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.

EMD with 4PLF DRAs

Document-Id:	Document-1660 (Revision: 3)
Document type:	Equivalence margin development/1
Last modified:	25.03.2020 12:57:31
Database:	FP014_Dose-Response-Analysis-Package @ VMS_DATABASE_04\SQL2008
Database GUID:	5e028520-d6e3-4e74-bc09-3beadb3b416d

Calculation information

Calculation performed:	25.03.2020 12:57:30, dominik.lenk@stegmannsystems.com (PLA 3.0.4 Build 762, NBDLE01, 10014)
Messages:	[I5213] Margin Development
	[I5214] A valid margin for test AdditionalTestMeanSquaredPureError is missing. The test will not be considered during verification and visualization.
	[I5215] Strategy Verification
	[I5216] Simulation Calculations (1 strategies)
	[I5217] Strategy 1: 30 acceptable configurations found. A total of 36 simulations have been calculated.
Report generated:	25.03.2020 12:57:46, dominik.lenk@stegmannsystems.com (PLA 3.0.4 Build 762, NBDLE01, 10014)

Signatures

....
Responsibility

....
Review

....
Approval

Documentation

Date	25.03.2020 08:47:28

Table of contents

DOCUMENT-1660

5E028520-D6E3-4E74-BC09-3BEADB3B416D

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

Overview

Introduction

The Equivalence margin development process in the Biological assay package is structured into several sections. After a detailed analysis of the source data, equivalence margins are calculated. Several test strategies can be defined. These test strategies are selections of available tests. The analysis of these strategies reveals whether a certain strategy is capable of qualifying assays which are sufficiently similar to the assays that have been used to develop the margins. The Equivalence margin development process is an implementation of the USP <1032> Tolerance interval approach for the development of Equivalence margins.

Section I Source assays contains the source assays. The development of Equivalence margins is very sensitive in regard to the selection of the assay runs used to develop the margins. Equivalence margin development distinguishes between Development assays and Verification assays. For the development of the margins the Development assay set is being used. The Tolerance interval approach is used to derive the requested Equivalence margins from this Development assay set. Assays marked as Verification assays are used to test strategies later. For this purpose, an expected test result needs to be defined for the Verification assays.

The Source assays section contains overlay plot of the development and verification assays as well as details for every development and verification assay. The assays are sorted to start with the development assays followed by the verification assays.

A prerequisite of the development and verification assays is a common dimension of the assay in terms of dilution steps and replicates as well as a common regression model.

Section II Equivalence margin development starts with an overview of the developed margins. By default, all available margins are calculated. In the details section, a profile for every developed Equivalence margins is being plotted. It is recommended to thoroughly analyze these profiles to identify misbehaved assays which can have a huge impact on a developed strategy.

Section III Strategy overview reports the selected tests along with their calculated or predefined margins.

Section IV Strategy verification reports the strategy test results for every development and verification assay. It needs to be verified that the development and verification assay are sufficiently qualified by the defined strategy. Depending on the sensitivity of the Tolerance interval approach it is expected that a certain number of development assays will be disqualified by the strategies.

Section V Strategy visualization is used to visualize the behavior of the strategies. This is done by running simulations for acceptable assay systems. The simulation plots a defined number of acceptable simulation assays within the range of the development and verification assays as a visual tool to verify the strategies. The report starts by comparing overlay plots of the development assays with overlay plot of the simulated assays. It is expected that the overlay plots prove a similar behavior of the development and simulation assays. The report ends with a summary page comparing the overlay plots of all defined strategies.

Notes: (1) All of the sections are optional. The Equivalence margin development process is also capable of verifying pre-defined strategies to test existing Equivalence margins strategies which have not been developed with the process itself. (2) The strategy visualization is not capable of using the test for sum of squares.

Literature

Callahan, J. D.; Sajjadi, N. C. Testing the null hypothesis for a specified difference - The right way to test for parallelism. Bioprocessing Journal. 2003, 2, 71 - 78

Hauck, W. W.; Carpen, R. C.; Callahan, J. D.; De Muth, J. E.; Hsu, H.; Lansky, D.; Sajjadi, N. C.; Seaver, S. S.; Singer, R. R.; Weisman, D. Assessing parallelism prior to determining relative potency. PDA Journal of Pharmaceutical Science and Technology. 2005, 59, 127 - 137.

The United States Pharmacopeia Convention. <1032> Design and development of biological assays. 2010.

The United States Pharmacopeia Convention. <1034> Analysis of biological assays. 2010.

Settings

Property	Value
Margin development	yes
Test strategy verification	yes
Test strategy visualization	yes
Confidence level	90%
Tolerance level	95%
Maximal number of simulations:	10000
Maximal number of configurations:	30

Section I: Source assays

Source assay properties

| Property	Value
Model	4 parameter logistic fit
Logarithm base	binary logarithm (base 2)
Step count	12
Replicate count	1
Working concentration	5, 3.33, 2.22, 1.48, 0.99, 0.66, 0.44, 0.29, 0.2, 0.13, 0.09, 0.06

Source assay overview

Index		Document key: Document title, Assay element	Dev/Ver	Assay result from source document	Scientifically acceptable
1	(1)	Document-1636: Assay 1, STD	Dev	Failed (warning)	yes
2	(2)	Document-1637: Assay 2, STD	Dev	Failed (warning)	yes
3	(3)	Document-1638: Assay 3, STD	Dev	Failed (warning)	yes
4	(4)	Document-1639: Assay 4, STD	Dev	Failed (warning)	yes
5	(5)	Document-1640: Assay 5, STD	Dev	Failed (warning)	yes
6	(6)	Document-1641: Assay 6, STD	Dev	Failed (warning)	yes
7	(7)	Document-1642: Assay 7, STD	Dev	Failed (warning)	yes
8	(8)	Document-1643: Assay 8, STD	Dev	Failed (warning)	yes
9	(9)	Document-1644: Assay 9, STD	Dev	Failed (warning)	yes
10	(10)	Document-1645: Assay 10, STD	Dev	Failed (warning)	yes
11	(11)	Document-1646: Assay 11, STD	Dev	Failed (warning)	yes
12	(12)	Document-1647: Assay 12, STD	Dev	Failed (warning)	yes
13	(13)	Document-1648: Assay 13, STD	Dev	Failed (warning)	yes
14	(14)	Document-1649: Assay 14, STD	Dev	Failed (warning)	yes
15	(15)	Document-1650: Assay 15, STD	Dev	Failed (warning)	yes
16	(16)	Document-1651: Assay 16, STD	Dev	Failed (warning)	yes
17	(17)	Document-1652: Assay 17, STD	Dev	Failed (warning)	yes
18	(18)	Document-1653: Assay 18, STD	Dev	Failed (warning)	yes
19	(19)	Document-1654: Assay 19, STD	Dev	Failed (warning)	yes
20	(20)	Document-1655: Assay 20, STD	Dev	Failed (warning)	yes
21	(21)	Document-1656: Assay 21, STD	Dev	Failed (warning)	yes
22	(22)	Document-1657: Assay 22, STD	Dev	Failed (warning)	yes
23	(23)	Document-1658: Assay 23, STD	Dev	Failed (warning)	yes
24	(24)	Document-1659: Assay 24, STD	Dev	Failed (warning)	yes

Index, in parenthesis, corresponds to row in the source data table.
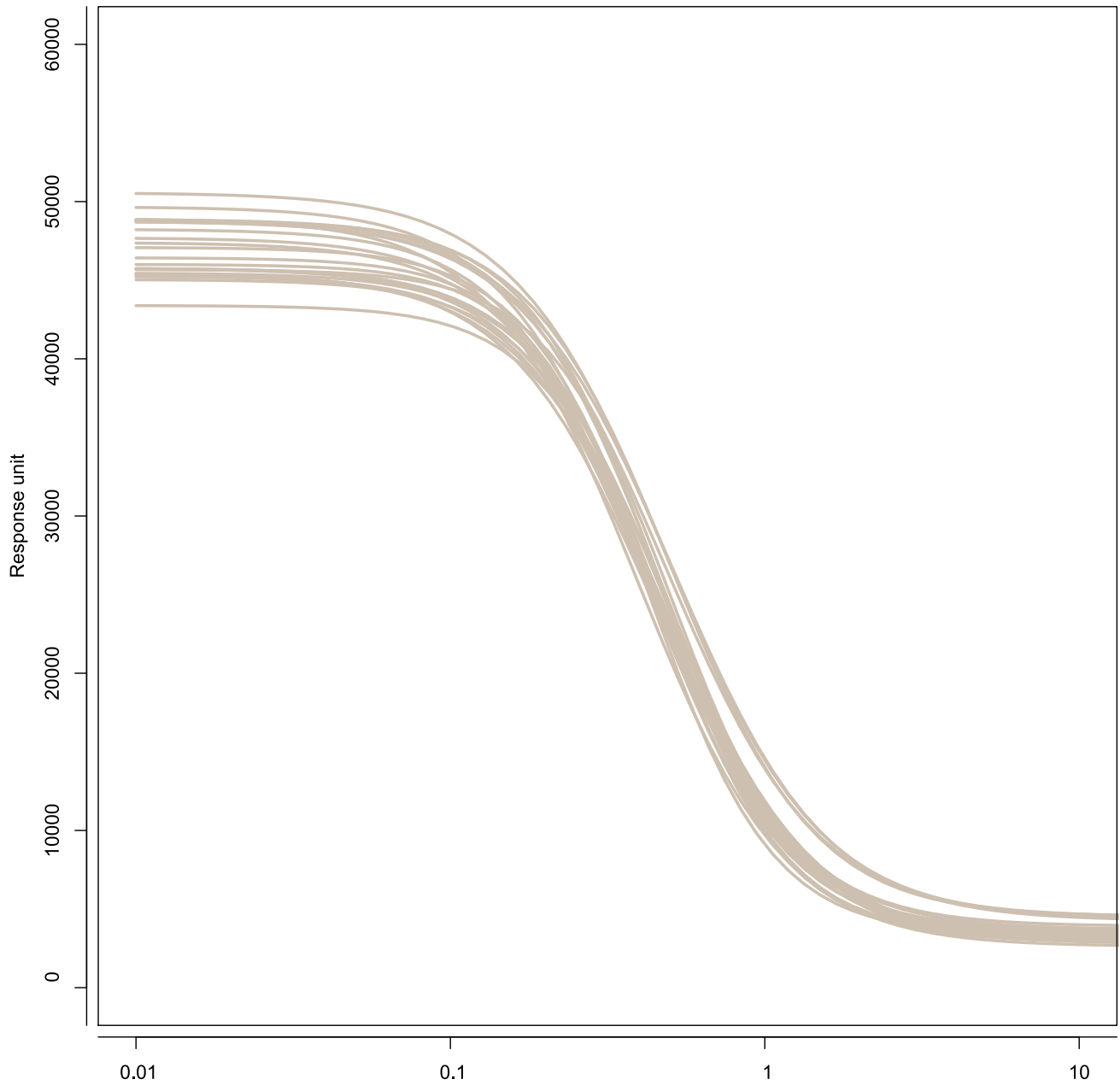Dev = Development assay. Ver = Verification assay.
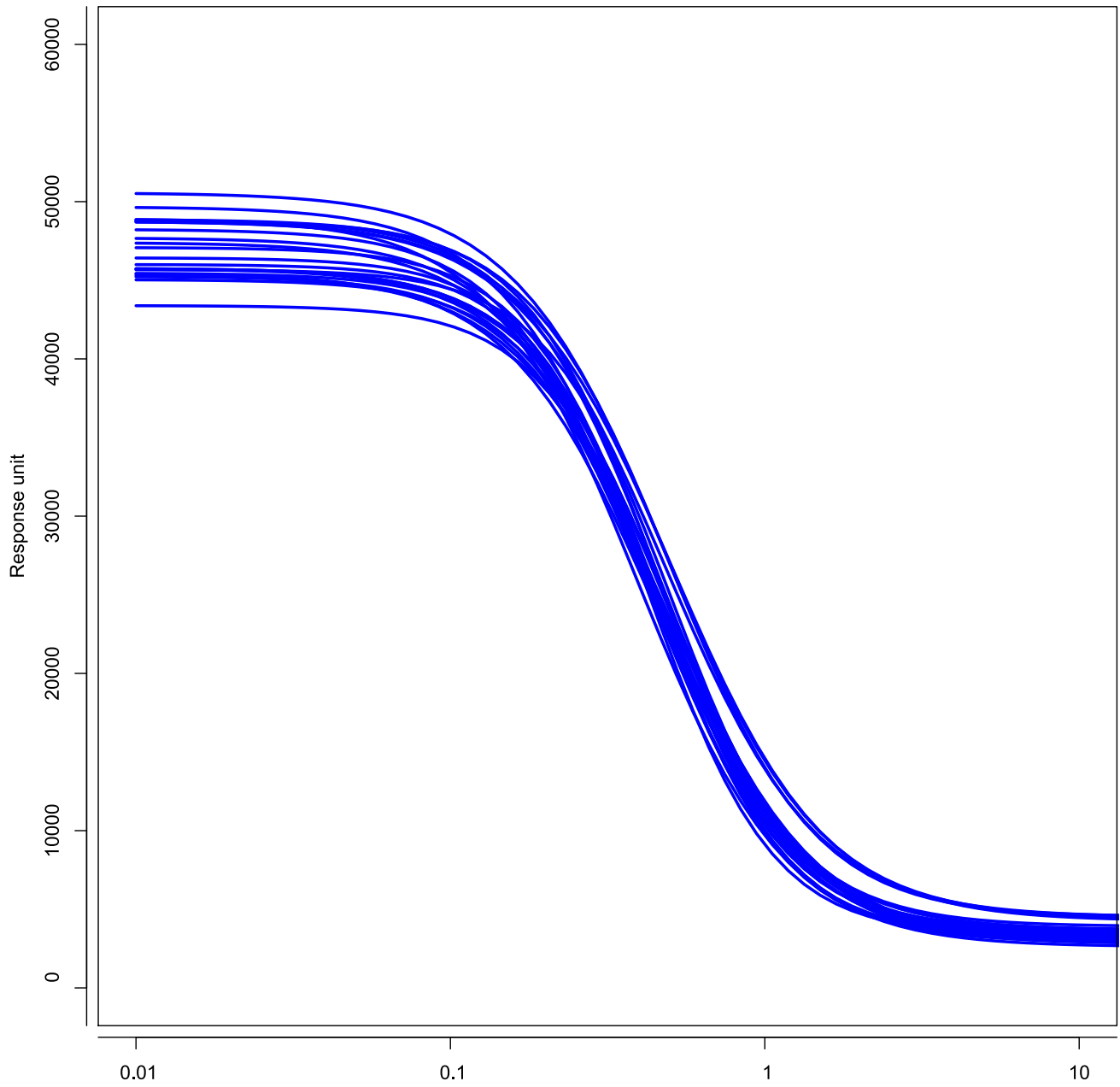
Development assays: Overlay plot

Verification assays: Overlay plot

Source assay details

The sort order of the source assays starts with development assays, followed by verification assays and finally excluded assays. This sort order may be different from the order of the source data table of the document. The index stated here is used consistently throughout all plots and tables of this document. The headline of every assay is constructed as:

A (B): C Assay name [D, E, F] where
A = Index used in this report for all plots and tables (sort order)
B = Index in the source data table of the Equivalence margin development document
C = Document key in the database
D = Development or verification assay
E = Assay test result from the source document
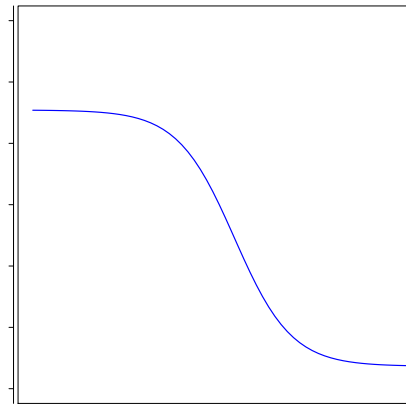F = Expected assay test result for verification assay.

