Equivalence Margins

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Signatures

Responsibility	Review	Approval

DOCUMENT-106

A23398AB-7853-4E3D-AA1A-5BEDEEC03463

Table of contents

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.

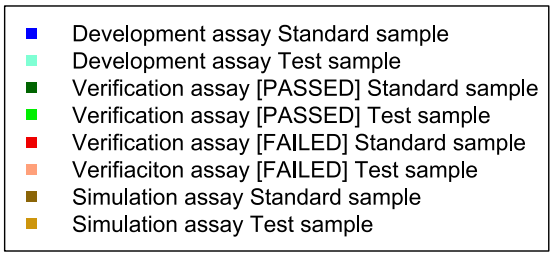
Settings

Property	Value
Margin development	Yes
Test strategy verification	Yes
Test strategy visualization	Yes
Confidence level	0.95
Tolerance level	0.99
Margin symmetry assumption	no
Max simulations	10000
Max configurations	30

Documentation

Date	17.03.2014 13:21:31

Common legend for the plots



Section I: Source assays

Source assay properties

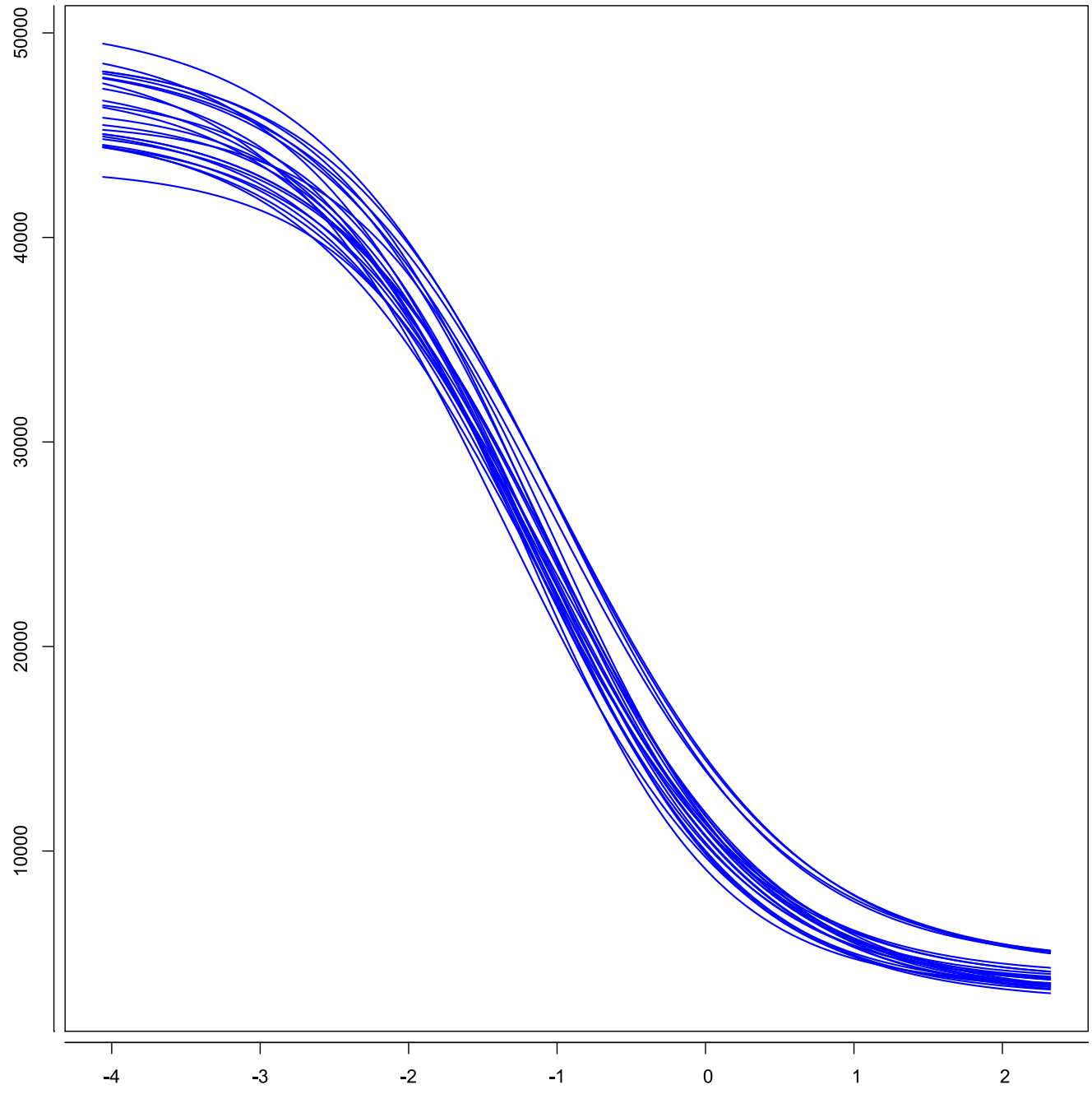
Property	Value
Model	4 Parameter logistic fit
Logarithm base	Binary logarithm (base 2)
Degrees of freedom	16
Standard sample	
Step count	12
Replicate count	1
Dilution scale	5.0, 3.33, 2.22, 1.48, 0.99, 0.66, 0.44, 0.29, 0.2, 0.13, 0.09, 0.06
Test sample	
Step count	12
Replicate count	1
Dilution scale	5.0, 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

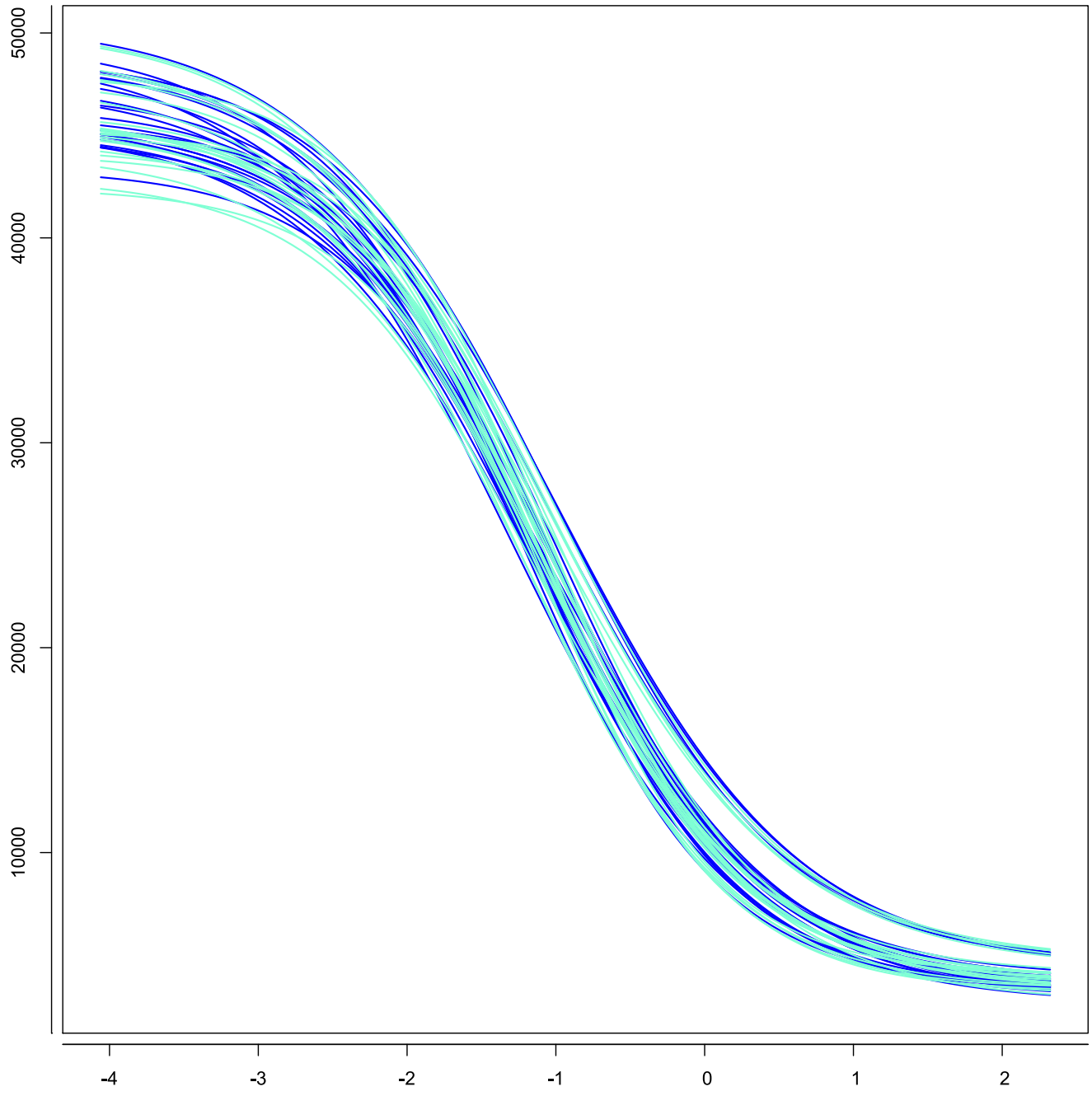
Index	Document key: Document title, Assay element	Dev/Ver	Assay result from source document	Expected assay result
1 (1)	Document-107: Assay 12, S1	Dev	Passed	Passed
2 (2)	Document-108: Assay 13, S1	Dev	Passed	Passed
3 (3)	Document-109: Assay 14, S1	Dev	Passed	Passed
4 (4)	Document-110: Assay 15, S1	Dev	Passed	Passed
5 (5)	Document-111: Assay 16, S1	Dev	Passed	Passed
6 (6)	Document-112: Assay 17, S1	Dev	Passed	Passed
7 (7)	Document-113: Assay 18, S1	Dev	Passed	Passed
8 (8)	Document-114: Assay 19, S1	Dev	Passed	Passed
9 (9)	Document-115: Assay 20, S1	Dev	Passed	Passed
10 (10)	Document-116: Assay 21, S1	Dev	Passed	Passed
11 (11)	Document-117: Assay 22, S1	Dev	Passed	Passed
12 (12)	Document-118: Assay 23, S1	Dev	Passed	Passed
13 (13)	Document-119: Assay 24, S1	Dev	Passed	Passed
14 (14)	Document-120: Assay 01, S1	Dev	Passed	Passed
15 (15)	Document-121: Assay 02, S1	Dev	Passed	Passed
16 (16)	Document-122: Assay 03, S1	Dev	Passed	Passed
17 (17)	Document-123: Assay 04, S1	Dev	Passed	Passed
18 (18)	Document-124: Assay 05, S1	Dev	Passed	Passed
19 (19)	Document-125: Assay 06, S1	Dev	Passed	Passed
20 (20)	Document-126: Assay 07, S1	Dev	Passed	Passed
21 (21)	Document-127: Assay 08, S1	Dev	Passed	Passed
22 (22)	Document-128: Assay 09, S1	Dev	Passed	Passed
23 (23)	Document-129: Assay 10, S1	Dev	Passed	Passed
24 (24)	Document-130: Assay 11, S1	Dev	Passed	Passed

Note: Index in this report. In parenthesis, row in the source data table. Dev = Development assay. Ver = Verification assay.

Development assays: Overlay plot regression of the Standard



Development assays: Overlay plot Standard and Test/Control samples



Source assay details

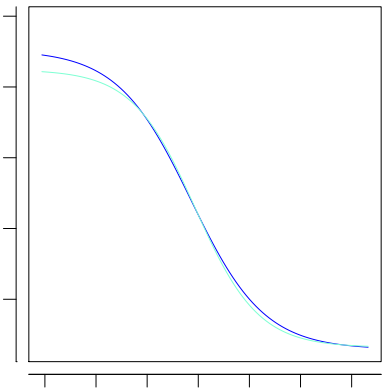
The sort order of the source assays starts with Development assays, followed by Verification assays and finally excluded assays. This sort order may be different from the order of the source data table of the document. The index stated here is used consistently throughout all plots and tables of this 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-107 Assay 12 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45240.143	807.89734	42454.850	667.88539
B parameter	-2.01369	0.14767	-2.34585	0.17483
C parameter	-1.14576	0.05420	-1.05630	0.04927
D lower asymptote	2896.4054	657.64846	3196.1250	591.77533

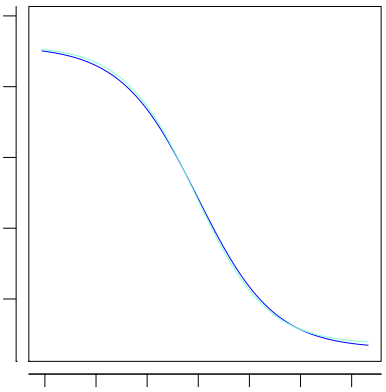
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.173 E+09		
$SS_{non\text{-}Parallelism}$	6480296.6		
$SS_{non\text{-}Linearity}$	1.313 E+07	6492579.7	6635514.1
$MS_{Residual\ error}$	820505.86		



2 (2): Document-108 Assay 13 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45756.364	511.55099	45828.581	481.69677
B parameter	-1.93716	0.09157	-2.07333	0.09606
C parameter	-1.01388	0.03566	-1.05194	0.03346
D lower asymptote	2984.0610	459.27422	3591.5949	422.69550

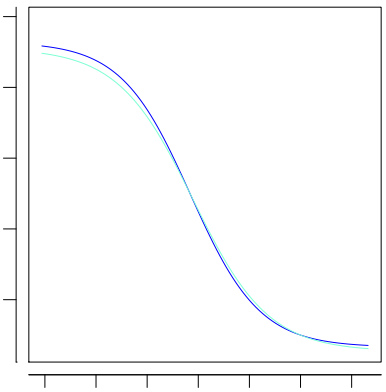
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.420 E+09		
$SS_{non\text{-}Parallelism}$	756331.70		
$SS_{non\text{-}Linearity}$	5393170.0	2935356.3	2457813.7
$MS_{Residual\ error}$	337073.12		



3 (3): Document-109 Assay 14 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	46429.229	642.83986	45566.854	688.64256
B parameter	-2.13433	0.12662	-1.96590	0.12163
C parameter	-1.15273	0.04213	-1.10067	0.04637
D lower asymptote	3285.7429	525.36088	2681.5679	578.54062

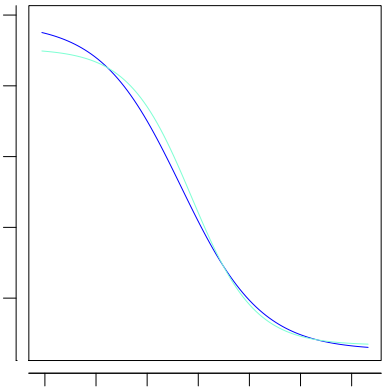
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.634 E+09		
$SS_{non\text{-}Parallelism}$	3324044.9		
$SS_{non\text{-}Linearity}$	9387980.2	6521855.0	2866125.2
$MS_{Residual\ error}$	586748.76		



4 (4): Document-110 Assay 15 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48913.692	1042.5449	45280.546	726.46096
B parameter	-1.84579	0.13903	-2.34348	0.17294
C parameter	-1.33785	0.05984	-1.13278	0.04892
D lower asymptote	2618.1995	714.48404	3345.8489	610.82122

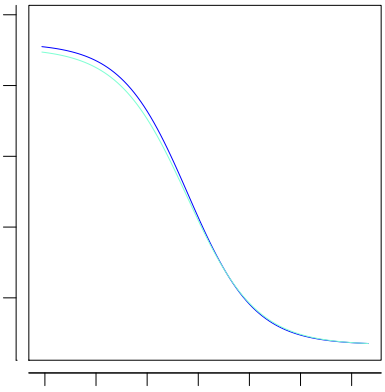
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.917 E+09		
$SS_{non\text{-}Parallelism}$	8377418.7		
$SS_{non\text{-}Linearity}$	1.462 E+07	3571656.9	1.105 E+07
$MS_{Residual\ error}$	913988.61		



5 (5): Document-111 Assay 16 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	46004.986	686.35591	45350.594	723.33669
B parameter	-2.23001	0.14430	-2.13563	0.14263
C parameter	-1.20308	0.04460	-1.22075	0.04753
D lower asymptote	3365.8152	544.86342	3324.5428	562.14344

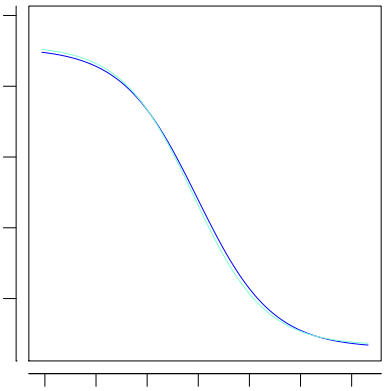
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.636 E+09		
$SS_{non\text{-}Parallelism}$	1522314.3		
$SS_{non\text{-}Linearity}$	1.122 E+07	5983400.5	5236009.5
$MS_{Residual\ error}$	701213.12		



6 (6): Document-112 Assay 17 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45454.742	438.58318	45804.209	430.37193
B parameter	-1.97743	0.08155	-2.06864	0.08368
C parameter	-1.02093	0.03071	-1.09519	0.02930
D lower asymptote	2997.8831	392.28658	3361.2838	365.48774

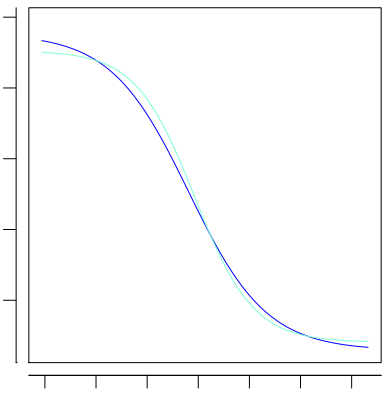
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.434 E+09		
$SS_{non\text{-}Parallelism}$	744608.63		
$SS_{non\text{-}Linearity}$	4132618.0	2158525.8	1974092.2
$MS_{Residual\ error}$	258288.63		



7 (7): Document-113 Assay 18 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	47695.770	973.28720	45270.689	698.48303
B parameter	-1.89534	0.14957	-2.51099	0.19326
C parameter	-1.18682	0.06084	-1.07416	0.04829
D lower asymptote	2907.6124	759.37769	4060.9214	615.91228

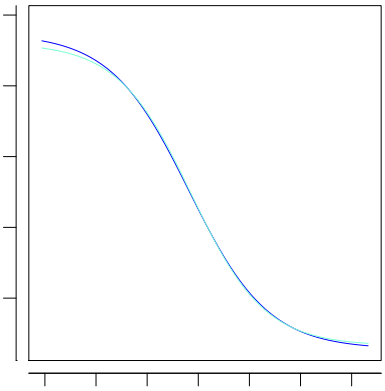
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.814 E+09		
$SS_{non\text{-}Parallelism}$	7191652.4		
$SS_{non\text{-}Linearity}$	1.586 E+07	2843534.4	1.302 E+07
$MS_{Residual\ error}$	991541.40		



8 (8): Document-114 Assay 19 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	47398.505	412.19118	46056.261	370.38885
B parameter	-1.87015	0.06246	-2.01040	0.06711
C parameter	-1.17683	0.02596	-1.13449	0.02469
D lower asymptote	2794.3126	323.47595	3265.8849	304.05986

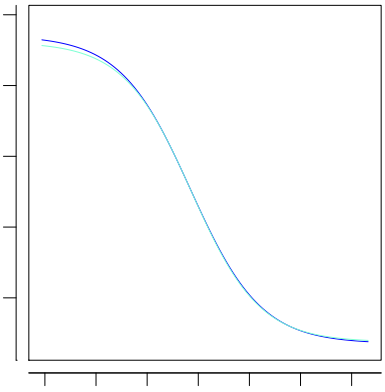
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.594 E+09		
$SS_{non\text{-}Parallelism}$	1063717.7		
$SS_{non\text{-}Linearity}$	2776500.2	1815749.6	960750.59
$MS_{Residual\ error}$	173531.26		



9 (9): Document-115 Assay 20 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	47084.566	824.69305	46158.634	786.45479
B parameter	-2.09558	0.15618	-2.17469	0.16391
C parameter	-1.15096	0.05361	-1.13051	0.05278
D lower asymptote	3522.0468	672.89147	3751.7844	655.16325

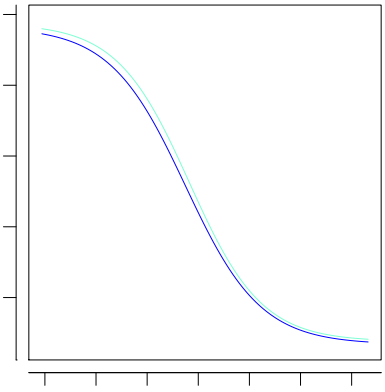
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.788 E+09		
$SS_{non\text{-}Parallelism}$	733272.70		
$SS_{non\text{-}Linearity}$	1.488 E+07	9224080.5	5656969.9
$MS_{Residual\ error}$	930065.65		



10 (10): Document-116 Assay 21 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48239.080	561.23453	48736.647	516.78839
B parameter	-1.96017	0.08867	-2.03939	0.08984
C parameter	-1.25237	0.03424	-1.17491	0.03232
D lower asymptote	3379.4210	418.19343	3790.2700	412.21631

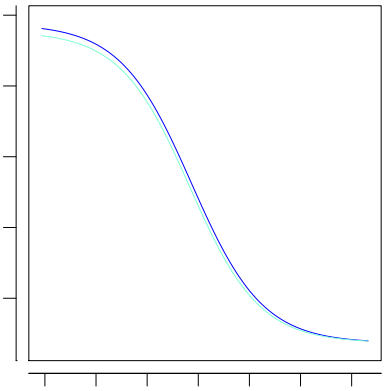
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	7.078 E+09		
$SS_{non\text{-}Parallelism}$	935836.18		
$SS_{non\text{-}Linearity}$	5387791.1	878078.08	4509713.0
$MS_{Residual\ error}$	336736.94		



11 (11): Document-117 Assay 22 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48775.166	512.31868	47712.791	507.80668
B parameter	-2.07420	0.09284	-2.11955	0.09645
C parameter	-1.13152	0.03240	-1.16523	0.03249
D lower asymptote	3673.1217	423.49540	3693.3282	410.71113

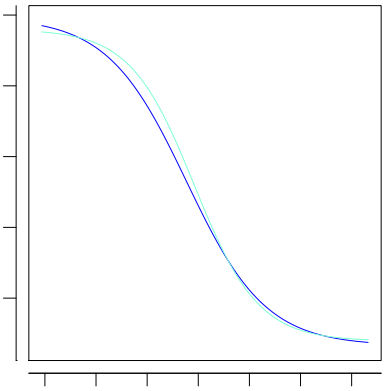
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	7.216 E+09		
$SS_{non\text{-}Parallelism}$	1086357.6		
$SS_{non\text{-}Linearity}$	5711117.0	2120315.5	3590801.5
$MS_{Residual\ error}$	356944.81		



12 (12): Document-118 Assay 23 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	49671.077	922.54308	47984.173	683.71760
B parameter	-1.86450	0.13082	-2.30496	0.15384
C parameter	-1.22927	0.05484	-1.07734	0.04473
D lower asymptote	3279.7931	693.26551	3928.0544	595.98089

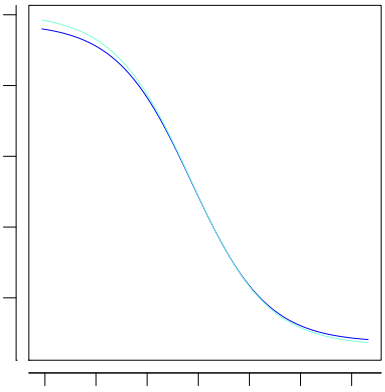
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	7.332 E+09		
$SS_{non\text{-}Parallelism}$	4426595.4		
$SS_{non\text{-}Linearity}$	1.312 E+07	5454517.3	7667800.0
$MS_{Residual\ error}$	820144.83		



13 (13): Document-119 Assay 24 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48826.062	734.90911	50218.760	765.24023
B parameter	-1.96338	0.12183	-1.91502	0.11579
C parameter	-1.12591	0.04660	-1.14885	0.04620
D lower asymptote	3694.7438	605.23151	3211.3341	616.57837

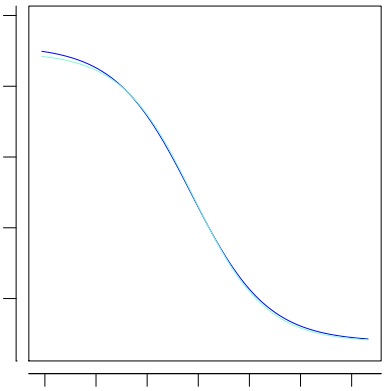
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	7.344 E+09		
$SS_{non\text{-}Parallelism}$	2162202.4		
$SS_{non\text{-}Linearity}$	1.042 E+07	3261953.8	7162335.9
$MS_{Residual\ error}$	651518.11		



14 (14): Document-120 Assay 01 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45727.277	641.67097	44812.191	593.66579
B parameter	-1.94779	0.11283	-2.04854	0.11788
C parameter	-1.13584	0.04375	-1.09044	0.04195
D lower asymptote	3901.4878	523.72311	3834.3689	505.34826

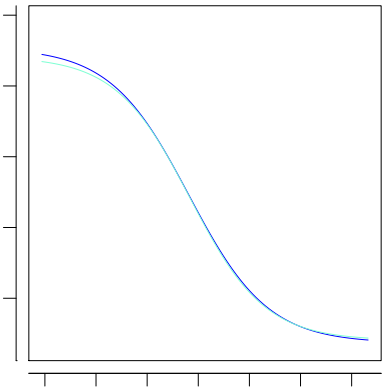
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.055 E+09		
$SS_{non\text{-}Parallelism}$	685295.48		
$SS_{non\text{-}Linearity}$	7728603.5	3808131.3	3920472.2
$MS_{Residual\ error}$	483037.72		



15 (15): Document-121 Assay 02 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45432.504	664.73343	44177.983	612.28018
B parameter	-1.87054	0.10740	-1.98184	0.11447
C parameter	-1.18123	0.04463	-1.15687	0.04317
D lower asymptote	3659.6143	519.81558	4038.4708	492.88472

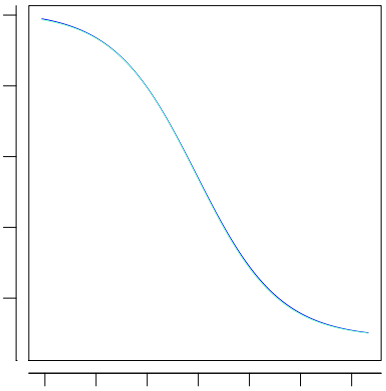
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	5.762 E+09		
$SS_{non\text{-}Parallelism}$	1035591.3		
$SS_{non\text{-}Linearity}$	7194741.4	3194885.8	3999855.5
$MS_{Residual\ error}$	449671.34		



16 (16): Document-122 Assay 03 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	50560.778	654.44758	50382.534	644.31821
B parameter	-1.77876	0.09356	-1.80160	0.09430
C parameter	-1.03662	0.04184	-1.03926	0.04133
D lower asymptote	4388.2403	572.63579	4383.7142	563.18795

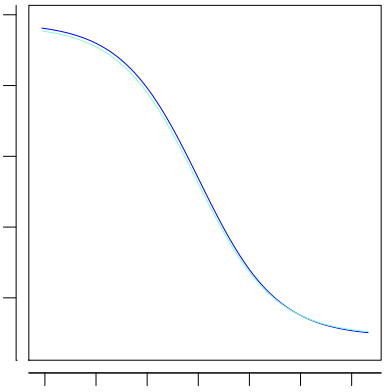
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.990 E+09		
$SS_{non\text{-}Parallelism}$	30022.459		
$SS_{non\text{-}Linearity}$	6992706.6	1806334.8	5186371.8
$MS_{Residual\ error}$	437044.16		



17 (17): Document-123 Assay 04 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48868.359	536.10814	48499.055	546.62657
B parameter	-1.90502	0.09110	-1.90455	0.09235
C parameter	-0.98587	0.03643	-1.03075	0.03700
D lower asymptote	4521.8083	491.47252	4715.4377	483.55167

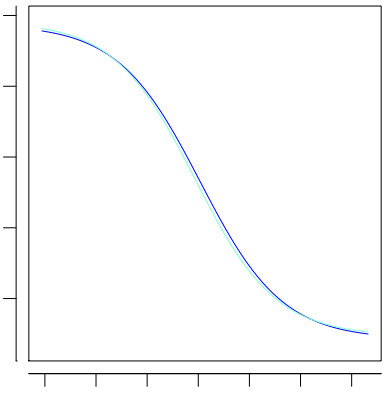
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.683 E+09		
$SS_{non\text{-}Parallelism}$	284041.09		
$SS_{non\text{-}Linearity}$	5830008.3	2709390.0	3120618.3
$MS_{Residual\ error}$	364375.52		



18 (18): Document-124 Assay 05 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48744.485	490.98682	49137.273	502.84313
B parameter	-1.79367	0.07621	-1.82436	0.07690
C parameter	-0.96158	0.03355	-1.06519	0.03307
D lower asymptote	4254.0085	457.39562	4688.3254	430.79402

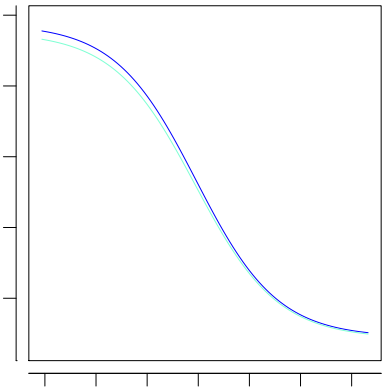
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.561 E+09		
$SS_{non\text{-}Parallelism}$	411922.98		
$SS_{non\text{-}Linearity}$	4298542.9	892490.03	3406052.9
$MS_{Residual\ error}$	268658.93		



19 (19): Document-125 Assay 06 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	48743.199	440.87897	47608.498	450.61259
B parameter	-1.81493	0.06789	-1.79433	0.06914
C parameter	-1.03969	0.02940	-1.05513	0.03051
D lower asymptote	4501.8963	385.48905	4306.9880	388.59791

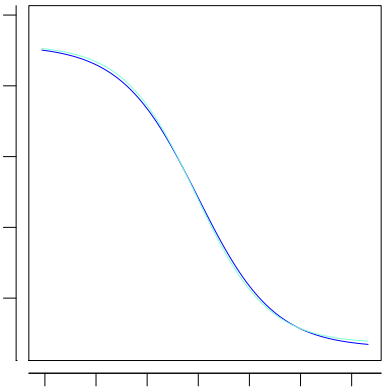
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.341 E+09		
$SS_{non\text{-}Parallelism}$	1786738.1		
$SS_{non\text{-}Linearity}$	3336056.0	1397402.9	1938653.1
$MS_{Residual\ error}$	208503.50		



20 (20): Document-126 Assay 07 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45756.364	511.55099	45828.581	481.69677
B parameter	-1.93716	0.09157	-2.07333	0.09606
C parameter	-1.01388	0.03566	-1.05194	0.03346
D lower asymptote	2984.0610	459.27422	3591.5949	422.69550

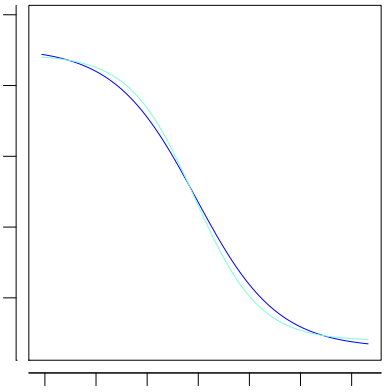
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.420 E+09		
$SS_{non\text{-}Parallelism}$	756331.70		
$SS_{non\text{-}Linearity}$	5393170.0	2935356.3	2457813.7
$MS_{Residual\ error}$	337073.12		



21 (21): Document-127 Assay 08 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45342.963	954.03751	44378.116	749.64360
B parameter	-1.81547	0.15274	-2.27932	0.18081
C parameter	-1.04695	0.06614	-1.07089	0.05360
D lower asymptote	2897.9937	829.24469	3925.6336	655.55617

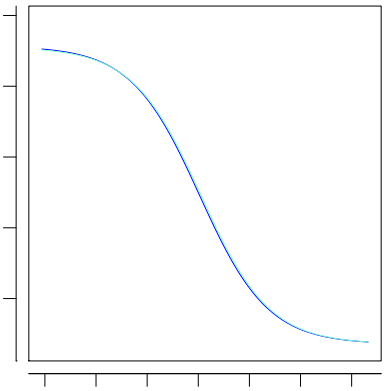
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.122 E+09		
$SS_{non\text{-}Parallelism}$	4630256.3		
$SS_{non\text{-}Linearity}$	1.553 E+07	1682338.1	1.385 E+07
$MS_{Residual\ error}$	970763.66		



22 (22): Document-128 Assay 09 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45676.520	580.13363	45499.978	571.89731
B parameter	-2.15750	0.12731	-2.16157	0.12798
C parameter	-0.97677	0.04139	-0.94393	0.04145
D lower asymptote	3556.8233	539.88061	3558.4469	545.09618

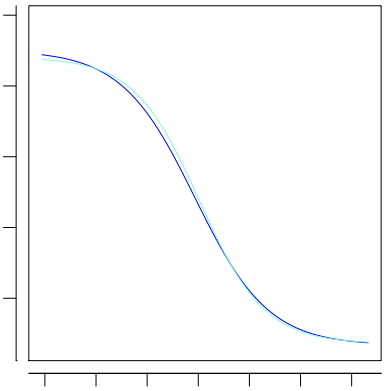
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.586 E+09		
$SS_{non\text{-}Parallelism}$	41109.417		
$SS_{non\text{-}Linearity}$	9008244.0	3631837.6	5376406.4
$MS_{Residual\ error}$	563015.25		



