

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.

4 PLF - Interpolation

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Calculation information

Calculation performed: 24.03.2020 14:15:39, odin.kleuser@stegmannsystems.com (PLA 3.0.4 Build 762, nbersatz02, 10014)
Messages (warning): [W5228] The fit of sample STD has a reduced accuracy.
Report generated: 25.03.2020 07:56:53, Administrator (PLA 3.0.4 Build 762, NBAFR01, 10014)

Signatures

Responsibility

Review

Approval

Documentation

Date 31.07.2019 13:22:55

Assay Summary

Assay elements	Summary
■ STD	Reference standard, multi-dose (10 dilution steps, 3 replicates)
■ TST1	Test sample, single-dose (3 replicates)
■ TST2 - Source Material with Pr...	Test sample, single-dose (3 replicates), defined concentration: 80.0 IU/L
■ TST3 - Transformaiton with Pre...	Test sample, single-dose (3 replicates)
■ TST4 - Mixed Response Data Han...	Test sample, single-dose (3 replicates), defined concentration: 3.0 IU/L



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Assay suitability tests

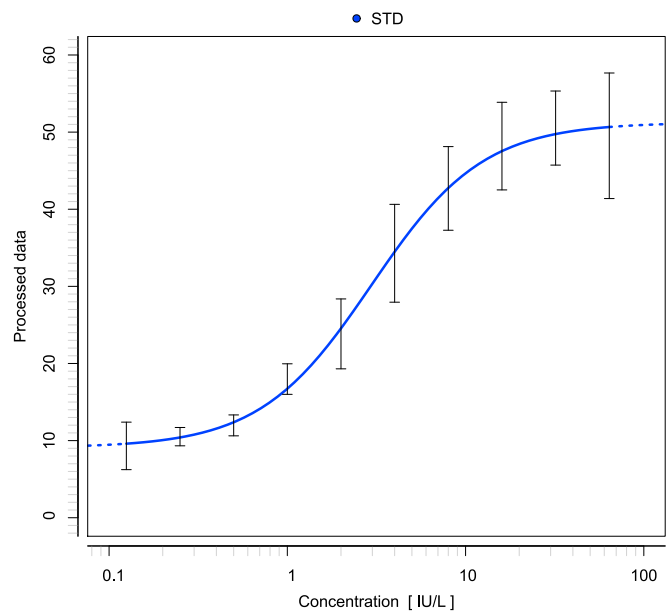
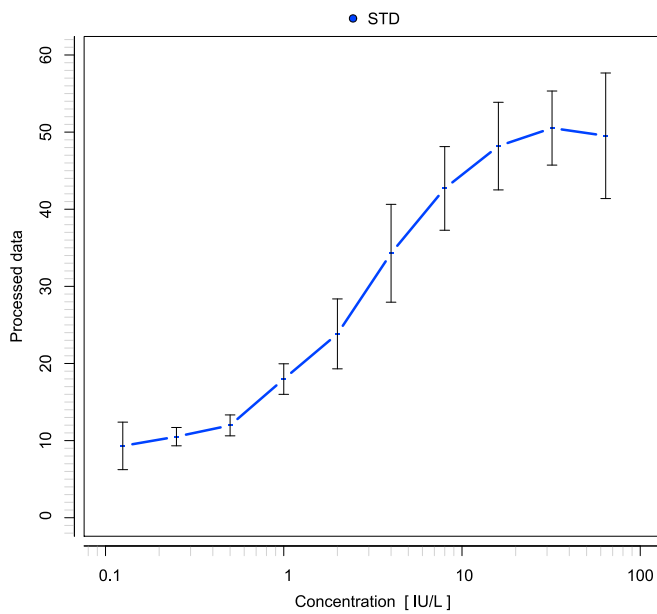
Test	Details	Test Status
Overall test result	Passed	
■ STD F-Test (hypothesis test) Equivalence test (parameter estimate), B parameter Test: Sum of squares (ANOVA)	$1052.3393 \geq 0.11587$ $1.00000 \leq 1.38702 ; 1.38702 \leq 2.00000$ $14.04239 \leq 20.00000$	Passed Passed Passed

