

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 - Curve Comparison

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Calculation information

Calculation performed: 24.03.2020 12:13:05, odin.kleuser@stegmannsystems.com (PLA 3.0.4 Build 762, nbersatz02, 10014)
Messages (warning): [W5228] The fit of sample CURVE 1 has a reduced accuracy.
[W5228] The fit of sample CURVE 2 has a reduced accuracy.
[W5228] The fit of sample CURVE 3 has a reduced accuracy.
Report generated: 25.03.2020 07:56:47, Administrator (PLA 3.0.4 Build 762, NBAFR01, 10014)

Signatures

Responsibility

Review

Approval

Documentation

Date 30.07.2019 07:49:21

Assay Summary

Assay elements	Summary
■ CURVE 1	Reference standard, multi-dose (8 dilution steps, 3 replicates)
■ CURVE 2	Test sample, multi-dose (8 dilution steps, 3 replicates)
■ CURVE 3	Test sample, multi-dose (8 dilution steps, 3 replicates)



DOCUMENT-26



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Assay suitability tests

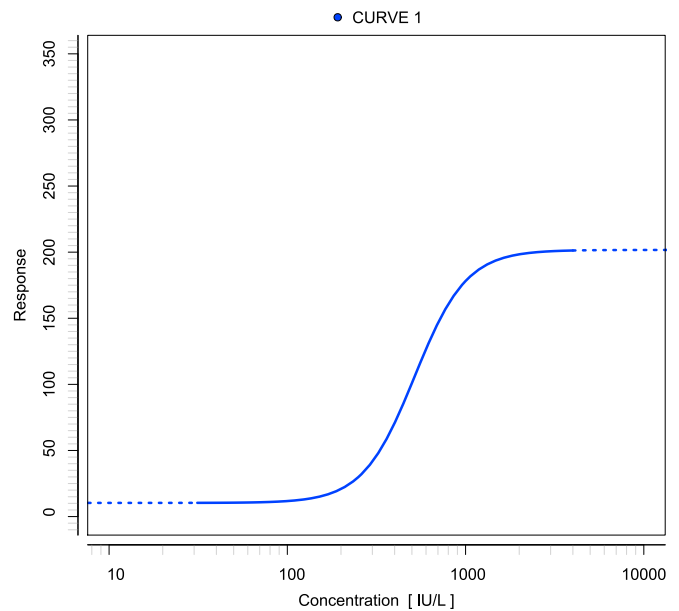
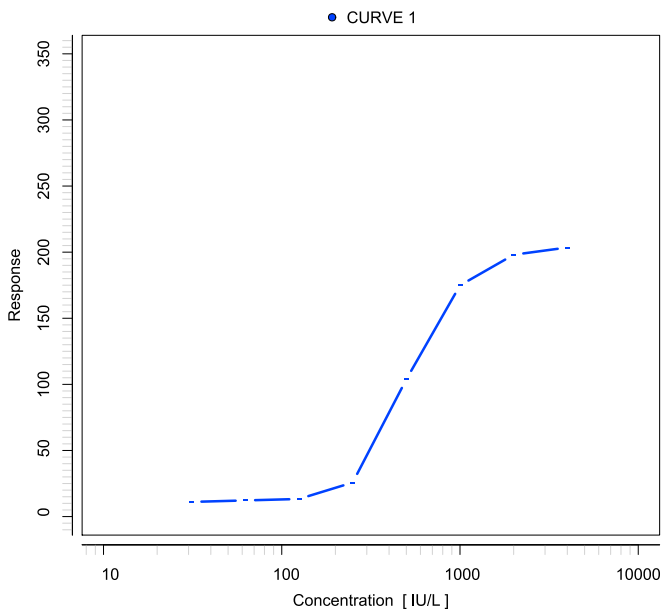
Test	Details	Test Status
Overall test result	Passed	
■ CURVE 1 F-Test (hypothesis test)	1000.3914 ≥ 0.11547	Passed
■ CURVE 2 F-Test (hypothesis test)	2972.9291 ≥ 0.11547	Passed
■ CURVE 3 F-Test (hypothesis test)	2017.0350 ≥ 0.11547	Passed

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

CURVE 1: Result

Data plot

Regression plot



Response data

Dilution step	1	2	3	4	5	6
Working concentration [IU/L]	4000.0000	2000.0000	1000.0000	500.00000	250.00000	125.00000
Response	211.91351 201.57012 197.06491	199.79343 195.20899 199.13072	177.24509 172.29252 175.07573	103.47476 104.81782 103.20709	17.17979 26.28608 33.82634	2.53044 12.83126 24.59858

Dilution step	7	8
Working concentration [IU/L]	62.50000	31.25000
Response	16.87861 1.75747 18.00377	23.64852 1.28774 8.34130