23 (23): Document-129 Assay 10 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	45044.640	457.27019	44089.729	394.21229
B parameter	-2.00899	0.08732	-2.25047	0.09607
C parameter	-1.06383	0.03208	-0.98111	0.02906
D lower asymptote	3339.2501	396.31310	3566.5281	366.69182

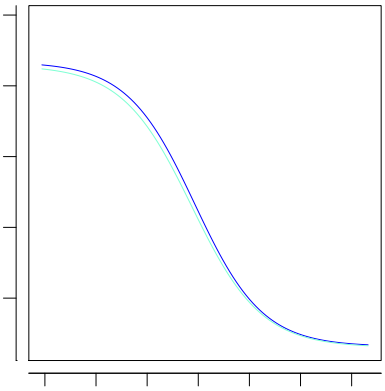
Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	6.223 E+09		
$SS_{non\text{-}Parallelism}$	1266178.3		
$SS_{non\text{-}Linearity}$	4490956.6	1186796.5	3304160.1
$MS_{Residual\ error}$	280684.79		



24 (24): Document-130 Assay 11 [Development, PASSED]

	Standard sample		Test/Control sample	
Parameter	Value	Std Err	Value	Std Err
A upper asymptote	43390.286	448.81397	42924.431	473.75657
B parameter	-2.18051	0.10143	-2.11920	0.10067
C parameter	-1.06713	0.03245	-1.12786	0.03387
D lower asymptote	3165.2539	391.58960	3019.7377	393.93972

Anova term	Assay	Standard	Test/Control
$SS_{Regression}$	5.938 E+09		
$SS_{non\text{-}Parallelism}$	645553.89		
$SS_{non\text{-}Linearity}$	5130042.8	3389389.2	1740653.6
$MS_{Residual\ error}$	320627.68		



Section II: Margin development

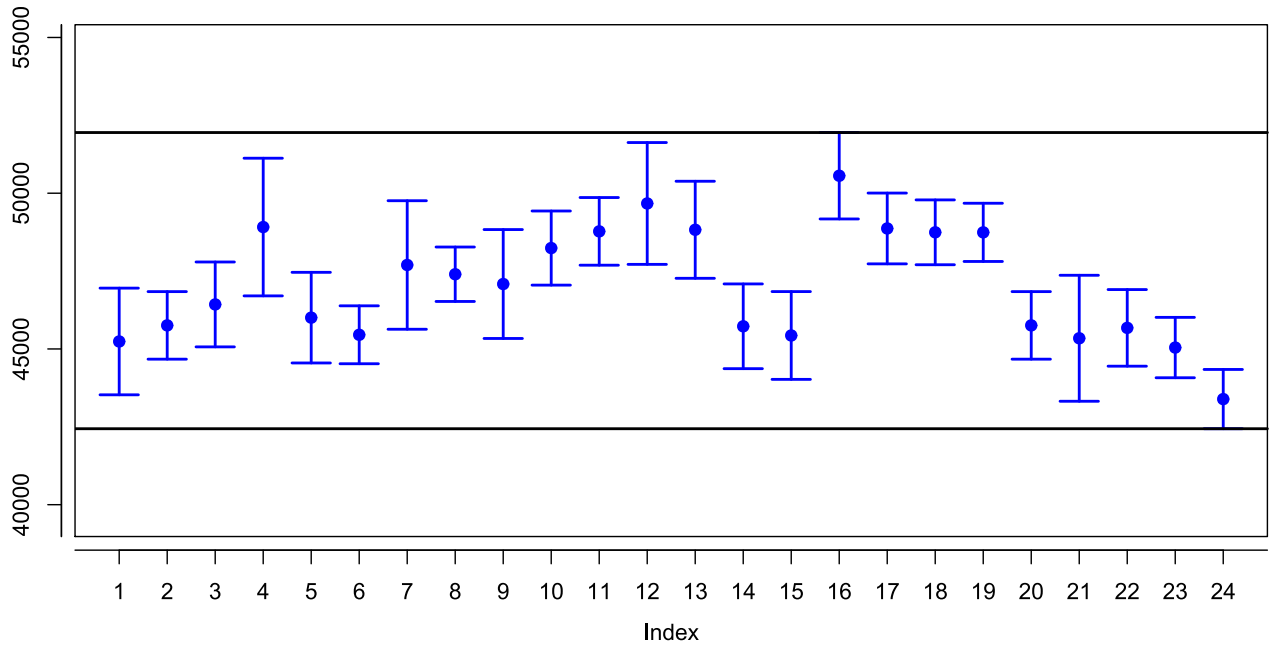
Margin development overview

	Equivalence margins		
	upper	lower	Reference mean
Equivalence test parameter estimate			
A upper asymptote (nonlinear models)	51948.145	42438.843	
B parameter (nonlinear models)	-1.49167	-2.53592	
C parameter (nonlinear models)	-0.88902	-1.46470	
D lower asymptote (nonlinear models)	5602.1740	1103.5610	
Difference of asymptotes (nonlinear models)	49435.246	38783.562	
Ratio of asymptotes (nonlinear models)	45.15183	8.69554	
Equivalence test difference of parameter estimates			
A upper asymptote (nonlinear models)	3641.8809	-6326.8815	
B parameter (nonlinear models)	0.54061	-1.13370	
C parameter (nonlinear models)	0.36892	-0.20440	
D lower asymptote (nonlinear models)	3268.5319	-2314.9809	
Difference of asymptotes (nonlinear models))	5261.5642	-8232.3529	
Equivalence test ratio of parameter estimates			
A upper asymptote (nonlinear models)	1.07631	0.87518	
B parameter (nonlinear models)	1.67929	0.76654	
C parameter (nonlinear models)	1.22397	0.74203	
D lower asymptote (nonlinear models)	3.57643	0.41699	
Difference of asymptotes (nonlinear models)	1.12109	0.83116	
Equivalence test scaled parameter range			
A upper asymptote (nonlinear models)	0.07743	-0.13452	47032.365
B parameter (nonlinear models)	0.27563	-0.57803	1.96134
C parameter (nonlinear models)	0.33239	-0.18417	1.10989
D lower asymptote (nonlinear models)	0.95004	-0.67288	3440.3998
Difference of asymptotes (nonlinear models, Standard only)	1.05109	0.82461	47032.365
Parameter/Property point estimate			
A upper asymptote (nonlinear models)	50560.778	43390.286	
B parameter (nonlinear models)	-1.77876	-2.23001	
C parameter (nonlinear models)	-0.96158	-1.33785	
D lower asymptote (nonlinear models)	4521.8083	2618.1995	
Slope (nonlinear models)	-13353.032	-16477.096	
Difference of asymptotes (nonlinear models)	46391.284	40225.032	
Ratio of asymtotes (nonlinear models)	18.68219	10.80726	
Difference of parameter/property point estimates			
A upper asymptote (nonlinear models)	1392.6983	-3633.1455	
B parameter (nonlinear models)	0.16842	-0.61565	
C parameter (nonlinear models)	0.20508	-0.10361	
D lower asymptote (nonlinear models)	1153.3090	-604.17498	
Difference of asymptotes (nonlinear models)	1876.1080	-4360.7949	
Ratio of parameter/property point estimates			
A upper asymptote (nonlinear models)	1.02852	0.92572	
B parameter (nonlinear models)	1.32482	0.92109	
C parameter (nonlinear models)	1.10775	0.84671	
D lower asymptote (nonlinear models)	1.39665	0.81612	
Difference of asymptotes (nonlinear models)	1.04157	0.90581	
Normalized difference of asymptotes			
Normalized difference of upper asymptotes	0.03086	-0.07848	
Normalized difference of lower asymptotes	0.02575	-0.01400	
Anova terms			
Sum of squares regression	7.344 E+09	5.762 E+09	
Sum of squares non-parallelism	8377418.7		
Sum of squares non-linearity	1.586 E+07		
Sum of squares non-linearity Standard	9224080.5		
Sum of squares non-linearity Test/Control	1.385 E+07		

(T) = Test, (S) = Standard, * = reference mean of the Standard

Margin development details

Equivalence test parameter estimate:
A upper asymptote (nonlinear models) A(S)

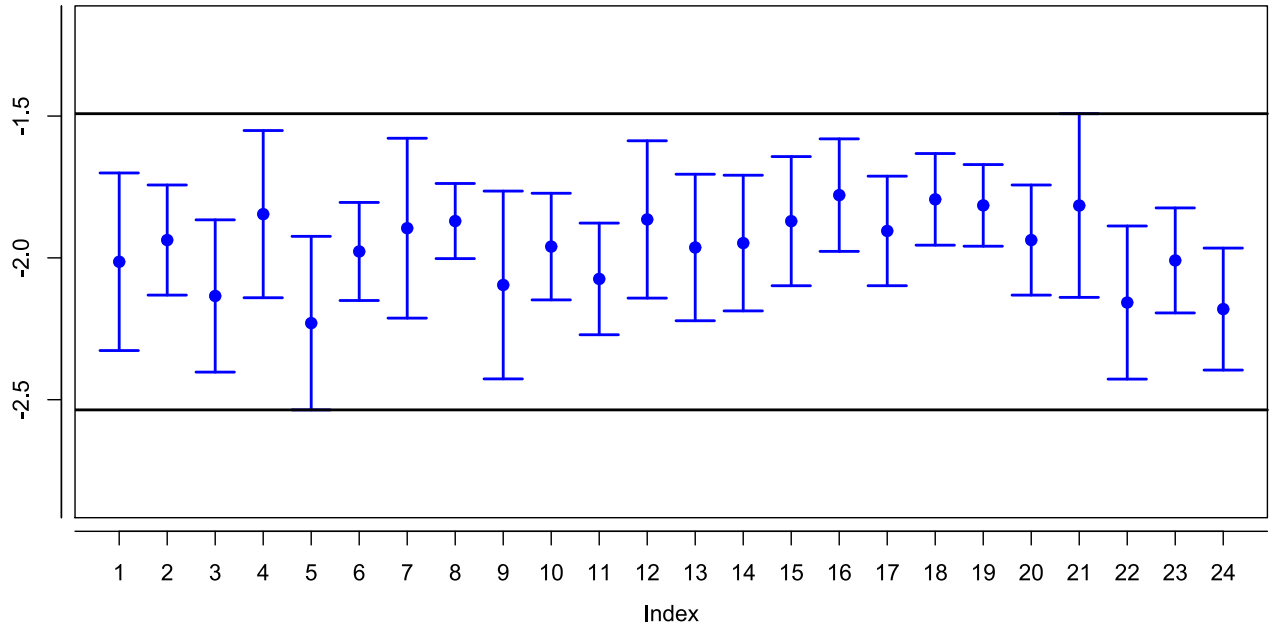


Mean	SD	CoV[%]	Margins
47032.365	1829.9016	0.03891	42438.843 – 51948.145

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	45240.143	43527.477 – 46952.809	✓
2	Assay 13 (Document-108), S1	45756.364	44671.925 – 46840.804	✓
3	Assay 14 (Document-109), S1	46429.229	45066.469 – 47791.989	✓
4	Assay 15 (Document-110), S1	48913.692	46703.595 – 51123.788	✓
5	Assay 16 (Document-111), S1	46004.986	44549.976 – 47459.995	✓
6	Assay 17 (Document-112), S1	45454.742	44524.987 – 46384.497	✓
7	Assay 18 (Document-113), S1	47695.770	45632.493 – 49759.046	✓
8	Assay 19 (Document-114), S1	47398.505	46524.699 – 48272.312	✓
9	Assay 20 (Document-115), S1	47084.566	45336.295 – 48832.837	✓
10	Assay 21 (Document-116), S1	48239.080	47049.316 – 49428.844	✓
11	Assay 22 (Document-117), S1	48775.166	47689.099 – 49861.233	✓
12	Assay 23 (Document-118), S1	49671.077	47715.373 – 51626.781	✓
13	Assay 24 (Document-119), S1	48826.062	47268.124 – 50384.000	✓
14	Assay 01 (Document-120), S1	45727.277	44366.996 – 47087.559	✓
15	Assay 02 (Document-121), S1	45432.504	44023.332 – 46841.676	✓
16	Assay 03 (Document-122), S1	50560.778	49173.411 – 51948.145	✓
17	Assay 04 (Document-123), S1	48868.359	47731.860 – 50004.857	✓
18	Assay 05 (Document-124), S1	48744.485	47703.640 – 49785.331	✓
19	Assay 06 (Document-125), S1	48743.199	47808.578 – 49677.821	✓
20	Assay 07 (Document-126), S1	45756.364	44671.925 – 46840.804	✓
21	Assay 08 (Document-127), S1	45342.963	43320.494 – 47365.432	✓
22	Assay 09 (Document-128), S1	45676.520	44446.692 – 46906.348	✓
23	Assay 10 (Document-129), S1	45044.640	44075.270 – 46014.009	✓
24	Assay 11 (Document-130), S1	43390.286	42438.843 – 44341.729	✓

Equivalence test parameter estimate:
B parameter (nonlinear models) B(S)

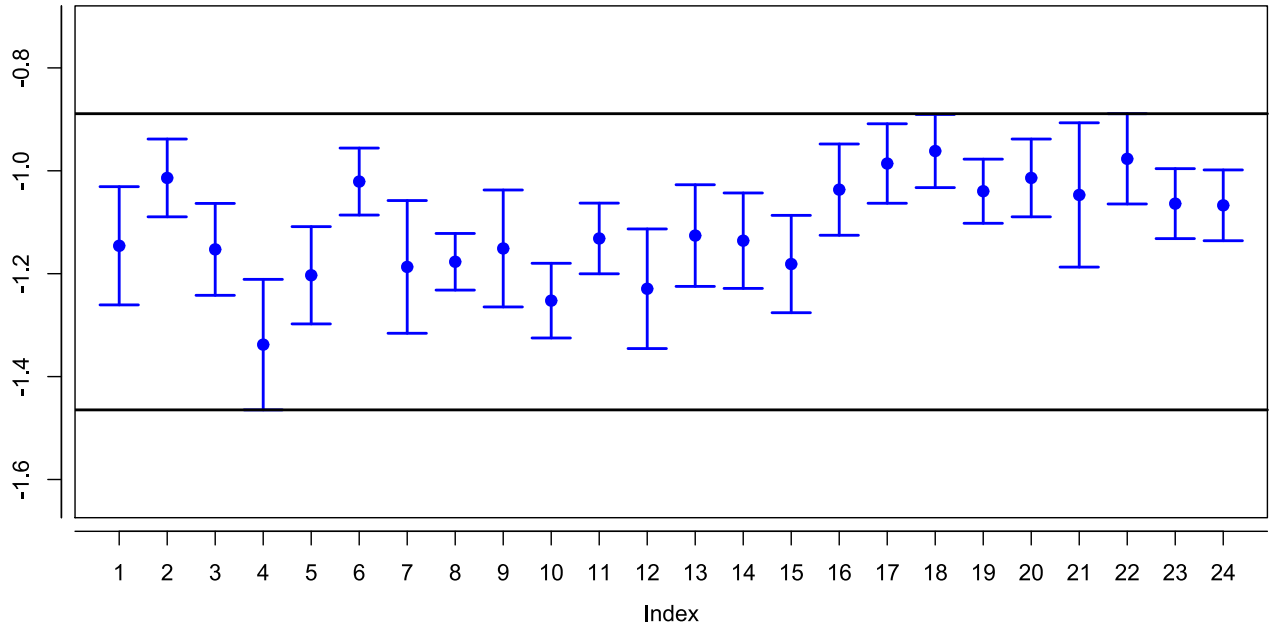


Mean	SD	CoV[%]	Margins
-1.96134	0.12803	0.06528	-2.53592 – -1.49167

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-2.01369	-2.32674 – -1.70065	✓
2	Assay 13 (Document-108), S1	-1.93716	-2.13128 – -1.74304	✓
3	Assay 14 (Document-109), S1	-2.13433	-2.40274 – -1.86591	✓
4	Assay 15 (Document-110), S1	-1.84579	-2.14053 – -1.55105	✓
5	Assay 16 (Document-111), S1	-2.23001	-2.53592 – -1.92410	✓
6	Assay 17 (Document-112), S1	-1.97743	-2.15030 – -1.80455	✓
7	Assay 18 (Document-113), S1	-1.89534	-2.21243 – -1.57826	✓
8	Assay 19 (Document-114), S1	-1.87015	-2.00257 – -1.73774	✓
9	Assay 20 (Document-115), S1	-2.09558	-2.42667 – -1.76449	✓
10	Assay 21 (Document-116), S1	-1.96017	-2.14814 – -1.77220	✓
11	Assay 22 (Document-117), S1	-2.07420	-2.27101 – -1.87739	✓
12	Assay 23 (Document-118), S1	-1.86450	-2.14184 – -1.58717	✓
13	Assay 24 (Document-119), S1	-1.96338	-2.22166 – -1.70510	✓
14	Assay 01 (Document-120), S1	-1.94779	-2.18697 – -1.70860	✓
15	Assay 02 (Document-121), S1	-1.87054	-2.09822 – -1.64287	✓
16	Assay 03 (Document-122), S1	-1.77876	-1.97710 – -1.58042	✓
17	Assay 04 (Document-123), S1	-1.90502	-2.09816 – -1.71189	✓
18	Assay 05 (Document-124), S1	-1.79367	-1.95522 – -1.63212	✓
19	Assay 06 (Document-125), S1	-1.81493	-1.95885 – -1.67101	✓
20	Assay 07 (Document-126), S1	-1.93716	-2.13128 – -1.74304	✓
21	Assay 08 (Document-127), S1	-1.81547	-2.13926 – -1.49167	✓
22	Assay 09 (Document-128), S1	-2.15750	-2.42739 – -1.88760	✓
23	Assay 10 (Document-129), S1	-2.00899	-2.19411 – -1.82388	✓
24	Assay 11 (Document-130), S1	-2.18051	-2.39554 – -1.96548	✓

Equivalence test parameter estimate:
C parameter (nonlinear models) C(S)

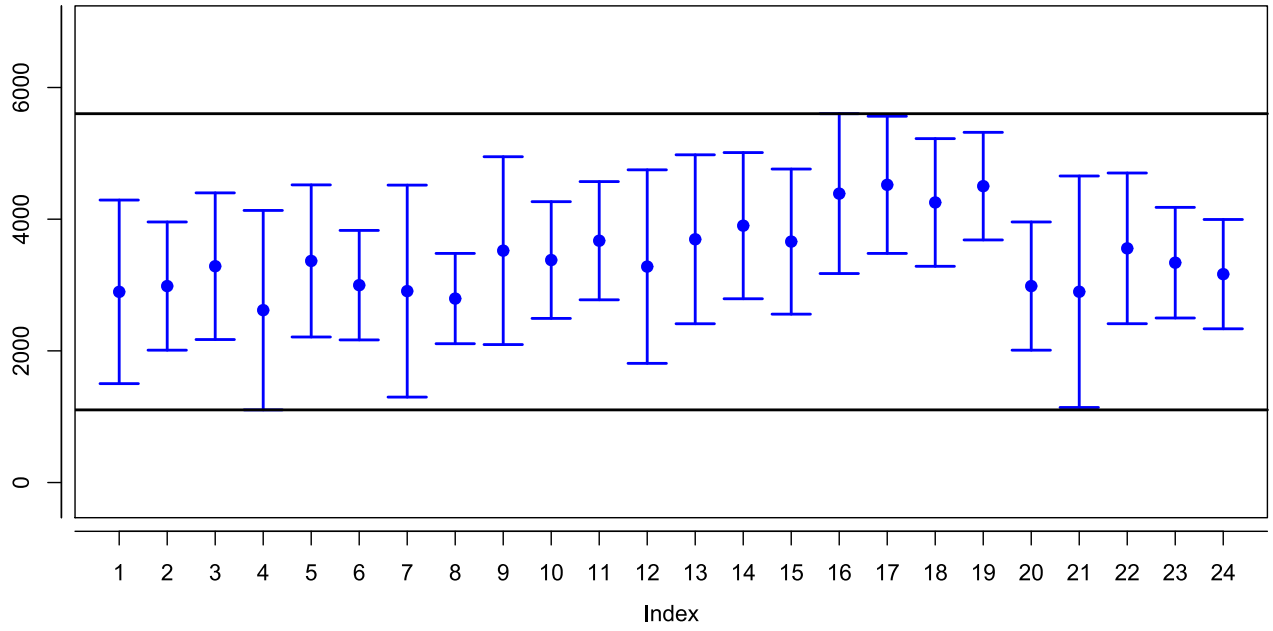


Mean	SD	CoV[%]	Margins
-1.10989	0.09703	0.08743	-1.46470 – -0.88902

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-1.14576	-1.26065 – -1.03086	✓
2	Assay 13 (Document-108), S1	-1.01388	-1.08948 – -0.93828	✓
3	Assay 14 (Document-109), S1	-1.15273	-1.24204 – -1.06342	✓
4	Assay 15 (Document-110), S1	-1.33785	-1.46470 – -1.21101	✓
5	Assay 16 (Document-111), S1	-1.20308	-1.29762 – -1.10853	✓
6	Assay 17 (Document-112), S1	-1.02093	-1.08603 – -0.95583	✓
7	Assay 18 (Document-113), S1	-1.18682	-1.31580 – -1.05784	✓
8	Assay 19 (Document-114), S1	-1.17683	-1.23186 – -1.12180	✓
9	Assay 20 (Document-115), S1	-1.15096	-1.26461 – -1.03732	✓
10	Assay 21 (Document-116), S1	-1.25237	-1.32496 – -1.17978	✓
11	Assay 22 (Document-117), S1	-1.13152	-1.20021 – -1.06284	✓
12	Assay 23 (Document-118), S1	-1.22927	-1.34552 – -1.11303	✓
13	Assay 24 (Document-119), S1	-1.12591	-1.22470 – -1.02712	✓
14	Assay 01 (Document-120), S1	-1.13584	-1.22859 – -1.04310	✓
15	Assay 02 (Document-121), S1	-1.18123	-1.27584 – -1.08662	✓
16	Assay 03 (Document-122), S1	-1.03662	-1.12531 – -0.94793	✓
17	Assay 04 (Document-123), S1	-0.98587	-1.06311 – -0.90863	✓
18	Assay 05 (Document-124), S1	-0.96158	-1.03269 – -0.89047	✓
19	Assay 06 (Document-125), S1	-1.03969	-1.10203 – -0.97736	✓
20	Assay 07 (Document-126), S1	-1.01388	-1.08948 – -0.93828	✓
21	Assay 08 (Document-127), S1	-1.04695	-1.18717 – -0.90674	✓
22	Assay 09 (Document-128), S1	-0.97677	-1.06451 – -0.88902	✓
23	Assay 10 (Document-129), S1	-1.06383	-1.13182 – -0.99583	✓
24	Assay 11 (Document-130), S1	-1.06713	-1.13593 – -0.99833	✓

Equivalence test parameter estimate:
D lower asymptote (nonlinear models) D(S)

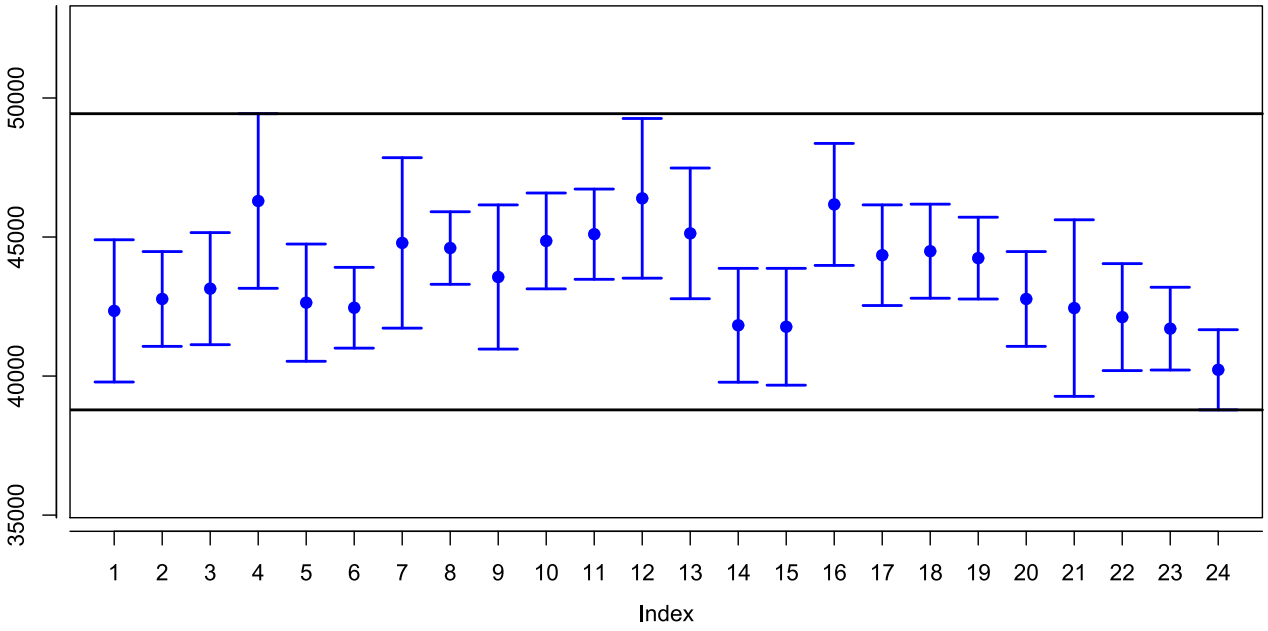


Mean	SD	CoV[%]	Margins
3440.3998	550.92765	0.16013	1103.5610 – 5602.1740

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	2896.4054	1502.2530 – 4290.5579	✓
2	Assay 13 (Document-108), S1	2984.0610	2010.4431 – 3957.6788	✓
3	Assay 14 (Document-109), S1	3285.7429	2172.0275 – 4399.4582	✓
4	Assay 15 (Document-110), S1	2618.1995	1103.5610 – 4132.8380	✓
5	Assay 16 (Document-111), S1	3365.8152	2210.7563 – 4520.8740	✓
6	Assay 17 (Document-112), S1	2997.8831	2166.2727 – 3829.4935	✓
7	Assay 18 (Document-113), S1	2907.6124	1297.8036 – 4517.4212	✓
8	Assay 19 (Document-114), S1	2794.3126	2108.5742 – 3480.0509	✓
9	Assay 20 (Document-115), S1	3522.0468	2095.5806 – 4948.5130	✓
10	Assay 21 (Document-116), S1	3379.4210	2492.8905 – 4265.9514	✓
11	Assay 22 (Document-117), S1	3673.1217	2775.3516 – 4570.8919	✓
12	Assay 23 (Document-118), S1	3279.7931	1810.1359 – 4749.4503	✓
13	Assay 24 (Document-119), S1	3694.7438	2411.7103 – 4977.7773	✓
14	Assay 01 (Document-120), S1	3901.4878	2791.2444 – 5011.7312	✓
15	Assay 02 (Document-121), S1	3659.6143	2557.6545 – 4761.5741	✓
16	Assay 03 (Document-122), S1	4388.2403	3174.3067 – 5602.1740	✓
17	Assay 04 (Document-123), S1	4521.8083	3479.9331 – 5563.6835	✓
18	Assay 05 (Document-124), S1	4254.0085	3284.3731 – 5223.6439	✓
19	Assay 06 (Document-125), S1	4501.8963	3684.6961 – 5319.0966	✓
20	Assay 07 (Document-126), S1	2984.0610	2010.4431 – 3957.6788	✓
21	Assay 08 (Document-127), S1	2897.9937	1140.0735 – 4655.9139	✓
22	Assay 09 (Document-128), S1	3556.8233	2412.3276 – 4701.3191	✓
23	Assay 10 (Document-129), S1	3339.2501	2499.1039 – 4179.3964	✓
24	Assay 11 (Document-130), S1	3165.2539	2335.1210 – 3995.3868	✓

Equivalence test parameter estimate:
Difference of asymptotes (nonlinear models) : A(S)-D(S)

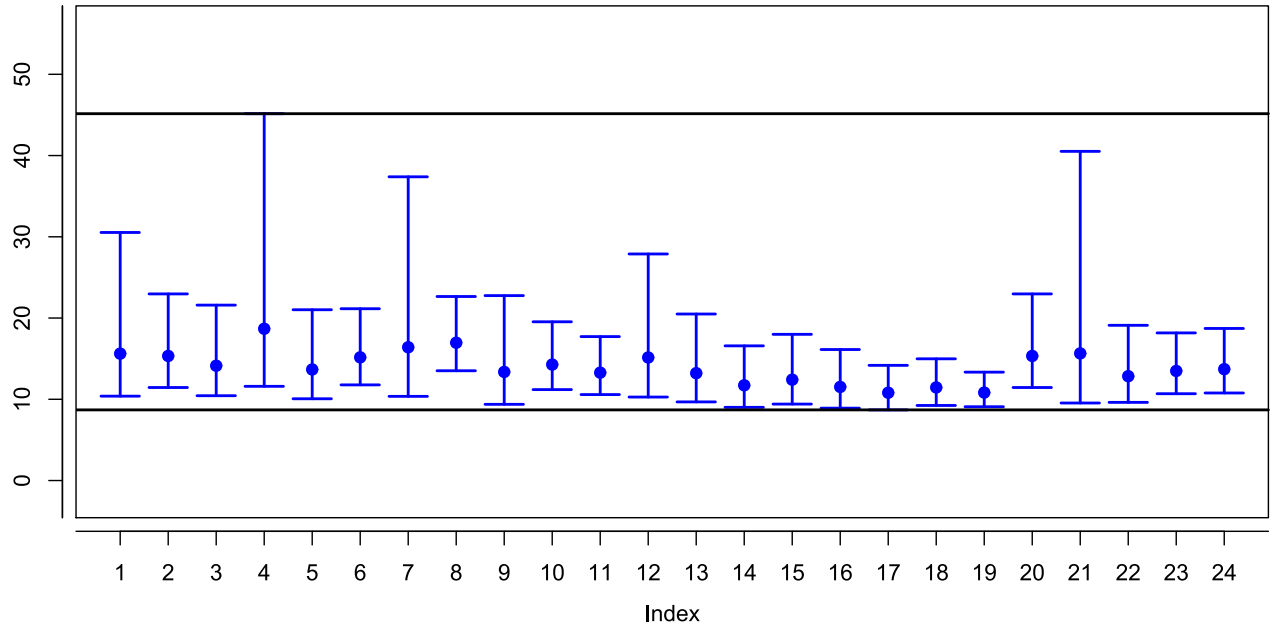


Mean	SD	CoV[%]	Margins
-43591.965	1647.4285	0.03779	38783.562 – 49435.246

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	42343.738	39786.090 – 44901.385	✓
2	Assay 13 (Document-108), S1	42772.303	41067.979 – 44476.627	✓
3	Assay 14 (Document-109), S1	43143.486	41128.272 – 45158.700	✓
4	Assay 15 (Document-110), S1	46295.492	43155.738 – 49435.246	✓
5	Assay 16 (Document-111), S1	42639.171	40530.898 – 44747.444	✓
6	Assay 17 (Document-112), S1	42456.859	41004.324 – 43909.394	✓
7	Assay 18 (Document-113), S1	44788.157	41723.229 – 47853.085	✓
8	Assay 19 (Document-114), S1	44604.193	43299.531 – 45908.855	✓
9	Assay 20 (Document-115), S1	43562.519	40969.732 – 46155.307	✓
10	Assay 21 (Document-116), S1	44859.659	43136.117 – 46583.202	✓
11	Assay 22 (Document-117), S1	45102.044	43479.164 – 46724.925	✓
12	Assay 23 (Document-118), S1	46391.284	43520.030 – 49262.538	✓
13	Assay 24 (Document-119), S1	45131.318	42781.253 – 47481.384	✓
14	Assay 01 (Document-120), S1	41825.790	39778.368 – 43873.211	✓
15	Assay 02 (Document-121), S1	41772.890	39672.032 – 43873.747	✓
16	Assay 03 (Document-122), S1	46172.538	43978.849 – 48366.227	✓
17	Assay 04 (Document-123), S1	44346.550	42536.760 – 46156.341	✓
18	Assay 05 (Document-124), S1	44490.477	42799.188 – 46181.765	✓
19	Assay 06 (Document-125), S1	44241.303	42770.187 – 45712.420	✓
20	Assay 07 (Document-126), S1	42772.303	41067.979 – 44476.627	✓
21	Assay 08 (Document-127), S1	42444.969	39270.238 – 45619.701	✓
22	Assay 09 (Document-128), S1	42119.697	40196.445 – 44042.948	✓
23	Assay 10 (Document-129), S1	41705.390	40217.192 – 43193.588	✓
24	Assay 11 (Document-130), S1	40225.032	38783.562 – 41666.503	✓

Equivalence test parameter estimate:
Ratio of asymptotes (nonlinear models) : A(S)/D(S)

