



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_Plate01_KL-S3	18OCT2024_Plate01_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	1.797e+10	19656.5	359645621.8	2.0013493063	.	.	10.254551883	3.508	Pass	.
50% L01-240910_1	14	2	1.130e+10	20631	235053015.22	2.0794349286	1.6e+1	1.2041199827	10.053220492	4.319	Pass	2.429
50% L01-240910_1	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	8e+0	0.903089987	9.7197899954	2.437	Pass	0.969
50% L01-240910_1	16	2	2.863e+9	20059	133535135.16	4.6637199832	4e+0	0.6020599913	9.4568630835	2.669	Pass	1.718
50% L01-240910_1	17	2	1.555e+10	19717.5	489935793.6	3.1497867731	.	.	10.191858014	0.233	Pass	.
50% L01-240910_1	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	1.6e+1	1.2041199827	9.9503544163	0.309	Pass	-0.157
50% L01-240910_1	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	8e+0	0.903089987	9.6479750835	0.071	Pass	-0.433
50% L01-240910_1	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	4e+0	0.6020599913	9.3904622856	0.115	Pass	0.149
50% L01-240910_1	21	2	1.433e+10	18854	691328511.13	4.8227318281	.	.	10.156391355	1.421	Pass	.
50% L01-240910_1	22	2	7.986e+9	19410.5	272371628.48	3.410460901	1.6e+1	1.2041199827	9.9023487925	1.261	Pass	-1.237
50% L01-240910_1	23	2	3.792e+9	19610	17206271.137	0.4537112028	8e+0	0.903089987	9.5789072595	1.863	Pass	-1.993
50% L01-240910_1	24	2	2.165e+9	19152	13728570.717	0.6341816577	4e+0	0.6020599913	9.3354116483	1.726	Pass	-1.055
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	.	.	10.539987978	1.175	Pass	.
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass	-1.298
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass	-0.761
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass	-0.066
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	.	.	10.55804215	0.356	Pass	.
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass	0.188
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass	0.070
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass	-0.228
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	.	.	10.608484012	4.985	Pass	.
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass	1.230
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass	0.443
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass	0.427

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

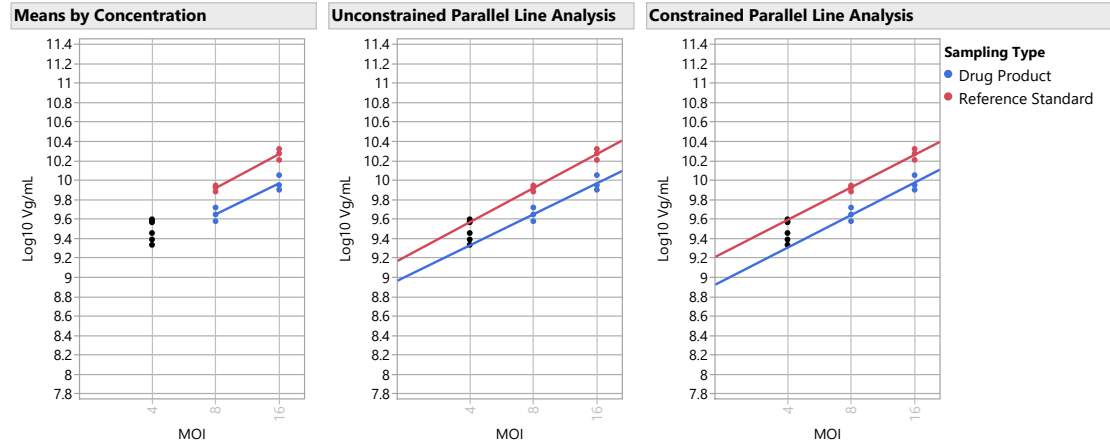
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
50% L01-240910_1	.	3	1.6e+10	1.85e+9
50% L01-240910_1	4e+0	3	2.5e+9	3.51e+8
50% L01-240910_1	8e+0	3	4.49e+9	7.28e+8
50% L01-240910_1	1.6e+1	3	9.4e+9	1.71e+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	0.911	0.000	0.951	0.062 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.833	3.064	0.974	0.054 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.752	0.000	0.955	0.050 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.944	0.000	0.932	0.055 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.927	0.931	0.967	0.053 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.848	5.148	0.953	0.055 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.818	5.154	0.971	0.060 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.739	1.028	0.981	0.049 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.726	0.000	0.980	0.057 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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.071	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.911	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.336	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
8.42	15.20	55.4	0	0	55.4	62.4	47.6	150	50	14.8	14.8	Bioassay Results are Reportable Assay is Valid and Within Limits		

Unconstrained RI	Constrained RI	Relative Infectivity Delta
55.3	55.4	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	4.333e+10	19449.5	1415326191.4	3.2663094426	.	.	10.636799217	2.752	Pass	.	.
150% L01-240910_1	26	2	2.527e+10	19744	642816777.6	2.5434988531	1.6e+1	1.2041199827	10.402655657	13.343	Pass	1.672	Ok
150% L01-240910_1	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	8e+0	0.903089987	10.078682607	7.469	Pass	-0.289	Ok
150% L01-240910_1	28	2	7.037e+9	20511	40166095.497	0.5707730578	4e+0	0.6020599913	9.8473961516	0.935	Pass	1.001	Ok
150% L01-240910_1	29	2	4.278e+10	19064	380998669.04	0.8906886483	.	.	10.631197541	0.129	Pass	.	.
150% L01-240910_1	30	2	2.291e+10	19624.5	1437202301	6.2733021375	1.6e+1	1.2041199827	10.360021699	0.565	Pass	0.082	Ok
150% L01-240910_1	31	2	1.109e+10	20716	889172320.19	8.0163895138	8e+0	0.903089987	10.045007123	1.003	Pass	-1.405	Ok
150% L01-240910_1	32	2	6.959e+9	19792	77086896.492	1.1077457191	4e+0	0.6020599913	9.842540481	0.511	Pass	0.821	Ok
150% L01-240910_1	33	2	4.239e+10	18382	931314530.59	2.1969287211	.	.	10.627280412	1.685	Pass	.	.
150% L01-240910_1	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	1.6e+1	1.2041199827	10.35497881	0.865	Pass	-0.088	Ok
150% L01-240910_1	35	2	1.125e+10	20499	114153032.32	1.0149997396	8e+0	0.903089987	10.051021522	0.463	Pass	-1.186	Ok
150% L01-240910_1	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	4e+0	0.6020599913	9.8111713961	9.472	Pass	-0.255	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	.	.	10.539987978	1.175	Pass	.	.
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass	-2.312	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass	-1.257	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass	-0.106	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	.	.	10.55804215	0.356	Pass	.	.
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass	0.300	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass	0.111	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass	-0.365	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	.	.	10.608484012	4.985	Pass	.	.
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass	2.164	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass	0.715	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass	0.688	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

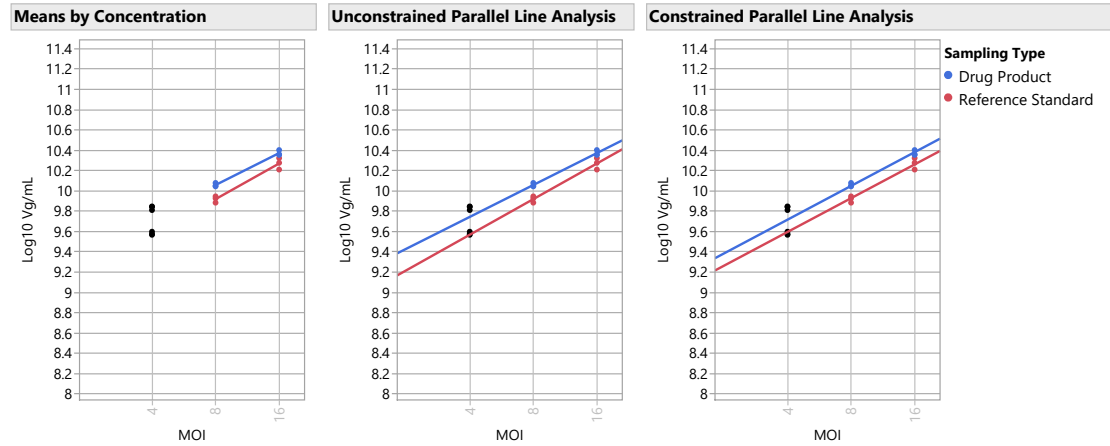
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
150% L01-240910_1	.	3	4.3e+10	4.72e+8
150% L01-240910_1	4e+0	3	6.82e+9	3.05e+8
150% L01-240910_1	8e+0	3	1.1e+10	4.78e+8
150% L01-240910_1	1.6e+1	3	2.4e+10	1.45e+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	0.896	0.000	0.973	0.036	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.781	4.157	0.988	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.928	0.000	0.995	0.024	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.912	0.939	0.991	0.032	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.796	7.276	0.991	0.029	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.768	7.342	0.976	0.037	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.663	0.000	0.989	0.022	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.651	1.082	0.987	0.031	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.640	0.000	0.971	0.035	Fails Parallelism and is Linear	

150% L01-240910_1 Graphs



150% 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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.098	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.896	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.336	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
12.83		9.98		Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
12.83		9.98		128.6	0	0	128.6	138.6	120.0	150	50	18.5	18.5	Bioassay Results are Reportable	Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
128.7		128.6		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	5.233e+10	18878	3273703267.4	6.2557892386				10.718757203	1.072	Pass		
200% L01-240910	38	2	3.009e+10	18845.5	740491509.11	2.4607466152	1.6e+1	1.2041199827	10.478453187	4.857	Pass		1.581	Ok
200% L01-240910	39	2	1.408e+10	20251	818244555.34	5.809870213	8e+0	0.903089987	10.148716693	1.385	Pass		-0.535	Ok
200% L01-240910	40	2	1.053e+10	20253.5	125817445.28	1.1943429664	4e+0	0.6020599913	10.022611806	50.409	Pass		3.452	Ok
200% L01-240910	41	2	5.709e+10	18423.5	293737605.16	0.5145218197			10.756555753	6.187	Pass			
200% L01-240910	42	2	2.693e+10	20411.5	185825277.73	0.6899810404	1.6e+1	1.2041199827	10.430267633	0.348	Pass		0.238	Ok
200% L01-240910	43	2	1.372e+10	20586.5	612192672.69	4.4622681989	8e+0	0.903089987	10.137332458	0.249	Pass		-0.806	Ok
200% L01-240910	44	2	8.036e+9	19101.5	405078446.6	5.0406160629	4e+0	0.6020599913	9.9050555168	0.668	Pass		-0.463	Ok
200% L01-240910	45	2	5.331e+10	19763	1654979461.6	3.1046232995			10.726783696	0.417	Pass			
200% L01-240910	46	2	2.585e+10	20229.5	2807020.1741	0.0108568237	1.6e+1	1.2041199827	10.412542748	1.189	Pass		-0.208	Ok
200% L01-240910	47	2	1.296e+10	19746.5	194907960.04	1.5039726731	8e+0	0.903089987	10.112589631	3.656	Pass		-1.452	Ok
200% L01-240910	48	2	7.965e+9	19460	83629922.415	1.0499404243	4e+0	0.6020599913	9.9011970368	0.747	Pass		-0.563	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913			10.539987978	1.175	Pass			
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass		-1.588	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass		-0.914	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass		-0.079	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559			10.55804215	0.356	Pass			
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass		0.223	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass		0.083	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass		-0.272	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946			10.608484012	4.985	Pass			
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass		1.500	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass		0.529	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass		0.510	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

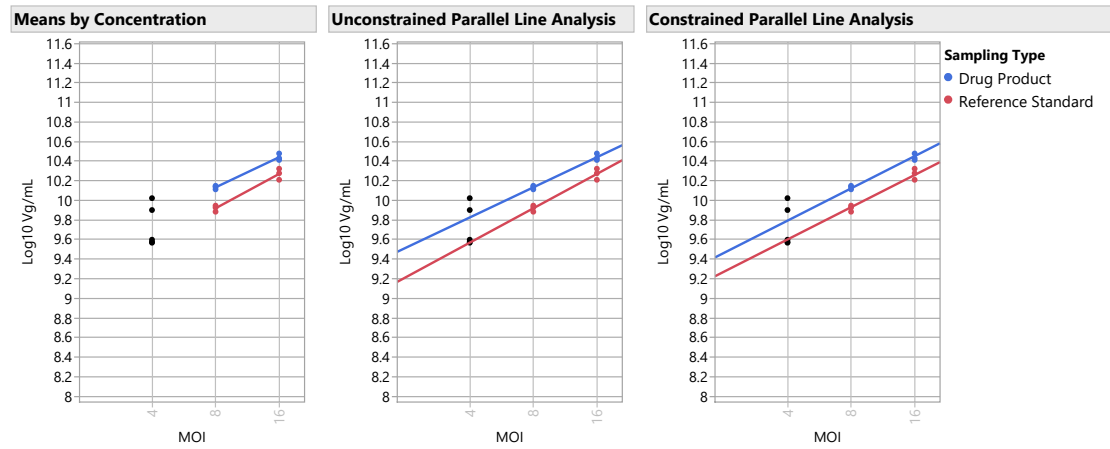
200% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
200% L01-240910	.	3	5.4e+10	2.51e+9
200% L01-240910	4e+0	3	8.85e+9	1.46e+9
200% L01-240910	8e+0	3	1.4e+10	5.74e+8
200% L01-240910	1.6e+1	3	2.8e+10	2.2e+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	0.876	0.000	0.974	0.038	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.721	5.475	0.980	0.045	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.908	0.000	0.995	0.026	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.892	0.948	0.991	0.033	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.735	9.816	0.982	0.045	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.709	10.003	0.954	0.050	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.561	0.000	0.974	0.040	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.551	1.152	0.977	0.042	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.541	0.000	0.930	0.048	Fails Parallelism and is Linear	

200% L01-240910 Graphs



200% L01-240910 Validity Report

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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.265	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.876	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.336	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 %			OOS Validity
				Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
13.85	9.24	149.8	0		0		149.8	163.2	138.9	150	50	24.3	24.3	Bioassay Results are Reportable	Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
150.1		149.8		0.3											
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	3.584e+10	18158.5	513669225.3	1.4330867287	.	.	10.554411073	1.078	Pass	.	.
100% L01-240910	50	2	1.644e+10	18226.5	20350893.08	0.1237600509	1.6e+1	1.2041199827	10.216002993	2.888	Pass	-1.895	Ok
100% L01-240910	51	2	7.608e+9	19725	256471113.81	3.3709586709	8e+0	0.903089987	9.8812850299	2.601	Pass	-1.157	Ok
100% L01-240910	52	2	3.716e+9	17735.5	289685040.08	7.7950422058	4e+0	0.6020599913	9.570107597	0.049	Pass	0.015	Ok
100% L01-240910	53	2	3.690e+10	19450	1728233892.7	4.6832199996	.	.	10.567057958	0.413	Pass	.	.
100% L01-240910	54	2	1.888e+10	18863.5	258789690.42	1.3710651781	1.6e+1	1.2041199827	10.27588887	0.151	Pass	0.311	Ok
100% L01-240910	55	2	8.320e+9	18746	56525600.254	0.6793927511	8e+0	0.903089987	9.9201242741	0.102	Pass	0.060	Ok
100% L01-240910	56	2	3.593e+9	12685.5	.	.	4e+0	0.6020599913	9.5554301725	1.940	Pass	-0.476	Ok
100% L01-240910	57	2	4.094e+10	18744	1870104954.7	4.5675232426	.	.	10.612185215	6.103	Pass	.	.
100% L01-240910	58	2	2.045e+10	20813.5	573367617.57	2.8035032798	1.6e+1	1.2041199827	10.310732093	1.624	Pass	1.604	Ok
100% L01-240910	59	2	8.852e+9	19702.5	137595150.53	1.5544659683	8e+0	0.903089987	9.9470219092	1.763	Pass	0.891	Ok
100% L01-240910	60	2	3.858e+9	19416	144262472.04	3.7393203403	4e+0	0.6020599913	9.586360698	2.330	Pass	0.561	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	.	.	10.539987978	1.175	Pass	.	.
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass	-2.267	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass	-1.238	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass	-0.104	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	.	.	10.55804215	0.356	Pass	.	.
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass	0.296	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass	0.110	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass	-0.360	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	.	.	10.608484012	4.985	Pass	.	.
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass	2.123	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass	0.705	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass	0.678	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

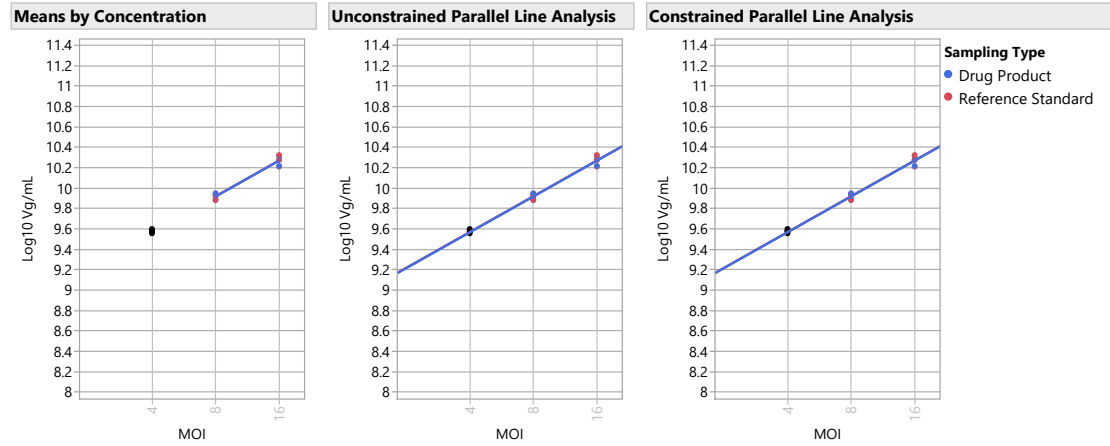
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
100% L01-240910	.	3	3.8e+10	2.69e+9
100% L01-240910	4e+0	3	3.72e+9	1.33e+8
100% L01-240910	8e+0	3	8.26e+9	6.24e+8
100% L01-240910	1.6e+1	3	1.9e+10	2.02e+9

100% L01-240910 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 2, Low Standard and Test Doses Excluded	1.001	0.000	0.960	0.044 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	1.011	0.658	0.989	0.034 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	1.020	0.000	0.985	0.026 Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.002	0.893	0.988	0.033 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.993	0.421	0.985	0.038 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.985	0.000	0.985	0.037 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.019	0.889	0.984	0.038 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	1.029	0.428	0.990	0.030 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	1.038	0.000	0.987	0.034 Parallel and Linear	

100% L01-240910 Graphs



100% 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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.001	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.336	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
11.28	11.34	99.5	0	0	0	0	99.5	107.3	92.2	150	50	15.1	15.1	Bioassay Results are Reportable Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta										
99.5		99.5		0.0										
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit										
0.8		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	1.807e+10	18507	67065519.327	0.371135865			.	10.256966367	3.436	Pass	.	.	.
50% L01-240910_2	62	2	1.102e+10	19613.5	190120617.32	1.7258574881	1.6e+1	1.2041199827	10.042024285	2.575	Pass		2.234	Ok	
50% L01-240910_2	63	2	5.159e+9	19546	199264473.2	3.8622715539	8e+0	0.903089987	9.7125870699	2.102	Pass		0.958	Ok	
50% L01-240910_2	64	2	2.761e+9	19386.5	142914635.79	5.1765314071	4e+0	0.6020599913	9.4410378536	2.485	Pass		1.554	Ok	
50% L01-240910_2	65	2	1.586e+10	19528	426059891.54	2.6857978728	.	.	10.200397327	0.224	Pass		.	.	.
50% L01-240910_2	66	2	9.172e+9	19640	381089296.09	4.1548290727	1.6e+1	1.2041199827	9.9624735888	0.098	Pass		0.152	Ok	
50% L01-240910_2	67	2	4.472e+9	20154	205743731.17	4.6005207441	8e+0	0.903089987	9.6505196182	0.005	Pass		-0.303	Ok	
50% L01-240910_2	68	2	2.420e+9	19772	116728454.59	4.8244854223	4e+0	0.6020599913	9.3837257373	0.080	Pass		0.169	Ok	
50% L01-240910_2	69	2	1.472e+10	19282.5	392975759.31	2.6697350163	.	.	10.167897604	1.440	Pass		.	.	.
50% L01-240910_2	70	2	7.776e+9	19753.5	311276312.65	4.0030128902	1.6e+1	1.2041199827	9.8907590846	1.778	Pass		-1.548	Ok	
50% L01-240910_2	71	2	3.776e+9	19467	89472972.022	2.3697464095	8e+0	0.903089987	9.5769899896	2.141	Pass		-2.013	Ok	
50% L01-240910_2	72	2	2.148e+9	19516	136835293.16	6.3705683843	4e+0	0.6020599913	9.332019945	1.832	Pass		-1.004	Ok	
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	.	.	10.539987978	1.175	Pass		.	.	.
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass		-1.357	Ok	
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass		-0.793	Ok	
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass		-0.069	Ok	
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	.	.	10.55804215	0.356	Pass		.	.	.
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass		0.195	Ok	
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass		0.073	Ok	
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass		-0.237	Ok	
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	.	.	10.608484012	4.985	Pass		.	.	.
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass		1.285	Ok	
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass		0.461	Ok	
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass		0.445	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

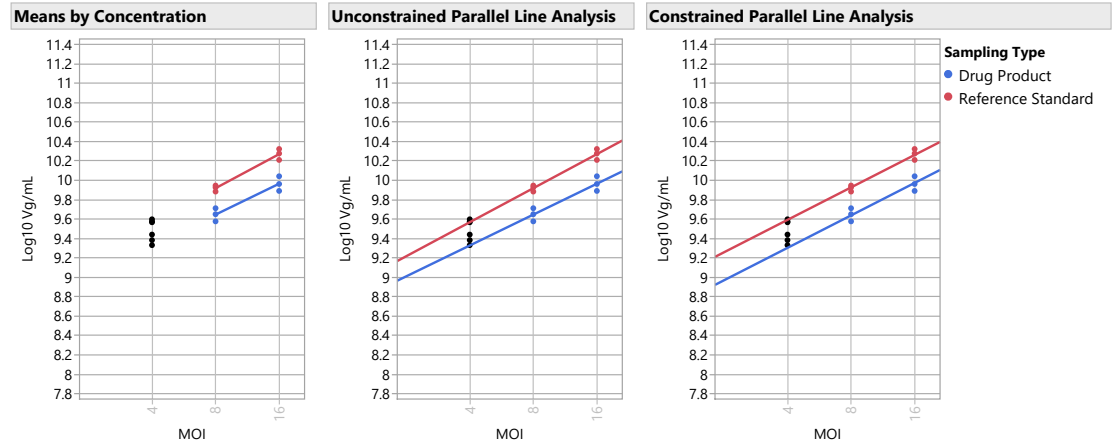
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
50% L01-240910_2	.	3	1.6e+10	1.7e+9
50% L01-240910_2	4e+0	3	2.44e+9	3.07e+8
50% L01-240910_2	8e+0	3	4.47e+9	6.92e+8
50% L01-240910_2	1.6e+1	3	9.32e+9	1.63e+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	0.907	0.000	0.953	0.060 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.840	2.744	0.976	0.052 Parallel and Linear		
Model 3, High Standard and Test Doses Excluded	0.771	0.000	0.961	0.047 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.940	0.000	0.935	0.054 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.924	0.933	0.969	0.052 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.856	4.517	0.958	0.053 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.826	4.511	0.974	0.058 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.757	1.017	0.983	0.047 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	0.744	0.000	0.982	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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.078	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.907	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.000	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	9.336	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	55.0	0	0	55.0	61.9	47.4	150	50	14.5	14.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Relative		
Unconstrained RI	Constrained RI	Infectivity Delta
54.9	55.0	0.1

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	4.346e+10	20242.5	164290989.13	0.3780442877	.	.	10.638071064	0.720	Pass	.	.
150% L01-240910_2	74	2	2.554e+10	19859.5	172756060.68	0.6764341882	1.6e+1	1.2041199827	10.407207743	18.374	Pass	1.622	Ok
150% L01-240910_2	75	2	1.238e+10	20354	532896929.11	4.304486152	8e+0	0.903089987	10.092721903	8.443	Pass	-0.063	Ok
150% L01-240910_2	76	2	6.956e+9	20033.5	95618993.904	1.3746652481	4e+0	0.6020599913	9.8423472161	0.242	Pass	0.613	Ok
150% L01-240910_2	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	.	.	10.635012399	161.86	Pass	.	.
150% L01-240910_2	78	2	2.312e+10	20364	1420489654.8	6.1439823415	1.6e+1	1.2041199827	10.363988116	0.602	Pass	-0.020	Ok
150% L01-240910_2	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	8e+0	0.903089987	10.054841391	0.966	Pass	-1.330	Ok
150% L01-240910_2	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	4e+0	0.6020599913	9.8550447888	1.400	Pass	1.092	Ok
150% L01-240910_2	81	2	4.346e+10	19857	175599334.22	0.4040901983	.	.	10.638044549	0.695	Pass	.	.
150% L01-240910_2	82	2	2.293e+10	20353	694780318.29	3.0304863146	1.6e+1	1.2041199827	10.36033518	0.820	Pass	-0.147	Ok
150% L01-240910_2	83	2	1.151e+10	19997.5	194500111.81	1.690454602	8e+0	0.903089987	10.060916343	0.489	Pass	-1.106	Ok
150% L01-240910_2	84	2	6.534e+9	19613	156104914.68	2.3889408814	4e+0	0.6020599913	9.8152111738	3.594	Pass	-0.338	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	.	.	10.539987978	1.175	Pass	.	.
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	1.6e+1	1.2041199827	10.210103028	2.499	Pass	-2.415	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	8e+0	0.903089987	9.8840460225	3.606	Pass	-1.301	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	4e+0	0.6020599913	9.5752976845	0.366	Pass	-0.109	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	.	.	10.55804215	0.356	Pass	.	.
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	1.6e+1	1.2041199827	10.276827009	0.083	Pass	0.309	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	8e+0	0.903089987	9.9268639631	0.243	Pass	0.115	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	4e+0	0.6020599913	9.5676487726	1.157	Pass	-0.376	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	.	.	10.608484012	4.985	Pass	.	.
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	1.6e+1	1.2041199827	10.3230886	1.823	Pass	2.257	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	8e+0	0.903089987	9.9463114	1.397	Pass	0.738	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	4e+0	0.6020599913	9.5985241259	5.157	Pass	0.710	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

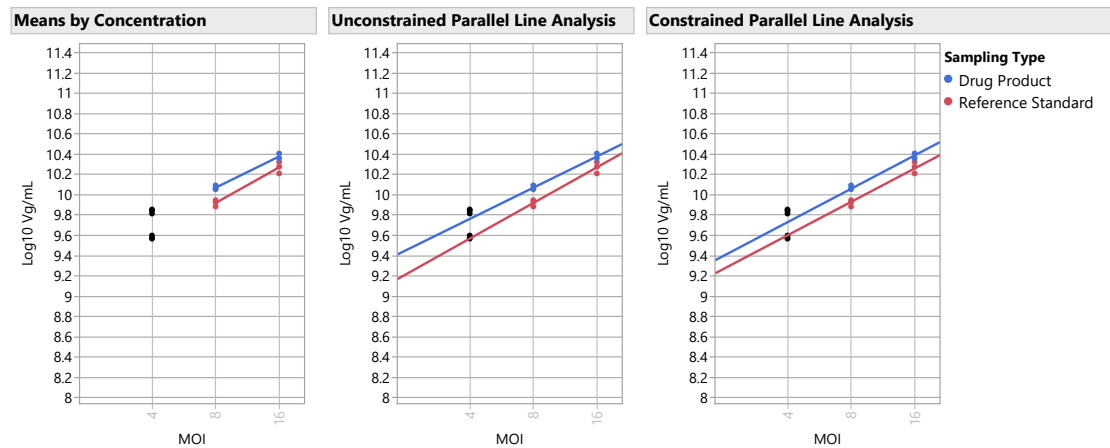
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	.	3	3.7e+10	3.08e+9
Ref.Std (L01-240910)	4e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	8e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	1.6e+1	3	1.9e+10	2.42e+9
150% L01-240910_2	.	3	4.3e+10	1.75e+8
150% L01-240910_2	4e+0	3	6.88e+9	3.2e+8
150% L01-240910_2	8e+0	3	1.2e+10	5.57e+8
150% L01-240910_2	1.6e+1	3	2.4e+10	1.46e+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	0.972	0.037	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.783	3.583	0.988	0.033	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.909	0.000	0.995	0.024	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.892	0.948	0.991	0.032	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.797	6.147	0.992	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.769	6.175	0.977	0.036	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.685	0.000	0.989	0.023	Fails Parallelism and is Linear	
Model 7, Test High Dose Only Excluded	0.673	1.068	0.987	0.031	Fails Parallelism and is Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.661	0.000	0.970	0.036	Fails Parallelism and is Linear	

150% L01-240910_2 Graphs



150% L01-240910_2 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.154	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	9.336	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

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					CI Range	% of Tolerance Check	OOS Validity	
12.96		9.88	131.1		0	131.1	141.7	122.1	150	50	19.7	19.7	Bioassay Results are Reportable					Assay is Valid and Within Limits	
			Relative																
Unconstrained RI		Constrained RI		Infectivity Delta															
131.3		131.1		0.2															
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit															
1.1		0.3		1.0															

Relative Infectivity All Samples

			Infectious			
Sample Name	EC50 Standard	EC50 Test	Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910_1	8.4205001409	15.200997311	0.5	55.4	47.6	62.4
150% L01-240910_1	12.831950769	9.9751006147	1.1	128.6	120.0	138.6
200% L01-240910	13.849393598	9.2422819158	1.3	149.8	138.9	163.2
100% L01-240910	11.283629128	11.343868055	0.8	99.5	92.2	107.3
50% L01-240910_2	8.3904272073	15.255480661	0.5	55.0	47.4	61.9
150% L01-240910_2	12.956050678	9.8795538221	1.1	131.1	122.1	141.7

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

BQT Infectivity_13Nov2024-13-45-02

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	1423.709229	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21479	15075	6404
A03	16	RS	REP3		BDNF	2840.367188	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19714	17951	1763
E10	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19126	0	19126
E11	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					20944	0	20944
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					18778	0	18778
F10	PC				BDNF	1280.408691	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					18318	12149	6169
F11	PC				BDNF	1218.153198	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					19227	12400	6827
F12	PC				BDNF	1202.61377	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM					17535	11226	6309

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	127.5908127	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19041	1957	17084
C01	4	RS	REP1		BDNF	260.693512	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18807	3738	15069
B01	8	RS	REP1		BDNF	551.6500854	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19425	7271	12154
A01	16	RS	REP1		BDNF	1169.609009	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					16931	10666	6265
D10	2	200	REP1		BDNF	348.1827393	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20431	5234	15197
C10	4	200	REP1		BDNF	450.1703796	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20145	6405	13740
B10	8	200	REP1		BDNF	985.618042	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19405	11009	8396
A10	16	200	REP1		BDNF	1667.197388	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19306	14626	4680
H07	2	150.2	REP1		BDNF	234.1138306	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20427	3686	16741
G07	4	150.2	REP1		BDNF	425.228363	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19787	6002	13785
F07	8	150.2	REP1		BDNF	847.2356567	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20344	10443	9901
E07	16	150.2	REP1		BDNF	1452.476807	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19756	14008	5748
D07	2	150	REP1		BDNF	235.5180359	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20813	3776	17037
C07	4	150	REP1		BDNF	408.2714844	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20299	5952	14347
B07	8	150	REP1		BDNF	857.5824585	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19821	10259	9562
A07	16	150	REP1		BDNF	1411.008789	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19095	13340	5755
H01	2	100.2	REP1		BDNF	130.7037048	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					17071	1795	15276
G01	4	100.2	REP1		BDNF	259.6535645	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18435	3651	14784
F01	8	100.2	REP1		BDNF	548.6073608	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					17108	6376	10732
E01	16	100.2	REP1		BDNF	1206.892456	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18313	11748	6565
H04	2	50.2	REP1		BDNF	95.39581299	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19811	1543	18268
G04	4	50.2	REP1		BDNF	176.6719055	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18976	2646	16330
F04	8	50.2	REP1		BDNF	362.7191162	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19656	5215	14441
E04	16	50.2	REP1		BDNF	600.7639771	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18915	7564	11351
D04	2	50	REP1		BDNF	98.58995819	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19369	1557	17812
C04	4	50	REP1		BDNF	182.5280457	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20047	2881	17166
B04	8	50	REP1		BDNF	382.3301392	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20367	5651	14716
A04	16	50	REP1		BDNF	590.5283203	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19478	7687	11791
D02	2	RS	REP2		BDNF	122.939415	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					17909	1777	16132
C02	4	RS	REP2		BDNF	279.7557678	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19392	4104	15288
B02	8	RS	REP2		BDNF	623.8641357	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18906	7781	11125
A02	16	RS	REP2		BDNF	1152.047852	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19079	11913	7166
D11	2	200	REP2		BDNF	277.4240723	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19822	4164	15658
C11	4	200	REP2		BDNF	471.7400513	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21018	6943	14075
B11	8	200	REP2		BDNF	902.1112671	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20704	11087	9617
A11	16	200	REP2		BDNF	1909.904663	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18943	15207	3736
H08	2	150.2	REP2		BDNF	245.6865997	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20624	3887	16737
G08	4	150.2	REP2		BDNF	392.8456421	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					21121	5996	15125
F08	8	150.2	REP2		BDNF	804.1484375	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19757	9783	9974
E08	16	150.2	REP2		BDNF	1451.810669	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20370	14440	5930
D08	2	150	REP2		BDNF	230.1463165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20008	3555	16453
C08	4	150	REP2		BDNF	390.6889954	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20745	5862	14883
B08	8	150	REP2		BDNF	797.5358887	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19989	9841	10148
A08	16	150	REP2		BDNF	1434.838257	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19225	13547	5678
H02	2	100.2	REP2		BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					5936	0	5936
G02	4	100.2	REP2		BDNF	276.0016174	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					18148	3795	14353
F02	8	100.2	REP2		BDNF	635.269165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19061	7953	11108
E02	16	100.2	REP2		BDNF	1189.354614	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19625	12484	7141
H05	2	50.2	REP2		BDNF	77.89870453	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20072	1286	18786
G05	4	50.2	REP2		BDNF	144.2233582	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20932	2415	18517
F05	8	50.2	REP2		BDNF	296.7576904	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19987	4456	15531
E05	16	50.2	REP2		BDNF	518.7389526	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20134	7179	12955
D05	2	50	REP2		BDNF	81.8263092	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					20688	1390	19298
C05	4	50	REP2		BDNF	148.734436	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM					19889	2362	17527
B05																			