



Astellas BQT Assay Report
Test Article Report

Assay Details

User Information
User Name: harding
Computer Name: DESKTOP-RFHI5SO
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Astellas BQT Infectivity PLA Script Version 0.1
JMP Version 18.1.0

Analyst Signature/Date

Approver Signature/Date

Astellas BQT Infectivity Files

First Data File	Second Data File
18OCT2024_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	1.6e+1	1.2041199827	10.254551883	3.508 Pass	0.907	Ok
50% L01-240910_1	14	2	1.130e+10	20631	235053015.22	2.0794349286	8e+0	0.903089987	10.053220492	4.319 Pass	2.695	Ok
50% L01-240910_1	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	2.437 Pass	1.122	Ok
50% L01-240910_1	16	2	2.863e+9	20059	133535135.16	4.6637199832	2e+0	0.3010299957	9.4568630835	2.669 Pass	1.503	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 Pass	-0.493	Ok
50% L01-240910_1	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	8e+0	0.903089987	9.9503544163	0.309 Pass	0.207	Ok
50% L01-240910_1	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	4e+0	0.6020599913	9.6479750835	0.071 Pass	-0.371	Ok
50% L01-240910_1	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	2e+0	0.3010299957	9.3904622856	0.115 Pass	-0.038	Ok
50% L01-240910_1	21	2	1.433e+10	18854	691328511.13	4.8227318281	1.6e+1	1.2041199827	10.156391355	1.421 Pass	-1.326	Ok
50% L01-240910_1	22	2	7.986e+9	19410.5	272371628.48	3.410460901	8e+0	0.903089987	9.9023487925	1.261 Pass	-0.779	Ok
50% L01-240910_1	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.863 Pass	-1.937	Ok
50% L01-240910_1	24	2	2.165e+9	19152	13728570.717	0.6341816577	2e+0	0.3010299957	9.3354116483	1.726 Pass	-1.302	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 Pass	-0.944	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-0.832	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-0.714	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.262	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.530	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.540	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.164	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.432	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.587	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	1.566	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.562	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.249	Ok

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

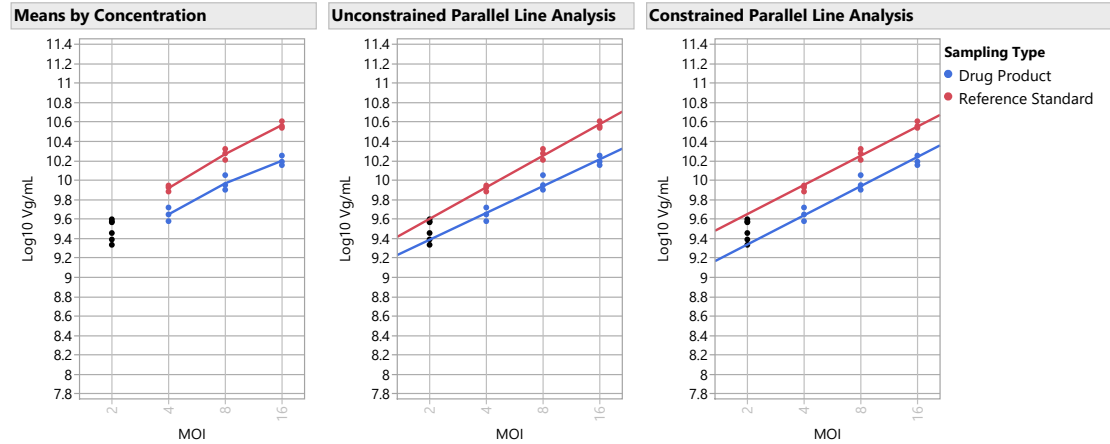
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	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	3	3.7e+10	3.08e+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	3	9.4e+9	1.71e+9
50% L01-240910_1	1.6e+1	3	1.6e+10	1.85e+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	0.850	5.806	0.973	0.055 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 3, High Standard and Test Doses Excluded	0.833	3.064	0.974	0.054 Parallel and Linear	
Model 1, All Doses	0.826	1.923	0.984	0.051 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.884	0.797	0.984	0.056 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.866	0.938	0.985	0.051 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.843	2.128	0.982	0.054 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.832	3.632	0.981	0.051 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.801	4.537	0.967	0.053 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.795	0.948	0.976	0.053 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	0.233	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.850	Passed Validity Criteria	
Linearity Ratio	.	26.3	5.806	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	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
5.57	11.48	48.6	0	0	48.6	53.6	43.5	150	50	10.1	10.1	Bioassay Results are Reportable Assay is Valid and OOS		

