

TECHNOLOGY PREVIEW 03/2020 – This report has been generated with the upcoming Dose-Response-Analysis Package for PLA 3.0.5 (or higher). The package has not been released and has not been finally verified for production use. Contact Stegmann Systems (<http://support.bioassay.de>) to report issues or suggest additional features.

Linear Fit - Interpolation

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Signatures

Responsibility

Review

Approval

Documentation

Date 31.07.2019 13:22:55

Assay Summary

Assay elements	Summary
■ STD	Reference standard, multi-dose (3 dilution steps, 6 replicates)
■ TST1 - Source Material	Test sample, single-dose (3 replicates), defined concentration: 45.0 IU/L
■ TST2 - Stock Solution with Pre...	Test sample, single-dose (3 replicates), defined concentration: 75.0 IU/L
■ TST3 - Mixed Response Data Han...	Test sample, single-dose (3 replicates)
■ TST4 - Adjustment	Test sample, single-dose (3 replicates)
■ TST5 - Normalization	Test sample, single-dose (3 replicates)
■ TST6 - Transformation	Test sample, single-dose (3 replicates)



DOCUMENT-28



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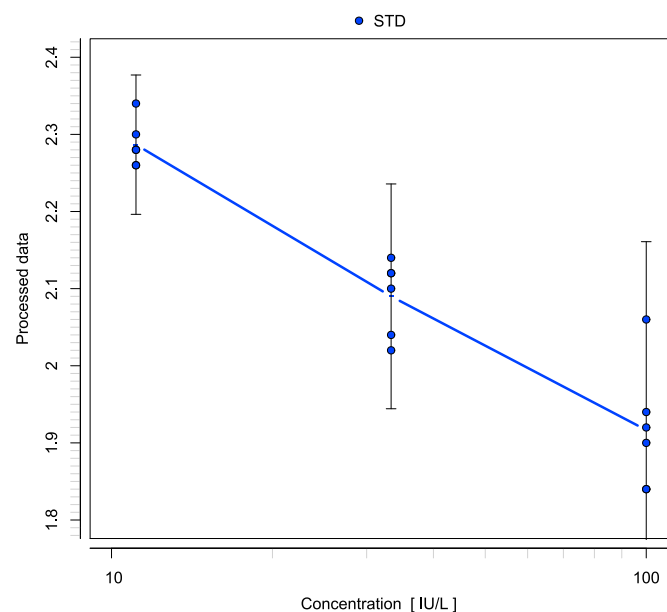
Assay suitability tests

Test	Details	Test Status
Overall test result	Passed	
■ STD F-Test (hypothesis test) Equivalence test (parameter estimate), Slope (nonlinear models)	$131.39480 \geq 0.00406$ $-6.00000 \leq -0.11672 ; -0.11672 \leq 0$	Passed Passed

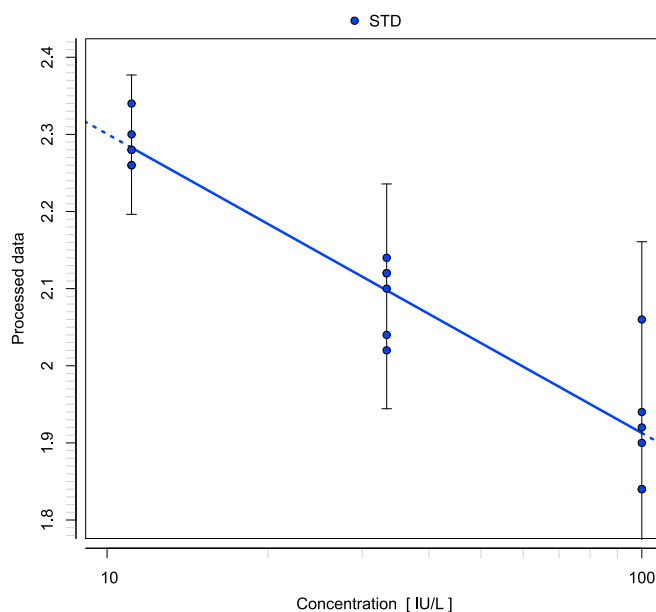
Details: Lower Margin \leq (Lower/ Upper) Value \leq Upper Margin

■ STD: Result

Data plot



Regression plot



Response data

Dilution step	1	2	3
Working concentration [IU/L]	100.00000	33.33333	11.11111
Response	1.92000 1.90000 1.84000 1.94000 2.06000 1.84000	2.12000 2.14000 2.10000 2.02000 2.12000 2.04000	2.34000 2.28000 2.28000 2.26000 2.26000 2.30000

Regression results

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
Intercept	2.68826	0.05317	2.57554 to 2.80098	8.39%
Slope (nonlinear models)	-0.11672	0.01018	-0.13831 to -0.09514	36.99%

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Interpolation

Concentration of the response mean

Sample	Interpolated concentration	Defined concentration	Recovery
TST1 - Source Mater...	8.85379 [IU/g]	9.00000 [IU/g]	98.38%
TST2 - Stock So...	72.66147 [IU/L]	75.00000 [IU/L]	96.88%
TST3 - Mixed Re...	37.04488 [IU/L]		N/A
TST4 - Adjustment	37.04488 [IU/L]		N/A
TST5 - Normalization	37.04488 [IU/L]		N/A
TST6 - Transformati...	37.04488 [IU/L]		N/A

Interpolation results

Sample	Response	Mean response	Calculated concentration of the working sample [IU/L]
TST1 - Source Materi...	2.20000	2.05000	44.26895
	1.95000		
	2.00000		
TST2 - Stock Solutio...	2.19000	2.20000	18.16537
	2.15000		
	2.26000		
TST3 - Mixed Respons...	2.12000	2.08000	37.04488
	2.08000		
	2.04000		
TST4 - Adjustment	3.12000	3.08000	37.04488
	3.08000		
	3.04000		
TST5 - Normalization	4.24000	4.16000	37.04488
	4.16000		
	4.08000		
TST6 - Transformatio...	4.49440	4.32747	37.04488
	4.32640		
	4.16160		