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

■ STD: Result

Data plot

Regression plot



Response data

Dilution step	1	2	3	4	5	6
Working concentration [IU/L]	64.00000	32.00000	16.00000	8.00000	4.00000	2.00000
Response	48.50084 52.60127 47.47226	48.76707 51.89881 50.91054	48.83845 46.05329 49.66799	44.77683 41.83346 41.48714	31.88864 35.87165 35.11109	24.75387 22.09473 24.66664

Dilution step	7	8	9	10
Working concentration [IU/L]	1.00000	0.50000	0.25000	0.12500
Response	18.25924 18.45370 17.22557	11.53347 11.95265 12.43647	10.68759 10.06012 10.79260	10.49572 8.63454 8.81395

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Regression results

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
A upper asymptote	51.24777	0.82313	49.55580 to 52.93974	6.60%
B parameter	1.38702	0.11292	1.15491 to 1.61913	33.47%
C parameter	1.56808	0.08598	1.39135 to 1.74482	22.54%
D lower asymptote	9.08670	0.79349	7.45566 to 10.71773	35.90%

Effective concentration (EC)

	25%	50%	75%
Percentile			
EC [IU/L]	1.34292	2.96511	6.54682
Response at EC	19.62697	30.16724	40.70750

Sample suitability tests

Test	Details	Test Status
■ STD Test: Mean squares (ANOVA)	2.53833 ≤ 25.00000	Passed

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

Interpolation

Concentration of the response mean

Sample	Interpolated concentration	Defined concentration	Recovery
■ TST1	1.64458 [IU/L]		N/A
■ TST2 - Source M...	6.25513 [IU/g]	6.40000 [IU/g]	97.74%
■ TST3 - Transf...	12.49967 [IU/L]		N/A
■ TST4 - Mixed Re...	2.54936 [IU/L]	3.00000 [IU/L]	84.98%

Interpolation results

Sample	Response	Mean response	Calculated concentration of the working sample [IU/L]
■ TST1	21.90000	22.00000	1.64458
	21.50000		
	22.60000		
■ TST2 - Source Materi...	39.00000	43.50000	8.68768
	47.50000		
	44.00000		
■ TST3 - Transformaito...	484.00000	402.66667	1.38885
	324.00000		
	400.00000		
■ TST4 - Mixed Respons...	260.00000	255.93333	2.54936
	250.00000		
	257.80000		

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Sample suitability tests

Test	Details	Test Status
Passed		
■ TST1		
Test: Interpolation interval	$1.00000 \leq 1.57901 ; 1.72491 \leq 10.00000$	Passed
Test: Interpolation interval	$0.10000 \leq 1.57901 ; 1.72491 \leq 100.00000$	Passed
Failed (warning)		
■ TST2 - Source Material with Pr...		
Test: Interpolation interval	$1.00000 \leq 5.64466 ; 15.87561 \leq 10.00000$	Failed
Test: Interpolation interval	$0.10000 \leq 5.64466 ; 15.87561 \leq 100.00000$	Passed
Passed		
■ TST3 - Transformaiton with Pre...		
Test: Interpolation interval	$1.00000 \leq 1.14774 ; 1.64458 \leq 10.00000$	Passed
Test: Interpolation interval	$0.10000 \leq 1.14774 ; 1.64458 \leq 100.00000$	Passed
Passed		
■ TST4 - Mixed Response Data Han...		
Test: Interpolation interval	$1.00000 \leq 2.06705 ; 2.93138 \leq 10.00000$	Passed
Test: Interpolation interval	$0.10000 \leq 2.06705 ; 2.93138 \leq 100.00000$	Passed

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