Unconstrained RI	Constrained RI	Relative Infectivity Delta
48.3	48.6	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.7	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	1.6e+1	1.2041199827	10.636799217	2.752	Pass	0.227	Ok
150% L01-240910_1	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	13.343	Pass	1.472	Ok
150% L01-240910_1	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	7.469	Pass	-0.323	Ok
150% L01-240910_1	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.935	Pass	1.067	Ok
150% L01-240910_1	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.129	Pass	0.030	Ok
150% L01-240910_1	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.565	Pass	0.017	Ok
150% L01-240910_1	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.003	Pass	-1.490	Ok
150% L01-240910_1	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.511	Pass	0.884	Ok
150% L01-240910_1	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	1.685	Pass	-0.107	Ok
150% L01-240910_1	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.865	Pass	-0.146	Ok
150% L01-240910_1	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.463	Pass	-1.266	Ok
150% L01-240910_1	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	9.472	Pass	-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	Pass	-1.563	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Pass	-1.365	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Pass	-1.162	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Pass	-0.419	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Pass	-0.855	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Pass	0.871	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Pass	0.261	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.693	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.949	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Pass	2.789	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Pass	0.908	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Pass	0.398	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

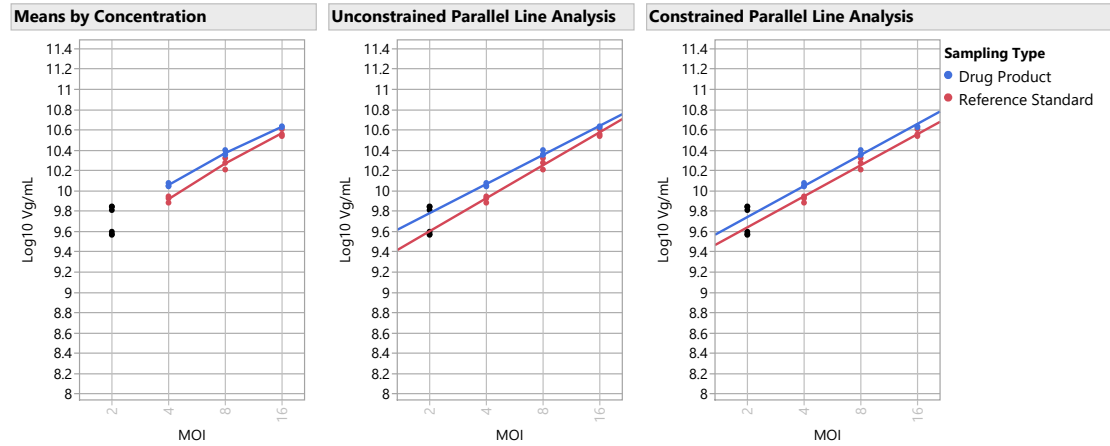
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

