



Astellas BQT Assay Report
Test Article Report

Assay Details

User Information
User Name: harding
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Astellas BQT Infectivity PLA Script Version 0.1
JMP Version 18.1.0

Analyst Signature/Date

Approver Signature/Date

Astellas BQT Infectivity Files

First Data File	Second Data File
18OCT2024_Plate02_KL-S3	18OCT2024_Plate02_KL-S4

50% L01-240910_1 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted	Std	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
50% L01-240910_1	13	2	1.821e+10	20851.5	94435265.333	0.5184670847	.	.	10.260413015	7.610	Pass	.	.
50% L01-240910_1	14	2	1.118e+10	20462.5	49645939.883	0.4438881443	1.6e+1	1.2041199827	10.048610191	3.296	Pass	2.037	Ok
50% L01-240910_1	15	2	5.151e+9	19885	42103690.407	0.8174463291	8e+0	0.903089987	9.7118609157	2.104	Pass	0.783	Ok
50% L01-240910_1	16	2	2.926e+9	20742	149980255.56	5.1253477381	4e+0	0.6020599913	9.4663107531	7.342	Pass	2.142	Ok
50% L01-240910_1	17	2	1.549e+10	19522.5	597112052.57	3.8558336802	.	.	10.189937545	0.467	Pass	.	.
50% L01-240910_1	18	2	9.173e+9	20427.5	131640590.54	1.4350393346	1.6e+1	1.2041199827	9.9625260166	0.207	Pass	-0.037	Ok
50% L01-240910_1	19	2	4.545e+9	20017.5	1488640.7937	0.0327556343	8e+0	0.903089987	9.6575039019	0.004	Pass	-0.267	Ok
50% L01-240910_1	20	2	2.295e+9	20649	42748637.553	1.8626139363	4e+0	0.6020599913	9.3607994298	0.459	Pass	-0.380	Ok
50% L01-240910_1	21	2	1.493e+10	20123.5	746021394.55	4.9977972131	.	.	10.173972652	0.997	Pass	.	.
50% L01-240910_1	22	2	8.075e+9	20094	265089947.14	3.2829854877	1.6e+1	1.2041199827	9.9071242956	1.480	Pass	-1.276	Ok
50% L01-240910_1	23	2	3.931e+9	20231	32494046.672	0.8265927734	8e+0	0.903089987	9.5945121959	2.139	Pass	-1.598	Ok
50% L01-240910_1	24	2	2.161e+9	20708	28653653.294	1.3262198343	4e+0	0.6020599913	9.3345644829	1.009	Pass	-0.963	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass	.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass	-0.981	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass	-1.301	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass	0.111	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass	.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass	0.127	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass	-0.293	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass	-0.072	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass	.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass	1.618	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass	0.335	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass	0.626	Ok

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

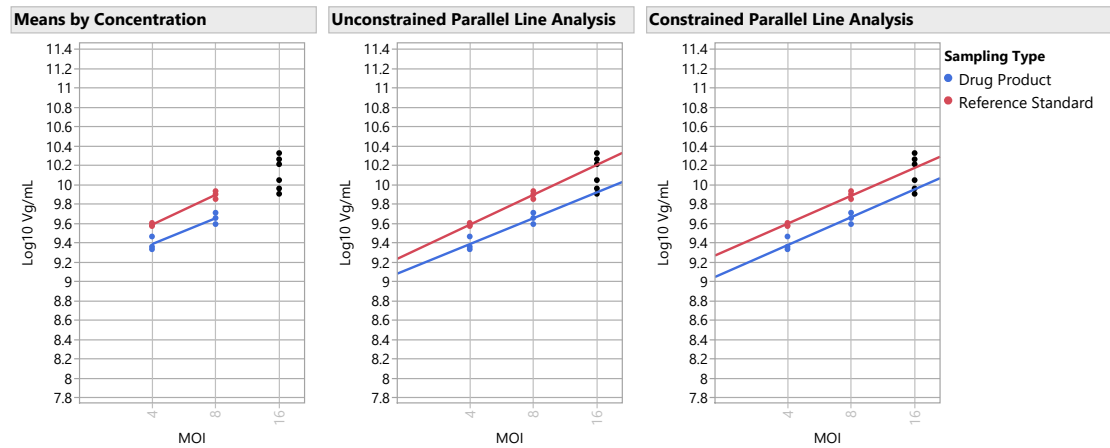
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
50% L01-240910_1	.	3	1.6e+10	1.76e+9
50% L01-240910_1	4e+0	3	2.46e+9	4.09e+8
50% L01-240910_1	8e+0	3	4.54e+9	6.1e+8
50% L01-240910_1	1.6e+1	3	9.48e+9	1.58e+9

50% L01-240910_1 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 3, High Standard and Test Doses Excluded	0.865	0.000	0.951	0.051 Parallel and Linear	Model 3, High Standard and Test Doses Excluded
Model 1, All Doses	0.860	4.467	0.973	0.054 Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	0.856	0.000	0.955	0.058 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	1.029	0.000	0.936	0.051 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.947	4.179	0.955	0.054 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.935	4.782	0.968	0.052 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.788	3.848	0.972	0.059 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.786	5.080	0.979	0.052 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.720	0.000	0.979	0.058 Parallel and Linear	

50% L01-240910_1 Graphs



50% L01-240910_1 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	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.164	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.865	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.461	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

50% L01-240910_1 Relative Infectivity and Infectious Particle Ratio

		RI	Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower	CI Range as %					
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance	CI Range % of Tolerance	Check	OOS Validity
4.33	7.38	58.7	0	0	58.7	65.9	50.9	150	50	14.9	14.9	Bioassay Results are Reportable Assay is Valid and Within Limits		

Unconstrained RI	Constrained RI	Relative Infectivity Delta
58.6	58.7	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.4	0.3	1.0

150% L01-240910_1 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted		Std		MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
150% L01-240910_1	25	2	4.328e+10	19590	656185083.84	1.516157548	.	.	.	10.636282022	0.797	Pass	.	.
150% L01-240910_1	26	2	2.548e+10	19257.5	127422942.19	0.5001095848	1.6e+1	1.2041199827	10.406182451	6.439	Pass		1.437	Ok
150% L01-240910_1	27	2	1.235e+10	20620.5	95067106.961	0.7697030114	8e+0	0.903089987	10.091707092	3.487	Pass		-0.095	Ok
150% L01-240910_1	28	2	7.267e+9	19589.5	124780027.36	1.7170178963	4e+0	0.6020599913	9.8613702547	0.645	Pass		0.948	Ok
150% L01-240910_1	29	2	4.320e+10	20041.5	479922826.41	1.1109143873	.	.	10.635490815	0.622	Pass		.	.
150% L01-240910_1	30	2	2.319e+10	19921	669588345.21	2.8877311629	1.6e+1	1.2041199827	10.365251126	0.427	Pass		0.137	Ok
150% L01-240910_1	31	2	1.108e+10	20170	136112012.44	1.2281117402	8e+0	0.903089987	10.044658572	1.427	Pass		-1.438	Ok
150% L01-240910_1	32	2	7.305e+9	19580.5	228548830.67	3.1286225929	4e+0	0.6020599913	9.8636258265	0.772	Pass		1.022	Ok
150% L01-240910_1	33	2	4.196e+10	19967	98481352.962	0.2346842141	.	.	10.622870128	22.921	Pass		.	.
150% L01-240910_1	34	2	2.262e+10	19692	154114236.92	0.681261223	1.6e+1	1.2041199827	10.35452909	1.056	Pass		-0.177	Ok
150% L01-240910_1	35	2	1.151e+10	19410.5	203413827.77	1.7671798668	8e+0	0.903089987	10.061099717	0.230	Pass		-0.932	Ok
150% L01-240910_1	36	2	6.446e+9	20595.5	356693271.03	5.5331329205	4e+0	0.6020599913	9.8093238133	31.380	Pass		-0.615	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass		.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass		-1.415	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass		-1.931	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass		0.154	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass		.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass		0.177	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass		-0.409	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass		-0.100	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass		.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass		2.498	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass		0.467	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass		0.884	Ok

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

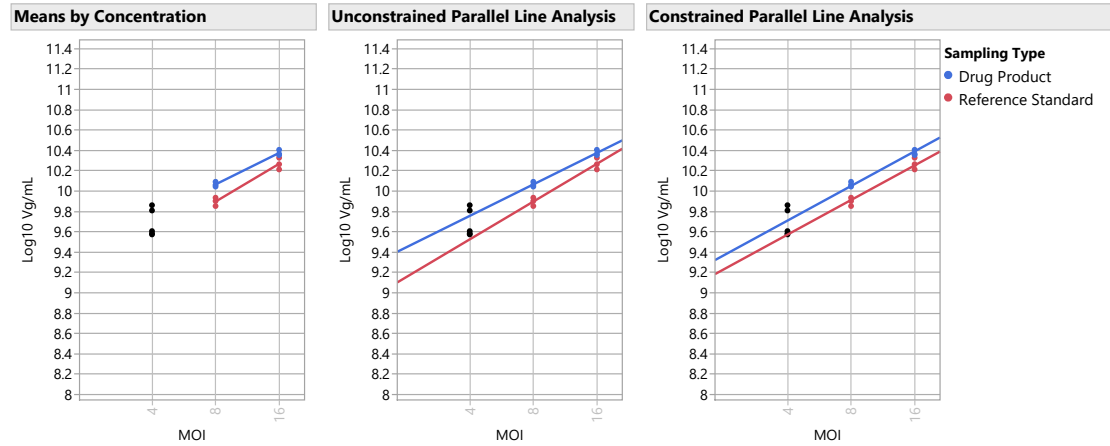
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
150% L01-240910_1	.	3	4.3e+10	7.38e+8
150% L01-240910_1	4e+0	3	7.01e+9	4.85e+8
150% L01-240910_1	8e+0	3	1.2e+10	6.45e+8
150% L01-240910_1	1.6e+1	3	2.4e+10	1.51e+9

150% L01-240910_1 Model Selection

Model	Parallelism		Linearity		R2	RMSE	Validity Evaluation	Selected Model
	Slope Ratio	Ratio	Ratio					
Model 2, Low Standard and Test Doses Excluded	0.833	0.000	0.970	0.040	Parallel and Linear		Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.780	6.227	0.984	0.039	Parallel and Linear			
Model 3, High Standard and Test Doses Excluded	0.715	0.000	0.980	0.030	Parallel and Linear			
Model 9, Standard High Dose and Test Low Dose Excluded	1.001	0.000	0.993	0.029	Parallel and Linear			
Model 6, Test Low Dose Only Excluded	0.910	4.846	0.987	0.037	Parallel and Linear			
Model 5, Standard High Dose Only Excluded	0.858	7.583	0.988	0.034	Parallel and Linear			
Model 4, Standard Low Dose Only Excluded	0.714	7.044	0.971	0.041	Parallel and Linear			
Model 7, Test High Dose Only Excluded	0.650	5.495	0.980	0.038	Fails Parallelism and is Linear			
Model 8, Standard Low Dose and Test High Dose Excluded	0.595	0.000	0.962	0.040	Fails Parallelism and is Linear			

150% L01-240910_1 Graphs



150% L01-240910_1 Validity Report

Validity Criteria	LSL		USL		Validity Results		Overall Validity
	Dose Response Test	Reference Standard Curve Depth	% Relative Infectivity Delta (Constrained - Unconstrained)	Parallelism Slope Ratio	Linearity Ratio	Unconstrained EC50 Standard	Number of Wells that Failed Accepted Droplets (<10000)
	.	2720000000	.	0.7	.	0.04	.
	0.05	.	15	1.4	0.000	61.8	1
	0.000	34071437681	0.311	0.833	0.000	9.461	0.000
	Passed Validity Criteria	Passed Validity Criteria	Passed Validity Criteria	Passed Validity Criteria	Passed Validity Criteria	Passed Validity Criteria	Passed Validity Criteria

150% L01-240910_1 Relative Infectivity and Infectious Particle Ratio

EC50 Ref		EC50 Test		RI		Reference		Relative Infectivity		Assay RI		Assay RI		Upper		Lower		CI Range as %									
13.02		9.83		132.4		Reference CF		Stability CF		Reportable Result		Upper 95%		Lower 95%		Spec Limit		Spec Limit		CI Range		of Tolerance		CI Range % of Tolerance		Check OOS Validity	
				0				0		132.4		144.3		122.4		150		50		22.0		22.0		Bioassay Results are Reportable		Assay is Valid and Within Limits	
				Relative																							
Unconstrained RI		Constrained RI		Infectivity Delta																							
132.7		132.4		0.3																							
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit																							
1.1		0.3		1.0																							

200% L01-240910 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted	Std		MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)				Jackknife z	Within Group	Studentized Residuals	Between Group
200% L01-240910	37	2	5.122e+10	19992	783580839.19	1.5299807737	.	.	10.709397834	0.859	Pass	.	.
200% L01-240910	38	2	3.003e+10	19829.5	1181939524.2	3.9352547599	1.6e+1	1.2041199827	10.477622403	5.054	Pass	1.236	Ok
200% L01-240910	39	2	1.444e+10	20205	633969738.98	4.3888702708	8e+0	0.903089987	10.159715785	0.986	Pass	-0.355	Ok
200% L01-240910	40	2	1.053e+10	20592.5	698524091.26	6.6343484073	4e+0	0.6020599913	10.022383114	43.028	Pass	3.236	Ok
200% L01-240910	41	2	5.692e+10	19740.5	1139795369.6	2.0023037825	.	.	10.755296921	13.863	Pass	.	.
200% L01-240910	42	2	2.738e+10	19903.5	659314495.92	2.4079566923	1.6e+1	1.2041199827	10.437443953	0.360	Pass	0.199	Ok
200% L01-240910	43	2	1.421e+10	19306.5	662221857.73	4.6616125322	8e+0	0.903089987	10.152467339	0.474	Pass	-0.516	Ok
200% L01-240910	44	2	7.868e+9	19962	351032941.35	4.4612955036	4e+0	0.6020599913	9.8958868825	0.754	Pass	-0.657	Ok
200% L01-240910	45	2	5.177e+10	20033.5	375780825.57	0.7258769233	.	.	10.714071626	0.570	Pass	.	.
200% L01-240910	46	2	2.652e+10	18917.5	798069096.51	3.0096351073	1.6e+1	1.2041199827	10.42352665	1.167	Pass	-0.137	Ok
200% L01-240910	47	2	1.299e+10	20733.5	142190222.08	1.0943764268	8e+0	0.903089987	10.113703003	7.882	Pass	-1.461	Ok
200% L01-240910	48	2	7.954e+9	20191	372262329.4	4.6799330306	4e+0	0.6020599913	9.9006094522	0.661	Pass	-0.538	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass	.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass	-1.140	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass	-1.525	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass	0.127	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass	.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass	0.146	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass	-0.337	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass	-0.082	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass	.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass	1.919	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass	0.385	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass	0.722	Ok

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

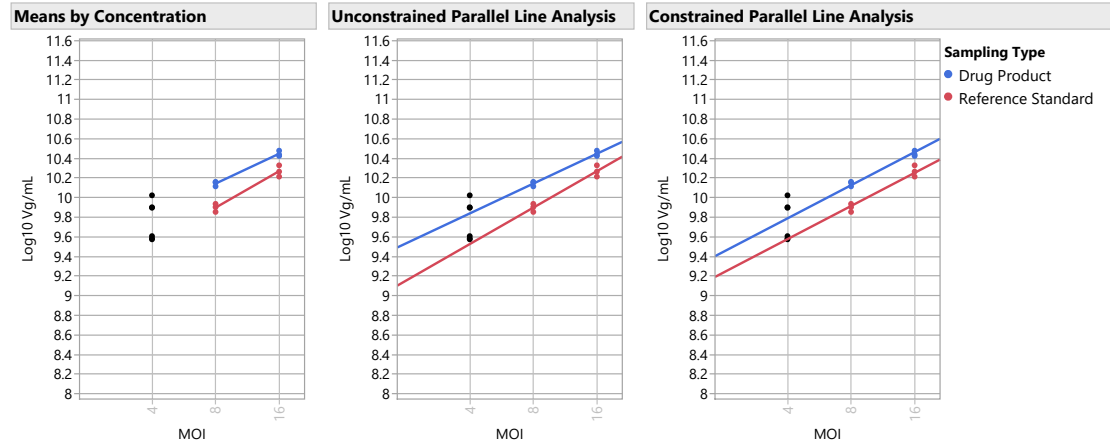
200% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
200% L01-240910	.	3	5.3e+10	3.15e+9
200% L01-240910	4e+0	3	8.78e+9	1.51e+9
200% L01-240910	8e+0	3	1.4e+10	7.79e+8
200% L01-240910	1.6e+1	3	2.8e+10	1.83e+9

200% L01-240910 Model Selection

	Parallelism	Linearity				
Model	Slope Ratio	Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.819	0.000	0.974	0.040	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.744	6.919	0.978	0.047	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.984	0.000	0.994	0.029	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.894	4.886	0.989	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.819	8.899	0.982	0.045	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.682	8.291	0.956	0.051	Fails Parallelism and is Linear	
Model 3, High Standard and Test Doses Excluded	0.655	0.000	0.968	0.044	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.595	5.682	0.971	0.047	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.545	0.000	0.927	0.052	Fails Parallelism and is Linear	

200% L01-240910 Graphs



200% L01-240910 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	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.671	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.819	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.461	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

200% L01-240910 Relative Infectivity and Infectious Particle Ratio

EC50 Ref		EC50 Test		RI		Reference Stability CF	Relative Infectivity Reportable Result	Assay RI		Upper Spec Limit	Lower Spec Limit	CI Range as % of Tolerance			OOS Validity
14.05		9.11		Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
14.05		9.11		154.3	0	0	154.3	169.8	142.0	150	50	27.8	27.8	Bioassay Results are Reportable	Assay is Valid and OOS
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
155.0		154.3		0.7											
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio											
1.3		0.3		1.0											

100% L01-240910 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted		Std		MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
100% L01-240910	49	2	3.677e+10	19203	117861205.29	0.320544712			.	10.565482261	0.792	Pass	.	.
100% L01-240910	50	2	1.712e+10	18946	389600987.9	2.276366175	1.6e+1	1.2041199827	10.233377926	2.164	Pass		-1.720	Ok
100% L01-240910	51	2	7.957e+9	20068	202754799.3	2.5482781986	8e+0	0.903089987	9.9007243042	10.649	Pass		-0.751	Ok
100% L01-240910	52	2	3.687e+9	19366	179490548.5	4.8680635883	4e+0	0.6020599913	9.5666853422	0.134	Pass		-0.121	Ok
100% L01-240910	53	2	3.701e+10	19265	1405677694.6	3.7978791033	.	.	10.568344618	0.627	Pass		.	.
100% L01-240910	54	2	1.924e+10	18664	1497416004.4	7.7830217781	1.6e+1	1.2041199827	10.284194225	0.011	Pass		0.004	Ok
100% L01-240910	55	2	8.908e+9	19092.5	465543327.06	5.226167867	8e+0	0.903089987	9.9497767506	0.908	Pass		0.629	Ok
100% L01-240910	56	2	3.572e+9	20039	153217941.95	4.2888527325	4e+0	0.6020599913	9.5529684905	1.672	Pass		-0.547	Ok
100% L01-240910	57	2	4.107e+10	18741	112923026.09	0.2749478765	.	.	10.613532138	24.314	Pass		.	.
100% L01-240910	58	2	2.130e+10	20008	537971703.31	2.5254998667	1.6e+1	1.2041199827	10.328412083	2.080	Pass		1.467	Ok
100% L01-240910	59	2	8.789e+9	19365.5	327411500.51	3.7250523238	8e+0	0.903089987	9.9439615528	0.531	Pass		0.462	Ok
100% L01-240910	60	2	3.855e+9	19808	168024878.86	4.3584371279	4e+0	0.6020599913	9.5860428055	2.780	Pass		0.476	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass		.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass		-1.492	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass		-2.050	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass		0.161	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass		.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass		0.185	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass		-0.428	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass		-0.104	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass		.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass		2.677	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass		0.490	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass		0.928	Ok

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

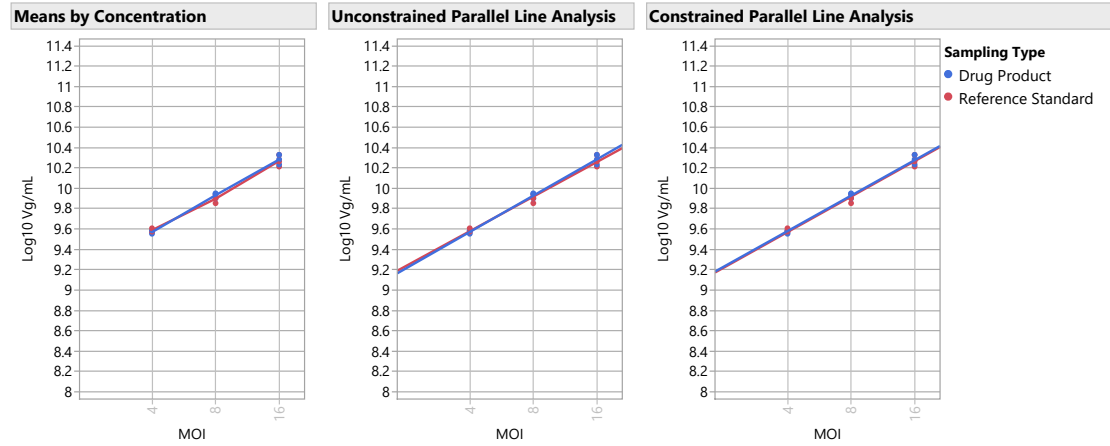
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
100% L01-240910	.	3	3.8e+10	2.42e+9
100% L01-240910	4e+0	3	3.7e+9	1.42e+8
100% L01-240910	8e+0	3	8.55e+9	5.18e+8
100% L01-240910	1.6e+1	3	1.9e+10	2.09e+9

100% L01-240910 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 1, All Doses	1.048	1.792	0.987	0.037	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.944	0.000	0.961	0.045	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	1.174	0.000	0.983	0.027	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.977	0.000	0.984	0.039	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.030	4.556	0.982	0.041	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.960	0.851	0.984	0.039	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.067	4.396	0.986	0.036	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	1.134	0.000	0.986	0.035	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	1.154	0.934	0.990	0.031	Parallel and Linear	

100% L01-240910 Graphs



100% L01-240910 Validity Report

Validity Criteria	LSL		USL		Validity		Overall Validity
	Dose Response Test		Results	Assay Validity	0.000	Passed Validity Criteria	
Reference Standard Curve Depth	2720000000	.	34071437681	Passed Validity Criteria			Assay is Valid
% Relative Infectivity Delta (Constrained - Unconstrained)	.	.	15	0.001	Passed Validity Criteria		
Parallelism Slope Ratio	0.7	.	1.4	1.048	Passed Validity Criteria		
Linearity Ratio	.	.	26.3	1.792	Passed Validity Criteria		
Unconstrained EC50 Standard	0.04	.	61.8	9.461	Passed Validity Criteria		
Number of Wells that Failed Accepted Droplets (<10000)	.	.	1	0.000	Passed Validity Criteria		

100% L01-240910 Relative Infectivity and Infectious Particle Ratio

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %				
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance	CI Range %	of Tolerance	Check	OOS Validity
8.08	7.92	101.9	0	0	101.9	107.4	96.8	150	50	10.5	10.5	Bioassay Results are Reportable			Assay is Valid and Within Limits
		Relative													
Unconstrained RI	Constrained RI	Infectivity Delta													
101.9	101.9	0.0													
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio											
Lower Limit		Upper Limit													
0.9	0.3	1.0													

50% L01-240910_2 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted	Std	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
50% L01-240910_2	61	2	1.836e+10	19242.5	578676092.33	3.1526420738	.	.	10.263760873	4.977	Pass	.	.
50% L01-240910_2	62	2	1.146e+10	19672.5	383744830.65	3.3484648371	1.6e+1	1.2041199827	10.059196796	4.500	Pass	2.174	Ok
50% L01-240910_2	63	2	5.320e+9	19670.5	143601825	2.6992944637	8e+0	0.903089987	9.7259096953	1.665	Pass	0.909	Ok
50% L01-240910_2	64	2	2.844e+9	18932.5	78820891.318	2.771568467	4e+0	0.6020599913	9.45391573	2.285	Pass	1.474	Ok
50% L01-240910_2	65	2	1.572e+10	20668	412066220.06	2.6208869292	.	.	10.196518729	0.355	Pass	.	.
50% L01-240910_2	66	2	9.122e+9	18914	97392479.23	1.0676937726	1.6e+1	1.2041199827	9.9600787117	0.323	Pass	-0.195	Ok
50% L01-240910_2	67	2	4.715e+9	20554	235510385.67	4.9945365046	8e+0	0.903089987	9.673514872	0.136	Pass	-0.099	Ok
50% L01-240910_2	68	2	2.498e+9	15224	.	.	4e+0	0.6020599913	9.3976468856	0.039	Pass	0.198	Ok
50% L01-240910_2	69	2	1.485e+10	19314.5	496404373.91	3.3426924038	.	.	10.171739185	1.175	Pass	.	.
50% L01-240910_2	70	2	8.250e+9	19914.5	77289525.011	0.9368708507	1.6e+1	1.2041199827	9.9164409116	1.234	Pass	-1.155	Ok
50% L01-240910_2	71	2	3.822e+9	19669.5	76628716.753	2.0047058585	8e+0	0.903089987	9.5823408932	2.796	Pass	-2.083	Ok
50% L01-240910_2	72	2	2.189e+9	14748	.	.	4e+0	0.6020599913	9.3401609307	1.975	Pass	-1.036	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass	.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass	-0.967	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass	-1.281	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass	0.109	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass	.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass	0.125	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass	-0.289	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass	-0.071	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass	.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass	1.591	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass	0.330	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass	0.617	Ok

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

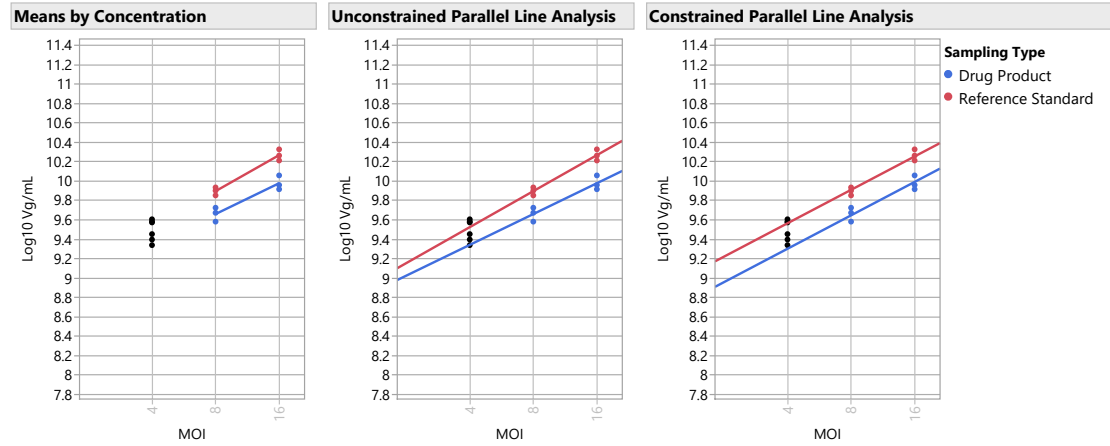
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
50% L01-240910_2	.	3	1.6e+10	1.82e+9
50% L01-240910_2	4e+0	3	2.51e+9	3.28e+8
50% L01-240910_2	8e+0	3	4.62e+9	7.53e+8
50% L01-240910_2	1.6e+1	3	9.61e+9	1.66e+9

50% L01-240910_2 Model Selection

Model	Parallelism	Linearity	Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation
Model 2, Low Standard and Test Doses Excluded	0.856	0.000	0.948	0.063 Parallel and Linear
Model 1, All Doses	0.854	4.636	0.972	0.055 Parallel and Linear
Model 3, High Standard and Test Doses Excluded	0.852	0.000	0.948	0.051 Parallel and Linear
Model 9, Standard High Dose and Test Low Dose Excluded	1.029	0.000	0.925	0.056 Parallel and Linear
Model 5, Standard High Dose Only Excluded	0.940	4.514	0.952	0.055 Parallel and Linear
Model 6, Test Low Dose Only Excluded	0.935	4.783	0.963	0.055 Parallel and Linear
Model 4, Standard Low Dose Only Excluded	0.783	4.160	0.971	0.060 Parallel and Linear
Model 7, Test High Dose Only Excluded	0.774	5.114	0.978	0.052 Parallel and Linear
Model 8, Standard Low Dose and Test High Dose Excluded	0.709	0.000	0.978	0.058 Parallel and Linear

50% L01-240910_2 Graphs



50% L01-240910_2 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	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.188	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.856	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.461	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (< 10000)	.	1	0.000	Passed Validity Criteria	

50% L01-240910_2 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	% of Tolerance Check	OOS Validity
8.68	14.74	58.9	0	0	58.9	66.3	50.8	150	50	15.5	15.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Relative Infectivity Delta			
Unconstrained RI	Constrained RI	Infectivity Delta	
58.7	58.9	0.2	

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.5	0.3	1.0

150% L01-240910_2 & 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
150% L01-240910_2	73	2	4.400e+10	19227.5	1011785905.7	2.2997680598	.	.	10.643404587	18.815	Pass	.	.
150% L01-240910_2	74	2	2.553e+10	19561	1022989391.8	4.0075911691	1.6e+1	1.2041199827	10.406987719	8.130	Pass	1.509	Ok
150% L01-240910_2	75	2	1.243e+10	19720	215002496.86	1.7291133125	8e+0	0.903089987	10.094620049	8.448	Pass	-0.093	Ok
150% L01-240910_2	76	2	7.210e+9	15797	460290519.99	6.3836280682	4e+0	0.6020599913	9.8579644548	0.278	Pass	0.648	Ok
150% L01-240910_2	77	2	4.318e+10	19239	1153369528.8	2.6708724835	.	.	10.63531532	0.605	Pass	.	.
150% L01-240910_2	78	2	2.311e+10	19181	16052321.661	0.0694549112	1.6e+1	1.2041199827	10.363834893	0.481	Pass	0.118	Ok
150% L01-240910_2	79	2	1.140e+10	20626	323785549.92	2.839103811	8e+0	0.903089987	10.05707619	0.489	Pass	-1.146	Ok
150% L01-240910_2	80	2	7.430e+9	15294.5	318946741.85	4.2927946804	4e+0	0.6020599913	9.8709780529	1.323	Pass	1.066	Ok
150% L01-240910_2	81	2	4.312e+10	19919	212901108.44	0.4937427852	.	.	10.63467716	0.818	Pass	.	.
150% L01-240910_2	82	2	2.265e+10	20149	1046904735.2	4.6217208411	1.6e+1	1.2041199827	10.355103454	0.977	Pass	-0.140	Ok
150% L01-240910_2	83	2	1.122e+10	20629	168546177.42	1.5026815525	8e+0	0.903089987	10.049851952	0.965	Pass	-1.375	Ok
150% L01-240910_2	84	2	6.707e+9	17865	246301164.67	3.6724316625	4e+0	0.6020599913	9.8265127424	3.955	Pass	-0.292	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	.	.	10.546779507	1.363	Pass	.	.
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	1.6e+1	1.2041199827	10.212942071	1.692	Pass	-1.430	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	8e+0	0.903089987	9.8531480751	2.625	Pass	-1.954	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	4e+0	0.6020599913	9.5826829306	0.343	Pass	0.156	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	.	.	10.570390775	0.259	Pass	.	.
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	1.6e+1	1.2041199827	10.263971072	0.126	Pass	0.178	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	8e+0	0.903089987	9.9022753147	0.107	Pass	-0.413	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	4e+0	0.6020599913	9.5740061513	1.198	Pass	-0.101	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	.	.	10.617280939	3.754	Pass	.	.
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	1.6e+1	1.2041199827	10.328108062	2.737	Pass	2.532	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	8e+0	0.903089987	9.9352489434	1.750	Pass	0.472	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	4e+0	0.6020599913	9.6067442937	4.780	Pass	0.892	Ok

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

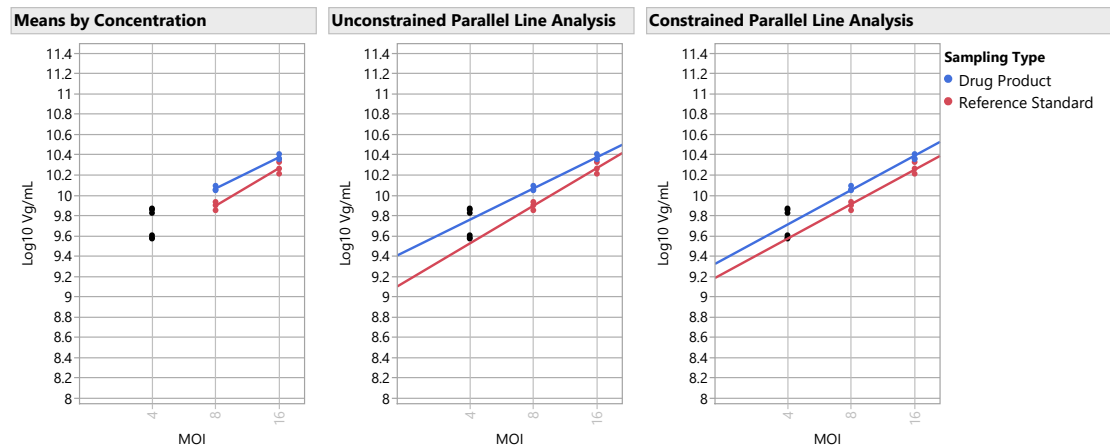
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.8e+10	3.17e+9
Ref.Std (L01-240910)	4e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	8e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.49e+9
150% L01-240910_2	.	3	4.3e+10	4.88e+8
150% L01-240910_2	4e+0	3	7.12e+9	3.71e+8
150% L01-240910_2	8e+0	3	1.2e+10	6.56e+8
150% L01-240910_2	1.6e+1	3	2.4e+10	1.54e+9

150% L01-240910_2 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.830	0.000	0.970	0.040	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.769	6.442	0.984	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.997	0.000	0.993	0.029	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.906	4.856	0.987	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.847	7.995	0.988	0.033	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.705	7.434	0.972	0.041	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.697	0.000	0.983	0.028	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.633	5.550	0.981	0.037	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.580	0.000	0.963	0.039	Fails Parallelism and is Linear	

150% L01-240910_2 Graphs



Validity Criteria			Validity		Overall Validity
	LSL	USL	Results	Assay Validity	
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.329	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.830	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.461	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

150% L01-240910_2 Relative Infectivity and Infectious Particle Ratio

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower	CI Range as %				
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance	CI Range % of Tolerance	Check	OOS Validity
13.03	9.82	132.7	0	0	132.7	144.7	122.5	150	50	22.2	22.2	Bioassay Results are Reportable Assay is Valid and Within Limits		
		Relative												
Unconstrained RI	Constrained RI	Infectivity Delta												
133.0	132.7	0.3												
Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit												
1.1	0.3	1.0												

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious		Reportable RI	RI Lower 95	RI Upper 95
			Ratio	Ratio			
50% L01-240910_1	4.334605821	7.3824475215	0.4		58.7	50.9	65.9
150% L01-240910_1	13.019421603	9.8314659362	1.1		132.4	122.4	144.3
200% L01-240910	14.054523902	9.1073878343	1.3		154.3	142.0	169.8
100% L01-240910	8.0772937992	7.923445846	0.9		101.9	96.8	107.4
50% L01-240910_2	8.6847004829	14.738562401	0.5		58.9	50.8	66.3
150% L01-240910_2	13.03207716	9.821918519	1.1		132.7	122.5	144.7

Sample Name	Overall Validity	OOS	Reportable
50% L01-240910_1	Assay is Valid	Within Limits	Reportable
150% L01-240910_1	Assay is Valid	Within Limits	Reportable
200% L01-240910	Assay is Valid	OOS	Reportable
100% L01-240910	Assay is Valid	Within Limits	Reportable
50% L01-240910_2	Assay is Valid	Within Limits	Reportable
150% L01-240910_2	Assay is Valid	Within Limits	Reportable

Astellas BQT Infectivity Bioassay Materials and Reference Standard Report

Assay Details

Assay	Date Assay		Bioassay		Analyst		Instrument	Bioassay preparation		Bioassay review
	Site:	Initiated:	Purpose:	Run Number	Name:	Signal Method	Instrument ID	internal no.	(date_operator)	(date_reviewer)
Astellas BQT Infectivity			PLA	BQT Test Run 2		Vg/mL KT430				

Notes
Assay Range Check

Materials

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

Reference Details

Reference		Description	Lot#	Expiry/ Reevaluation		RS Correction		RS Stability	
Reference/Control	Standard (RS)			Test	Test	Factor	Factor	Correction Factor	
1 Ref.Std		Test		Test		0		0	

[illegible]

BQT Infectivity_13Nov2024-13-51-04

Well	Sample		Sample		Sample		Sample		Conc(copies/ µL)		Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted		
	description 1	description 2	description 3	description 4	Target				Droplets	Positives							Negatives		
B03	8	RS	REP3		BDNF	1394.334961	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18015	12508	5507
A03	16	RS	REP3		BDNF	2789.517822	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19030	17253	1777
E10	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					20448	0	20448
E11	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					20903	0	20903
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					20513	0	20513
F10	PC				BDNF	1426.414185	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					18476	12980	5496
F11	PC				BDNF	1468.001953	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19503	13903	5600
F12	PC				BDNF	1407.259521	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19193	13390	5803

Well	Sample		Sample		Sample		Sample		Conc(copies/ µL)		Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted		
	description 1	description 2	description 3	description 4	Target				Droplets	Positives							Negatives		
D04	2	50	REP1		BDNF	101.0765839	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20637	1699	18938
C04	4	50	REP1		BDNF	172.6802826	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21082	2878	18204
B04	8	50	REP1		BDNF	371.6410217	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19759	5352	14407
A04	16	50	REP1		BDNF	609.3699341	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20103	8127	11976
D05	2	50	REP2		BDNF	75.4953537	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20497	1274	19223
C05	4	50	REP2		BDNF	151.4544525	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20448	2470	17978
B05	8	50	REP2		BDNF	302.6741638	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20199	4582	15617
A05	16	50	REP2		BDNF	502.1239014	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20034	6960	13074
D06	2	50	REP3		BDNF	72.69373322	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21095	1264	19831
C06	4	50	REP3		BDNF	131.8019867	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20588	2182	18406
B06	8	50	REP3		BDNF	262.907135	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19849	3975	15874
A06	16	50	REP3		BDNF	479.9829102	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20062	6721	13341
H04	2	50.2	REP1		BDNF	92.93914795	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					16667	1266	15401
G04	4	50.2	REP1		BDNF	180.7172699	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21251	3026	18225
F04	8	50.2	REP1		BDNF	391.0556641	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20474	5790	14684
E04	16	50.2	REP1		BDNF	598.2029419	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19667	7839	11828
H05	2	50.2	REP2		BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					9646	632	9014
G05	4	50.2	REP2		BDNF	162.7297058	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20274	2619	17655
F05	8	50.2	REP2		BDNF	306.3542786	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19236	4410	14826
E05	16	50.2	REP2		BDNF	514.3673706	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21185	7503	13682
H06	2	50.2	REP3		BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					9811	474	9337
G06	4	50.2	REP3		BDNF	125.6085739	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20629	2089	18540
F06	8	50.2	REP3		BDNF	273.1700134	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20144	4174	15970
E06	16	50.2	REP3		BDNF	483.3141479	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19297	6501	12796
H01	2	100.2	REP1		BDNF	118.672821	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19166	1839	17327
G01	4	100.2	REP1		BDNF	269.9970093	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19696	4039	15657
F01	8	100.2	REP1		BDNF	579.6843262	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19954	7763	12191
E01	16	100.2	REP1		BDNF	1228.412598	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19617	12712	6905
H02	2	100.2	REP2		BDNF	115.4709244	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20345	1902	18443
G02	4	100.2	REP2		BDNF	307.9039307	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19655	4526	15129
F02	8	100.2	REP2		BDNF	676.6117554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19565	8557	11008
E02	16	100.2	REP2		BDNF	1200.607056	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19858	12701	7157
H03	2	100.2	REP3		BDNF	124.5450668	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20557	2065	18492
G03	4	100.2	REP3		BDNF	285.2644043	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19404	4178	15226
F03	8	100.2	REP3		BDNF	722.7332153	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19704	9044	10660
E03	16	100.2	REP3		BDNF	1366.361816	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19946	13702	6244
D07	2	150	REP1		BDNF	245.1828461	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20593	3874	16719
C07	4	150	REP1		BDNF	409.4639587	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20964	6162	14802
B07	8	150	REP1		BDNF	846.2967529	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19718	10114	9604
A07	16	150	REP1		BDNF	1427.182861	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19763	13888	5875
D08	2	150	REP2		BDNF	248.8900909	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20443	3898	16545
C08	4	150	REP2		BDNF	372.6425781	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20480	5560	14920
B08	8	150	REP2		BDNF	788.6940308	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19767	9656	10111
A08	16	150	REP2		BDNF	1428.711548	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20075	14115	5960
D09	2	150	REP3		BDNF	223.2905884	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21027	3635	17392
C09	4	150	REP3		BDNF	388.4827271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20791	5847	14944
B09	8	150	REP3		BDNF	757.6958618	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20822	9887	10935
A09	16	150	REP3		BDNF	1401.099487	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18948	13189	5759
H07	2	150.2	REP1		BDNF	251.1986389	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					10340	1988	8352
G07	4	150.2	REP1		BDNF	409.4077759	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20422	6002	14420
F07	8	150.2	REP1		BDNF	874.9884644	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19986	10486	9500
E07	16	150.2	REP1		BDNF	1442.65625	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20086	14193	5893
H08	2	150.2	REP2		BDNF	255.1781769	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					10221	1993	8228
G08	4	150.2	REP2		BDNF	387.7816467	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20926	5876	