



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

**Assay Details**

**User Information**  
User Name: harding  
Computer Name: DESKTOP-RFHI5SO  
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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	Std		MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)						Studentized Residuals	Between Group
50% L01-240910_1	13	2	1.797e+10	19656.5	359645621.8	2.0013493063	1.6e+1	1.2041199827	10.254551883	3.508	Ok		1.528 Ok
50% L01-240910_1	14	2	1.130e+10	20631	235053015.22	2.0794349286	8e+0	0.903089987	10.053220492	4.319	Outlier		2.970 Ok
50% L01-240910_1	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	2.437	Ok		1.512 Ok
50% L01-240910_1	16	2	2.863e+9	20059	133535135.16	4.6637199832	2e+0	0.3010299957	9.4568630835	2.669	Ok		1.872 Ok
50% L01-240910_1	17	2	1.555e+10	19717.5	489935793.6	3.1497867731	1.6e+1	1.2041199827	10.191858014	0.233	Ok		-0.139 Ok
50% L01-240910_1	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	8e+0	0.903089987	9.9503544163	0.309	Ok		0.527 Ok
50% L01-240910_1	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	4e+0	0.6020599913	9.6479750835	0.071	Ok		-0.226 Ok
50% L01-240910_1	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	2e+0	0.3010299957	9.3904622856	0.115	Ok		0.061 Ok
50% L01-240910_1	21	2	1.433e+10	18854	691328511.13	4.8227318281	1.6e+1	1.2041199827	10.156391355	1.421	Ok		-1.061 Ok
50% L01-240910_1	22	2	7.986e+9	19410.5	272371628.48	3.410460901	8e+0	0.903089987	9.9023487925	1.261	Ok		-0.586 Ok
50% L01-240910_1	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.863	Ok		-2.010 Ok
50% L01-240910_1	24	2	2.165e+9	19152	13728570.717	0.6341816577	2e+0	0.3010299957	9.3354116483	1.726	Ok		-1.373 Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175	Ok		-0.903 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Ok		-0.843 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Ok		-0.782 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Ok		-0.354 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Ok		-0.415 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Ok		0.729 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Ok		0.211 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Ok		-0.548 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Outlier		0.923 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Ok		1.985 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Ok		0.663 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error		0.224 Ok

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

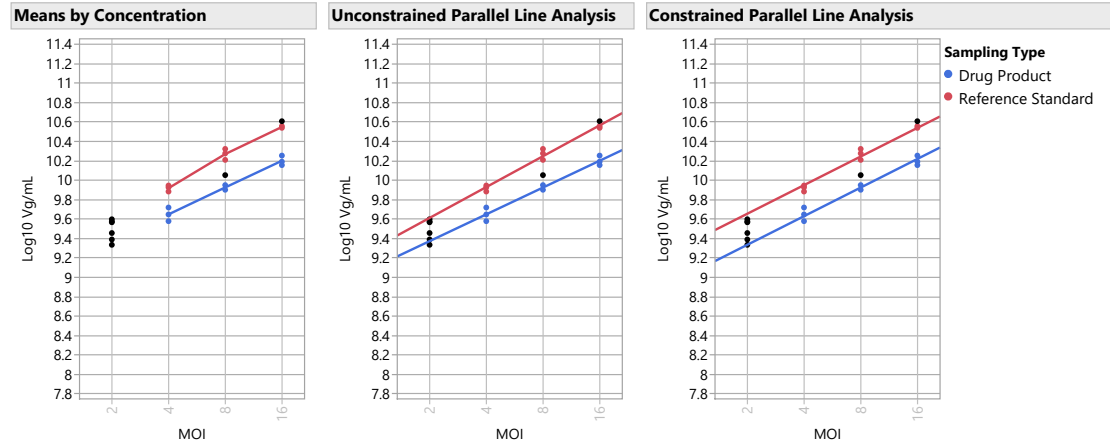
50% L01-240910\_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
50% L01-240910_1	2e+0	3	2.5e+9	3.51e+8
50% L01-240910_1	4e+0	3	4.49e+9	7.28e+8
50% L01-240910_1	8e+0	2	8.45e+9	6.6e+8
50% L01-240910_1	1.6e+1	3	1.6e+10	1.85e+9

50% L01-240910\_1 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 2, Low Standard and Test Doses Excluded	0.869	3.430	0.979	0.047 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.822	1.105	0.987	0.045 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.769	1.427	0.981	0.046 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.849	0.157	0.986	0.048 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.841	3.152	0.985	0.044 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.835	3.136	0.987	0.050 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.808	2.668	0.988	0.046 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.801	0.704	0.979	0.044 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.783	1.343	0.983	0.045 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	.	31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.074	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.869	Passed Validity Criteria	
Linearity Ratio	.	26.3	3.430	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	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
5.26	11.16	Uncorrected	Reference CF	0	47.1	51.7	42.6	150	50	9.1	9.1	Bioassay Results are Reportable	Assay is Valid and OOS

Relative Infectivity Delta		
Unconstrained RI	Constrained RI	Infectivity Delta
47.2	47.1	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.6	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	Jackknife z	Outlier Within Group	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)							Studentized Residuals	Between Group
150% L01-240910_1	25	2	4.333e+10	19449.5	1415326191.4	3.2663094426		1.6e+1	1.2041199827	10.636799217	2.752	Ok		0.240 Ok
150% L01-240910_1	26	2	2.527e+10	19744	642816777.6	2.5434988531		8e+0	0.903089987	10.402655657	13.343	Within Analytical Error		1.422 Ok
150% L01-240910_1	27	2	1.199e+10	19708.5	370403067.43	3.0902382741		4e+0	0.6020599913	10.078682607	7.469	Within Analytical Error		-0.354 Ok
150% L01-240910_1	28	2	7.037e+9	20511	40166095.497	0.5707730578		2e+0	0.3010299957	9.8473961516	0.935	Ok		1.012 Ok
150% L01-240910_1	29	2	4.278e+10	19064	380998669.04	0.8906886483		1.6e+1	1.2041199827	10.631197541	0.129	Ok		0.049 Ok
150% L01-240910_1	30	2	2.291e+10	19624.5	1437202301	6.2733021375		8e+0	0.903089987	10.360021699	0.565	Ok		0.008 Ok
150% L01-240910_1	31	2	1.109e+10	20716	889172320.19	8.0163895138		4e+0	0.6020599913	10.045007123	1.003	Ok		-1.514 Ok
150% L01-240910_1	32	2	6.959e+9	19792	77086896.492	1.1077457191		2e+0	0.3010299957	9.842540481	0.511	Ok		0.826 Ok
150% L01-240910_1	33	2	4.239e+10	18382	931314530.59	2.1969287211		1.6e+1	1.2041199827	10.627280412	1.685	Ok		-0.085 Ok
150% L01-240910_1	34	2	2.265e+10	19918.5	228694495.38	1.0098965802		8e+0	0.903089987	10.35497881	0.865	Ok		-0.150 Ok
150% L01-240910_1	35	2	1.125e+10	20499	114153032.32	1.0149997396		4e+0	0.6020599913	10.051021522	0.463	Ok		-1.289 Ok
150% L01-240910_1	36	2	6.474e+9	19781.5	69066883.248	1.0668379646		2e+0	0.3010299957	9.8111713961	9.472	Outlier		-0.317 Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913		1.6e+1	1.2041199827	10.539987978	1.175	Ok		-1.266 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473		8e+0	0.903089987	10.210103028	2.499	Ok		-1.178 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469		4e+0	0.6020599913	9.8840460225	3.606	Ok		-1.090 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532		2e+0	0.3010299957	9.5752976845	0.366	Ok		-0.488 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559		1.6e+1	1.2041199827	10.55804215	0.356	Ok		-0.572 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497		8e+0	0.903089987	10.276827009	0.083	Ok		1.014 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488		4e+0	0.6020599913	9.9268639631	0.243	Ok		0.290 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438		2e+0	0.3010299957	9.5676487726	1.157	Ok		-0.757 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946		1.6e+1	1.2041199827	10.608484012	4.985	Outlier		1.267 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715		8e+0	0.903089987	10.3230886	1.823	Ok		3.053 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859		4e+0	0.6020599913	9.9463114	1.397	Ok		0.921 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456		2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error		0.308 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

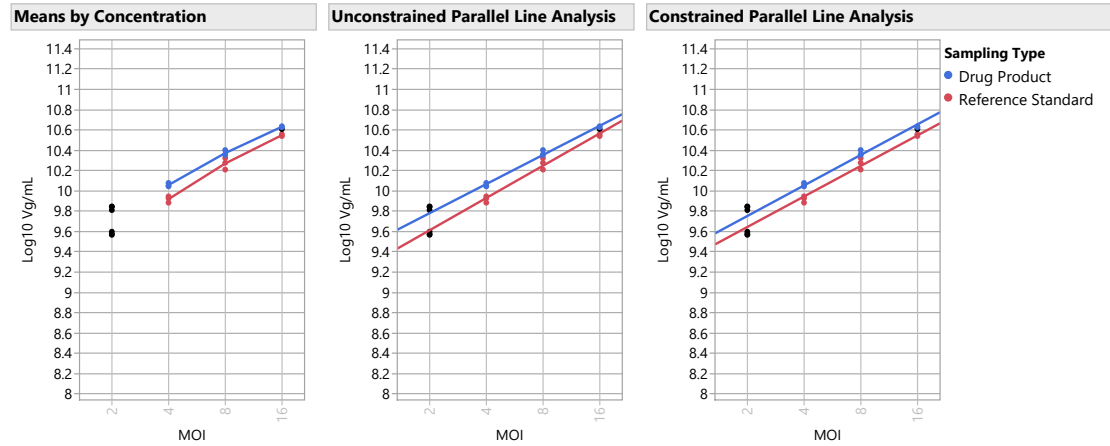
150% L01-240910\_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
150% L01-240910_1	2e+0	2	7e+9	5.53e+7
150% L01-240910_1	4e+0	3	1.1e+10	4.78e+8
150% L01-240910_1	8e+0	3	2.4e+10	1.45e+9
150% L01-240910_1	1.6e+1	3	4.3e+10	4.72e+8

150% L01-240910\_1 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model	
Model 2, Low Standard and Test Doses Excluded	0.903	5.183	0.987	0.034 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.823	0.482	0.992	0.033 Parallel and Linear		
Model 3, High Standard and Test Doses Excluded	0.776	4.452	0.987	0.035 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.874	3.985	0.993	0.032 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.850	0.942	0.988	0.035 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	0.842	1.866	0.980	0.038 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.832	2.539	0.994	0.030 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.816	1.216	0.989	0.036 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.783	2.392	0.993	0.032 Parallel and Linear		

150% L01-240910\_1 Graphs



150% L01-240910\_1 Validity Report

Validity Criteria	LSL		USL		Validity		Overall Validity
	Dose Response Test				Results	Assay Validity	
Dose Response Test		.	0.05		0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000				31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		.	15		0.246	Passed Validity Criteria	
Parallelism Slope Ratio	0.7		1.4		0.903	Passed Validity Criteria	
Linearity Ratio	.		26.3		5.183	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04		61.8		4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.		5		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
				Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
8.77		6.83		128.4	0	0	128.4	136.4	121.1	150	50	15.2	15.2	Bioassay Results are Reportable	Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
128.2		128.4		0.2											
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit											
1.7		0.3		1.0											

200% L01-240910 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted		Std		MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)							Studentized Residuals	Between Group
200% L01-240910	37	2	5.233e+10	18878	3273703267.4	6.2557892386		1.6e+1	1.2041199827	10.718757203	1.072	Ok	0.475	Ok
200% L01-240910	38	2	3.009e+10	18845.5	740491509.11	2.4607466152		8e+0	0.903089987	10.478453187	4.857	Outlier	1.614	Ok
200% L01-240910	39	2	1.408e+10	20251	818244555.34	5.809870213		4e+0	0.6020599913	10.148716693	1.385	Ok	-0.185	Ok
200% L01-240910	40	2	1.053e+10	20253.5	125817445.28	1.1943429664		2e+0	0.3010299957	10.022611806	50.409	Outlier	5.402	Outlier
200% L01-240910	41	2	5.709e+10	18423.5	293737605.16	0.5145218197		1.6e+1	1.2041199827	10.756555753	6.187	Outlier	1.940	Ok
200% L01-240910	42	2	2.693e+10	20411.5	185825277.73	0.6899810404		8e+0	0.903089987	10.430267633	0.348	Ok	0.000	Ok
200% L01-240910	43	2	1.372e+10	20586.5	612192672.69	4.4622681989		4e+0	0.6020599913	10.137332458	0.249	Ok	-0.557	Ok
200% L01-240910	44	2	8.036e+9	19101.5	405078446.6	5.0406160629		2e+0	0.3010299957	9.9050555168	0.668	Ok	0.991	Ok
200% L01-240910	45	2	5.331e+10	19763	1654979461.6	3.1046232995		1.6e+1	1.2041199827	10.726783696	0.417	Ok	0.786	Ok
200% L01-240910	46	2	2.585e+10	20229.5	2807020.1741	0.0108568237		8e+0	0.903089987	10.412542748	1.189	Ok	-0.581	Ok
200% L01-240910	47	2	1.296e+10	19746.5	194907960.04	1.5039726731		4e+0	0.6020599913	10.112589631	3.656	Ok	-1.439	Ok
200% L01-240910	48	2	7.965e+9	19460	83629922.415	1.0499404243		2e+0	0.3010299957	9.9011970368	0.747	Ok	0.839	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913		1.6e+1	1.2041199827	10.539987978	1.175	Ok	-1.290	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473		8e+0	0.903089987	10.210103028	2.499	Ok	-1.199	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469		4e+0	0.6020599913	9.8840460225	3.606	Ok	-1.108	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532		2e+0	0.3010299957	9.5752976845	0.366	Ok	-0.494	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559		1.6e+1	1.2041199827	10.55804215	0.356	Ok	-0.579	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497		8e+0	0.903089987	10.276827009	0.083	Ok	1.031	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488		4e+0	0.6020599913	9.9268639631	0.243	Ok	0.293	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438		2e+0	0.3010299957	9.5676487726	1.157	Ok	-0.768	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946		1.6e+1	1.2041199827	10.608484012	4.985	Outlier	1.286	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715		8e+0	0.903089987	10.3230886	1.823	Ok	3.231	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859		4e+0	0.6020599913	9.9463114	1.397	Ok	0.935	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456		2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error	0.312	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

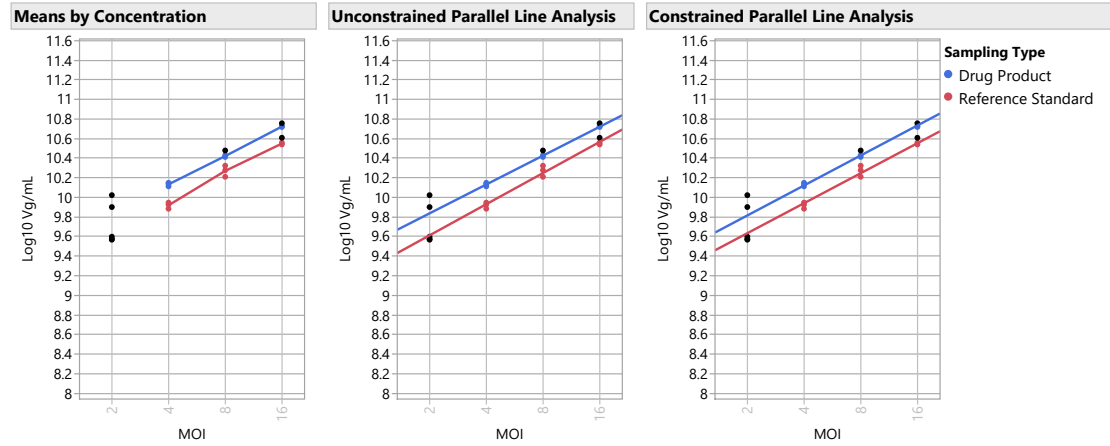
200% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
200% L01-240910	2e+0	3	8.85e+9	1.46e+9
200% L01-240910	4e+0	3	1.4e+10	5.74e+8
200% L01-240910	8e+0	2	2.6e+10	7.62e+8
200% L01-240910	1.6e+1	2	5.3e+10	6.9e+8

200% L01-240910 Model Selection

	Parallelism	Linearity	Validity		
Model	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.927	2.841	0.989	0.033	Parallel and Linear
Model 1, All Doses	0.841	0.139	0.993	0.032	Parallel and Linear
Model 3, High Standard and Test Doses Excluded	0.752	2.796	0.990	0.031	Parallel and Linear
Model 6, Test Low Dose Only Excluded	0.898	2.847	0.994	0.031	Parallel and Linear
Model 4, Standard Low Dose Only Excluded	0.868	2.334	0.988	0.034	Parallel and Linear
Model 9, Standard High Dose and Test Low Dose Excluded	0.854	1.479	0.995	0.029	Parallel and Linear
Model 8, Standard Low Dose and Test High Dose Excluded	0.816	1.169	0.983	0.035	Parallel and Linear
Model 5, Standard High Dose Only Excluded	0.800	3.955	0.994	0.031	Parallel and Linear
Model 7, Test High Dose Only Excluded	0.790	2.129	0.991	0.032	Parallel and Linear

200% L01-240910 Graphs



200% L01-240910 Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.242	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.927	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.841	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	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
8.83		5.86		Uncorrected	Reference CF			Upper 95%	Lower 95%			CI Range	of Tolerance	CI Range % of Tolerance	
150.7		0		0	0	150.7	160.9	141.5	150	50	19.4	19.4	Bioassay Results are Reportable	Assay is Valid and OOS	
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
150.9		150.7		0.2											
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio											
2.0		0.3		1.0											

100% L01-240910 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted		Std		MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)							Studentized Residuals	Between Group
100% L01-240910	49	2	3.584e+10	18158.5	513669225.3	1.4330867287		1.6e+1	1.2041199827	10.554411073	1.078	Ok	-0.941	Ok
100% L01-240910	50	2	1.644e+10	18226.5	20350893.08	0.1237600509		8e+0	0.903089987	10.216002993	2.888	Ok	-0.964	Ok
100% L01-240910	51	2	7.608e+9	19725	256471113.81	3.3709586709		4e+0	0.6020599913	9.8812850299	2.601	Ok	-0.965	Ok
100% L01-240910	52	2	3.716e+9	17735.5	289685040.08	7.7950422058		2e+0	0.3010299957	9.570107597	0.049	Ok	-0.287	Ok
100% L01-240910	53	2	3.690e+10	19450	1728233892.7	4.6832199996		1.6e+1	1.2041199827	10.567057958	0.413	Ok	-0.500	Ok
100% L01-240910	54	2	1.888e+10	18863.5	258789690.42	1.3710651781		8e+0	0.903089987	10.27588887	0.151	Ok	0.854	Ok
100% L01-240910	55	2	8.320e+9	18746	56525600.254	0.6793927511		4e+0	0.6020599913	9.9201242741	0.102	Ok	0.198	Ok
100% L01-240910	56	2	3.593e+9	12685.5	.	.		2e+0	0.3010299957	9.5554301725	1.940	Ok	-0.766	Ok
100% L01-240910	57	2	4.094e+10	18744	1870104954.7	4.5675232426		1.6e+1	1.2041199827	10.612185215	6.103	Outlier	1.034	Ok
100% L01-240910	58	2	2.045e+10	20813.5	573367617.57	2.8035032798		8e+0	0.903089987	10.310732093	1.624	Ok	2.097	Ok
100% L01-240910	59	2	8.852e+9	19702.5	137595150.53	1.5544659683		4e+0	0.6020599913	9.9470219092	1.763	Ok	1.014	Ok
100% L01-240910	60	2	3.858e+9	19416	144262472.04	3.7393203403		2e+0	0.3010299957	9.586360698	2.330	Ok	0.232	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913		1.6e+1	1.2041199827	10.539987978	1.175	Ok	-1.175	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473		8e+0	0.903089987	10.210103028	2.499	Ok	-1.094	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469		4e+0	0.6020599913	9.8840460225	3.606	Ok	-1.013	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532		2e+0	0.3010299957	9.5752976845	0.366	Ok	-0.455	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559		1.6e+1	1.2041199827	10.55804215	0.356	Ok	-0.533	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497		8e+0	0.903089987	10.276827009	0.083	Ok	0.944	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488		4e+0	0.6020599913	9.9268639631	0.243	Ok	0.270	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438		2e+0	0.3010299957	9.5676487726	1.157	Ok	-0.706	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946		1.6e+1	1.2041199827	10.608484012	4.985	Outlier	1.183	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715		8e+0	0.903089987	10.3230886	1.823	Ok	2.755	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859		4e+0	0.6020599913	9.9463114	1.397	Ok	0.857	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456		2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error	0.288	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

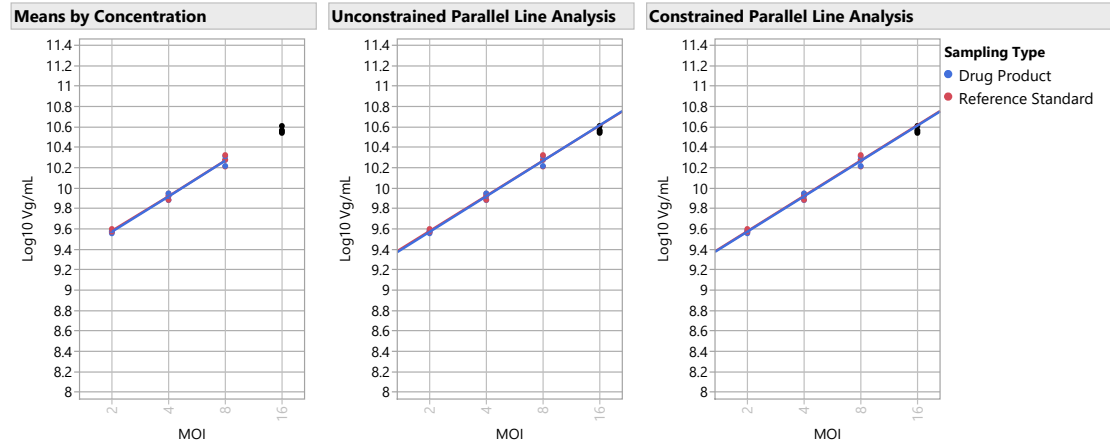
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
100% L01-240910	2e+0	3	3.72e+9	1.33e+8
100% L01-240910	4e+0	3	8.26e+9	6.24e+8
100% L01-240910	8e+0	3	1.9e+10	2.02e+9
100% L01-240910	1.6e+1	2	3.6e+10	7.49e+8

100% L01-240910 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model	
Model 3, High Standard and Test Doses Excluded	1.011	0.658	0.989	0.034 Parallel and Linear	Model 3, High Standard and Test Doses Excluded	
Model 1, All Doses	1.019	3.047	0.992	0.035 Parallel and Linear		
Model 2, Low Standard and Test Doses Excluded	1.021	4.978	0.981	0.040 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.989	3.757	0.990	0.037 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.970	2.144	0.991	0.034 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	1.052	3.664	0.990	0.037 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.941	2.400	0.989	0.037 Parallel and Linear		
Model 7, Test High Dose Only Excluded	1.062	2.580	0.991	0.035 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	1.097	3.519	0.989	0.038 Parallel and Linear		

100% L01-240910 Graphs



100% L01-240910 Validity Report

Validity Criteria	LSL		USL		Validity		Overall Validity
	Dose Response Test				Results	Assay Validity	
Dose Response Test	.		0.05		0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		.		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.		15		0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7		1.4		1.011	Passed Validity Criteria	
Linearity Ratio	.		26.3		0.658	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04		61.8		4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.		5		0.000	Passed Validity Criteria	

100% L01-240910 Relative Infectivity and Infectious Particle Ratio

EC50 Ref		EC50 Test		RI		Reference		Relative Infectivity		Assay RI		Assay RI		Upper		Lower		CI Range as %		OOS Validity
				Uncorrected	Reference CF	Stability CF		Reportable Result		Upper 95%		Lower 95%		Spec Limit		Spec Limit		CI Range	of Tolerance	
3.98		4.02		99.0	0	0		99.0		103.8		94.4		150		50		9.3	9.3	Bioassay Results are Reportable
																				Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta																
99.0		99.0		0.0																
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio																
1.3		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	Jackknife z	Outlier Within Group	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)							Studentized Residuals	Between Group
50% L01-240910_2	61	2	1.807e+10	18507	67065519.327	0.371135865		1.6e+1	1.2041199827	10.256966367	3.436	Ok	0.865	Ok
50% L01-240910_2	62	2	1.102e+10	19613.5	190120617.32	1.7258574881		8e+0	0.903089987	10.042024285	2.575	Ok	2.435	Ok
50% L01-240910_2	63	2	5.159e+9	19546	199264473.2	3.8622715539		4e+0	0.6020599913	9.7125870699	2.102	Ok	1.087	Ok
50% L01-240910_2	64	2	2.761e+9	19386.5	142914635.79	5.1765314071		2e+0	0.3010299957	9.4410378536	2.485	Ok	1.368	Ok
50% L01-240910_2	65	2	1.586e+10	19528	426059891.54	2.6857978728		1.6e+1	1.2041199827	10.200397327	0.224	Ok	-0.434	Ok
50% L01-240910_2	66	2	9.172e+9	19640	381089296.09	4.1548290727		8e+0	0.903089987	9.9624735888	0.098	Ok	0.455	Ok
50% L01-240910_2	67	2	4.472e+9	20154	205743731.17	4.6005207441		4e+0	0.6020599913	9.6505196182	0.005	Ok	-0.242	Ok
50% L01-240910_2	68	2	2.420e+9	19772	116728454.59	4.8244854223		2e+0	0.3010299957	9.3837257373	0.080	Ok	0.007	Ok
50% L01-240910_2	69	2	1.472e+10	19282.5	392975759.31	2.6697350163		1.6e+1	1.2041199827	10.167897604	1.440	Ok	-1.213	Ok
50% L01-240910_2	70	2	7.776e+9	19753.5	311276312.65	4.0030128902		8e+0	0.903089987	9.8907590846	1.778	Ok	-1.077	Ok
50% L01-240910_2	71	2	3.776e+9	19467	89472972.022	2.3697464095		4e+0	0.6020599913	9.5769899896	2.141	Ok	-1.955	Ok
50% L01-240910_2	72	2	2.148e+9	19516	136835293.16	6.3705683843		2e+0	0.3010299957	9.332019945	1.832	Ok	-1.208	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913		1.6e+1	1.2041199827	10.539987978	1.175	Ok	-0.821	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473		8e+0	0.903089987	10.210103028	2.499	Ok	-0.767	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469		4e+0	0.6020599913	9.8840460225	3.606	Ok	-0.711	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532		2e+0	0.3010299957	9.5752976845	0.366	Ok	-0.323	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559		1.6e+1	1.2041199827	10.55804215	0.356	Ok	-0.379	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497		8e+0	0.903089987	10.276827009	0.083	Ok	0.664	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488		4e+0	0.6020599913	9.9268639631	0.243	Ok	0.193	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438		2e+0	0.3010299957	9.5676487726	1.157	Ok	-0.499	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946		1.6e+1	1.2041199827	10.608484012	4.985	Outlier	0.842	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715		8e+0	0.903089987	10.3230886	1.823	Ok	1.770	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859		4e+0	0.6020599913	9.9463114	1.397	Ok	0.604	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456		2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error	0.205	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

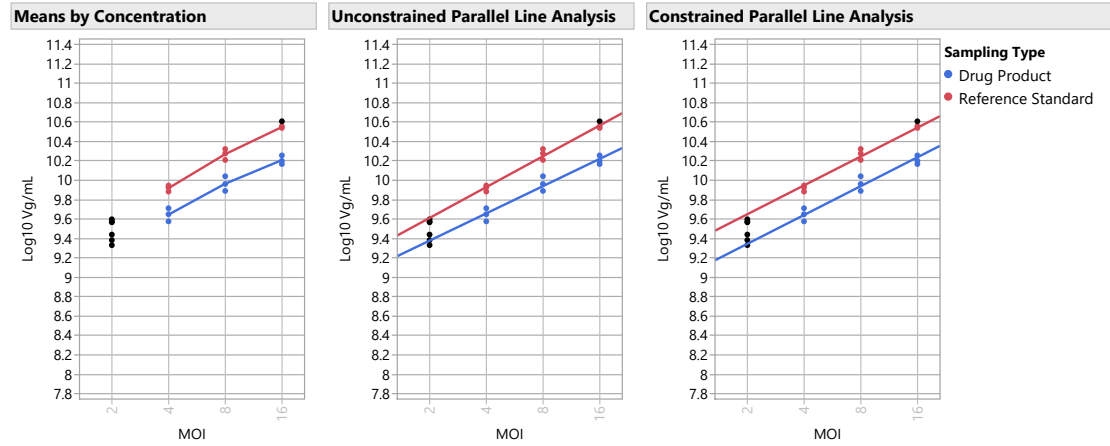
50% L01-240910\_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
50% L01-240910_2	2e+0	3	2.44e+9	3.07e+8
50% L01-240910_2	4e+0	3	4.47e+9	6.92e+8
50% L01-240910_2	8e+0	3	9.32e+9	1.63e+9
50% L01-240910_2	1.6e+1	3	1.6e+10	1.7e+9

50% L01-240910\_2 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 2, Low Standard and Test Doses Excluded	0.884	6.084	0.971	0.054 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.849	2.251	0.984	0.049 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.840	2.744	0.976	0.052 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.912	0.584	0.983	0.055 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.883	1.844	0.984	0.050 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.877	2.164	0.982	0.053 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.856	4.405	0.979	0.050 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.815	3.758	0.970	0.051 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.808	0.704	0.979	0.050 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	.	31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.191	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.884	Passed Validity Criteria	
Linearity Ratio	.	26.3	6.084	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (< 10000)	.	5	0.000	Passed Validity Criteria	

50% 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
5.27	10.73	49.1	0	0	49.1	54.0	44.3	150	50	9.7	9.7	Bioassay Results are Reportable	Assay is Valid and OOS	

		Relative
Unconstrained RI	Constrained RI	Infectivity Delta
49.3	49.1	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.7	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	Studentized Residuals	Externally Outlier Between Group
150% L01-240910_2	73	2	4.346e+10	20242.5	164290989.13	0.3780442877	1.6e+1	1.2041199827	10.638071064	0.720	Ok	0.291	Ok
150% L01-240910_2	74	2	2.554e+10	19859.5	172756060.68	0.6764341882	8e+0	0.903089987	10.407207743	18.374	Outlier	1.586	Ok
150% L01-240910_2	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	8.443	Outlier	0.031	Ok
150% L01-240910_2	76	2	6.956e+9	20033.5	95618993.904	1.3746652481	2e+0	0.3010299957	9.8423472161	0.242	Ok	0.722	Ok
150% L01-240910_2	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	1.6e+1	1.2041199827	10.635012399	161.86	Within Analytical Error	0.180	Ok
150% L01-240910_2	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.602	Ok	0.102	Ok
150% L01-240910_2	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.966	Ok	-1.293	Ok
150% L01-240910_2	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.400	Ok	1.224	Ok
150% L01-240910_2	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.695	Ok	0.290	Ok
150% L01-240910_2	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.820	Ok	-0.020	Ok
150% L01-240910_2	83	2	1.151e+10	19997.5	194500111.81	1.690454602	4e+0	0.6020599913	10.060916343	0.489	Ok	-1.064	Ok
150% L01-240910_2	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	3.594	Ok	-0.272	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175	Ok	-1.342	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Ok	-1.248	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Ok	-1.153	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Ok	-0.513	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Ok	-0.602	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Ok	1.072	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Ok	0.305	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Ok	-0.799	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Outlier	1.334	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Ok	3.375	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Ok	0.972	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Within Analytical Error	0.324	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

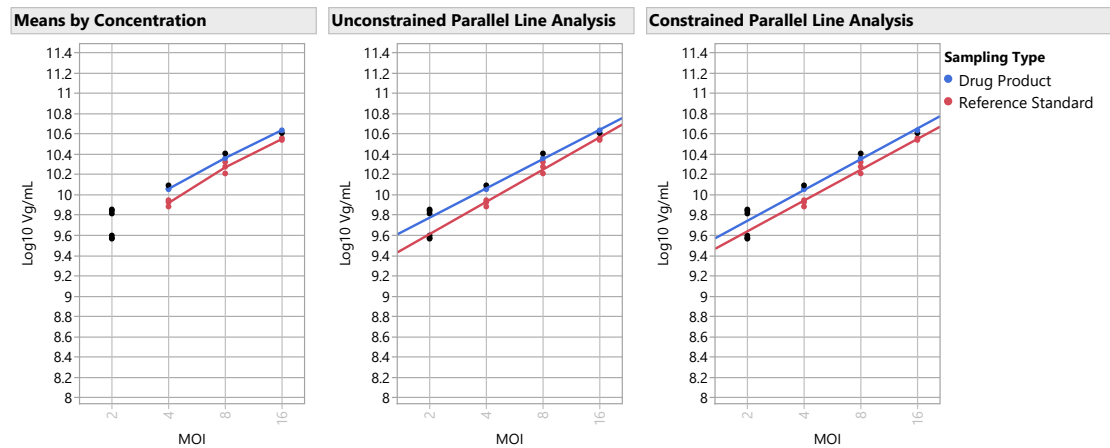
150% L01-240910\_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	2	3.5e+10	1.04e+9
150% L01-240910_2	2e+0	3	6.88e+9	3.2e+8
150% L01-240910_2	4e+0	2	1.1e+10	1.13e+8
150% L01-240910_2	8e+0	2	2.3e+10	1.37e+8
150% L01-240910_2	1.6e+1	3	4.3e+10	1.75e+8

150% L01-240910\_2 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.909	4.414	0.989	0.032 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.820	0.283	0.994	0.031 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.754	3.494	0.989	0.032 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.880	3.484	0.994	0.030 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.847	1.444	0.990	0.033 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.837	0.583	0.995	0.028 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.818	0.569	0.985	0.036 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.792	1.988	0.991	0.034 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.781	3.014	0.994	0.029 Parallel and Linear	

150% L01-240910\_2 Graphs





150% L01-240910\_2 Validity Report

Validity Criteria			Validity		Overall Validity
	LSL	USL	Results	Assay Validity	
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.299	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.909	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.414	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.760	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	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
8.94	7.05	126.7	0	0	126.7	135.5	118.9	150	50	16.6	16.6	Bioassay Results are Reportable Assay is Valid and Within Limits		
		Relative												
Unconstrained RI	Constrained RI	Infectivity Delta												
127.0	126.7	0.3												
Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit												
1.7	0.3	1.0												

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious			
			Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910_1	5.2600554481	11.157346029	0.6	47.1	42.6	51.7
150% L01-240910_1	8.7673145259	6.8278698132	1.7	128.4	121.1	136.4
200% L01-240910	8.8323386383	5.8607726426	2.0	150.7	141.5	160.9
100% L01-240910	3.9797170781	4.0203862953	1.3	99.0	94.4	103.8
50% L01-240910_2	5.2698045757	10.734794737	0.7	49.1	44.3	54.0
150% L01-240910_2	8.9351490447	7.0504906686	1.7	126.7	118.9	135.5
Sample Name	Overall					
	Validity	OOS	Reportable			
50% L01-240910_1	Assay is Valid	OOS	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	OOS	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

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

Reference Details

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



[illegible]

BQT Infectivity\_19Nov2024-13-49-59

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