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	3	3.7e+10	3.08e+9
150% L01-240910_1	2e+0	3	6.82e+9	3.05e+8
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	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 2, Low Standard and Test Doses Excluded	0.883	4.382	0.987	0.034 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.817	0.158	0.993	0.032 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.781	4.157	0.988	0.034 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.865	3.013	0.993	0.032 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.834	0.935	0.989	0.034 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 8, Standard Low Dose and Test High Dose Excluded	0.829	2.378	0.984	0.037 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.813	0.526	0.990	0.034 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.786	2.021	0.993	0.031 Parallel and 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	0.113	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.883	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.382	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	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 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range as % of Tolerance		OOS Validity
8.98		7.13		Uncorrected 125.9		Reference CF 0	0	125.9	133.7	118.6	150	15.1	15.1	Bioassay Results are Reportable Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta										
126.0		125.9		0.1										
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	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)					Jackknife z	Within Group	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	Pass	0.105	Ok
200% L01-240910	38	2	3.009e+10	18845.5	740491509.11	2.4607466152	8e+0	0.903089987	10.478453187	4.857	Pass	0.769	Ok
200% L01-240910	39	2	1.408e+10	20251	818244555.34	5.809870213	4e+0	0.6020599913	10.148716693	1.385	Pass	-0.719	Ok
200% L01-240910	40	2	1.053e+10	20253.5	125817445.28	1.1943429664	2e+0	0.3010299957	10.022611806	50.409	Pass	3.861	Ok
200% L01-240910	41	2	5.709e+10	18423.5	293737605.16	0.5145218197	1.6e+1	1.2041199827	10.756555753	6.187	Pass	1.114	Ok
200% L01-240910	42	2	2.693e+10	20411.5	185825277.73	0.6899810404	8e+0	0.903089987	10.430267633	0.348	Pass	-0.390	Ok
200% L01-240910	43	2	1.372e+10	20586.5	612192672.69	4.4622681989	4e+0	0.6020599913	10.137332458	0.249	Pass	-1.006	Ok
200% L01-240910	44	2	8.036e+9	19101.5	405078446.6	5.0406160629	2e+0	0.3010299957	9.9050555168	0.668	Pass	-0.139	Ok
200% L01-240910	45	2	5.331e+10	19763	1654979461.6	3.1046232995	1.6e+1	1.2041199827	10.726783696	0.417	Pass	0.313	Ok
200% L01-240910	46	2	2.585e+10	20229.5	2807020.1741	0.0108568237	8e+0	0.903089987	10.412542748	1.189	Pass	-0.825	Ok
200% L01-240910	47	2	1.296e+10	19746.5	194907960.04	1.5039726731	4e+0	0.6020599913	10.112589631	3.656	Pass	-1.681	Ok
200% L01-240910	48	2	7.965e+9	19460	83629922.415	1.0499404243	2e+0	0.3010299957	9.9011970368	0.747	Pass	-0.239	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	Pass	-1.118	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Pass	-0.983	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Pass	-0.842	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Pass	-0.308	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Pass	-0.624	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Pass	0.635	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Pass	0.192	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.507	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.691	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Pass	1.883	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Pass	0.662	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Pass	0.292	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

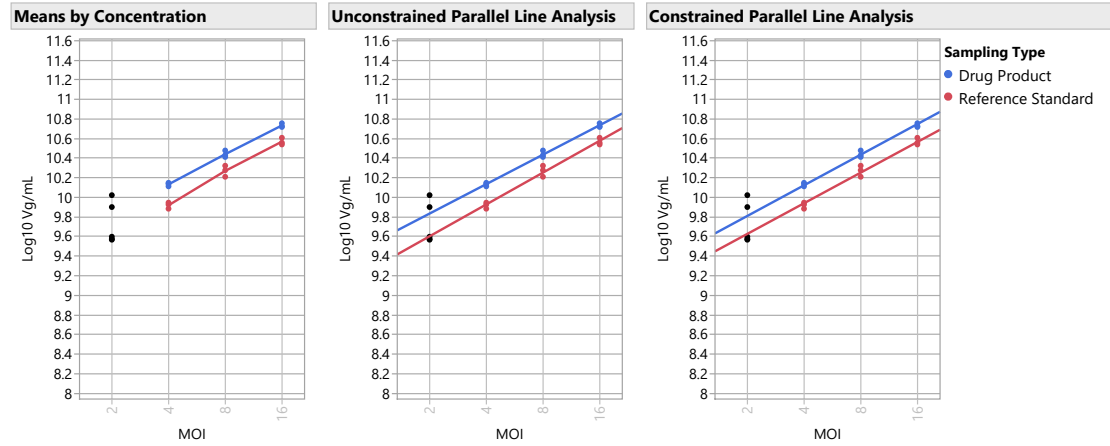
200% L01-240910 Test Sample & Reference Standard Summary Statistics