Sample suitability tests

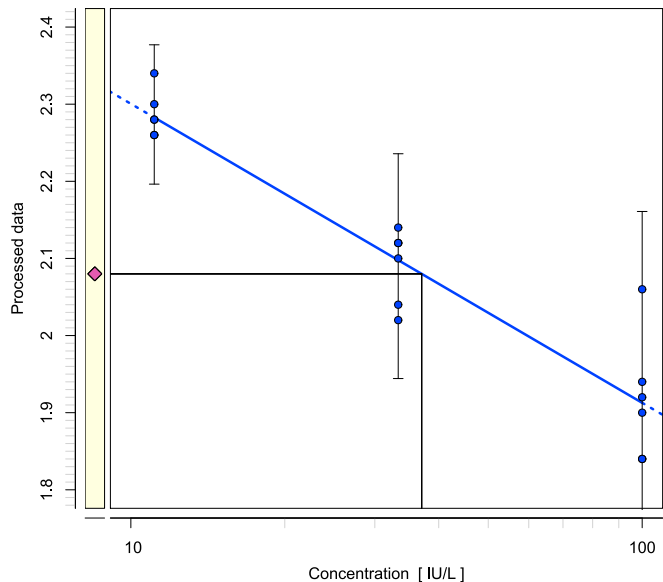
Test	Details	Test Status	
TST1 - Source Material	Failed (rejected)		
	Test: Interpolation interval	15.00000 ≤ 18.16537 ; 80.16829 ≤ 85.00000	Passed
	Test: Interpolation interval	25.00000 ≤ 18.16537 ; 80.16829 ≤ 75.00000	Failed
	Test: Width of interpolation interval	0 ≤ 1.40060 ; 1.40060 ≤ 0.70000	Failed
TST2 - Stock Solution with Pre...	Failed (warning)		
	Test: Interpolation interval	15.00000 ≤ 12.72044 ; 24.44533 ≤ 85.00000	Failed
	Test: Interpolation interval	25.00000 ≤ 12.72044 ; 24.44533 ≤ 75.00000	Failed
	Test: Width of interpolation interval	0 ≤ 0.64545 ; 0.64545 ≤ 0.70000	Passed
TST3 - Mixed Response Data Han...	Passed		
	Test: Interpolation interval	15.00000 ≤ 29.21238 ; 46.97747 ≤ 85.00000	Passed
	Test: Interpolation interval	25.00000 ≤ 29.21238 ; 46.97747 ≤ 75.00000	Passed
	Test: Width of interpolation interval	0 ≤ 0.47956 ; 0.47956 ≤ 0.70000	Passed
TST4 - Adjustment	Passed		
	Test: Interpolation interval	15.00000 ≤ 29.21238 ; 46.97747 ≤ 85.00000	Passed
	Test: Interpolation interval	25.00000 ≤ 29.21238 ; 46.97747 ≤ 75.00000	Passed
	Test: Width of interpolation interval	0 ≤ 0.47956 ; 0.47956 ≤ 0.70000	Passed
TST5 - Normalization	Passed		
	Test: Interpolation interval	15.00000 ≤ 29.21238 ; 46.97747 ≤ 85.00000	Passed
	Test: Interpolation interval	25.00000 ≤ 29.21238 ; 46.97747 ≤ 75.00000	Passed
	Test: Width of interpolation interval	0 ≤ 0.47956 ; 0.47956 ≤ 0.70000	Passed
TST6 - Transformation	Passed		
	Test: Interpolation interval	15.00000 ≤ 29.21238 ; 46.97747 ≤ 85.00000	Passed
	Test: Interpolation interval	25.00000 ≤ 29.21238 ; 46.97747 ≤ 75.00000	Passed
	Test: Width of interpolation interval	0 ≤ 0.47956 ; 0.47956 ≤ 0.70000	Passed

Details: Lower Margin ≤ (Lower/ Upper) Value ≤ Upper Margin

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Group-RDH: Result

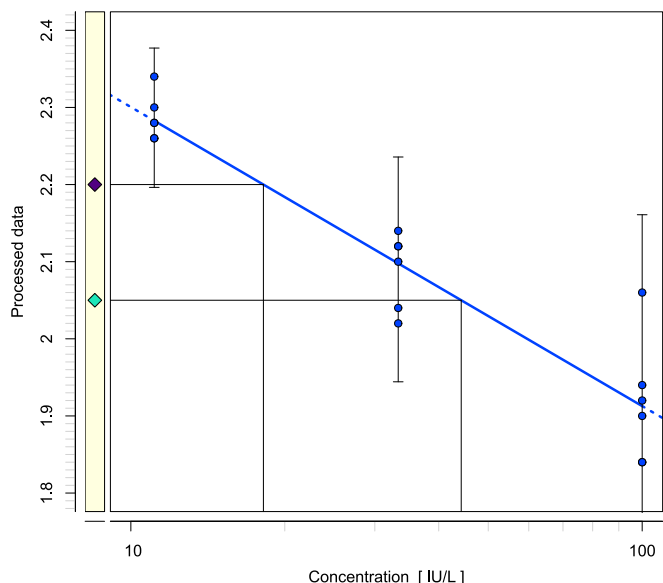
Interpolation plot



Assay elements	Suitability test status
TST3 - Mixed Respons...	Passed
TST4 - Adjustment	Passed
TST5 - Normalization	Passed
TST6 - Transformatio...	Passed

Group-Others: Result

Interpolation plot



Assay elements	Suitability test status
TST1 - Source Materi...	Failed (rejected)
TST2 - Stock Solutio...	Failed (warning)

Interpolation results

Assay elements	Calculated working concentration	Calculated absolute concentration	Recovery
TST1 - Source Material	44.26895 [IU/L]	8.85379 [IU/g]	98.38%
TST2 - Stock Solution with Predilution	18.16537 [IU/L]	72.66147 [IU/L]	96.88%