Astellas KT430 Infectivity Assay Report

Test Article Report

Assay Details

User Information
User Name: John
Computer Name: DESKTOP-VCKNAII
Logon Server: \\DESKTOP-VCKNAII
User Domain: DESKTOP-VCKNAII
Astellas KT430 PLA Script Version 0.1
JMP Version 17.2.0

Analyst Signature/Date

Approver Signature/Date

Astellas KT430 Infectivity Files

First Data File	Second Data File
07Feb24-Infection02-KL-01	07Feb24-Infection02-KL-02

AC & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
AC	13	2	3.726e+10	19481	1018233764.9	2.7327798307	1.24e+1	1.09342169	10.571242851	0.325	Ok	-0.368	Ok
AC	14	2	2.397e+10	21239.5	127279220.61	0.5309938282	6.18e+0	0.79098848	10.379668034	2.233	Ok	2.571	Outlier
AC	15	2	9.765e+9	21216	21213203.436	0.2172371064	3.09e+0	0.48995848	9.9896722476	0.851	Ok	-0.371	Ok
AC	16	2	4.938e+9	20431	313955410.85	6.3579467567	1.54e+0	0.18752072	9.6935510856	0.722	Ok	-0.551	Ok
AC	17	2	3.888e+10	21182	1781909088.6	4.5830995077	1.24e+1	1.09342169	10.589726256	4.525	Ok	0.145	Ok
AC	18	2	2.110e+10	21900.5	1294005409.6	6.131274151	6.18e+0	0.79098848	10.324385356	0.027	Ok	0.800	Ok
AC	19	2	9.675e+9	22165	148492424.05	1.5348054165	3.09e+0	0.48995848	9.9856509737	0.577	Ok	-0.476	Ok
AC	20	2	6.081e+9	22055.5	453962553.52	7.4652615281	1.54e+0	0.18752072	9.7839750034	134.00	Ok	2.207	Ok
AC	21	2	3.666e+10	21155.5	1187939392.4	3.2404238745	1.24e+1	1.09342169	10.564192461	1.231	Ok	-0.567	Ok
AC	22	2	1.845e+10	20427.5	636396103.07	3.4493013716	6.18e+0	0.79098848	10.26599637	2.018	Ok	-0.716	Ok
AC	23	2	8.790e+9	21406	127279220.61	1.4480002345	3.09e+0	0.48995848	9.9439888751	14.614	Ok	-1.649	Ok
AC	24	2	4.950e+9	22329.5	84852813.742	1.7141982574	1.54e+0	0.18752072	9.6946051989	0.692	Ok	-0.521	Ok
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-1.565	Ok
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	1.811	Ok
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.346	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.037	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.029	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	1.373	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.054	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.280	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.053	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-0.828	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.245	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

AC Test Sample & Reference Standard Summary Statistics

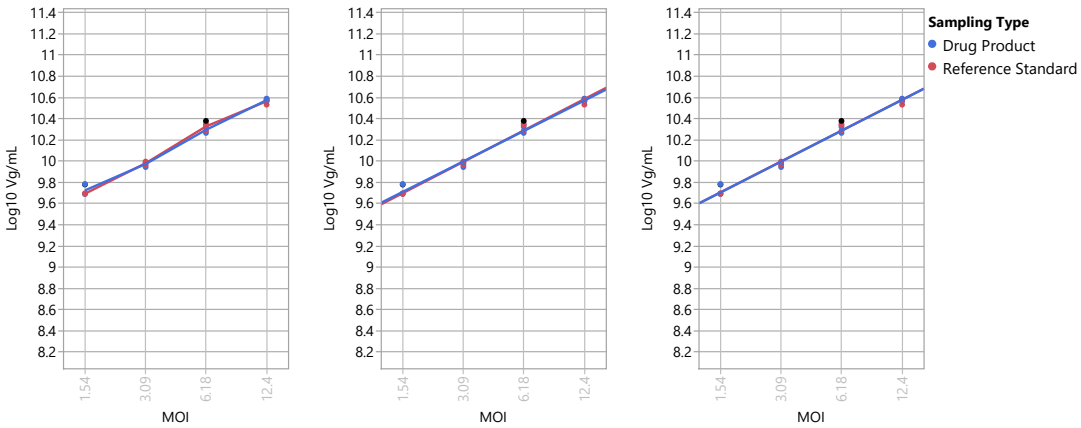
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std	1.24e+1	3	3.7e+10	2.37e+9
AC	1.54e+0	3	5.32e+9	6.56e+8
AC	3.09e+0	3	9.41e+9	5.39e+8
AC	6.18e+0	2	2e+10	1.88e+9
AC	1.24e+1	3	3.8e+10	1.15e+9

AC Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.971	0.470	0.990	0.035	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.030	6.914	0.986	0.034	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.885	5.649	0.983	0.036	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.982	0.143	0.988	0.037	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.018	3.621	0.991	0.032	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.967	2.868	0.984	0.041	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.956	1.544	0.987	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.942	1.751	0.993	0.027	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.899	3.103	0.991	0.033	Parallel and Linear	

AC Graphs

Means by Concentration | **Unconstrained Parallel Line Analysis** | **Constrained Parallel Line Analysis**



AC Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.012	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	0.971	Passed Validity Criteria	
Linearity Ratio	.	25	0.470	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

AC Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	RI Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
4.50	4.52	99.7	1	2	102.7	108.1	97.6	150	50	10.5	10.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
99.7	99.7	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
1.9	0.3	1.0

S1: KT430 50% & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-2.451	Outlier
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	2.926	Outlier
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.502	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.054	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.043	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	2.109	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.077	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.406	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.076	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-1.223	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.355	Ok
S1: KT430 50%	25	2	4.881e+10	20912.5	9206530291	18.861975601	1.24e+1	1.09342169	10.688508808	4.233	Ok	-0.995	Ok
S1: KT430 50%	26	2	2.787e+10	21255.5	1315218613	4.71911953	6.18e+0	0.79098848	10.445136969	3.024	Ok	0.950	Ok
S1: KT430 50%	27	2	1.360e+10	21931	742462120.25	5.4572739452	3.09e+0	0.48995848	10.133698546	2.230	Ok	0.182	Ok
S1: KT430 50%	28	2	7.050e+9	20269.5	381837661.84	5.4161370474	1.54e+0	0.18752072	9.848189117	0.463	Ok	0.486	Ok
S1: KT430 50%	29	2	5.154e+10	21200	84852813.742	0.1646348734	1.24e+1	1.09342169	10.712144414	0.302	Ok	-0.022	Ok
S1: KT430 50%	30	2	2.672e+10	21377	1124299782.1	4.2084962833	6.18e+0	0.79098848	10.426755179	0.171	Ok	0.248	Ok
S1: KT430 50%	31	2	1.340e+10	21627.5	700035713.37	5.226097151	3.09e+0	0.48995848	10.126942718	0.026	Ok	-0.068	Ok
S1: KT430 50%	32	2	6.258e+9	20572.5	25455844.123	0.4067728367	1.54e+0	0.18752072	9.7964355588	7.495	Ok	-1.715	Ok
S1: KT430 50%	33	2	5.264e+10	19628	1887975105.8	3.5869195512	1.24e+1	1.09342169	10.721274627	1.274	Ok	0.344	Ok
S1: KT430 50%	34	2	2.601e+10	20392	636396103.07	2.4467362671	6.18e+0	0.79098848	10.415140352	1.570	Ok	-0.182	Ok
S1: KT430 50%	35	2	1.320e+10	21559.5	254558441.23	1.9284730396	3.09e+0	0.48995848	10.120573931	2.020	Ok	-0.304	Ok
S1: KT430 50%	36	2	7.215e+9	22117	148492424.05	2.0581070554	1.54e+0	0.18752072	9.8582363354	1.002	Ok	0.905	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S1: KT430 50% Test Sample & Reference Standard Summary Statistics

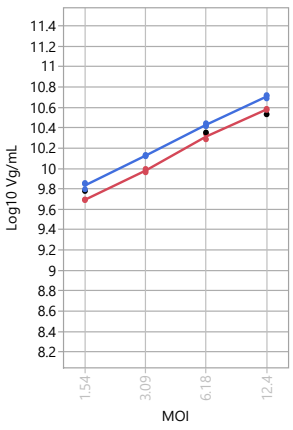
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	2	2.1e+10	1.78e+9
Ref.Std	1.24e+1	2	3.8e+10	6.89e+8
S1: KT430 50%	1.54e+0	3	6.84e+9	5.12e+8
S1: KT430 50%	3.09e+0	3	1.3e+10	2.03e+8
S1: KT430 50%	6.18e+0	3	2.7e+10	9.39e+8
S1: KT430 50%	1.24e+1	3	5.1e+10	1.97e+9

S1: KT430 50% Model Selection

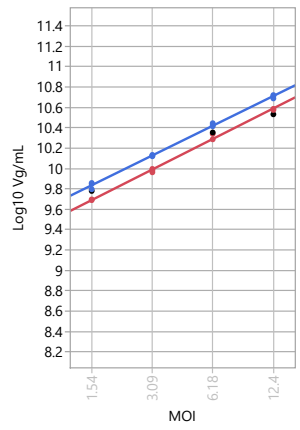
Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.973	0.871	0.997	0.021	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.959	3.577	0.995	0.021	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.959	2.295	0.994	0.022	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.991	0.414	0.996	0.022	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.983	2.714	0.994	0.023	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.967	1.246	0.997	0.019	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.966	1.706	0.996	0.022	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.941	0.041	0.997	0.021	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.935	1.094	0.997	0.019	Parallel and Linear	

S1: KT430 50% Graphs

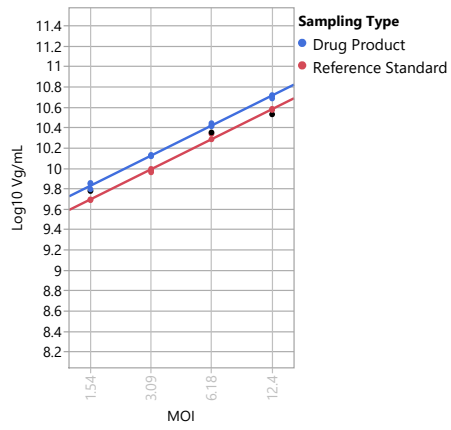
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S1: KT430 50% Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.211	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	0.973	Passed Validity Criteria	
Linearity Ratio	.	25	0.871	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

S1: KT430 50% Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
5.15	3.75	137.1	1	2	140.1	144.3	136.1	150	50	8.2	8.2	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
136.9	137.1	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.6	0.3	1.0

S2: KT430 75% & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-1.801	Ok
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	2.098	Ok
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.391	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.042	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.033	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	1.573	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.060	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.317	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.059	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-0.940	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.277	Ok
S2: KT430 75%	37	2	4.419e+10	10652.5	2757716446.6	6.2405893791	1.24e+1	1.09342169	10.645324002	1.873	Ok	-1.202	Ok
S2: KT430 75%	38	2	2.538e+10	20641	84852813.742	0.3343294474	6.18e+0	0.79098848	10.404491618	3.253	Ok	-0.034	Ok
S2: KT430 75%	39	2	1.420e+10	21687	615182899.63	4.3307490294	3.09e+0	0.48995848	10.152441238	0.562	Ok	0.646	Ok
S2: KT430 75%	40	2	7.200e+9	21071.5	424264068.71	5.8925565099	1.54e+0	0.18752072	9.8573324964	0.047	Ok	0.115	Ok
S2: KT430 75%	41	2	5.136e+10	19993	1697056274.8	3.3042372953	1.24e+1	1.09342169	10.710625015	2.422	Ok	0.905	Ok
S2: KT430 75%	42	2	2.619e+10	20981	296984848.1	1.1339627648	6.18e+0	0.79098848	10.418135498	0.202	Ok	0.361	Ok
S2: KT430 75%	43	2	1.146e+10	21169	424264068.71	3.7021297444	3.09e+0	0.48995848	10.059184618	13.031	Ok	-2.345	Ok
S2: KT430 75%	44	2	6.447e+9	21696.5	123036579.93	1.9084315174	1.54e+0	0.18752072	9.8093576702	2.321	Ok	-1.465	Ok
S2: KT430 75%	45	2	4.743e+10	20081	1824335495.5	3.8463746478	1.24e+1	1.09342169	10.676053125	0.068	Ok	-0.196	Ok
S2: KT430 75%	46	2	2.664e+10	21580.5	1951614716.1	7.3258810663	6.18e+0	0.79098848	10.42553422	1.493	Ok	0.578	Ok
S2: KT430 75%	47	2	1.452e+10	21135	1103086578.7	7.5970150045	3.09e+0	0.48995848	10.161966616	0.869	Ok	0.936	Ok
S2: KT430 75%	48	2	7.860e+9	22283	593969696.2	7.5568663638	1.54e+0	0.18752072	9.895422546	1.947	Ok	1.373	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S2: KT430 75% Test Sample & Reference Standard Summary Statistics

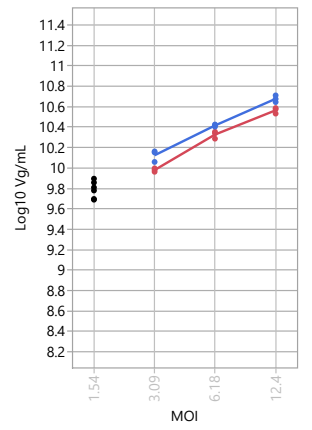
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std	1.24e+1	3	3.7e+10	2.37e+9
S2: KT430 75%	1.54e+0	3	7.17e+9	7.07e+8
S2: KT430 75%	3.09e+0	3	1.3e+10	1.68e+9
S2: KT430 75%	6.18e+0	3	2.6e+10	6.39e+8
S2: KT430 75%	1.24e+1	3	4.8e+10	3.59e+9

S2: KT430 75% Model Selection

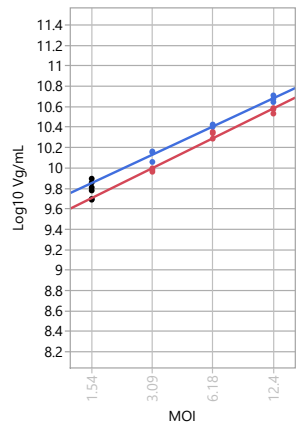
Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.946	6.259	0.981	0.038	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.934	1.974	0.990	0.036	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.880	3.416	0.985	0.035	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.961	5.796	0.981	0.039	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.951	2.483	0.987	0.037	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.944	2.598	0.986	0.037	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.935	3.607	0.989	0.036	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.866	1.662	0.991	0.033	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.864	0.531	0.991	0.033	Parallel and Linear	

S2: KT430 75% Graphs

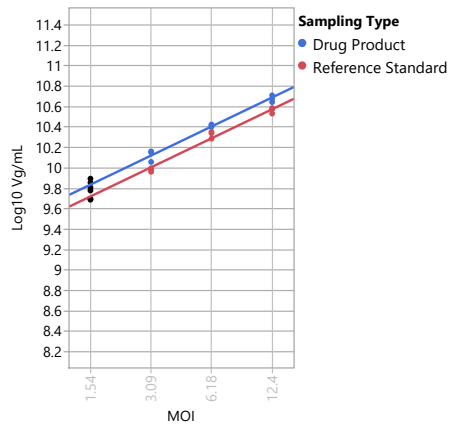
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S2: KT430 75% Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.029	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	0.946	Passed Validity Criteria	
Linearity Ratio	.	25	6.259	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

S2: KT430 75% Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
7.12	5.37	132.6	1	2	135.6	144.7	127.2	150	50	17.5	17.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
132.6	132.6	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.6	0.3	1.0

S3: KT430 125% & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-1.228	Ok
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	1.411	Ok
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.278	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.030	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.024	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	1.084	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.043	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.225	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.042	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-0.661	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.197	Ok
S3: KT430 125%	49	2	4.080e+10	19400.5	1697056274.8	4.159451654	1.24e+1	1.09342169	10.610660163	17.678	Ok	0.612	Ok
S3: KT430 125%	50	2	2.271e+10	19101	212132034.36	0.9340908602	6.18e+0	0.79098848	10.356217134	21.355	Ok	1.204	Ok
S3: KT430 125%	51	2	1.125e+10	19787.5	466690475.58	4.148359783	3.09e+0	0.48995848	10.051152522	0.024	Ok	0.700	Ok
S3: KT430 125%	52	2	6.255e+9	19002	21213203.436	0.339139943	1.54e+0	0.18752072	9.796227314	1.948	Ok	1.467	Ok
S3: KT430 125%	53	2	3.666e+10	19057.5	678822509.94	1.8516707854	1.24e+1	1.09342169	10.564192461	0.598	Ok	-0.431	Ok
S3: KT430 125%	54	2	1.803e+10	20421.5	212132034.36	1.1765503847	6.18e+0	0.79098848	10.255995727	0.804	Ok	-0.922	Ok
S3: KT430 125%	55	2	9.510e+9	20693.5	127279220.61	1.3383724565	3.09e+0	0.48995848	9.9781805169	2.030	Ok	-0.824	Ok
S3: KT430 125%	56	2	5.307e+9	19006.5	4242640.6871	0.0799442376	1.54e+0	0.18752072	9.7248490876	0.046	Ok	-0.203	Ok
S3: KT430 125%	57	2	3.632e+10	20830.5	7360981592.2	20.26981025	1.24e+1	1.09342169	10.560086048	0.825	Ok	-0.524	Ok
S3: KT430 125%	58	2	1.833e+10	20399.5	1060660171.8	5.7864712045	6.18e+0	0.79098848	10.263162465	0.616	Ok	-0.766	Ok
S3: KT430 125%	59	2	1.311e+10	21174	466690475.58	3.5598053057	3.09e+0	0.48995848	10.117602692	2.219	Ok	2.350	Ok
S3: KT430 125%	60	2	4.227e+9	19721.5	301227488.79	7.1262713221	1.54e+0	0.18752072	9.6260322478	2.318	Ok	-2.915	Outlier

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S3: KT430 125% Test Sample & Reference Standard Summary Statistics

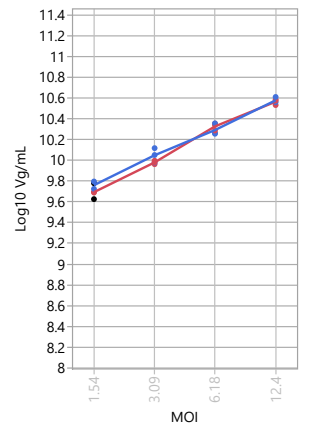
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std	1.24e+1	3	3.7e+10	2.37e+9
S3: KT430 125%	1.54e+0	2	5.78e+9	6.7e+8
S3: KT430 125%	3.09e+0	3	1.1e+10	1.8e+9
S3: KT430 125%	6.18e+0	3	2e+10	2.62e+9
S3: KT430 125%	1.24e+1	3	3.8e+10	2.5e+9

S3: KT430 125% Model Selection

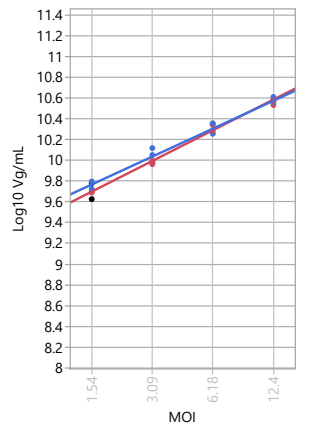
Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.910	1.774	0.984	0.042	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.906	3.070	0.970	0.046	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.827	0.741	0.972	0.045	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.920	2.319	0.978	0.045	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.903	10.868	0.972	0.048	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.896	2.123	0.982	0.043	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.893	3.978	0.980	0.045	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.842	1.161	0.983	0.042	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.829	6.566	0.981	0.042	Parallel and Linear	

S3: KT430 125% Graphs

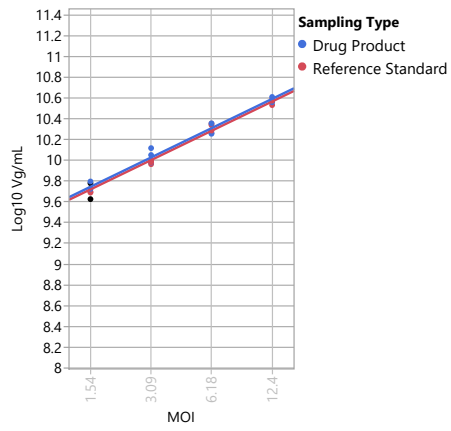
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S3: KT430 125% Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.015	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	0.910	Passed Validity Criteria	
Linearity Ratio	.	25	1.774	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

S3: KT430 125% Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
4.96	4.66	106.4	1	2	109.4	116.9	102.4	150	50	14.6	14.6	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
106.4	106.4	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.1	0.3	1.0

S4: KT430 135% & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-1.537	Ok
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	1.781	Ok
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.339	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.037	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.029	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	1.349	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.053	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.275	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.052	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-0.813	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.241	Ok
S4: KT430 135%	61	2	5.202e+10	20628.5	1612203461.1	3.0991992716	1.24e+1	1.09342169	10.716170348	1.241	Ok	1.564	Ok
S4: KT430 135%	62	2	2.478e+10	10128	1103086578.7	4.4515196879	6.18e+0	0.79098848	10.394101302	8.753	Ok	0.327	Ok
S4: KT430 135%	63	2	1.286e+10	20357	106066017.18	0.8250954273	3.09e+0	0.48995848	10.109072081	2.989	Ok	0.254	Ok
S4: KT430 135%	64	2	8.070e+9	20106.5	42426406.871	0.5257299488	1.54e+0	0.18752072	9.9068735347	3.691	Ok	3.138	Outlier
S4: KT430 135%	65	2	4.764e+10	20332	6873077913.1	14.427115687	1.24e+1	1.09342169	10.677971753	0.320	Ok	0.374	Ok
S4: KT430 135%	66	2	2.187e+10	21315.5	890954544.3	4.0738662291	6.18e+0	0.79098848	10.339848783	0.956	Ok	-1.089	Ok
S4: KT430 135%	67	2	1.179e+10	21163	42426406.871	0.3598507792	3.09e+0	0.48995848	10.071513805	0.166	Ok	-0.699	Ok
S4: KT430 135%	68	2	6.690e+9	20523	212132034.36	3.1708824268	1.54e+0	0.18752072	9.8254261178	0.252	Ok	0.276	Ok
S4: KT430 135%	69	2	3.603e+10	20820	15825049763	43.921870005	1.24e+1	1.09342169	10.556664262	4.456	Outlier	.	
S4: KT430 135%	70	2	2.230e+10	20775	445477272.15	1.9972081244	6.18e+0	0.79098848	10.348402228	0.496	Ok	-0.853	Ok
S4: KT430 135%	71	2	1.113e+10	21316.5	42426406.871	0.3811896395	3.09e+0	0.48995848	10.046495164	1.584	Ok	-1.390	Ok
S4: KT430 135%	72	2	6.036e+9	21069.5	161220346.11	2.6709798892	1.54e+0	0.18752072	9.7807492311	1.377	Ok	-0.969	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S4: KT430 135% Test Sample & Reference Standard Summary Statistics

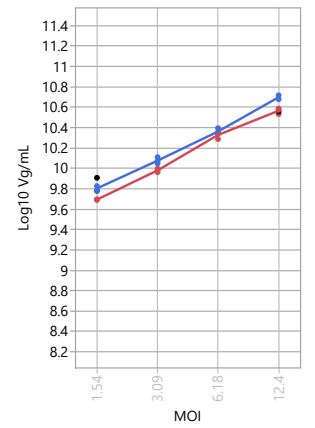
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std	1.24e+1	3	3.7e+10	2.37e+9
S4: KT430 135%	1.54e+0	2	6.36e+9	4.62e+8
S4: KT430 135%	3.09e+0	3	1.2e+10	8.7e+8
S4: KT430 135%	6.18e+0	3	2.3e+10	1.57e+9
S4: KT430 135%	1.24e+1	2	5e+10	3.1e+9

S4: KT430 135% Model Selection

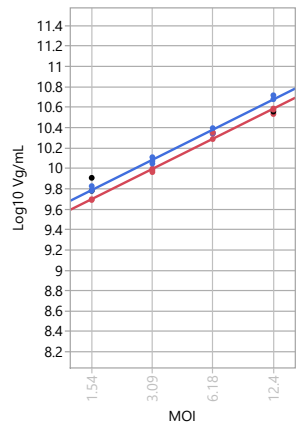
Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	1.002	0.123	0.991	0.033	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.056	2.796	0.984	0.036	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.875	3.118	0.989	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.013	0.927	0.987	0.035	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.967	6.660	0.992	0.029	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.956	6.784	0.985	0.035	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.045	1.919	0.990	0.033	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.945	2.732	0.990	0.032	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.927	4.428	0.992	0.030	Parallel and Linear	

S4: KT430 135% Graphs

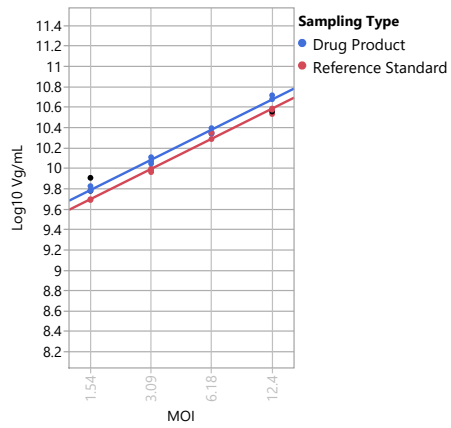
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S4: KT430 135% Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.002	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	1.002	Passed Validity Criteria	
Linearity Ratio	.	25	0.123	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

S4: KT430 135% Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
5.08	4.11	123.4	1	2	126.4	132.8	120.3	150	50	12.6	12.6	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
123.4	123.4	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.3	0.3	1.0

S5: KT430 150% & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Within Group	Studentized Residuals	Between Group
Ref.Std	1	2	3.408e+10	18464.5	763675323.68	2.2408313488	1.24e+1	1.09342169	10.532499586	5.820	Ok	-1.596	Ok
Ref.Std	2	2	2.260e+10	18952	869741340.86	3.8475617822	6.18e+0	0.79098848	10.354204511	1.111	Ok	1.849	Ok
Ref.Std	3	2	9.570e+9	19429.5	42426406.871	0.4433271355	3.09e+0	0.48995848	9.9809119378	0.043	Ok	-0.352	Ok
Ref.Std	4	2	4.974e+9	19953	178190908.86	3.5824469011	1.54e+0	0.18752072	9.6967057809	0.000	Ok	-0.038	Ok
Ref.Std	5	2	3.858e+10	17354.5	.	.	1.24e+1	1.09342169	10.586362223	1.098	Ok	0.030	Ok
Ref.Std	6	2	2.188e+10	10664	63639610.307	0.2907909998	6.18e+0	0.79098848	10.340146551	0.393	Ok	1.400	Ok
Ref.Std	7	2	9.915e+9	21061	445477272.15	4.4929629062	3.09e+0	0.48995848	9.9962927185	1.958	Ok	0.054	Ok
Ref.Std	8	2	6.021e+9	9853.5	156977705.42	2.6071699954	1.54e+0	0.18752072	9.7796686272	.		.	
Ref.Std	9	2	3.760e+10	19097.5	487903679.02	1.2974436352	1.24e+1	1.09342169	10.575245593	0.401	Ok	-0.285	Ok
Ref.Std	10	2	1.936e+10	20523.5	403050865.28	2.0813367688	6.18e+0	0.79098848	10.287017501	5.657	Ok	-0.054	Ok
Ref.Std	11	2	9.180e+9	10349	339411254.97	3.6972903591	3.09e+0	0.48995848	9.9628426812	2.306	Ok	-0.843	Ok
Ref.Std	12	2	4.893e+9	21197.5	462447834.9	9.4512126486	1.54e+0	0.18752072	9.6895752158	0.000	Ok	-0.250	Ok
S5: KT430 150%	73	2	4.390e+10	20981.5	233345237.79	0.5314775943	1.24e+1	1.09342169	10.642513981	0.055	Ok	0.105	Ok
S5: KT430 150%	74	2	2.120e+10	20228	190918830.92	0.9007729697	6.18e+0	0.79098848	10.326233421	10.119	Ok	-0.719	Ok
S5: KT430 150%	75	2	1.092e+10	21267	0	0	3.09e+0	0.48995848	10.038222638	0.042	Ok	-0.830	Ok
S5: KT430 150%	76	2	6.675e+9	20652.5	148492424.05	2.2246056037	1.54e+0	0.18752072	9.82445127	0.354	Ok	1.175	Ok
S5: KT430 150%	77	2	4.287e+10	21101.5	127279220.61	0.2968957794	1.24e+1	1.09342169	10.632153484	2.361	Ok	-0.187	Ok
S5: KT430 150%	78	2	2.409e+10	20732	296984848.1	1.2328138153	6.18e+0	0.79098848	10.3818368	0.522	Ok	0.748	Ok
S5: KT430 150%	79	2	1.188e+10	20382.5	169705627.48	1.4284985479	3.09e+0	0.48995848	10.074816441	1.964	Ok	0.137	Ok
S5: KT430 150%	80	2	5.412e+9	19669	237587878.48	4.3900199275	1.54e+0	0.18752072	9.7333577879	4.960	Ok	-1.525	Ok
S5: KT430 150%	81	2	4.479e+10	21365	1230365799.3	2.7469653924	1.24e+1	1.09342169	10.651181062	1.916	Ok	0.351	Ok
S5: KT430 150%	82	2	2.452e+10	22260.5	233345237.79	0.9514586658	6.18e+0	0.79098848	10.389609016	0.920	Ok	0.963	Ok
S5: KT430 150%	83	2	9.840e+9	21794.5	848528137.42	8.6232534291	3.09e+0	0.48995848	9.9929950984	2.298	Ok	-2.255	Ok
S5: KT430 150%	84	2	7.095e+9	20053.5	360624458.41	5.0827971586	1.54e+0	0.18752072	9.8509523998	1.177	Ok	2.096	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

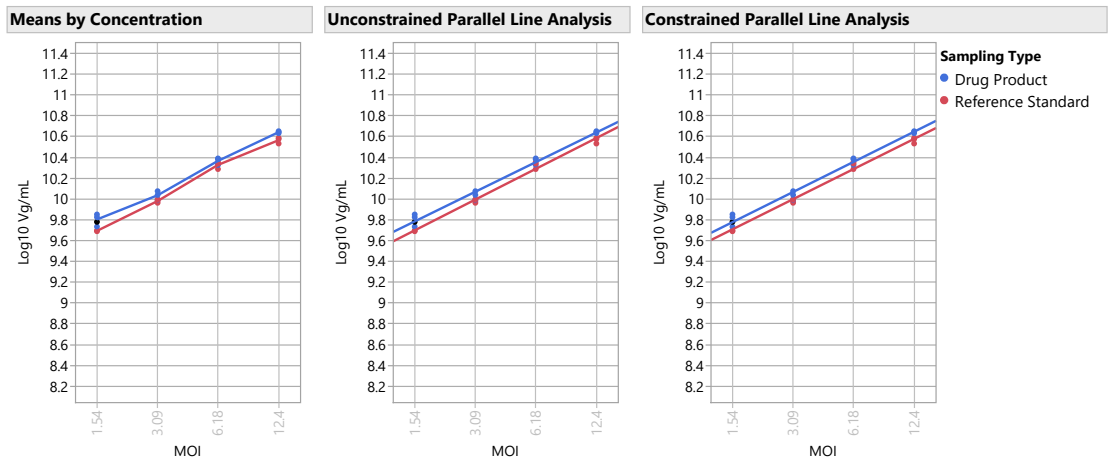
S5: KT430 150% Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std	1.24e+1	3	3.7e+10	2.37e+9
S5: KT430 150%	1.54e+0	3	6.39e+9	8.76e+8
S5: KT430 150%	3.09e+0	3	1.1e+10	1.02e+9
S5: KT430 150%	6.18e+0	3	2.3e+10	1.81e+9
S5: KT430 150%	1.24e+1	3	4.4e+10	9.61e+8

S5: KT430 150% Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.963	0.138	0.987	0.039	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.038	6.999	0.983	0.036	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.881	6.694	0.977	0.042	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.026	3.926	0.990	0.034	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.974	0.376	0.984	0.042	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.963	0.749	0.976	0.046	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.952	0.898	0.982	0.043	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.950	0.068	0.992	0.031	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.891	3.340	0.988	0.038	Parallel and Linear	

S5: KT430 150% Graphs



S5: KT430 150% Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	1000000000	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.018	Passed Validity Criteria	
Parallelism Slope Ratio	0.5	1.5	0.963	Passed Validity Criteria	
Linearity Ratio	.	25	0.138	Passed Validity Criteria	
Unconstrained EC50 Standard	3	800	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	1.000	Passed Validity Criteria	

S5: KT430 150% Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	RI Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
4.99	4.22	118.0	1	2	121.0	127.9	114.6	150	50	13.3	13.3	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
118.0	118.0	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.2	0.3	1.0

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious Ratio	Reportable RI	RI Lower 95	RI Upper 95
AC	4.50410343	4.51679583	1.9	102.7	97.6	108.1
S1: KT430 50%	5.14816032	3.75443618	2.6	140.1	136.1	144.3
S2: KT430 75%	7.12299624	5.37340668	2.6	135.6	127.2	144.7
S3: KT430 125%	4.95551393	4.65812157	2.1	109.4	102.4	116.9
S4: KT430 135%	5.07515819	4.11426974	2.3	126.4	120.3	132.8
S5: KT430 150%	4.98552258	4.22425205	2.2	121.0	114.6	127.9

Sample Name	Overall Validity	OOS	Reportable
AC	Assay is Valid	Within Limits	Reportable
S1: KT430 50%	Assay is Valid	Within Limits	Reportable
S2: KT430 75%	Assay is Valid	Within Limits	Reportable
S3: KT430 125%	Assay is Valid	Within Limits	Reportable
S4: KT430 135%	Assay is Valid	Within Limits	Reportable
S5: KT430 150%	Assay is Valid	Within Limits	Reportable

Astellas KT430 Infectivity Bioassay Materials and Reference Standard Report

Assay Details

Assay	Site:	Date Assay Initiated:	Purpose:	Bioassay Run Number	Analyst Name:	Signal	Method	Instrument ID	Instrument internal no.	Bioassay preparation (date_operator)	Bioassay review (date_reviewer)
Astellas KT430 Infectivity	South San Francisco	2/7/2024	PLA	07Feb24-Infection02-KL	Kathy anh Lam	Vg/mL	KT430				

Notes
Assay Range Check

Materials

Reagents	Material	Source	Catalog#	Lot#	Expiration Date
1	Material 1	Source 1	Catalog 1	Lot 1	Expiry 1
2	Material 2	Source 2	Catalog 2	Lot 2	Expiry 2
3	Material 3	Source 3	Catalog 3	Lot 3	Expiry 3
4	Material 4	Source 4	Catalog 4	Lot 4	Expiry 4
5	Material 5	Source 5	Catalog 5	Lot 5	Expiry 5
6	Material 6	Source 6	Catalog 6	Lot 6	Expiry 6
7	Material 7	Source 7	Catalog 7	Lot 7	Expiry 7
8	Material 8	Source 8	Catalog 8	Lot 8	Expiry 8

Reference Details

Reference/Control	Reference Standard (RS)	Description	Lot#	Expiry/ Reevalution	RS Correction Factor	RS Stability Correction Factor
1	Ref.Std	Test	Test	Test	1	2