

**TECHNOLOGY PREVIEW 08/2021** – This report has been generated with the upcoming Control Chart Package for PLA 3.0.5 (or higher). The package has not been released and has not been finally verified for production use. Contact Stegmann Systems (<http://support.bioassay.de>) to report issues or suggest additional features.

# 05 Performing Statistical Process Control



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## Calculation

Calculation performed: 18.08.2021 16:01:37, Benjamin Schneider (PLA 3.0.5 Build 816, NBARW01, 10014)  
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## Signatures

..... Responsibility Review Approval

## Comments

### Comment by Benjamin Schneider: (13.07.2021 15:00:56)

This document shows the statistical process control features of the Control Chart Package. Each chart shows a different data series and the rule sets applied to this data series. It is possible to reference the same rule set in different data series and to reference multiple rule sets in the same data series. For rules for which mean and standard deviation intervals are relevant, these values are plotted as a colored horizontal line. If set, the control limits are plotted in the same way. If an observation violates a limit/rule, it is marked with a colored circle. An overview of all violations is shown in the 'Rule violations' section. Violated rules will set the 'traffic light' of the containing rule set, chart, and document according to their severity

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DOCUMENT-1781



996FAEA8-9EC8-4FB7-8524-EA8686FFDF5D

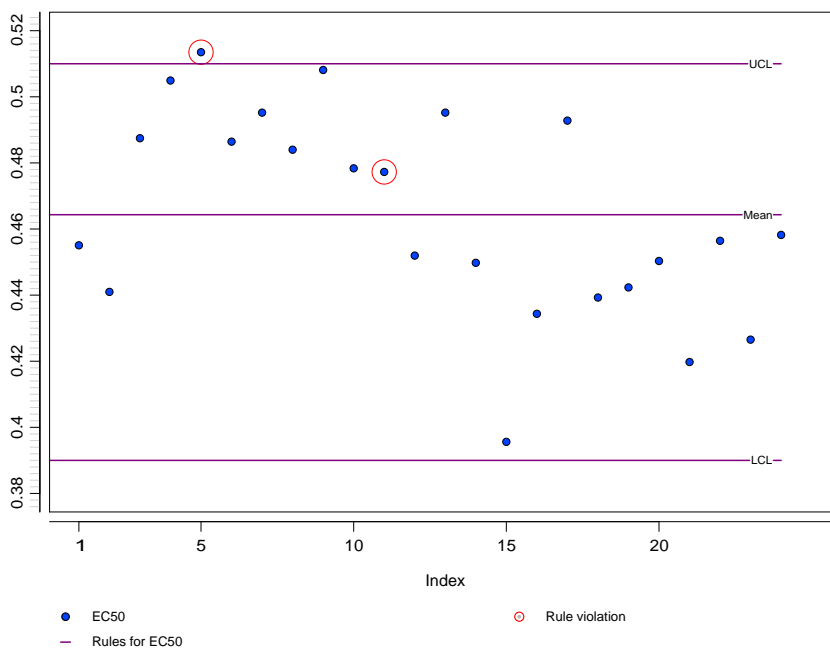
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## Chart: EC50



Elements	Summary
■ EC50	Points, Column: EC50, ■ Rules for EC50

### Full chart



### Parameter statistics

Name	Mean	SD	1st quartile	Min value	Number of values
	Median	CV	3rd quartile	Max value	Missing values
EC50	0.46433	0.03087	0.44199	0.39561	24
	0.45732	6.65%	0.48880	0.51349	0

### Rule set: Rules for EC50



EC50, Mean = 0.46433, SD = 0.03087

Rules	Summary	State
1: Limit of Specificati...	Control limit, Margins: 0.39000 – 0.51000	
2: Nelson rule 2	9 on same side, Margins: 0.46433 – 0.46433 [0 SD – 0 SD]	
3: Nelson rule 3	6 monotonous	

### Violations

Index	Date	Value	Rules		
			1	2	3
5	05.05.2013 10:39:45	0.51349	✗	–	–
11	11.05.2013 10:39:45	0.47727	–	✗	–

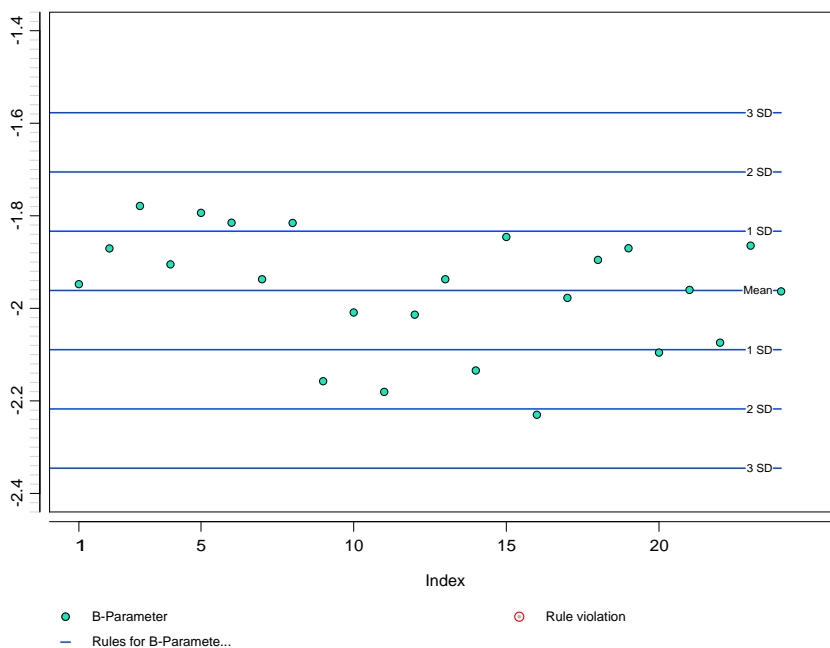
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## Chart: B-Parameter



Elements	Summary
B-Parameter	Points, Column: B-Parameter, Rules for B-Parameter

### Full chart



### Parameter statistics

Name	Mean	SD	1st quartile	Min value	Number of values
	Median	CV	3rd quartile	Max value	Missing values
B-Parameter	-1.96134	0.12803	-2.02882	-2.23001	24
	-1.94247	6.53%	-1.86874	-1.77876	0

### Rule set: Rules for B-Parameter



B-Parameter, Mean = -1.96134, SD = 0.12803

Rules	Summary	State
1: Nelson rule 1	1 beyond 3 SD, Margins: -2.34542 – -1.57726 [3 SD – 3 SD]	
2: Nelson rule 5	2 beyond 2 SD, Margins: -2.21739 – -1.70528 [2 SD – 2 SD]	
3: Nelson rule 6	4 beyond 1 SD, Margins: -2.08936 – -1.83331 [1 SD – 1 SD]	

