



**Astellas BQT Assay Report**  
**Test Article Report**

**Assay Details**

**User Information**  
User Name: harding  
Computer Name: DESKTOP-RFHI5SO  
Logon Server: \\DESKTOP-RFHI5SO  
User Domain: DESKTOP-RFHI5SO  
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_Plate03_KL-S3	18OCT2024_Plate03_KL-S4

50% L01-240910\_1 & 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	Externally Studentized Residuals	Outlier Between Group
50% L01-240910_1	13	2	1.846e+10	19212	1046797271.2	5.669173539	.	.	10.26634283	2.307	Pass	.
50% L01-240910_1	14	2	1.154e+10	20496	133015616.6	1.1528235451	1.6e+1	1.2041199827	10.062139794	2.656	Pass	2.075
50% L01-240910_1	15	2	5.404e+9	20282	177405513.34	3.2830346726	8e+0	0.903089987	9.7326916431	1.807	Pass	0.940
50% L01-240910_1	16	2	2.944e+9	19460.5	56060299.031	1.9039125695	4e+0	0.6020599913	9.4690084089	1.996	Pass	1.672
50% L01-240910_1	17	2	1.643e+10	19077.5	1033162251.4	6.2868996979	.	.	10.215731998	0.043	Pass	.
50% L01-240910_1	18	2	9.459e+9	19732.5	188463982.8	1.9924404129	1.6e+1	1.2041199827	9.9758430228	0.112	Pass	0.097
50% L01-240910_1	19	2	4.726e+9	20131.5	98091321.701	2.075351646	8e+0	0.903089987	9.6745388925	0.088	Pass	-0.124
50% L01-240910_1	20	2	2.551e+9	20294	40150072.104	1.5738839181	4e+0	0.6020599913	9.4067136317	0.033	Pass	0.289
50% L01-240910_1	21	2	1.464e+10	19522	173507016.57	1.1853448318	.	.	10.165472332	1.958	Pass	.
50% L01-240910_1	22	2	7.950e+9	19997	155852437.26	1.9603972923	1.6e+1	1.2041199827	9.9003695043	1.733	Pass	-1.508
50% L01-240910_1	23	2	3.856e+9	20129.5	151481358.05	3.9288780116	8e+0	0.903089987	9.5860906454	2.526	Pass	-1.922
50% L01-240910_1	24	2	2.119e+9	20119.5	64724449.5	3.0542138986	4e+0	0.6020599913	9.3261689162	2.259	Pass	-1.394
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass	-1.326
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass	-0.622
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass	-0.494
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass	0.128
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass	0.173
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass	-0.186
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass	1.034
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass	0.673
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass	0.559

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

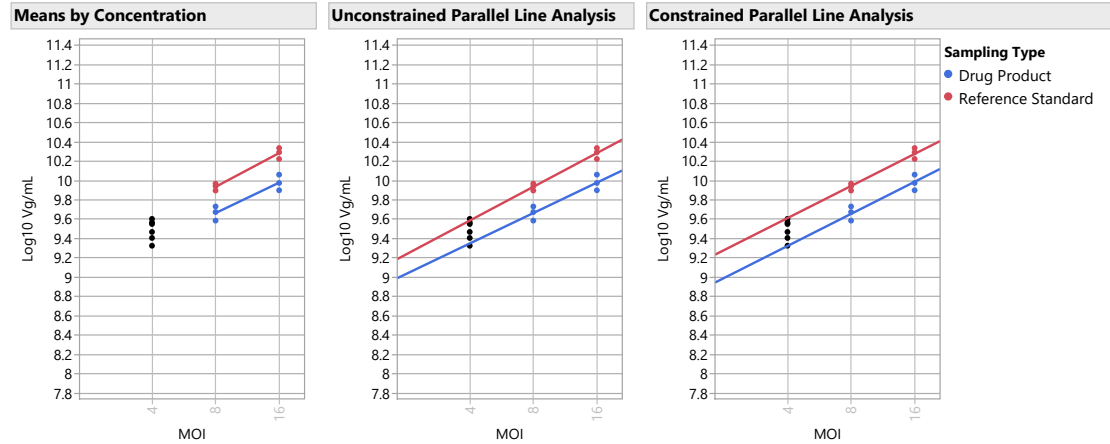
50% L01-240910\_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
50% L01-240910_1	.	3	1.7e+10	1.91e+9
50% L01-240910_1	4e+0	3	2.54e+9	4.13e+8
50% L01-240910_1	8e+0	3	4.66e+9	7.76e+8
50% L01-240910_1	1.6e+1	3	9.65e+9	1.8e+9

50% L01-240910\_1 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.901	0.000	0.946	0.064 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.814	1.501	0.971	0.058 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.729	0.000	0.947	0.056 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.886	0.928	0.965	0.056 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.870	0.000	0.927	0.059 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.828	4.039	0.968	0.064 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.800	3.900	0.948	0.060 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.755	0.000	0.977	0.062 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.742	1.009	0.978	0.054 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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.089	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.901	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.138	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

EC50 Ref	EC50 Test	RI		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
8.37	15.29	Uncorrected	Reference CF	0	54.8	62.1	46.5	150	50	15.6	15.6	Bioassay Results are Reportable	Assay is Valid and Within Limits

Relative Infectivity Delta		
Unconstrained RI	Constrained RI	Infectivity Delta
54.7	54.8	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.5	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	4.418e+10	19996	1117564494.5	2.5297475867	.	.	10.645195405	6.522	Pass	.	.
150% L01-240910_1	26	2	2.550e+10	20365.5	562893082.9	2.2074702976	1.6e+1	1.2041199827	10.406531043	80.472	Pass	1.547	Ok
150% L01-240910_1	27	2	1.230e+10	20080.5	129517198.73	1.0529509883	8e+0	0.903089987	10.089919286	5.187	Pass	-0.078	Ok
150% L01-240910_1	28	2	7.105e+9	20666.5	120860492.39	1.7010399847	4e+0	0.6020599913	9.851569837	0.478	Pass	0.816	Ok
150% L01-240910_1	29	2	4.324e+10	19797	760109575.1	1.7580116665	.	.	10.635854451	0.430	Pass	.	.
150% L01-240910_1	30	2	2.298e+10	20092.5	31656665.012	0.1377308391	1.6e+1	1.2041199827	10.361433967	0.682	Pass	0.044	Ok
150% L01-240910_1	31	2	1.094e+10	20710	52721619.976	0.4817384535	8e+0	0.903089987	10.039177432	1.154	Pass	-1.616	Ok
150% L01-240910_1	32	2	7.215e+9	20526	88293615.492	1.2237302372	4e+0	0.6020599913	9.8582436097	0.981	Pass	1.041	Ok
150% L01-240910_1	33	2	4.301e+10	19822.5	1751865687.7	4.073324556	.	.	10.633551791	1.051	Pass	.	.
150% L01-240910_1	34	2	2.294e+10	20557	341864810.14	1.49026602	1.6e+1	1.2041199827	10.3605906	0.732	Pass	0.019	Ok
150% L01-240910_1	35	2	1.127e+10	20848	21155586.254	0.1877249333	8e+0	0.903089987	10.051903106	0.368	Pass	-1.183	Ok
150% L01-240910_1	36	2	6.536e+9	20632	262772342.09	4.0203525339	4e+0	0.6020599913	9.8153155151	8.021	Pass	-0.312	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass	.	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass	-2.282	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass	-0.984	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass	-0.776	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass	.	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass	0.199	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass	0.269	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass	-0.289	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass	.	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass	1.702	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass	1.069	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass	0.881	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

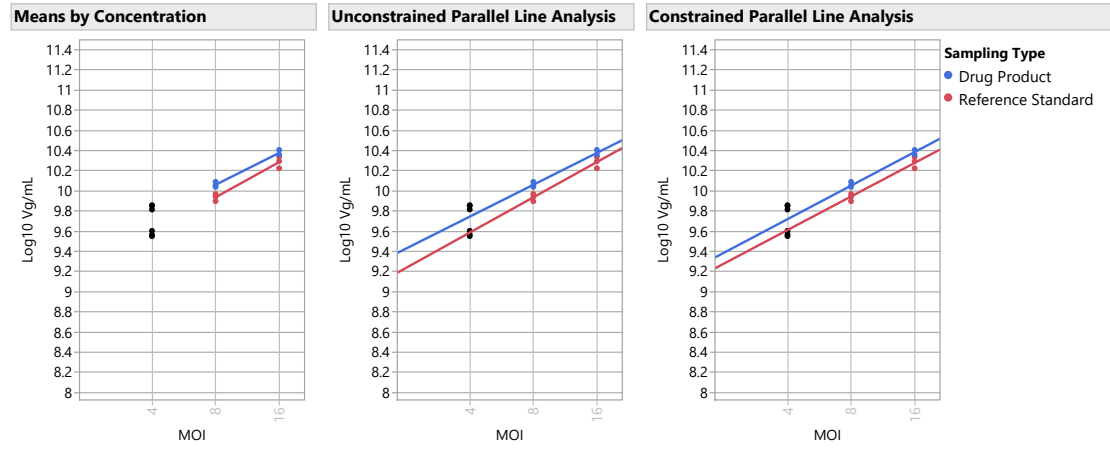
150% L01-240910\_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
150% L01-240910_1	.	3	4.3e+10	6.19e+8
150% L01-240910_1	4e+0	3	6.95e+9	3.64e+8
150% L01-240910_1	8e+0	3	1.2e+10	7.08e+8
150% L01-240910_1	1.6e+1	3	2.4e+10	1.47e+9

150% L01-240910\_1 Model Selection

Model	Parallelism	Linearity	R2	RMSE	Validity Evaluation	Selected Model
	Slope Ratio	Ratio				
Model 2, Low Standard and Test Doses Excluded	0.904	0.000	0.969	0.039	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.751	3.401	0.985	0.037	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.888	0.927	0.989	0.035	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.873	0.000	0.993	0.029	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.765	8.009	0.972	0.040	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.738	7.609	0.988	0.034	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.626	0.000	0.966	0.038	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.615	1.089	0.984	0.035	Fails Parallelism and is Linear	
Model 3, High Standard and Test Doses Excluded	0.604	0.000	0.983	0.029	Fails Parallelism and is Linear	