1 (1): Document-1636 Assay 1 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45727.277	636.99027
B parameter	-1.94779	0.11201
C parameter	-1.13584	0.04343
D lower asymptote	3901.4881	519.90281
Anova	Value	
d.f.	8	
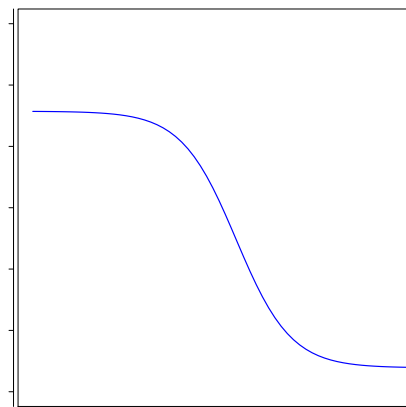
2 (2): Document-1637 Assay 2 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45432.504	626.44449
B parameter	-1.87054	0.10121
C parameter	-1.18123	0.04206
D lower asymptote	3659.6141	489.87396
Anova	Value	
d.f.	8	

3 (3): Document-1638 Assay 3 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	50560.779	470.39893
B parameter	-1.77876	0.06725
C parameter	-1.03662	0.03007
D lower asymptote	4388.2405	411.59486
Anova	Value	
d.f.	8	
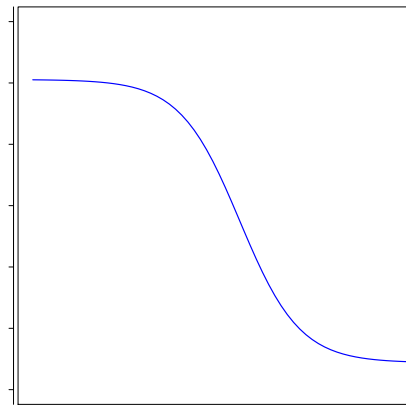
4 (4): Document-1639 Assay 4 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48868.359	516.85485
B parameter	-1.90502	0.08783
C parameter	-0.98587	0.03513
D lower asymptote	4521.8083	473.82223

Anova	Value
d.f.	8
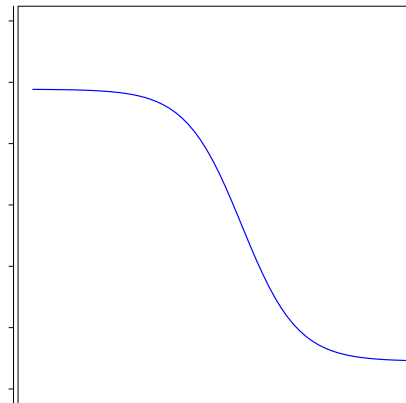
5 (5): Document-1640 Assay 5 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48744.485	316.39230
B parameter	-1.79367	0.04911
C parameter	-0.96158	0.02162
D lower asymptote	4254.0086	294.74609

Anova	Value
d.f.	8
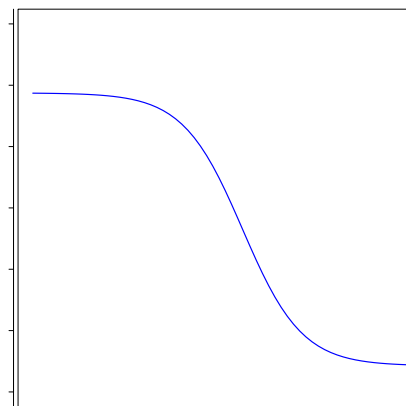
6 (6): Document-1641 Assay 6 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48743.199	403.53248
B parameter	-1.81493	0.06214
C parameter	-1.03969	0.02691
D lower asymptote	4501.8964	352.83462

Anova	Value
d.f.	8
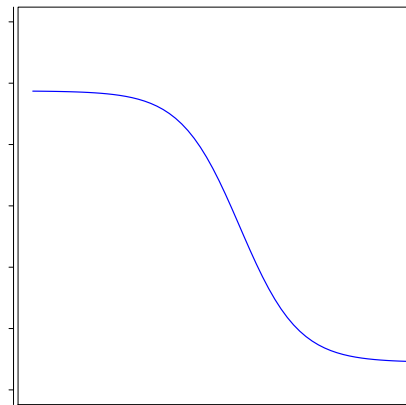
7 (7): Document-1642 Assay 7 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45756.364	533.71854
B parameter	-1.93716	0.09554
C parameter	-1.01388	0.03721
D lower asymptote	2984.0608	479.17643
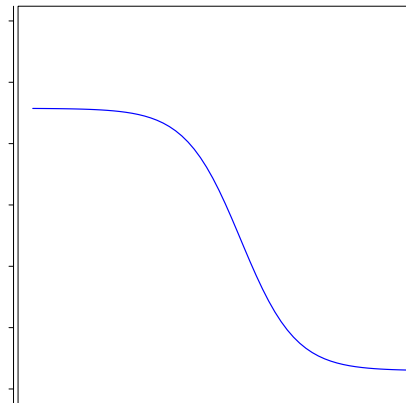
Anova	Value
d.f.	8

8 (8): Document-1643 Assay 8 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45342.963	444.03822
B parameter	-1.81547	0.07109
C parameter	-1.04695	0.03078
D lower asymptote	2897.9937	385.95583

Anova	Value
d.f.	8
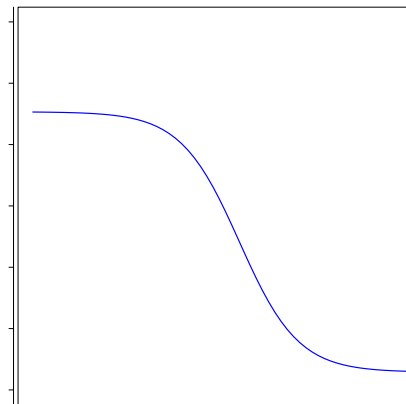
9 (9): Document-1644 Assay 9 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45676.520	520.93818
B parameter	-2.15750	0.11432
C parameter	-0.97677	0.03717
D lower asymptote	3556.8233	484.79248

Anova	Value
d.f.	8
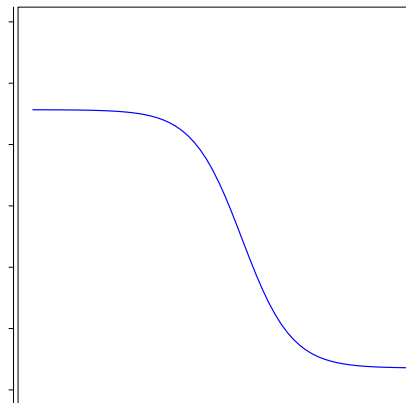
10 (10): Document-1645 Assay 10 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45044.640	332.43487
B parameter	-2.00899	0.06348
C parameter	-1.06383	0.02332
D lower asymptote	3339.2501	288.11915
Anova	Value	
d.f.		8
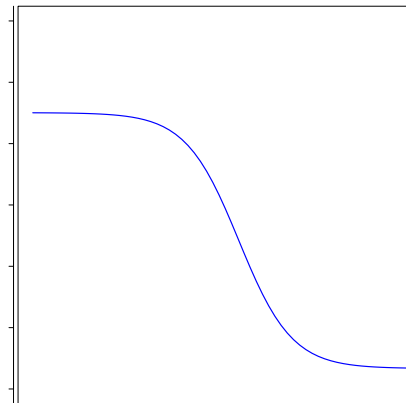
11 (11): Document-1646 Assay 11 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	43390.286	515.91909
B parameter	-2.18051	0.11660
C parameter	-1.06713	0.03731
D lower asymptote	3165.2540	450.13872
Anova	Value	
d.f.		8
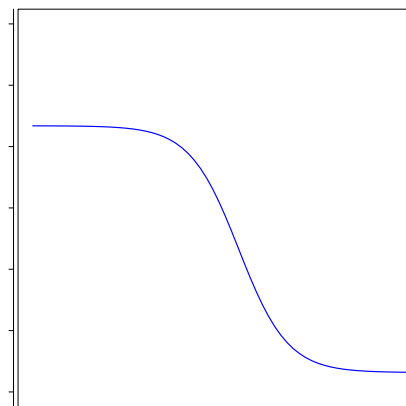
12 (12): Document-1647 Assay 12 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45240.143	803.48729
B parameter	-2.01369	0.14686
C parameter	-1.14576	0.05390
D lower asymptote	2896.4053	654.05856
Anova	Value	
d.f.		8
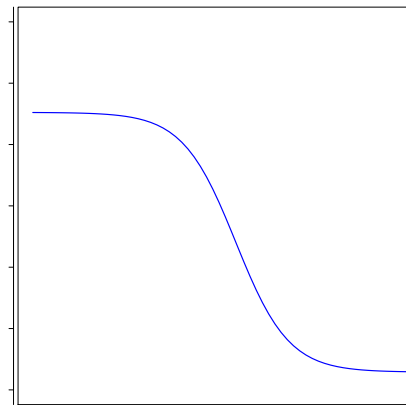
TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

13 (13): Document-1648 Assay 13 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45756.364	533.71854
B parameter	-1.93716	0.09554
C parameter	-1.01388	0.03721
D lower asymptote	2984.0608	479.17643

Anova	Value
d.f.	8
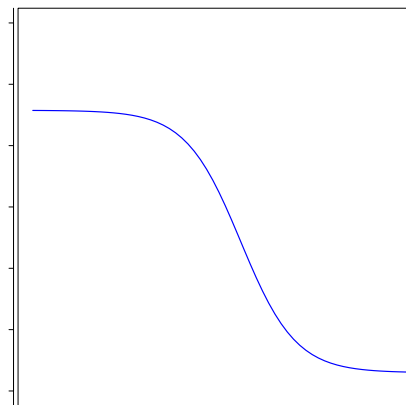
14 (14): Document-1649 Assay 14 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	46429.228	757.73482
B parameter	-2.13433	0.14925
C parameter	-1.15273	0.04966
D lower asymptote	3285.7430	619.25882

Anova	Value
d.f.	8
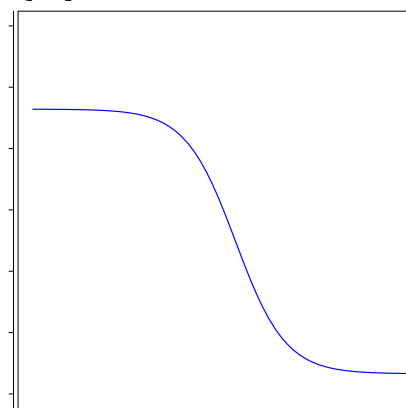
15 (15): Document-1650 Assay 15 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48913.692	728.64207
B parameter	-1.84579	0.09717
C parameter	-1.33785	0.04182
D lower asymptote	2618.1994	499.35802

Anova	Value
d.f.	8
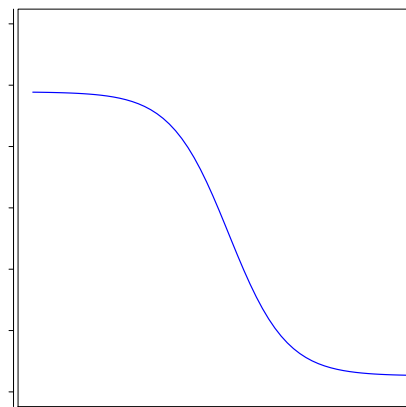
16 (16): Document-1651 Assay 16 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	46004.986	708.84843
B parameter	-2.23001	0.14903
C parameter	-1.20308	0.04606
D lower asymptote	3365.8153	562.71912
Anova	Value	
d.f.		8
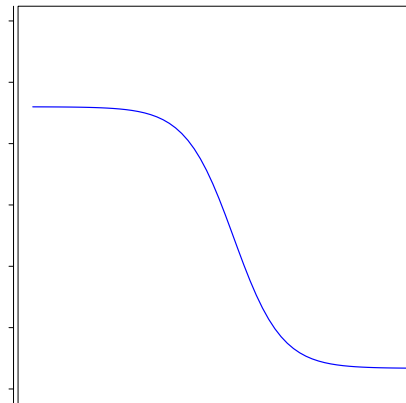
17 (17): Document-1652 Assay 17 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	45454.742	448.26306
B parameter	-1.97743	0.08335
C parameter	-1.02093	0.03139
D lower asymptote	2997.8831	400.94465
Anova	Value	
d.f.		8
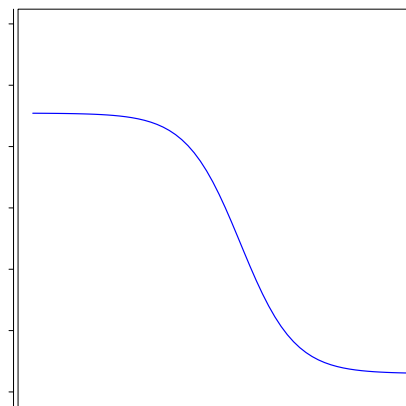
18 (18): Document-1653 Assay 18 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	47695.770	582.73337
B parameter	-1.89534	0.08955
C parameter	-1.18682	0.03643
D lower asymptote	2907.6123	454.65993
Anova	Value	
d.f.		8
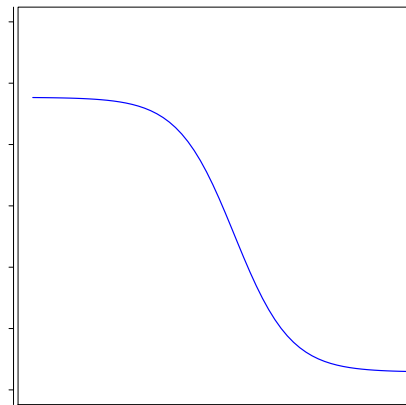
19 (19): Document-1654 Assay 19 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	47398.505	471.40349
B parameter	-1.87015	0.07144
C parameter	-1.17683	0.02969
D lower asymptote	2794.3128	369.94408
Anova	Value	
d.f.		8
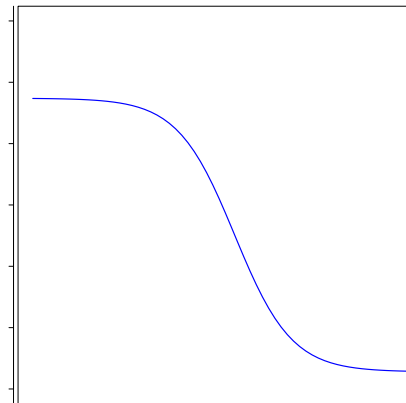
20 (20): Document-1655 Assay 20 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	47084.565	918.23108
B parameter	-2.09558	0.17390
C parameter	-1.15096	0.05969
D lower asymptote	3522.0470	749.21200
Anova	Value	
d.f.		8
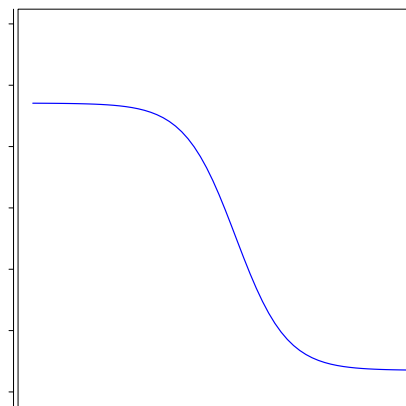
21 (21): Document-1656 Assay 21 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48239.080	320.42070
B parameter	-1.96017	0.05062
C parameter	-1.25237	0.01955
D lower asymptote	3379.4209	238.75551
Anova	Value	
d.f.		8
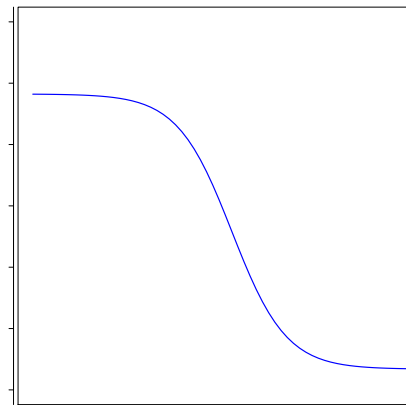
22 (22): Document-1657 Assay 22 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48775.166	441.46363
B parameter	-2.07420	0.08000
C parameter	-1.13152	0.02792
D lower asymptote	3673.1214	364.92484
Anova	Value	
d.f.	8	
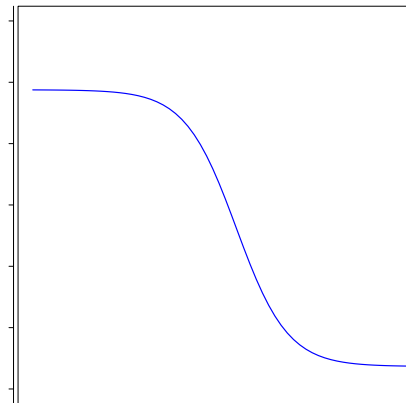
23 (23): Document-1658 Assay 23 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	49671.078	841.15224
B parameter	-1.86450	0.11928
C parameter	-1.22927	0.05000
D lower asymptote	3279.7920	632.10259
Anova	Value	
d.f.	8	
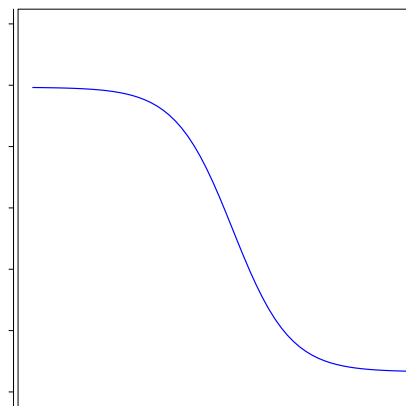
24 (24): Document-1659 Assay 24 [Development, FAILED, Scientifically acceptable: yes]

Parameter	Value	Std Error
A upper asymptote	48826.062	581.38560
B parameter	-1.96338	0.09638
C parameter	-1.12591	0.03687
D lower asymptote	3694.7441	478.79782
Anova	Value	
d.f.	8	
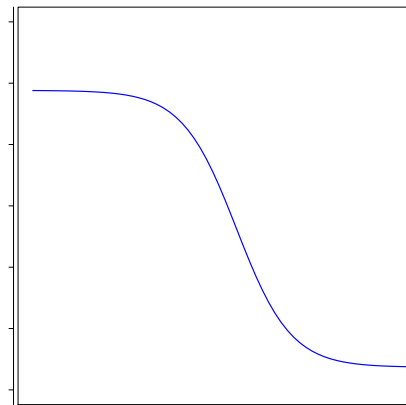
Section II: Margin development

Margin development overview

	Equivalence margins	
	upper	lower
Equivalence test parameter estimate		
A upper asymptote (nonlinear models)	51235.241	43746.020
B parameter (nonlinear models)	-1.65371	-2.41895
C parameter (nonlinear models)	-0.92055	-1.32225
D lower asymptote (nonlinear models)	5158.0093	1689.6192
Difference of asymptotes (nonlinear models)	48220.383	40036.199
Ratio of asymptotes (nonlinear models)	27.25354	9.29039
Test parameter/property point estimate		
A upper asymptote (nonlinear models)	49671.078	45044.640
B parameter (nonlinear models)	-1.79367	-2.18051
C parameter (nonlinear models)	-0.97677	-1.25237
D lower asymptote (nonlinear models)	4501.8964	2794.3128
Difference of asymptotes (nonlinear models)	46295.492	41705.390
Ratio of asymptotes (nonlinear models)	16.96249	10.82726
Anova terms		
Sum of squares model	3.601 E+09	2.994 E+09
Sum of squares residual error	6521855.0	892490.03
Sum of squares lack of fit	6521855.0	892490.03
Sum of squares pure error	0	0
Sum of squares total	3.606 E+09	2.995 E+09
Mean squared model	1.200 E+09	9.979 E+08
Mean squared residual error	815231.88	111561.25
Mean squared lack of fit	815231.88	111561.25
Mean squared pure error	N/A	N/A
Mean squared total	3.278 E+08	2.723 E+08

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

Margin development details

### Equivalence test parameter estimate: A upper asymptote (nonlinear models)
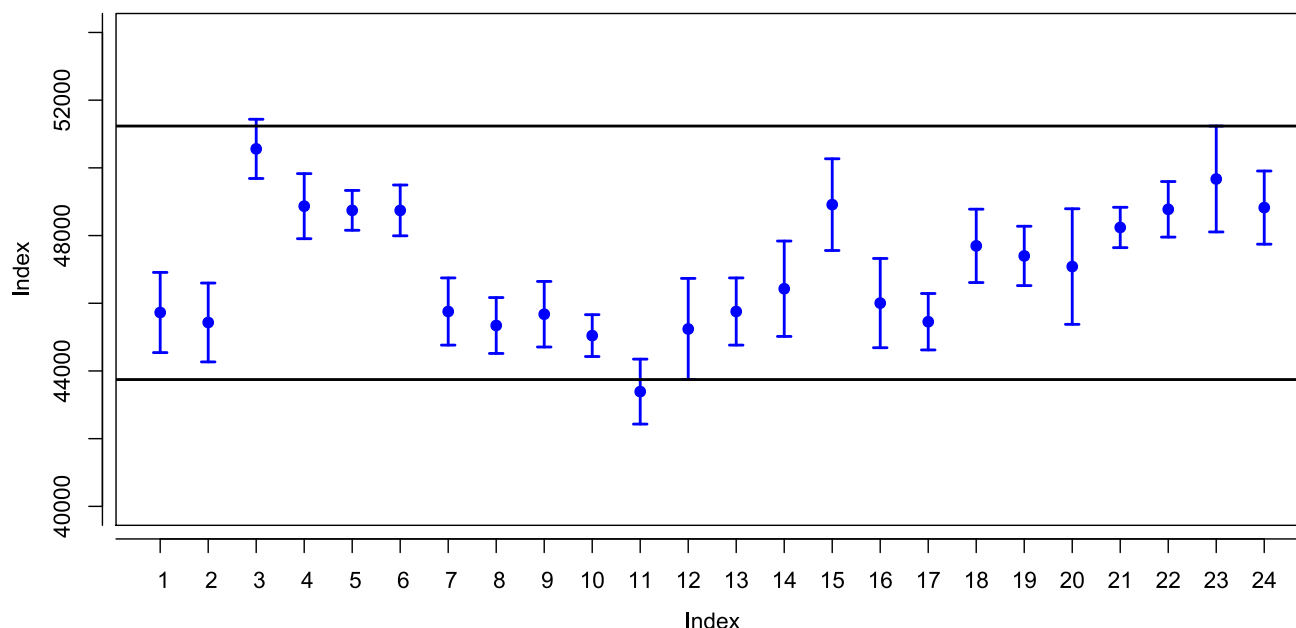
Mean	SD	CV		Margins	
47032.365	1829.9017		3.89%	43746.020	− 51235.241

Development assays

Index	Assay	Value	Confidence interval			
1	Document-1636: Assay 1, STD	45727.277	44542.763	–	46911.791	✓
2	Document-1637: Assay 2, STD	45432.504	44267.601	–	46597.408	✓
3	Document-1638: Assay 3, STD	50560.779	49686.049	–	51435.508	✗
4	Document-1639: Assay 4, STD	48868.359	47907.242	–	49829.475	✓
5	Document-1640: Assay 5, STD	48744.485	48156.138	–	49332.832	✓
6	Document-1641: Assay 6, STD	48743.199	47992.811	–	49493.588	✓
7	Document-1642: Assay 7, STD	45756.364	44763.889	–	46748.840	✓
8	Document-1643: Assay 8, STD	45342.963	44517.253	–	46168.673	✓
9	Document-1644: Assay 9, STD	45676.520	44707.810	–	46645.230	✓
10	Document-1645: Assay 10, STD	45044.640	44426.461	–	45662.818	✓
11	Document-1646: Assay 11, STD	43390.286	42430.910	–	44349.662	✗
12	Document-1647: Assay 12, STD	45240.143	43746.020	–	46734.266	✓
13	Document-1648: Assay 13, STD	45756.364	44763.889	–	46748.840	✓
14	Document-1649: Assay 14, STD	46429.228	45020.184	–	47838.273	✓
15	Document-1650: Assay 15, STD	48913.692	47558.747	–	50268.637	✓
16	Document-1651: Assay 16, STD	46004.986	44686.848	–	47323.123	✓
17	Document-1652: Assay 17, STD	45454.742	44621.175	–	46288.309	✓
18	Document-1653: Assay 18, STD	47695.770	46612.149	–	48779.391	✓
19	Document-1654: Assay 19, STD	47398.505	46521.908	–	48275.102	✓
20	Document-1655: Assay 20, STD	47084.565	45377.070	–	48792.059	✓
21	Document-1656: Assay 21, STD	48239.080	47643.242	–	48834.918	✓
22	Document-1657: Assay 22, STD	48775.166	47954.243	–	49596.089	✓
23	Document-1658: Assay 23, STD	49671.078	48106.915	–	51235.241	✓
24	Document-1659: Assay 24, STD	48826.062	47744.948	–	49907.176	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

**Equivalence test parameter estimate: B parameter (nonlinear models)**
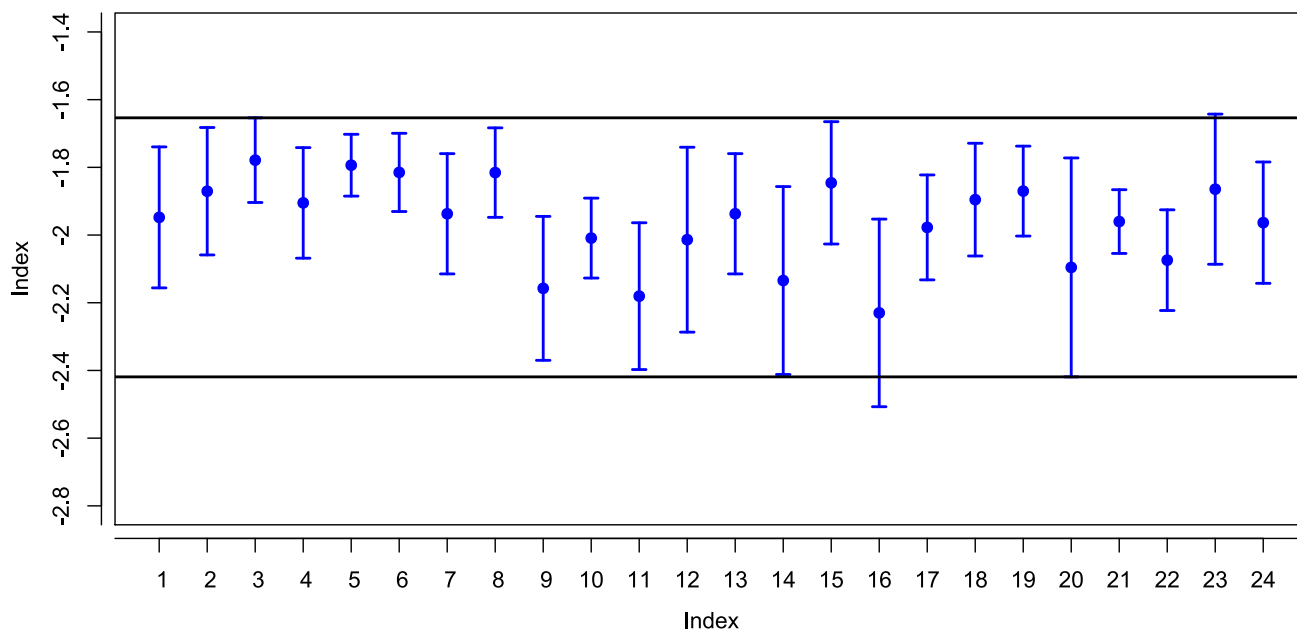
Mean	SD	CV	Margins
-1.96134	0.12803	-6.53%	-2.41895 – -1.65371

Development assays

Index	Assay	Value	Confidence interval	
1	Document-1636: Assay 1, STD	-1.94779	-2.15607 – -1.73951	✓
2	Document-1637: Assay 2, STD	-1.87054	-2.05875 – -1.68233	✓
3	Document-1638: Assay 3, STD	-1.77876	-1.90381 – -1.65371	✓
4	Document-1639: Assay 4, STD	-1.90502	-2.06835 – -1.74170	✓
5	Document-1640: Assay 5, STD	-1.79367	-1.88499 – -1.70235	✓
6	Document-1641: Assay 6, STD	-1.81493	-1.93048 – -1.69938	✓
7	Document-1642: Assay 7, STD	-1.93716	-2.11481 – -1.75950	✓
8	Document-1643: Assay 8, STD	-1.81547	-1.94766 – -1.68327	✓
9	Document-1644: Assay 9, STD	-2.15750	-2.37008 – -1.94491	✓
10	Document-1645: Assay 10, STD	-2.00899	-2.12704 – -1.89095	✓
11	Document-1646: Assay 11, STD	-2.18051	-2.39733 – -1.96369	✓
12	Document-1647: Assay 12, STD	-2.01369	-2.28679 – -1.74059	✓
13	Document-1648: Assay 13, STD	-1.93716	-2.11481 – -1.75950	✓
14	Document-1649: Assay 14, STD	-2.13433	-2.41186 – -1.85680	✓
15	Document-1650: Assay 15, STD	-1.84579	-2.02649 – -1.66509	✓
16	Document-1651: Assay 16, STD	-2.23001	-2.50714 – -1.95287	✗
17	Document-1652: Assay 17, STD	-1.97743	-2.13242 – -1.82244	✓
18	Document-1653: Assay 18, STD	-1.89534	-2.06187 – -1.72882	✓
19	Document-1654: Assay 19, STD	-1.87015	-2.00299 – -1.73731	✓
20	Document-1655: Assay 20, STD	-2.09558	-2.41895 – -1.77221	✓
21	Document-1656: Assay 21, STD	-1.96017	-2.05431 – -1.86603	✓
22	Document-1657: Assay 22, STD	-2.07420	-2.22296 – -1.92544	✓
23	Document-1658: Assay 23, STD	-1.86450	-2.08631 – -1.64269	✗
24	Document-1659: Assay 24, STD	-1.96338	-2.14261 – -1.78415	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

## Equivalence test parameter estimate: C parameter (nonlinear models)
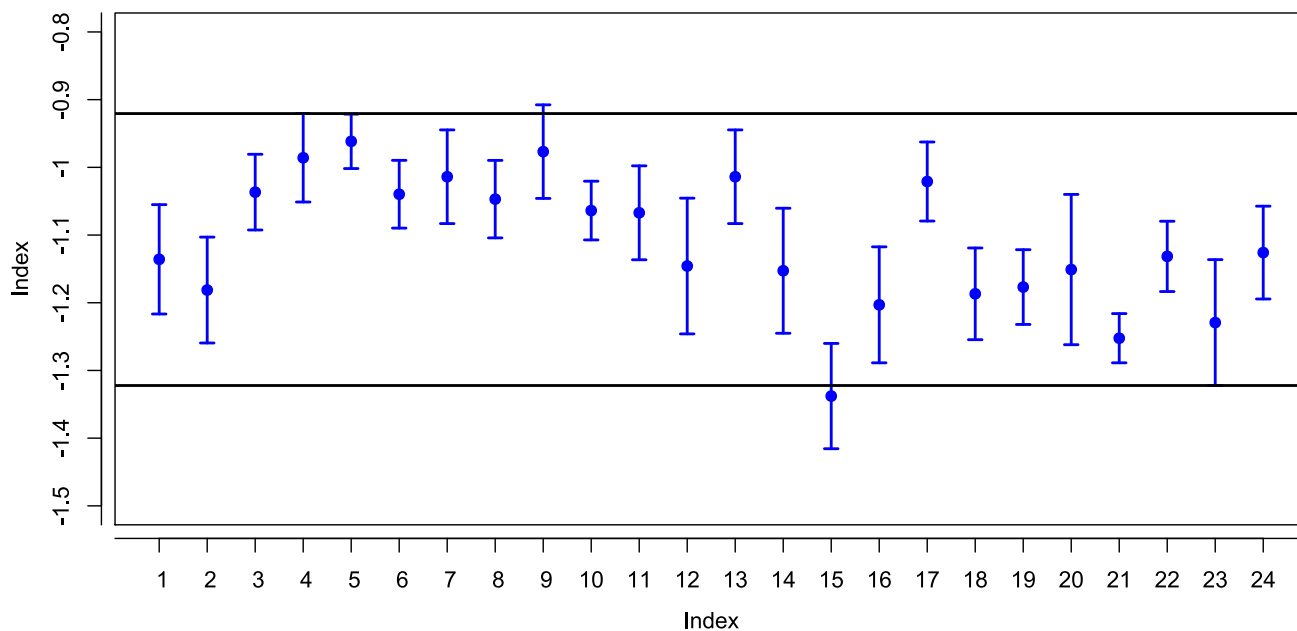
Mean	SD	CV	Margins
-1.10989	0.09703	-8.74%	-1.32225 – -0.92055

Development assays

Index	Assay	Value	Confidence interval	
1	Document-1636: Assay 1, STD	-1.13584	-1.21661 – -1.05508	✓
2	Document-1637: Assay 2, STD	-1.18123	-1.25945 – -1.10302	✓
3	Document-1638: Assay 3, STD	-1.03662	-1.09254 – -0.98070	✓
4	Document-1639: Assay 4, STD	-0.98587	-1.05119 – -0.92055	✓
5	Document-1640: Assay 5, STD	-0.96158	-1.00178 – -0.92138	✓
6	Document-1641: Assay 6, STD	-1.03969	-1.08974 – -0.98965	✓
7	Document-1642: Assay 7, STD	-1.01388	-1.08307 – -0.94469	✓
8	Document-1643: Assay 8, STD	-1.04695	-1.10420 – -0.98971	✓
9	Document-1644: Assay 9, STD	-0.97677	-1.04588 – -0.90765	✗
10	Document-1645: Assay 10, STD	-1.06383	-1.10719 – -1.02046	✓
11	Document-1646: Assay 11, STD	-1.06713	-1.13650 – -0.99776	✓
12	Document-1647: Assay 12, STD	-1.14576	-1.24599 – -1.04552	✓
13	Document-1648: Assay 13, STD	-1.01388	-1.08307 – -0.94469	✓
14	Document-1649: Assay 14, STD	-1.15273	-1.24507 – -1.06039	✓
15	Document-1650: Assay 15, STD	-1.33785	-1.41562 – -1.26009	✗
16	Document-1651: Assay 16, STD	-1.20308	-1.28873 – -1.11742	✓
17	Document-1652: Assay 17, STD	-1.02093	-1.07930 – -0.96256	✓
18	Document-1653: Assay 18, STD	-1.18682	-1.25456 – -1.11908	✓
19	Document-1654: Assay 19, STD	-1.17683	-1.23203 – -1.12162	✓
20	Document-1655: Assay 20, STD	-1.15096	-1.26196 – -1.03997	✓
21	Document-1656: Assay 21, STD	-1.25237	-1.28872 – -1.21601	✓
22	Document-1657: Assay 22, STD	-1.13152	-1.18344 – -1.07960	✓
23	Document-1658: Assay 23, STD	-1.22927	-1.32225 – -1.13630	✓
24	Document-1659: Assay 24, STD	-1.12591	-1.19446 – -1.05735	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

**Equivalence test parameter estimate: D lower asymptote (nonlinear models)**
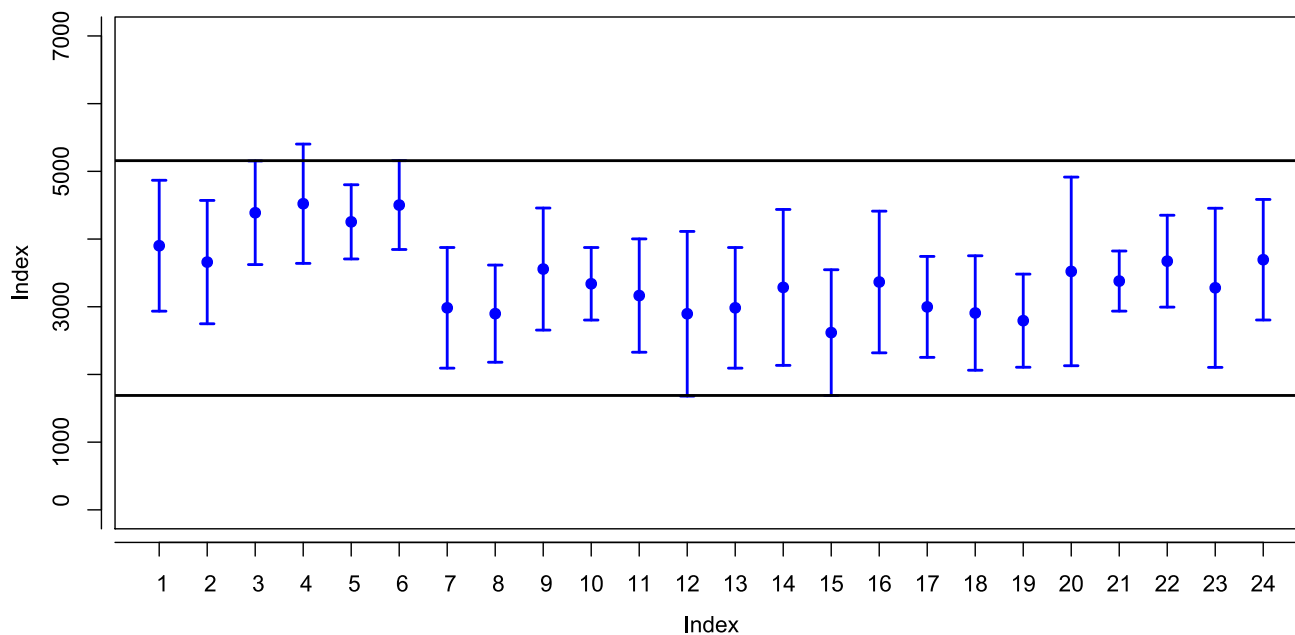
Mean	SD	CV	Margins
3440.3998	550.92770	16.01%	1689.6192 – 5158.0093

Development assays

Index	Assay	Value	Confidence interval	
1	Document-1636: Assay 1, STD	3901.4881	2934.7039 – 4868.2723	✓
2	Document-1637: Assay 2, STD	3659.6141	2748.6699 – 4570.5583	✓
3	Document-1638: Assay 3, STD	4388.2405	3622.8601 – 5153.6210	✓
4	Document-1639: Assay 4, STD	4521.8083	3640.7131 – 5402.9035	✗
5	Document-1640: Assay 5, STD	4254.0086	3705.9141 – 4802.1031	✓
6	Document-1641: Assay 6, STD	4501.8964	3845.7834 – 5158.0093	✓
7	Document-1642: Assay 7, STD	2984.0608	2093.0093 – 3875.1124	✓
8	Document-1643: Assay 8, STD	2897.9937	2180.2903 – 3615.6971	✓
9	Document-1644: Assay 9, STD	3556.8233	2655.3284 – 4458.3182	✓
10	Document-1645: Assay 10, STD	3339.2501	2803.4787 – 3875.0215	✓
11	Document-1646: Assay 11, STD	3165.2540	2328.1994 – 4002.3086	✓
12	Document-1647: Assay 12, STD	2896.4053	1680.1520 – 4112.6586	✗
13	Document-1648: Assay 13, STD	2984.0608	2093.0093 – 3875.1124	✓
14	Document-1649: Assay 14, STD	3285.7430	2134.2014 – 4437.2845	✓
15	Document-1650: Assay 15, STD	2618.1994	1689.6192 – 3546.7796	✓
16	Document-1651: Assay 16, STD	3365.8153	2319.4120 – 4412.2185	✓
17	Document-1652: Assay 17, STD	2997.8831	2252.3073 – 3743.4590	✓
18	Document-1653: Assay 18, STD	2907.6123	2062.1503 – 3753.0742	✓
19	Document-1654: Assay 19, STD	2794.3128	2106.3840 – 3482.2416	✓
20	Document-1655: Assay 20, STD	3522.0470	2128.8513 – 4915.2427	✓
21	Document-1656: Assay 21, STD	3379.4209	2935.4436 – 3823.3983	✓
22	Document-1657: Assay 22, STD	3673.1214	2994.5261 – 4351.7166	✓
23	Document-1658: Assay 23, STD	3279.7920	2104.3668 – 4455.2171	✓
24	Document-1659: Assay 24, STD	3694.7441	2804.3965 – 4585.0916	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

**Equivalence test parameter estimate: Difference of asymptotes (nonlinear models)**
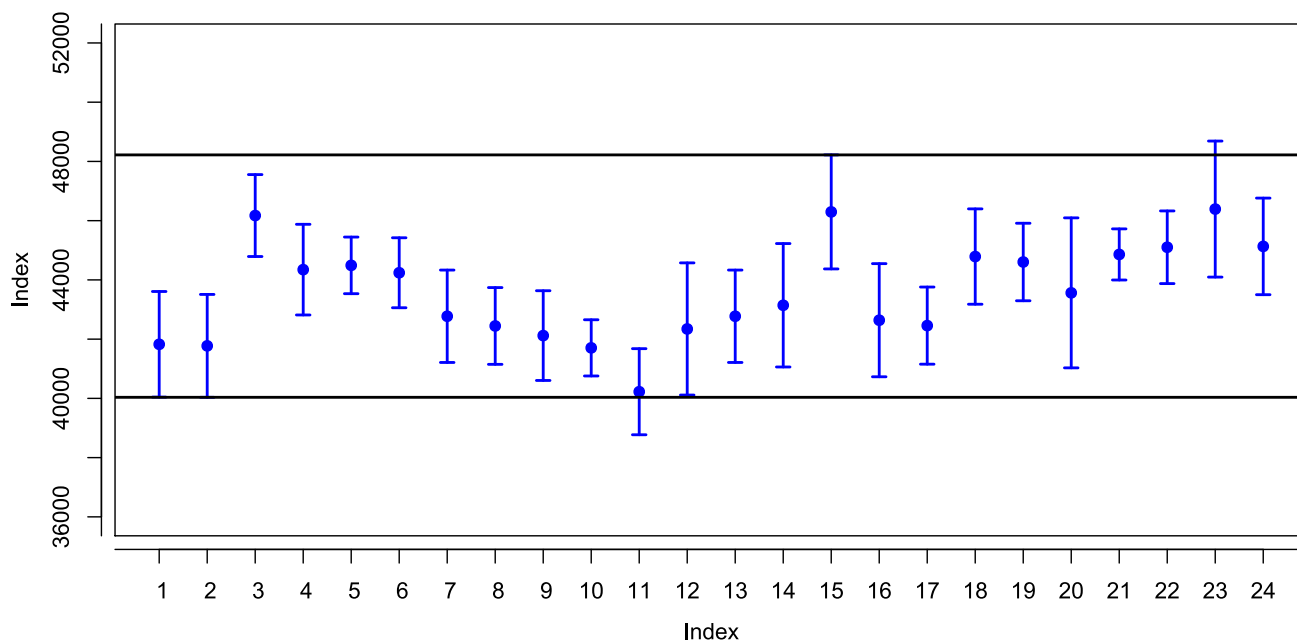
Mean	SD	CV	Margins	
43591.965	1647.4287	3.78%	40036.199	– 48220.383

Development assays

Index	Assay	Value	Confidence interval		
1	Document-1636: Assay 1, STD	41825.789	40042.924 – 43608.655	✓
2	Document-1637: Assay 2, STD	41772.890	40036.199 – 43509.581	✓
3	Document-1638: Assay 3, STD	46172.538	44789.426 – 47555.650	✓
4	Document-1639: Assay 4, STD	44346.551	42816.043 – 45877.058	✓
5	Document-1640: Assay 5, STD	44490.477	43534.461 – 45446.492	✓
6	Document-1641: Assay 6, STD	44241.303	43060.175 – 45422.432	✓
7	Document-1642: Assay 7, STD	42772.304	41212.512 – 44332.095	✓
8	Document-1643: Assay 8, STD	42444.969	41148.826 – 43741.112	✓
9	Document-1644: Assay 9, STD	42119.697	40604.793 – 43634.601	✓
10	Document-1645: Assay 10, STD	41705.390	40756.348 – 42654.431	✓
11	Document-1646: Assay 11, STD	40225.032	38771.542 – 41678.522	✗
12	Document-1647: Assay 12, STD	42343.738	40112.456 – 44575.020	✓
13	Document-1648: Assay 13, STD	42772.304	41212.512 – 44332.095	✓
14	Document-1649: Assay 14, STD	43143.485	41059.827 – 45227.144	✓
15	Document-1650: Assay 15, STD	46295.492	44370.602 – 48220.383	✓
16	Document-1651: Assay 16, STD	42639.170	40729.221 – 44549.120	✓
17	Document-1652: Assay 17, STD	42456.859	41154.597 – 43759.121	✓
18	Document-1653: Assay 18, STD	44788.158	43178.476 – 46397.840	✓
19	Document-1654: Assay 19, STD	44604.192	43295.363 – 45913.022	✓
20	Document-1655: Assay 20, STD	43562.518	41030.204 – 46094.831	✓
21	Document-1656: Assay 21, STD	44859.659	43996.503 – 45722.815	✓
22	Document-1657: Assay 22, STD	45102.045	43875.362 – 46328.728	✓
23	Document-1658: Assay 23, STD	46391.286	44094.871 – 48687.702	✗
24	Document-1659: Assay 24, STD	45131.318	43500.515 – 46762.121	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

## Equivalence test parameter estimate: Ratio of asymptotes (nonlinear models)
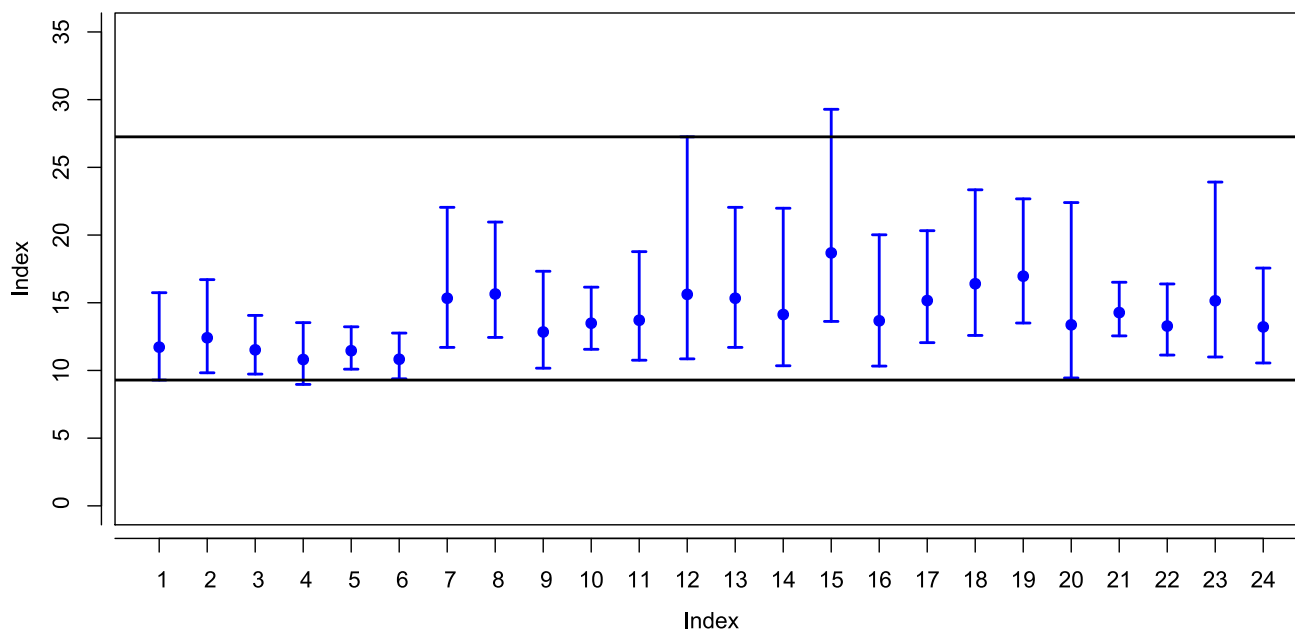
Mean	SD	CV	Margins
13.95890	1.99980	14.33%	9.29039 – 27.25354

Development assays

Index	Assay	Value	Confidence interval	
1	Document-1636: Assay 1, STD	11.72047	9.29039 – 15.74294	✓
2	Document-1637: Assay 2, STD	12.41456	9.82734 – 16.70783	✓
3	Document-1638: Assay 3, STD	11.52188	9.73168 – 14.06519	✓
4	Document-1639: Assay 4, STD	10.80726	8.96853 – 13.53170	✗
5	Document-1640: Assay 5, STD	11.45848	10.09470 – 13.22414	✓
6	Document-1641: Assay 6, STD	10.82726	9.38366 – 12.76103	✓
7	Document-1642: Assay 7, STD	15.33359	11.70291 – 22.04699	✓
8	Document-1643: Assay 8, STD	15.64633	12.43903 – 20.95959	✓
9	Document-1644: Assay 9, STD	12.84194	10.16756 – 17.32545	✓
10	Document-1645: Assay 10, STD	13.48945	11.56187 – 16.15121	✓
11	Document-1646: Assay 11, STD	13.70831	10.75677 – 18.77414	✓
12	Document-1647: Assay 12, STD	15.61941	10.85625 – 27.25354	✓
13	Document-1648: Assay 13, STD	15.33359	11.70291 – 22.04699	✓
14	Document-1649: Assay 14, STD	14.13051	10.34640 – 21.98066	✓
15	Document-1650: Assay 15, STD	18.68219	13.62169 – 29.28692	✗
16	Document-1651: Assay 16, STD	13.66830	10.32241 – 20.01876	✓
17	Document-1652: Assay 17, STD	15.16228	12.05400 – 20.32266	✓
18	Document-1653: Assay 18, STD	16.40376	12.58578 – 23.34252	✓
19	Document-1654: Assay 19, STD	16.96249	13.50342 – 22.67464	✓
20	Document-1655: Assay 20, STD	13.36852	9.44644 – 22.39892	✓
21	Document-1656: Assay 21, STD	14.27436	12.55305 – 16.51426	✓
22	Document-1657: Assay 22, STD	13.27894	11.13678 – 16.38801	✓
23	Document-1658: Assay 23, STD	15.14458	10.99387 – 23.91307	✓
24	Document-1659: Assay 24, STD	13.21501	10.55210 – 17.56160	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

## Test parameter/property point estimate: A upper asymptote (nonlinear models)
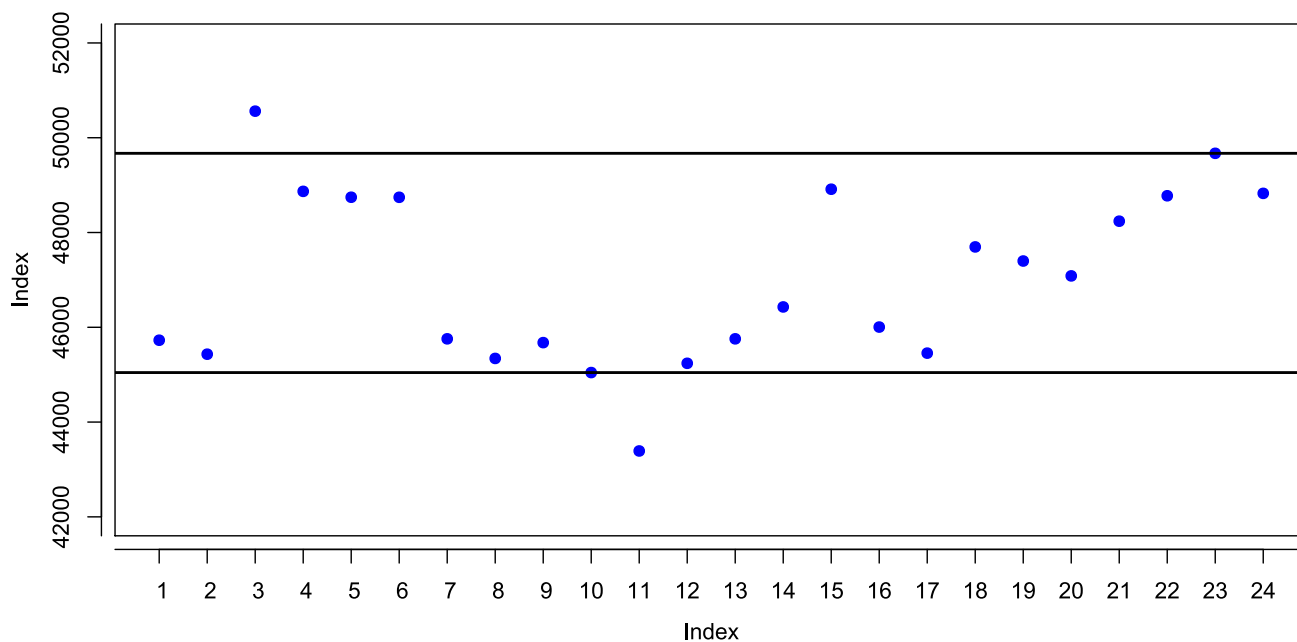
Mean	SD	CV	Margins	
47032.365	1829.9017	3.89%	45044.640	– 49671.078

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	45727.277	✓
2	Document-1637: Assay 2, STD	45432.504	✓
3	Document-1638: Assay 3, STD	50560.779	✗
4	Document-1639: Assay 4, STD	48868.359	✓
5	Document-1640: Assay 5, STD	48744.485	✓
6	Document-1641: Assay 6, STD	48743.199	✓
7	Document-1642: Assay 7, STD	45756.364	✓
8	Document-1643: Assay 8, STD	45342.963	✓
9	Document-1644: Assay 9, STD	45676.520	✓
10	Document-1645: Assay 10, STD	45044.640	✓
11	Document-1646: Assay 11, STD	43390.286	✗
12	Document-1647: Assay 12, STD	45240.143	✓
13	Document-1648: Assay 13, STD	45756.364	✓
14	Document-1649: Assay 14, STD	46429.228	✓
15	Document-1650: Assay 15, STD	48913.692	✓
16	Document-1651: Assay 16, STD	46004.986	✓
17	Document-1652: Assay 17, STD	45454.742	✓
18	Document-1653: Assay 18, STD	47695.770	✓
19	Document-1654: Assay 19, STD	47398.505	✓
20	Document-1655: Assay 20, STD	47084.565	✓
21	Document-1656: Assay 21, STD	48239.080	✓
22	Document-1657: Assay 22, STD	48775.166	✓
23	Document-1658: Assay 23, STD	49671.078	✓
24	Document-1659: Assay 24, STD	48826.062	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

**Test parameter/property point estimate: B parameter (nonlinear models)**
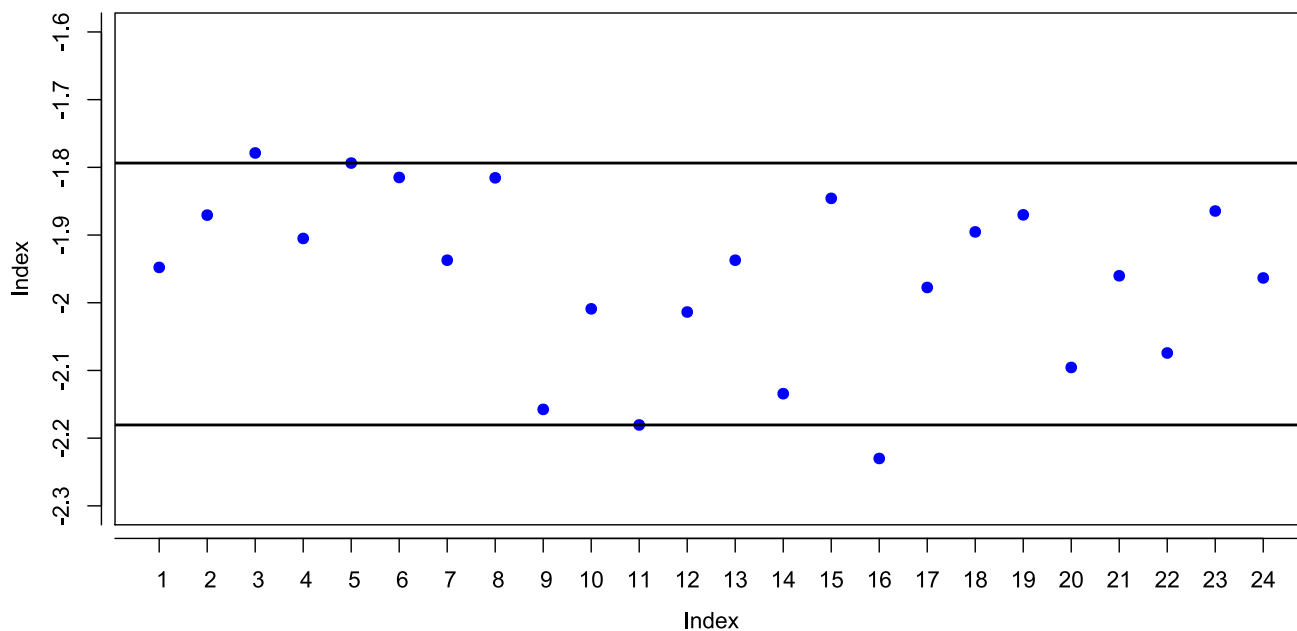
Mean	SD	CV	Margins
-1.96134	0.12803	-6.53%	-2.18051 – -1.79367

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	-1.94779	✓
2	Document-1637: Assay 2, STD	-1.87054	✓
3	Document-1638: Assay 3, STD	-1.77876	✗
4	Document-1639: Assay 4, STD	-1.90502	✓
5	Document-1640: Assay 5, STD	-1.79367	✓
6	Document-1641: Assay 6, STD	-1.81493	✓
7	Document-1642: Assay 7, STD	-1.93716	✓
8	Document-1643: Assay 8, STD	-1.81547	✓
9	Document-1644: Assay 9, STD	-2.15750	✓
10	Document-1645: Assay 10, STD	-2.00899	✓
11	Document-1646: Assay 11, STD	-2.18051	✓
12	Document-1647: Assay 12, STD	-2.01369	✓
13	Document-1648: Assay 13, STD	-1.93716	✓
14	Document-1649: Assay 14, STD	-2.13433	✓
15	Document-1650: Assay 15, STD	-1.84579	✓
16	Document-1651: Assay 16, STD	-2.23001	✗
17	Document-1652: Assay 17, STD	-1.97743	✓
18	Document-1653: Assay 18, STD	-1.89534	✓
19	Document-1654: Assay 19, STD	-1.87015	✓
20	Document-1655: Assay 20, STD	-2.09558	✓
21	Document-1656: Assay 21, STD	-1.96017	✓
22	Document-1657: Assay 22, STD	-2.07420	✓
23	Document-1658: Assay 23, STD	-1.86450	✓
24	Document-1659: Assay 24, STD	-1.96338	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

## Test parameter/property point estimate: C parameter (nonlinear models)
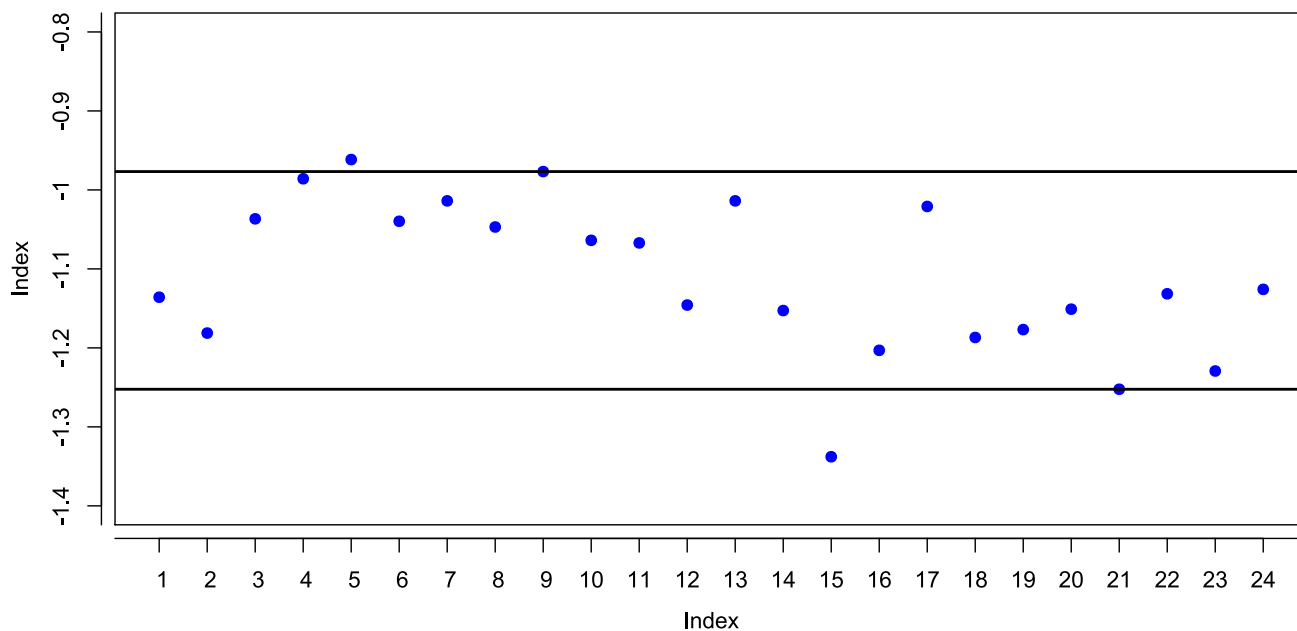
Mean	SD	CV	Margins
-1.10989	0.09703	-8.74%	-1.25237 – -0.97677

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	-1.13584	✓
2	Document-1637: Assay 2, STD	-1.18123	✓
3	Document-1638: Assay 3, STD	-1.03662	✓
4	Document-1639: Assay 4, STD	-0.98587	✓
5	Document-1640: Assay 5, STD	-0.96158	✗
6	Document-1641: Assay 6, STD	-1.03969	✓
7	Document-1642: Assay 7, STD	-1.01388	✓
8	Document-1643: Assay 8, STD	-1.04695	✓
9	Document-1644: Assay 9, STD	-0.97677	✓
10	Document-1645: Assay 10, STD	-1.06383	✓
11	Document-1646: Assay 11, STD	-1.06713	✓
12	Document-1647: Assay 12, STD	-1.14576	✓
13	Document-1648: Assay 13, STD	-1.01388	✓
14	Document-1649: Assay 14, STD	-1.15273	✓
15	Document-1650: Assay 15, STD	-1.33785	✗
16	Document-1651: Assay 16, STD	-1.20308	✓
17	Document-1652: Assay 17, STD	-1.02093	✓
18	Document-1653: Assay 18, STD	-1.18682	✓
19	Document-1654: Assay 19, STD	-1.17683	✓
20	Document-1655: Assay 20, STD	-1.15096	✓
21	Document-1656: Assay 21, STD	-1.25237	✓
22	Document-1657: Assay 22, STD	-1.13152	✓
23	Document-1658: Assay 23, STD	-1.22927	✓
24	Document-1659: Assay 24, STD	-1.12591	✓

Test parameter/property point estimate: D lower asymptote (nonlinear models)
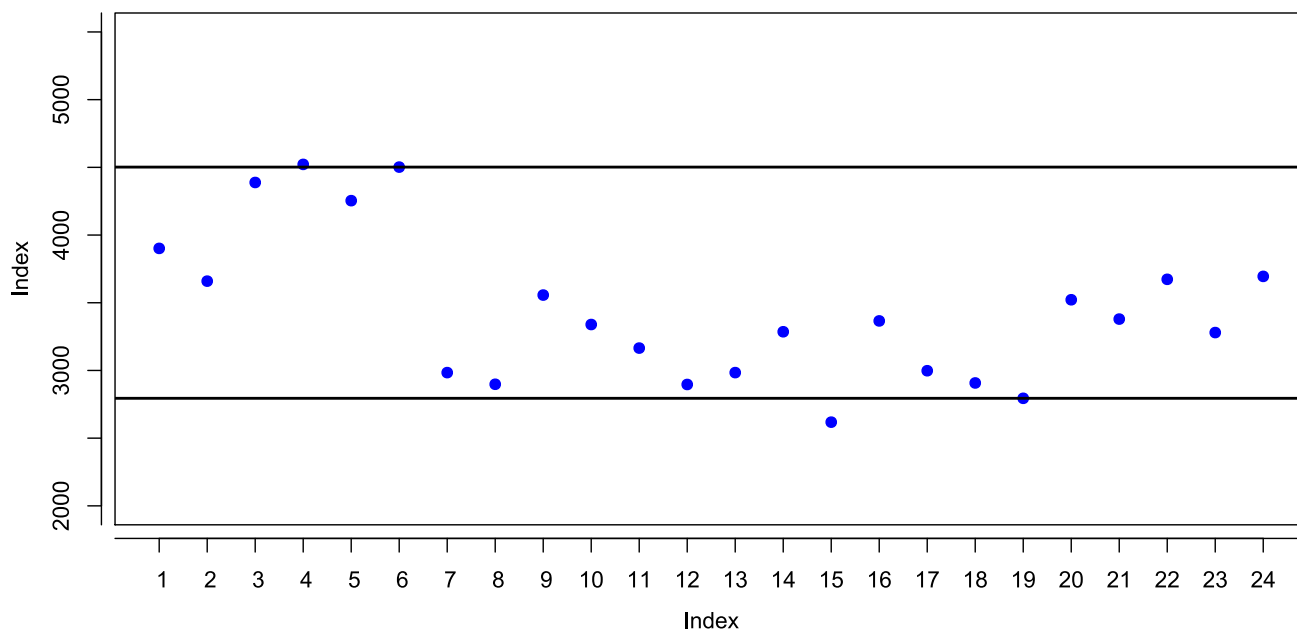
Mean	SD	CV	Margins
3440.3998	550.92770	16.01%	2794.3128 – 4501.8964

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	3901.4881	✓
2	Document-1637: Assay 2, STD	3659.6141	✓
3	Document-1638: Assay 3, STD	4388.2405	✓
4	Document-1639: Assay 4, STD	4521.8083	✗
5	Document-1640: Assay 5, STD	4254.0086	✓
6	Document-1641: Assay 6, STD	4501.8964	✓
7	Document-1642: Assay 7, STD	2984.0608	✓
8	Document-1643: Assay 8, STD	2897.9937	✓
9	Document-1644: Assay 9, STD	3556.8233	✓
10	Document-1645: Assay 10, STD	3339.2501	✓
11	Document-1646: Assay 11, STD	3165.2540	✓
12	Document-1647: Assay 12, STD	2896.4053	✓
13	Document-1648: Assay 13, STD	2984.0608	✓
14	Document-1649: Assay 14, STD	3285.7430	✓
15	Document-1650: Assay 15, STD	2618.1994	✗
16	Document-1651: Assay 16, STD	3365.8153	✓
17	Document-1652: Assay 17, STD	2997.8831	✓
18	Document-1653: Assay 18, STD	2907.6123	✓
19	Document-1654: Assay 19, STD	2794.3128	✓
20	Document-1655: Assay 20, STD	3522.0470	✓
21	Document-1656: Assay 21, STD	3379.4209	✓
22	Document-1657: Assay 22, STD	3673.1214	✓
23	Document-1658: Assay 23, STD	3279.7920	✓
24	Document-1659: Assay 24, STD	3694.7441	✓

Test parameter/property point estimate: Difference of asymptotes (nonlinear models)
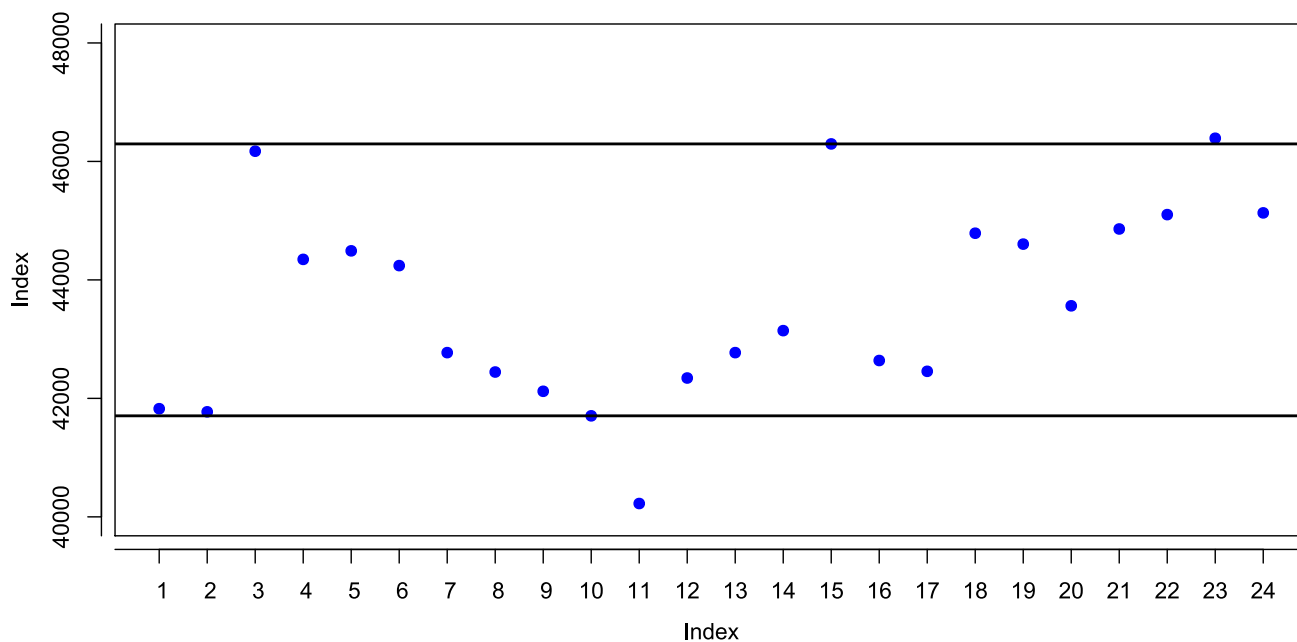
Mean	SD	CV	Margins	
43591.965	1647.4287	3.78%	41705.390	− 46295.492

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	41825.789	✓
2	Document-1637: Assay 2, STD	41772.890	✓
3	Document-1638: Assay 3, STD	46172.538	✓
4	Document-1639: Assay 4, STD	44346.551	✓
5	Document-1640: Assay 5, STD	44490.477	✓
6	Document-1641: Assay 6, STD	44241.303	✓
7	Document-1642: Assay 7, STD	42772.304	✓
8	Document-1643: Assay 8, STD	42444.969	✓
9	Document-1644: Assay 9, STD	42119.697	✓
10	Document-1645: Assay 10, STD	41705.390	✓
11	Document-1646: Assay 11, STD	40225.032	✗
12	Document-1647: Assay 12, STD	42343.738	✓
13	Document-1648: Assay 13, STD	42772.304	✓
14	Document-1649: Assay 14, STD	43143.485	✓
15	Document-1650: Assay 15, STD	46295.492	✓
16	Document-1651: Assay 16, STD	42639.170	✓
17	Document-1652: Assay 17, STD	42456.859	✓
18	Document-1653: Assay 18, STD	44788.158	✓
19	Document-1654: Assay 19, STD	44604.192	✓
20	Document-1655: Assay 20, STD	43562.518	✓
21	Document-1656: Assay 21, STD	44859.659	✓
22	Document-1657: Assay 22, STD	45102.045	✓
23	Document-1658: Assay 23, STD	46391.286	✗
24	Document-1659: Assay 24, STD	45131.318	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

## Test parameter/property point estimate: Ratio of asymptotes (nonlinear models)
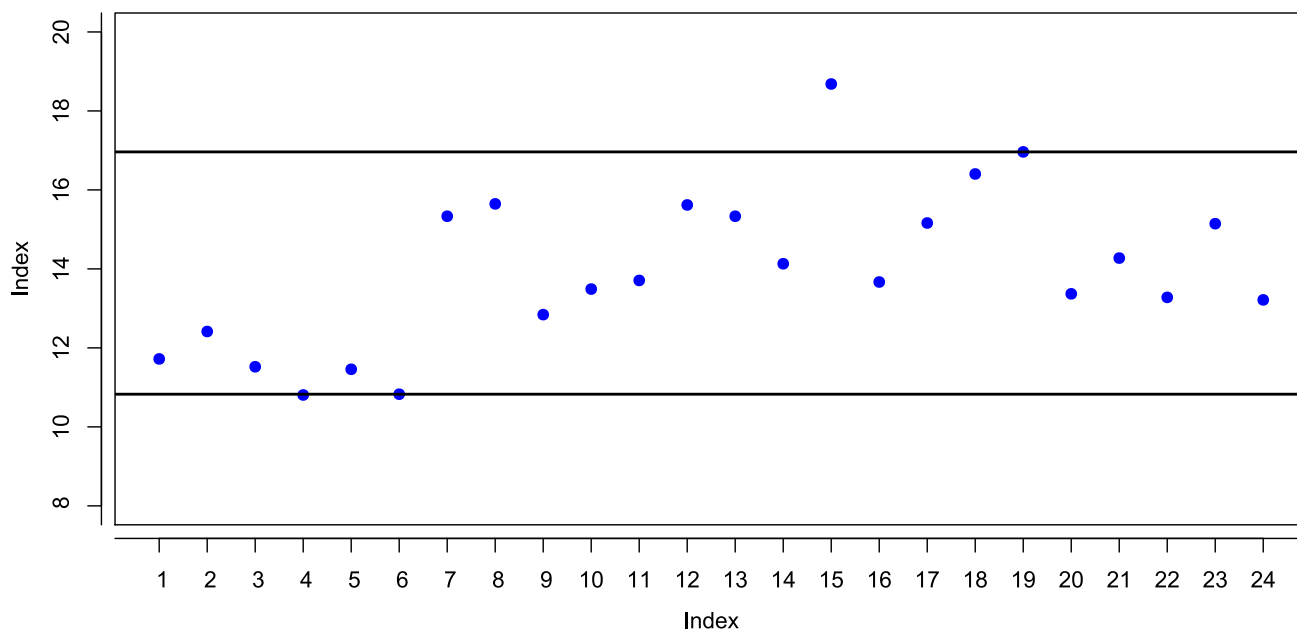
Mean	SD	CV	Margins
13.95890	1.99980	14.33%	10.82726 – 16.96249

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	11.72047	✓
2	Document-1637: Assay 2, STD	12.41456	✓
3	Document-1638: Assay 3, STD	11.52188	✓
4	Document-1639: Assay 4, STD	10.80726	✗
5	Document-1640: Assay 5, STD	11.45848	✓
6	Document-1641: Assay 6, STD	10.82726	✓
7	Document-1642: Assay 7, STD	15.33359	✓
8	Document-1643: Assay 8, STD	15.64633	✓
9	Document-1644: Assay 9, STD	12.84194	✓
10	Document-1645: Assay 10, STD	13.48945	✓
11	Document-1646: Assay 11, STD	13.70831	✓
12	Document-1647: Assay 12, STD	15.61941	✓
13	Document-1648: Assay 13, STD	15.33359	✓
14	Document-1649: Assay 14, STD	14.13051	✓
15	Document-1650: Assay 15, STD	18.68219	✗
16	Document-1651: Assay 16, STD	13.66830	✓
17	Document-1652: Assay 17, STD	15.16228	✓
18	Document-1653: Assay 18, STD	16.40376	✓
19	Document-1654: Assay 19, STD	16.96249	✓
20	Document-1655: Assay 20, STD	13.36852	✓
21	Document-1656: Assay 21, STD	14.27436	✓
22	Document-1657: Assay 22, STD	13.27894	✓
23	Document-1658: Assay 23, STD	15.14458	✓
24	Document-1659: Assay 24, STD	13.21501	✓

Anova terms: Sum of squares model
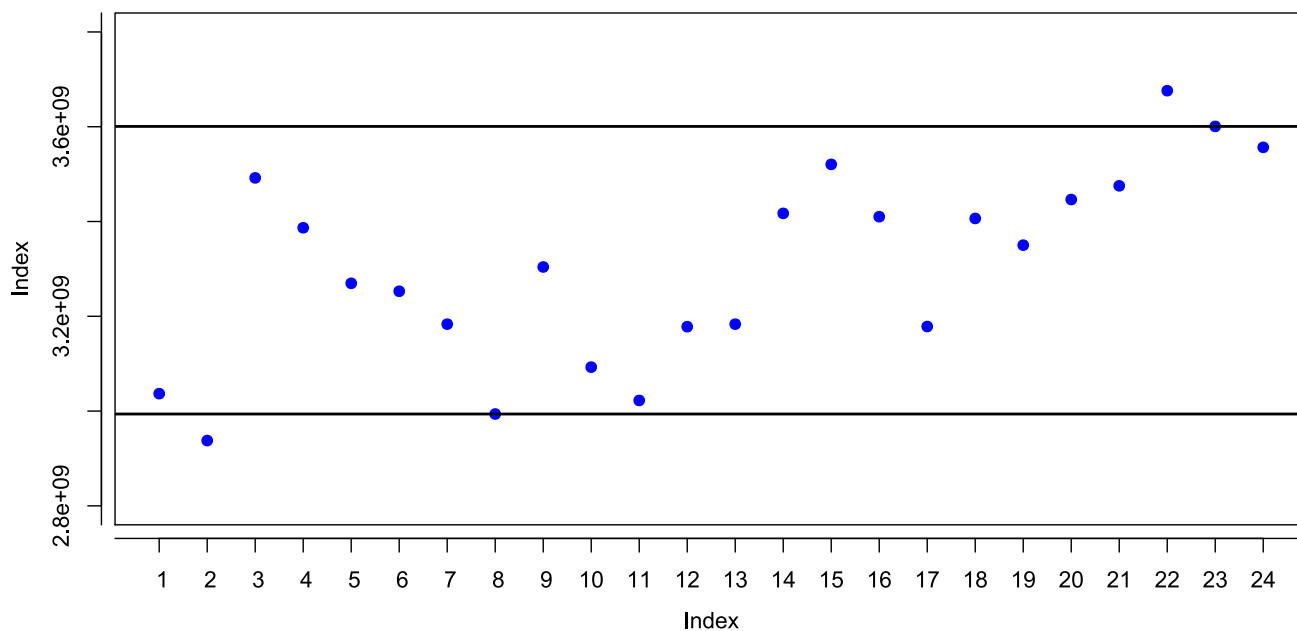
Mean	SD	CV	Margins
3.307 E+09	2.038 E+08	6.16%	2.994 E+09 – 3.601 E+09

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	3.037 E+09	✓
2	Document-1637: Assay 2, STD	2.938 E+09	✗
3	Document-1638: Assay 3, STD	3.492 E+09	✓
4	Document-1639: Assay 4, STD	3.387 E+09	✓
5	Document-1640: Assay 5, STD	3.270 E+09	✓
6	Document-1641: Assay 6, STD	3.253 E+09	✓
7	Document-1642: Assay 7, STD	3.183 E+09	✓
8	Document-1643: Assay 8, STD	2.994 E+09	✓
9	Document-1644: Assay 9, STD	3.304 E+09	✓
10	Document-1645: Assay 10, STD	3.093 E+09	✓
11	Document-1646: Assay 11, STD	3.022 E+09	✓
12	Document-1647: Assay 12, STD	3.178 E+09	✓
13	Document-1648: Assay 13, STD	3.183 E+09	✓
14	Document-1649: Assay 14, STD	3.417 E+09	✓
15	Document-1650: Assay 15, STD	3.521 E+09	✓
16	Document-1651: Assay 16, STD	3.410 E+09	✓
17	Document-1652: Assay 17, STD	3.178 E+09	✓
18	Document-1653: Assay 18, STD	3.406 E+09	✓
19	Document-1654: Assay 19, STD	3.350 E+09	✓
20	Document-1655: Assay 20, STD	3.446 E+09	✓
21	Document-1656: Assay 21, STD	3.475 E+09	✓
22	Document-1657: Assay 22, STD	3.676 E+09	✗
23	Document-1658: Assay 23, STD	3.601 E+09	✓
24	Document-1659: Assay 24, STD	3.557 E+09	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE
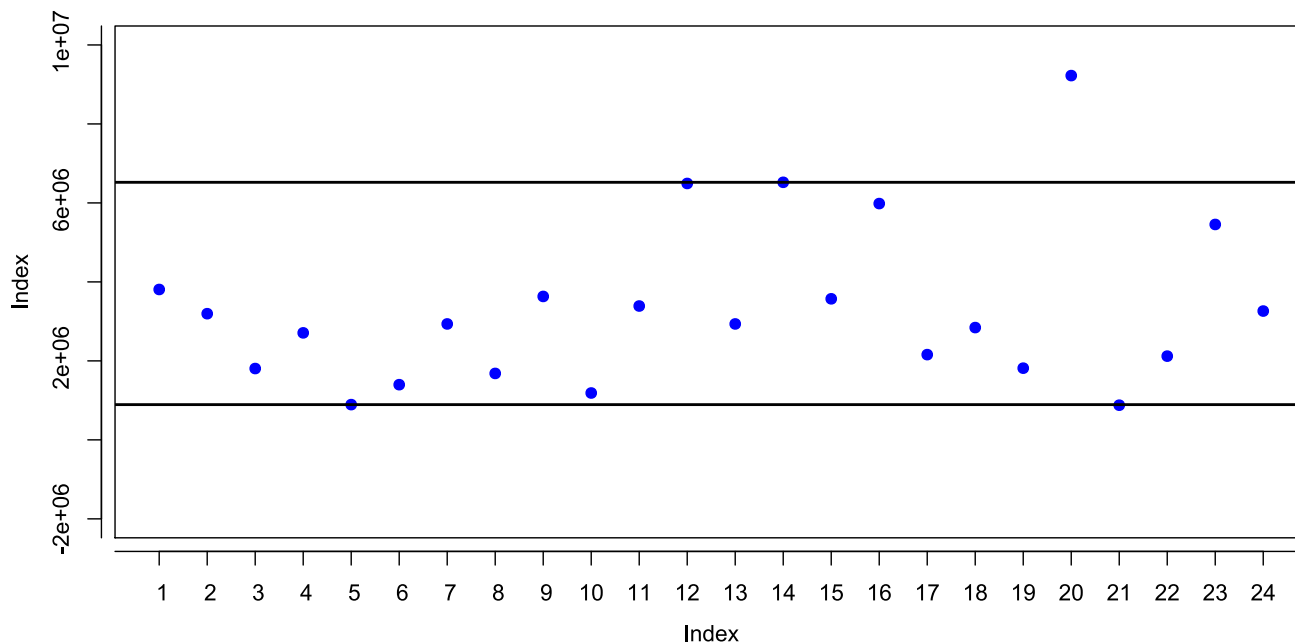
Anova terms: Sum of squares residual error

Mean	SD	CV	Margins	
3328998.2	2067013.7	62.09%	892490.03	− 6521855.0

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	3808131.3	✓
2	Document-1637: Assay 2, STD	3194885.8	✓
3	Document-1638: Assay 3, STD	1806334.8	✓
4	Document-1639: Assay 4, STD	2709390.0	✓
5	Document-1640: Assay 5, STD	892490.03	✓
6	Document-1641: Assay 6, STD	1397402.9	✓
7	Document-1642: Assay 7, STD	2935356.3	✓
8	Document-1643: Assay 8, STD	1682338.1	✓
9	Document-1644: Assay 9, STD	3631837.6	✓
10	Document-1645: Assay 10, STD	1186796.5	✓
11	Document-1646: Assay 11, STD	3389389.2	✓
12	Document-1647: Assay 12, STD	6492579.7	✓
13	Document-1648: Assay 13, STD	2935356.3	✓
14	Document-1649: Assay 14, STD	6521855.0	✓
15	Document-1650: Assay 15, STD	3571656.9	✓
16	Document-1651: Assay 16, STD	5983400.5	✓
17	Document-1652: Assay 17, STD	2158525.8	✓
18	Document-1653: Assay 18, STD	2843534.4	✓
19	Document-1654: Assay 19, STD	1815749.6	✓
20	Document-1655: Assay 20, STD	9224080.5	✗
21	Document-1656: Assay 21, STD	878078.08	✗
22	Document-1657: Assay 22, STD	2120315.5	✓
23	Document-1658: Assay 23, STD	5454517.3	✓
24	Document-1659: Assay 24, STD	3261953.8	✓

Anova terms: Sum of squares lack of fit

Mean	SD	CV		Margins	
3328998.2	2067013.7	62.09%	892490.03	− 6521855.0	

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	3808131.3	✓
2	Document-1637: Assay 2, STD	3194885.8	✓
3	Document-1638: Assay 3, STD	1806334.8	✓
4	Document-1639: Assay 4, STD	2709390.0	✓
5	Document-1640: Assay 5, STD	892490.03	✓
6	Document-1641: Assay 6, STD	1397402.9	✓
7	Document-1642: Assay 7, STD	2935356.3	✓
8	Document-1643: Assay 8, STD	1682338.1	✓
9	Document-1644: Assay 9, STD	3631837.6	✓
10	Document-1645: Assay 10, STD	1186796.5	✓
11	Document-1646: Assay 11, STD	3389389.2	✓
12	Document-1647: Assay 12, STD	6492579.7	✓
13	Document-1648: Assay 13, STD	2935356.3	✓
14	Document-1649: Assay 14, STD	6521855.0	✓
15	Document-1650: Assay 15, STD	3571656.9	✓
16	Document-1651: Assay 16, STD	5983400.5	✓
17	Document-1652: Assay 17, STD	2158525.8	✓
18	Document-1653: Assay 18, STD	2843534.4	✓
19	Document-1654: Assay 19, STD	1815749.6	✓
20	Document-1655: Assay 20, STD	9224080.5	✗
21	Document-1656: Assay 21, STD	878078.08	✗
22	Document-1657: Assay 22, STD	2120315.5	✓
23	Document-1658: Assay 23, STD	5454517.3	✓
24	Document-1659: Assay 24, STD	3261953.8	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE
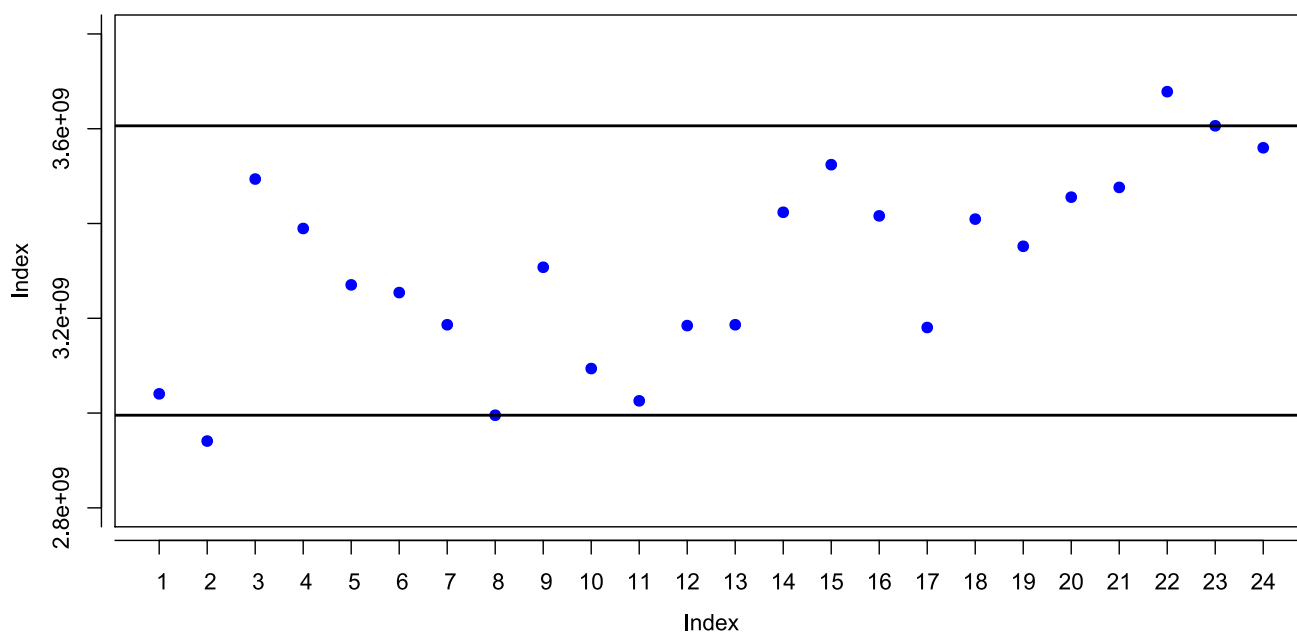
Anova terms: Sum of squares pure error
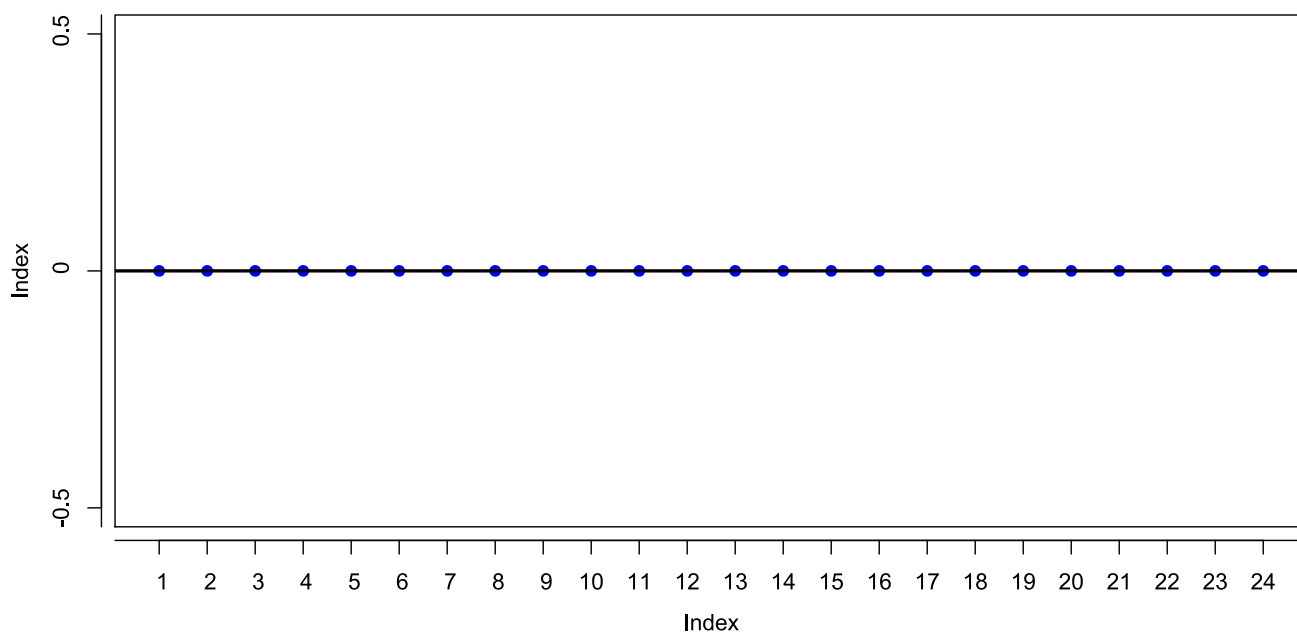
Mean	SD	CV	Margins	
0	0	N/A	0	− 0

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	0	✓
2	Document-1637: Assay 2, STD	0	✓
3	Document-1638: Assay 3, STD	0	✓
4	Document-1639: Assay 4, STD	0	✓
5	Document-1640: Assay 5, STD	0	✓
6	Document-1641: Assay 6, STD	0	✓
7	Document-1642: Assay 7, STD	0	✓
8	Document-1643: Assay 8, STD	0	✓
9	Document-1644: Assay 9, STD	0	✓
10	Document-1645: Assay 10, STD	0	✓
11	Document-1646: Assay 11, STD	0	✓
12	Document-1647: Assay 12, STD	0	✓
13	Document-1648: Assay 13, STD	0	✓
14	Document-1649: Assay 14, STD	0	✓
15	Document-1650: Assay 15, STD	0	✓
16	Document-1651: Assay 16, STD	0	✓
17	Document-1652: Assay 17, STD	0	✓
18	Document-1653: Assay 18, STD	0	✓
19	Document-1654: Assay 19, STD	0	✓
20	Document-1655: Assay 20, STD	0	✓
21	Document-1656: Assay 21, STD	0	✓
22	Document-1657: Assay 22, STD	0	✓
23	Document-1658: Assay 23, STD	0	✓
24	Document-1659: Assay 24, STD	0	✓

Anova terms: Sum of squares total

Mean	SD	CV	Margins
3.310 E+09	2.042 E+08	6.17%	2.995 E+09 – 3.606 E+09

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	3.041 E+09	✓
2	Document-1637: Assay 2, STD	2.941 E+09	✗
3	Document-1638: Assay 3, STD	3.494 E+09	✓
4	Document-1639: Assay 4, STD	3.389 E+09	✓
5	Document-1640: Assay 5, STD	3.270 E+09	✓
6	Document-1641: Assay 6, STD	3.254 E+09	✓
7	Document-1642: Assay 7, STD	3.186 E+09	✓
8	Document-1643: Assay 8, STD	2.995 E+09	✓
9	Document-1644: Assay 9, STD	3.308 E+09	✓
10	Document-1645: Assay 10, STD	3.094 E+09	✓
11	Document-1646: Assay 11, STD	3.026 E+09	✓
12	Document-1647: Assay 12, STD	3.185 E+09	✓
13	Document-1648: Assay 13, STD	3.186 E+09	✓
14	Document-1649: Assay 14, STD	3.424 E+09	✓
15	Document-1650: Assay 15, STD	3.524 E+09	✓
16	Document-1651: Assay 16, STD	3.416 E+09	✓
17	Document-1652: Assay 17, STD	3.181 E+09	✓
18	Document-1653: Assay 18, STD	3.409 E+09	✓
19	Document-1654: Assay 19, STD	3.352 E+09	✓
20	Document-1655: Assay 20, STD	3.456 E+09	✓
21	Document-1656: Assay 21, STD	3.476 E+09	✓
22	Document-1657: Assay 22, STD	3.678 E+09	✗
23	Document-1658: Assay 23, STD	3.606 E+09	✓
24	Document-1659: Assay 24, STD	3.560 E+09	✓

Anova terms: Mean squared model
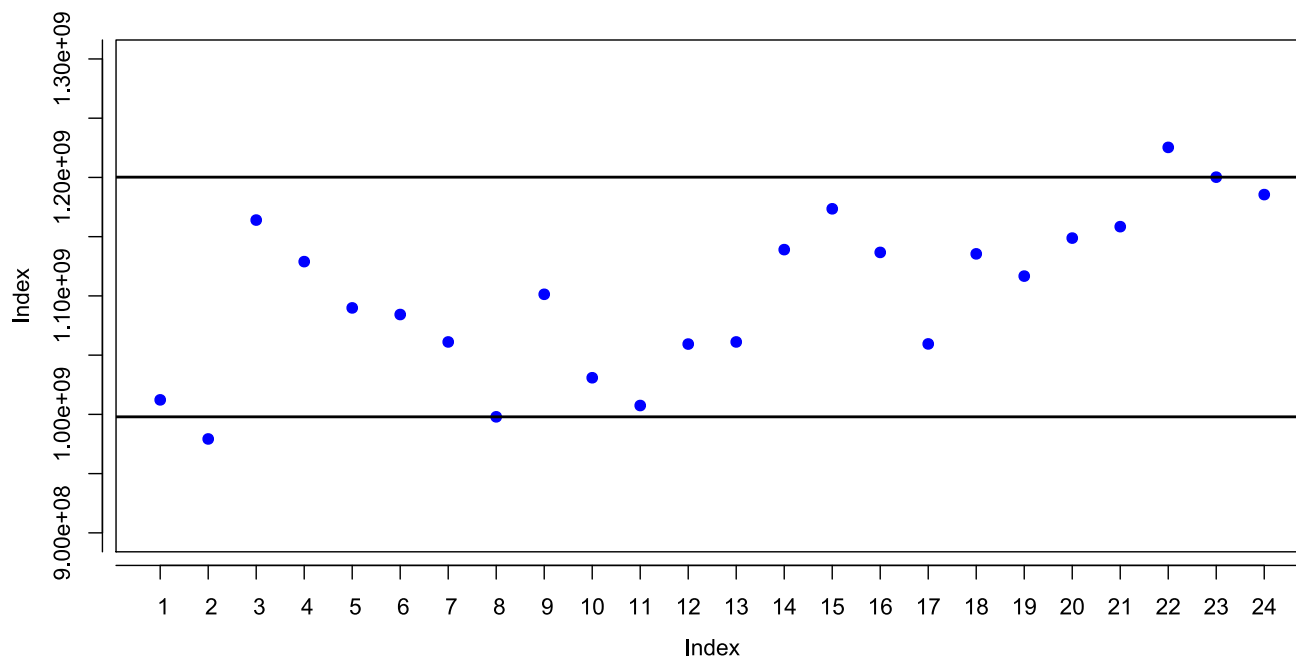
Mean	SD	CV	Margins
1.102 E+09	6.795 E+07	6.16%	9.979 E+08 – 1.200 E+09

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	1.012 E+09	✓
2	Document-1637: Assay 2, STD	9.793 E+08	✗
3	Document-1638: Assay 3, STD	1.164 E+09	✓
4	Document-1639: Assay 4, STD	1.129 E+09	✓
5	Document-1640: Assay 5, STD	1.090 E+09	✓
6	Document-1641: Assay 6, STD	1.084 E+09	✓
7	Document-1642: Assay 7, STD	1.061 E+09	✓
8	Document-1643: Assay 8, STD	9.979 E+08	✓
9	Document-1644: Assay 9, STD	1.101 E+09	✓
10	Document-1645: Assay 10, STD	1.031 E+09	✓
11	Document-1646: Assay 11, STD	1.007 E+09	✓
12	Document-1647: Assay 12, STD	1.059 E+09	✓
13	Document-1648: Assay 13, STD	1.061 E+09	✓
14	Document-1649: Assay 14, STD	1.139 E+09	✓
15	Document-1650: Assay 15, STD	1.174 E+09	✓
16	Document-1651: Assay 16, STD	1.137 E+09	✓
17	Document-1652: Assay 17, STD	1.059 E+09	✓
18	Document-1653: Assay 18, STD	1.135 E+09	✓
19	Document-1654: Assay 19, STD	1.117 E+09	✓
20	Document-1655: Assay 20, STD	1.149 E+09	✓
21	Document-1656: Assay 21, STD	1.158 E+09	✓
22	Document-1657: Assay 22, STD	1.225 E+09	✗
23	Document-1658: Assay 23, STD	1.200 E+09	✓
24	Document-1659: Assay 24, STD	1.186 E+09	✓

Anova terms: Mean squared residual error

Mean	SD	CV	Margins	
416124.77	258376.72	62.09%	111561.25	− 815231.88

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	476016.41	✓
2	Document-1637: Assay 2, STD	399360.73	✓
3	Document-1638: Assay 3, STD	225791.84	✓
4	Document-1639: Assay 4, STD	338673.75	✓
5	Document-1640: Assay 5, STD	111561.25	✓
6	Document-1641: Assay 6, STD	174675.36	✓
7	Document-1642: Assay 7, STD	366919.54	✓
8	Document-1643: Assay 8, STD	210292.26	✓
9	Document-1644: Assay 9, STD	453979.70	✓
10	Document-1645: Assay 10, STD	148349.57	✓
11	Document-1646: Assay 11, STD	423673.65	✓
12	Document-1647: Assay 12, STD	811572.46	✓
13	Document-1648: Assay 13, STD	366919.54	✓
14	Document-1649: Assay 14, STD	815231.88	✓
15	Document-1650: Assay 15, STD	446457.11	✓
16	Document-1651: Assay 16, STD	747925.06	✓
17	Document-1652: Assay 17, STD	269815.73	✓
18	Document-1653: Assay 18, STD	355441.80	✓
19	Document-1654: Assay 19, STD	226968.70	✓
20	Document-1655: Assay 20, STD	1153010.1	✗
21	Document-1656: Assay 21, STD	109759.76	✗
22	Document-1657: Assay 22, STD	265039.44	✓
23	Document-1658: Assay 23, STD	681814.66	✓
24	Document-1659: Assay 24, STD	407744.23	✓

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

Anova terms: Mean squared lack of fit

Mean	SD	CV	Margins	
416124.77	258376.72	62.09%	111561.25	− 815231.88

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	476016.41	✓
2	Document-1637: Assay 2, STD	399360.73	✓
3	Document-1638: Assay 3, STD	225791.84	✓
4	Document-1639: Assay 4, STD	338673.75	✓
5	Document-1640: Assay 5, STD	111561.25	✓
6	Document-1641: Assay 6, STD	174675.36	✓
7	Document-1642: Assay 7, STD	366919.54	✓
8	Document-1643: Assay 8, STD	210292.26	✓
9	Document-1644: Assay 9, STD	453979.70	✓
10	Document-1645: Assay 10, STD	148349.57	✓
11	Document-1646: Assay 11, STD	423673.65	✓
12	Document-1647: Assay 12, STD	811572.46	✓
13	Document-1648: Assay 13, STD	366919.54	✓
14	Document-1649: Assay 14, STD	815231.88	✓
15	Document-1650: Assay 15, STD	446457.11	✓
16	Document-1651: Assay 16, STD	747925.06	✓
17	Document-1652: Assay 17, STD	269815.73	✓
18	Document-1653: Assay 18, STD	355441.80	✓
19	Document-1654: Assay 19, STD	226968.70	✓
20	Document-1655: Assay 20, STD	1153010.1	✗
21	Document-1656: Assay 21, STD	109759.76	✗
22	Document-1657: Assay 22, STD	265039.44	✓
23	Document-1658: Assay 23, STD	681814.66	✓
24	Document-1659: Assay 24, STD	407744.23	✓

Anova terms: Mean squared pure error

Mean	SD	CV	Margins
N/A	N/A	N/A	N/A – N/A

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	N/A	✗
2	Document-1637: Assay 2, STD	N/A	✗
3	Document-1638: Assay 3, STD	N/A	✗
4	Document-1639: Assay 4, STD	N/A	✗
5	Document-1640: Assay 5, STD	N/A	✗
6	Document-1641: Assay 6, STD	N/A	✗
7	Document-1642: Assay 7, STD	N/A	✗
8	Document-1643: Assay 8, STD	N/A	✗
9	Document-1644: Assay 9, STD	N/A	✗
10	Document-1645: Assay 10, STD	N/A	✗
11	Document-1646: Assay 11, STD	N/A	✗
12	Document-1647: Assay 12, STD	N/A	✗
13	Document-1648: Assay 13, STD	N/A	✗
14	Document-1649: Assay 14, STD	N/A	✗
15	Document-1650: Assay 15, STD	N/A	✗
16	Document-1651: Assay 16, STD	N/A	✗
17	Document-1652: Assay 17, STD	N/A	✗
18	Document-1653: Assay 18, STD	N/A	✗
19	Document-1654: Assay 19, STD	N/A	✗
20	Document-1655: Assay 20, STD	N/A	✗
21	Document-1656: Assay 21, STD	N/A	✗
22	Document-1657: Assay 22, STD	N/A	✗
23	Document-1658: Assay 23, STD	N/A	✗
24	Document-1659: Assay 24, STD	N/A	✗

Anova terms: Mean squared total
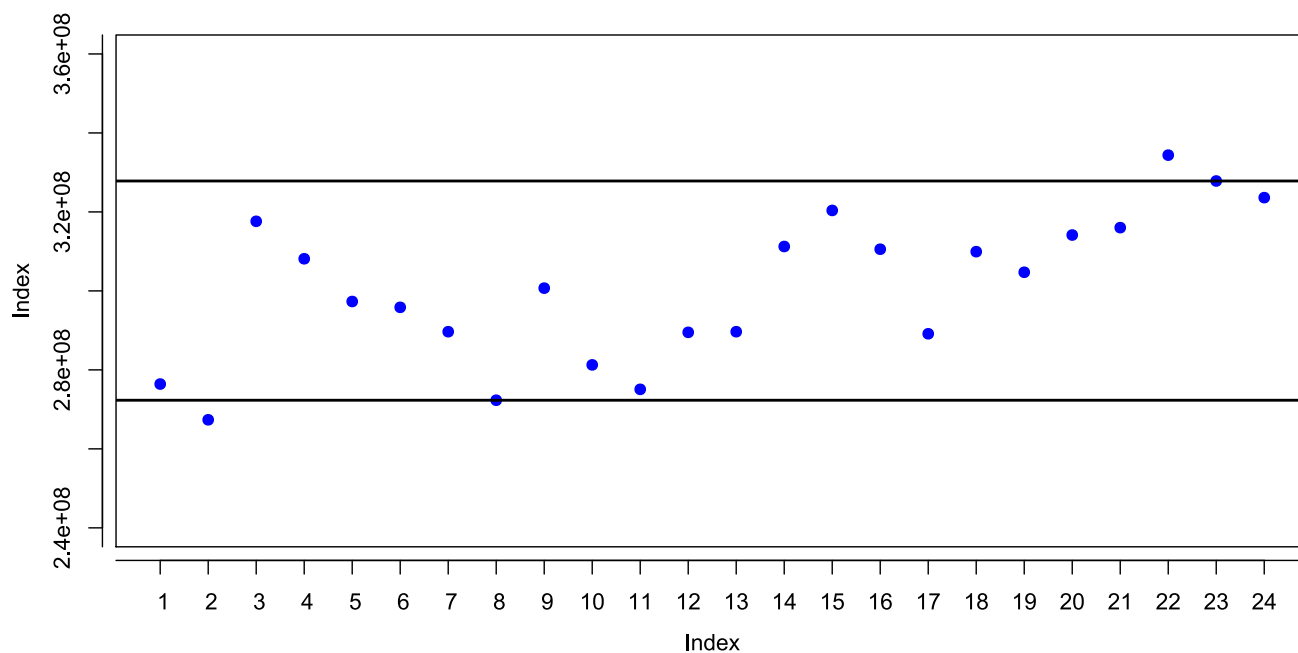
Mean	SD	CV	Margins
3.010 E+08	1.856 E+07	6.17%	2.723 E+08 – 3.278 E+08

Development assays

Index	Assay	Value	
1	Document-1636: Assay 1, STD	2.764 E+08	✓
2	Document-1637: Assay 2, STD	2.674 E+08	✗
3	Document-1638: Assay 3, STD	3.176 E+08	✓
4	Document-1639: Assay 4, STD	3.081 E+08	✓
5	Document-1640: Assay 5, STD	2.973 E+08	✓
6	Document-1641: Assay 6, STD	2.958 E+08	✓
7	Document-1642: Assay 7, STD	2.897 E+08	✓
8	Document-1643: Assay 8, STD	2.723 E+08	✓
9	Document-1644: Assay 9, STD	3.007 E+08	✓
10	Document-1645: Assay 10, STD	2.813 E+08	✓
11	Document-1646: Assay 11, STD	2.751 E+08	✓
12	Document-1647: Assay 12, STD	2.895 E+08	✓
13	Document-1648: Assay 13, STD	2.897 E+08	✓
14	Document-1649: Assay 14, STD	3.112 E+08	✓
15	Document-1650: Assay 15, STD	3.204 E+08	✓
16	Document-1651: Assay 16, STD	3.106 E+08	✓
17	Document-1652: Assay 17, STD	2.891 E+08	✓
18	Document-1653: Assay 18, STD	3.099 E+08	✓
19	Document-1654: Assay 19, STD	3.047 E+08	✓
20	Document-1655: Assay 20, STD	3.141 E+08	✓
21	Document-1656: Assay 21, STD	3.160 E+08	✓
22	Document-1657: Assay 22, STD	3.344 E+08	✗
23	Document-1658: Assay 23, STD	3.278 E+08	✓
24	Document-1659: Assay 24, STD	3.236 E+08	✓

Section III: Strategies overview

Test strategy: Strategy 1

	Upper margin	Lower margin
Equivalence test parameter estimate		
A upper asymptote (nonlinear models)	51235.241	43746.020
B parameter (nonlinear models)	-1.65371	-2.41895
C parameter (nonlinear models)	-0.92055	-1.32225
D lower asymptote (nonlinear models)	5158.0093	1689.6192
Difference of asymptotes (nonlinear models)	48220.383	40036.199
Ratio of asymptotes (nonlinear models)	27.25354	9.29039
Test parameter/property point estimate		
A upper asymptote (nonlinear models)	49671.078	45044.640
B parameter (nonlinear models)	-1.79367	-2.18051
C parameter (nonlinear models)	-0.97677	-1.25237
D lower asymptote (nonlinear models)	4501.8964	2794.3128
Difference of asymptotes (nonlinear models)	46295.492	41705.390
Ratio of asymptotes (nonlinear models)	16.96249	10.82726
Anova terms		
Sum of squares model	3.601 E+09	
Sum of squares residual error	6521855.0	
Sum of squares lack of fit	6521855.0	
Sum of squares pure error	0	
Sum of squares total	3.606 E+09	
Mean squared model	1.200 E+09	
Mean squared residual error	815231.88	
Mean squared lack of fit	815231.88	
Mean squared total	3.278 E+08	

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

Section IV: Strategy verification

Test strategy: Strategy 1

Development assays

Test	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Equivalence test parameter estimate																					
A upper asymptote (nonlinear models)	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Test parameter/property point estimate																					
A upper asymptote (nonlinear models)	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓
Anova terms																					
Sum of squares model	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares residual error	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Sum of squares lack of fit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Sum of squares pure error	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares total	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mean squared model	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mean squared residual error	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Mean squared lack of fit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Mean squared total	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Strategy test result	✓	✓	✗	✗	✗	✓	✓	✓	✗	✓	✗	✗	✓	✓	✗	✗	✓	✓	✓	✗	✓
Expected test result	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Strategy correctly qualifies assay	✓	✓	✗	✗	✗	✓	✓	✓	✗	✓	✗	✗	✓	✓	✗	✗	✓	✓	✓	✗	✓

| Test	22	23	24
Equivalence test parameter estimate			
A upper asymptote (nonlinear models)	✓	✓	✓
B parameter (nonlinear models)	✓	✗	✓
C parameter (nonlinear models)	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✗	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓
Test parameter/property point estimate			
A upper asymptote (nonlinear models)	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✗	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓
Anova terms			
Sum of squares model	✗	✓	✓
Sum of squares residual error	✓	✓	✓
Sum of squares lack of fit	✓	✓	✓
Sum of squares pure error	✓	✓	✓
Sum of squares total	✗	✓	✓
Mean squared model	✗	✓	✓
Mean squared residual error	✓	✓	✓
Mean squared lack of fit	✓	✓	✓
Mean squared total	✗	✓	✓
Strategy test result	✗	✗	✓
Expected test result	✓	✓	✓
Strategy correctly qualifies assay	✗	✗	✓

Section V: Strategy visualization
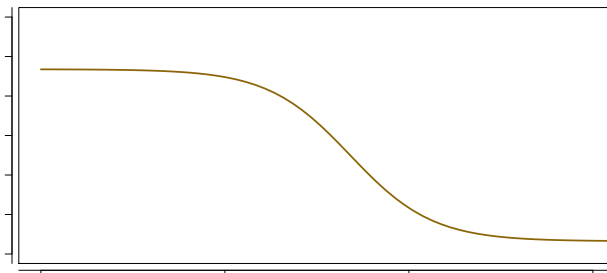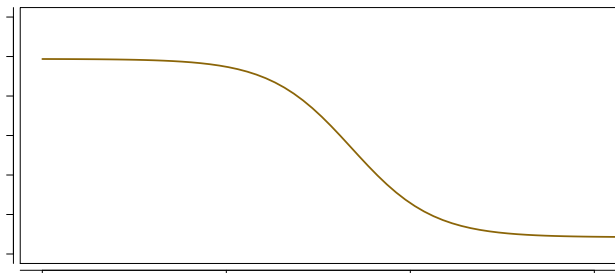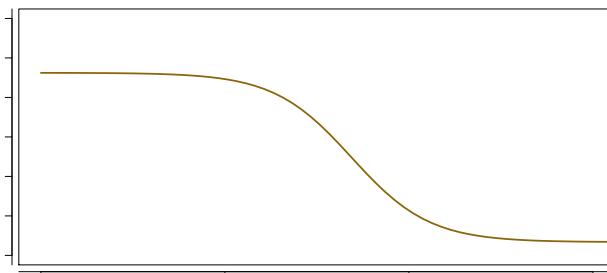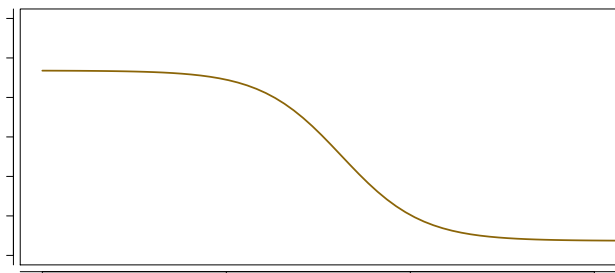
Test strategy: Strategy 1

Development assays: Overlay plot (for comparison)   **Simulation assays: Overlay plot**
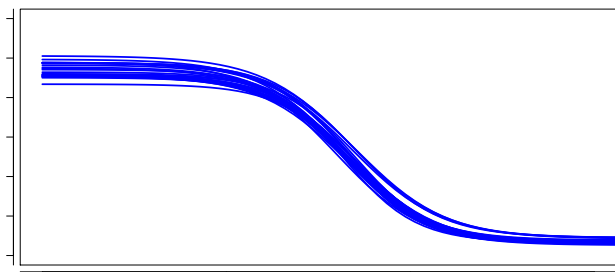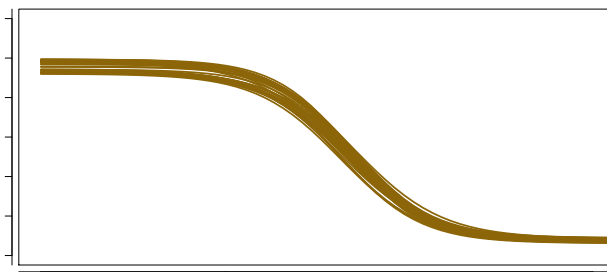
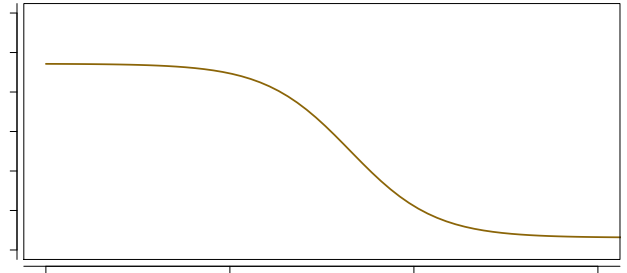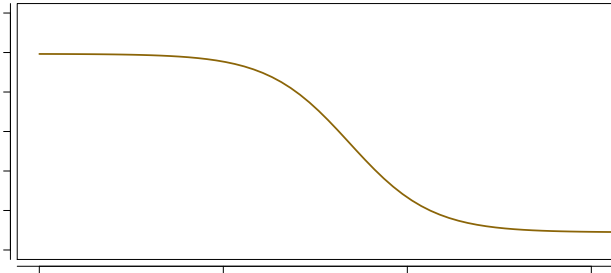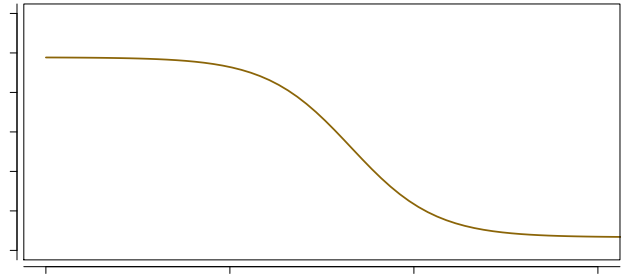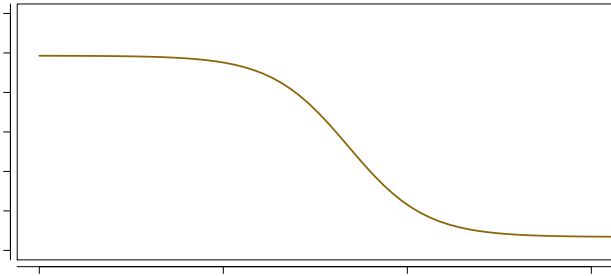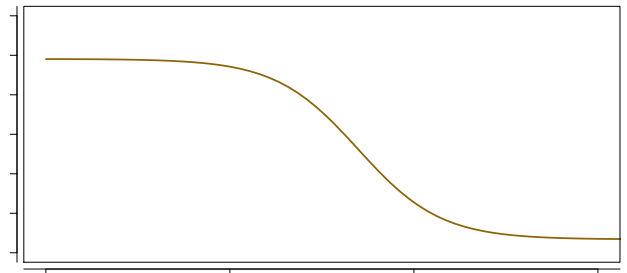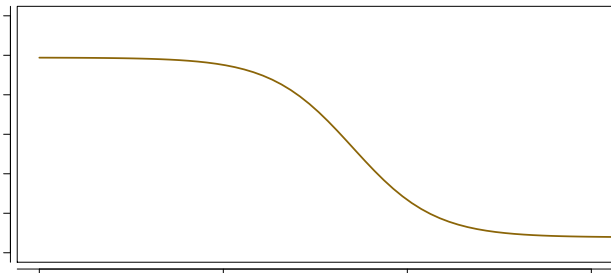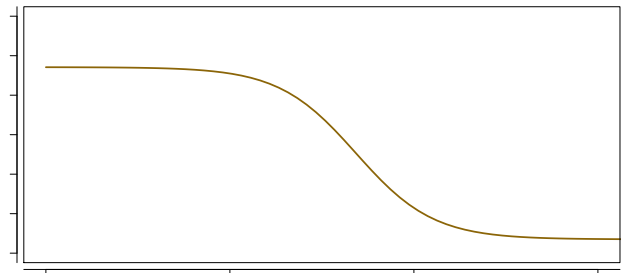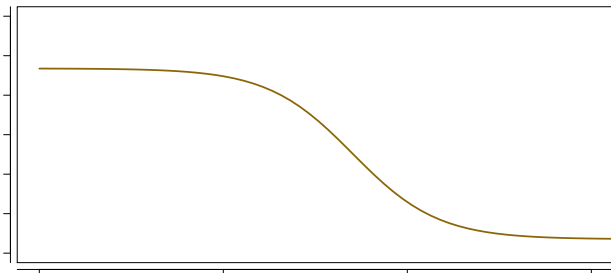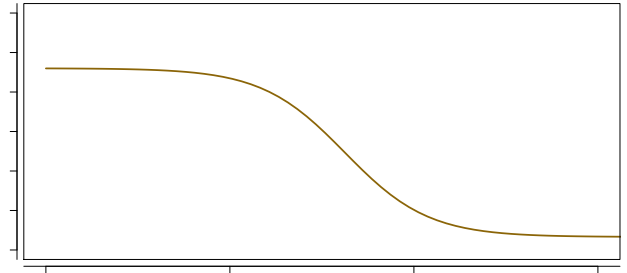|	
Number of simulations:	36
Number of configurations found:	30

Simulation assays: Assay plots

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE

Document-1660 (FP014_Dose-Response-Analysis-Package @ VMS_DATABASE_04\SQL2008)

TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE