BioAssay SCIENCES
A Division of Thomas A. Little Consulting

Specificity Interference report

Data Files:	Date:	Time:
Specificity interference.jmp	Wednesday, June 7, 2023	10:59:53

Specification	Value
Accuracy (%)	10
Tolerance (USL-LSL)	30

Analytical Method:

User Information
User Name: paule
User Domain: PADC-SURFACE
Logon Server: \\PADC-SURFACE
User Domain: PADC-SURFACE
Addin version: 2306071058
JMP Version: 16.2.0

- -
Analyst Signature/Date

- -
Reviewer Signature/Date

© 2021 BioAssay Sciences, Thomas A. Little Consulting

Data table

Theoretical Concentration/Dilution	Relative Potency % Unspiked	RP with Media	RP with Forced Deg	RP with interaction
125	128.2	131.6	133	160.25
125	129.6	133.4	135.1	162
125	127.8	133.8	131.3	159.75
125	117.1	.	.	146.375
125	126.3	.	.	157.875
125	125.3	.	.	156.625
100	97.9	103	100	97.9
100	99.5	106.1	104.4	99.5
100	99.4	103.1	101.9	99.4
100	99	.	.	99
100	101.7	.	.	101.7
100	101.1	.	.	101.1
75	76.7	81	79	57.525
75	79.9	85.2	83.1	59.925
75	80.1	83.9	82.6	60.075
75	73.4	.	.	55.05
75	81.2	.	.	60.9
75	81.4	.	.	61.05

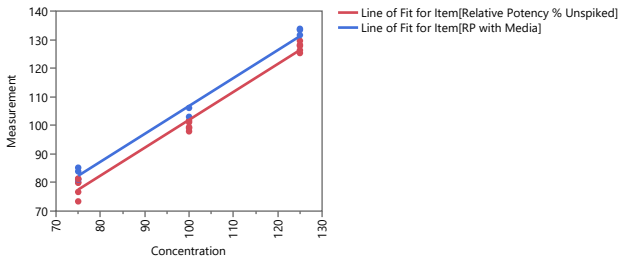
© 2021 BioAssay Sciences, Thomas A. Little Consulting

Specificity RP with Media

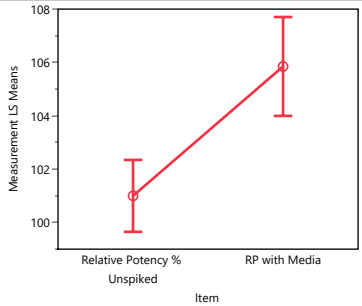
Effect Tests

Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	1.6036	0.2140	0.6482
Concentration	1	1	9305.3042	1241.510	<.0001*
Item*Concentration	1	1	1.2278	0.1638	0.6896

Interaction not significant



Least Squares Means Plot



LSMeans Differences Student's t

α= 0.050 t= 2.06866

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with Media	Relative Potency % Unspiked	4.852431	1.108537	2.559247	7.145614	0.0002*

Result

Level	- Level	Difference ()	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL)	Result
RP with Media	Relative Potency % Unspiked	4.852431	2.559247	7.145614	16.2	Fail

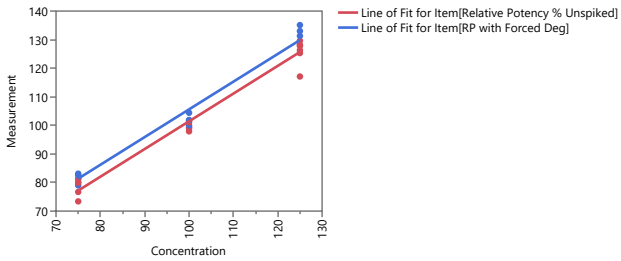
© 2021 BioAssay Sciences, Thomas A. Little Consulting

Specificity RP with Forced Deg

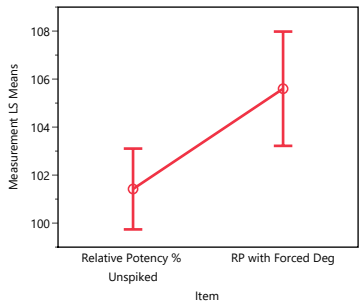
Effect Tests

Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	6.2152	0.5376	0.4708
Concentration	1	1	9702.2500	839.1810	<.0001*
Item*Concentration	1	1	21.4678	1.8568	0.1862

Interaction not significant



Least Squares Means Plot



LSMeans Differences Student's t

α= 0.050 t= 2.0639

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with Forced Deg	Relative Potency % Unspiked	4.177778	1.412700	1.262108	7.093447	0.0069*

Result

Level	- Level	Difference ()	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL)	Result
RP with Forced Deg	Relative Potency % Unspiked	4.177778	1.262108	7.093447	13.9	Fail

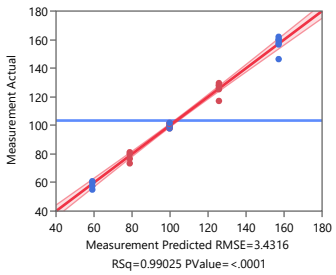
© 2021 BioAssay Sciences, Thomas A. Little Consulting

Specificity RP with interaction

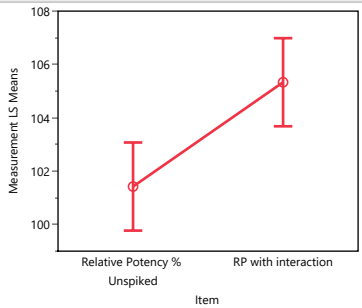
Effect Tests

Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	3481.393	169.6091	<.0001*
Concentration	1	1	31533.875	1536.291	<.0001*
Item*Concentration	1	1	3920.648	191.0091	<.0001*

Significant interaction



Least Squares Means Plot

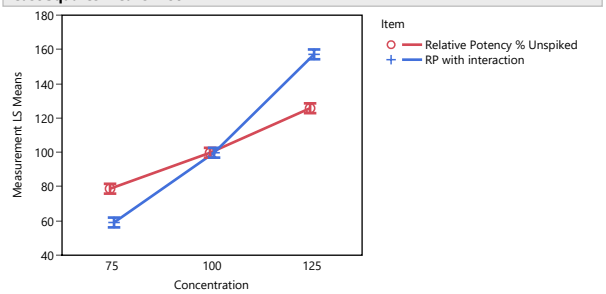


LSMeans Differences Student's t

α= 0.050 t= 2.04227

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with interaction	Relative Potency % Unspiked	3.911111	1.143862	1.575033	6.247189	0.0018*

Least Squares Means Plot



Result

Level	- Level	Difference ()	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL)	Result
RP with interaction,125	Relative Potency % Unspiked,125	31.42917	25.4031	37.4553	104.8	Fail
Relative Potency % Unspiked,75	RP with interaction,75	19.69583	13.6697	25.7219	65.7	Fail
RP with interaction,100	Relative Potency % Unspiked,100	0.00000	-6.0261	6.0261	0.0	Pass

© 2021 BioAssay Sciences, Thomas A. Little Consulting

Data table with outlier test result

Concentration	Item	Measurement	Externally Studentized Residuals Measurement	Outlier	Include/ Exclude	Externally Studentized Residuals Measurement 2	Outlier 2	Include/ Exclude 2	Externally Studentized Residuals Measurement 3	Outlier 3	Include/ Exclude 3
125	Relative Potency % Unspiked	128.2	1.122	Ok	Included	1.052	Ok	Included	0.783	Ok	Included
125	RP with Media	131.6	0.010	Ok	Included	.		Included	.		Included
125	RP with Forced Deg	133	.		Included	0.551	Ok	Included	.		Included
125	RP with interaction	160.25	.		Included	.		Included	1.423	Ok	Included
125	Relative Potency % Unspiked	129.6	1.645	Ok	Included	1.537	Ok	Included	1.125	Ok	Included
125	RP with Media	133.4	0.664	Ok	Included	.		Included	.		Included
125	RP with Forced Deg	135.1	.		Included	1.306	Ok	Included	.		Included
125	RP with interaction	162	.		Included	.		Included	1.888	Ok	Included
125	Relative Potency % Unspiked	127.8	0.980	Ok	Included	0.920	Ok	Included	0.687	Ok	Included
125	RP with Media	133.8	0.813	Ok	Included	.		Included	.		Included
125	RP with Forced Deg	131.3	.		Included	-0.028	Ok	Included	.		Included
125	RP with interaction	159.75	.		Included	.		Included	1.295	Ok	Included
125	Relative Potency % Unspiked	117.1	-3.066	Outlier	Excluded	-2.816	Ok	Included	-1.930	Ok	Included
125	RP with interaction	146.375	.		Included	.		Included	-1.985	Ok	Included
125	Relative Potency % Unspiked	126.3	0.467	Ok	Included	0.439	Ok	Included	0.331	Ok	Included
125	RP with interaction	157.875	.		Included	.		Included	0.831	Ok	Included
125	Relative Potency % Unspiked	125.3	0.136	Ok	Included	0.127	Ok	Included	0.096	Ok	Included
125	RP with interaction	156.625	.		Included	.		Included	0.532	Ok	Included
100	Relative Potency % Unspiked	97.9	-1.140	Ok	Included	-1.069	Ok	Included	-0.795	Ok	Included
100	RP with Media	103	-1.273	Ok	Included	.		Included	.		Included
100	RP with Forced Deg	100	.		Included	-1.834	Ok	Included	.		Included
100	RP with interaction	97.9	.		Included	.		Included	-1.741	Ok	Included
100	Relative Potency % Unspiked	99.5	-0.610	Ok	Included	-0.573	Ok	Included	-0.431	Ok	Included
100	RP with Media	106.1	-0.224	Ok	Included	.		Included	.		Included
100	RP with Forced Deg	104.4	.		Included	-0.367	Ok	Included	.		Included
100	RP with interaction	99.5	.		Included	.		Included	-1.341	Ok	Included
100	Relative Potency % Unspiked	99.4	-0.642	Ok	Included	-0.603	Ok	Included	-0.454	Ok	Included
100	RP with Media	103.1	-1.237	Ok	Included	.		Included	.		Included
100	RP with Forced Deg	101.9	.		Included	-1.163	Ok	Included	.		Included
100	RP with interaction	99.4	.		Included	.		Included	-1.366	Ok	Included
100	Relative Potency % Unspiked	99	-0.772	Ok	Included	-0.725	Ok	Included	-0.544	Ok	Included
100	RP with interaction	99	.		Included	.		Included	-1.464	Ok	Included
100	Relative Potency % Unspiked	101.7	0.087	Ok	Included	0.082	Ok	Included	0.062	Ok	Included
100	RP with interaction	101.7	.		Included	.		Included	-0.821	Ok	Included
100	Relative Potency % Unspiked	101.1	-0.101	Ok	Included	-0.095	Ok	Included	-0.072	Ok	Included
100	RP with interaction	101.1	.		Included	.		Included	-0.960	Ok	Included
75	Relative Potency % Unspiked	76.7	-0.415	Ok	Included	-0.391	Ok	Included	-0.294	Ok	Included
75	RP with Media	81	-0.363	Ok	Included	.		Included	.		Included
75	RP with Forced Deg	79	.		Included	-0.277	Ok	Included	.		Included
75	RP with interaction	57.525	.		Included	.		Included	0.286	Ok	Included
75	Relative Potency % Unspiked	79.9	0.647	Ok	Included	0.608	Ok	Included	0.457	Ok	Included
75	RP with Media	85.2	1.185	Ok	Included	.		Included	.		Included
75	RP with Forced Deg	83.1	.		Included	1.144	Ok	Included	.		Included
75	RP with interaction	59.925	.		Included	.		Included	0.858	Ok	Included
75	Relative Potency % Unspiked	80.1	0.715	Ok	Included	0.671	Ok	Included	0.504	Ok	Included
75	RP with Media	83.9	0.689	Ok	Included	.		Included	.		Included
75	RP with Forced Deg	82.6	.		Included	0.962	Ok	Included	.		Included
75	RP with interaction	60.075	.		Included	.		Included	0.894	Ok	Included
75	Relative Potency % Unspiked	73.4	-1.584	Ok	Included	-1.481	Ok	Included	-1.087	Ok	Included
75	RP with interaction	55.05	.		Included	.		Included	-0.294	Ok	Included
75	Relative Potency % Unspiked	81.2	1.098	Ok	Included	1.030	Ok	Included	0.767	Ok	Included
75	RP with interaction	60.9	.		Included	.		Included	1.097	Ok	Included
75	Relative Potency % Unspiked	81.4	1.170	Ok	Included	1.096	Ok	Included	0.815	Ok	Included
75	RP with interaction	61.05	.		Included	.		Included	1.134	Ok	Included

K Sigma: 3

Report generated on 2023-06-07 10:59:53, Addin Version: 2306071058

© 2021 BioAssay Sciences, Thomas A. Little Consulting