150% L01-240910\_1 Graphs



150% L01-240910\_1 Validity Report

Validity Criteria	Validity		Overall Validity
	LSL	USL	
Dose Response Test	.	0.05	0.000 Passed Validity Criteria
Reference Standard Curve Depth	2720000000	.	35056142037 Passed Validity Criteria
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.072 Passed Validity Criteria
Parallelism Slope Ratio	0.7	1.4	0.904 Passed Validity Criteria
Linearity Ratio	.	26.3	0.000 Passed Validity Criteria
Unconstrained EC50 Standard	0.04	61.8	9.138 Passed Validity Criteria
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000 Passed Validity Criteria

150% L01-240910\_1 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 %			OOS Validity
12.66		10.11		Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
12.66		10.11		125.1	0	0	125.1	135.3	116.4	150	50	18.9	18.9	Bioassay Results are Reportable	Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
125.2		125.1		0.1											
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio											
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	5.344e+10	19290.5	80196876.213	0.1500625229	.	.	10.727885209	2.668	Pass	.	.
200% L01-240910	38	2	3.096e+10	19264.5	154005481.06	0.4974087484	1.6e+1	1.2041199827	10.490822758	6.431	Pass	1.291	Ok
200% L01-240910	39	2	1.470e+10	20635	560906281.84	3.8146779658	8e+0	0.903089987	10.167432423	1.692	Pass	-0.610	Ok
200% L01-240910	40	2	1.091e+10	20539	257568089.92	2.3602328346	4e+0	0.6020599913	10.03793721	7.404	Pass	3.320	Ok
200% L01-240910	41	2	5.776e+10	19541.5	249954306.34	0.4327798418	.	.	10.7615936	1.727	Pass	.	.
200% L01-240910	42	2	2.763e+10	20939.5	269194304.26	0.9743799903	1.6e+1	1.2041199827	10.44133751	1.057	Pass	-0.059	Ok
200% L01-240910	43	2	1.404e+10	19917	594811930.38	4.2353940345	8e+0	0.903089987	10.14748585	2.738	Pass	-1.114	Ok
200% L01-240910	44	2	8.118e+9	19609.5	102821370.74	1.2666382592	4e+0	0.6020599913	9.9094307874	1.006	Pass	-0.892	Ok
200% L01-240910	45	2	5.595e+10	19982	932086203.29	1.6659818239	.	.	10.747785821	0.115	Pass	.	.
200% L01-240910	46	2	2.829e+10	19188	978378731.34	3.4586506089	1.6e+1	1.2041199827	10.451600311	0.427	Pass	0.206	Ok
200% L01-240910	47	2	1.443e+10	20530.5	91625658.209	0.6348367112	8e+0	0.903089987	10.159355074	0.127	Pass	-0.809	Ok
200% L01-240910	48	2	8.605e+9	20956.5	277911220.03	3.2296461072	4e+0	0.6020599913	9.9347511442	0.461	Pass	-0.215	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass	.	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass	-1.821	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass	-0.821	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass	-0.649	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass	.	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass	0.167	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass	0.226	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass	-0.244	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass	.	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass	1.391	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass	0.890	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass	0.737	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

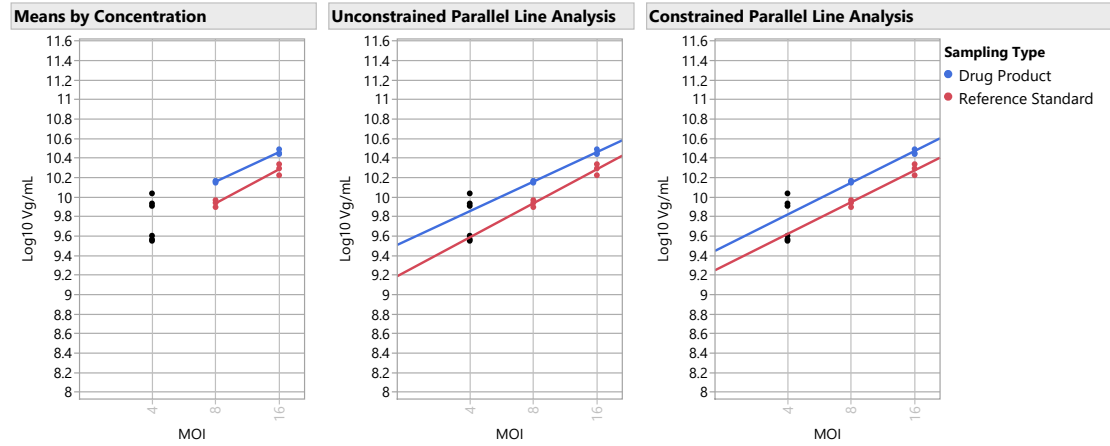
200% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
200% L01-240910	.	3	5.6e+10	2.17e+9
200% L01-240910	4e+0	3	9.21e+9	1.49e+9
200% L01-240910	8e+0	3	1.4e+10	3.32e+8
200% L01-240910	1.6e+1	3	2.9e+10	1.77e+9