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Regression results

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
A upper asymptote	201.67853	3.34665	194.69754 to 208.65952	6.92%
B parameter	2.98947	0.28139	2.40249 to 3.57644	39.27%
C parameter	9.01692	0.04702	8.91884 to 9.11500	2.18%
D lower asymptote	10.34121	2.58468	4.94966 to 15.73276	104.27%

Effective concentration (EC)

	5%	20%	50%	80%	95%
Percentile					
EC [IU/L]	193.46829	325.81340	518.03913	823.67558	1387.1241
Response at EC	19.90808	48.60868	106.00987	163.41106	192.11166

Sample suitability tests

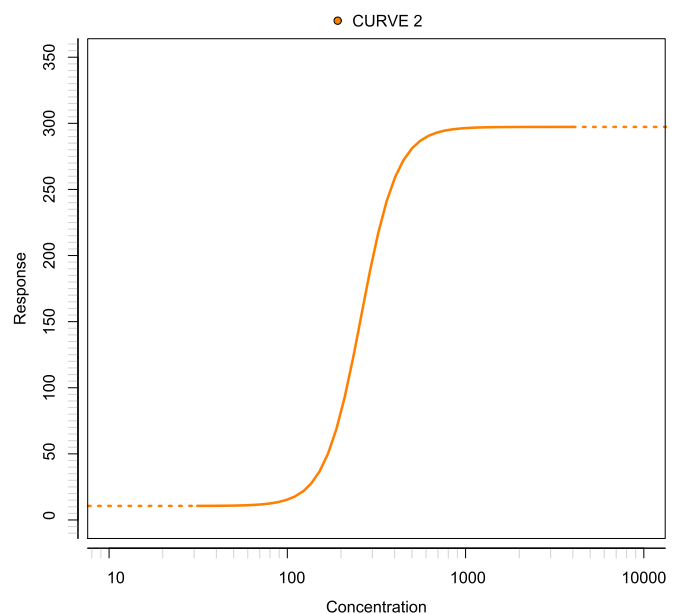
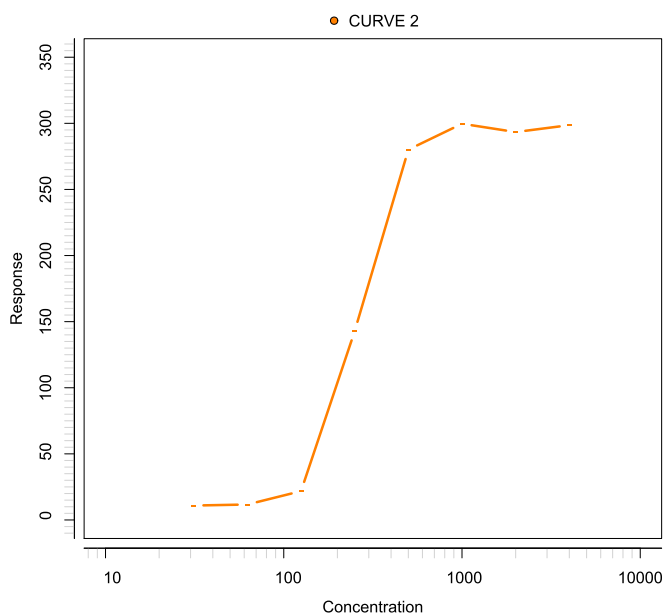
Test	Details	Test Status
CURVE 1	Passed	
Test: Parameter/Property point estimate, A/D ratio of asymptotes	10.00000 ≤ 19.50241 ; 19.50241 ≤ 25.00000	Passed
Test: Mean squares (ANOVA)	54.10809 ≤ 64.00000	Passed
Test: Sum of squares (ANOVA)	131.34765 ≤ 256.00000	Passed

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

CURVE 2: Result

Data plot

Regression plot



Response data

Dilution step	1	2	3	4	5	6
Working concentration	4000.0000	2000.0000	1000.0000	500.00000	250.00000	125.00000
Response	292.56633 295.98557 307.28481	304.10191 282.55916 293.54266	307.14955 296.29104 295.61676	283.19310 286.59337 270.46342	133.84735 144.47419 150.09980	19.20772 24.55355 21.67286

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Dilution step	7	8
Working concentration	62.50000	31.25000
Response	17.29848 6.86793 10.90535	11.51796 14.25892 6.93715

Regression results

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
A upper asymptote	297.28356	2.23964	292.61175 to 301.95536	3.14%
B parameter	4.28465	0.34888	3.55689 to 5.01240	33.97%
C parameter	8.01963	0.02032	7.97723 to 8.06202	1.06%
D lower asymptote	10.62306	2.57761	5.24627 to 15.99986	101.23%

Effective concentration (EC)

	5%	20%	50%	80%	95%
EC	130.52638	187.77284	259.50660	358.64438	515.93916
Response at EC	24.95609	67.95516	153.95331	239.95146	282.95053

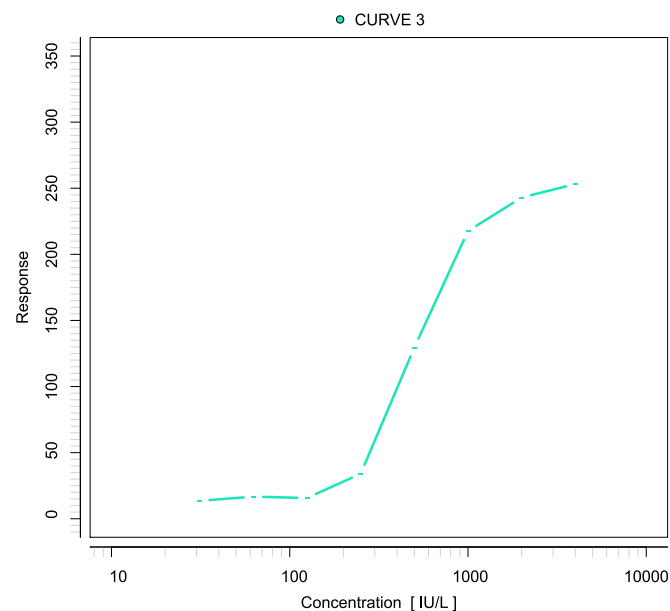
Sample suitability tests

Test	Details	Test Status
■ CURVE 2		Failed (warning)
Test: Parameter/Property point estimate, A/D ratio of asymptotes	10.00000 ≤ 27.98473 ; 27.98473 ≤ 25.00000	Failed
Test: Mean squares (ANOVA)	44.98895 ≤ 64.00000	Passed
Test: Sum of squares (ANOVA)	87.40599 ≤ 256.00000	Passed

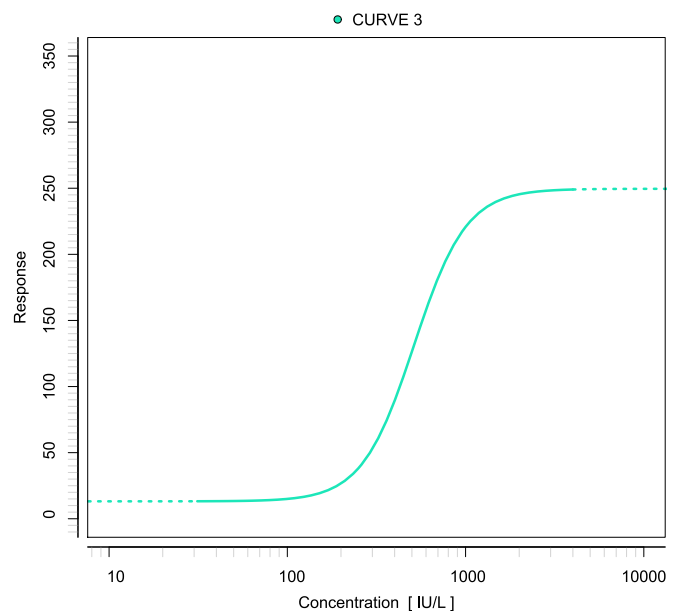
Details: Lower Margin ≤ (Lower/ Upper) Value ≤ Upper Margin

■ **CURVE 3: Result**

Data plot



Regression plot



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Response data

Dilution step	1	2	3	4	5	6
Working concentration [IU/L]	4000.0000	2000.0000	1000.0000	500.00000	250.00000	125.00000
Response	250.19531 250.70353 258.68016	247.79815 232.95436 248.16306	216.72223 210.83509 225.38977	125.05083 126.28014 137.13765	28.80068 39.18680 34.20951	16.37005 19.97453 10.73337

Dilution step	7	8
Working concentration [IU/L]	62.50000	31.25000
Response	14.30931 20.65082 15.22821	6.01348 14.71754 19.97839

Regression results

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
A upper asymptote	249.57541	2.90828	243.50885 to 255.64197	4.86%
B parameter	2.96754	0.19593	2.55883 to 3.37625	27.55%
C parameter	9.00610	0.03327	8.93671 to 9.07550	1.54%
D lower asymptote	13.18506	2.25901	8.47286 to 17.89726	71.48%

Effective concentration (EC)

	5%	20%	50%	80%	95%
Percentile EC [IU/L]	190.63113	322.27428	514.17090	820.33141	1386.8235
Response at EC	25.00458	60.46313	131.38023	202.29734	237.75589

Sample suitability tests

Test	Details	Test Status
<div style="background-color: #008000; color: white; padding: 2px;">CURVE 3</div> Test: Parameter/Property point estimate, A/D ratio of asymptotes	10.00000 ≤ 18.92865 ; 18.92865 ≤ 25.00000	Passed
Test: Mean squares (ANOVA)	40.90570 ≤ 64.00000	Passed
Test: Sum of squares (ANOVA)	206.19810 ≤ 256.00000	Passed

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