rel. Reproducibility (%)
1	3,99333	0,24552	6,14829	0,63012	15,77932
2	8,39944	0,47228	5,62275	1,63591	19,47642
3	14,50833	0,47025	3,24121	2,97468	20,50327
4	15,99278	0,88909	5,55935	3,72243	23,27569
5	20,51056	1,63883	7,99018	4,97223	24,24232

Conclusion: Repeatability and Reproducibility values on individual Levels are shown in the table above.



4

CONTROL CHARTS

4.1 INDIVIDUAL MEASUREMENTS – CHARACTERISTICS DETERMINED

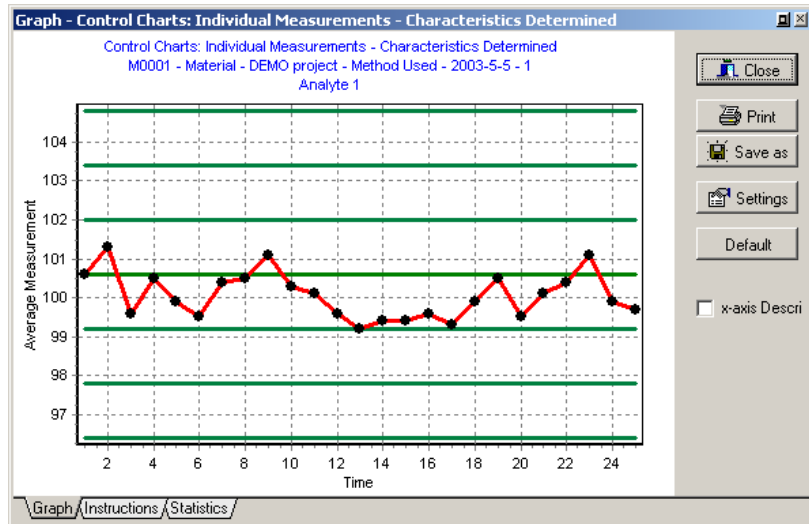
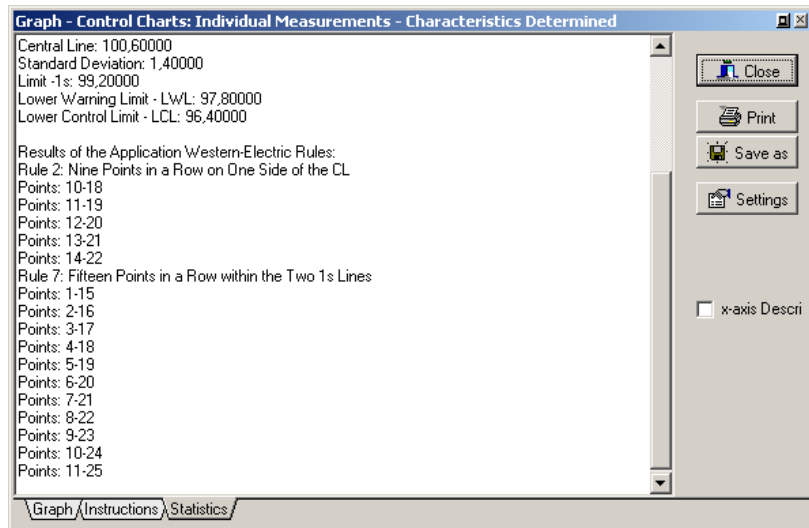
Data source: ISO 8258:1991, 1991, page 22, Table 6: data in the standard are shown for the control chart with repetitions, number of repetitions $n = 5$. These data are used here, because other data for individual measurements are not presented.

Determined Central line of the weight for the control chart of the packaging process is 100,6 g and standard deviation is 1,4

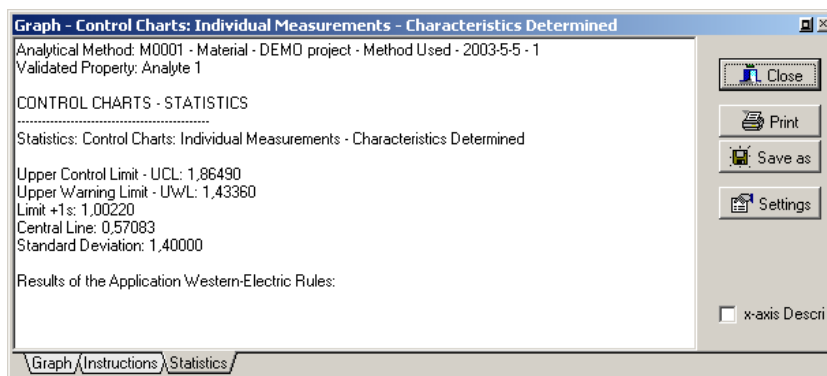
Measrt N. [1]	Weight [g]
1	100,6
2	101,3
3	99,6
4	100,5
5	99,9
6	99,5
7	100,4
8	100,5
9	101,1
10	100,3
11	100,1
12	99,6
13	99,2
14	99,4
15	99,4
16	99,6
17	99,3
18	99,9
19	100,5
20	99,5
21	100,1
22	100,4
23	101,1
24	99,9
25	99,7

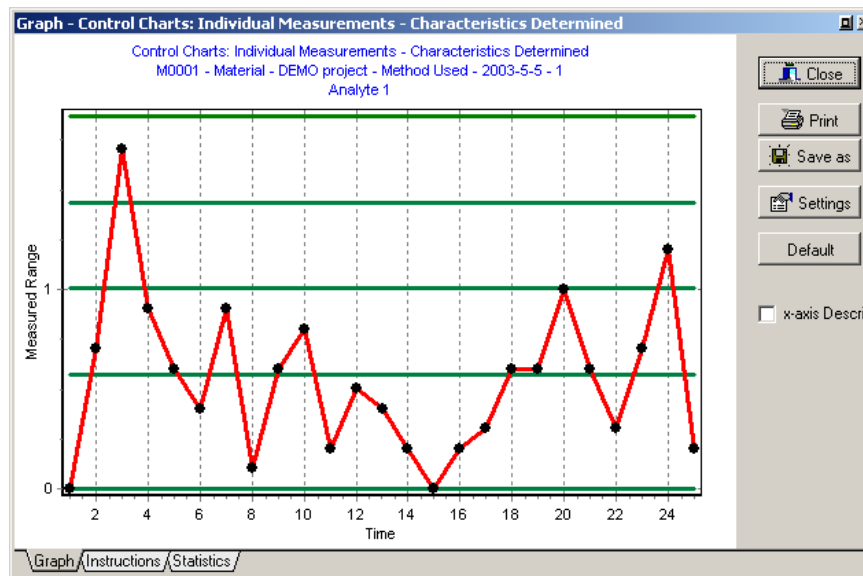
X-chart (control chart for mean)

Window Results in EffiValidation 3.0:



R-chart (control chart for range)





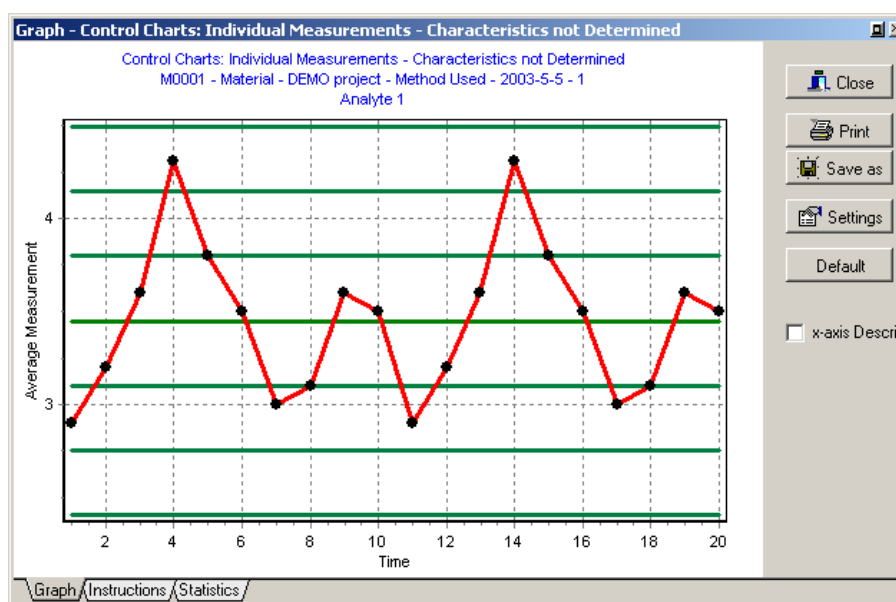
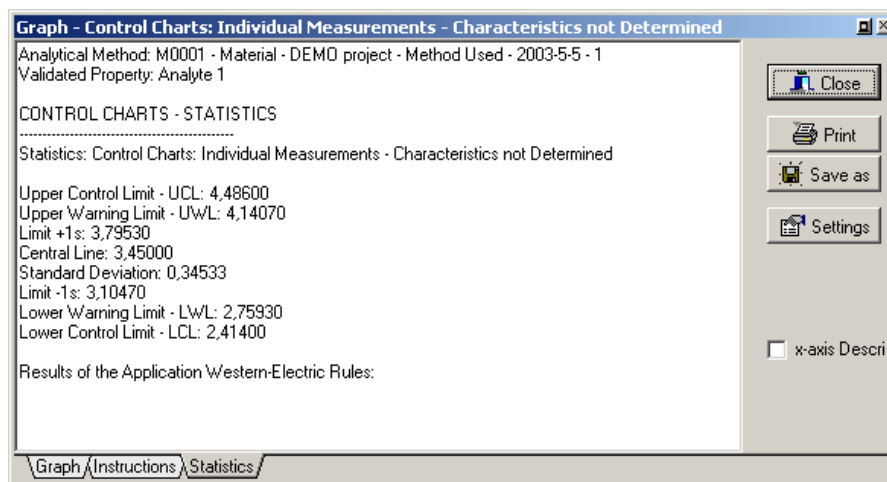
4.2 INDIVIDUAL MEASUREMENTS – CHARACTERISTICS NOT DETERMINED

Data source: ISO 8258:1991, 1991, page 27, Table 8: data shown in the ISO standard are data 1-10. Because the application of Western-Electric rules requires min. 15 measurements, data in the table are repeated, resulting in 20 values.

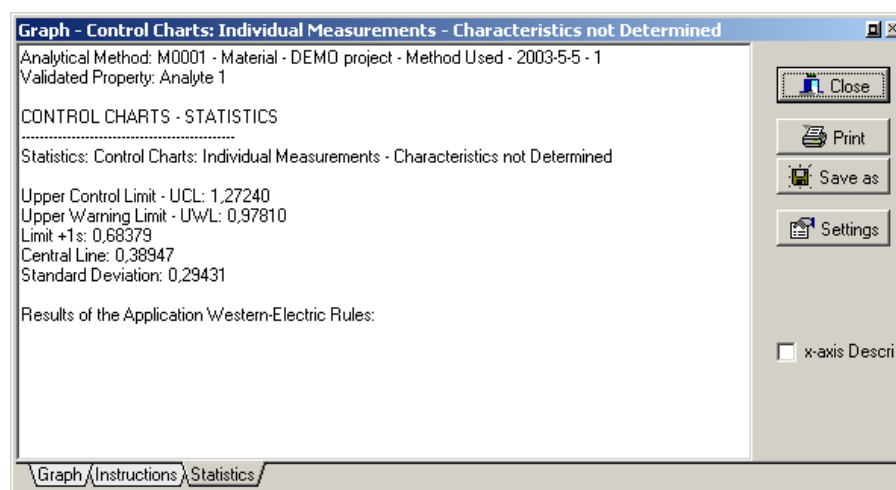
Measrt N. [1]	Weight [g]
1	2,9
2	3,2
3	3,6
4	4,3
5	3,8
6	3,5
7	3
8	3,1
9	3,6
10	3,5
11	2,9
12	3,2
13	3,6
14	4,3
15	3,8
16	3,5
17	3
18	3,1
19	3,6
20	3,5

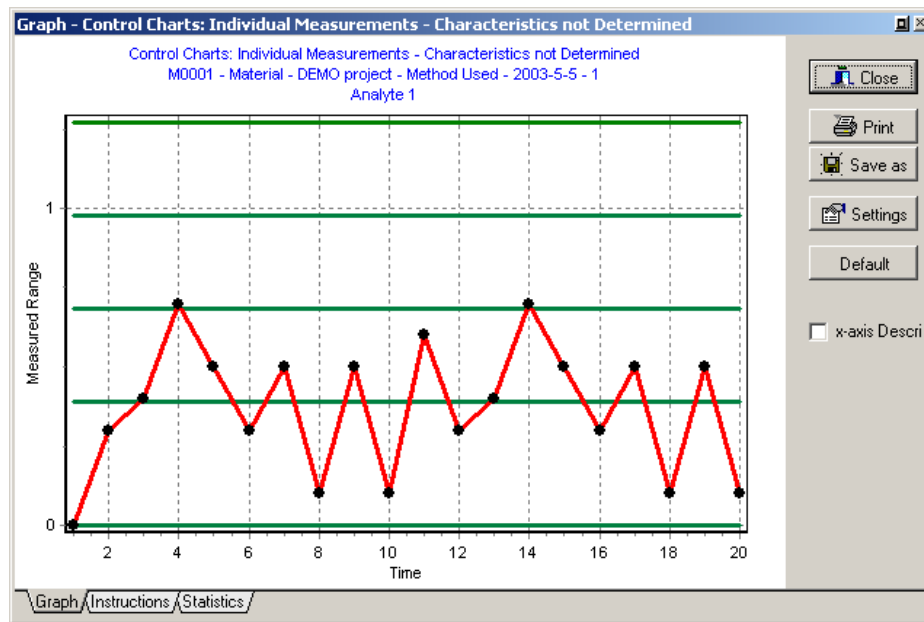
X-chart (control chart for mean)

Window Results in EffiValidation 3.0:



R-chart (control chart for range)





4.3 REPEATED MEASUREMENTS – CHARACTERISTICS NOT DETERMINED

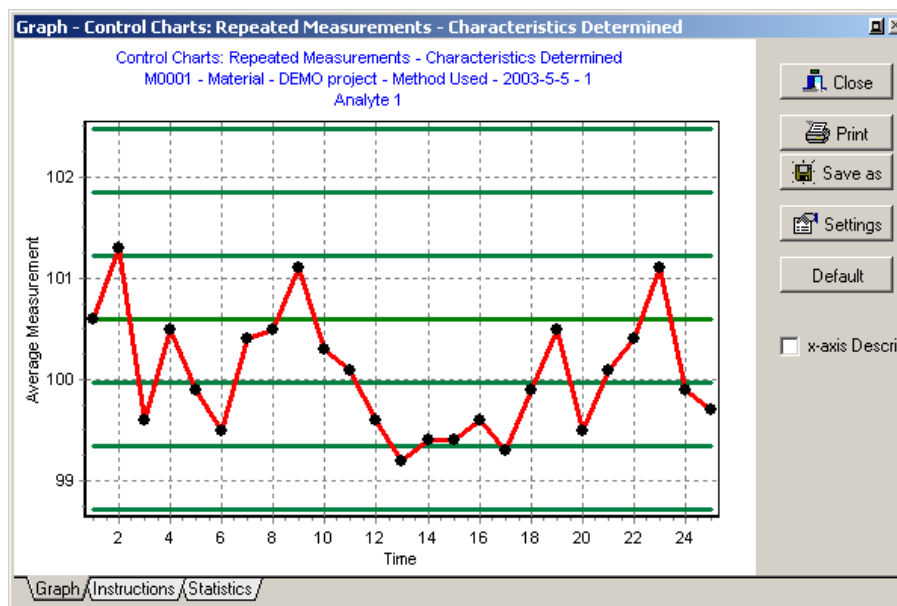
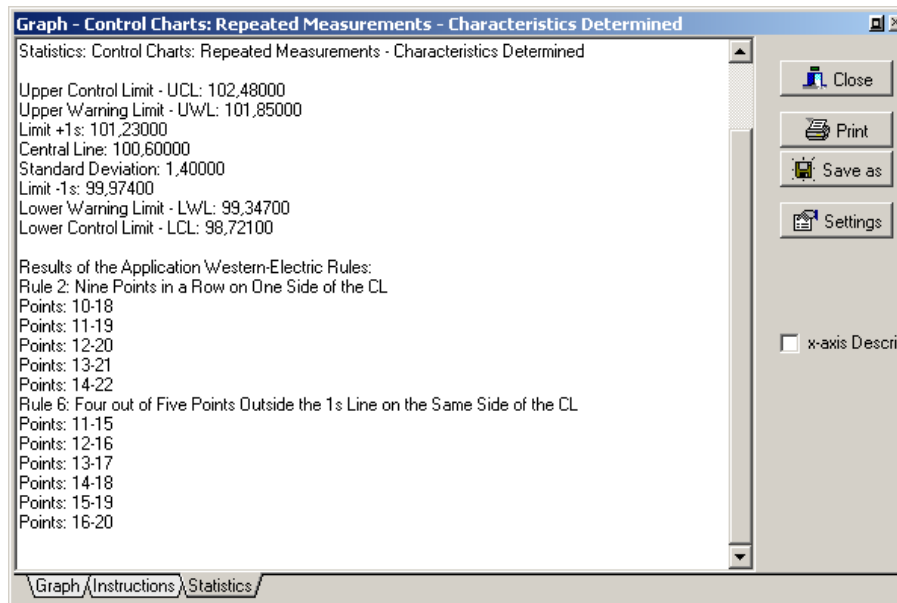
Data source: ISO 8258:1991, 1991, page 22, Table 6.

Determined Central line of the weight for the control chart of the packaging process is 100,6 g and standard deviation is 1,4

Subgroup N. [1]	Weight 1 [g]	Weight 2 [g]	Weight 3 [g]	Weight 4 [g]	Weight 5 [g]	Average [g]	Range [g]
1	98,9	99,75	100,6	101,45	102,3	100,6	3,4
2	99,3	100,3	101,3	102,3	103,3	101,3	4
3	98,5	99,05	99,6	100,15	100,7	99,6	2,2
4	98,25	99,375	100,5	101,625	102,75	100,5	4,5
5	97,5	98,7	99,9	101,1	102,3	99,9	4,8
6	97,6	98,55	99,5	100,45	101,4	99,5	3,8
7	98,35	99,375	100,4	101,425	102,45	100,4	4,1
8	99,65	100,075	100,5	100,925	101,35	100,5	1,7
9	100	100,55	101,1	101,65	102,2	101,1	2,2
10	98	99,15	100,3	101,45	102,6	100,3	4,6
11	97,6	98,85	100,1	101,35	102,6	100,1	5
12	96,55	98,075	99,6	101,125	102,65	99,6	6,1
13	97,45	98,325	99,2	100,075	100,95	99,2	3,5
14	96,85	98,125	99,4	100,675	101,95	99,4	5,1
15	97,15	98,275	99,4	100,525	101,65	99,4	4,5
16	97,55	98,575	99,6	100,625	101,65	99,6	4,1
17	96,95	98,125	99,3	100,475	101,65	99,3	4,7
18	97,4	98,65	99,9	101,15	102,4	99,9	5
19	98,55	99,525	100,5	101,475	102,45	100,5	3,9
20	97,15	98,325	99,5	100,675	101,85	99,5	4,7
21	97,8	98,95	100,1	101,25	102,4	100,1	4,6
22	98,2	99,3	100,4	101,5	102,6	100,4	4,4
23	98,65	99,875	101,1	102,325	103,55	101,1	4,9
24	97,55	98,725	99,9	101,075	102,25	99,9	4,7
25	98	98,85	99,7	100,55	101,4	99,7	3,4

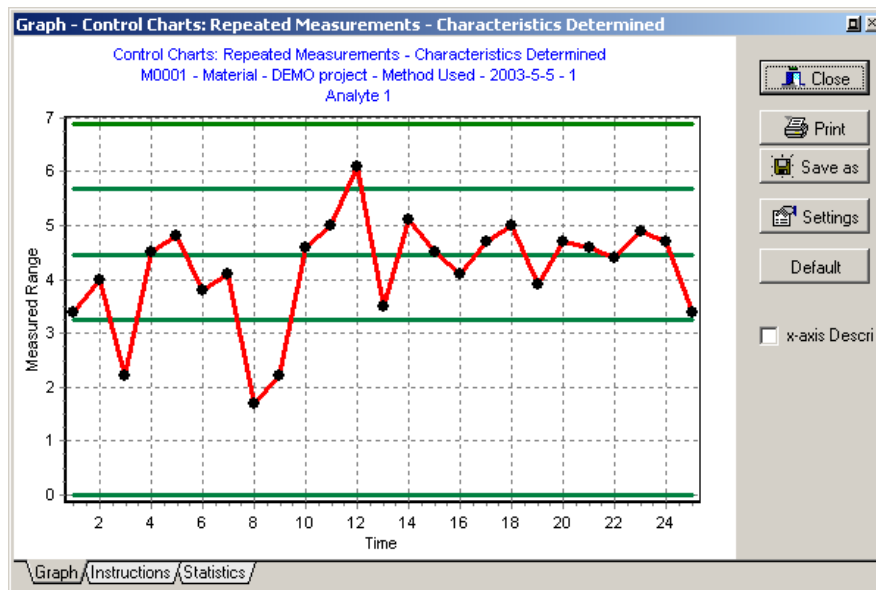
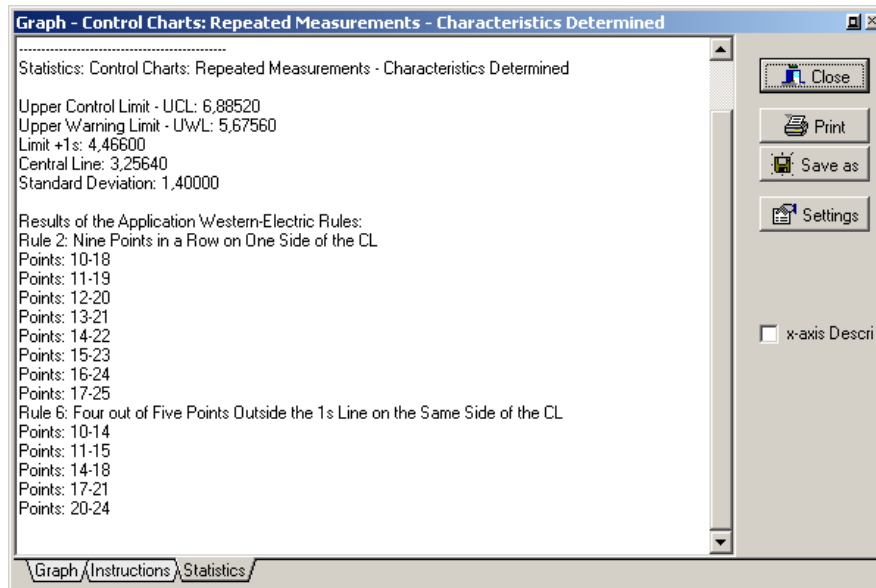
X-chart (control chart for mean)

Window Results in EffiValidation 3.0:



R-chart (control chart for range)

Window Results in EffiValidation 3.0:



4.4 REPEATED MEASUREMENTS – CHARACTERISTICS NOT DETERMINED

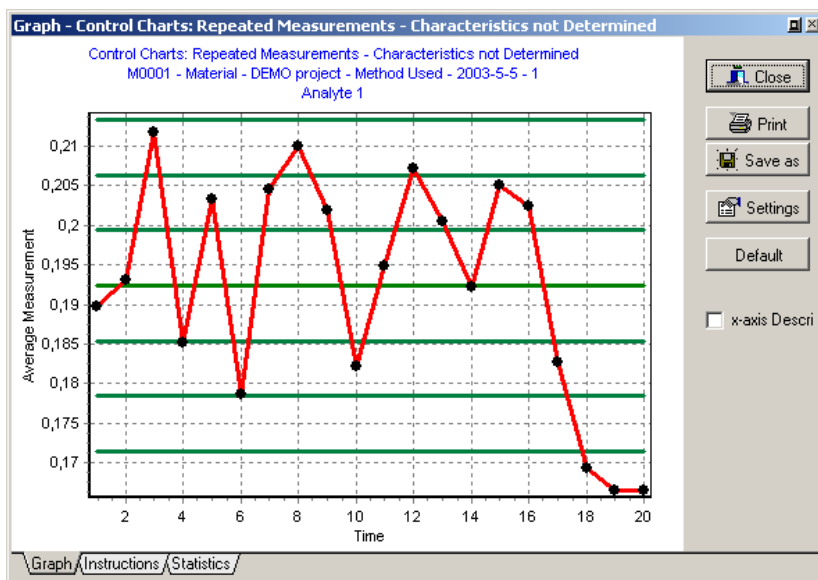
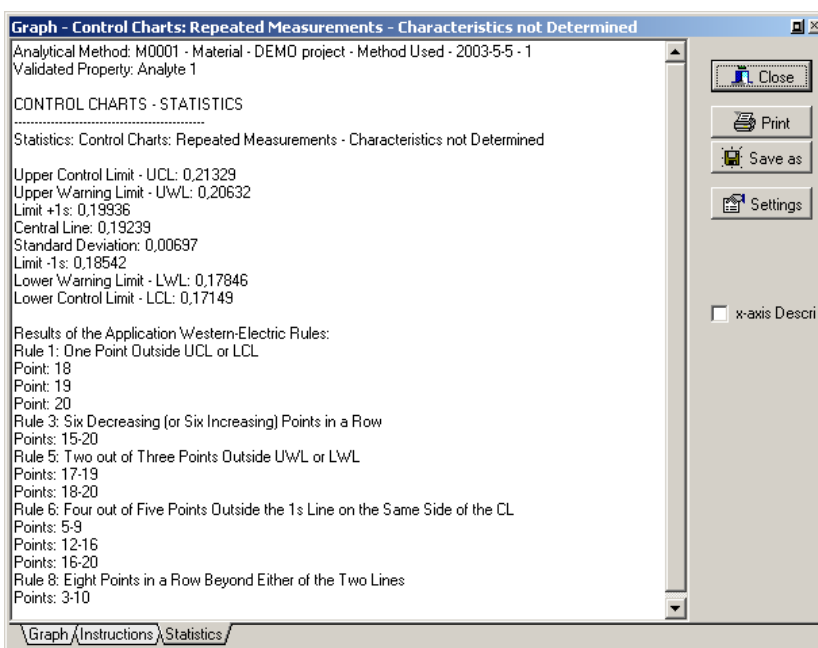
Data source: ISO 8258:1991, 1991, page 24, Table 7.

Subgroup N. [1]	Average 1 [cm]	Average 2 [cm]	Average 3 [cm]	Average 4 [cm]	Average [cm]	Range [cm]
1	0,1898	0,1729	0,2067	0,1898	0,1898	0,0338
2	0,2012	0,1913	0,1878	0,1921	0,2012	0,0134
3	0,2217	0,2192	0,2078	0,198	0,2217	0,0237
4	0,1832	0,1812	0,1963	0,18	0,1832	0,0163
5	0,1692	0,2263	0,2086	0,2091	0,1692	0,0571
6	0,1621	0,1832	0,1914	0,1783	0,1621	0,0293
7	0,2001	0,1927	0,2169	0,2082	0,2001	0,0242
8	0,2401	0,1825	0,191	0,2264	0,2401	0,0576

9	0,1996	0,198	0,2076	0,2023	0,1996	0,0096
10	0,1783	0,1715	0,1829	0,1961	0,1783	0,0246
11	0,2166	0,1748	0,196	0,1923	0,2166	0,0418
12	0,1924	0,1984	0,2377	0,2003	0,1924	0,0453
13	0,1768	0,1986	0,2241	0,2022	0,1768	0,0473
14	0,1923	0,1876	0,1903	0,1986	0,1923	0,0110
15	0,1924	0,1996	0,212	0,216	0,1924	0,0236
16	0,172	0,194	0,2117	0,232	0,172	0,0600
17	0,1824	0,179	0,1876	0,1821	0,1824	0,0086
18	0,1812	0,1585	0,1699	0,168	0,1812	0,0227
19	0,17	0,1567	0,1694	0,1702	0,17	0,0135
20	0,1698	0,1664	0,17	0,16	0,1698	0,0100

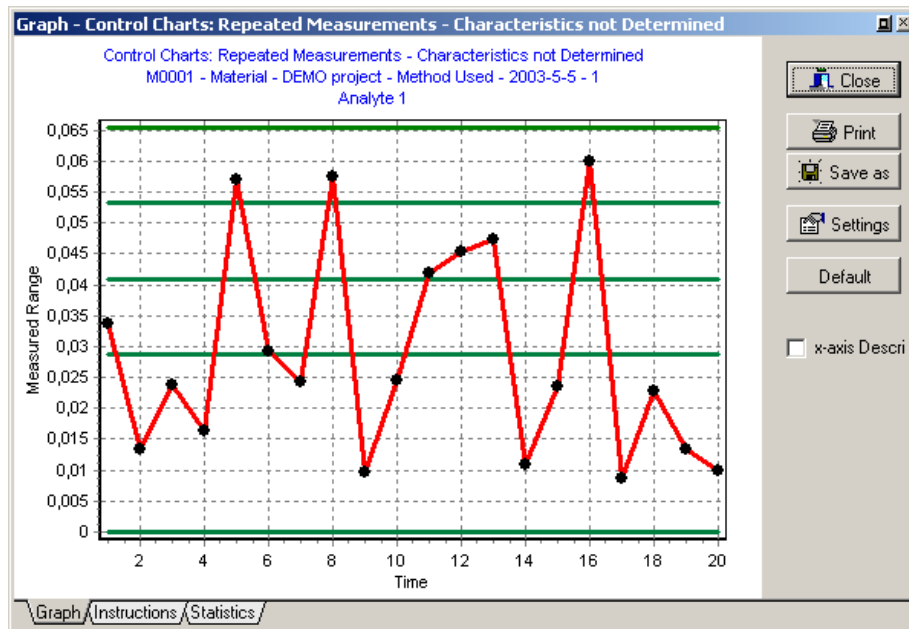
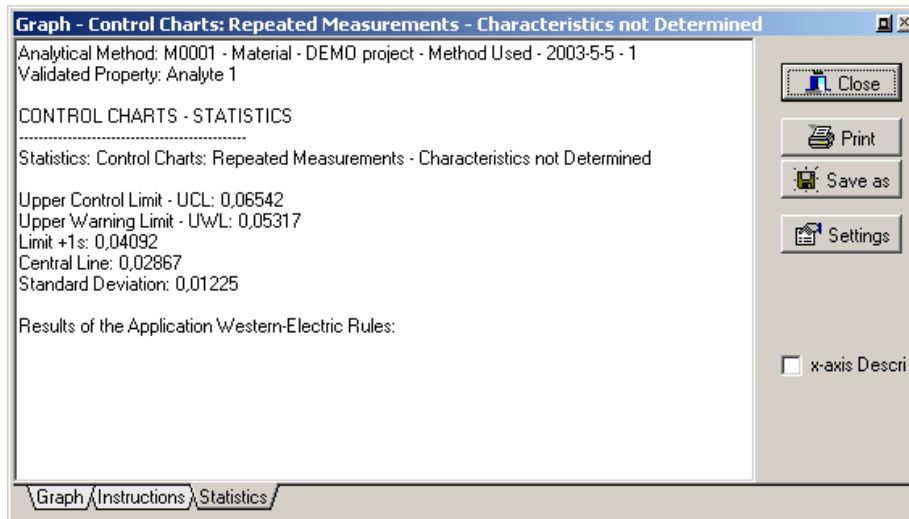
X-chart (control chart fro mean)

Window Results in EffiValidation 3.0:



R-chart (control chart for Range)

Window Results in EffiValidation 3.0:



5.1 LINEAR CALIBRATION

Data source: ISO 8466:1, 1990, page 7, Table 5

Concentration [mg / l]	Absorbance [1]
0,05	0,14
0,1	0,281
0,15	0,405
0,2	0,535
0,25	0,662
0,3	0,789
0,35	0,916
0,4	1,058
0,45	1,173
0,5	1,303

Window Results in EffiValidation 3.0:

Statistics

Analytical Method: M0001 - Material - DEMO project - Method Used - 2003-5-5 - 1
Validated Property: Analyte 1

CALIBRATION - STATISTICS

1. Calibration Model

Intercept (Estimate): 0,018
Slope (Estimate) = 2,57527
Intercept Standard Deviation (Estimate) = 0,00353
Slope Standard Deviation (Estimate) = 0,01137
Confidence Interval for Intercept: 0,00986 - 0,02614
Confidence Interval for Slope: 2,54904 - 2,6015

2. Data Fitting:

Residual Variance (Estimate) = 0,00003
Residual Standard Deviation (Estimate) = 0,00517
Correlation Coefficient = 0,99992
QC Coefficient = 0,67068

3. Calibration Limits:

Measurement on the Limit of Detection = 0,04685
Concentration on the Limit of Detection = 0,0112
Measurement on the Limit of Quantification = 0,08056
Concentration on the Limit of Quantification = 0,02429

\Results\Instructions\Statistics

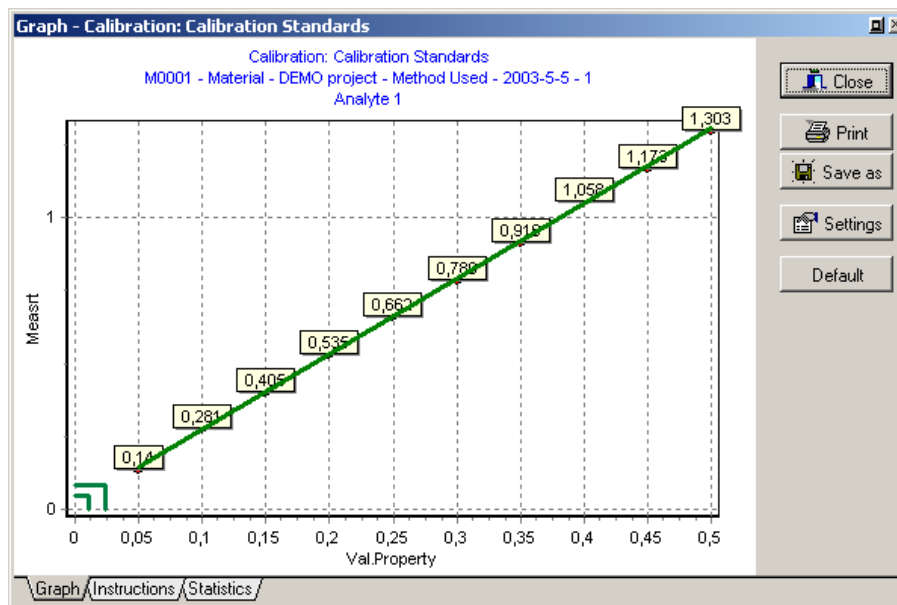
Unknown samples:

Concentration [mg / l]	Absorbance [1]
?	0,0542
?	0,854
?	1,123
?	0,01

Window Results in EffiValidation 3.0:

Level	Description	Validated Property	+ -	Confidence Interval
1		0,01406		Not Quant.
2		0,32463	0,00488	0,3197 - 0,3295
3		0,42908	0,0051	0,4240 - 0,4342
4		-0,00311		Not Detected

Results / Instructions / Statistics

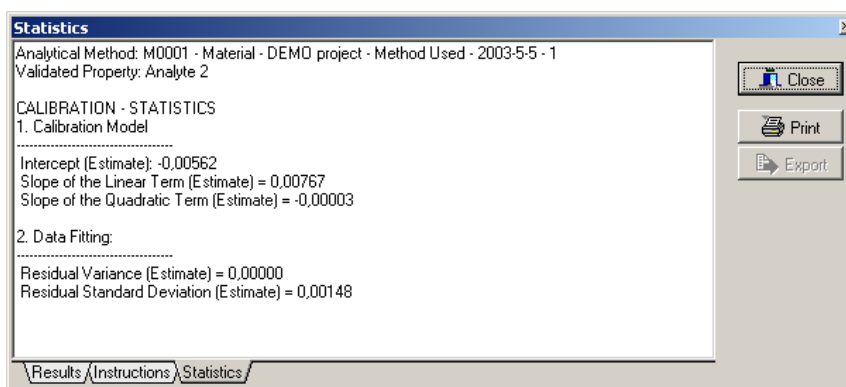


5.2 QUADRATIC CALIBRATION

Data source: ISO 8466:2, 1993, page 8, Table 7

Concentration [mg / l]	Absorbance [1]
12	0,083
18	0,123
24	0,164
30	0,203
36	0,24
42	0,273
48	0,303
54	0,334
60	0,364
66	0,393

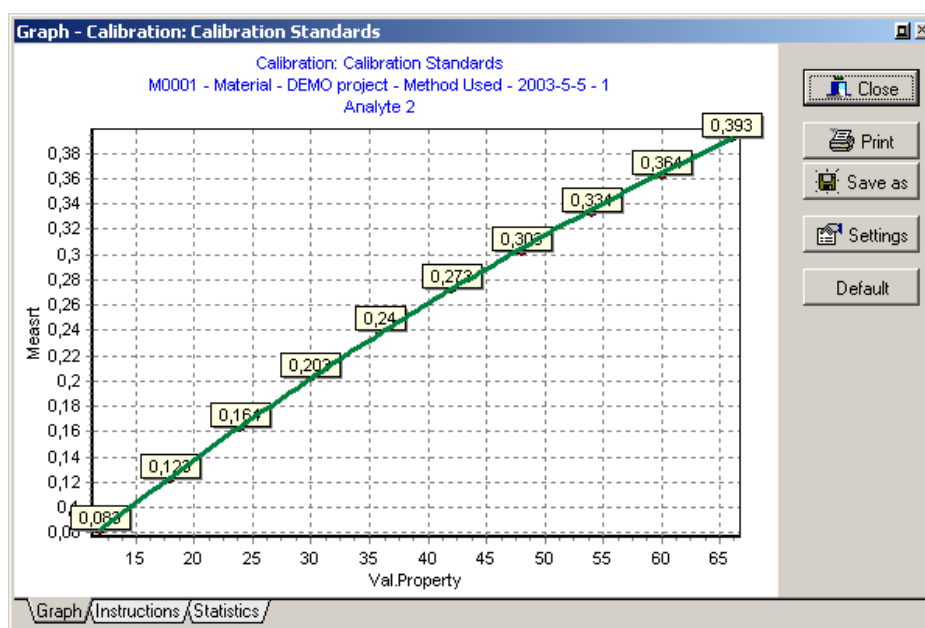
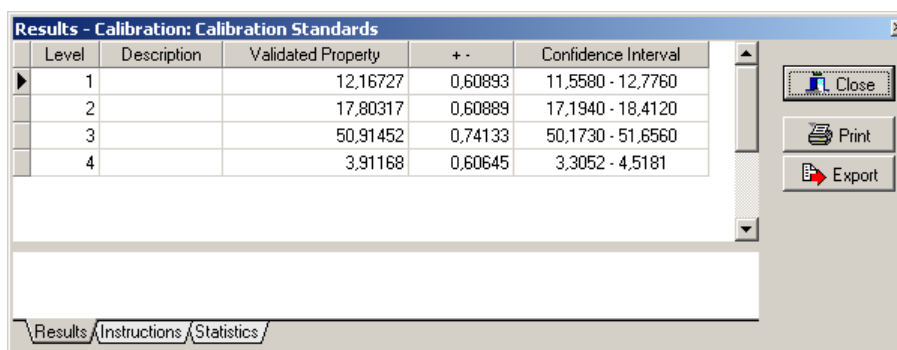
Window Results in EffiValidation 3.0:



Unknown samples:

Concentration [mg / l]	Absorbance [1]
?	0,084
?	0,123
?	0,32
?	0,024

Window Results in EffiValidation 3.0:



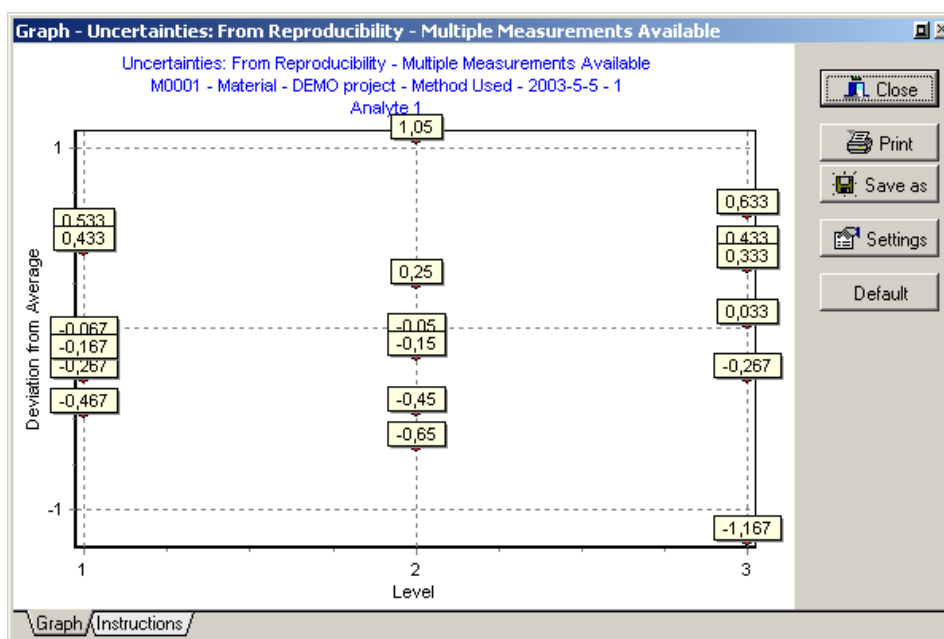
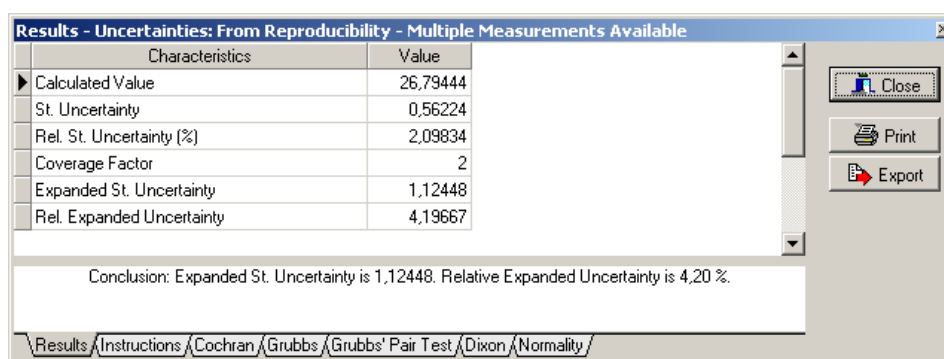
UNCERTAINTIES

6.1 FROM PRECISION DATA – MULTIPLE MEASUREMENTS

Data obtained by experimental measurements in a laboratory. Coverage factor: 2.0

	Measrt 1	Measrt 2	Measrt 3	Measrt 4	Measrt 5	Measrt 6
Level 1	5	5,2	5,8	4,8	5,7	5,1
Level 2	25	24,7	24,1	25,8	24,6	24,3
Level 3	50,8	50,1	49,2	51	50,4	50,7

Window Results in EffiValidation 3.0:

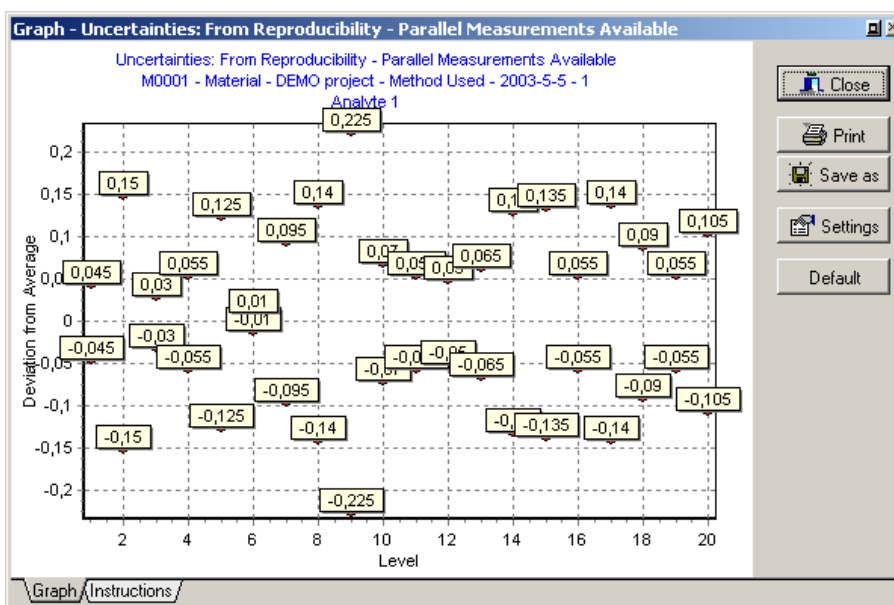
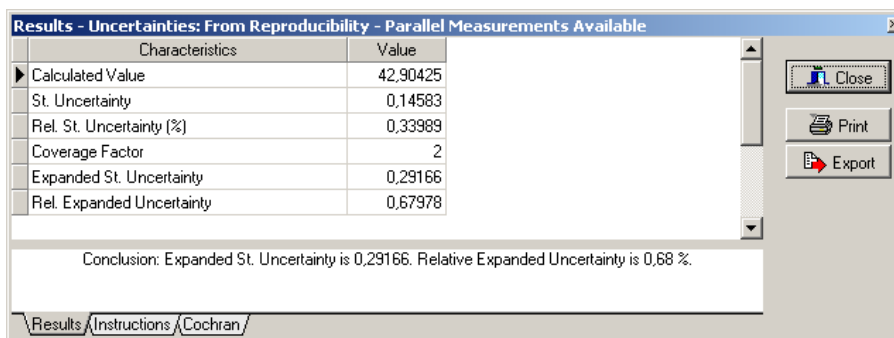


6.2 FROM PRECISION DATA – PARALLEL MEASUREMENTS

Data source: D.L. Massart et al., Handbook of Chemometrics and Qualimetrics, Part A, Elsevier, Amsterdam, 1997, page 30, Table 2.4. Coverage factor: 2.0

Experiment	Measrt 1	Measrt 2
1	42,68	42,77
2	42,08	42,38
3	43,39	43,33
4	42,87	42,98
5	42,7	42,95
6	42,93	42,95
7	42,78	42,97
8	42,92	43,2
9	43,34	42,89
10	43,12	43,26
11	42,43	42,54
12	43,05	43,15
13	42,99	42,86
14	43,04	42,78
15	43,41	43,14
16	43,12	43,23
17	42,25	42,53
18	42,96	42,78
19	42,83	42,72
20	42,83	43,04

Window Results in EffiValidation 3.0:

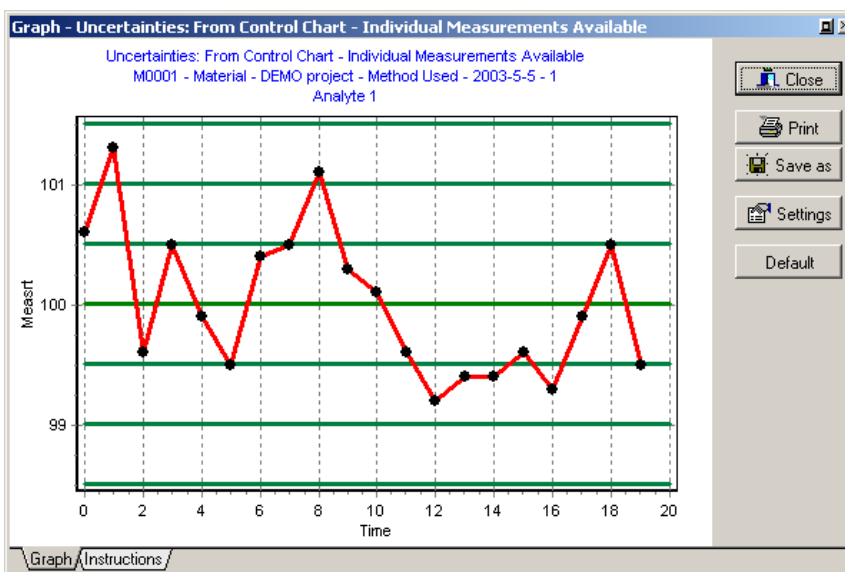
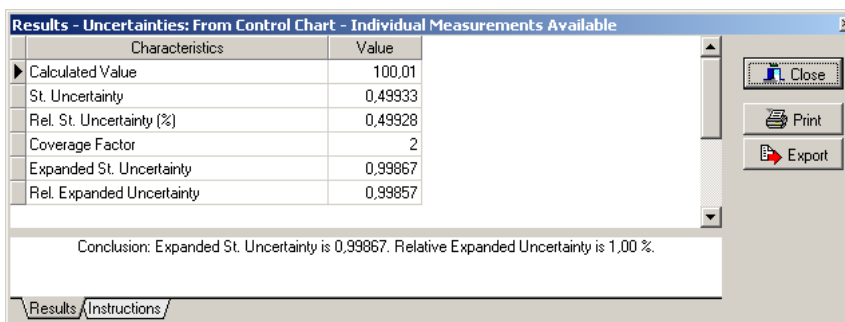


6.3 FROM CONTROL CHART – INDIVIDUAL MEASUREMENTS

Data source: ISO 8258:1991, 1991, page 27, Table 8: data presented in the ISO standard are 1-10. Because the application of the Western-Electric rules requires min. 15 measurements, data in the table are repeated, resulting in 20 values.

Measrt N. [1]	Weight [g]
1	100,6
2	101,3
3	99,6
4	100,5
5	99,9
6	99,5
7	100,4
8	100,5
9	101,1
10	100,3
11	100,1
12	99,6
13	99,2
14	99,4
15	99,4
16	99,6
17	99,3
18	99,9
19	100,5
20	99,5

Window Results in EffiValidation 3.0:

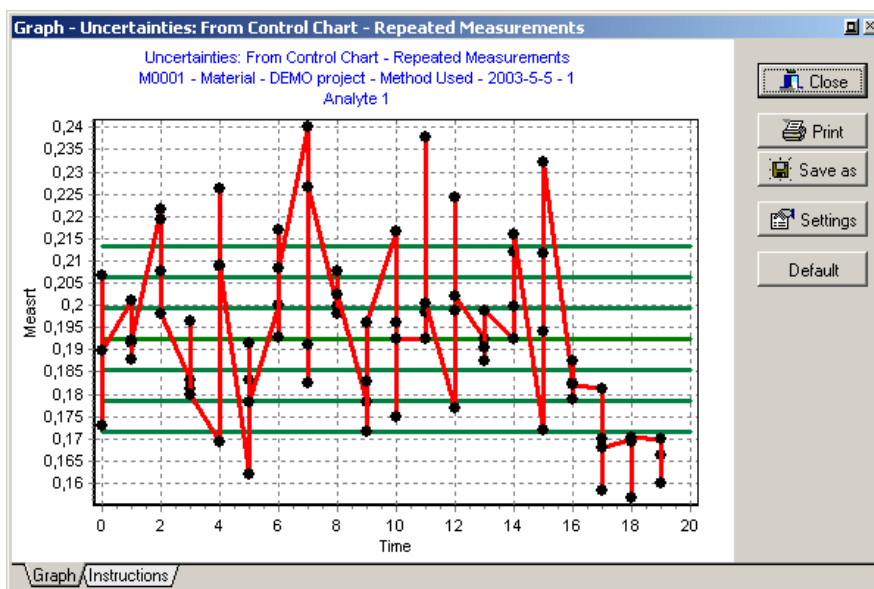
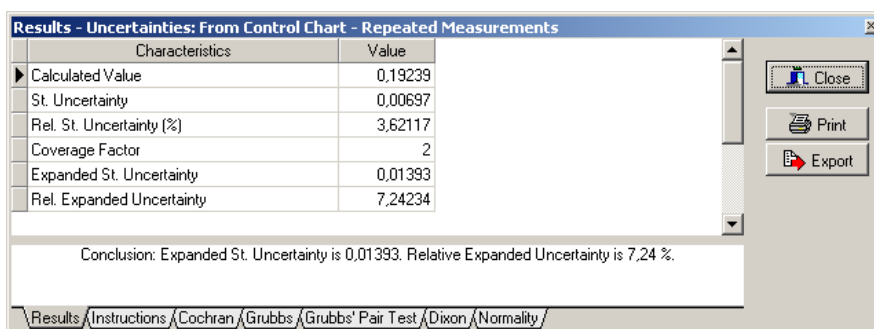


6.4 FROM CONTROL CHART – REPEATED MEASUREMENTS

Data source: ISO 8258:1991, 1991, page 24, Table 7.

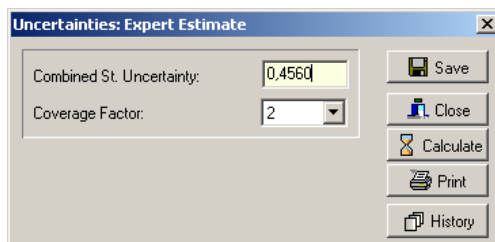
Subgroup N. [1]	Average 1 [cm]	Average 2 [cm]	Average 3 [cm]	Average 4 [cm]
1	0,1898	0,1729	0,2067	0,1898
2	0,2012	0,1913	0,1878	0,1921
3	0,2217	0,2192	0,2078	0,198
4	0,1832	0,1812	0,1963	0,18
5	0,1692	0,2263	0,2086	0,2091
6	0,1621	0,1832	0,1914	0,1783
7	0,2001	0,1927	0,2169	0,2082
8	0,2401	0,1825	0,191	0,2264
9	0,1996	0,198	0,2076	0,2023
10	0,1783	0,1715	0,1829	0,1961
11	0,2166	0,1748	0,196	0,1923
12	0,1924	0,1984	0,2377	0,2003
13	0,1768	0,1986	0,2241	0,2022
14	0,1923	0,1876	0,1903	0,1986
15	0,1924	0,1996	0,212	0,216
16	0,172	0,194	0,2117	0,232
17	0,1824	0,179	0,1876	0,1821
18	0,1812	0,1585	0,1699	0,168
19	0,17	0,1567	0,1694	0,1702
20	0,1698	0,1664	0,17	0,16

Window Results in EffiValidation 3.0:

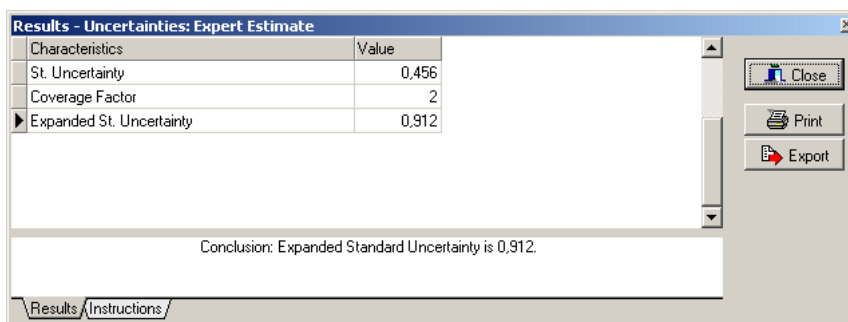


6.5 EXPERT ESTIMATE

Data source: not found. Data obtained by experimental measurements in a laboratory. Coverage factor: 2.0



Window Results in EffiValidation 3.0:



6.6 FROM PARTIAL UNCERTAINTIES

EURACHEM/CITAC Guide, Quantifying Uncertainty in Analytical Measurement, Second Edition, June 1999, Example 3.

$y = (1000 \cdot x_1 \cdot x_2 \cdot x_3) / (x_4 \cdot (8 \cdot x_5 + 5 \cdot x_6 + 4 \cdot x_7 + x_8) \cdot x_9)$. Coverage factor: 2.0

Source	Value	St. uncertainty
X1	0,3888	0,00013
X2	1	0,00029
X3	14,89	0,015
X4	18,64	0,016
X5	12,0107	0,00046
X6	1,00794	4E-5
X7	15,9994	0,00017
X8	39,0983	5,8E-5
X9	15	0,011

Window Results in EffiValidation 3.0:

