



**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

## Assay overview

Assay elements	Summary
<ul style="list-style-type: none"> <li><span style="color: blue;">■</span> STD</li> <li><span style="color: cyan;">■</span> TST1 - Source Material</li> <li><span style="color: purple;">■</span> TST2 - Stock Solution with Pre...</li> <li><span style="color: yellow;">■</span> TST3 - Mixed Response Data Han...</li> <li><span style="color: orange;">■</span> TST4 - Adjustment</li> <li><span style="color: green;">■</span> TST5 - Normalization</li> <li><span style="color: pink;">■</span> TST6 - Transformation</li> </ul>	<p>Reference standard, multi-dose (3 dilution steps, 6 replicates)</p> <p>Test sample, single-dose (3 replicates), defined concentration: 45.0 IU/L</p> <p>Test sample, single-dose (3 replicates), defined concentration: 75.0 IU/L</p> <p>Test sample, single-dose (3 replicates)</p> <p>Test sample, single-dose (3 replicates)</p> <p>Test sample, single-dose (3 replicates)</p> <p>Test sample, single-dose (3 replicates)</p>

Property	Value
<i>Response data processing*</i>	
Response adjustment	Adjustment by fixed value: 1 (TST4 - Adjustme...)
Response adjustment	Adjustment by fixed value: 1 (TST3 - Mixed Re...)
Response normalization	Normalization by fixed value: 2 (TST3 - Mixed Re...)
Response adjustment	Adjustment by fixed value: -0.5 (TST3 - Mixed Re...)
Response normalization	Normalization by fixed value: 0.5 (TST3 - Mixed Re...)
Response normalization	Normalization by fixed value: 2 (TST5 - Normaliz...)
Response transformation	Square root response transformation (TST6 - Transfor...)
<i>Analytical model</i>	
Model	Linear model
Dose transformation	Logarithmic: binary logarithm (base 2)

\* The response data processing steps are executed in the reported order.

## Plate layout

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B		[1] 1.920	[1] 1.900	[1] 1.840	[1] 1.940	[1] 2.060	[1] 1.840		[1] 2.200	[1] 1.950	[1] 2.000	
C		[2] 2.120	[2] 2.140	[2] 2.100	[2] 2.020	[2] 2.120	[2] 2.040		[1] 2.190	[1] 2.150	[1] 2.260	
D		[3] 2.340	[3] 2.280	[3] 2.280	[3] 2.260	[3] 2.260	[3] 2.300		[1] 2.120	[1] 2.080	[1] 2.040	
E									[1] 3.120	[1] 3.080	[1] 3.040	
F									[1] 4.240	[1] 4.160	[1] 4.080	
G									[1] 4.494	[1] 4.326	[1] 4.162	
H												

## Assay suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Overall test result	<b>Passed</b>			

<ul style="list-style-type: none"> <li><span style="color: blue;">■</span> <b>STD</b></li> </ul>		<b>Passed</b>
F-Test (hypothesis test): Model Scope: Standard only; Severity level: rejection		
Calculated F-value	131.39480	<b>Passed</b>
F <sub>critical</sub> (95%)	0.00406	
<ul style="list-style-type: none"> <li><span style="color: blue;">■</span> <b>STD</b></li> </ul>		<b>Passed</b>
Equivalence test (parameter estimate), Parameter: Slope (nonlinear models) Scope: Standard only; Severity level: warning		
Calculated value	-0.11672	<b>Passed</b>
Limits	-0.13831 to -0.09514	
Margins	-6.00000 to 0	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

**Interpolation results overview**

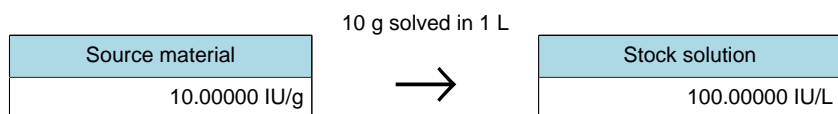
Assay elements	Calculated working concentration	Calculated absolute concentration	Recovery	Suitability test status
TST1 - Source Material	44.26895 [IU/L]	8.85379 [IU/g]	98.38%	Failed (rejected)
TST2 - Stock Solution with Predilution	18.16537 [IU/L]	72.66147 [IU/L]	96.88%	Failed (warning)
TST3 - Mixed Response Data Handling	37.04488 [IU/L]	37.04488 [IU/L]	N/A	Passed
TST4 - Adjustment	37.04488 [IU/L]	37.04488 [IU/L]	N/A	Passed
TST5 - Normalization	37.04488 [IU/L]	37.04488 [IU/L]	N/A	Passed
TST6 - Transformation	37.04488 [IU/L]	37.04488 [IU/L]	N/A	Passed

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

## STD: Setup

Property	Value
Concentration: Defined by source material	10.00000 IU/g
Preparation scheme	MultiDoseScheme-1
Number of replicates	6
Dilution scale	Stepwise dilution sequence
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## Working concentration



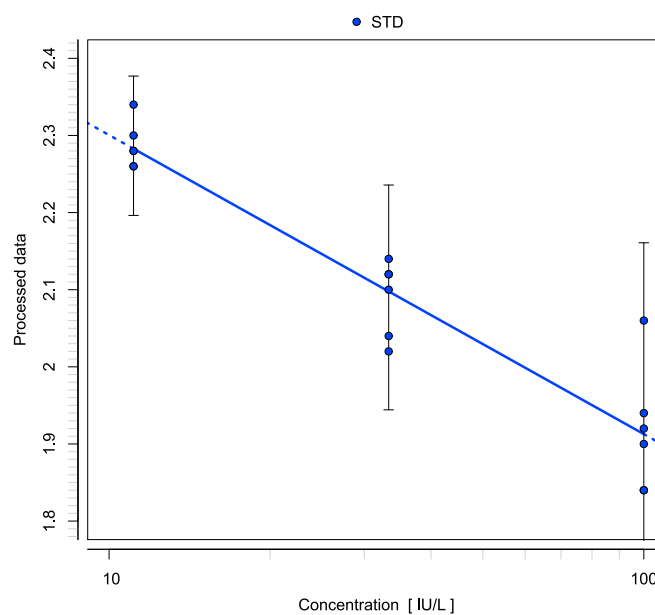
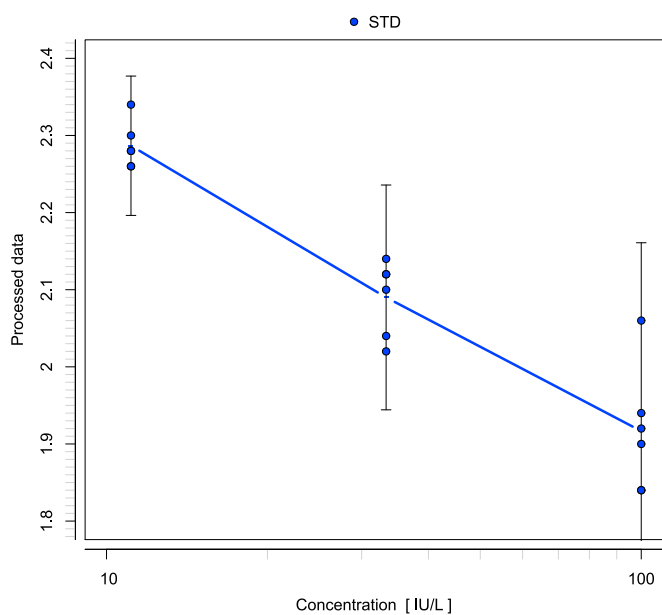
Dilution step	1	2	3
Working concentration [IU/L]	100.00000	33.33333	11.11111
Dilution factor*		3	3

\* Dilution factors are defined by the user.

## STD: Result

Data plot

Regression plot



**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

**Response data**

Dilution step	1	2	3
Working concentration [IU/L]	100.00000	33.33333	11.11111
Response	1.92000 1.90000 1.84000 1.94000 2.06000 1.84000	2.12000 2.14000 2.10000 2.02000 2.12000 2.04000	2.34000 2.28000 2.28000 2.26000 2.26000 2.30000
Mean response	1.91667	2.09000	2.28667
SD	0.08140	0.04858	0.03011
CV	4.25%	2.32%	1.32%

**Analysis of variance (ANOVA)**

Source of variation	d.f.	Sum of squares	Mean squares	F-ratio	Probability
Model	1	0.41070	0.41070	131.39480	3.983 E-09
Residual error	16	0.05001	0.00313		
Lack of fit	1	5.444 E-04	5.444 E-04	0.16509	0.69025
Pure error	15	0.04947	0.00330		
Total	17	0.46071	0.02710		

**Regression results**

Parameter	Estimate	Standard error	Confidence interval (95%)	Width of CI
Intercept	2.68826	0.05317	2.57554 to 2.80098	8.39%
Slope (nonlinear models)	-0.11672	0.01018	-0.13831 to -0.09514	36.99%

	Quality of regression
r <sup>2</sup>	0.89145
r <sup>2</sup> adjusted	0.88466

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

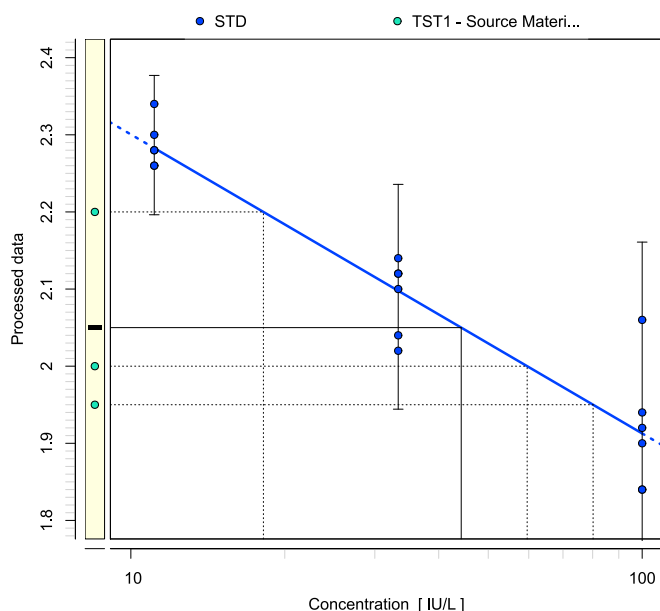
## TST1 - Source Material: Setup

The assay element "TST1 - Source Material" is included in the group "Group-Others". The aggregated evaluation for this group is displayed on page 19 of this report.

Property	Value
Concentration: Defined by source material	9.00000 IU/g
Preparation scheme	SingleDoseScheme-1
Number of replicates	3
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST1 - Source Material: Result

Interpolation plot



Response data

	Raw Data
Response(s)	2.20000 1.95000 2.00000
Mean response	2.05000
SD	0.13229
CV	6.45%

### Interpolation results

Property	Value
Mean response	2.05000
Calculated concentration of the working sample [IU/L]	44.26895
Calculated concentration of the sample stock solution [IU/L]	44.26895
Calculated concentration of the sample source material [IU/g]	8.85379
Defined concentration of the sample source material [IU/g]	9.00000
Recovery	98.38%

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	1	1	0	1
Overall test result	<b>Failed (rejected)</b>			

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<p><b>■ TST1 - Source Material</b>                      Test: Interpolation interval: Working concentration                      Scope: Test samples only; Severity level: warning</p>		Passed
Calculated value	18.16537 ; 80.16829	
Margins	15.00000 to 85.00000	Failed
<p><b>■ TST1 - Source Material</b>                      Test: Interpolation interval: Working concentration                      Scope: Test samples only; Severity level: information</p>		
Calculated value	18.16537 ; 80.16829	Failed
Margins	25.00000 to 75.00000	
<p><b>■ TST1 - Source Material</b>                      Test: Width of interpolation interval                      Scope: all assay elements; Severity level: rejection</p>		Failed
Calculated value	1.40060	
Margins	0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

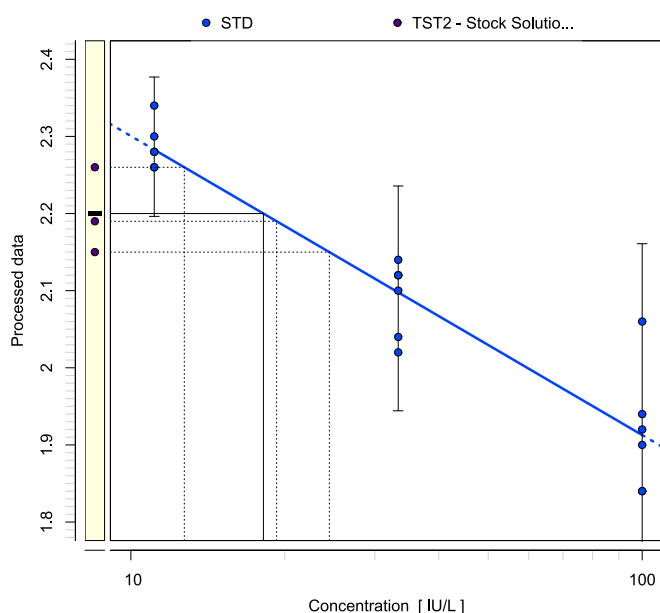
## TST2 - Stock Solution with Predilution: Setup

The assay element "TST2 - Stock Solution with Predilution" is included in the group "Group-Others". The aggregated evaluation for this group is displayed on page 19 of this report.

Property	Value
Concentration: Defined by stock solution	75.00000 IU/L
Preparation scheme	SingleDoseScheme-2
Number of replicates	3
Predilution factors	4
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST2 - Stock Solution with Predilution: Result

Interpolation plot



### Response data

	Raw Data
Response(s)	2.19000 2.15000 2.26000
Mean response	2.20000
SD	0.05568
CV	2.53%

### Interpolation results

Property	Value
Mean response	2.20000
Calculated concentration of the working sample [IU/L]	18.16537
Calculated concentration of the sample stock solution [IU/L]	72.66147
Defined concentration of the sample stock solution [IU/L]	75.00000
Recovery	96.88%

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	1	0	1	1
Overall test result	<b>Failed (warning)</b>			



**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<p>■ <b>TST2 - Stock Solution with Predilution</b>                      Test: Interpolation interval: Working concentration                      Scope: Test samples only; Severity level: warning</p>		Failed
Calculated value	12.72044 ; 24.44533	
Margins	15.00000 to 85.00000	Failed
<p>■ <b>TST2 - Stock Solution with Predilution</b>                      Test: Interpolation interval: Working concentration                      Scope: Test samples only; Severity level: information</p>		
Calculated value	12.72044 ; 24.44533	Failed
Margins	25.00000 to 75.00000	
<p>■ <b>TST2 - Stock Solution with Predilution</b>                      Test: Width of interpolation interval                      Scope: all assay elements; Severity level: rejection</p>		Passed
Calculated value	0.64545	
Margins	0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

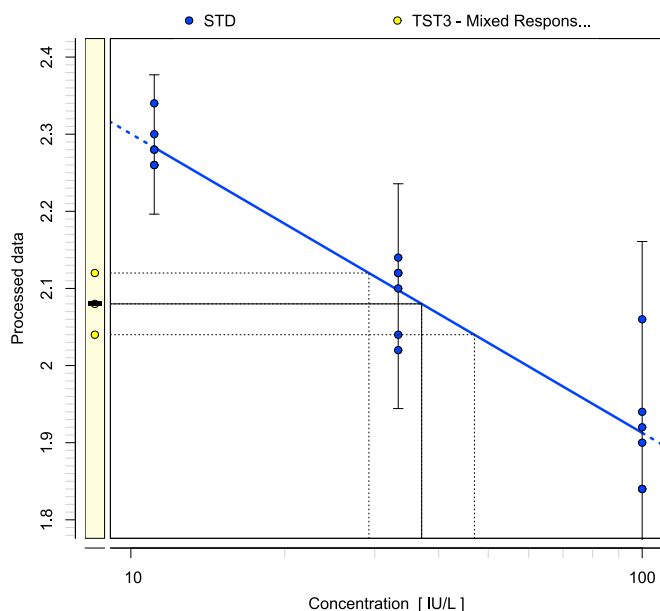
## TST3 - Mixed Response Data Handling: Setup

The assay element "TST3 - Mixed Response Data Handling" is included in the group "Group-RDH". The aggregated evaluation for this group is displayed on page 18 of this report.

Property	Value
Preparation scheme	SingleDoseScheme-1
Number of replicates	3
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST3 - Mixed Response Data Handling: Result

Interpolation plot



Response data

	Raw Data
Response(s)	2.12000 2.08000 2.04000
Mean response	2.08000
SD	0.04000
CV	1.92%

### Interpolation results

Property	Value
Mean response (processed data)	2.08000
Calculated concentration of the working sample [IU/L]	37.04488
Calculated concentration of the sample stock solution [IU/L]	37.04488

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	3	0	0	0
Overall test result	<b>Passed</b>			

<b>TST3 - Mixed Response Data Handling</b> Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: warning		<b>Passed</b>
Calculated value	29.21238 ; 46.97747	
Margins	15.00000 to 85.00000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<b>■ TST3 - Mixed Response Data Handling</b> Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: information		Passed
Calculated value	29.21238 ; 46.97747	
Margins	25.00000 to 75.00000	Passed
<b>■ TST3 - Mixed Response Data Handling</b> Test: Width of interpolation interval Scope: all assay elements; Severity level: rejection		
Calculated value	0.47956	
Margins	0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

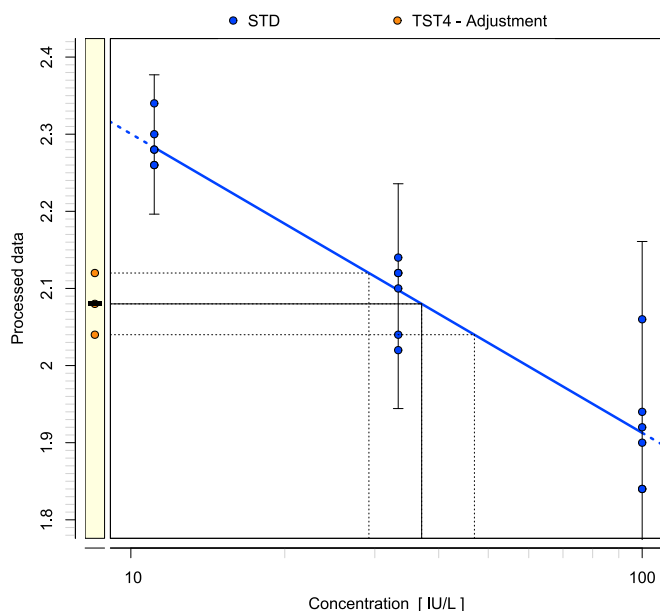
## TST4 - Adjustment: Setup

The assay element "TST4 - Adjustment" is included in the group "Group-RDH". The aggregated evaluation for this group is displayed on page 18 of this report.

Property	Value
Preparation scheme	SingleDoseScheme-1
Number of replicates	3
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST4 - Adjustment: Result

Interpolation plot



Response data

	Raw Data
Response(s)	3.12000 3.08000 3.04000
Mean response	3.08000
SD	0.04000
CV	1.30%

### Interpolation results

Property	Value
Mean response (processed data)	2.08000
Calculated concentration of the working sample [IU/L]	37.04488
Calculated concentration of the sample stock solution [IU/L]	37.04488

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	3	0	0	0
Overall test result	<b>Passed</b>			

TST4 - Adjustment		Passed
Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: warning		
Calculated value Margins	29.21238 ; 46.97747 15.00000 to 85.00000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<b>■ TST4 - Adjustment</b> Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: information		Passed
Calculated value Margins	29.21238 ; 46.97747 25.00000 to 75.00000	
<b>■ TST4 - Adjustment</b> Test: Width of interpolation interval Scope: all assay elements; Severity level: rejection		Passed
Calculated value Margins	0.47956 0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

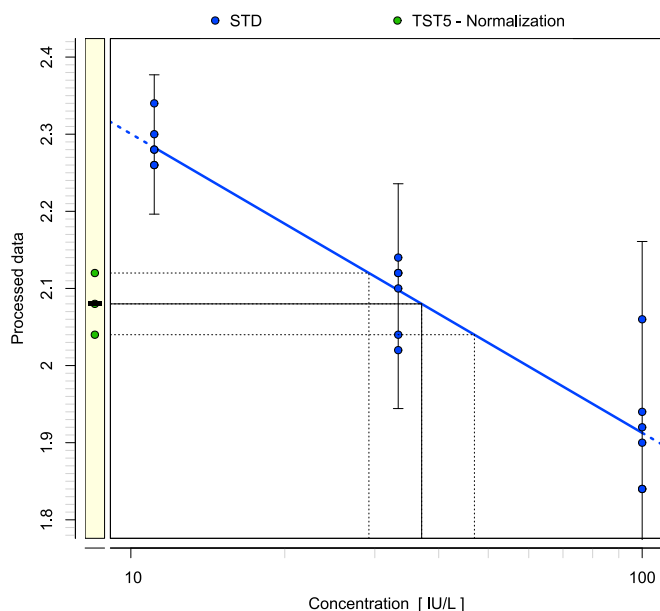
## TST5 - Normalization: Setup

The assay element "TST5 - Normalization" is included in the group "Group-RDH". The aggregated evaluation for this group is displayed on page 18 of this report.

Property	Value
Preparation scheme	SingleDoseScheme-1
Number of replicates	3
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST5 - Normalization: Result

Interpolation plot



Response data

	Raw Data
Response(s)	4.24000 4.16000 4.08000
Mean response	4.16000
SD	0.08000
CV	1.92%

### Interpolation results

Property	Value
Mean response (processed data)	2.08000
Calculated concentration of the working sample [IU/L]	37.04488
Calculated concentration of the sample stock solution [IU/L]	37.04488

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	3	0	0	0
Overall test result	<b>Passed</b>			

TST5 - Normalization		Passed
Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: warning		
Calculated value	29.21238 ; 46.97747	
Margins	15.00000 to 85.00000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<b>■ TST5 - Normalization</b> Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: information		Passed
Calculated value Margins	29.21238 ; 46.97747 25.00000 to 75.00000	
<b>■ TST5 - Normalization</b> Test: Width of interpolation interval Scope: all assay elements; Severity level: rejection		Passed
Calculated value Margins	0.47956 0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

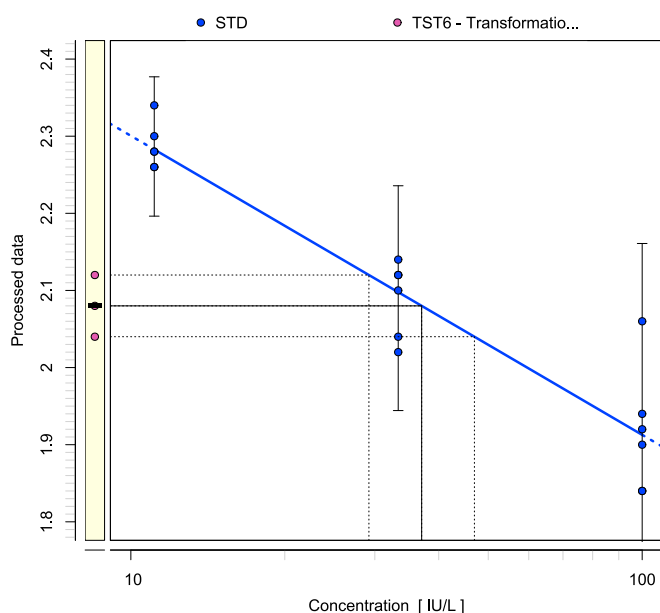
## TST6 - Transformation: Setup

The assay element "TST6 - Transformation" is included in the group "Group-RDH". The aggregated evaluation for this group is displayed on page 18 of this report.

Property	Value
Preparation scheme	SingleDoseScheme-1
Number of replicates	3
Data selection scheme	FullSequenceScheme
Outlier detection	No outlier detection
Response range	Not restricted

## TST6 - Transformation: Result

Interpolation plot



Response data

	Raw Data
Response(s)	4.49440 4.32640 4.16160
Mean response	4.32747
SD	0.16640
CV	3.85%

### Interpolation results

Property	Value
Mean response (processed data)	2.08000
Calculated concentration of the working sample [IU/L]	37.04488
Calculated concentration of the sample stock solution [IU/L]	37.04488

### Sample suitability tests

	Passed	Failed (rejected)	Failed (warning)	Info
Assay suitability tests	2	0	0	0
Sample suitability tests	3	0	0	0
Overall test result	<b>Passed</b>			

TST6 - Transformation		Passed
Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: warning		
Calculated value	29.21238 ; 46.97747	
Margins	15.00000 to 85.00000	



**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

<b>■ TST6 - Transformation</b> Test: Interpolation interval: Working concentration Scope: Test samples only; Severity level: information		Passed
Calculated value Margins	29.21238 ; 46.97747 25.00000 to 75.00000	
<b>■ TST6 - Transformation</b> Test: Width of interpolation interval Scope: all assay elements; Severity level: rejection		Passed
Calculated value Margins	0.47956 0 to 0.70000	

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

## Group-RDH: Setup

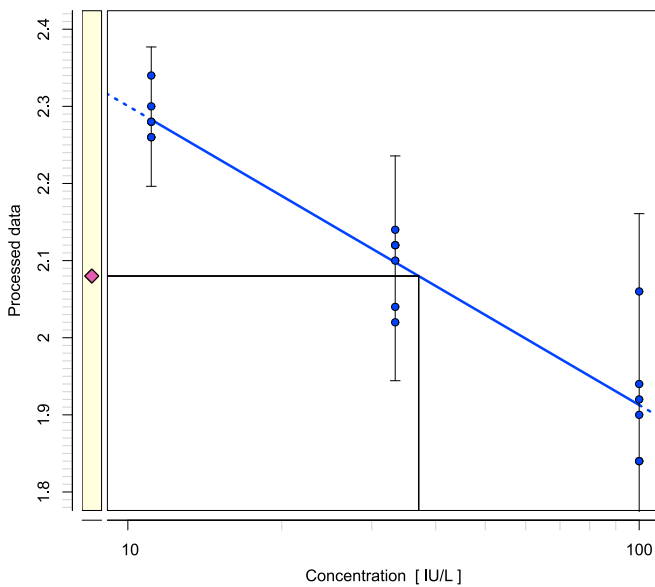
Assay elements	Summary
■ TST3 - Mixed Response Data Han...	Test sample, single-dose (3 replicates)
■ TST4 - Adjustment	Test sample, single-dose (3 replicates)
■ TST5 - Normalization	Test sample, single-dose (3 replicates)
■ TST6 - Transformation	Test sample, single-dose (3 replicates)

### Information

All samples have the same result, but start different response values and response data handling.

## Group-RDH: Result

Interpolation plot



Assay elements	Suitability test status
■ TST3 - Mixed Respons...	Passed
■ TST4 - Adjustment	Passed
■ TST5 - Normalization	Passed
■ TST6 - Transformatio...	Passed

**TECHNOLOGY PREVIEW - NOT FOR PRODUCTION USE**

## Group-Others: Setup

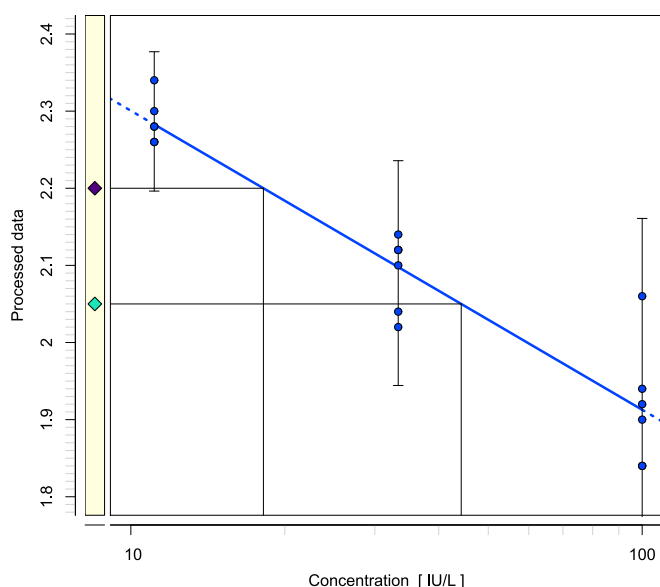
Assay elements	Summary
■ TST1 - Source Material	Test sample, single-dose (3 replicates), defined concentration: 45.0 IU/L
■ TST2 - Stock Solution with Pre...	Test sample, single-dose (3 replicates), defined concentration: 75.0 IU/L

### Information

A group with some samples in it.

## Group-Others: Result

Interpolation plot



Assay elements	Suitability test status
■ TST1 - Source Materi...	Failed (rejected)
■ TST2 - Stock Solutio...	Failed (warning)

### Interpolation results

Assay elements	Calculated working concentration	Calculated absolute concentration	Recovery
TST1 - Source Material	44.26895 [IU/L]	8.85379 [IU/g]	98.38%
TST2 - Stock Solution with Predilution	18.16537 [IU/L]	72.66147 [IU/L]	96.88%