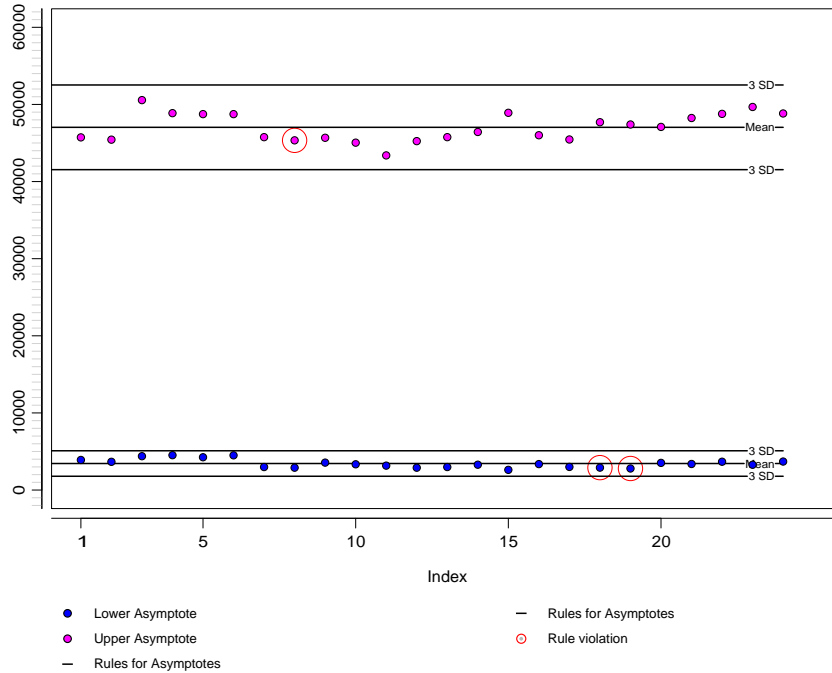
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## Chart: Asymptotes



Elements	Summary
<ul style="list-style-type: none"> <li>Lower Asymptote</li> <li>Upper Asymptote</li> </ul>	<ul style="list-style-type: none"> <li>Points, Column: Lower Asymptote, ■ Rules for Asymptotes</li> <li>Points, Column: Upper Asymptote, ■ Rules for Asymptotes</li> </ul>

### Full chart



### Parameter statistics

Name	Mean	SD	1st quartile	Min value	Number of values
	Median	CV	3rd quartile	Max value	Missing values
Lower Asymptote	3440.3998	550.92765	2984.0610	2618.1995	24
	3352.5326	16.01%	3678.5272	4521.8083	0
Upper Asymptote	47032.365	1829.9016	45621.076	43390.286	24
	46756.898	3.89%	48752.155	50560.778	0

### Rule set: Rules for Asymptotes



Lower Asymptote, Mean = 3440.3998, SD = 550.92765

Rules	Summary	State
1: Nelson rule 1	1 beyond 3 SD, Margins: 1787.6169 – 5093.1828 [3 SD – 3 SD]	
2: Nelson rule 2	9 on same side, Margins: 3440.3998 – 3440.3998 [0 SD – 0 SD]	
3: Nelson rule 3	6 monotonous	

### Violations

Index	Date	Value	Rules		
			1	2	3
18	18.05.2013 10:39:45	2907.6124	–	✗	–
19	19.05.2013 10:39:45	2794.3126	–	✗	–

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### Rule set: Rules for Asymptotes



Upper Asymptote, Mean = 47032.365, SD = 1829.9016

Rules	Summary	State
1: Nelson rule 1	1 beyond 3 SD, Margins: 41542.660 – 52522.070 [3 SD – 3 SD]	
2: Nelson rule 2	9 on same side, Margins: 47032.365 – 47032.365 [0 SD – 0 SD]	
3: Nelson rule 3	6 monotonous	

### Violations

Index	Date	Value	Rules		
			1	2	3
8	08.05.2013 10:39:45	45342.963	–	–	✘

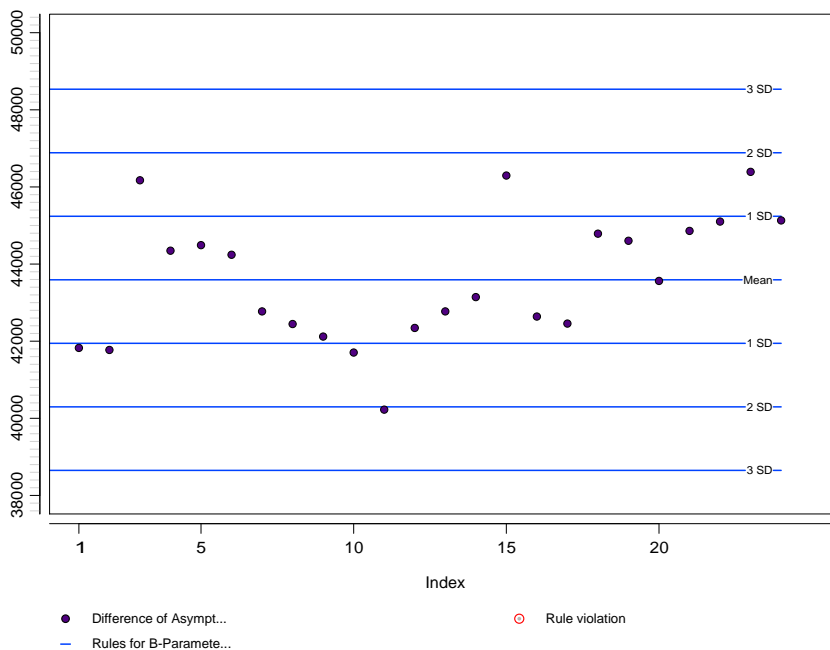
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## Chart: Difference of Asymptotes



Elements	Summary
■ Difference of Asympt...	Points, Column: Difference of Asymptotes, ■ Rules for B-Parameter

Full chart



### Parameter statistics

Name	Mean	SD	1st quartile	Min value	Number of values
	Median	CV	3rd quartile	Max value	Missing values
Difference of Asympt...	43591.965	1647.4285	42419.662	40225.032	24
	43353.003	3.78%	44806.033	46391.284	0

### Rule set: Rules for B-Parameter



Difference of Asymptotes, Mean = 43591.965, SD = 1647.4285

Rules	Summary	State
1: Nelson rule 1	1 beyond 3 SD, Margins: 38649.680 – 48534.251 [3 SD – 3 SD]	
2: Nelson rule 5	2 beyond 2 SD, Margins: 40297.108 – 46886.822 [2 SD – 2 SD]	
3: Nelson rule 6	4 beyond 1 SD, Margins: 41944.537 – 45239.394 [1 SD – 1 SD]	

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## Appendix

### Rule sets

Rule set	Summary
<ul style="list-style-type: none"> <li>■ Violations</li> <li>■ Rules for EC50                             <ul style="list-style-type: none"> <li>1: Limit of Specificati...</li> <li>2: Nelson rule 2</li> <li>3: Nelson rule 3</li> </ul> </li> <li>■ Rules for Asymptotes                             <ul style="list-style-type: none"> <li>1: Nelson rule 1</li> <li>2: Nelson rule 2</li> <li>3: Nelson rule 3</li> </ul> </li> <li>■ Rules for B-Paramete...                             <ul style="list-style-type: none"> <li>1: Nelson rule 1</li> <li>2: Nelson rule 5</li> <li>3: Nelson rule 6</li> </ul> </li> </ul>	<p>Scope all data, Mean and SD defined by data                      Limits: 0.39 – 0.51, Severity: Alarm                      9 on same side, Severity: Warning                      6 monotonous, Severity: Information</p> <p>Scope all data, Mean and SD defined by data                      1 beyond 3 SD, Severity: Alarm                      9 on same side, Severity: Information                      6 monotonous, Severity: Warning</p> <p>Scope all data, Mean and SD defined by data                      1 beyond 3 SD, Severity: Information                      2 beyond 2 SD, Severity: Information                      4 beyond 1 SD, Severity: Information</p>

### Dataset

Index*	Document key	Document title	Section	Date	EC50
1 (1)	Document-1791	Assay 01	Ref	01.05.2013 10:39:45	0.45507
2 (2)	Document-1792	Assay 02	Ref	02.05.2013 10:39:45	0.44097
3 (3)	Document-1793	Assay 03	Ref	03.05.2013 10:39:45	0.48747
4 (4)	Document-1794	Assay 04	Ref	04.05.2013 10:39:45	0.50492
5 (5)	Document-1795	Assay 05	Ref	05.05.2013 10:39:45	0.51349
6 (6)	Document-1796	Assay 06	Ref	06.05.2013 10:39:45	0.48643
7 (7)	Document-1797	Assay 07	Ref	07.05.2013 10:39:45	0.49521
8 (8)	Document-1798	Assay 08	Ref	08.05.2013 10:39:45	0.48399
9 (9)	Document-1799	Assay 09	Ref	09.05.2013 10:39:45	0.50812
10 (10)	Document-1800	Assay 10	Ref	10.05.2013 10:39:45	0.47836
11 (11)	Document-1801	Assay 11	Ref	11.05.2013 10:39:45	0.47727
12 (12)	Document-1802	Assay 12	Ref	12.05.2013 10:39:45	0.45195
13 (13)	Document-1803	Assay 13	Ref	13.05.2013 10:39:45	0.49521
14 (14)	Document-1804	Assay 14	Ref	14.05.2013 10:39:45	0.44977
15 (15)	Document-1805	Assay 15	Ref	15.05.2013 10:39:45	0.39561
16 (16)	Document-1806	Assay 16	Ref	16.05.2013 10:39:45	0.43435
17 (17)	Document-1807	Assay 17	Ref	17.05.2013 10:39:45	0.49280
18 (18)	Document-1808	Assay 18	Ref	18.05.2013 10:39:45	0.43927
19 (19)	Document-1809	Assay 19	Ref	19.05.2013 10:39:45	0.44232
20 (20)	Document-1810	Assay 20	Ref	20.05.2013 10:39:45	0.45032
21 (21)	Document-1811	Assay 21	Ref	21.05.2013 10:39:45	0.41976
22 (22)	Document-1812	Assay 22	Ref	22.05.2013 10:39:45	0.45643
23 (23)	Document-1813	Assay 23	Ref	23.05.2013 10:39:45	0.42653
24 (24)	Document-1814	Assay 24	Ref	24.05.2013 10:39:45	0.45821

Index*	B-Parameter	Lower Asymptote	Upper Asymptote	Difference of Asympt...
1 (1)	-1.94779	3901.4878	45727.277	41825.790
2 (2)	-1.87054	3659.6143	45432.504	41772.890
3 (3)	-1.77876	4388.2403	50560.778	46172.538
4 (4)	-1.90502	4521.8083	48868.359	44346.550
5 (5)	-1.79367	4254.0085	48744.485	44490.477
6 (6)	-1.81493	4501.8963	48743.199	44241.303
7 (7)	-1.93716	2984.0610	45756.364	42772.303
8 (8)	-1.81547	2897.9937	45342.963	42444.969
9 (9)	-2.15750	3556.8233	45676.520	42119.697
10 (10)	-2.00899	3339.2501	45044.640	41705.390
11 (11)	-2.18051	3165.2539	43390.286	40225.032
12 (12)	-2.01369	2896.4054	45240.143	42343.738
13 (13)	-1.93716	2984.0610	45756.364	42772.303
14 (14)	-2.13433	3285.7429	46429.229	43143.486
15 (15)	-1.84579	2618.1995	48913.692	46295.492
16 (16)	-2.23001	3365.8152	46004.986	42639.171
17 (17)	-1.97743	2997.8831	45454.742	42456.859
18 (18)	-1.89534	2907.6124	47695.770	44788.157
19 (19)	-1.87015	2794.3126	47398.505	44604.193
20 (20)	-2.09558	3522.0468	47084.566	43562.519
21 (21)	-1.96017	3379.4210	48239.080	44859.659

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Index*	B-Parameter	Lower Asymptote	Upper Asymptote	Difference of Asympt...
22 (22)	-2.07420	3673.1217	48775.166	45102.044
23 (23)	-1.86450	3279.7931	49671.077	46391.284
24 (24)	-1.96338	3694.7438	48826.062	45131.318

\* The first index sorts the assays by date. The index in parentheses indicates the original order of the assays in the dataset.