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	3	3.7e+10	3.08e+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	3	2.8e+10	2.2e+9
200% L01-240910	1.6e+1	3	5.4e+10	2.51e+9

200% L01-240910 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 2, Low Standard and Test Doses Excluded	0.925	2.639	0.988	0.034 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.808	1.999	0.988	0.043 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.721	5.475	0.980	0.045 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.906	2.252	0.994	0.032 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.872	0.092	0.995	0.030 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.825	4.700	0.979	0.046 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.778	5.624	0.987	0.044 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.766	4.283	0.970	0.048 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.750	0.030	0.984	0.044 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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.092	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.925	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.639	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

200% L01-240910 Relative Infectivity and Infectious Particle Ratio

EC50 Ref		EC50 Test		RI		Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range as % of Tolerance		OOS Validity
9.80		6.53		Uncorrected 150.1		0	150.1	158.9	142.0	150	50	17.0	17.0	Bioassay Results are Reportable Assay is Valid and OOS
Unconstrained RI		Constrained RI		Relative Infectivity Delta										
150.2		150.1		0.1										
Infectious Particle Ratio		Infectious Particle Ratio Lower Limit		Infectious Particle Ratio Upper Limit										
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	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	1.6e+1	1.2041199827	10.554411073	1.078	Pass	-1.158	Ok
100% L01-240910	50	2	1.644e+10	18226.5	20350893.08	0.1237600509	8e+0	0.903089987	10.216002993	2.888	Pass	-1.099	Ok
100% L01-240910	51	2	7.608e+9	19725	256471113.81	3.3709586709	4e+0	0.6020599913	9.8812850299	2.601	Pass	-1.015	Ok
100% L01-240910	52	2	3.716e+9	17735.5	289685040.08	7.7950422058	2e+0	0.3010299957	9.570107597	0.049	Pass	-0.226	Ok
100% L01-240910	53	2	3.690e+10	19450	1728233892.7	4.6832199996	1.6e+1	1.2041199827	10.567057958	0.413	Pass	-0.720	Ok
100% L01-240910	54	2	1.888e+10	18863.5	258789690.42	1.3710651781	8e+0	0.903089987	10.27588887	0.151	Pass	0.732	Ok
100% L01-240910	55	2	8.320e+9	18746	56525600.254	0.6793927511	4e+0	0.6020599913	9.9201242741	0.102	Pass	0.171	Ok
100% L01-240910	56	2	3.593e+9	12685.5	.	.	2e+0	0.3010299957	9.5554301725	1.940	Pass	-0.709	Ok
100% L01-240910	57	2	4.094e+10	18744	1870104954.7	4.5675232426	1.6e+1	1.2041199827	10.612185215	6.103	Pass	0.761	Ok
100% L01-240910	58	2	2.045e+10	20813.5	573367617.57	2.8035032798	8e+0	0.903089987	10.310732093	1.624	Pass	1.927	Ok
100% L01-240910	59	2	8.852e+9	19702.5	137595150.53	1.5544659683	4e+0	0.6020599913	9.9470219092	1.763	Pass	0.999	Ok
100% L01-240910	60	2	3.858e+9	19416	144262472.04	3.7393203403	2e+0	0.3010299957	9.586360698	2.330	Pass	0.301	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	Pass	-1.430	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Pass	-1.252	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Pass	-1.068	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Pass	-0.387	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Pass	-0.787	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Pass	0.802	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Pass	0.241	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.639	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.874	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Pass	2.502	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Pass	0.836	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Pass	0.367	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

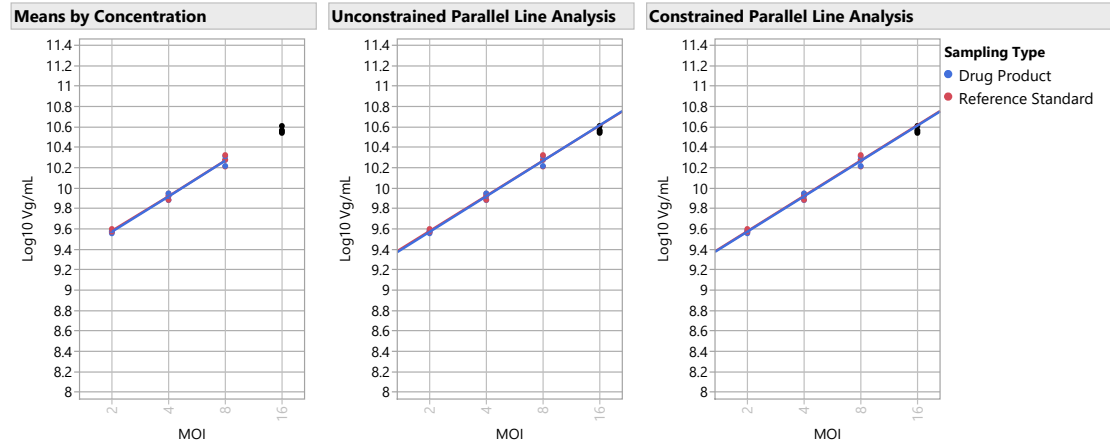
100% L01-240910 Test Sample & Reference Standard Summary Statistics

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	3	3.7e+10	3.08e+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	3	3.8e+10	2.69e+9

100% L01-240910 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
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	1.017	2.100	0.993	0.034 Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	1.018	3.551	0.983	0.039 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.998	2.586	0.991	0.037 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.978	1.465	0.992	0.034 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.038	2.544	0.991	0.037 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.960	1.593	0.990	0.036 Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.051	1.789	0.992	0.035 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.073	2.574	0.990	0.037 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	1.011	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.658	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	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
3.98	4.02	99.0	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 Lower Limit		Infectious Particle Ratio Upper Limit										
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	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		1.6e+1	1.2041199827	10.256966367	3.436	Pass	0.879	Ok
50% L01-240910_2	62	2	1.102e+10	19613.5	190120617.32	1.7258574881		8e+0	0.903089987	10.042024285	2.575	Pass	2.469	Ok
50% L01-240910_2	63	2	5.159e+9	19546	199264473.2	3.8622715539		4e+0	0.6020599913	9.7125870699	2.102	Pass	1.105	Ok
50% L01-240910_2	64	2	2.761e+9	19386.5	142914635.79	5.1765314071		2e+0	0.3010299957	9.4410378536	2.485	Pass	1.391	Ok
50% L01-240910_2	65	2	1.586e+10	19528	426059891.54	2.6857978728		1.6e+1	1.2041199827	10.200397327	0.224	Pass	-0.441	Ok
50% L01-240910_2	66	2	9.172e+9	19640	381089296.09	4.1548290727		8e+0	0.903089987	9.9624735888	0.098	Pass	0.463	Ok
50% L01-240910_2	67	2	4.472e+9	20154	205743731.17	4.6005207441		4e+0	0.6020599913	9.6505196182	0.005	Pass	-0.246	Ok
50% L01-240910_2	68	2	2.420e+9	19772	116728454.59	4.8244854223		2e+0	0.3010299957	9.3837257373	0.080	Pass	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	Pass	-1.233	Ok
50% L01-240910_2	70	2	7.776e+9	19753.5	311276312.65	4.0030128902		8e+0	0.903089987	9.8907590846	1.778	Pass	-1.095	Ok
50% L01-240910_2	71	2	3.776e+9	19467	89472972.022	2.3697464095		4e+0	0.6020599913	9.5769899896	2.141	Pass	-1.985	Ok
50% L01-240910_2	72	2	2.148e+9	19516	136835293.16	6.3705683843		2e+0	0.3010299957	9.332019945	1.832	Pass	-1.228	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	Pass	-0.991	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473		8e+0	0.903089987	10.210103028	2.499	Pass	-0.872	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469		4e+0	0.6020599913	9.8840460225	3.606	Pass	-0.748	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532		2e+0	0.3010299957	9.5752976845	0.366	Pass	-0.274	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559		1.6e+1	1.2041199827	10.55804215	0.356	Pass	-0.555	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497		8e+0	0.903089987	10.276827009	0.083	Pass	0.566	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488		4e+0	0.6020599913	9.9268639631	0.243	Pass	0.171	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438		2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.452	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946		1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.615	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715		8e+0	0.903089987	10.3230886	1.823	Pass	1.649	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859		4e+0	0.6020599913	9.9463114	1.397	Pass	0.589	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456		2e+0	0.3010299957	9.5985241259	5.157	Pass	0.261	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

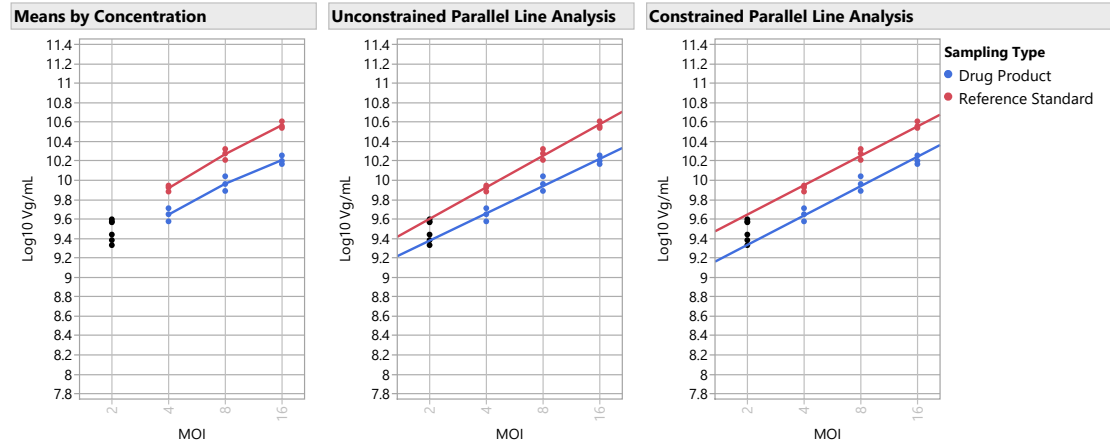
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

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	3	3.7e+10	3.08e+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		Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model	
Model 2, Low Standard and Test Doses Excluded	0.865	5.248	0.975	0.053 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.840	1.767	0.986	0.048 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	0.892	0.316	0.985	0.054 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.874	1.070	0.987	0.049 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.858	1.868	0.984	0.052 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.847	3.388	0.982	0.049 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	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.185	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.865	Passed Validity Criteria	
Linearity Ratio	.	26.3	5.248	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	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
5.59	11.44	48.9	0	0	48.9	53.7	44.1	150	50	9.7	9.7	Bioassay Results are Reportable	Assay is Valid and OOS

Relative		
Unconstrained RI	Constrained RI	Infectivity Delta
48.7	48.9	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	Externally Studentized Residuals	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	Pass	0.066	Ok
150% L01-240910_2	74	2	2.554e+10	19859.5	172756060.68	0.6764341882	8e+0	0.903089987	10.407207743	18.374	Pass	1.453	Ok
150% L01-240910_2	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	8.443	Pass	-0.076	Ok
150% L01-240910_2	76	2	6.956e+9	20033.5	95618993.904	1.3746652481	2e+0	0.3010299957	9.8423472161	0.242	Pass	0.652	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	Pass	-0.044	Ok
150% L01-240910_2	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.602	Pass	-0.054	Ok
150% L01-240910_2	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.966	Pass	-1.398	Ok
150% L01-240910_2	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.400	Pass	1.138	Ok
150% L01-240910_2	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.695	Pass	0.065	Ok
150% L01-240910_2	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.820	Pass	-0.175	Ok
150% L01-240910_2	83	2	1.151e+10	19997.5	194500111.81	1.690454602	4e+0	0.6020599913	10.060916343	0.489	Pass	-1.170	Ok
150% L01-240910_2	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	3.594	Pass	-0.330	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	Pass	-1.608	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499	Pass	-1.403	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Pass	-1.194	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Pass	-0.430	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356	Pass	-0.877	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Pass	0.894	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Pass	0.268	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.711	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.974	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Pass	2.890	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Pass	0.932	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Pass	0.408	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

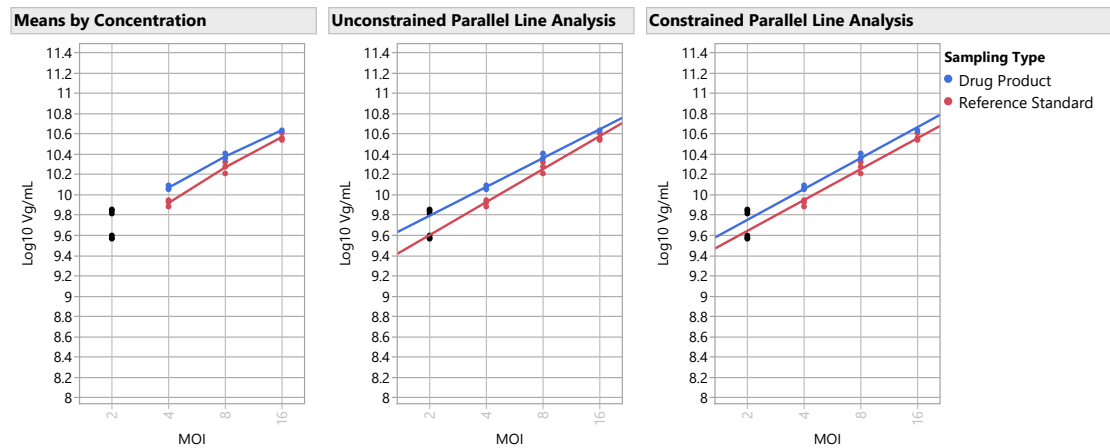
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

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	3	3.7e+10	3.08e+9
150% L01-240910_2	2e+0	3	6.88e+9	3.2e+8
150% L01-240910_2	4e+0	3	1.2e+10	5.57e+8
150% L01-240910_2	8e+0	3	2.4e+10	1.46e+9
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	0.873	4.104	0.987	0.033 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.816	0.369	0.993	0.031 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.783	3.583	0.988	0.033 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.856	2.901	0.993	0.031 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.833	0.569	0.990	0.033 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.831	1.490	0.985	0.036 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.823	2.116	0.994	0.030 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.814	0.776	0.991	0.034 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.785	1.670	0.994	0.030 Parallel and Linear	

150% L01-240910_2 Graphs



Validity Criteria			Validity		Overall Validity
	LSL	USL	Results	Assay Validity	
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.145	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.873	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.104	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower	CI Range as %				
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance	CI Range % of Tolerance	Check	OOS Validity
9.05	7.07	128.1	0	0	128.1	136.2	120.6	150	50	15.7	15.7	Bioassay Results are Reportable Assay is Valid and Within Limits		
		Relative												
Unconstrained RI	Constrained RI	Infectivity Delta												
128.2	128.1	0.1												
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	5.5745946199	11.480655431	0.7	48.6	43.5	53.6
150% L01-240910_1	8.9756559112	7.1303981161	1.7	125.9	118.6	133.7
200% L01-240910	9.8001683441	6.5305000642	2.0	150.1	142.0	158.9
100% L01-240910	3.9797170781	4.0203862953	1.3	99.0	94.4	103.8
50% L01-240910_2	5.5944150952	11.439980572	0.7	48.9	44.1	53.7
150% L01-240910_2	9.0531686713	7.0693480177	1.7	128.1	120.6	136.2
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

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

Reference Details

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

[illegible]

BQT Infectivity_13Nov2024-14-10-03

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