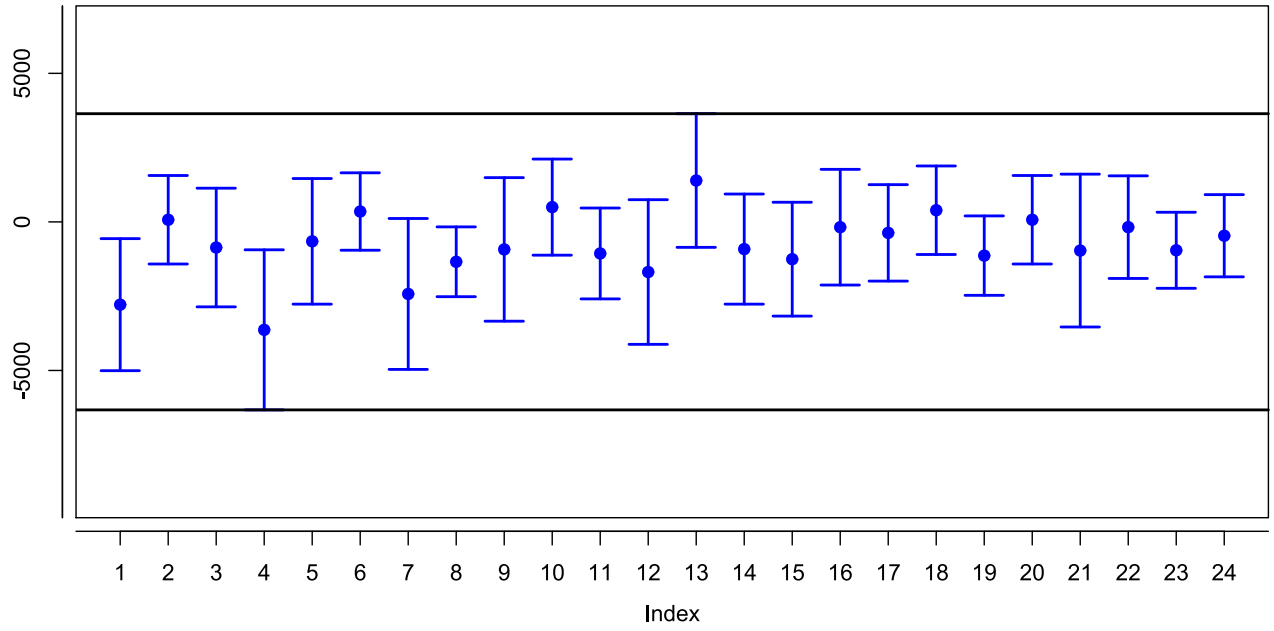


Mean	SD	CoV[%]	Margins
13.95889	1.99980	0.14326	8.69554 – 45.15183

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	15.61941	10.38511 – 30.53214	✓
2	Assay 13 (Document-108), S1	15.33359	11.44901 – 22.96987	✓
3	Assay 14 (Document-109), S1	14.13051	10.43937 – 21.59085	✓
4	Assay 15 (Document-110), S1	18.68219	11.59453 – 45.15183	✓
5	Assay 16 (Document-111), S1	13.66830	10.06332 – 21.02184	✓
6	Assay 17 (Document-112), S1	15.16228	11.77299 – 21.14634	✓
7	Assay 18 (Document-113), S1	16.40376	10.36024 – 37.38322	✓
8	Assay 19 (Document-114), S1	16.96249	13.51227 – 22.65056	✓
9	Assay 20 (Document-115), S1	13.36852	9.37964 – 22.76106	✓
10	Assay 21 (Document-116), S1	14.27436	11.19239 – 19.53852	✓
11	Assay 22 (Document-117), S1	13.27894	10.58023 – 17.71610	✓
12	Assay 23 (Document-118), S1	15.14458	10.27505 – 27.88657	✓
13	Assay 24 (Document-119), S1	13.21501	9.67907 – 20.49588	✓
14	Assay 01 (Document-120), S1	11.72047	9.00925 – 16.57647	✓
15	Assay 02 (Document-121), S1	12.41456	9.40973 – 17.99475	✓
16	Assay 03 (Document-122), S1	11.52188	8.90888 – 16.12397	✓
17	Assay 04 (Document-123), S1	10.80726	8.69554 – 14.17721	✓
18	Assay 05 (Document-124), S1	11.45848	9.23977 – 14.98185	✓
19	Assay 06 (Document-125), S1	10.82726	9.08342 – 13.34072	✓
20	Assay 07 (Document-126), S1	15.33359	11.44901 – 22.96987	✓
21	Assay 08 (Document-127), S1	15.64633	9.54098 – 40.51579	✓
22	Assay 09 (Document-128), S1	12.84194	9.62151 – 19.10608	✓
23	Assay 10 (Document-129), S1	13.48945	10.68616 – 18.17044	✓
24	Assay 11 (Document-130), S1	13.70831	10.77612 – 18.71739	✓

Equivalence test difference of parameter estimates: A upper asymptote (nonlinear models) A(T)-A(S)

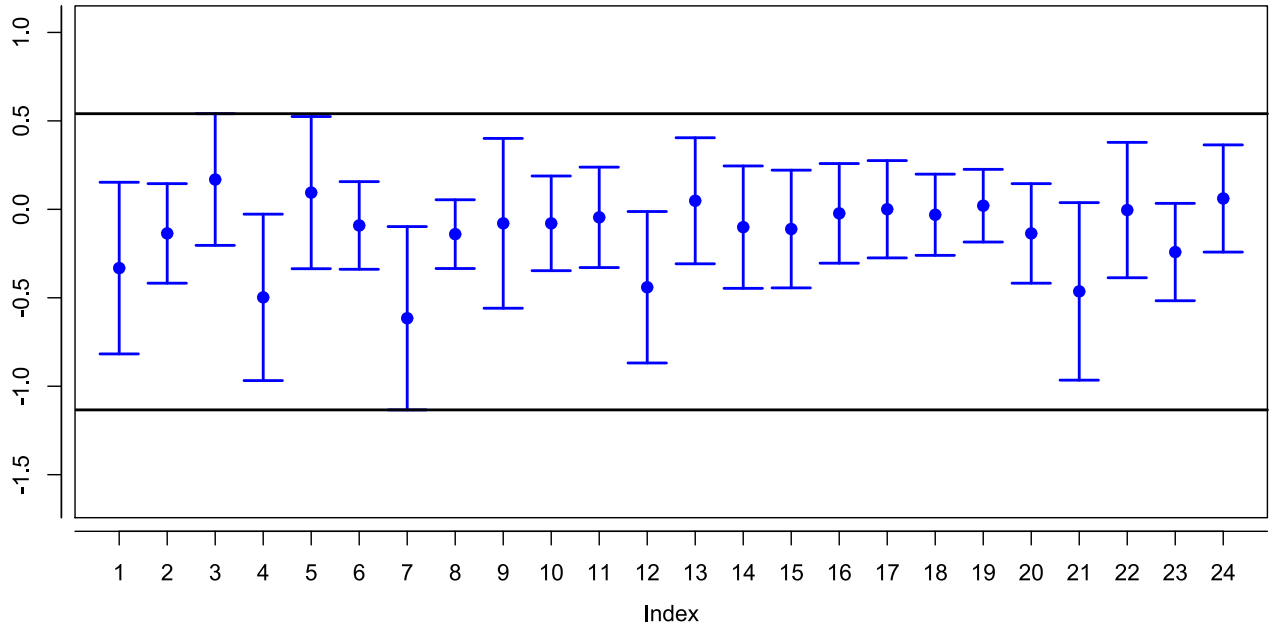


Mean	SD	CoV[%]	Margins
-792.28332	1103.5632	1.39289	-6326.8815 – 3641.8809

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-2785.2929	-5007.4239 – -563.16189	✓
2	Assay 13 (Document-108), S1	72.21642	-1417.3338 – 1561.7666	✓
3	Assay 14 (Document-109), S1	-862.37532	-2859.4472 – 1134.6966	✓
4	Assay 15 (Document-110), S1	-3633.1455	-6326.8815 – -939.40952	✓
5	Assay 16 (Document-111), S1	-654.39140	-2768.2468 – 1459.4640	✓
6	Assay 17 (Document-112), S1	349.46726	-953.15409 – 1652.0886	✓
7	Assay 18 (Document-113), S1	-2425.0804	-4964.6938 – 114.53295	✓
8	Assay 19 (Document-114), S1	-1342.2441	-2517.0035 – -167.48477	✓
9	Assay 20 (Document-115), S1	-925.93182	-3341.7216 – 1489.8579	✓
10	Assay 21 (Document-116), S1	497.56741	-1119.7612 – 2114.8960	✓
11	Assay 22 (Document-117), S1	-1062.3751	-2591.5574 – 466.80714	✓
12	Assay 23 (Document-118), S1	-1686.9044	-4121.1572 – 747.34830	✓
13	Assay 24 (Document-119), S1	1392.6983	-856.48422 – 3641.8809	✓
14	Assay 01 (Document-120), S1	-915.08616	-2768.2529 – 938.08056	✓
15	Assay 02 (Document-121), S1	-1254.5214	-3170.3782 – 661.33538	✓
16	Assay 03 (Document-122), S1	-178.24427	-2125.1526 – 1768.6641	✓
17	Assay 04 (Document-123), S1	-369.30327	-1992.3985 – 1253.7920	✓
18	Assay 05 (Document-124), S1	392.78780	-1097.0687 – 1882.6443	✓
19	Assay 06 (Document-125), S1	-1134.7016	-2471.1266 – 201.72336	✓
20	Assay 07 (Document-126), S1	72.21642	-1417.3338 – 1561.7666	✓
21	Assay 08 (Document-127), S1	-964.84734	-3536.9775 – 1607.2829	✓
22	Assay 09 (Document-128), S1	-176.54167	-1903.4795 – 1550.3962	✓
23	Assay 10 (Document-129), S1	-954.91106	-2234.7781 – 324.95594	✓
24	Assay 11 (Document-130), S1	-465.85542	-1849.2935 – 917.58261	✓

Equivalence test difference of parameter estimates: B parameter (nonlinear models) B(T)-B(S)

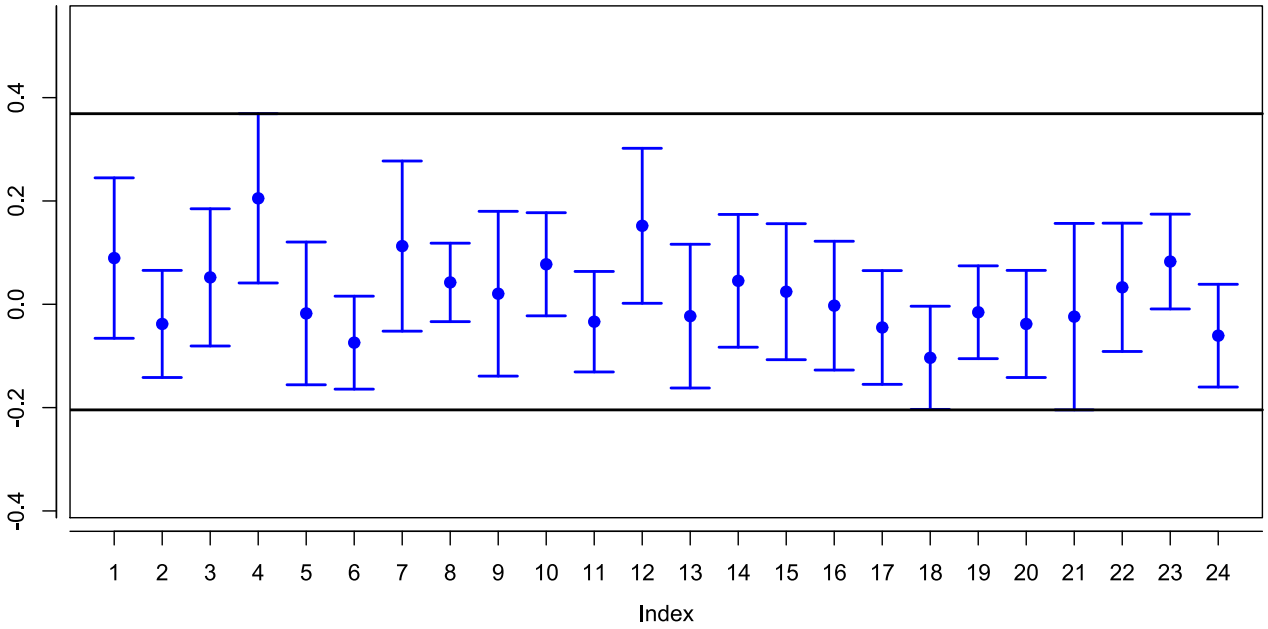


Mean	SD	CoV[%]	Margins
-0.13229	0.20130	1.52170	-1.13370 – 0.54061

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-0.33216	-0.81731 – 0.15298	✓
2	Assay 13 (Document-108), S1	-0.13617	-0.41751 – 0.14517	✓
3	Assay 14 (Document-109), S1	0.16842	-0.20377 – 0.54061	✓
4	Assay 15 (Document-110), S1	-0.49768	-0.96808 – -0.02729	✓
5	Assay 16 (Document-111), S1	0.09438	-0.33574 – 0.52449	✓
6	Assay 17 (Document-112), S1	-0.09122	-0.33892 – 0.15649	✓
7	Assay 18 (Document-113), S1	-0.61565	-1.13370 – -0.09759	✓
8	Assay 19 (Document-114), S1	-0.14025	-0.33461 – 0.05411	✓
9	Assay 20 (Document-115), S1	-0.07911	-0.55907 – 0.40085	✓
10	Assay 21 (Document-116), S1	-0.07921	-0.34680 – 0.18837	✓
11	Assay 22 (Document-117), S1	-0.04535	-0.32914 – 0.23844	✓
12	Assay 23 (Document-118), S1	-0.44045	-0.86855 – -0.01236	✓
13	Assay 24 (Document-119), S1	0.04836	-0.30795 – 0.40468	✓
14	Assay 01 (Document-120), S1	-0.10075	-0.44667 – 0.24517	✓
15	Assay 02 (Document-121), S1	-0.11130	-0.44405 – 0.22146	✓
16	Assay 03 (Document-122), S1	-0.02284	-0.30445 – 0.25877	✓
17	Assay 04 (Document-123), S1	4.697 E-04	-0.27454 – 0.27548	✓
18	Assay 05 (Document-124), S1	-0.03069	-0.26021 – 0.19882	✓
19	Assay 06 (Document-125), S1	0.02060	-0.18481 – 0.22601	✓
20	Assay 07 (Document-126), S1	-0.13617	-0.41751 – 0.14517	✓
21	Assay 08 (Document-127), S1	-0.46386	-0.96561 – 0.03790	✓
22	Assay 09 (Document-128), S1	-0.00408	-0.38676 – 0.37860	✓
23	Assay 10 (Document-129), S1	-0.24148	-0.51669 – 0.03374	✓
24	Assay 11 (Document-130), S1	0.06131	-0.24164 – 0.36426	✓

Equivalence test difference of parameter estimates: C parameter (nonlinear models) C(T)-C(S)

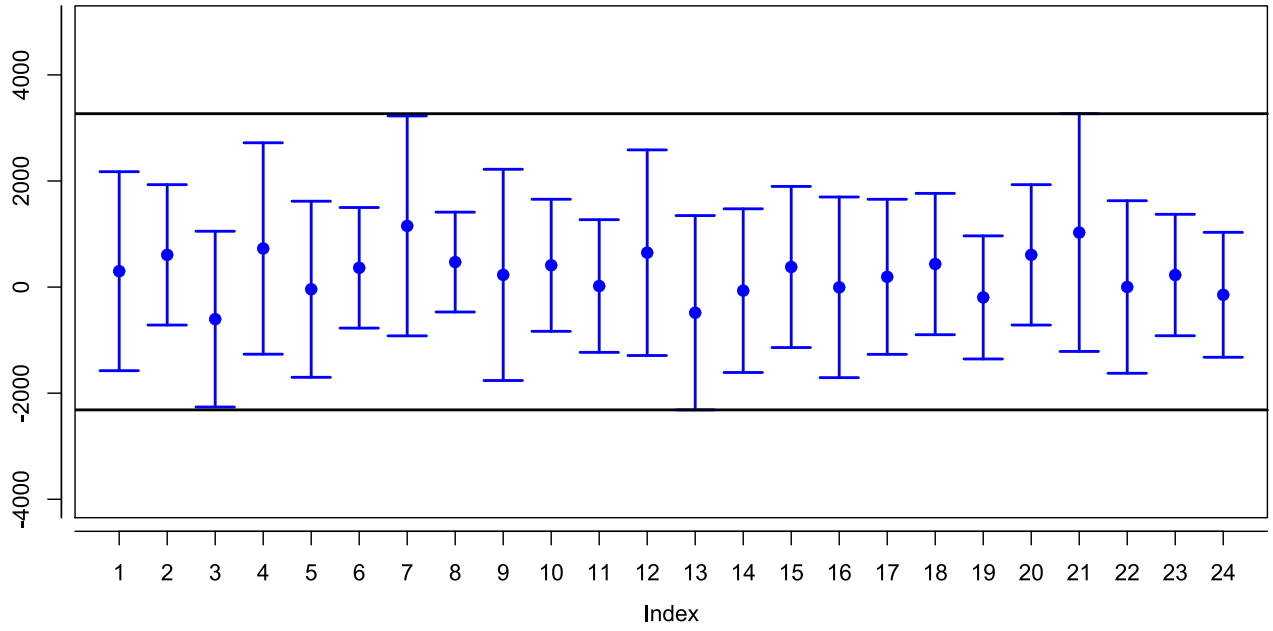


Mean	SD	CoV[%]	Margins
0.01920	0.07405	3.85662	-0.20440 – 0.36892

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.08945	-0.06583 – 0.24473	✓
2	Assay 13 (Document-108), S1	-0.03806	-0.14173 – 0.06561	✓
3	Assay 14 (Document-109), S1	0.05206	-0.08076 – 0.18488	✓
4	Assay 15 (Document-110), S1	0.20508	0.04124 – 0.36892	✓
5	Assay 16 (Document-111), S1	-0.01767	-0.15584 – 0.12050	✓
6	Assay 17 (Document-112), S1	-0.07426	-0.16425 – 0.01572	✓
7	Assay 18 (Document-113), S1	0.11265	-0.05202 – 0.27733	✓
8	Assay 19 (Document-114), S1	0.04234	-0.03360 – 0.11828	✓
9	Assay 20 (Document-115), S1	0.02045	-0.13903 – 0.17994	✓
10	Assay 21 (Document-116), S1	0.07745	-0.02236 – 0.17727	✓
11	Assay 22 (Document-117), S1	-0.03370	-0.13097 – 0.06357	✓
12	Assay 23 (Document-118), S1	0.15193	0.00192 – 0.30195	✓
13	Assay 24 (Document-119), S1	-0.02294	-0.16206 – 0.11618	✓
14	Assay 01 (Document-120), S1	0.04540	-0.08309 – 0.17390	✓
15	Assay 02 (Document-121), S1	0.02437	-0.10726 – 0.15600	✓
16	Assay 03 (Document-122), S1	-0.00264	-0.12731 – 0.12202	✓
17	Assay 04 (Document-123), S1	-0.04488	-0.15496 – 0.06519	✓
18	Assay 05 (Document-124), S1	-0.10361	-0.20347 – -0.00375	✓
19	Assay 06 (Document-125), S1	-0.01543	-0.10526 – 0.07440	✓
20	Assay 07 (Document-126), S1	-0.03806	-0.14173 – 0.06561	✓
21	Assay 08 (Document-127), S1	-0.02393	-0.20440 – 0.15654	✓
22	Assay 09 (Document-128), S1	0.03284	-0.09134 – 0.15701	✓
23	Assay 10 (Document-129), S1	0.08272	-0.00903 – 0.17446	✓
24	Assay 11 (Document-130), S1	-0.06073	-0.16017 – 0.03872	✓

Equivalence test difference of parameter estimates: D lower asymptote (nonlinear models) D(T)-D(S)

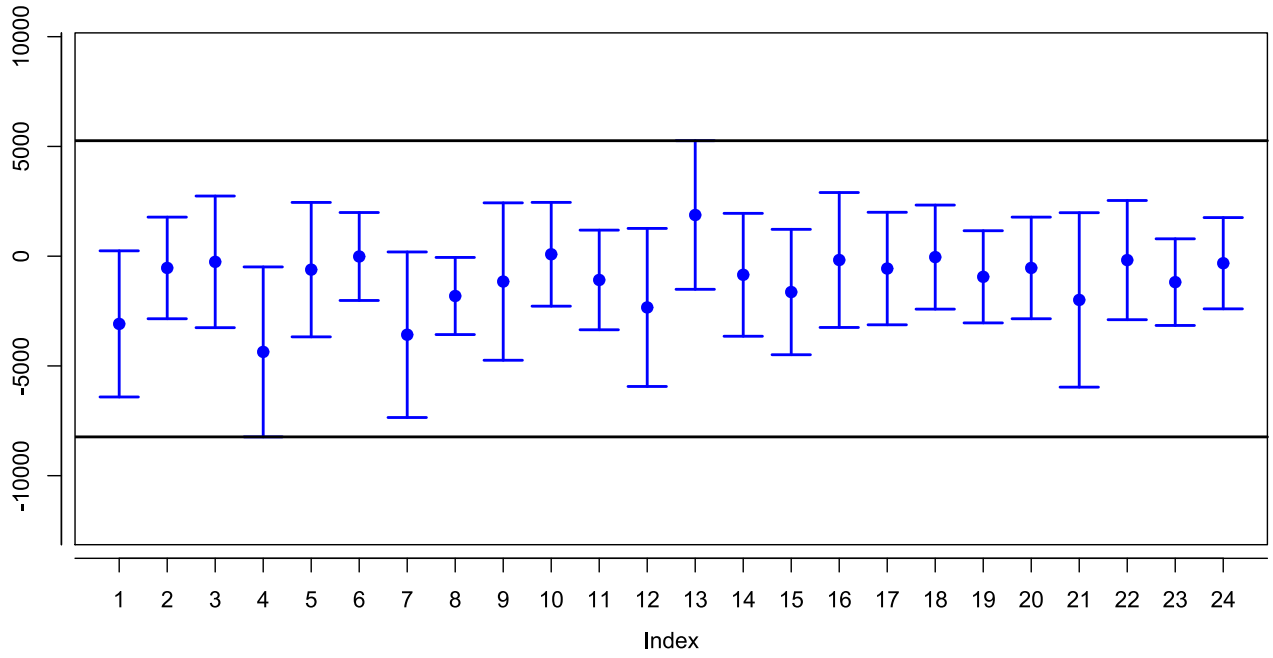


Mean	SD	CoV[%]	Margins
260.92462	426.90967	1.63614	-2314.9809 – 3268.5319

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	299.71954	-1575.7672 – 2175.2063	✓
2	Assay 13 (Document-108), S1	607.53392	-715.67472 – 1930.7426	✓
3	Assay 14 (Document-109), S1	-604.17498	-2260.8417 – 1052.4917	✓
4	Assay 15 (Document-110), S1	727.64937	-1265.0503 – 2720.3491	✓
5	Assay 16 (Document-111), S1	-41.27237	-1700.8772 – 1618.3324	✓
6	Assay 17 (Document-112), S1	363.40077	-773.21260 – 1500.0141	✓
7	Assay 18 (Document-113), S1	1153.3090	-919.43641 – 3226.0543	✓
8	Assay 19 (Document-114), S1	471.57239	-469.55356 – 1412.6983	✓
9	Assay 20 (Document-115), S1	229.73762	-1761.1930 – 2220.6682	✓
10	Assay 21 (Document-116), S1	410.84902	-833.96693 – 1655.6650	✓
11	Assay 22 (Document-117), S1	20.20651	-1230.4154 – 1270.8285	✓
12	Assay 23 (Document-118), S1	648.26130	-1289.8125 – 2586.3351	✓
13	Assay 24 (Document-119), S1	-483.40967	-2314.9809 – 1348.1616	✓
14	Assay 01 (Document-120), S1	-67.11892	-1609.9422 – 1475.7043	✓
15	Assay 02 (Document-121), S1	378.85651	-1139.7173 – 1897.4303	✓
16	Assay 03 (Document-122), S1	-4.52618	-1707.1842 – 1698.1318	✓
17	Assay 04 (Document-123), S1	193.62941	-1267.9795 – 1655.2383	✓
18	Assay 05 (Document-124), S1	434.31693	-897.67583 – 1766.3097	✓
19	Assay 06 (Document-125), S1	-194.90835	-1355.2736 – 965.45691	✓
20	Assay 07 (Document-126), S1	607.53392	-715.67472 – 1930.7426	✓
21	Assay 08 (Document-127), S1	1027.6399	-1213.2520 – 3268.5319	✓
22	Assay 09 (Document-128), S1	1.62358	-1624.7748 – 1628.0219	✓
23	Assay 10 (Document-129), S1	227.27795	-917.32755 – 1371.8834	✓
24	Assay 11 (Document-130), S1	-145.51622	-1323.0295 – 1031.9970	✓

Equivalence test difference of parameter estimates: Difference of asymptotes (nonlinear models)) (A(T)-D(T))-(A(S)-D(S))

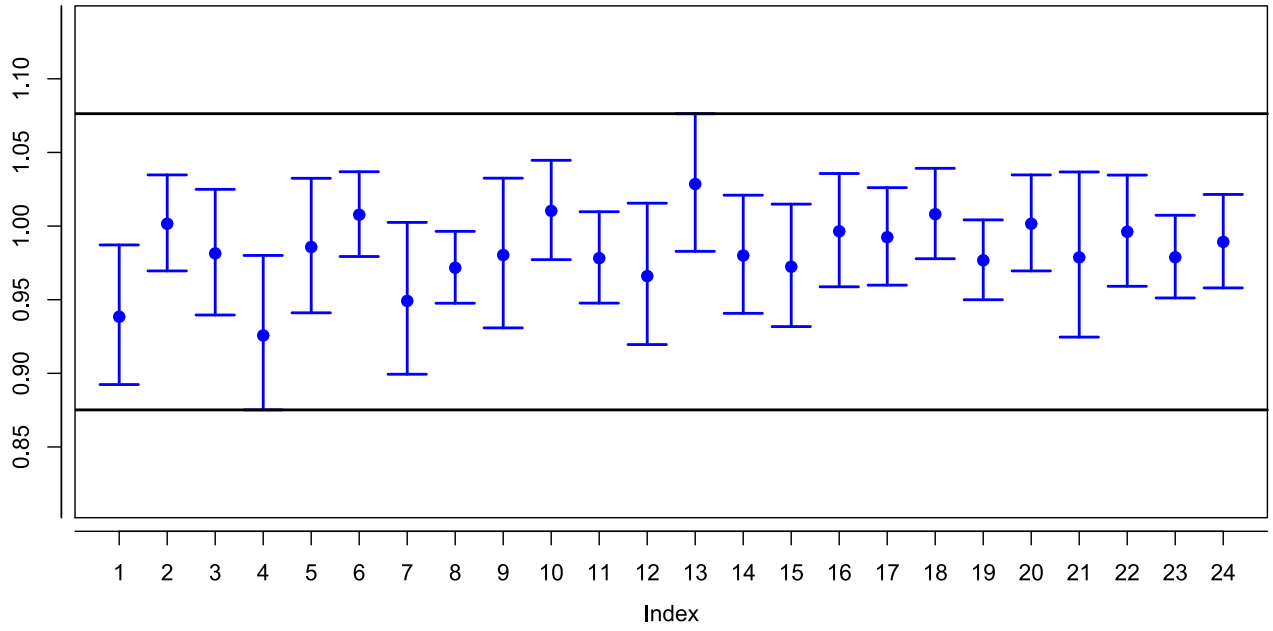


Mean	SD	CoV[%]	Margins
-1053.2079	1329.1283	1.26198	-8232.3529 – 5261.5642

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-3085.0124	-6413.9477 – 243.92284	✓
2	Assay 13 (Document-108), S1	-535.31749	-2850.1638 – 1779.5289	✓
3	Assay 14 (Document-109), S1	-258.20033	-3256.8123 – 2740.4116	✓
4	Assay 15 (Document-110), S1	-4360.7949	-8232.3529 – -489.23694	✓
5	Assay 16 (Document-111), S1	-613.11903	-3675.3798 – 2449.1417	✓
6	Assay 17 (Document-112), S1	-13.93351	-2017.4939 – 1989.6269	✓
7	Assay 18 (Document-113), S1	-3578.3894	-7349.7702 – 192.99141	✓
8	Assay 19 (Document-114), S1	-1813.8165	-3571.0415 – -56.59161	✓
9	Assay 20 (Document-115), S1	-1155.6694	-4741.1998 – 2429.8609	✓
10	Assay 21 (Document-116), S1	86.71839	-2277.3888 – 2450.8256	✓
11	Assay 22 (Document-117), S1	-1082.5817	-3352.5395 – 1187.3762	✓
12	Assay 23 (Document-118), S1	-2335.1657	-5935.5587 – 1265.2273	✓
13	Assay 24 (Document-119), S1	1876.1080	-1509.3481 – 5261.5642	✓
14	Assay 01 (Document-120), S1	-847.96723	-3647.4834 – 1951.5489	✓
15	Assay 02 (Document-121), S1	-1633.3779	-4489.9229 – 1223.1671	✓
16	Assay 03 (Document-122), S1	-173.71809	-3247.3974 – 2899.9612	✓
17	Assay 04 (Document-123), S1	-562.93268	-3126.2409 – 2000.3756	✓
18	Assay 05 (Document-124), S1	-41.52913	-2411.9394 – 2328.8811	✓
19	Assay 06 (Document-125), S1	-939.79326	-3039.2779 – 1159.6914	✓
20	Assay 07 (Document-126), S1	-535.31749	-2850.1638 – 1779.5289	✓
21	Assay 08 (Document-127), S1	-1992.4873	-5966.3097 – 1981.3352	✓
22	Assay 09 (Document-128), S1	-178.16525	-2893.6572 – 2537.3267	✓
23	Assay 10 (Document-129), S1	-1182.1890	-3155.6713 – 791.29326	✓
24	Assay 11 (Document-130), S1	-320.33920	-2399.3736 – 1758.6952	✓

Equivalence test ratio of parameter estimates:
A upper asymptote (nonlinear models) A(T)/A(S)

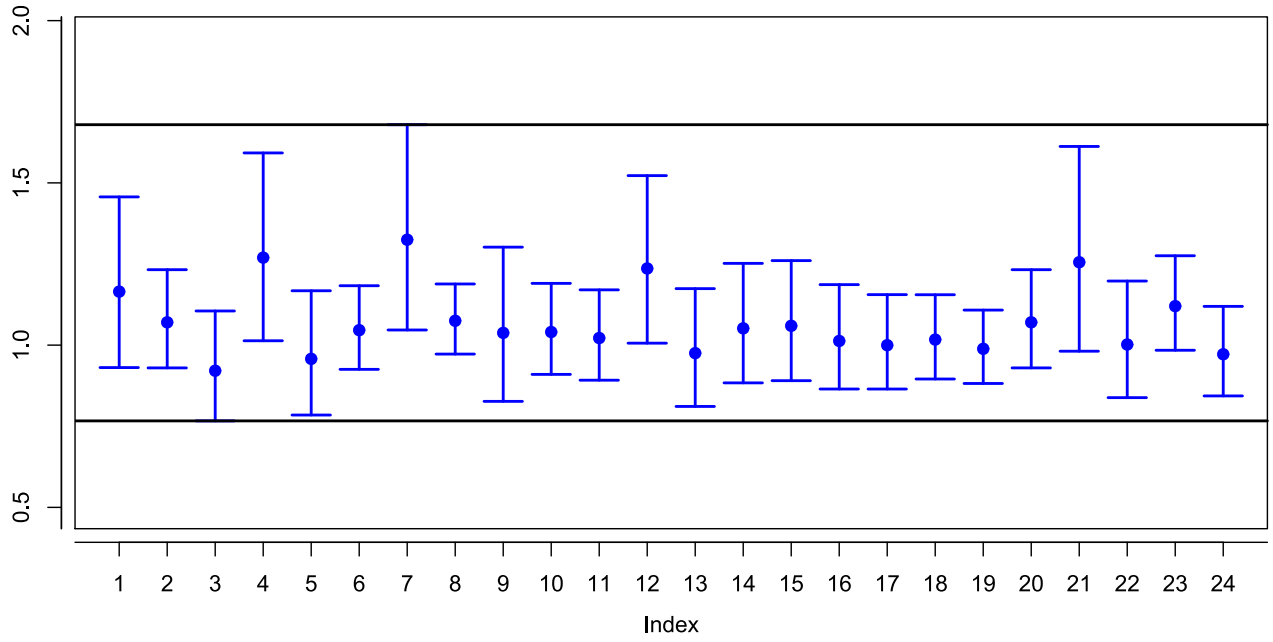


Mean	SD	CoV[%]	Margins
0.98314	0.02312	0.02352	0.87518 – 1.07631

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.93843	0.89238 – 0.98718	✓
2	Assay 13 (Document-108), S1	1.00158	0.96955 – 1.03474	✓
3	Assay 14 (Document-109), S1	0.98143	0.93960 – 1.02494	✓
4	Assay 15 (Document-110), S1	0.92572	0.87518 – 0.98006	✓
5	Assay 16 (Document-111), S1	0.98578	0.94109 – 1.03244	✓
6	Assay 17 (Document-112), S1	1.00769	0.97933 – 1.03689	✓
7	Assay 18 (Document-113), S1	0.94916	0.89938 – 1.00249	✓
8	Assay 19 (Document-114), S1	0.97168	0.94761 – 0.99642	✓
9	Assay 20 (Document-115), S1	0.98033	0.93085 – 1.03252	✓
10	Assay 21 (Document-116), S1	1.01031	0.97720 – 1.04466	✓
11	Assay 22 (Document-117), S1	0.97822	0.94768 – 1.00972	✓
12	Assay 23 (Document-118), S1	0.96604	0.91954 – 1.01554	✓
13	Assay 24 (Document-119), S1	1.02852	0.98284 – 1.07631	✓
14	Assay 01 (Document-120), S1	0.97999	0.94074 – 1.02097	✓
15	Assay 02 (Document-121), S1	0.97239	0.93175 – 1.01490	✓
16	Assay 03 (Document-122), S1	0.99647	0.95877 – 1.03568	✓
17	Assay 04 (Document-123), S1	0.99244	0.95988 – 1.02608	✓
18	Assay 05 (Document-124), S1	1.00806	0.97782 – 1.03921	✓
19	Assay 06 (Document-125), S1	0.97672	0.94997 – 1.00419	✓
20	Assay 07 (Document-126), S1	1.00158	0.96955 – 1.03474	✓
21	Assay 08 (Document-127), S1	0.97872	0.92460 – 1.03674	✓
22	Assay 09 (Document-128), S1	0.99613	0.95910 – 1.03461	✓
23	Assay 10 (Document-129), S1	0.97880	0.95117 – 1.00733	✓
24	Assay 11 (Document-130), S1	0.98926	0.95801 – 1.02147	✓

Equivalence test ratio of parameter estimates:
B parameter (nonlinear models) B(T)/B(S)

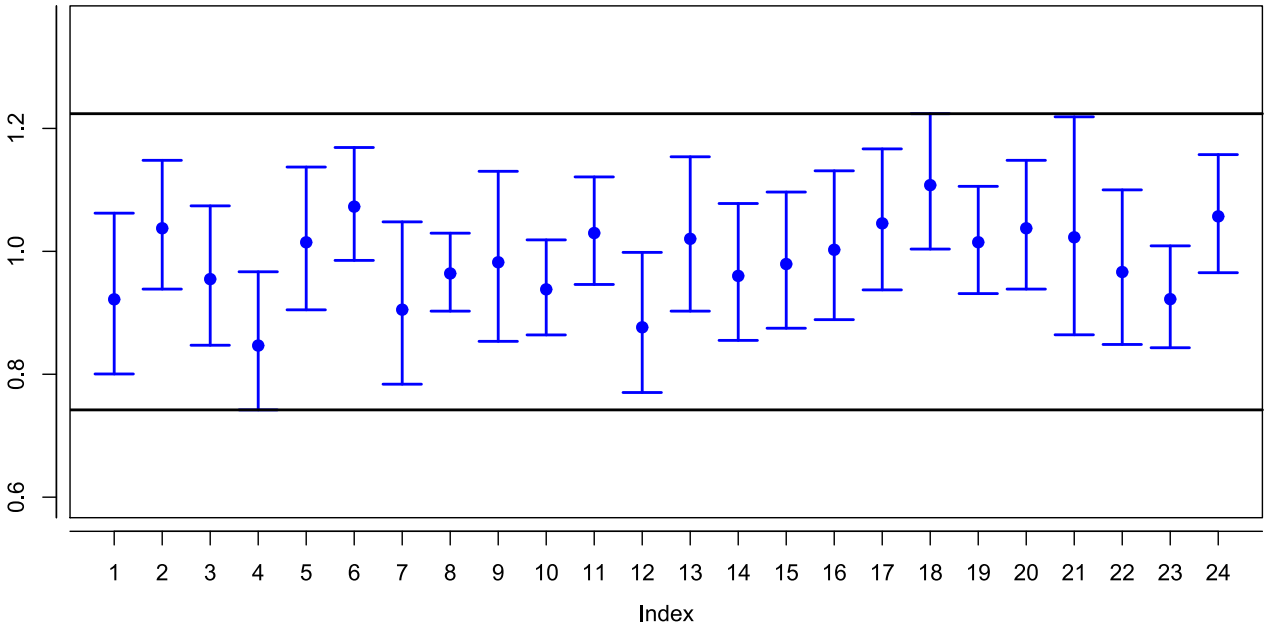


Mean	SD	CoV[%]	Margins
1.07044	0.10617	0.09918	0.76654 – 1.67929

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	1.16495	0.93082 – 1.45678	✓
2	Assay 13 (Document-108), S1	1.07029	0.92982 – 1.23248	✓
3	Assay 14 (Document-109), S1	0.92109	0.76654 – 1.10524	✓
4	Assay 15 (Document-110), S1	1.26963	1.01344 – 1.59227	✓
5	Assay 16 (Document-111), S1	0.95768	0.78457 – 1.16752	✓
6	Assay 17 (Document-112), S1	1.04613	0.92533 – 1.18304	✓
7	Assay 18 (Document-113), S1	1.32482	1.04664 – 1.67929	✓
8	Assay 19 (Document-114), S1	1.07499	0.97239 – 1.18843	✓
9	Assay 20 (Document-115), S1	1.03775	0.82667 – 1.30196	✓
10	Assay 21 (Document-116), S1	1.04041	0.90983 – 1.19031	✓
11	Assay 22 (Document-117), S1	1.02186	0.89195 – 1.17035	✓
12	Assay 23 (Document-118), S1	1.23623	1.00604 – 1.52236	✓
13	Assay 24 (Document-119), S1	0.97537	0.81101 – 1.17407	✓
14	Assay 01 (Document-120), S1	1.05173	0.88369 – 1.25197	✓
15	Assay 02 (Document-121), S1	1.05950	0.89045 – 1.26041	✓
16	Assay 03 (Document-122), S1	1.01284	0.86476 – 1.18643	✓
17	Assay 04 (Document-123), S1	0.99975	0.86467 – 1.15560	✓
18	Assay 05 (Document-124), S1	1.01711	0.89559 – 1.15527	✓
19	Assay 06 (Document-125), S1	0.98865	0.88183 – 1.10798	✓
20	Assay 07 (Document-126), S1	1.07029	0.92982 – 1.23248	✓
21	Assay 08 (Document-127), S1	1.25550	0.98127 – 1.61224	✓
22	Assay 09 (Document-128), S1	1.00189	0.83816 – 1.19747	✓
23	Assay 10 (Document-129), S1	1.12020	0.98418 – 1.27540	✓
24	Assay 11 (Document-130), S1	0.97188	0.84344 – 1.11941	✓

Equivalence test ratio of parameter estimates:
C parameter (nonlinear models) C(T)/C(S)

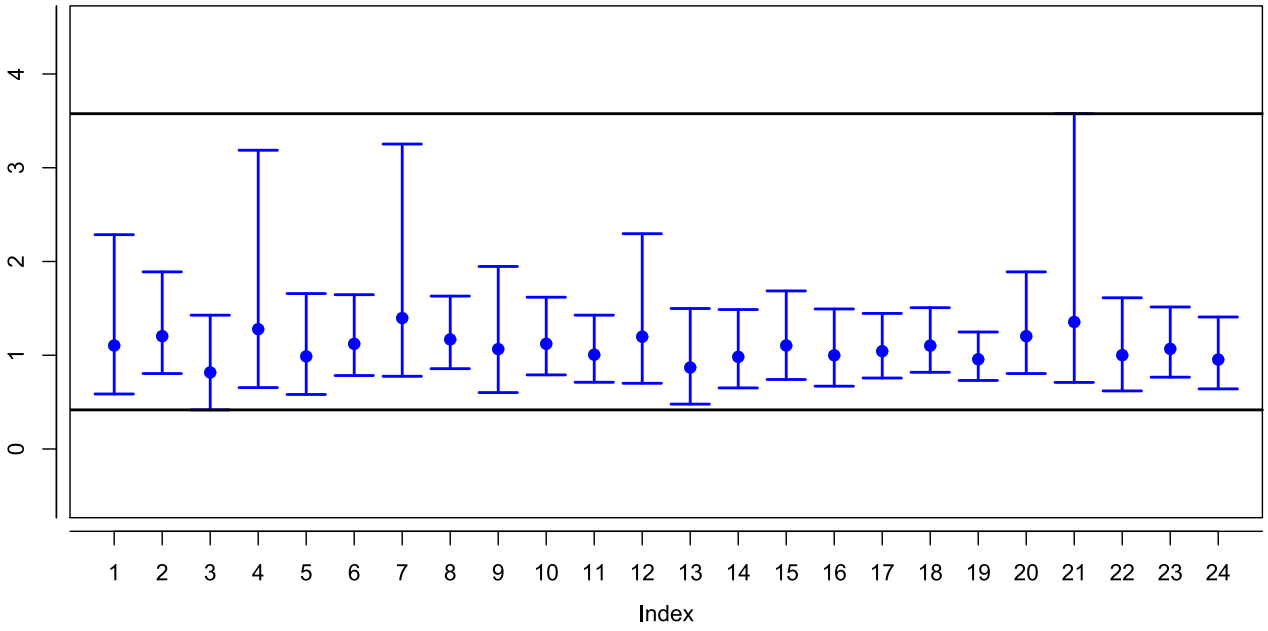


Mean	SD	CoV[%]	Margins
0.98669	0.06379	0.06465	0.74203 – 1.22397

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.92193	0.80046 – 1.06212	✓
2	Assay 13 (Document-108), S1	1.03754	0.93858 – 1.14810	✓
3	Assay 14 (Document-109), S1	0.95484	0.84722 – 1.07399	✓
4	Assay 15 (Document-110), S1	0.84671	0.74203 – 0.96675	✓
5	Assay 16 (Document-111), S1	1.01469	0.90483 – 1.13716	✓
6	Assay 17 (Document-112), S1	1.07274	0.98528 – 1.16896	✓
7	Assay 18 (Document-113), S1	0.90508	0.78384 – 1.04795	✓
8	Assay 19 (Document-114), S1	0.96402	0.90271 – 1.02956	✓
9	Assay 20 (Document-115), S1	0.98223	0.85357 – 1.13023	✓
10	Assay 21 (Document-116), S1	0.93815	0.86399 – 1.01864	✓
11	Assay 22 (Document-117), S1	1.02979	0.94610 – 1.12109	✓
12	Assay 23 (Document-118), S1	0.87640	0.77031 – 0.99832	✓
13	Assay 24 (Document-119), S1	1.02037	0.90272 – 1.15386	✓
14	Assay 01 (Document-120), S1	0.96003	0.85512 – 1.07783	✓
15	Assay 02 (Document-121), S1	0.97937	0.87490 – 1.09648	✓
16	Assay 03 (Document-122), S1	1.00255	0.88886 – 1.13103	✓
17	Assay 04 (Document-123), S1	1.04553	0.93726 – 1.16670	✓
18	Assay 05 (Document-124), S1	1.10775	1.00371 – 1.22397	✓
19	Assay 06 (Document-125), S1	1.01484	0.93125 – 1.10576	✓
20	Assay 07 (Document-126), S1	1.03754	0.93858 – 1.14810	✓
21	Assay 08 (Document-127), S1	1.02286	0.86420 – 1.21888	✓
22	Assay 09 (Document-128), S1	0.96638	0.84847 – 1.10001	✓
23	Assay 10 (Document-129), S1	0.92225	0.84315 – 1.00891	✓
24	Assay 11 (Document-130), S1	1.05691	0.96525 – 1.15738	✓

Equivalence test ratio of parameter estimates:
D lower asymptote (nonlinear models) D(T)/D(S)

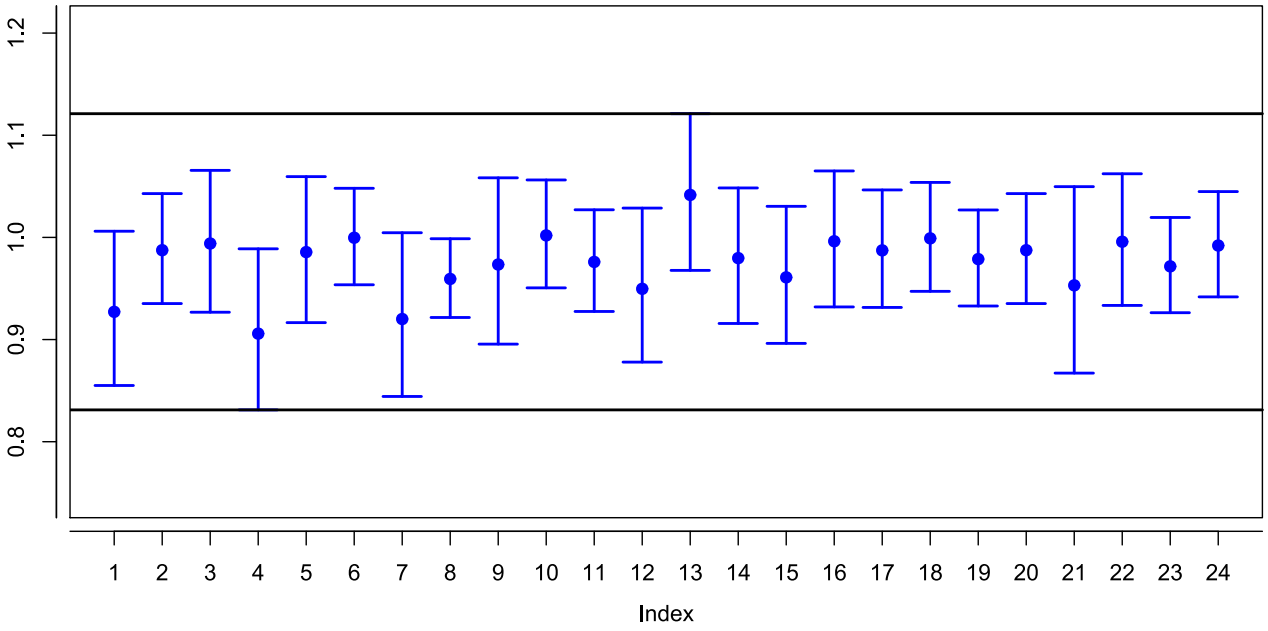


Mean	SD	CoV[%]	Margins
1.08759	0.14050	0.12919	0.41699 – 3.57643

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	1.10348	0.58648 – 2.28599	✓
2	Assay 13 (Document-108), S1	1.20359	0.80471 – 1.88926	✓
3	Assay 14 (Document-109), S1	0.81612	0.41699 – 1.42712	✓
4	Assay 15 (Document-110), S1	1.27792	0.65491 – 3.18653	✓
5	Assay 16 (Document-111), S1	0.98774	0.58134 – 1.65784	✓
6	Assay 17 (Document-112), S1	1.12122	0.78353 – 1.64585	✓
7	Assay 18 (Document-113), S1	1.39665	0.77540 – 3.25262	✓
8	Assay 19 (Document-114), S1	1.16876	0.85666 – 1.63066	✓
9	Assay 20 (Document-115), S1	1.06523	0.60167 – 1.94682	✓
10	Assay 21 (Document-116), S1	1.12157	0.79016 – 1.61876	✓
11	Assay 22 (Document-117), S1	1.00550	0.71151 – 1.42726	✓
12	Assay 23 (Document-118), S1	1.19765	0.70069 – 2.29640	✓
13	Assay 24 (Document-119), S1	0.86916	0.47834 – 1.49836	✓
14	Assay 01 (Document-120), S1	0.98280	0.65148 – 1.48731	✓
15	Assay 02 (Document-121), S1	1.10352	0.74114 – 1.68597	✓
16	Assay 03 (Document-122), S1	0.99897	0.66980 – 1.49370	✓
17	Assay 04 (Document-123), S1	1.04282	0.75681 – 1.44576	✓
18	Assay 05 (Document-124), S1	1.10210	0.81779 – 1.50720	✓
19	Assay 06 (Document-125), S1	0.95671	0.73070 – 1.24791	✓
20	Assay 07 (Document-126), S1	1.20359	0.80471 – 1.88926	✓
21	Assay 08 (Document-127), S1	1.35460	0.71003 – 3.57643	✓
22	Assay 09 (Document-128), S1	1.00046	0.61932 – 1.61269	✓
23	Assay 10 (Document-129), S1	1.06806	0.76587 – 1.51461	✓
24	Assay 11 (Document-130), S1	0.95403	0.64116 – 1.40783	✓

Equivalence test ratio of parameter estimates: Difference of asymptotes (nonlinear models) (A(T)-D(T))/(A(S)-D(S))

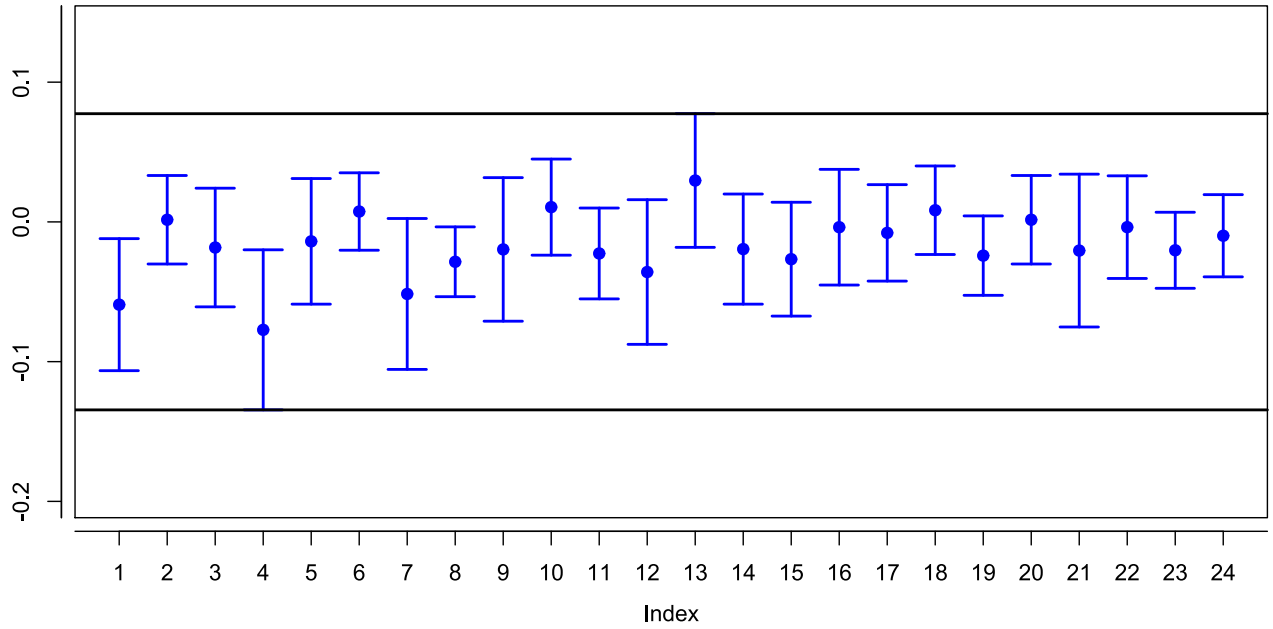


Mean	SD	CoV[%]	Margins
0.97599	0.02959	0.03032	0.83116 – 1.12109

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.92714	0.85504 – 1.00604	✓
2	Assay 13 (Document-108), S1	0.98748	0.93524 – 1.04287	✓
3	Assay 14 (Document-109), S1	0.99402	0.92676 – 1.06561	✓
4	Assay 15 (Document-110), S1	0.90581	0.83116 – 0.98882	✓
5	Assay 16 (Document-111), S1	0.98562	0.91658 – 1.05949	✓
6	Assay 17 (Document-112), S1	0.99967	0.95362 – 1.04807	✓
7	Assay 18 (Document-113), S1	0.92010	0.84430 – 1.00456	✓
8	Assay 19 (Document-114), S1	0.95934	0.92161 – 0.99870	✓
9	Assay 20 (Document-115), S1	0.97347	0.89554 – 1.05832	✓
10	Assay 21 (Document-116), S1	1.00193	0.95060 – 1.05623	✓
11	Assay 22 (Document-117), S1	0.97600	0.92750 – 1.02703	✓
12	Assay 23 (Document-118), S1	0.94966	0.87793 – 1.02870	✓
13	Assay 24 (Document-119), S1	1.04157	0.96771 – 1.12109	✓
14	Assay 01 (Document-120), S1	0.97973	0.91575 – 1.04841	✓
15	Assay 02 (Document-121), S1	0.96090	0.89626 – 1.03041	✓
16	Assay 03 (Document-122), S1	0.99624	0.93194 – 1.06505	✓
17	Assay 04 (Document-123), S1	0.98731	0.93144 – 1.04646	✓
18	Assay 05 (Document-124), S1	0.99907	0.94720 – 1.05382	✓
19	Assay 06 (Document-125), S1	0.97876	0.93284 – 1.02684	✓
20	Assay 07 (Document-126), S1	0.98748	0.93524 – 1.04287	✓
21	Assay 08 (Document-127), S1	0.95306	0.86716 – 1.04967	✓
22	Assay 09 (Document-128), S1	0.99577	0.93342 – 1.06229	✓
23	Assay 10 (Document-129), S1	0.97165	0.92628 – 1.01950	✓
24	Assay 11 (Document-130), S1	0.99204	0.94178 – 1.04485	✓

Equivalence test scaled parameter range:
A upper asymptote (nonlinear models) (A(T)-A(S))/A*

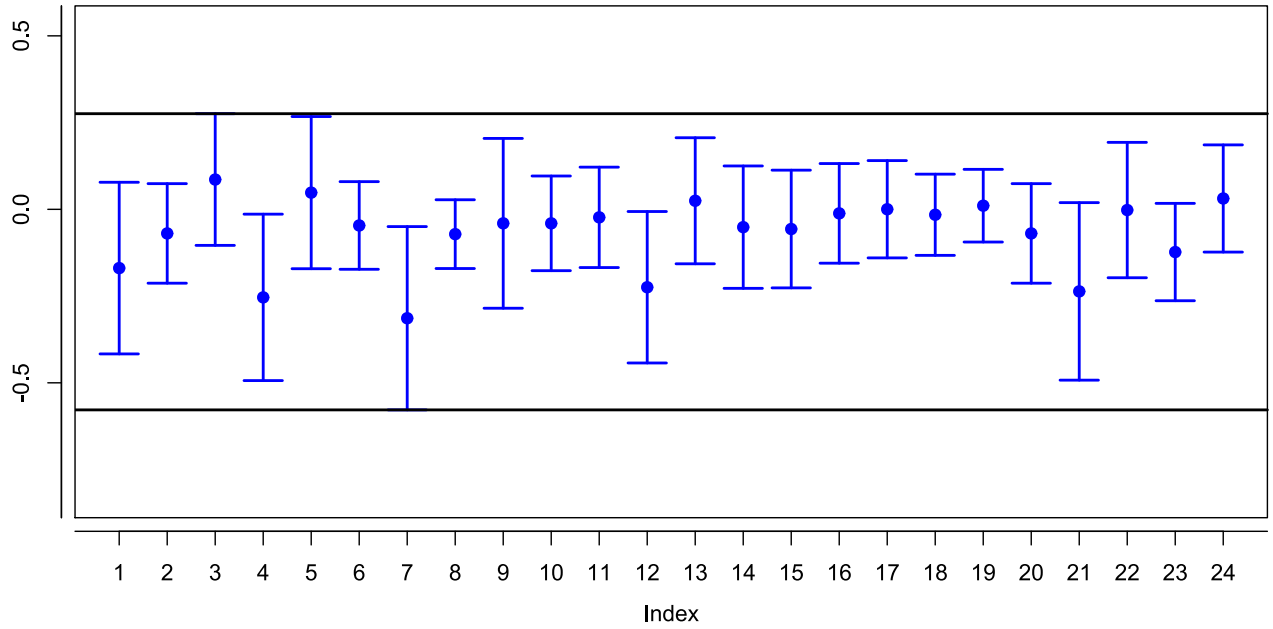


Mean	SD	CoV[%]	Margins	Reference mean
-0.01685	0.02346	1.39289	-0.13452 – 0.07743	47032.365

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-0.05922	-0.10647 – -0.01197	✓
2	Assay 13 (Document-108), S1	0.00154	-0.03014 – 0.03321	✓
3	Assay 14 (Document-109), S1	-0.01834	-0.06080 – 0.02413	✓
4	Assay 15 (Document-110), S1	-0.07725	-0.13452 – -0.01997	✓
5	Assay 16 (Document-111), S1	-0.01391	-0.05886 – 0.03103	✓
6	Assay 17 (Document-112), S1	0.00743	-0.02027 – 0.03513	✓
7	Assay 18 (Document-113), S1	-0.05156	-0.10556 – 0.00244	✓
8	Assay 19 (Document-114), S1	-0.02854	-0.05352 – -0.00356	✓
9	Assay 20 (Document-115), S1	-0.01969	-0.07105 – 0.03168	✓
10	Assay 21 (Document-116), S1	0.01058	-0.02381 – 0.04497	✓
11	Assay 22 (Document-117), S1	-0.02259	-0.05510 – 0.00993	✓
12	Assay 23 (Document-118), S1	-0.03587	-0.08762 – 0.01589	✓
13	Assay 24 (Document-119), S1	0.02961	-0.01821 – 0.07743	✓
14	Assay 01 (Document-120), S1	-0.01946	-0.05886 – 0.01995	✓
15	Assay 02 (Document-121), S1	-0.02667	-0.06741 – 0.01406	✓
16	Assay 03 (Document-122), S1	-0.00379	-0.04518 – 0.03761	✓
17	Assay 04 (Document-123), S1	-0.00785	-0.04236 – 0.02666	✓
18	Assay 05 (Document-124), S1	0.00835	-0.02333 – 0.04003	✓
19	Assay 06 (Document-125), S1	-0.02413	-0.05254 – 0.00429	✓
20	Assay 07 (Document-126), S1	0.00154	-0.03014 – 0.03321	✓
21	Assay 08 (Document-127), S1	-0.02051	-0.07520 – 0.03417	✓
22	Assay 09 (Document-128), S1	-0.00375	-0.04047 – 0.03296	✓
23	Assay 10 (Document-129), S1	-0.02030	-0.04752 – 0.00691	✓
24	Assay 11 (Document-130), S1	-0.00990	-0.03932 – 0.01951	✓

Equivalence test scaled parameter range:
B parameter (nonlinear models) (B(T)-B(S))/B*

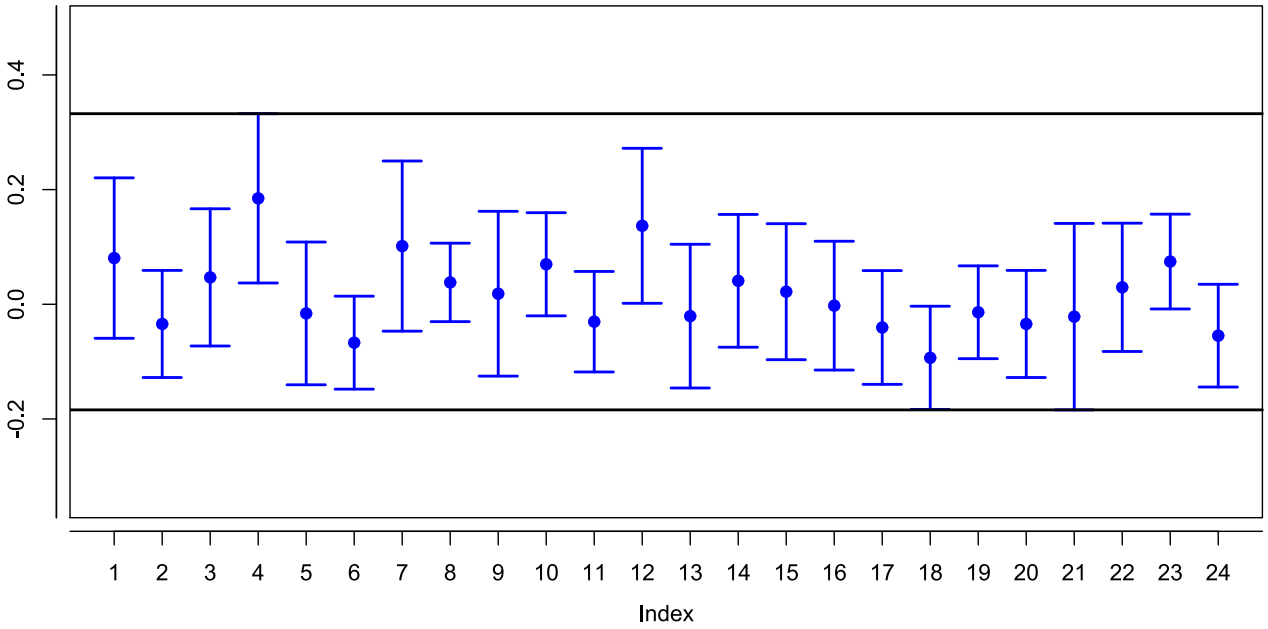


Mean	SD	CoV[%]	Margins	Reference mean
-0.06745	0.10263	1.52170	-0.57803 – 0.27563	1.96134

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	-0.16936	-0.41671 – 0.07800	✓
2	Assay 13 (Document-108), S1	-0.06943	-0.21287 – 0.07402	✓
3	Assay 14 (Document-109), S1	0.08587	-0.10389 – 0.27563	✓
4	Assay 15 (Document-110), S1	-0.25375	-0.49358 – -0.01391	✓
5	Assay 16 (Document-111), S1	0.04812	-0.17118 – 0.26742	✓
6	Assay 17 (Document-112), S1	-0.04651	-0.17280 – 0.07979	✓
7	Assay 18 (Document-113), S1	-0.31389	-0.57803 – -0.04976	✓
8	Assay 19 (Document-114), S1	-0.07151	-0.17060 – 0.02759	✓
9	Assay 20 (Document-115), S1	-0.04034	-0.28505 – 0.20438	✓
10	Assay 21 (Document-116), S1	-0.04039	-0.17682 – 0.09604	✓
11	Assay 22 (Document-117), S1	-0.02312	-0.16781 – 0.12157	✓
12	Assay 23 (Document-118), S1	-0.22457	-0.44284 – -0.00630	✓
13	Assay 24 (Document-119), S1	0.02466	-0.15701 – 0.20633	✓
14	Assay 01 (Document-120), S1	-0.05137	-0.22774 – 0.12500	✓
15	Assay 02 (Document-121), S1	-0.05675	-0.22640 – 0.11291	✓
16	Assay 03 (Document-122), S1	-0.01164	-0.15522 – 0.13194	✓
17	Assay 04 (Document-123), S1	2.395 E-04	-0.13998 – 0.14045	✓
18	Assay 05 (Document-124), S1	-0.01565	-0.13267 – 0.10137	✓
19	Assay 06 (Document-125), S1	0.01050	-0.09423 – 0.11523	✓
20	Assay 07 (Document-126), S1	-0.06943	-0.21287 – 0.07402	✓
21	Assay 08 (Document-127), S1	-0.23650	-0.49232 – 0.01932	✓
22	Assay 09 (Document-128), S1	-0.00208	-0.19719 – 0.19303	✓
23	Assay 10 (Document-129), S1	-0.12312	-0.26344 – 0.01720	✓
24	Assay 11 (Document-130), S1	0.03126	-0.12320 – 0.18572	✓

Equivalence test scaled parameter range:
C parameter (nonlinear models) (C(T)-C(S))/C*

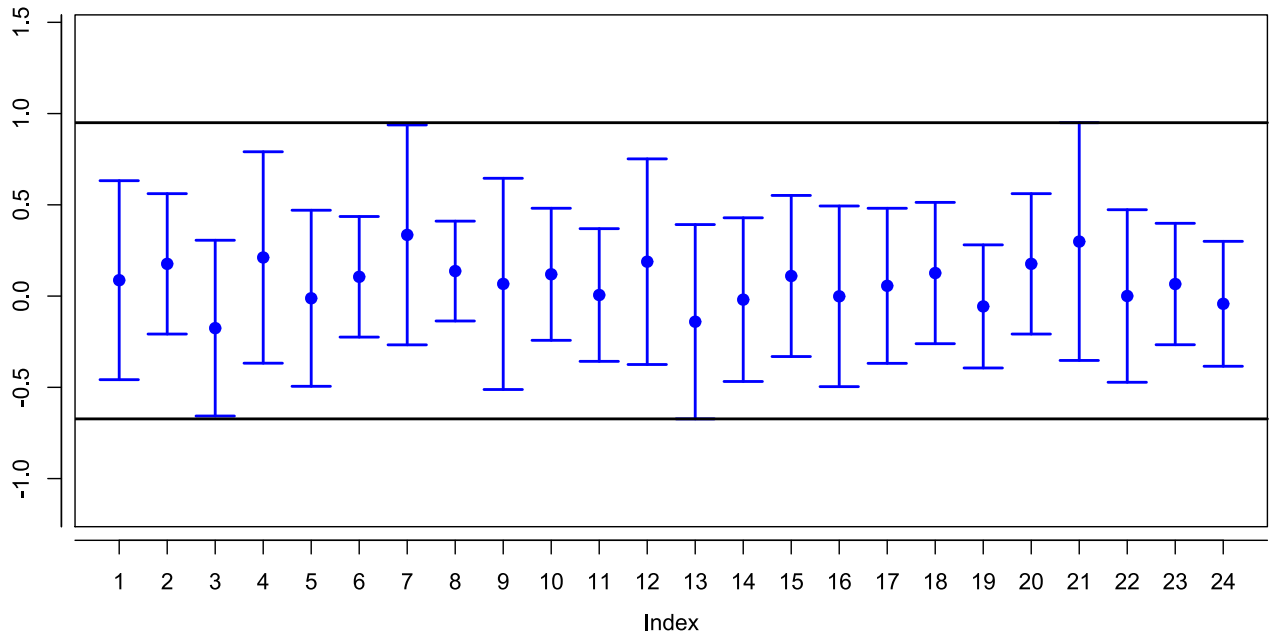


Mean	SD	CoV[%]	Margins	Reference mean
0.01730	0.06672	3.85662	-0.18417 – 0.33239	1.10989

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.08060	-0.05931 – 0.22050	✓
2	Assay 13 (Document-108), S1	-0.03429	-0.12770 – 0.05912	✓
3	Assay 14 (Document-109), S1	0.04691	-0.07276 – 0.16657	✓
4	Assay 15 (Document-110), S1	0.18477	0.03716 – 0.33239	✓
5	Assay 16 (Document-111), S1	-0.01592	-0.14041 – 0.10857	✓
6	Assay 17 (Document-112), S1	-0.06691	-0.14799 – 0.01416	✓
7	Assay 18 (Document-113), S1	0.10150	-0.04687 – 0.24987	✓
8	Assay 19 (Document-114), S1	0.03815	-0.03028 – 0.10657	✓
9	Assay 20 (Document-115), S1	0.01843	-0.12526 – 0.16212	✓
10	Assay 21 (Document-116), S1	0.06979	-0.02015 – 0.15972	✓
11	Assay 22 (Document-117), S1	-0.03037	-0.11800 – 0.05727	✓
12	Assay 23 (Document-118), S1	0.13689	0.00173 – 0.27206	✓
13	Assay 24 (Document-119), S1	-0.02067	-0.14601 – 0.10468	✓
14	Assay 01 (Document-120), S1	0.04091	-0.07487 – 0.15668	✓
15	Assay 02 (Document-121), S1	0.02196	-0.09664 – 0.14055	✓
16	Assay 03 (Document-122), S1	-0.00238	-0.11470 – 0.10994	✓
17	Assay 04 (Document-123), S1	-0.04044	-0.13962 – 0.05874	✓
18	Assay 05 (Document-124), S1	-0.09335	-0.18332 – -0.00338	✓
19	Assay 06 (Document-125), S1	-0.01390	-0.09484 – 0.06703	✓
20	Assay 07 (Document-126), S1	-0.03429	-0.12770 – 0.05912	✓
21	Assay 08 (Document-127), S1	-0.02156	-0.18417 – 0.14104	✓
22	Assay 09 (Document-128), S1	0.02959	-0.08230 – 0.14147	✓
23	Assay 10 (Document-129), S1	0.07453	-0.00814 – 0.15719	✓
24	Assay 11 (Document-130), S1	-0.05471	-0.14431 – 0.03489	✓

Equivalence test scaled parameter range:
D lower asymptote (nonlinear models) (D(T)-D(S))/D*

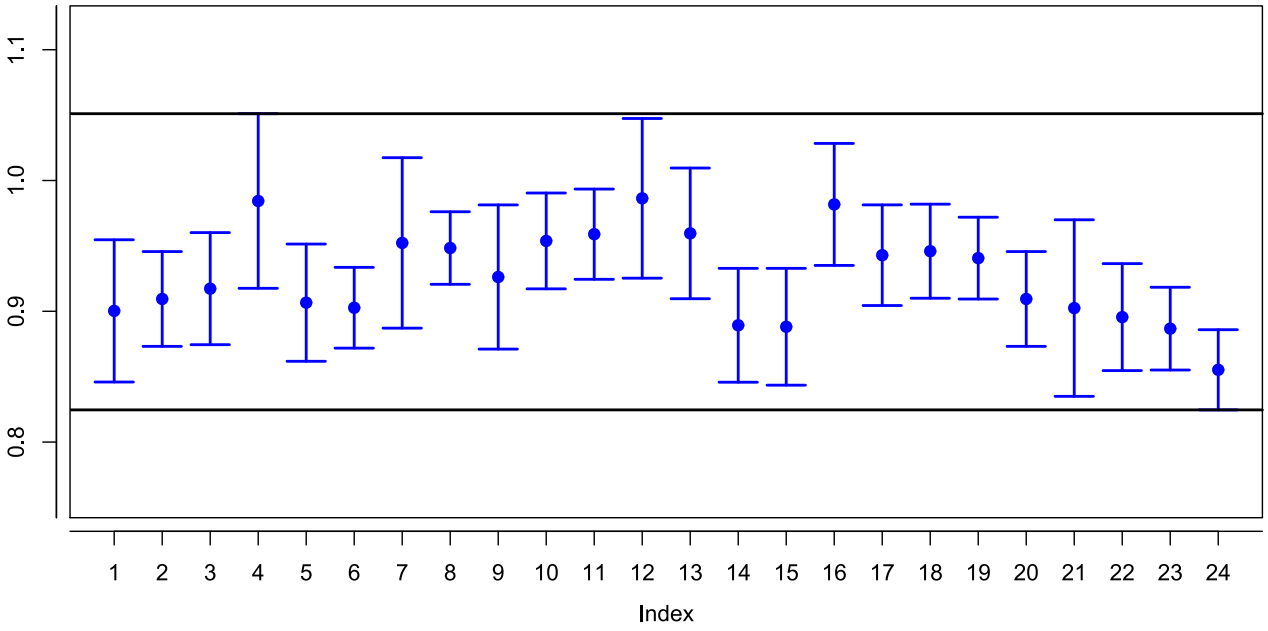


Mean	SD	CoV[%]	Margins	Reference mean
0.07584	0.12409	1.63614	-0.67288 – 0.95004	3440.3998

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.08712	-0.45802 – 0.63225	✓
2	Assay 13 (Document-108), S1	0.17659	-0.20802 – 0.56120	✓
3	Assay 14 (Document-109), S1	-0.17561	-0.65715 – 0.30592	✓
4	Assay 15 (Document-110), S1	0.21150	-0.36770 – 0.79071	✓
5	Assay 16 (Document-111), S1	-0.01200	-0.49438 – 0.47039	✓
6	Assay 17 (Document-112), S1	0.10563	-0.22474 – 0.43600	✓
7	Assay 18 (Document-113), S1	0.33523	-0.26725 – 0.93770	✓
8	Assay 19 (Document-114), S1	0.13707	-0.13648 – 0.41062	✓
9	Assay 20 (Document-115), S1	0.06678	-0.51192 – 0.64547	✓
10	Assay 21 (Document-116), S1	0.11942	-0.24240 – 0.48124	✓
11	Assay 22 (Document-117), S1	0.00587	-0.35764 – 0.36938	✓
12	Assay 23 (Document-118), S1	0.18843	-0.37490 – 0.75175	✓
13	Assay 24 (Document-119), S1	-0.14051	-0.67288 – 0.39186	✓
14	Assay 01 (Document-120), S1	-0.01951	-0.46795 – 0.42893	✓
15	Assay 02 (Document-121), S1	0.11012	-0.33127 – 0.55151	✓
16	Assay 03 (Document-122), S1	-0.00132	-0.49622 – 0.49359	✓
17	Assay 04 (Document-123), S1	0.05628	-0.36856 – 0.48112	✓
18	Assay 05 (Document-124), S1	0.12624	-0.26092 – 0.51340	✓
19	Assay 06 (Document-125), S1	-0.05665	-0.39393 – 0.28062	✓
20	Assay 07 (Document-126), S1	0.17659	-0.20802 – 0.56120	✓
21	Assay 08 (Document-127), S1	0.29870	-0.35265 – 0.95004	✓
22	Assay 09 (Document-128), S1	4.719 E-04	-0.47226 – 0.47321	✓
23	Assay 10 (Document-129), S1	0.06606	-0.26663 – 0.39876	✓
24	Assay 11 (Document-130), S1	-0.04230	-0.38456 – 0.29996	✓

Equivalence test scaled parameter range:
Difference of asymptotes (nonlinear models, Standard only) : (A(S)-D(S))/A*

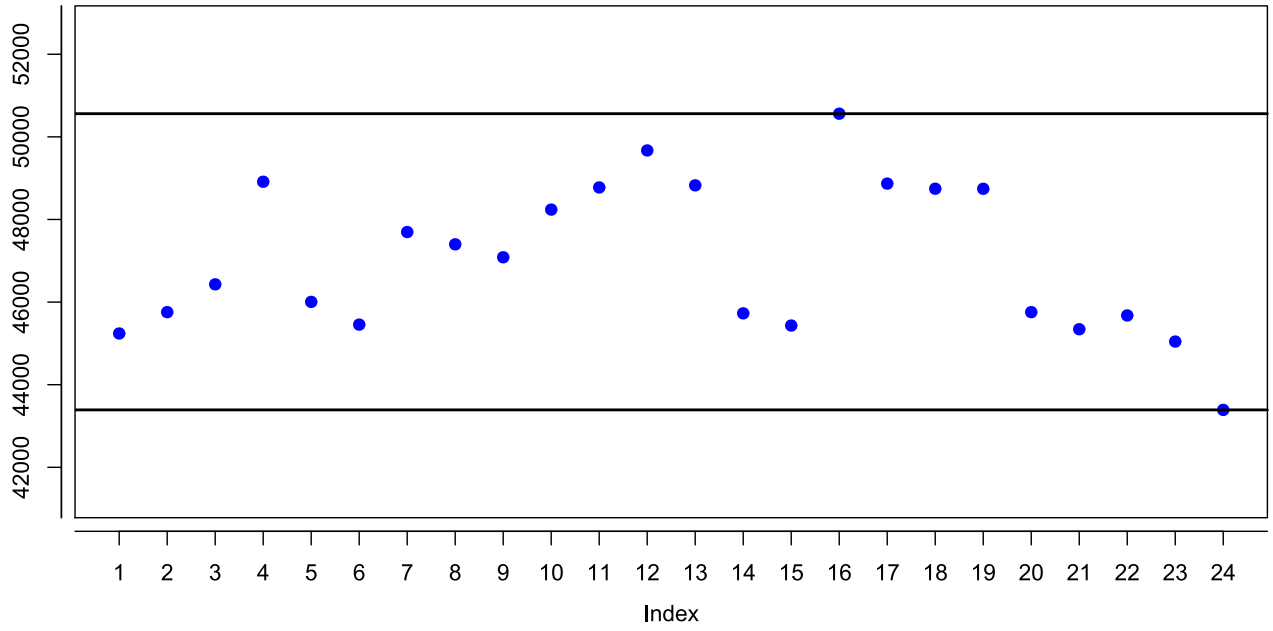


Mean	SD	CoV[%]	Margins	Reference mean
-0.92685	0.03503	0.03779	0.82461 – 1.05109	47032.365

Development assays

Index	Assay element	Value	Confidence interval	
1	Assay 12 (Document-107), S1	0.90031	0.84593 – 0.95469	✓
2	Assay 13 (Document-108), S1	0.90942	0.87319 – 0.94566	✓
3	Assay 14 (Document-109), S1	0.91731	0.87447 – 0.96016	✓
4	Assay 15 (Document-110), S1	0.98433	0.91758 – 1.05109	✓
5	Assay 16 (Document-111), S1	0.90659	0.86177 – 0.95142	✓
6	Assay 17 (Document-112), S1	0.90272	0.87183 – 0.93360	✓
7	Assay 18 (Document-113), S1	0.95228	0.88712 – 1.01745	✓
8	Assay 19 (Document-114), S1	0.94837	0.92063 – 0.97611	✓
9	Assay 20 (Document-115), S1	0.92622	0.87110 – 0.98135	✓
10	Assay 21 (Document-116), S1	0.95380	0.91716 – 0.99045	✓
11	Assay 22 (Document-117), S1	0.95896	0.92445 – 0.99346	✓
12	Assay 23 (Document-118), S1	0.98637	0.92532 – 1.04742	✓
13	Assay 24 (Document-119), S1	0.95958	0.90961 – 1.00955	✓
14	Assay 01 (Document-120), S1	0.88930	0.84577 – 0.93283	✓
15	Assay 02 (Document-121), S1	0.88817	0.84350 – 0.93284	✓
16	Assay 03 (Document-122), S1	0.98172	0.93508 – 1.02836	✓
17	Assay 04 (Document-123), S1	0.94289	0.90441 – 0.98137	✓
18	Assay 05 (Document-124), S1	0.94595	0.90999 – 0.98191	✓
19	Assay 06 (Document-125), S1	0.94066	0.90938 – 0.97194	✓
20	Assay 07 (Document-126), S1	0.90942	0.87319 – 0.94566	✓
21	Assay 08 (Document-127), S1	0.90246	0.83496 – 0.96996	✓
22	Assay 09 (Document-128), S1	0.89555	0.85465 – 0.93644	✓
23	Assay 10 (Document-129), S1	0.88674	0.85510 – 0.91838	✓
24	Assay 11 (Document-130), S1	0.85526	0.82461 – 0.88591	✓

Parameter/Property point estimate:
A upper asymptote (nonlinear models) A(S)

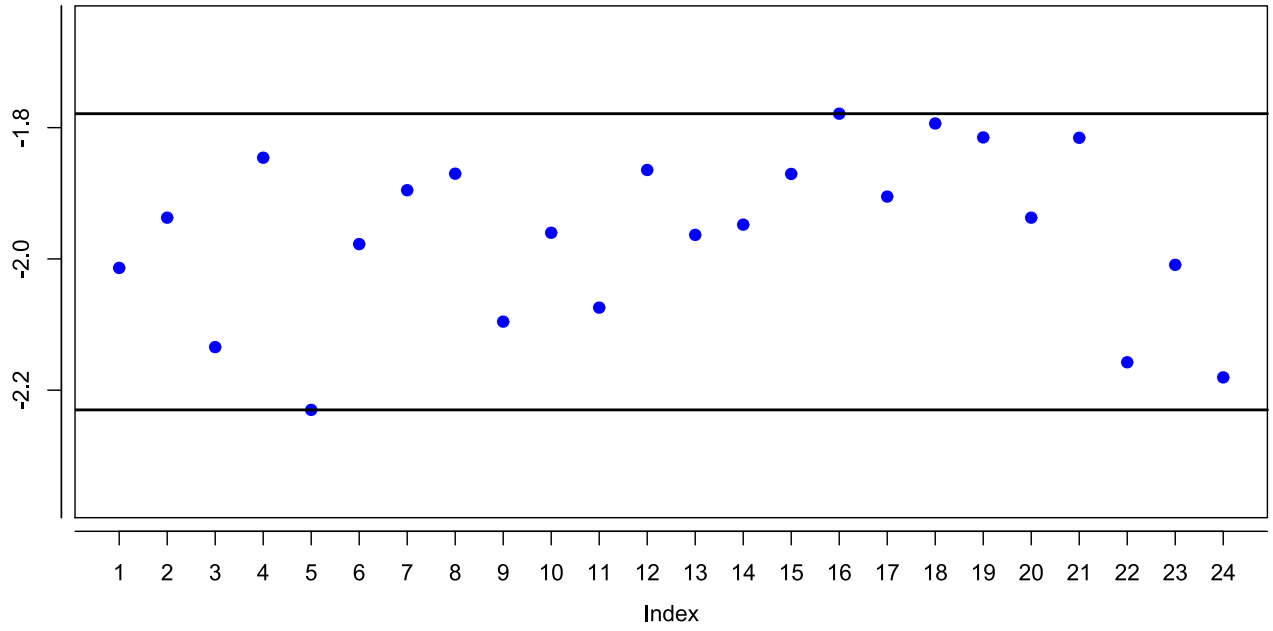


Mean	SD	CoV[%]	Margins
47032.365	1829.9016	0.03891	43390.286 – 50560.778

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	45240.143	–	✓
2	Assay 13 (Document-108), S1	45756.364	–	✓
3	Assay 14 (Document-109), S1	46429.229	–	✓
4	Assay 15 (Document-110), S1	48913.692	–	✓
5	Assay 16 (Document-111), S1	46004.986	–	✓
6	Assay 17 (Document-112), S1	45454.742	–	✓
7	Assay 18 (Document-113), S1	47695.770	–	✓
8	Assay 19 (Document-114), S1	47398.505	–	✓
9	Assay 20 (Document-115), S1	47084.566	–	✓
10	Assay 21 (Document-116), S1	48239.080	–	✓
11	Assay 22 (Document-117), S1	48775.166	–	✓
12	Assay 23 (Document-118), S1	49671.077	–	✓
13	Assay 24 (Document-119), S1	48826.062	–	✓
14	Assay 01 (Document-120), S1	45727.277	–	✓
15	Assay 02 (Document-121), S1	45432.504	–	✓
16	Assay 03 (Document-122), S1	50560.778	–	✓
17	Assay 04 (Document-123), S1	48868.359	–	✓
18	Assay 05 (Document-124), S1	48744.485	–	✓
19	Assay 06 (Document-125), S1	48743.199	–	✓
20	Assay 07 (Document-126), S1	45756.364	–	✓
21	Assay 08 (Document-127), S1	45342.963	–	✓
22	Assay 09 (Document-128), S1	45676.520	–	✓
23	Assay 10 (Document-129), S1	45044.640	–	✓
24	Assay 11 (Document-130), S1	43390.286	–	✓

Parameter/Property point estimate:
B parameter (nonlinear models) B(S)

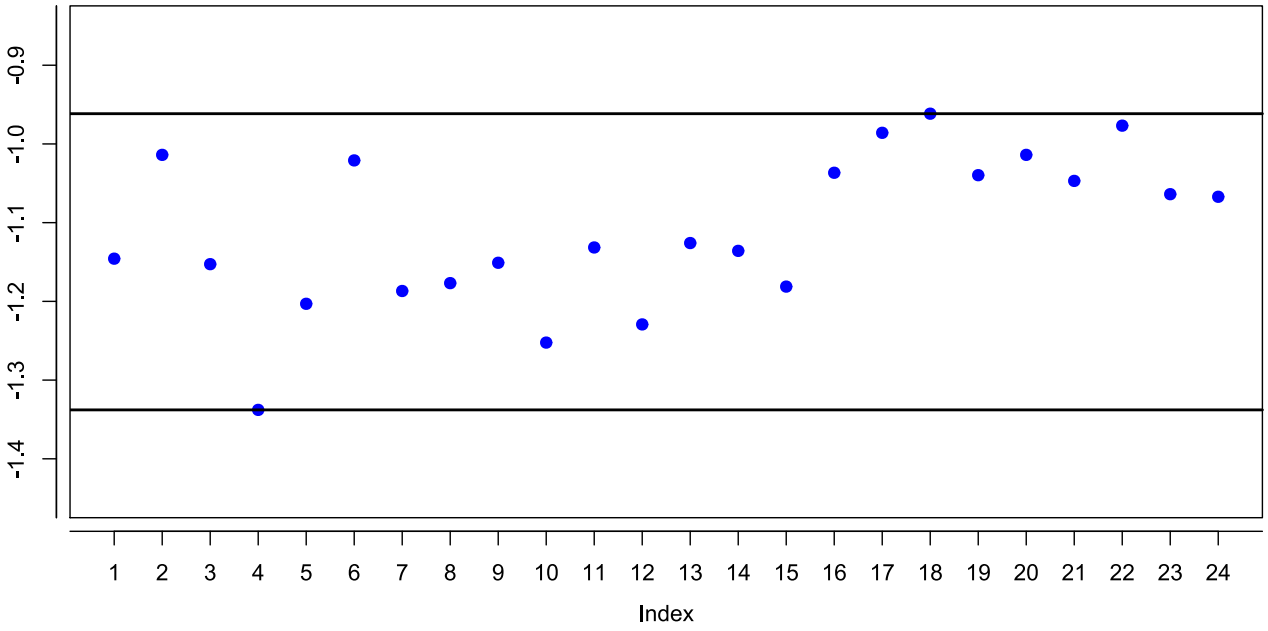


Mean	SD	CoV[%]	Margins
-1.96134	0.12803	0.06528	-2.23001 – -1.77876

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-2.01369	–	✓
2	Assay 13 (Document-108), S1	-1.93716	–	✓
3	Assay 14 (Document-109), S1	-2.13433	–	✓
4	Assay 15 (Document-110), S1	-1.84579	–	✓
5	Assay 16 (Document-111), S1	-2.23001	–	✓
6	Assay 17 (Document-112), S1	-1.97743	–	✓
7	Assay 18 (Document-113), S1	-1.89534	–	✓
8	Assay 19 (Document-114), S1	-1.87015	–	✓
9	Assay 20 (Document-115), S1	-2.09558	–	✓
10	Assay 21 (Document-116), S1	-1.96017	–	✓
11	Assay 22 (Document-117), S1	-2.07420	–	✓
12	Assay 23 (Document-118), S1	-1.86450	–	✓
13	Assay 24 (Document-119), S1	-1.96338	–	✓
14	Assay 01 (Document-120), S1	-1.94779	–	✓
15	Assay 02 (Document-121), S1	-1.87054	–	✓
16	Assay 03 (Document-122), S1	-1.77876	–	✓
17	Assay 04 (Document-123), S1	-1.90502	–	✓
18	Assay 05 (Document-124), S1	-1.79367	–	✓
19	Assay 06 (Document-125), S1	-1.81493	–	✓
20	Assay 07 (Document-126), S1	-1.93716	–	✓
21	Assay 08 (Document-127), S1	-1.81547	–	✓
22	Assay 09 (Document-128), S1	-2.15750	–	✓
23	Assay 10 (Document-129), S1	-2.00899	–	✓
24	Assay 11 (Document-130), S1	-2.18051	–	✓

Parameter/Property point estimate:
C parameter (nonlinear models) C(S)

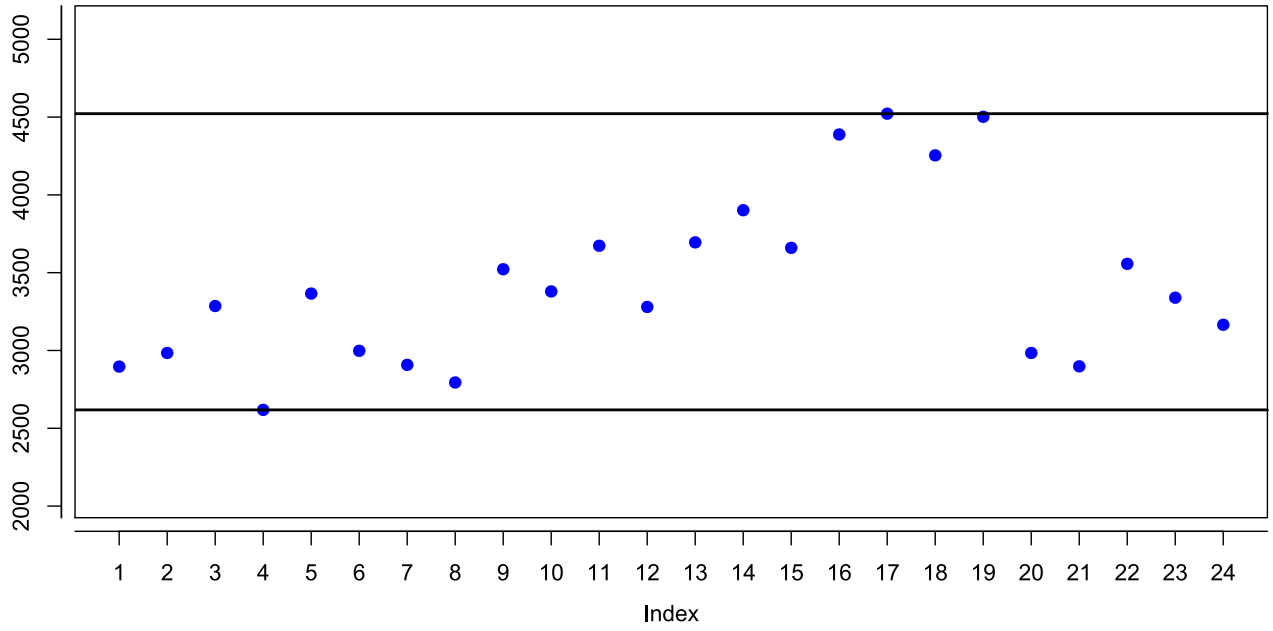


Mean	SD	CoV[%]	Margins
-1.10989	0.09703	0.08743	-1.33785 – -0.96158

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-1.14576	–	✓
2	Assay 13 (Document-108), S1	-1.01388	–	✓
3	Assay 14 (Document-109), S1	-1.15273	–	✓
4	Assay 15 (Document-110), S1	-1.33785	–	✓
5	Assay 16 (Document-111), S1	-1.20308	–	✓
6	Assay 17 (Document-112), S1	-1.02093	–	✓
7	Assay 18 (Document-113), S1	-1.18682	–	✓
8	Assay 19 (Document-114), S1	-1.17683	–	✓
9	Assay 20 (Document-115), S1	-1.15096	–	✓
10	Assay 21 (Document-116), S1	-1.25237	–	✓
11	Assay 22 (Document-117), S1	-1.13152	–	✓
12	Assay 23 (Document-118), S1	-1.22927	–	✓
13	Assay 24 (Document-119), S1	-1.12591	–	✓
14	Assay 01 (Document-120), S1	-1.13584	–	✓
15	Assay 02 (Document-121), S1	-1.18123	–	✓
16	Assay 03 (Document-122), S1	-1.03662	–	✓
17	Assay 04 (Document-123), S1	-0.98587	–	✓
18	Assay 05 (Document-124), S1	-0.96158	–	✓
19	Assay 06 (Document-125), S1	-1.03969	–	✓
20	Assay 07 (Document-126), S1	-1.01388	–	✓
21	Assay 08 (Document-127), S1	-1.04695	–	✓
22	Assay 09 (Document-128), S1	-0.97677	–	✓
23	Assay 10 (Document-129), S1	-1.06383	–	✓
24	Assay 11 (Document-130), S1	-1.06713	–	✓

Parameter/Property point estimate:
D lower asymptote (nonlinear models) D(S)

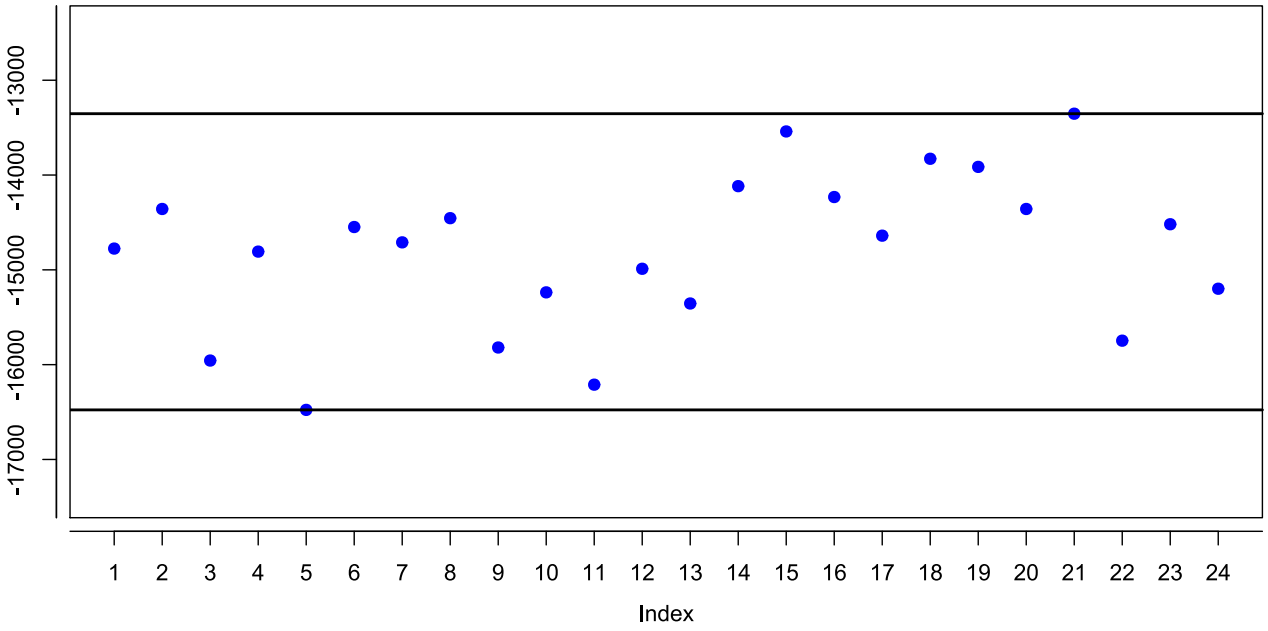


Mean	SD	CoV[%]	Margins
3440.3998	550.92765	0.16013	2618.1995 – 4521.8083

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	2896.4054	–	✓
2	Assay 13 (Document-108), S1	2984.0610	–	✓
3	Assay 14 (Document-109), S1	3285.7429	–	✓
4	Assay 15 (Document-110), S1	2618.1995	–	✓
5	Assay 16 (Document-111), S1	3365.8152	–	✓
6	Assay 17 (Document-112), S1	2997.8831	–	✓
7	Assay 18 (Document-113), S1	2907.6124	–	✓
8	Assay 19 (Document-114), S1	2794.3126	–	✓
9	Assay 20 (Document-115), S1	3522.0468	–	✓
10	Assay 21 (Document-116), S1	3379.4210	–	✓
11	Assay 22 (Document-117), S1	3673.1217	–	✓
12	Assay 23 (Document-118), S1	3279.7931	–	✓
13	Assay 24 (Document-119), S1	3694.7438	–	✓
14	Assay 01 (Document-120), S1	3901.4878	–	✓
15	Assay 02 (Document-121), S1	3659.6143	–	✓
16	Assay 03 (Document-122), S1	4388.2403	–	✓
17	Assay 04 (Document-123), S1	4521.8083	–	✓
18	Assay 05 (Document-124), S1	4254.0085	–	✓
19	Assay 06 (Document-125), S1	4501.8963	–	✓
20	Assay 07 (Document-126), S1	2984.0610	–	✓
21	Assay 08 (Document-127), S1	2897.9937	–	✓
22	Assay 09 (Document-128), S1	3556.8233	–	✓
23	Assay 10 (Document-129), S1	3339.2501	–	✓
24	Assay 11 (Document-130), S1	3165.2539	–	✓

Parameter/Property point estimate:
Slope (nonlinear models) ln(2)*(1/4)*(A(S)-D(S))*B(S)

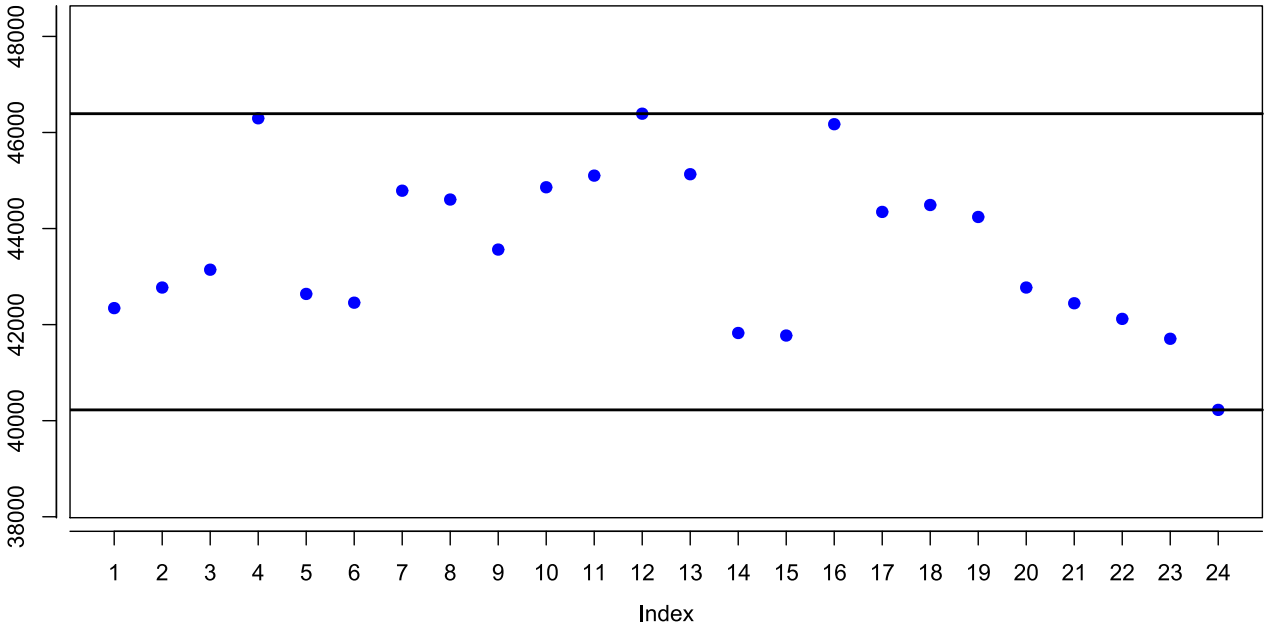


Mean	SD	CoV[%]	Margins
-14797.830	825.04875	0.05575	-16477.096 – -13353.032

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-14775.679	–	✓
2	Assay 13 (Document-108), S1	-14357.987	–	✓
3	Assay 14 (Document-109), S1	-15956.649	–	✓
4	Assay 15 (Document-110), S1	-14807.663	–	✓
5	Assay 16 (Document-111), S1	-16477.096	–	✓
6	Assay 17 (Document-112), S1	-14548.363	–	✓
7	Assay 18 (Document-113), S1	-14710.143	–	✓
8	Assay 19 (Document-114), S1	-14454.999	–	✓
9	Assay 20 (Document-115), S1	-15819.126	–	✓
10	Assay 21 (Document-116), S1	-15237.554	–	✓
11	Assay 22 (Document-117), S1	-16211.115	–	✓
12	Assay 23 (Document-118), S1	-14988.735	–	✓
13	Assay 24 (Document-119), S1	-15354.914	–	✓
14	Assay 01 (Document-120), S1	-14117.277	–	✓
15	Assay 02 (Document-121), S1	-13540.276	–	✓
16	Assay 03 (Document-122), S1	-14232.013	–	✓
17	Assay 04 (Document-123), S1	-14639.489	–	✓
18	Assay 05 (Document-124), S1	-13828.492	–	✓
19	Assay 06 (Document-125), S1	-13914.046	–	✓
20	Assay 07 (Document-126), S1	-14357.987	–	✓
21	Assay 08 (Document-127), S1	-13353.032	–	✓
22	Assay 09 (Document-128), S1	-15747.099	–	✓
23	Assay 10 (Document-129), S1	-14518.992	–	✓
24	Assay 11 (Document-130), S1	-15199.187	–	✓

Parameter/Property point estimate:
Difference of asymptotes (nonlinear models) A(S)-D(S)

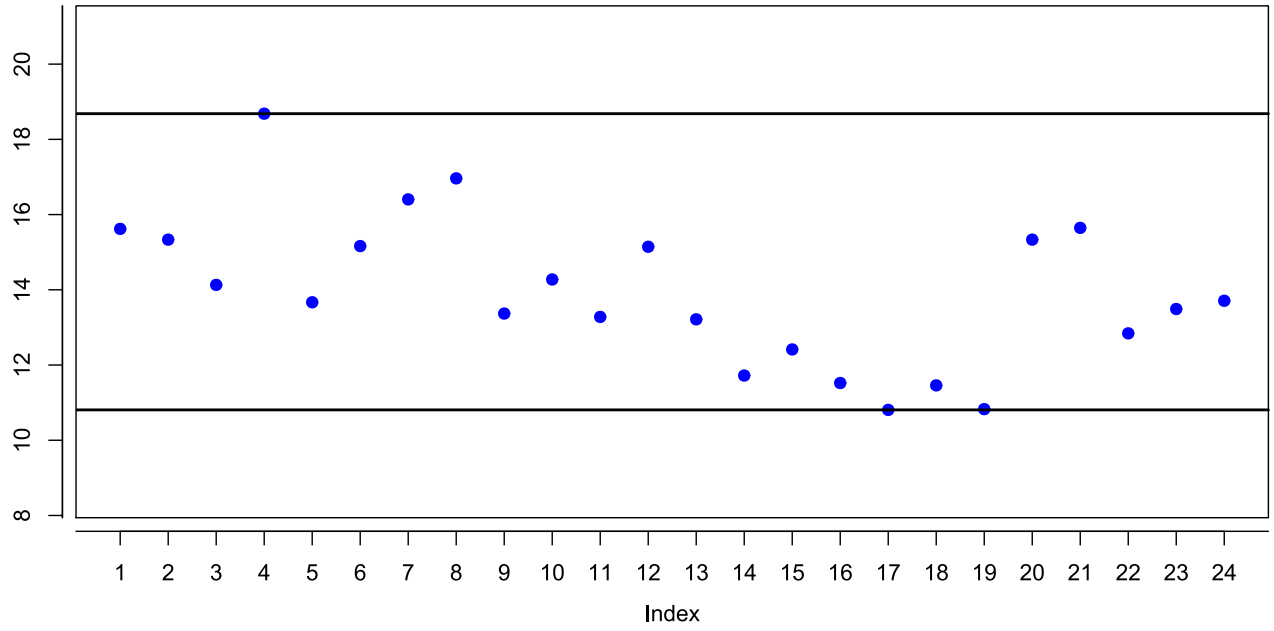


Mean	SD	CoV[%]	Margins
43591.965	1647.4285	0.03779	40225.032 – 46391.284

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	42343.738	–	✓
2	Assay 13 (Document-108), S1	42772.303	–	✓
3	Assay 14 (Document-109), S1	43143.486	–	✓
4	Assay 15 (Document-110), S1	46295.492	–	✓
5	Assay 16 (Document-111), S1	42639.171	–	✓
6	Assay 17 (Document-112), S1	42456.859	–	✓
7	Assay 18 (Document-113), S1	44788.157	–	✓
8	Assay 19 (Document-114), S1	44604.193	–	✓
9	Assay 20 (Document-115), S1	43562.519	–	✓
10	Assay 21 (Document-116), S1	44859.659	–	✓
11	Assay 22 (Document-117), S1	45102.044	–	✓
12	Assay 23 (Document-118), S1	46391.284	–	✓
13	Assay 24 (Document-119), S1	45131.318	–	✓
14	Assay 01 (Document-120), S1	41825.790	–	✓
15	Assay 02 (Document-121), S1	41772.890	–	✓
16	Assay 03 (Document-122), S1	46172.538	–	✓
17	Assay 04 (Document-123), S1	44346.550	–	✓
18	Assay 05 (Document-124), S1	44490.477	–	✓
19	Assay 06 (Document-125), S1	44241.303	–	✓
20	Assay 07 (Document-126), S1	42772.303	–	✓
21	Assay 08 (Document-127), S1	42444.969	–	✓
22	Assay 09 (Document-128), S1	42119.697	–	✓
23	Assay 10 (Document-129), S1	41705.390	–	✓
24	Assay 11 (Document-130), S1	40225.032	–	✓

Parameter/Property point estimate:
Ratio of asymtotes (nonlinear models) A(S)/D(S)

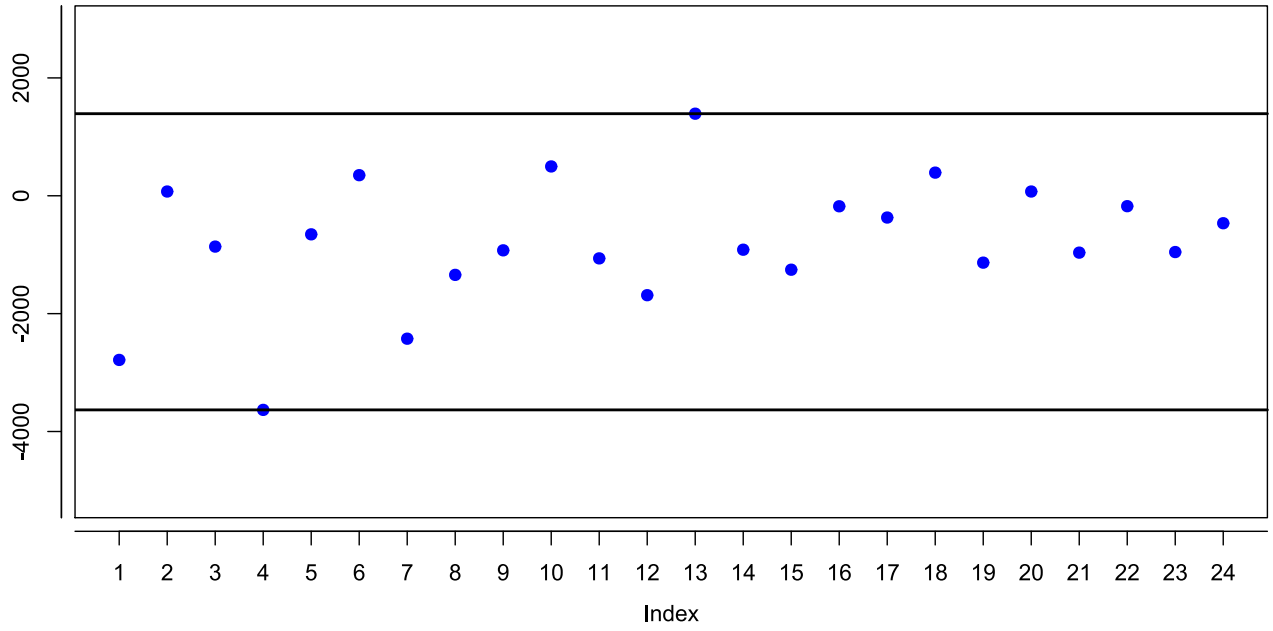


Mean	SD	CoV[%]	Margins
13.95889	1.99980	0.14326	10.80726 – 18.68219

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	15.61941	–	✓
2	Assay 13 (Document-108), S1	15.33359	–	✓
3	Assay 14 (Document-109), S1	14.13051	–	✓
4	Assay 15 (Document-110), S1	18.68219	–	✓
5	Assay 16 (Document-111), S1	13.66830	–	✓
6	Assay 17 (Document-112), S1	15.16228	–	✓
7	Assay 18 (Document-113), S1	16.40376	–	✓
8	Assay 19 (Document-114), S1	16.96249	–	✓
9	Assay 20 (Document-115), S1	13.36852	–	✓
10	Assay 21 (Document-116), S1	14.27436	–	✓
11	Assay 22 (Document-117), S1	13.27894	–	✓
12	Assay 23 (Document-118), S1	15.14458	–	✓
13	Assay 24 (Document-119), S1	13.21501	–	✓
14	Assay 01 (Document-120), S1	11.72047	–	✓
15	Assay 02 (Document-121), S1	12.41456	–	✓
16	Assay 03 (Document-122), S1	11.52188	–	✓
17	Assay 04 (Document-123), S1	10.80726	–	✓
18	Assay 05 (Document-124), S1	11.45848	–	✓
19	Assay 06 (Document-125), S1	10.82726	–	✓
20	Assay 07 (Document-126), S1	15.33359	–	✓
21	Assay 08 (Document-127), S1	15.64633	–	✓
22	Assay 09 (Document-128), S1	12.84194	–	✓
23	Assay 10 (Document-129), S1	13.48945	–	✓
24	Assay 11 (Document-130), S1	13.70831	–	✓

Difference of parameter/property point estimates: A upper asymptote (nonlinear models) A(T)-A(S)

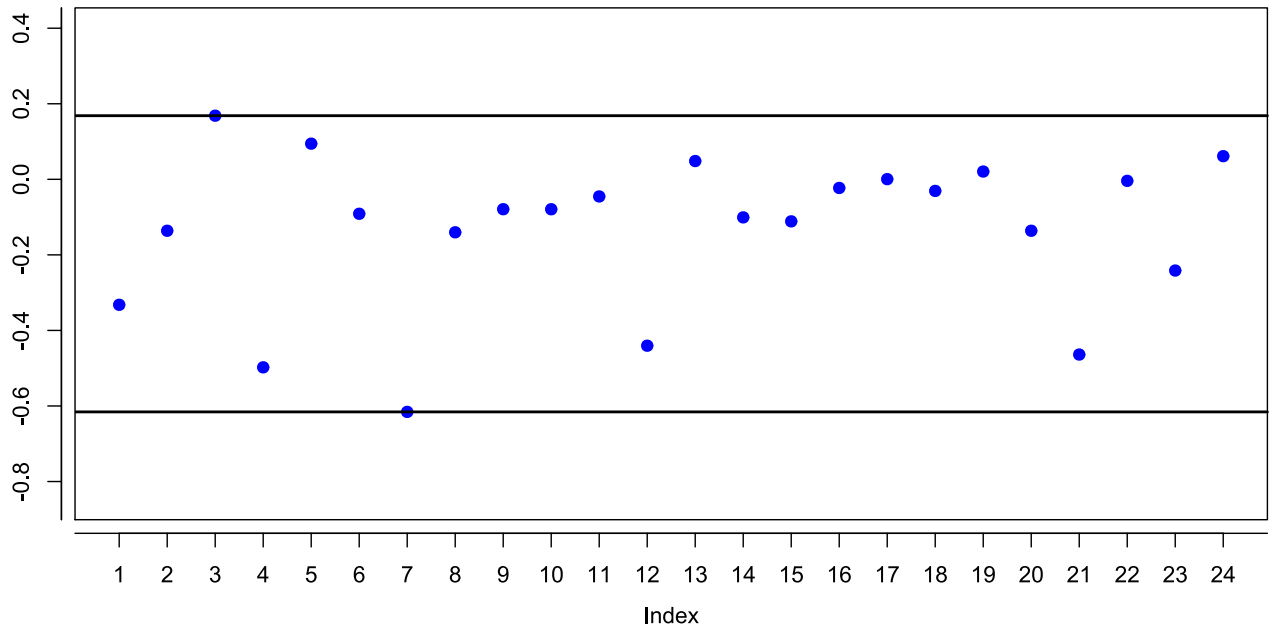


Mean	SD	CoV[%]	Margins
-792.28332	1103.5632	1.39289	-3633.1455 – 1392.6983

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-2785.2929	–	✓
2	Assay 13 (Document-108), S1	72.21642	–	✓
3	Assay 14 (Document-109), S1	-862.37532	–	✓
4	Assay 15 (Document-110), S1	-3633.1455	–	✓
5	Assay 16 (Document-111), S1	-654.39140	–	✓
6	Assay 17 (Document-112), S1	349.46726	–	✓
7	Assay 18 (Document-113), S1	-2425.0804	–	✓
8	Assay 19 (Document-114), S1	-1342.2441	–	✓
9	Assay 20 (Document-115), S1	-925.93182	–	✓
10	Assay 21 (Document-116), S1	497.56741	–	✓
11	Assay 22 (Document-117), S1	-1062.3751	–	✓
12	Assay 23 (Document-118), S1	-1686.9044	–	✓
13	Assay 24 (Document-119), S1	1392.6983	–	✓
14	Assay 01 (Document-120), S1	-915.08616	–	✓
15	Assay 02 (Document-121), S1	-1254.5214	–	✓
16	Assay 03 (Document-122), S1	-178.24427	–	✓
17	Assay 04 (Document-123), S1	-369.30327	–	✓
18	Assay 05 (Document-124), S1	392.78780	–	✓
19	Assay 06 (Document-125), S1	-1134.7016	–	✓
20	Assay 07 (Document-126), S1	72.21642	–	✓
21	Assay 08 (Document-127), S1	-964.84734	–	✓
22	Assay 09 (Document-128), S1	-176.54167	–	✓
23	Assay 10 (Document-129), S1	-954.91106	–	✓
24	Assay 11 (Document-130), S1	-465.85542	–	✓

Difference of parameter/property point estimates: B parameter (nonlinear models) B(T)-B(S)

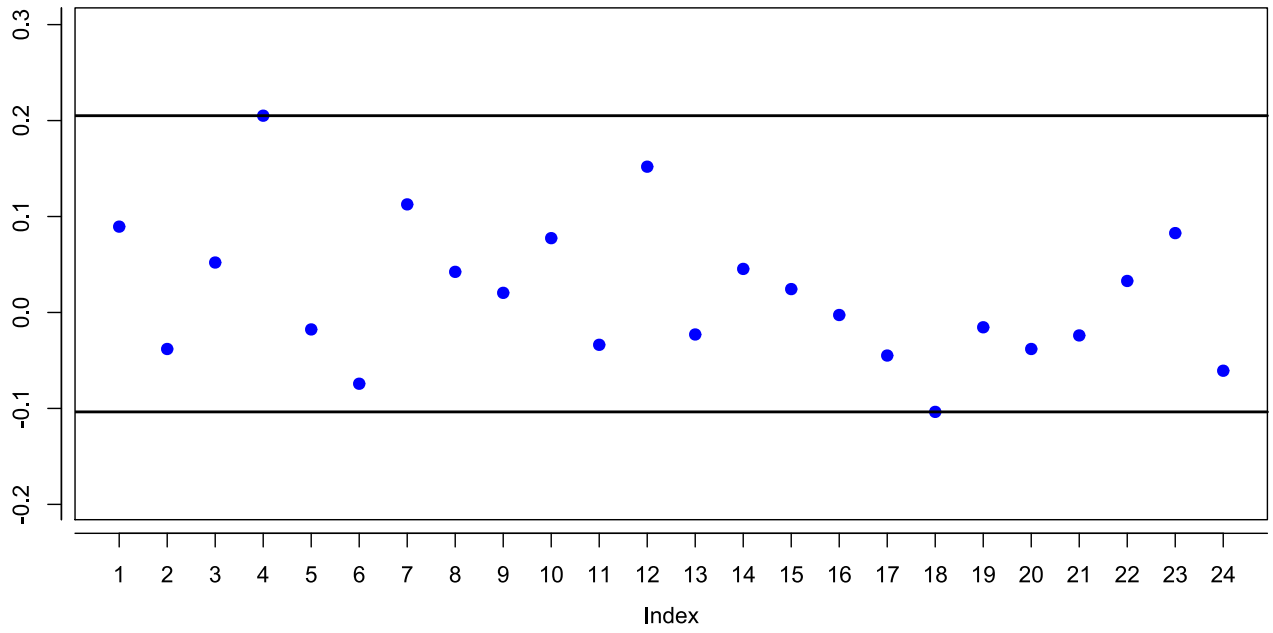


Mean	SD	CoV[%]	Margins
-0.13229	0.20130	1.52170	-0.61565 – 0.16842

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-0.33216	–	✓
2	Assay 13 (Document-108), S1	-0.13617	–	✓
3	Assay 14 (Document-109), S1	0.16842	–	✓
4	Assay 15 (Document-110), S1	-0.49768	–	✓
5	Assay 16 (Document-111), S1	0.09438	–	✓
6	Assay 17 (Document-112), S1	-0.09122	–	✓
7	Assay 18 (Document-113), S1	-0.61565	–	✓
8	Assay 19 (Document-114), S1	-0.14025	–	✓
9	Assay 20 (Document-115), S1	-0.07911	–	✓
10	Assay 21 (Document-116), S1	-0.07921	–	✓
11	Assay 22 (Document-117), S1	-0.04535	–	✓
12	Assay 23 (Document-118), S1	-0.44045	–	✓
13	Assay 24 (Document-119), S1	0.04836	–	✓
14	Assay 01 (Document-120), S1	-0.10075	–	✓
15	Assay 02 (Document-121), S1	-0.11130	–	✓
16	Assay 03 (Document-122), S1	-0.02284	–	✓
17	Assay 04 (Document-123), S1	4.697 E-04	–	✓
18	Assay 05 (Document-124), S1	-0.03069	–	✓
19	Assay 06 (Document-125), S1	0.02060	–	✓
20	Assay 07 (Document-126), S1	-0.13617	–	✓
21	Assay 08 (Document-127), S1	-0.46386	–	✓
22	Assay 09 (Document-128), S1	-0.00408	–	✓
23	Assay 10 (Document-129), S1	-0.24148	–	✓
24	Assay 11 (Document-130), S1	0.06131	–	✓

Difference of parameter/property point estimates: C parameter (nonlinear models) C(T)-C(S)

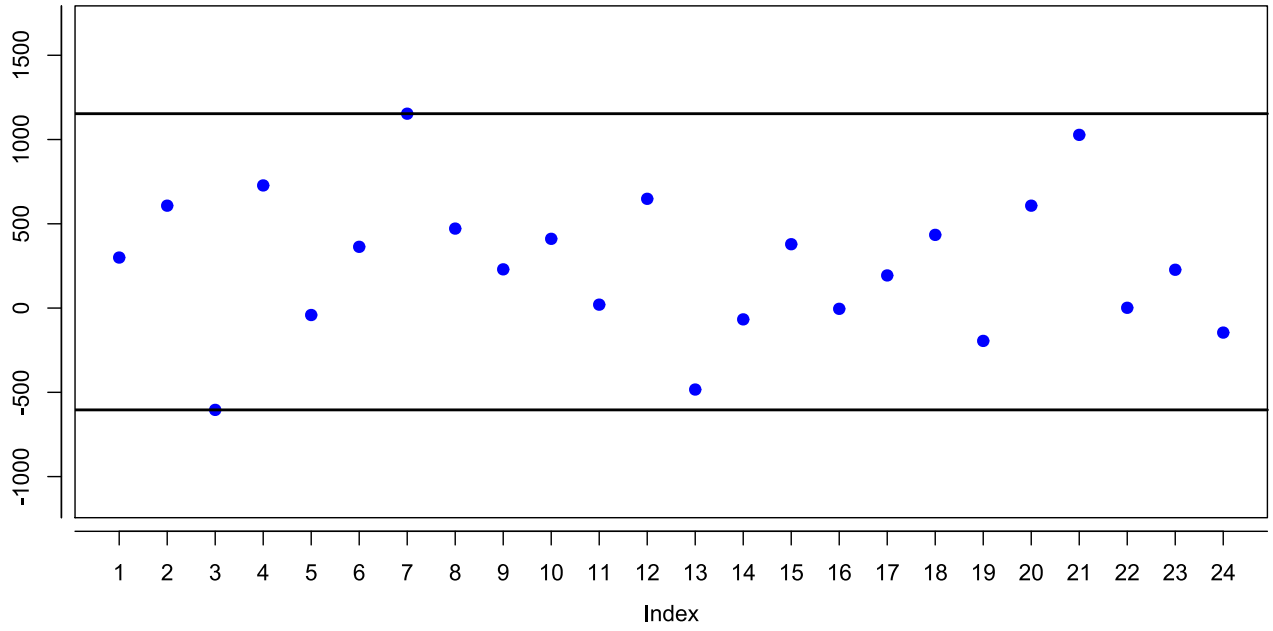


Mean	SD	CoV[%]	Margins
0.01920	0.07405	3.85662	-0.10361 – 0.20508

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	0.08945	–	✓
2	Assay 13 (Document-108), S1	-0.03806	–	✓
3	Assay 14 (Document-109), S1	0.05206	–	✓
4	Assay 15 (Document-110), S1	0.20508	–	✓
5	Assay 16 (Document-111), S1	-0.01767	–	✓
6	Assay 17 (Document-112), S1	-0.07426	–	✓
7	Assay 18 (Document-113), S1	0.11265	–	✓
8	Assay 19 (Document-114), S1	0.04234	–	✓
9	Assay 20 (Document-115), S1	0.02045	–	✓
10	Assay 21 (Document-116), S1	0.07745	–	✓
11	Assay 22 (Document-117), S1	-0.03370	–	✓
12	Assay 23 (Document-118), S1	0.15193	–	✓
13	Assay 24 (Document-119), S1	-0.02294	–	✓
14	Assay 01 (Document-120), S1	0.04540	–	✓
15	Assay 02 (Document-121), S1	0.02437	–	✓
16	Assay 03 (Document-122), S1	-0.00264	–	✓
17	Assay 04 (Document-123), S1	-0.04488	–	✓
18	Assay 05 (Document-124), S1	-0.10361	–	✓
19	Assay 06 (Document-125), S1	-0.01543	–	✓
20	Assay 07 (Document-126), S1	-0.03806	–	✓
21	Assay 08 (Document-127), S1	-0.02393	–	✓
22	Assay 09 (Document-128), S1	0.03284	–	✓
23	Assay 10 (Document-129), S1	0.08272	–	✓
24	Assay 11 (Document-130), S1	-0.06073	–	✓

Difference of parameter/property point estimates: D lower asymptote (nonlinear models) D(T)-D(S)

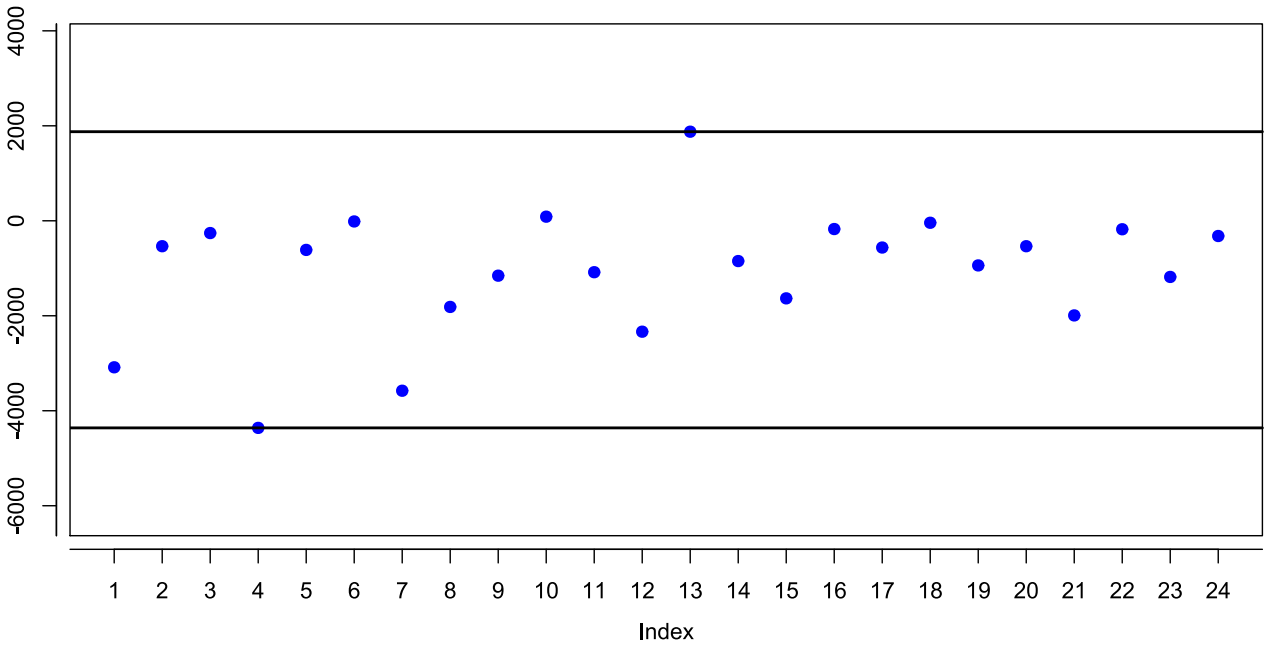


Mean	SD	CoV[%]	Margins
260.92462	426.90967	1.63614	-604.17498 – 1153.3090

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	299.71954	–	✓
2	Assay 13 (Document-108), S1	607.53392	–	✓
3	Assay 14 (Document-109), S1	-604.17498	–	✓
4	Assay 15 (Document-110), S1	727.64937	–	✓
5	Assay 16 (Document-111), S1	-41.27237	–	✓
6	Assay 17 (Document-112), S1	363.40077	–	✓
7	Assay 18 (Document-113), S1	1153.3090	–	✓
8	Assay 19 (Document-114), S1	471.57239	–	✓
9	Assay 20 (Document-115), S1	229.73762	–	✓
10	Assay 21 (Document-116), S1	410.84902	–	✓
11	Assay 22 (Document-117), S1	20.20651	–	✓
12	Assay 23 (Document-118), S1	648.26130	–	✓
13	Assay 24 (Document-119), S1	-483.40967	–	✓
14	Assay 01 (Document-120), S1	-67.11892	–	✓
15	Assay 02 (Document-121), S1	378.85651	–	✓
16	Assay 03 (Document-122), S1	-4.52618	–	✓
17	Assay 04 (Document-123), S1	193.62941	–	✓
18	Assay 05 (Document-124), S1	434.31693	–	✓
19	Assay 06 (Document-125), S1	-194.90835	–	✓
20	Assay 07 (Document-126), S1	607.53392	–	✓
21	Assay 08 (Document-127), S1	1027.6399	–	✓
22	Assay 09 (Document-128), S1	1.62358	–	✓
23	Assay 10 (Document-129), S1	227.27795	–	✓
24	Assay 11 (Document-130), S1	-145.51622	–	✓

Difference of parameter/property point estimates: Difference of asymptotes (nonlinear models) (A(T)-D(T))-(A(S)-D(S))

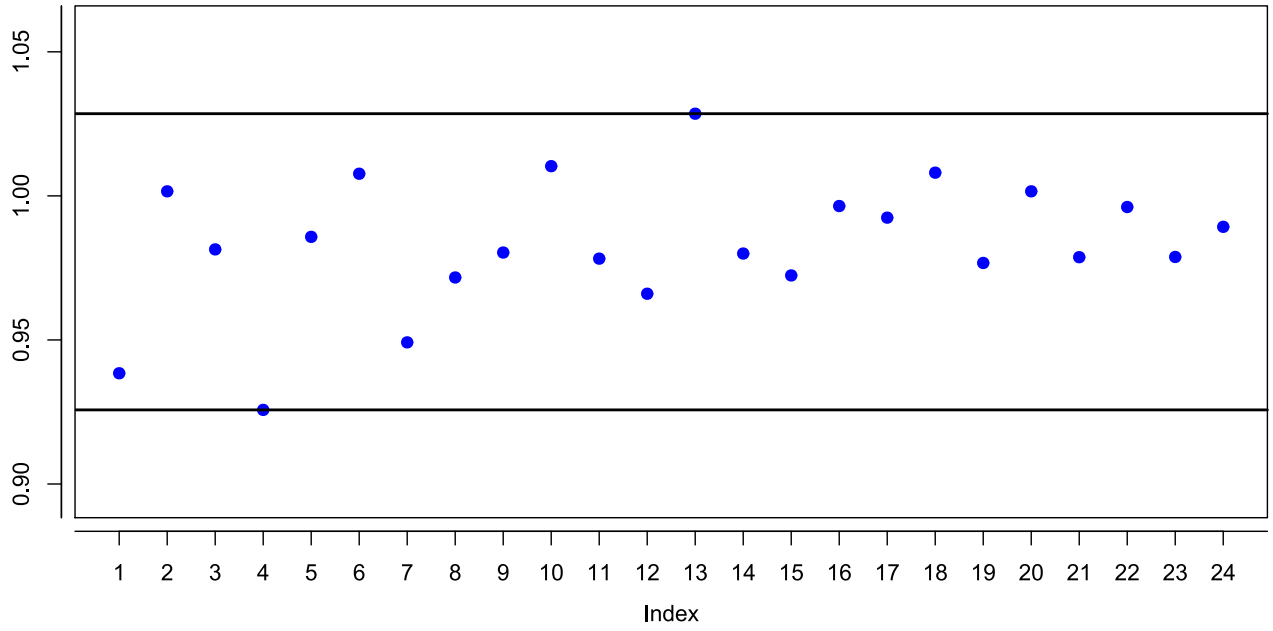


Mean	SD	CoV[%]	Margins
-1053.2079	1329.1283	1.26198	-4360.7949 – 1876.1080

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-3085.0124	–	✓
2	Assay 13 (Document-108), S1	-535.31749	–	✓
3	Assay 14 (Document-109), S1	-258.20033	–	✓
4	Assay 15 (Document-110), S1	-4360.7949	–	✓
5	Assay 16 (Document-111), S1	-613.11903	–	✓
6	Assay 17 (Document-112), S1	-13.93351	–	✓
7	Assay 18 (Document-113), S1	-3578.3894	–	✓
8	Assay 19 (Document-114), S1	-1813.8165	–	✓
9	Assay 20 (Document-115), S1	-1155.6694	–	✓
10	Assay 21 (Document-116), S1	86.71839	–	✓
11	Assay 22 (Document-117), S1	-1082.5817	–	✓
12	Assay 23 (Document-118), S1	-2335.1657	–	✓
13	Assay 24 (Document-119), S1	1876.1080	–	✓
14	Assay 01 (Document-120), S1	-847.96723	–	✓
15	Assay 02 (Document-121), S1	-1633.3779	–	✓
16	Assay 03 (Document-122), S1	-173.71809	–	✓
17	Assay 04 (Document-123), S1	-562.93268	–	✓
18	Assay 05 (Document-124), S1	-41.52913	–	✓
19	Assay 06 (Document-125), S1	-939.79326	–	✓
20	Assay 07 (Document-126), S1	-535.31749	–	✓
21	Assay 08 (Document-127), S1	-1992.4873	–	✓
22	Assay 09 (Document-128), S1	-178.16525	–	✓
23	Assay 10 (Document-129), S1	-1182.1890	–	✓
24	Assay 11 (Document-130), S1	-320.33920	–	✓

Ratio of parameter/property point estimates:
A upper asymptote (nonlinear models) A(T)/A(S)

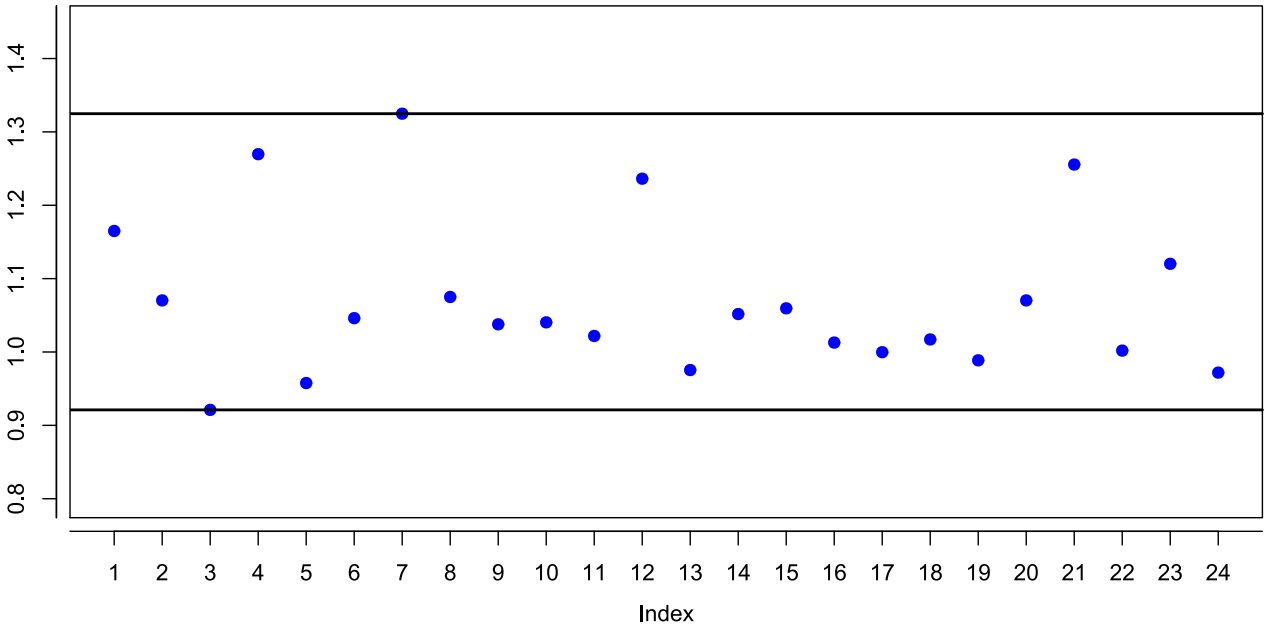


Mean	SD	CoV[%]	Margins
0.98314	0.02312	0.02352	0.92572 – 1.02852

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	0.93843	–	✓
2	Assay 13 (Document-108), S1	1.00158	–	✓
3	Assay 14 (Document-109), S1	0.98143	–	✓
4	Assay 15 (Document-110), S1	0.92572	–	✓
5	Assay 16 (Document-111), S1	0.98578	–	✓
6	Assay 17 (Document-112), S1	1.00769	–	✓
7	Assay 18 (Document-113), S1	0.94916	–	✓
8	Assay 19 (Document-114), S1	0.97168	–	✓
9	Assay 20 (Document-115), S1	0.98033	–	✓
10	Assay 21 (Document-116), S1	1.01031	–	✓
11	Assay 22 (Document-117), S1	0.97822	–	✓
12	Assay 23 (Document-118), S1	0.96604	–	✓
13	Assay 24 (Document-119), S1	1.02852	–	✓
14	Assay 01 (Document-120), S1	0.97999	–	✓
15	Assay 02 (Document-121), S1	0.97239	–	✓
16	Assay 03 (Document-122), S1	0.99647	–	✓
17	Assay 04 (Document-123), S1	0.99244	–	✓
18	Assay 05 (Document-124), S1	1.00806	–	✓
19	Assay 06 (Document-125), S1	0.97672	–	✓
20	Assay 07 (Document-126), S1	1.00158	–	✓
21	Assay 08 (Document-127), S1	0.97872	–	✓
22	Assay 09 (Document-128), S1	0.99613	–	✓
23	Assay 10 (Document-129), S1	0.97880	–	✓
24	Assay 11 (Document-130), S1	0.98926	–	✓

Ratio of parameter/property point estimates:
B parameter (nonlinear models) B(T)/B(S)

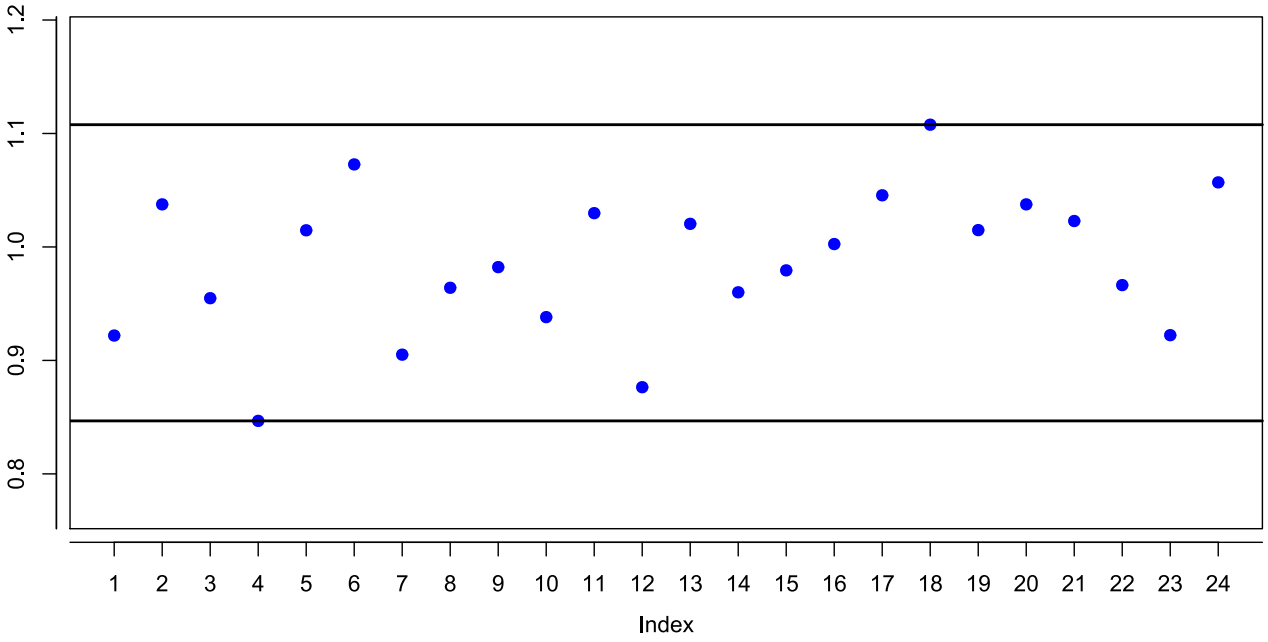


Mean	SD	CoV[%]	Margins
1.07044	0.10617	0.09918	0.92109 – 1.32482

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	1.16495	–	✓
2	Assay 13 (Document-108), S1	1.07029	–	✓
3	Assay 14 (Document-109), S1	0.92109	–	✓
4	Assay 15 (Document-110), S1	1.26963	–	✓
5	Assay 16 (Document-111), S1	0.95768	–	✓
6	Assay 17 (Document-112), S1	1.04613	–	✓
7	Assay 18 (Document-113), S1	1.32482	–	✓
8	Assay 19 (Document-114), S1	1.07499	–	✓
9	Assay 20 (Document-115), S1	1.03775	–	✓
10	Assay 21 (Document-116), S1	1.04041	–	✓
11	Assay 22 (Document-117), S1	1.02186	–	✓
12	Assay 23 (Document-118), S1	1.23623	–	✓
13	Assay 24 (Document-119), S1	0.97537	–	✓
14	Assay 01 (Document-120), S1	1.05173	–	✓
15	Assay 02 (Document-121), S1	1.05950	–	✓
16	Assay 03 (Document-122), S1	1.01284	–	✓
17	Assay 04 (Document-123), S1	0.99975	–	✓
18	Assay 05 (Document-124), S1	1.01711	–	✓
19	Assay 06 (Document-125), S1	0.98865	–	✓
20	Assay 07 (Document-126), S1	1.07029	–	✓
21	Assay 08 (Document-127), S1	1.25550	–	✓
22	Assay 09 (Document-128), S1	1.00189	–	✓
23	Assay 10 (Document-129), S1	1.12020	–	✓
24	Assay 11 (Document-130), S1	0.97188	–	✓

Ratio of parameter/property point estimates:
C parameter (nonlinear models) C(T)/C(S)

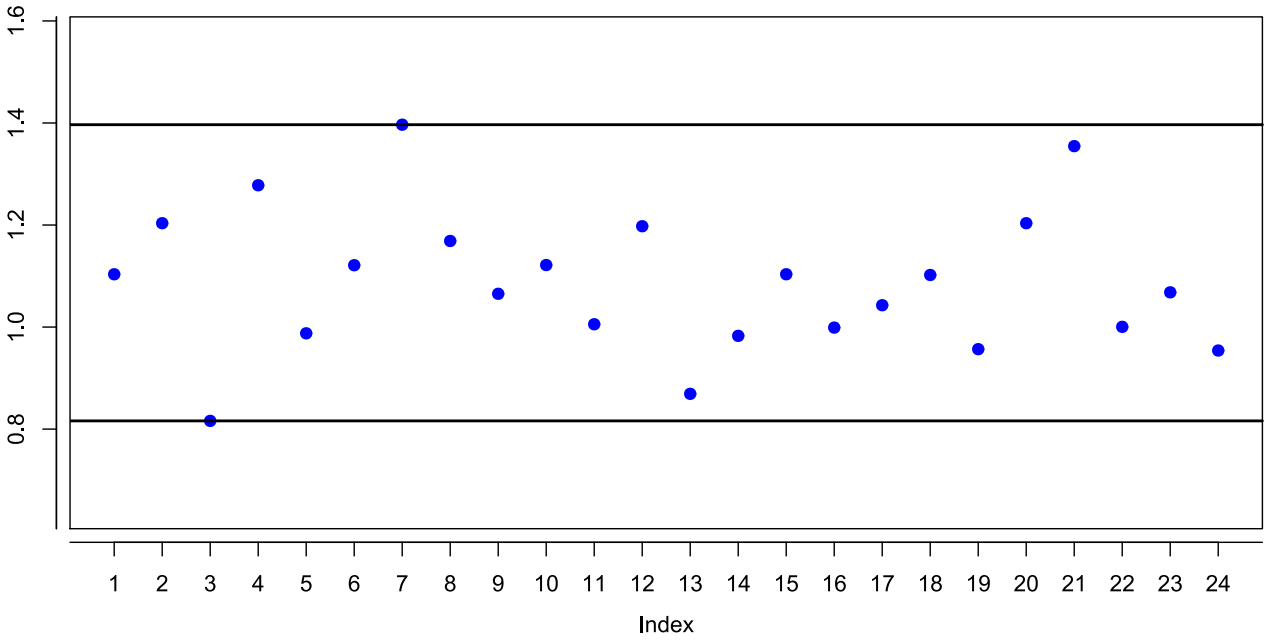


Mean	SD	CoV[%]	Margins
0.98669	0.06379	0.06465	0.84671 – 1.10775

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	0.92193	–	✓
2	Assay 13 (Document-108), S1	1.03754	–	✓
3	Assay 14 (Document-109), S1	0.95484	–	✓
4	Assay 15 (Document-110), S1	0.84671	–	✓
5	Assay 16 (Document-111), S1	1.01469	–	✓
6	Assay 17 (Document-112), S1	1.07274	–	✓
7	Assay 18 (Document-113), S1	0.90508	–	✓
8	Assay 19 (Document-114), S1	0.96402	–	✓
9	Assay 20 (Document-115), S1	0.98223	–	✓
10	Assay 21 (Document-116), S1	0.93815	–	✓
11	Assay 22 (Document-117), S1	1.02979	–	✓
12	Assay 23 (Document-118), S1	0.87640	–	✓
13	Assay 24 (Document-119), S1	1.02037	–	✓
14	Assay 01 (Document-120), S1	0.96003	–	✓
15	Assay 02 (Document-121), S1	0.97937	–	✓
16	Assay 03 (Document-122), S1	1.00255	–	✓
17	Assay 04 (Document-123), S1	1.04553	–	✓
18	Assay 05 (Document-124), S1	1.10775	–	✓
19	Assay 06 (Document-125), S1	1.01484	–	✓
20	Assay 07 (Document-126), S1	1.03754	–	✓
21	Assay 08 (Document-127), S1	1.02286	–	✓
22	Assay 09 (Document-128), S1	0.96638	–	✓
23	Assay 10 (Document-129), S1	0.92225	–	✓
24	Assay 11 (Document-130), S1	1.05691	–	✓

Ratio of parameter/property point estimates:
D lower asymptote (nonlinear models) D(T)/D(S)

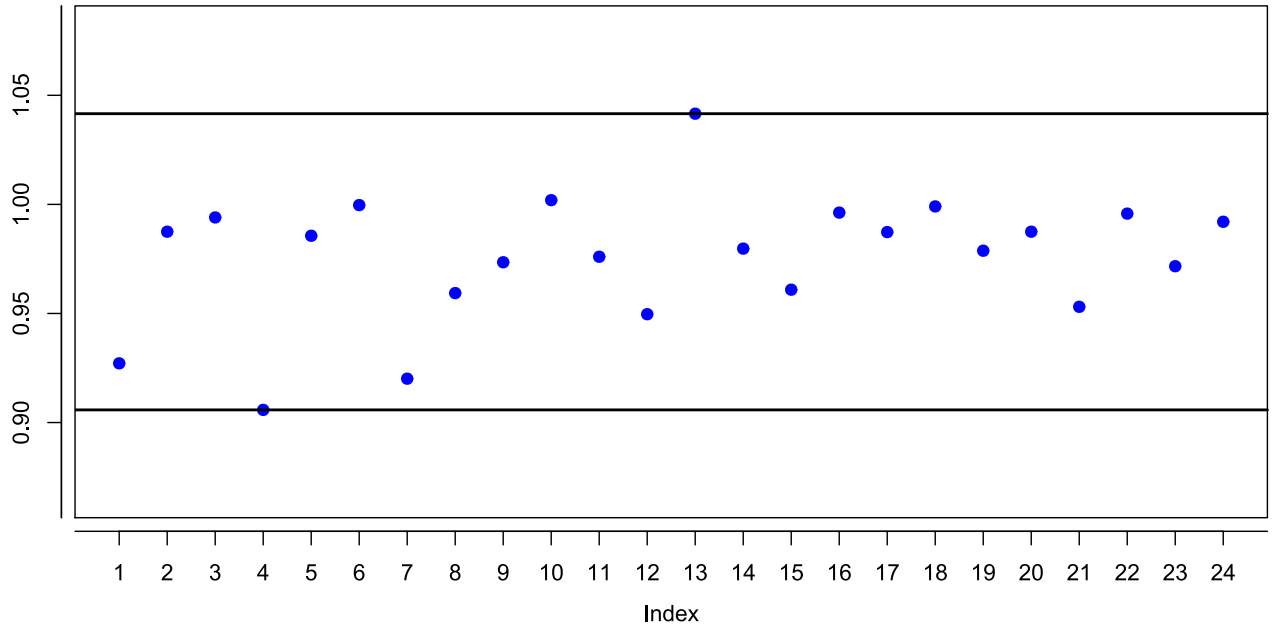


Mean	SD	CoV[%]	Margins
1.08759	0.14050	0.12919	0.81612 – 1.39665

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	1.10348	–	✓
2	Assay 13 (Document-108), S1	1.20359	–	✓
3	Assay 14 (Document-109), S1	0.81612	–	✓
4	Assay 15 (Document-110), S1	1.27792	–	✓
5	Assay 16 (Document-111), S1	0.98774	–	✓
6	Assay 17 (Document-112), S1	1.12122	–	✓
7	Assay 18 (Document-113), S1	1.39665	–	✓
8	Assay 19 (Document-114), S1	1.16876	–	✓
9	Assay 20 (Document-115), S1	1.06523	–	✓
10	Assay 21 (Document-116), S1	1.12157	–	✓
11	Assay 22 (Document-117), S1	1.00550	–	✓
12	Assay 23 (Document-118), S1	1.19765	–	✓
13	Assay 24 (Document-119), S1	0.86916	–	✓
14	Assay 01 (Document-120), S1	0.98280	–	✓
15	Assay 02 (Document-121), S1	1.10352	–	✓
16	Assay 03 (Document-122), S1	0.99897	–	✓
17	Assay 04 (Document-123), S1	1.04282	–	✓
18	Assay 05 (Document-124), S1	1.10210	–	✓
19	Assay 06 (Document-125), S1	0.95671	–	✓
20	Assay 07 (Document-126), S1	1.20359	–	✓
21	Assay 08 (Document-127), S1	1.35460	–	✓
22	Assay 09 (Document-128), S1	1.00046	–	✓
23	Assay 10 (Document-129), S1	1.06806	–	✓
24	Assay 11 (Document-130), S1	0.95403	–	✓

Ratio of parameter/property point estimates: Difference of asymptotes (nonlinear models) (A(T)-D(T))/(A(S)-D(S))

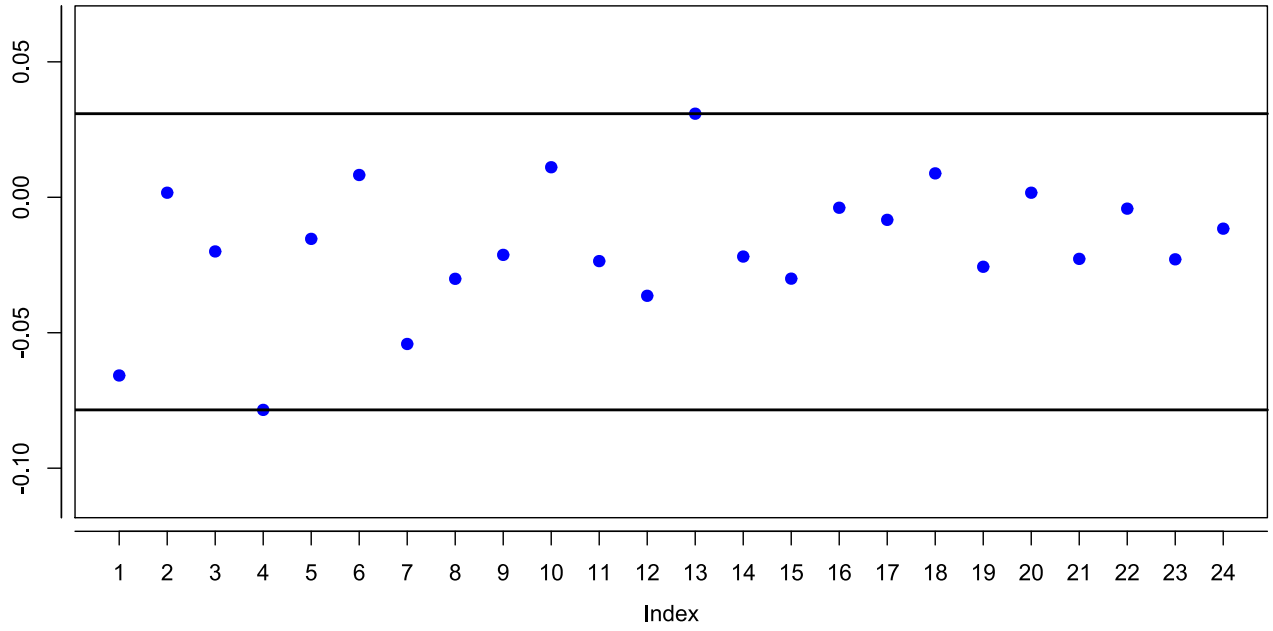


Mean	SD	CoV[%]	Margins
0.97599	0.02959	0.03032	0.90581 – 1.04157

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	0.92714	–	✓
2	Assay 13 (Document-108), S1	0.98748	–	✓
3	Assay 14 (Document-109), S1	0.99402	–	✓
4	Assay 15 (Document-110), S1	0.90581	–	✓
5	Assay 16 (Document-111), S1	0.98562	–	✓
6	Assay 17 (Document-112), S1	0.99967	–	✓
7	Assay 18 (Document-113), S1	0.92010	–	✓
8	Assay 19 (Document-114), S1	0.95934	–	✓
9	Assay 20 (Document-115), S1	0.97347	–	✓
10	Assay 21 (Document-116), S1	1.00193	–	✓
11	Assay 22 (Document-117), S1	0.97600	–	✓
12	Assay 23 (Document-118), S1	0.94966	–	✓
13	Assay 24 (Document-119), S1	1.04157	–	✓
14	Assay 01 (Document-120), S1	0.97973	–	✓
15	Assay 02 (Document-121), S1	0.96090	–	✓
16	Assay 03 (Document-122), S1	0.99624	–	✓
17	Assay 04 (Document-123), S1	0.98731	–	✓
18	Assay 05 (Document-124), S1	0.99907	–	✓
19	Assay 06 (Document-125), S1	0.97876	–	✓
20	Assay 07 (Document-126), S1	0.98748	–	✓
21	Assay 08 (Document-127), S1	0.95306	–	✓
22	Assay 09 (Document-128), S1	0.99577	–	✓
23	Assay 10 (Document-129), S1	0.97165	–	✓
24	Assay 11 (Document-130), S1	0.99204	–	✓

Normalized difference of asymptotes:
Normalized difference of upper asymptotes (A(T)-A(S))/(A(S)-D(S))

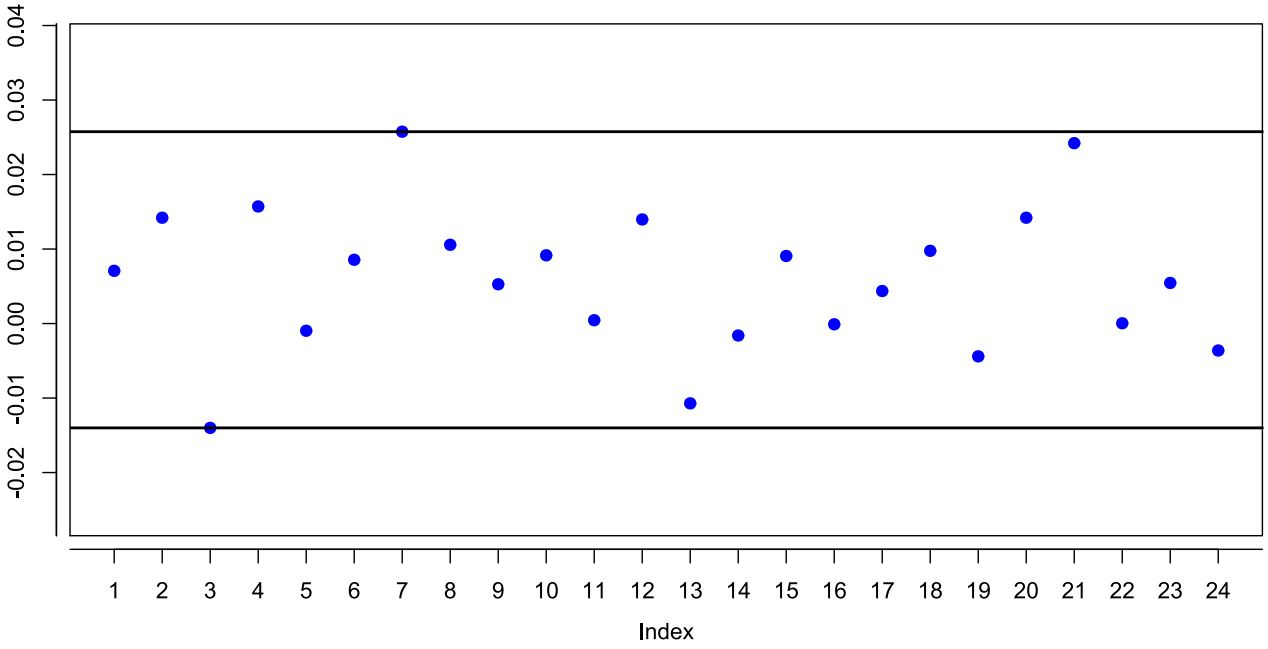


Mean	SD	CoV[%]	Margins
-0.01807	0.02466	1.36455	-0.07848 – 0.03086

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	-0.06578	–	✓
2	Assay 13 (Document-108), S1	0.00169	–	✓
3	Assay 14 (Document-109), S1	-0.01999	–	✓
4	Assay 15 (Document-110), S1	-0.07848	–	✓
5	Assay 16 (Document-111), S1	-0.01535	–	✓
6	Assay 17 (Document-112), S1	0.00823	–	✓
7	Assay 18 (Document-113), S1	-0.05415	–	✓
8	Assay 19 (Document-114), S1	-0.03009	–	✓
9	Assay 20 (Document-115), S1	-0.02126	–	✓
10	Assay 21 (Document-116), S1	0.01109	–	✓
11	Assay 22 (Document-117), S1	-0.02355	–	✓
12	Assay 23 (Document-118), S1	-0.03636	–	✓
13	Assay 24 (Document-119), S1	0.03086	–	✓
14	Assay 01 (Document-120), S1	-0.02188	–	✓
15	Assay 02 (Document-121), S1	-0.03003	–	✓
16	Assay 03 (Document-122), S1	-0.00386	–	✓
17	Assay 04 (Document-123), S1	-0.00833	–	✓
18	Assay 05 (Document-124), S1	0.00883	–	✓
19	Assay 06 (Document-125), S1	-0.02565	–	✓
20	Assay 07 (Document-126), S1	0.00169	–	✓
21	Assay 08 (Document-127), S1	-0.02273	–	✓
22	Assay 09 (Document-128), S1	-0.00419	–	✓
23	Assay 10 (Document-129), S1	-0.02290	–	✓
24	Assay 11 (Document-130), S1	-0.01158	–	✓

Normalized difference of asymptotes:
Normalized difference of lower asymptotes (D(T)-D(S))/(A(S)-D(S))

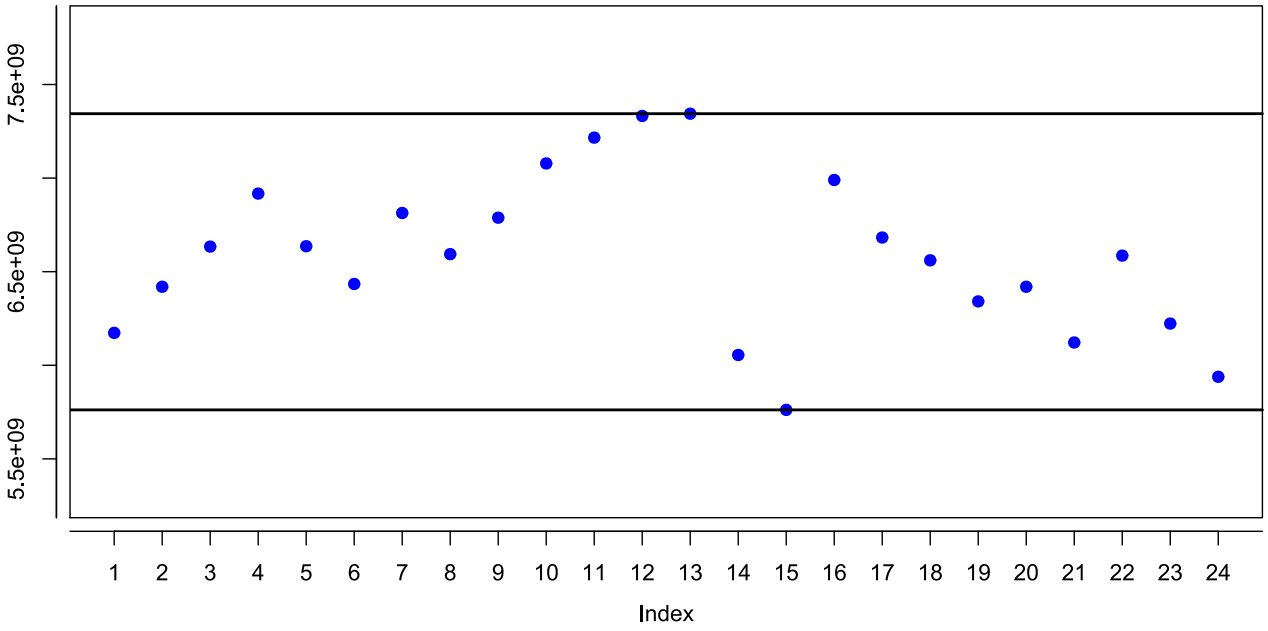


Mean	SD	CoV[%]	Margins
0.00593	0.00971	1.63676	-0.01400 – 0.02575

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	0.00708	–	✓
2	Assay 13 (Document-108), S1	0.01420	–	✓
3	Assay 14 (Document-109), S1	-0.01400	–	✓
4	Assay 15 (Document-110), S1	0.01572	–	✓
5	Assay 16 (Document-111), S1	-9.679 E-04	–	✓
6	Assay 17 (Document-112), S1	0.00856	–	✓
7	Assay 18 (Document-113), S1	0.02575	–	✓
8	Assay 19 (Document-114), S1	0.01057	–	✓
9	Assay 20 (Document-115), S1	0.00527	–	✓
10	Assay 21 (Document-116), S1	0.00916	–	✓
11	Assay 22 (Document-117), S1	4.480 E-04	–	✓
12	Assay 23 (Document-118), S1	0.01397	–	✓
13	Assay 24 (Document-119), S1	-0.01071	–	✓
14	Assay 01 (Document-120), S1	-0.00160	–	✓
15	Assay 02 (Document-121), S1	0.00907	–	✓
16	Assay 03 (Document-122), S1	-9.803 E-05	–	✓
17	Assay 04 (Document-123), S1	0.00437	–	✓
18	Assay 05 (Document-124), S1	0.00976	–	✓
19	Assay 06 (Document-125), S1	-0.00441	–	✓
20	Assay 07 (Document-126), S1	0.01420	–	✓
21	Assay 08 (Document-127), S1	0.02421	–	✓
22	Assay 09 (Document-128), S1	3.855 E-05	–	✓
23	Assay 10 (Document-129), S1	0.00545	–	✓
24	Assay 11 (Document-130), S1	-0.00362	–	✓

Anova terms:
Sum of squares regression

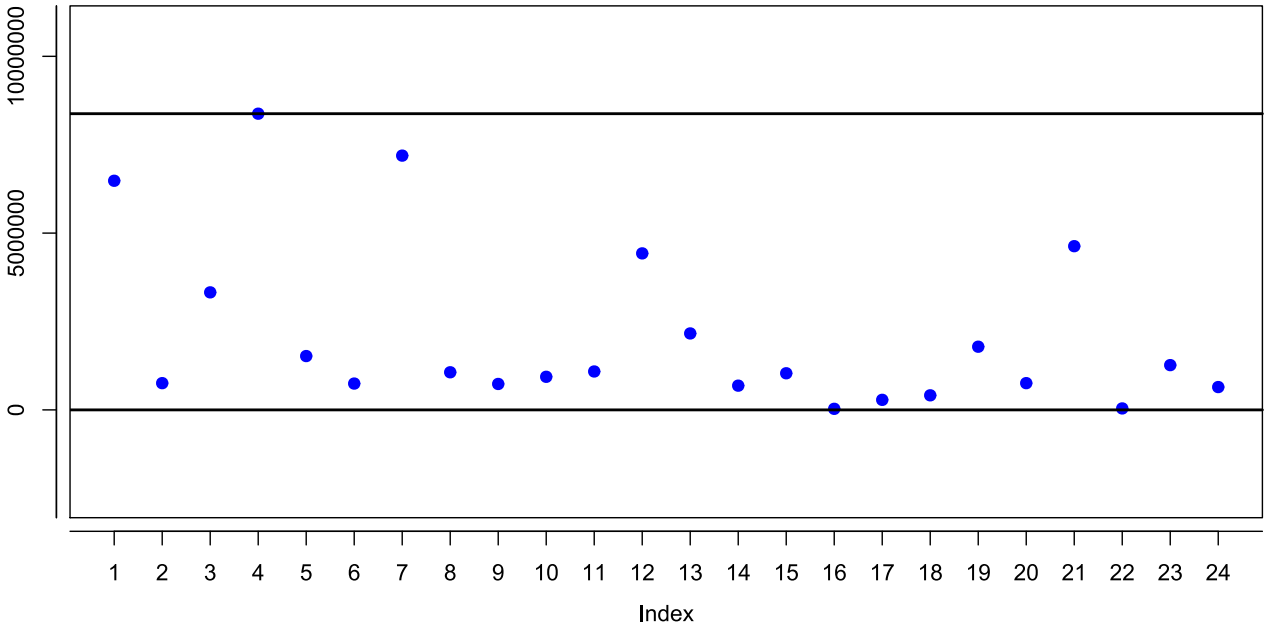


Mean	SD	CoV[%]	Margins
6.586 E+09	4.267 E+08	0.06479	5.762 E+09 – 7.344 E+09

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	6.173 E+09	–	✓
2	Assay 13 (Document-108), S1	6.420 E+09	–	✓
3	Assay 14 (Document-109), S1	6.634 E+09	–	✓
4	Assay 15 (Document-110), S1	6.917 E+09	–	✓
5	Assay 16 (Document-111), S1	6.636 E+09	–	✓
6	Assay 17 (Document-112), S1	6.434 E+09	–	✓
7	Assay 18 (Document-113), S1	6.814 E+09	–	✓
8	Assay 19 (Document-114), S1	6.594 E+09	–	✓
9	Assay 20 (Document-115), S1	6.788 E+09	–	✓
10	Assay 21 (Document-116), S1	7.078 E+09	–	✓
11	Assay 22 (Document-117), S1	7.216 E+09	–	✓
12	Assay 23 (Document-118), S1	7.332 E+09	–	✓
13	Assay 24 (Document-119), S1	7.344 E+09	–	✓
14	Assay 01 (Document-120), S1	6.055 E+09	–	✓
15	Assay 02 (Document-121), S1	5.762 E+09	–	✓
16	Assay 03 (Document-122), S1	6.990 E+09	–	✓
17	Assay 04 (Document-123), S1	6.683 E+09	–	✓
18	Assay 05 (Document-124), S1	6.561 E+09	–	✓
19	Assay 06 (Document-125), S1	6.341 E+09	–	✓
20	Assay 07 (Document-126), S1	6.420 E+09	–	✓
21	Assay 08 (Document-127), S1	6.122 E+09	–	✓
22	Assay 09 (Document-128), S1	6.586 E+09	–	✓
23	Assay 10 (Document-129), S1	6.223 E+09	–	✓
24	Assay 11 (Document-130), S1	5.938 E+09	–	✓

Anova terms:
Sum of squares non-parallelism

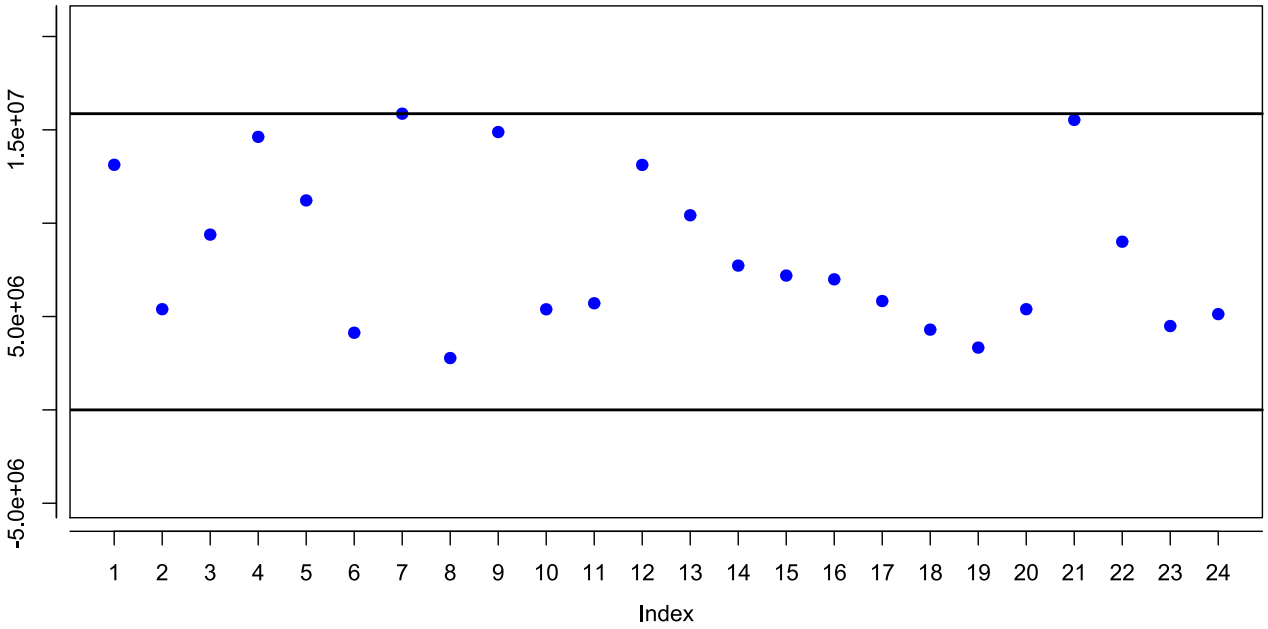


Mean	SD	CoV[%]	Upper margin
2099070.4	2374281.2	1.13111	8377418.7

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	6480296.6	–	✓
2	Assay 13 (Document-108), S1	756331.70	–	✓
3	Assay 14 (Document-109), S1	3324044.9	–	✓
4	Assay 15 (Document-110), S1	8377418.7	–	✓
5	Assay 16 (Document-111), S1	1522314.3	–	✓
6	Assay 17 (Document-112), S1	744608.63	–	✓
7	Assay 18 (Document-113), S1	7191652.4	–	✓
8	Assay 19 (Document-114), S1	1063717.7	–	✓
9	Assay 20 (Document-115), S1	733272.70	–	✓
10	Assay 21 (Document-116), S1	935836.18	–	✓
11	Assay 22 (Document-117), S1	1086357.6	–	✓
12	Assay 23 (Document-118), S1	4426595.4	–	✓
13	Assay 24 (Document-119), S1	2162202.4	–	✓
14	Assay 01 (Document-120), S1	685295.48	–	✓
15	Assay 02 (Document-121), S1	1035591.3	–	✓
16	Assay 03 (Document-122), S1	30022.459	–	✓
17	Assay 04 (Document-123), S1	284041.09	–	✓
18	Assay 05 (Document-124), S1	411922.98	–	✓
19	Assay 06 (Document-125), S1	1786738.1	–	✓
20	Assay 07 (Document-126), S1	756331.70	–	✓
21	Assay 08 (Document-127), S1	4630256.3	–	✓
22	Assay 09 (Document-128), S1	41109.417	–	✓
23	Assay 10 (Document-129), S1	1266178.3	–	✓
24	Assay 11 (Document-130), S1	645553.89	–	✓

Anova terms:
Sum of squares non-linearity

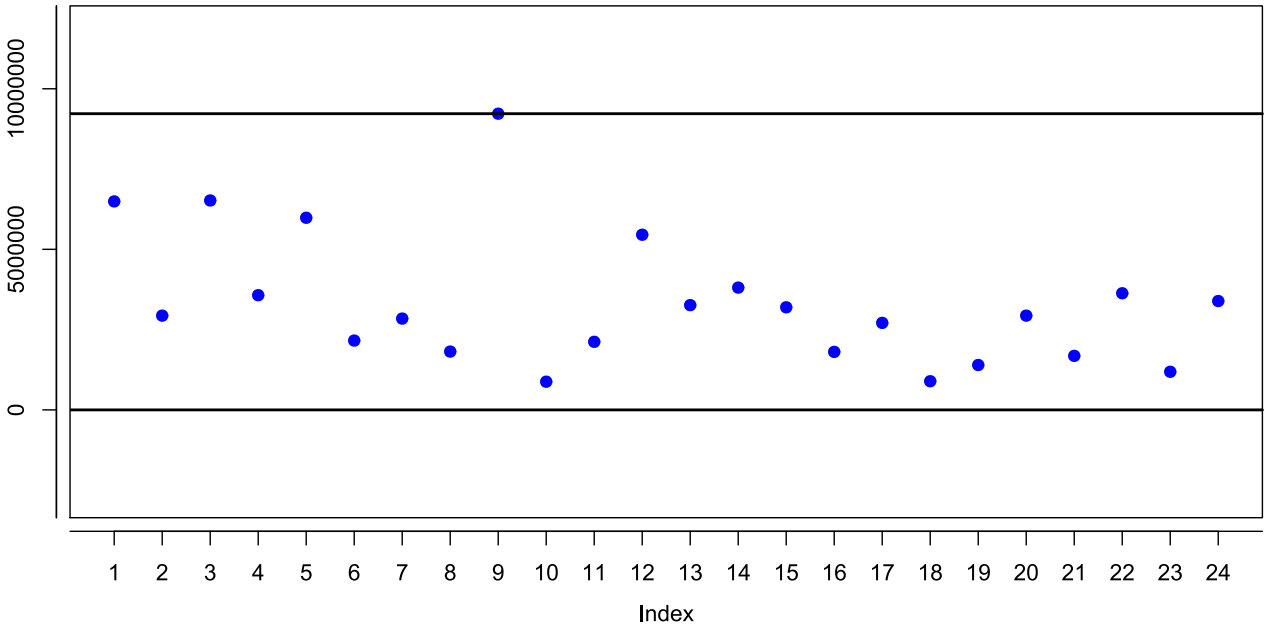


Mean	SD	CoV[%]	Upper margin
8374504.5	4214413.2	0.50324	1.586 E+07

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	1.313 E+07	–	✓
2	Assay 13 (Document-108), S1	5393170.0	–	✓
3	Assay 14 (Document-109), S1	9387980.2	–	✓
4	Assay 15 (Document-110), S1	1.462 E+07	–	✓
5	Assay 16 (Document-111), S1	1.122 E+07	–	✓
6	Assay 17 (Document-112), S1	4132618.0	–	✓
7	Assay 18 (Document-113), S1	1.586 E+07	–	✓
8	Assay 19 (Document-114), S1	2776500.2	–	✓
9	Assay 20 (Document-115), S1	1.488 E+07	–	✓
10	Assay 21 (Document-116), S1	5387791.1	–	✓
11	Assay 22 (Document-117), S1	5711117.0	–	✓
12	Assay 23 (Document-118), S1	1.312 E+07	–	✓
13	Assay 24 (Document-119), S1	1.042 E+07	–	✓
14	Assay 01 (Document-120), S1	7728603.5	–	✓
15	Assay 02 (Document-121), S1	7194741.4	–	✓
16	Assay 03 (Document-122), S1	6992706.6	–	✓
17	Assay 04 (Document-123), S1	5830008.3	–	✓
18	Assay 05 (Document-124), S1	4298542.9	–	✓
19	Assay 06 (Document-125), S1	3336056.0	–	✓
20	Assay 07 (Document-126), S1	5393170.0	–	✓
21	Assay 08 (Document-127), S1	1.553 E+07	–	✓
22	Assay 09 (Document-128), S1	9008244.0	–	✓
23	Assay 10 (Document-129), S1	4490956.6	–	✓
24	Assay 11 (Document-130), S1	5130042.8	–	✓

Anova terms:
Sum of squares non-linearity Standard

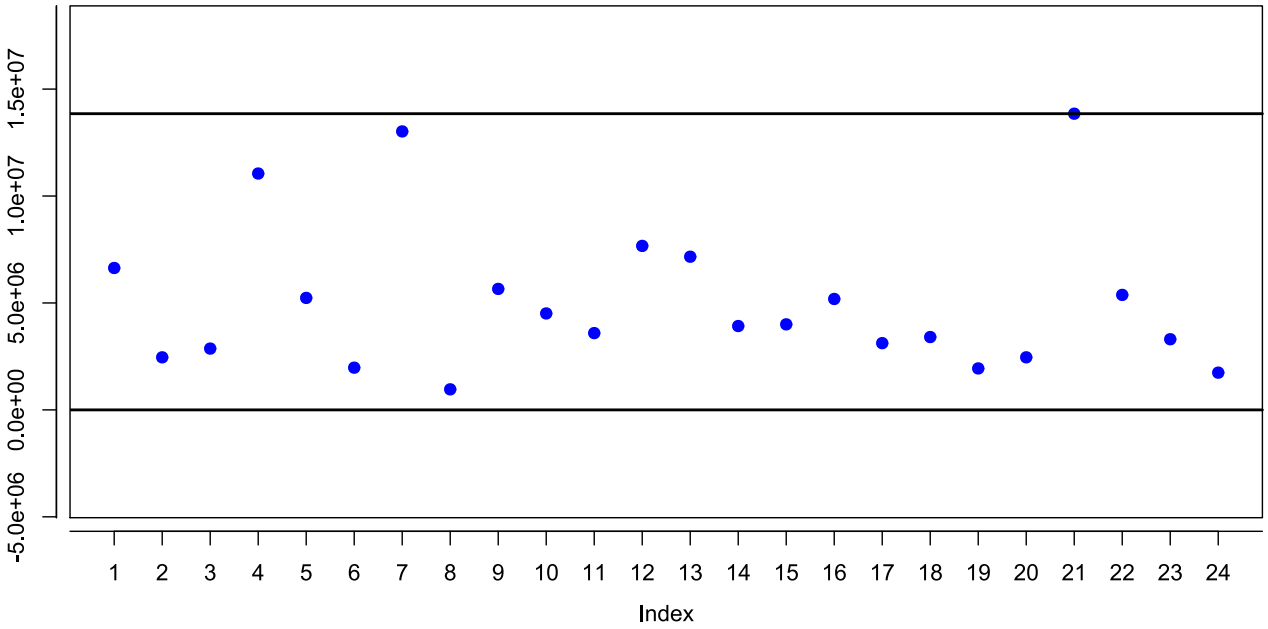


Mean	SD	CoV[%]	Upper margin
3328998.2	2067013.7	0.62091	9224080.5

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	6492579.7	–	✓
2	Assay 13 (Document-108), S1	2935356.3	–	✓
3	Assay 14 (Document-109), S1	6521855.0	–	✓
4	Assay 15 (Document-110), S1	3571656.9	–	✓
5	Assay 16 (Document-111), S1	5983400.5	–	✓
6	Assay 17 (Document-112), S1	2158525.8	–	✓
7	Assay 18 (Document-113), S1	2843534.4	–	✓
8	Assay 19 (Document-114), S1	1815749.6	–	✓
9	Assay 20 (Document-115), S1	9224080.5	–	✓
10	Assay 21 (Document-116), S1	878078.08	–	✓
11	Assay 22 (Document-117), S1	2120315.5	–	✓
12	Assay 23 (Document-118), S1	5454517.3	–	✓
13	Assay 24 (Document-119), S1	3261953.8	–	✓
14	Assay 01 (Document-120), S1	3808131.3	–	✓
15	Assay 02 (Document-121), S1	3194885.8	–	✓
16	Assay 03 (Document-122), S1	1806334.8	–	✓
17	Assay 04 (Document-123), S1	2709390.0	–	✓
18	Assay 05 (Document-124), S1	892490.03	–	✓
19	Assay 06 (Document-125), S1	1397402.9	–	✓
20	Assay 07 (Document-126), S1	2935356.3	–	✓
21	Assay 08 (Document-127), S1	1682338.1	–	✓
22	Assay 09 (Document-128), S1	3631837.6	–	✓
23	Assay 10 (Document-129), S1	1186796.5	–	✓
24	Assay 11 (Document-130), S1	3389389.2	–	✓

Anova terms:
Sum of squares non-linearity Test/Control



Mean	SD	CoV[%]	Upper margin
5045506.4	3430398.0	0.67989	1.385 E+07

Development assays

Index	Assay element	Value		
1	Assay 12 (Document-107), S1	6635514.1	–	✓
2	Assay 13 (Document-108), S1	2457813.7	–	✓
3	Assay 14 (Document-109), S1	2866125.2	–	✓
4	Assay 15 (Document-110), S1	1.105 E+07	–	✓
5	Assay 16 (Document-111), S1	5236009.5	–	✓
6	Assay 17 (Document-112), S1	1974092.2	–	✓
7	Assay 18 (Document-113), S1	1.302 E+07	–	✓
8	Assay 19 (Document-114), S1	960750.59	–	✓
9	Assay 20 (Document-115), S1	5656969.9	–	✓
10	Assay 21 (Document-116), S1	4509713.0	–	✓
11	Assay 22 (Document-117), S1	3590801.5	–	✓
12	Assay 23 (Document-118), S1	7667800.0	–	✓
13	Assay 24 (Document-119), S1	7162335.9	–	✓
14	Assay 01 (Document-120), S1	3920472.2	–	✓
15	Assay 02 (Document-121), S1	3999855.5	–	✓
16	Assay 03 (Document-122), S1	5186371.8	–	✓
17	Assay 04 (Document-123), S1	3120618.3	–	✓
18	Assay 05 (Document-124), S1	3406052.9	–	✓
19	Assay 06 (Document-125), S1	1938653.1	–	✓
20	Assay 07 (Document-126), S1	2457813.7	–	✓
21	Assay 08 (Document-127), S1	1.385 E+07	–	✓
22	Assay 09 (Document-128), S1	5376406.4	–	✓
23	Assay 10 (Document-129), S1	3304160.1	–	✓
24	Assay 11 (Document-130), S1	1740653.6	–	✓

Section III: Strategies overview

Strategy: Strategy 1

	Margins		
	Upper	Lower	Reference mean
Equivalence test parameter estimate			
A upper asymptote (nonlinear models)	51948.145	42438.843	
B parameter (nonlinear models)	-1.49167	-2.53592	
C parameter (nonlinear models)	-0.88902	-1.46470	
D lower asymptote (nonlinear models)	5602.1740	1103.5610	
Difference of asymptotes (nonlinear models)	49435.246	38783.562	
Ratio of asymptotes (nonlinear models)	45.15183	8.69554	
Equivalence test difference of parameter estimates			
A upper asymptote (nonlinear models)	3641.8809	-6326.8815	
B parameter (nonlinear models)	0.54061	-1.13370	
C parameter (nonlinear models)	0.36892	-0.20440	
D lower asymptote (nonlinear models)	3268.5319	-2314.9809	
Difference of asymptotes (nonlinear models)	5261.5642	-8232.3529	
Equivalence test ratio of parameter estimates			
A upper asymptote (nonlinear models)	1.07631	0.87518	
B parameter (nonlinear models)	1.67929	0.76654	
C parameter (nonlinear models)	1.22397	0.74203	
D lower asymptote (nonlinear models)	3.57643	0.41699	
Difference of asymptotes (nonlinear models)	1.12109	0.83116	
Equivalence test scaled parameter range			
A upper asymptote (nonlinear models)	0.07743	-0.13452	47032.365
B parameter (nonlinear models)	0.27563	-0.57803	1.96134
C parameter (nonlinear models)	0.33239	-0.18417	1.10989
D lower asymptote (nonlinear models)	0.95004	-0.67288	3440.3998
Difference of asymptotes (nonlinear models, Standard only)	1.05109	0.82461	47032.365
Test parameter/property point estimate			
A upper asymptote (nonlinear models)	50560.778	43390.286	
B parameter (nonlinear models)	-1.77876	-2.23001	
C parameter (nonlinear models)	-0.96158	-1.33785	
D lower asymptote (nonlinear models)	4521.8083	2618.1995	
Slope (Nonlinear Models)	-13353.032	-16477.096	
Difference of asymptotes (nonlinear models)	46391.284	40225.032	
Ratio of asymptotes (nonlinear models)	18.68219	10.80726	
Test Difference of parameter/property point estimates			
A upper asymptote (nonlinear models)	1392.6983	-3633.1455	
B parameter (nonlinear models)	0.16842	-0.61565	
C parameter (nonlinear models)	0.20508	-0.10361	
D lower asymptote (nonlinear models)	1153.3090	-604.17498	
Difference of asymptotes (nonlinear models)	1876.1080	-4360.7949	
Test Ratio of parameter/property point estimates			
A upper asymptote (nonlinear models)	1.02852	0.92572	
B parameter (nonlinear models)	1.32482	0.92109	
C parameter (nonlinear models)	1.10775	0.84671	
D lower asymptote (nonlinear models)	1.39665	0.81612	
Difference of asymptotes (nonlinear models)	1.04157	0.90581	
Test normalized difference of asymptotes			
A upper asymptote (nonlinear models)	0.03086	-0.07848	
D lower asymptote (nonlinear models)	0.02575	-0.01400	
Anova terms*			
Sum of squares regression	7.344 E+09	5.762 E+09	
Sum of squares non-parallelism	8377418.7		
Sum of squares non-linearity	1.586 E+07		
Sum of squares non-linearity Standard	9224080.5		
Sum of squares non-linearity Test/Control	1.385 E+07		

* not used in simulation

Section IV: Strategy verification

Strategy: Strategy 1

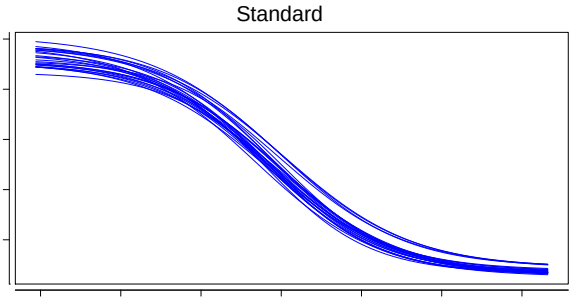
Strategy verification result: Development assays

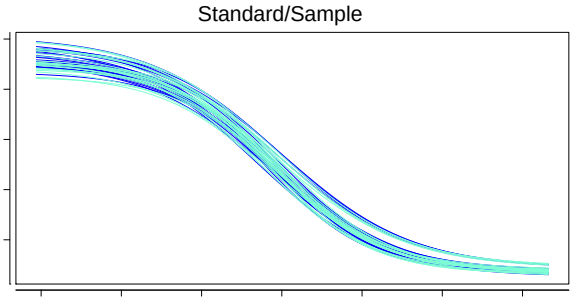
Test	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Equivalence test parameter estimate																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equivalence test difference of parameter estimates																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equivalence test ratio of parameter estimates																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equivalence test scaled parameter range																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models, Standard only)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Test parameter/property point estimate																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Slope (Nonlinear Models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ratio of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Test Difference of parameter/property point estimates																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Test Ratio of parameter/property point estimates																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
B parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C parameter (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Difference of asymptotes (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Test normalized difference of asymptotes																								
A upper asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
D lower asymptote (nonlinear models)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Anova terms																								
Sum of squares regression	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares non-parallelism	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares non-linearity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares non-linearity Standard	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sum of squares non-linearity Test/Control	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Strategy test result	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Expected test result	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Strategy correctly qualifies assay	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Section V: Strategy visualization

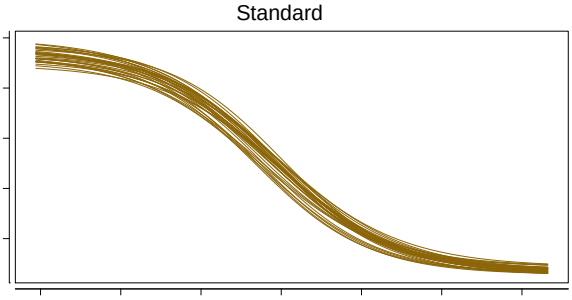
Strategy: Strategy 1

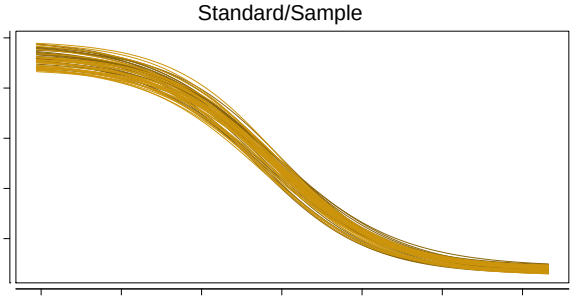
Development assays overplay plot (for comparison)





Simulation assays: Overlay plot

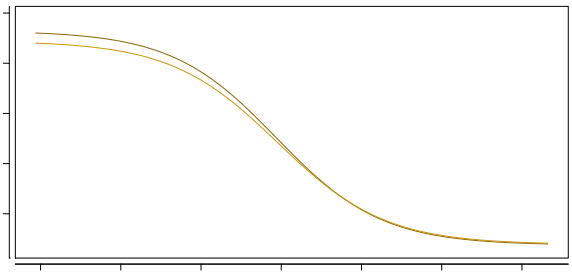


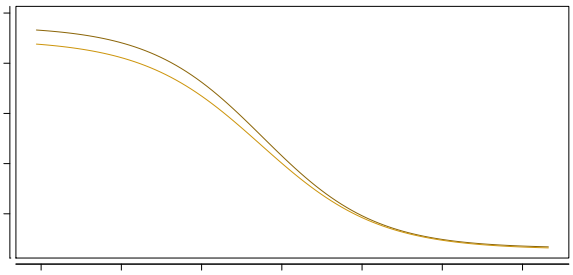


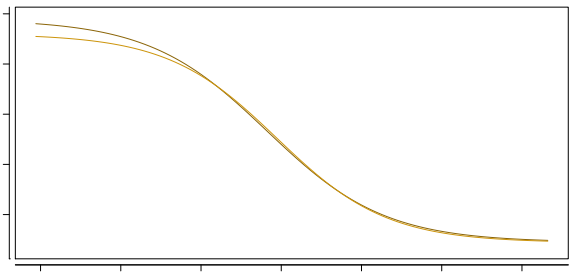
Number of simulations (Standard):	46
Number of configurations found:	30

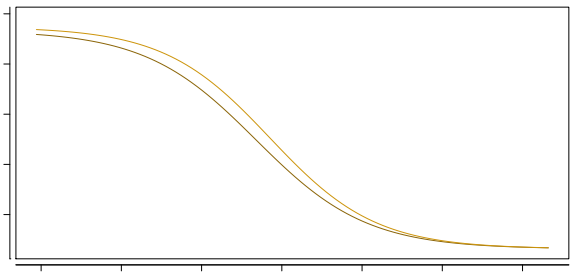
Mean number of simulations (Sample):	1.00
Number of configurations found:	30

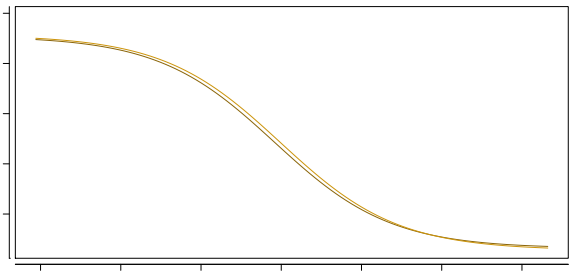
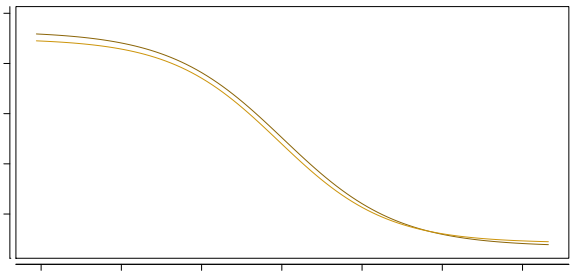
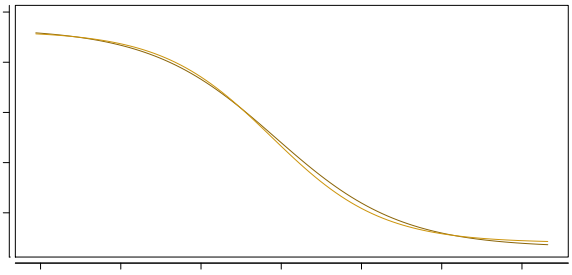
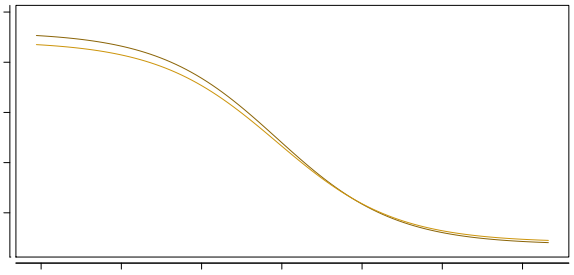
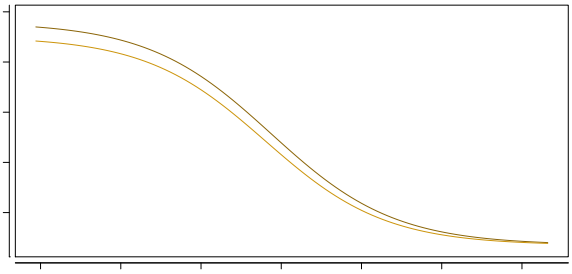
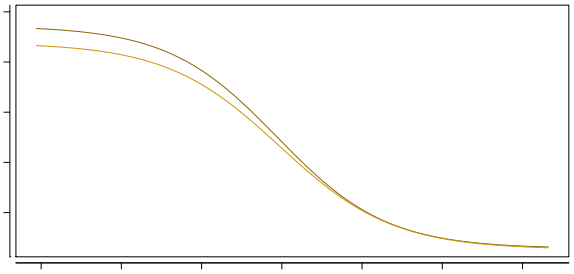
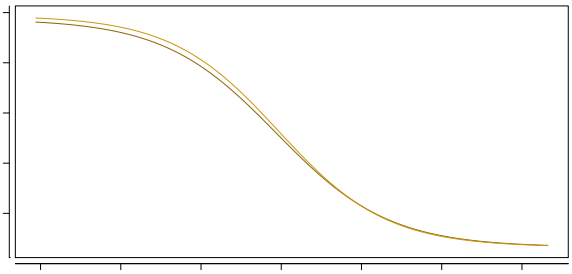
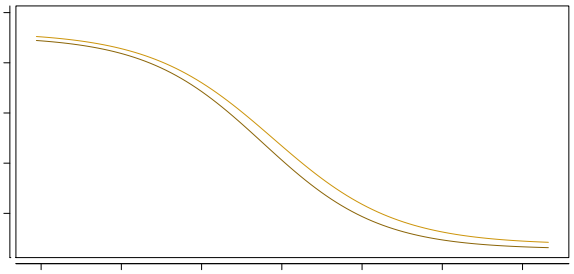
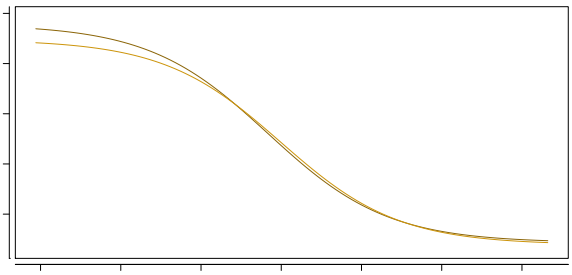
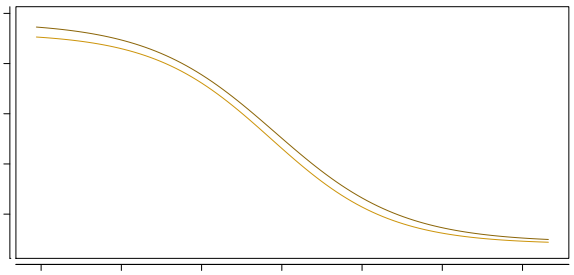
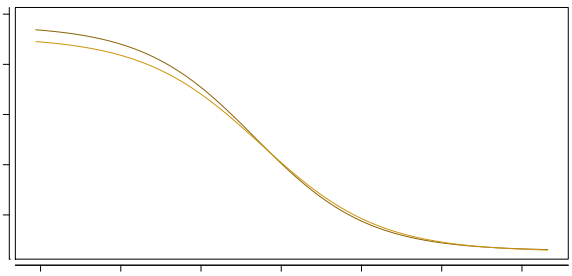
Simulation assays: Assay plots

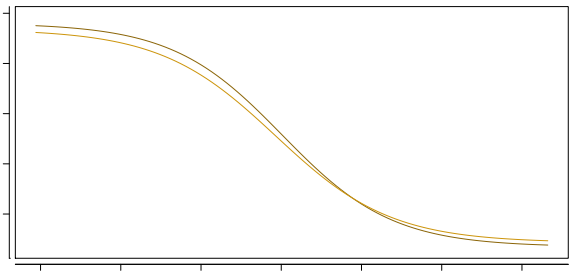
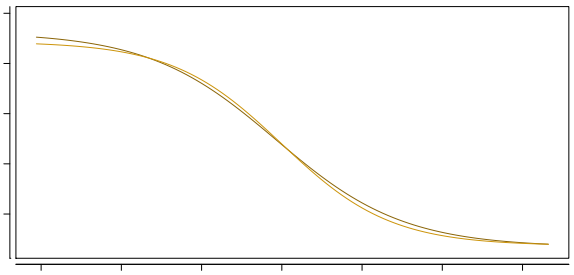
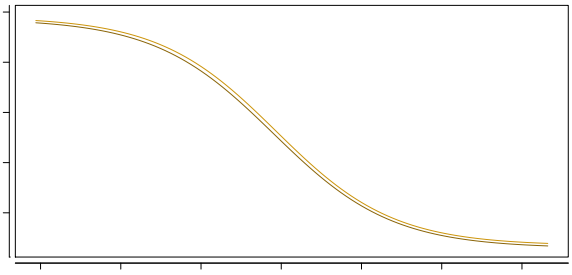
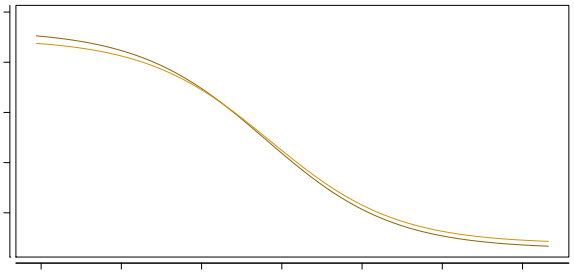
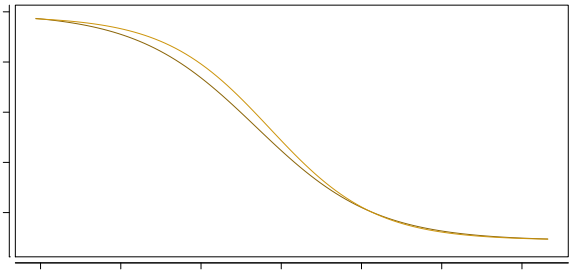
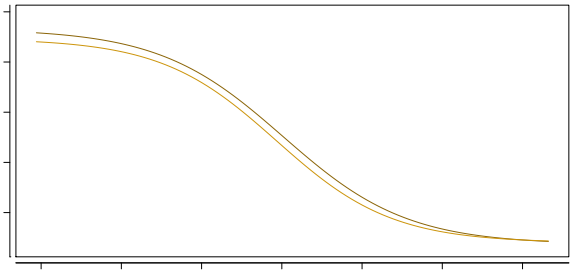
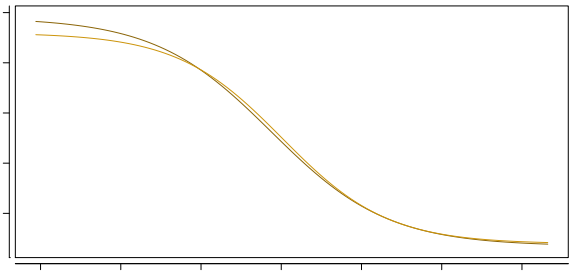
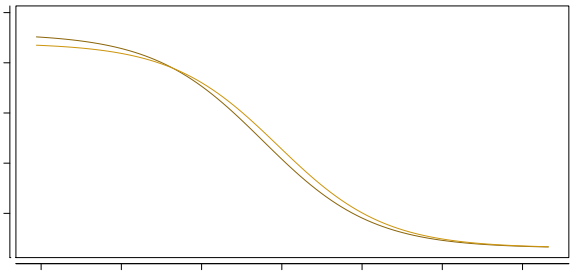
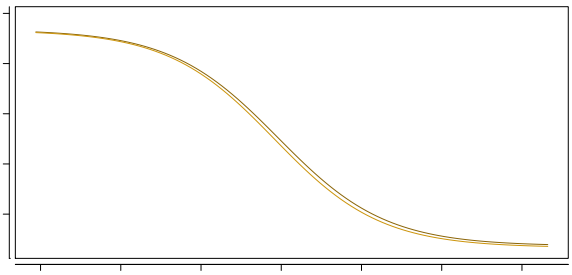
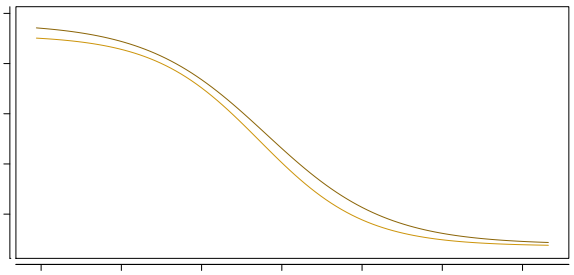
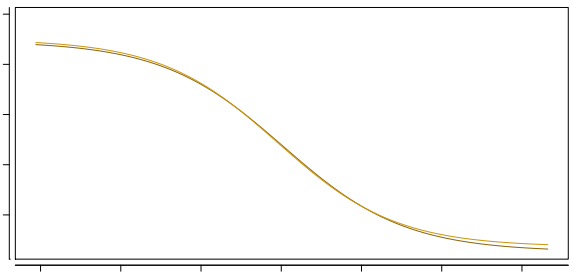


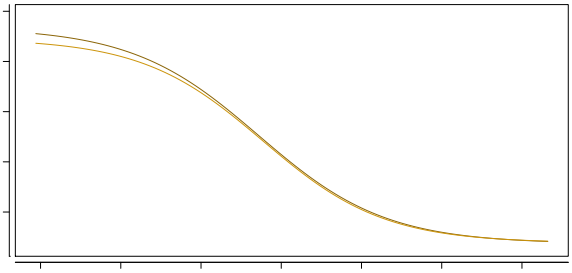


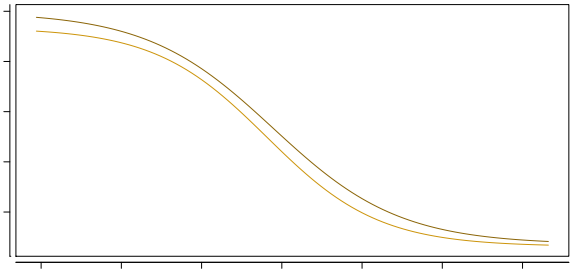




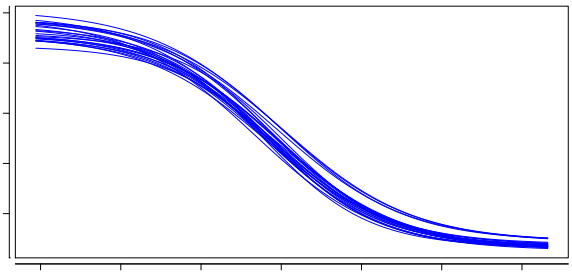


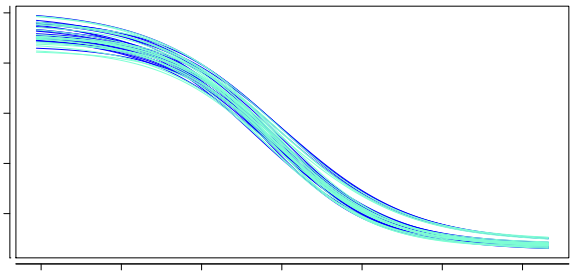


Visualization summary

Left plot: Overlay plot of Standard. Right plot: Overlay plot of Standard and Test samples

Development assays





Strategy: Strategy 1