200% L01-240910 Model Selection

Model	Parallelism	Linearity	R2	RMSE	Validity Evaluation	Selected Model
	Slope Ratio	Ratio				
Model 2, Low Standard and Test Doses Excluded	0.868	0.000	0.976	0.037	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.704	3.849	0.982	0.044	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.852	0.945	0.991	0.033	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.838	0.000	0.996	0.027	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.716	8.977	0.958	0.048	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.691	8.492	0.984	0.043	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.565	0.000	0.930	0.048	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.555	1.130	0.977	0.043	Fails Parallelism and is Linear	
Model 3, High Standard and Test Doses Excluded	0.545	0.000	0.975	0.041	Fails Parallelism and is Linear	

200% L01-240910 Graphs



200% L01-240910 Validity Report

Validity Criteria	LSL		USL		Validity Results	Assay Validity	Overall Validity
	.		0.05		0.000	Passed Validity Criteria	Assay is Valid
Dose Response Test	.		0.05		0.000	Passed Validity Criteria	
Reference Standard Curve Depth	2720000000		.		35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.		15		0.327	Passed Validity Criteria	
Parallelism Slope Ratio	0.7		1.4		0.868	Passed Validity Criteria	
Linearity Ratio	.		26.3		0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04		61.8		9.138	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 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range as %			OOS Validity
13.98		9.16		Uncorrected	Reference CF							CI Range	of Tolerance	CI Range % of Tolerance	
13.98		9.16		152.6	0	0	152.6	166.1	141.5	150	50	24.6	24.6	Bioassay Results are Reportable	Assay is Valid and OOS
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
152.9		152.6		0.3											
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio											
1.4		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	3.683e+10	19073.5	1778869003.2	4.8304881343	.	.	10.566152948	0.971	Pass	.	.
100% L01-240910	50	2	1.680e+10	19201	199492668.93	1.1876932528	1.6e+1	1.2041199827	10.225222651	5.468	Pass	-1.555	Ok
100% L01-240910	51	2	7.499e+9	19370	678147945.98	9.0435733427	8e+0	0.903089987	9.8749843856	2.185	Pass	-1.447	Ok
100% L01-240910	52	2	3.707e+9	19538	299090113.23	8.0676914922	4e+0	0.6020599913	9.5690527747	0.450	Pass	-0.194	Ok
100% L01-240910	53	2	3.785e+10	18893	3580292594.9	9.459908583	.	.	10.578031581	0.485	Pass	.	.
100% L01-240910	54	2	1.945e+10	18662.5	1149824505.5	5.9125325644	1.6e+1	1.2041199827	10.288858015	0.383	Pass	0.528	Ok
100% L01-240910	55	2	8.368e+9	19716.5	128843280.71	1.5397191217	8e+0	0.903089987	9.9226202714	0.016	Pass	-0.027	Ok
100% L01-240910	56	2	3.646e+9	20386.5	178059200.32	4.8830356341	4e+0	0.6020599913	9.561874525	1.022	Pass	-0.417	Ok
100% L01-240910	57	2	4.332e+10	20021.5	1706528670.2	3.9391021166	.	.	10.636716349	8.291	Pass	.	.
100% L01-240910	58	2	2.023e+10	19822.5	2634087129.5	13.017781226	1.6e+1	1.2041199827	10.306093168	1.127	Pass	1.098	Ok
100% L01-240910	59	2	9.200e+9	20137.5	101459939.16	1.1028389063	8e+0	0.903089987	9.9637825187	2.060	Pass	1.166	Ok
100% L01-240910	60	2	3.981e+9	19947.5	380929556.42	9.5696095024	4e+0	0.6020599913	9.5999504547	7.068	Pass	0.770	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass	.	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass	-2.292	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass	-0.987	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass	-0.778	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass	.	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass	0.199	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass	0.270	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass	-0.290	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass	.	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass	1.709	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass	1.072	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass	0.885	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

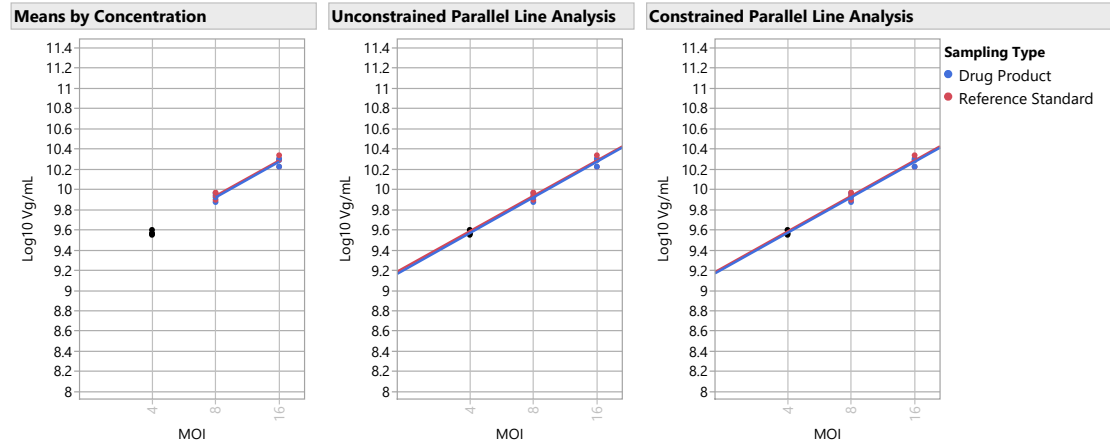
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
100% L01-240910	.	3	3.9e+10	3.49e+9
100% L01-240910	4e+0	3	3.78e+9	1.78e+8
100% L01-240910	8e+0	3	8.36e+9	8.51e+8
100% L01-240910	1.6e+1	3	1.9e+10	1.8e+9

100% L01-240910 Model Selection

Model	Parallelism	Linearity	Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation
Model 2, Low Standard and Test Doses Excluded	1.010	0.000	0.957	0.046 Parallel and Linear
Model 1, All Doses	0.979	0.108	0.987	0.037 Parallel and Linear
Model 3, High Standard and Test Doses Excluded	0.949	0.000	0.977	0.033 Parallel and Linear
Model 4, Standard Low Dose Only Excluded	0.996	0.676	0.983	0.040 Parallel and Linear
Model 6, Test Low Dose Only Excluded	0.992	0.879	0.983	0.041 Parallel and Linear
Model 8, Standard Low Dose and Test High Dose Excluded	0.983	0.000	0.982	0.042 Parallel and Linear
Model 9, Standard High Dose and Test Low Dose Excluded	0.975	0.000	0.984	0.038 Parallel and Linear
Model 7, Test High Dose Only Excluded	0.966	0.894	0.986	0.038 Parallel and Linear
Model 5, Standard High Dose Only Excluded	0.962	0.663	0.988	0.034 Parallel and Linear

100% L01-240910 Graphs



100% L01-240910 Validity Report

Validity Criteria	LSL	USL	Validity Results	Overall Validity
Dose Response Test	.	0.05	0.000 Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	35056142037 Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.000 Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.010 Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000 Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.138 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

EC50 Ref		EC50 Test		RI		Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range as % of Tolerance		OOS Validity
11.16	11.47	97.3	0	0	0	0	97.3	105.4	89.8	150	50	15.5	15.5	Bioassay Results are Reportable Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta										
97.3		97.3		0.0										
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit										
0.9		0.3		1.0										

50% L01-240910\_2 & 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	
50% L01-240910_2	61	2	1.834e+10	19737	203751104.97	1.1111170816	.	.	.	10.263340148	2.562	Pass	.	.	.
50% L01-240910_2	62	2	1.130e+10	20211	262898579.74	2.3266742485	1.6e+1	1.2041199827	10.053052657	2.246	Pass		1.868	Ok	
50% L01-240910_2	63	2	5.357e+9	21162.5	66651202.129	1.2441699278	8e+0	0.903089987	9.7289282868	2.055	Pass		0.996	Ok	
50% L01-240910_2	64	2	2.820e+9	19762	168860802.11	5.9869546674	4e+0	0.6020599913	9.4503228782	1.566	Pass		1.503	Ok	
50% L01-240910_2	65	2	1.644e+10	20267.5	452436562.64	2.7520219303	.	.	10.215905804	0.095	Pass		.	.	.
50% L01-240910_2	66	2	9.639e+9	19391	154759020.72	1.6054847679	1.6e+1	1.2041199827	9.9840497834	0.030	Pass		0.271	Ok	
50% L01-240910_2	67	2	4.560e+9	21001	18127.742997	0.000397543	8e+0	0.903089987	9.6589596546	0.017	Pass		-0.309	Ok	
50% L01-240910_2	68	2	2.548e+9	19777.5	91143848.022	3.5773123313	4e+0	0.6020599913	9.4061705006	0.173	Pass		0.504	Ok	
50% L01-240910_2	69	2	1.499e+10	19994	579169394.77	3.8628534835	.	.	10.175897368	1.786	Pass		.	.	.
50% L01-240910_2	70	2	8.114e+9	20973	65816734.103	0.8111860937	1.6e+1	1.2041199827	9.9092158315	2.007	Pass		-1.314	Ok	
50% L01-240910_2	71	2	3.723e+9	20849	22105610.024	0.5936871551	8e+0	0.903089987	9.5709448514	2.191	Pass		-2.242	Ok	
50% L01-240910_2	72	2	2.099e+9	20993	13367658.82	0.6368196257	4e+0	0.6020599913	9.3220389135	3.035	Pass		-1.264	Ok	
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass		.	.	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass		-1.357	Ok	
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass		-0.635	Ok	
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass		-0.504	Ok	
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass		.	.	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass		0.131	Ok	
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass		0.177	Ok	
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass		-0.190	Ok	
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass		.	.	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass		1.056	Ok	
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass		0.687	Ok	
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass		0.571	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

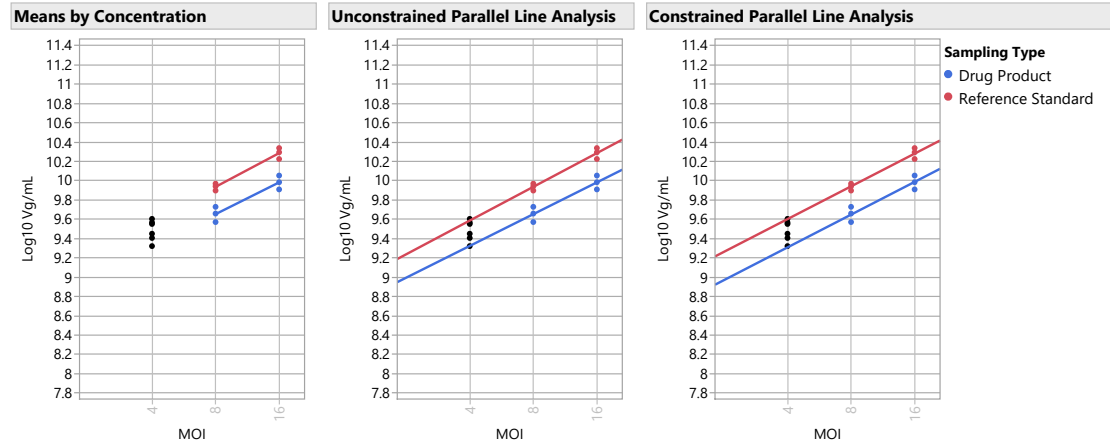
50% L01-240910\_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
50% L01-240910_2	.	3	1.7e+10	1.68e+9
50% L01-240910_2	4e+0	3	2.49e+9	3.64e+8
50% L01-240910_2	8e+0	3	4.55e+9	8.17e+8
50% L01-240910_2	1.6e+1	3	9.68e+9	1.59e+9

50% L01-240910\_2 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model	
Model 2, Low Standard and Test Doses Excluded	0.942	0.000	0.950	0.063 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.828	2.175	0.973	0.056 Parallel and Linear		
Model 3, High Standard and Test Doses Excluded	0.719	0.000	0.948	0.056 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.925	0.909	0.966	0.055 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.909	0.000	0.932	0.058 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.843	5.419	0.970	0.062 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.814	5.205	0.951	0.059 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	0.744	0.000	0.978	0.061 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.731	1.015	0.979	0.054 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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.029	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.942	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.138	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
8.39	15.26	54.9	0	0	54.9	62.0	47.1	150	50	14.9	14.9	Bioassay Results are Reportable	Assay is Valid and Within Limits

Relative Infectivity Delta			
Unconstrained RI	Constrained RI	Infectivity Delta	
54.9	54.9	0.0	

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	4.494e+10	20268.5	1382444686.6	3.0760724392	.	.	10.652651205	1.953	Pass	.	.
150% L01-240910_2	74	2	2.566e+10	20858	639666646.59	2.4930803141	1.6e+1	1.2041199827	10.409217437	3.857	Pass	1.639	Ok
150% L01-240910_2	75	2	1.222e+10	20415.5	212403284.41	1.7378576067	8e+0	0.903089987	10.087147039	5.758	Pass	-0.306	Ok
150% L01-240910_2	76	2	7.248e+9	19921	49605155.379	0.6844349971	4e+0	0.6020599913	9.8601946062	0.933	Pass	0.942	Ok
150% L01-240910_2	77	2	4.381e+10	19580	1157150209.5	2.6411706984	.	.	10.641593268	0.045	Pass	.	.
150% L01-240910_2	78	2	2.344e+10	20742.5	482974557.86	2.0600966742	1.6e+1	1.2041199827	10.370036653	0.269	Pass	0.224	Ok
150% L01-240910_2	79	2	1.144e+10	20183	480465980.94	4.1993236748	8e+0	0.903089987	10.058483293	1.103	Pass	-1.203	Ok
150% L01-240910_2	80	2	7.163e+9	19195	3819839.2688	0.0533236786	4e+0	0.6020599913	9.8551249868	0.513	Pass	0.764	Ok
150% L01-240910_2	81	2	4.253e+10	19371.5	109815609.98	0.2582091481	.	.	10.628692453	2.312	Pass	.	.
150% L01-240910_2	82	2	2.245e+10	20023.5	582856847.74	2.596168258	1.6e+1	1.2041199827	10.351229067	1.342	Pass	-0.387	Ok
150% L01-240910_2	83	2	1.161e+10	20684	214437339.99	1.8466429905	8e+0	0.903089987	10.064917469	0.398	Pass	-0.988	Ok
150% L01-240910_2	84	2	6.636e+9	19439	77730062.789	1.1713325325	4e+0	0.6020599913	9.821908813	9.576	Pass	-0.329	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	.	.	10.56893682	0.993	Pass	.	.
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	1.6e+1	1.2041199827	10.224314572	2.677	Pass	-2.481	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	8e+0	0.903089987	9.8972706745	2.803	Pass	-1.048	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	4e+0	0.6020599913	9.5512272121	1.253	Pass	-0.824	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	.	.	10.577690117	0.469	Pass	.	.
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	1.6e+1	1.2041199827	10.293937987	0.116	Pass	0.211	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	8e+0	0.903089987	9.9414859483	0.137	Pass	0.285	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	4e+0	0.6020599913	9.5666065868	0.313	Pass	-0.307	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	.	.	10.618589688	7.706	Pass	.	.
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	1.6e+1	1.2041199827	10.337832323	1.723	Pass	1.829	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	8e+0	0.903089987	9.9689589413	1.661	Pass	1.139	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	4e+0	0.6020599913	9.6040850374	4.371	Pass	0.938	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

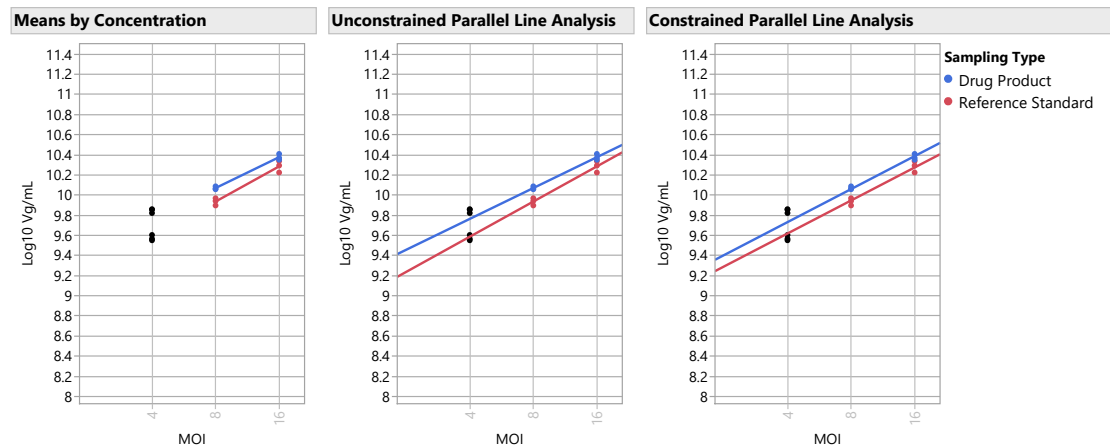
150% L01-240910\_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.9e+10	2.4e+9
Ref.Std (L01-240910)	4e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	8e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.51e+9
150% L01-240910_2	.	3	4.4e+10	1.21e+9
150% L01-240910_2	4e+0	3	7.02e+9	3.31e+8
150% L01-240910_2	8e+0	3	1.2e+10	4.1e+8
150% L01-240910_2	1.6e+1	3	2.4e+10	1.64e+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	0.877	0.000	0.970	0.038	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.747	2.806	0.987	0.035	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.862	0.940	0.989	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.847	0.000	0.994	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.760	6.774	0.975	0.038	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.734	6.466	0.990	0.031	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.642	0.000	0.969	0.036	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.631	1.078	0.986	0.033	Fails Parallelism and is Linear	
Model 3, High Standard and Test Doses Excluded	0.620	0.000	0.987	0.026	Fails Parallelism and is Linear	

150% L01-240910\_2 Graphs





Validity Criteria	LSL		USL		Validity		Overall Validity
					Results	Assay Validity	
Dose Response Test			0.05		0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000				35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)			15		0.130	Passed Validity Criteria	
Parallelism Slope Ratio	0.7		1.4		0.877	Passed Validity Criteria	
Linearity Ratio			26.3		0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04		61.8		9.138	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
12.75	10.04	126.9	0	0	126.9	137.4	117.9	150	50	19.5	19.5	Bioassay Results are Reportable Assay is Valid and Within Limits		
		Relative												
Unconstrained RI	Constrained RI	Infectivity Delta												
127.1	126.9	0.1												
Infectious	Infectious Particle	Infectious Particle												
Particle Ratio	Ratio Lower Limit	Ratio Upper Limit												
1.1	0.3	1.0												

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious		RI Lower 95	RI Upper 95
			Ratio	Reportable RI		
50% L01-240910_1	8.3717813229	15.289458129	0.5	54.8	46.5	62.1
150% L01-240910_1	12.656164414	10.113648639	1.1	125.1	116.4	135.3
200% L01-240910	13.977020322	9.1578889526	1.4	152.6	141.5	166.1
100% L01-240910	11.161706252	11.467780741	0.9	97.3	89.8	105.4
50% L01-240910_2	8.3865697324	15.262497551	0.5	54.9	47.1	62.0
150% L01-240910_2	12.746541619	10.041939518	1.1	126.9	117.9	137.4

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

	Date Assay		Bioassay		Analyst		Instrument		Bioassay preparation		Bioassay review	
Assay	Site:	Initiated:	Purpose:	Run Number	Name:	Signal	Method	Instrument ID	internal no.	(date_operator)	(date_reviewer)	
Astellas BQT Infectivity			PLA	BQT Test Run 3		Vg/mL	KT430					
Notes												
Assay Range Check												

Materials

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

Reference Details

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



[illegible]

BQT Infectivity\_13Nov2024-13-51-45

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		
B06	8	50	REP3		BDNF	537.3498535	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19064	6990	12074
A06	16	50	REP3		BDNF	984.0247192	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19568	11090	8478
E10	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19747	0	19747
E11	NTC				BDNF	0.34029907	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					20746	6	20740
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19958	0	19958
F10	PC				BDNF	1509.848633	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19141	13837	5304
F11	PC				BDNF	1421.419922	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19171	13444	5727
F12	PC				BDNF	1506.818848	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					18865	13624	5241

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		
D01	2	RS	REP1		BDNF	121.4333801	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19741	1936	17805
C01	4	RS	REP1		BDNF	267.2140503	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19219	3905	15314
B01	8	RS	REP1		BDNF	548.1389771	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20030	7460	12570
A01	16	RS	REP1		BDNF	1253.342529	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19361	12689	6672
D10	2	200	REP1		BDNF	369.8317871	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21528	5807	15721
C10	4	200	REP1		BDNF	503.3505554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20963	7297	13666
B10	8	200	REP1		BDNF	1035.681763	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20128	11782	8346
A10	16	200	REP1		BDNF	1779.52002	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19343	15081	4262
H07	2	150.2	REP1		BDNF	240.4176788	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19548	3613	15935
G07	4	150.2	REP1		BDNF	402.3980713	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20502	5939	14563
F07	8	150.2	REP1		BDNF	840.1790161	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20639	10534	10105
E07	16	150.2	REP1		BDNF	1465.478027	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20191	14381	5810
D07	2	150	REP1		BDNF	239.6851807	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20790	3832	16958
C07	4	150	REP1		BDNF	413.0661316	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20389	6037	14352
B07	8	150	REP1		BDNF	836.7145996	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20505	10436	10069
A07	16	150	REP1		BDNF	1446.222656	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19641	13896	5745
H01	2	100.2	REP1		BDNF	130.6248779	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19355	2034	17321
G01	4	100.2	REP1		BDNF	265.9398499	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19820	4010	15810
F01	8	100.2	REP1		BDNF	564.5903931	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18255	6958	11297
E01	16	100.2	REP1		BDNF	1269.457153	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19528	12890	6638
H04	2	50.2	REP1		BDNF	97.9960556	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19957	1595	18362
G04	4	50.2	REP1		BDNF	180.1403809	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20997	2981	18016
F04	8	50.2	REP1		BDNF	382.8408813	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20128	5591	14537
E04	16	50.2	REP1		BDNF	606.4475708	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19308	7777	11531
D04	2	50	REP1		BDNF	99.47064209	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20031	1624	18407
C04	4	50	REP1		BDNF	175.9420166	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20388	2832	17556
B04	8	50	REP1		BDNF	381.4729919	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20626	5712	14914
A04	16	50	REP1		BDNF	590.8175659	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19843	7834	12009
D02	2	RS	REP2		BDNF	123.2781067	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20315	2021	18294
C02	4	RS	REP2		BDNF	282.6411133	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19816	4232	15584
B02	8	RS	REP2		BDNF	632.5710449	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19382	8061	11321
A02	16	RS	REP2		BDNF	1198.491821	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19177	12253	6924
D11	2	200	REP2		BDNF	273.012146	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21178	4386	16792
C11	4	200	REP2		BDNF	482.1478271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21604	7264	14340
B11	8	200	REP2		BDNF	914.5630493	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21292	11506	9786
A11	16	200	REP2		BDNF	1931.075928	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19256	15526	3730
H08	2	150.2	REP2		BDNF	238.8732147	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19232	3534	15698
G08	4	150.2	REP2		BDNF	392.708313	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21543	6114	15429
F08	8	150.2	REP2		BDNF	792.859375	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20822	10209	10613
E08	16	150.2	REP2		BDNF	1433.126343	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20448	14400	6048
D08	2	150	REP2		BDNF	242.5851288	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20523	3824	16699
C08	4	150	REP2		BDNF	366.0437927	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20648	5521	15127
B08	8	150	REP2		BDNF	765.4019165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20610	9857	10753
A08	16	150	REP2		BDNF	1423.313721	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19450	13649	5801
H02	2	100.2	REP2		BDNF	117.3526306	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20972	1991	18981
G02	4	100.2	REP2		BDNF	275.8955688	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19972	4175	15797
F02	8	100.2	REP2		BDNF	621.1397705	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18513	7594	10919
E02	16	100.2	REP2		BDNF	1177.178711	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20005	12650	7355
H05	2	50.2	REP2		BDNF	87.07595825	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19764	1410	18354
G05	4	50.2	REP2		BDNF	151.9986115	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21353	2588	18765
F05	8	50.2	REP2		BDNF	324.9608765	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19859	4793	15066
E05	16	50.2	REP2		BDNF	537.3410034	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19847	7277	12570
D05	2	50	REP2		BDNF	85.9803009	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20333	1433	18900
C05	4	50	REP2		BDNF	159.8617554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM							