



Astellas BQT Assay Report
Test Article Report

Assay Details

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

Analyst Signature/Date

Approver Signature/Date

Astellas BQT Infectivity Files

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

50% L01-240910_1 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted	Std	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
50% L01-240910_1	13	2	1.821e+10	20851.5	94435265.333	0.5184670847	1.6e+1	1.2041199827	10.260413015	7.610	Pass	0.853	Ok
50% L01-240910_1	14	2	1.118e+10	20462.5	49645939.883	0.4438881443	8e+0	0.903089987	10.048610191	3.296	Pass	2.449	Ok
50% L01-240910_1	15	2	5.151e+9	19885	42103690.407	0.8174463291	4e+0	0.6020599913	9.7118609157	2.104	Pass	0.951	Ok
50% L01-240910_1	16	2	2.926e+9	20742	149980255.56	5.1253477381	2e+0	0.3010299957	9.4663107531	7.342	Pass	1.886	Ok
50% L01-240910_1	17	2	1.549e+10	19522.5	597112052.57	3.8558336802	1.6e+1	1.2041199827	10.189937545	0.467	Pass	-0.742	Ok
50% L01-240910_1	18	2	9.173e+9	20427.5	131640590.54	1.4350393346	8e+0	0.903089987	9.9625260166	0.207	Pass	0.367	Ok
50% L01-240910_1	19	2	4.545e+9	20017.5	1488640.7937	0.0327556343	4e+0	0.6020599913	9.6575039019	0.004	Pass	-0.188	Ok
50% L01-240910_1	20	2	2.295e+9	20649	42748637.553	1.8626139363	2e+0	0.3010299957	9.3607994298	0.459	Pass	-0.624	Ok
50% L01-240910_1	21	2	1.493e+10	20123.5	746021394.55	4.9977972131	1.6e+1	1.2041199827	10.173972652	0.997	Pass	-1.122	Ok
50% L01-240910_1	22	2	8.075e+9	20094	265089947.14	3.2829854877	8e+0	0.903089987	9.9071242956	1.480	Pass	-0.785	Ok
50% L01-240910_1	23	2	3.931e+9	20231	32494046.672	0.8265927734	4e+0	0.6020599913	9.5945121959	2.139	Pass	-1.576	Ok
50% L01-240910_1	24	2	2.161e+9	20708	28653653.294	1.3262198343	2e+0	0.3010299957	9.3345644829	1.009	Pass	-1.251	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass	-0.848	Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass	-0.772	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass	-1.345	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass	0.028	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass	-0.308	Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass	0.289	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass	-0.276	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass	-0.165	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass	0.748	Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass	1.728	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass	0.404	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass	0.568	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

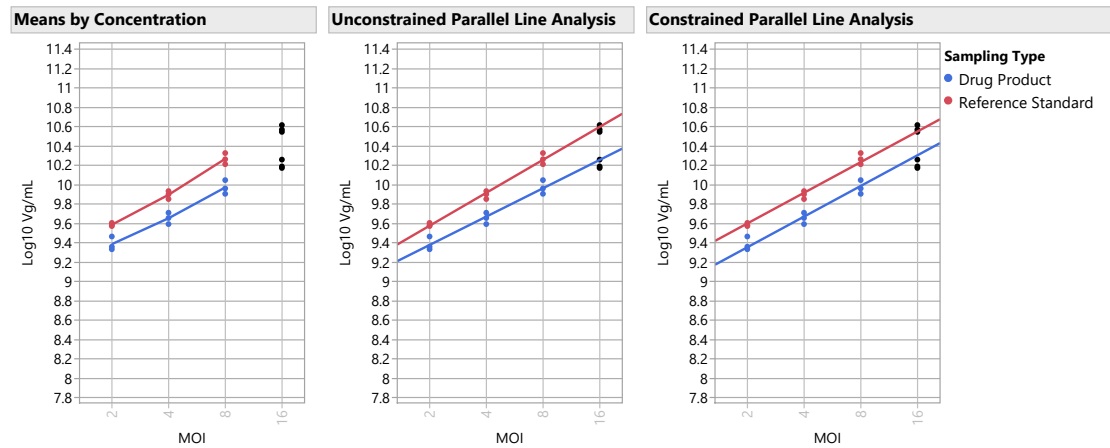
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
50% L01-240910_1	2e+0	3	2.46e+9	4.09e+8
50% L01-240910_1	4e+0	3	4.54e+9	6.1e+8
50% L01-240910_1	8e+0	3	9.48e+9	1.58e+9
50% L01-240910_1	1.6e+1	3	1.6e+10	1.76e+9

50% L01-240910_1 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 3, High Standard and Test Doses Excluded	0.860	4.467	0.973	0.054 Parallel and Linear	Model 3, High Standard and Test Doses Excluded
Model 1, All Doses	0.832	0.959	0.985	0.050 Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	0.812	5.848	0.976	0.053 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.876	0.903	0.986	0.051 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.859	0.646	0.984	0.055 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.828	1.411	0.982	0.049 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.817	0.585	0.976	0.053 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.816	2.725	0.983	0.054 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.813	1.240	0.969	0.052 Parallel and Linear	

50% L01-240910_1 Graphs



50% L01-240910_1 Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.178	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.860	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.467	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	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

		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
3.05	5.24	58.3	0	0	58.3	63.8	53.0	150	50	10.8	10.8	Bioassay Results are Reportable Assay is Valid and Within Limits		

Unconstrained RI	Constrained RI	Relative Infectivity Delta
58.2	58.3	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	Jackknife z	Outlier	Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)					Within Group	Studentized Residuals	Between Group
150% L01-240910_1	25	2	4.328e+10	19590	656185083.84	1.516157548	1.6e+1	1.2041199827	10.636282022	0.797	Pass		0.207 Ok
150% L01-240910_1	26	2	2.548e+10	19257.5	127422942.19	0.5001095848	8e+0	0.903089987	10.406182451	6.439	Pass		1.342 Ok
150% L01-240910_1	27	2	1.235e+10	20620.5	95067106.961	0.7697030114	4e+0	0.6020599913	10.091707092	3.487	Pass		-0.123 Ok
150% L01-240910_1	28	2	7.267e+9	19589.5	124780027.36	1.7170178963	2e+0	0.3010299957	9.8613702547	0.645	Pass		1.073 Ok
150% L01-240910_1	29	2	4.320e+10	20041.5	479922826.41	1.1109143873	1.6e+1	1.2041199827	10.635490815	0.622	Pass		0.181 Ok
150% L01-240910_1	30	2	2.319e+10	19921	669588345.21	2.8877311629	8e+0	0.903089987	10.365251126	0.427	Pass		0.071 Ok
150% L01-240910_1	31	2	1.108e+10	20170	136112012.44	1.2281117402	4e+0	0.6020599913	10.044658572	1.427	Pass		-1.617 Ok
150% L01-240910_1	32	2	7.305e+9	19580.5	228548830.67	3.1286225929	2e+0	0.3010299957	9.8636258265	0.772	Pass		1.152 Ok
150% L01-240910_1	33	2	4.196e+10	19967	98481352.962	0.2346842141	1.6e+1	1.2041199827	10.622870128	22.921	Pass		-0.224 Ok
150% L01-240910_1	34	2	2.262e+10	19692	154114236.92	0.681261223	8e+0	0.903089987	10.35452909	1.056	Pass		-0.247 Ok
150% L01-240910_1	35	2	1.151e+10	19410.5	203413827.77	1.7671798668	4e+0	0.6020599913	10.061099717	0.230	Pass		-1.059 Ok
150% L01-240910_1	36	2	6.446e+9	20595.5	356693271.03	5.5331329205	2e+0	0.3010299957	9.8093238133	31.380	Pass		-0.634 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass		-1.247 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass		-1.131 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass		-2.044 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass		0.040 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass		-0.444 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass		0.418 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass		-0.398 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass		-0.238 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass		1.095 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass		2.731 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass		0.585 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass		0.826 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

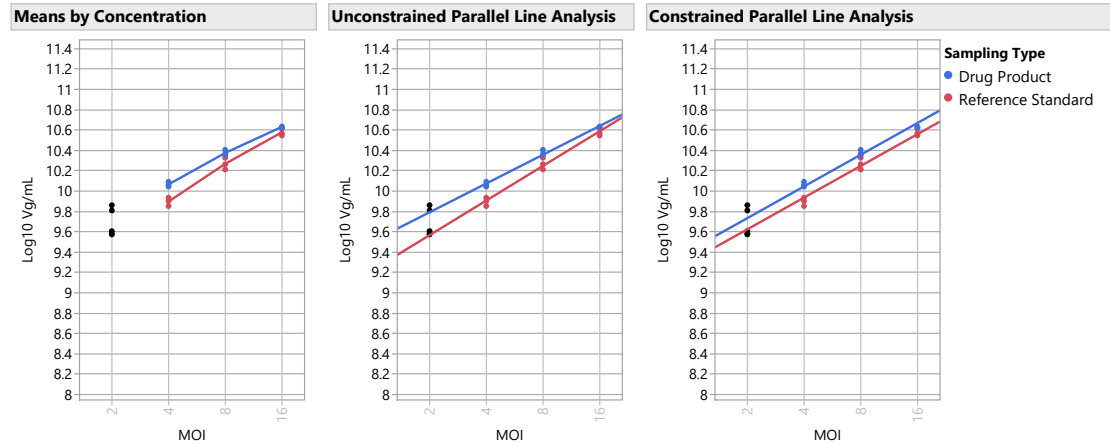
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
150% L01-240910_1	2e+0	3	7.01e+9	4.85e+8
150% L01-240910_1	4e+0	3	1.2e+10	6.45e+8
150% L01-240910_1	8e+0	3	2.4e+10	1.51e+9
150% L01-240910_1	1.6e+1	3	4.3e+10	7.38e+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	0.830	4.608	0.985	0.037 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.799	1.120	0.992	0.035 Parallel and Linear		
Model 3, High Standard and Test Doses Excluded	0.780	6.227	0.984	0.039 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.846	0.886	0.992	0.034 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.831	0.547	0.992	0.035 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.794	1.617	0.989	0.038 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.785	2.954	0.991	0.035 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.784	0.775	0.987	0.037 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	0.779	1.659	0.982	0.041 Parallel and Linear		

150% L01-240910_1 Graphs



150% L01-240910_1 Validity Report

Validity Criteria			Validity		Overall
	LSL	USL	Results	Assay Validity	Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.270	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.830	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.608	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	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		Relative Infectivity		Assay RI		Assay RI		Upper		Lower		CI Range as %		of Tolerance		CI Range % of Tolerance		Check		OOS Validity	
9.04		7.08		127.6		0		0		127.6		137.0		119.1		150		50		17.9		17.9		Bioassay Results are Reportable		Assay is Valid and Within Limits	
Unconstrained RI		Constrained RI		Relative Infectivity Delta																							
127.9		127.6		0.3																							
Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio		Infectious Particle Ratio	
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	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)				Jackknife z	Within Group	Studentized Residuals	Between Group
200% L01-240910	37	2	5.122e+10	19992	783580839.19	1.5299807737	1.6e+1	1.2041199827	10.709397834	0.859	Pass	-0.097	Ok
200% L01-240910	38	2	3.003e+10	19829.5	1181939524.2	3.9352547599	8e+0	0.903089987	10.477622403	5.054	Pass	0.751	Ok
200% L01-240910	39	2	1.444e+10	20205	633969738.98	4.3888702708	4e+0	0.6020599913	10.159715785	0.986	Pass	-0.496	Ok
200% L01-240910	40	2	1.053e+10	20592.5	698524091.26	6.6343484073	2e+0	0.3010299957	10.022383114	43.028	Pass	3.687	Ok
200% L01-240910	41	2	5.692e+10	19740.5	1139795369.6	2.0023037825	1.6e+1	1.2041199827	10.755296921	13.863	Pass	1.130	Ok
200% L01-240910	42	2	2.738e+10	19903.5	659314495.92	2.4079566923	8e+0	0.903089987	10.437443953	0.360	Pass	-0.222	Ok
200% L01-240910	43	2	1.421e+10	19306.5	662221857.73	4.6616125322	4e+0	0.6020599913	10.152467339	0.474	Pass	-0.675	Ok
200% L01-240910	44	2	7.868e+9	19962	351032941.35	4.4612955036	2e+0	0.3010299957	9.8958868825	0.754	Pass	-0.470	Ok
200% L01-240910	45	2	5.177e+10	20033.5	375780825.57	0.7258769233	1.6e+1	1.2041199827	10.714071626	0.570	Pass	0.024	Ok
200% L01-240910	46	2	2.652e+10	18917.5	798069096.51	3.0096351073	8e+0	0.903089987	10.42352665	1.167	Pass	-0.560	Ok
200% L01-240910	47	2	1.299e+10	20733.5	142190222.08	1.0943764268	4e+0	0.6020599913	10.113703003	7.882	Pass	-1.714	Ok
200% L01-240910	48	2	7.954e+9	20191	372262329.4	4.6799330306	2e+0	0.3010299957	9.9006094522	0.661	Pass	-0.346	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass	-0.995	Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass	-0.904	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass	-1.594	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass	0.033	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass	-0.359	Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass	0.337	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass	-0.322	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass	-0.193	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass	0.876	Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass	2.073	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass	0.472	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass	0.664	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

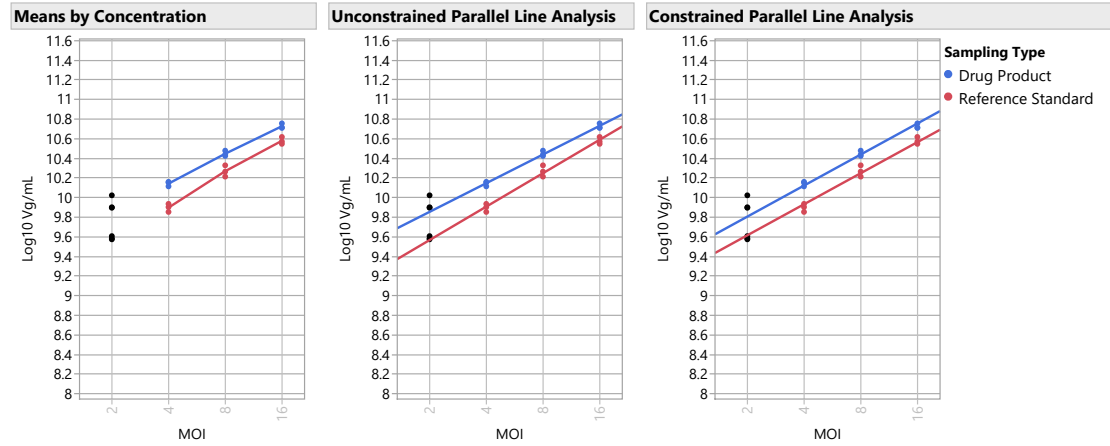
200% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
200% L01-240910	2e+0	3	8.78e+9	1.51e+9
200% L01-240910	4e+0	3	1.4e+10	7.79e+8
200% L01-240910	8e+0	3	2.8e+10	1.83e+9
200% L01-240910	1.6e+1	3	5.3e+10	3.15e+9

200% L01-240910 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE Evaluation	Selected Model	
Model 2, Low Standard and Test Doses Excluded	0.858	3.391	0.986	0.037 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded	
Model 1, All Doses	0.797	2.449	0.988	0.043 Parallel and Linear		
Model 3, High Standard and Test Doses Excluded	0.744	6.919	0.978	0.047 Parallel and Linear		
Model 6, Test Low Dose Only Excluded	0.874	0.376	0.993	0.034 Parallel and Linear		
Model 9, Standard High Dose and Test Low Dose Excluded	0.859	2.265	0.993	0.035 Parallel and Linear		
Model 5, Standard High Dose Only Excluded	0.783	5.194	0.987	0.045 Parallel and Linear		
Model 4, Standard Low Dose Only Excluded	0.782	3.036	0.980	0.046 Parallel and Linear		
Model 7, Test High Dose Only Excluded	0.758	1.895	0.984	0.045 Parallel and Linear		
Model 8, Standard Low Dose and Test High Dose Excluded	0.744	2.542	0.971	0.048 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	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.374	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.858	Passed Validity Criteria	
Linearity Ratio	.	26.3	3.391	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	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 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range as % of Tolerance		OOS Validity
9.85		6.49		Uncorrected 151.7		Reference CF 0	151.7	162.5	142.1	150	50	20.4	20.4	Bioassay Results are Reportable Assay is Valid and OOS
Unconstrained RI		Constrained RI		Relative Infectivity Delta										
152.1		151.7		0.4										
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	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)	CV(Vg/mL)	Jackknife z				Within Group	Studentized Residuals	Between Group	
100% L01-240910	49	2	3.677e+10	19203	117861205.29	0.320544712	1.6e+1	1.2041199827	10.565482261	0.792	Pass		-1.083	Ok
100% L01-240910	50	2	1.712e+10	18946	389600987.9	2.276366175	8e+0	0.903089987	10.233377926	2.164	Pass		-0.782	Ok
100% L01-240910	51	2	7.957e+9	20068	202754799.3	2.5482781986	4e+0	0.6020599913	9.9007243042	10.649	Pass		-0.591	Ok
100% L01-240910	52	2	3.687e+9	19366	179490548.5	4.8680635883	2e+0	0.3010299957	9.566853422	0.134	Pass		-0.479	Ok
100% L01-240910	53	2	3.701e+10	19265	1405677694.6	3.7978791033	1.6e+1	1.2041199827	10.568344618	0.627	Pass		-0.989	Ok
100% L01-240910	54	2	1.924e+10	18664	1497416004.4	7.7830217781	8e+0	0.903089987	10.284194225	0.011	Pass		0.668	Ok
100% L01-240910	55	2	8.908e+9	19092.5	465543327.06	5.226167867	4e+0	0.6020599913	9.9497767506	0.908	Pass		0.809	Ok
100% L01-240910	56	2	3.572e+9	20039	153217941.95	4.2888527325	2e+0	0.3010299957	9.5529684905	1.672	Pass		-0.914	Ok
100% L01-240910	57	2	4.107e+10	18741	112923026.09	0.2749478765	1.6e+1	1.2041199827	10.613532138	24.314	Pass		0.416	Ok
100% L01-240910	58	2	2.130e+10	20008	537971703.31	2.5254998667	8e+0	0.903089987	10.328412083	2.080	Pass		2.118	Ok
100% L01-240910	59	2	8.789e+9	19365.5	327411500.51	3.7250523238	4e+0	0.6020599913	9.9439615528	0.531	Pass		0.639	Ok
100% L01-240910	60	2	3.855e+9	19808	168024878.86	4.3584371279	2e+0	0.3010299957	9.5860428055	2.780	Pass		0.114	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass		-1.182	Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass		-1.072	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass		-1.924	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass		0.038	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass		-0.422	Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass		0.397	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass		-0.379	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass		-0.227	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass		1.038	Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass		2.550	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass		0.556	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass		0.785	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

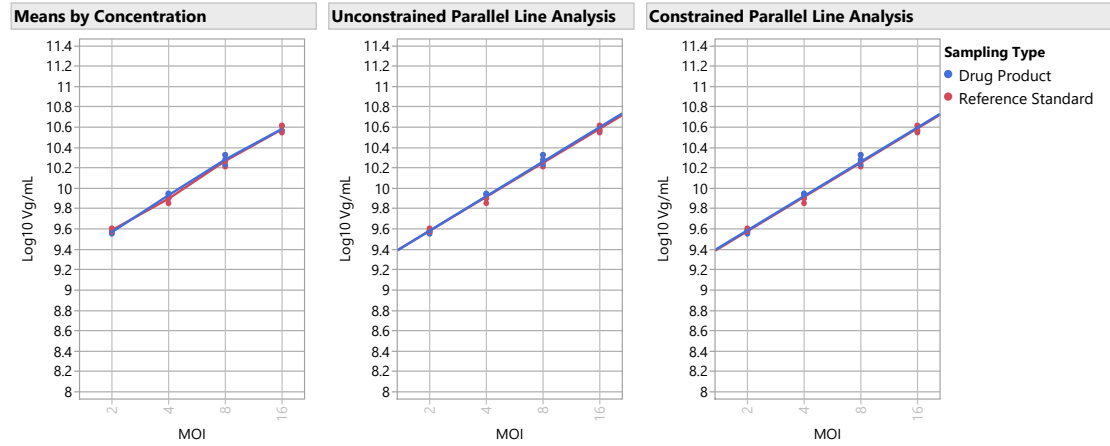
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
100% L01-240910	2e+0	3	3.7e+9	1.42e+8
100% L01-240910	4e+0	3	8.55e+9	5.18e+8
100% L01-240910	8e+0	3	1.9e+10	2.09e+9
100% L01-240910	1.6e+1	3	3.8e+10	2.42e+9

100% L01-240910 Model Selection

Model	Parallelism		Linearity		Validity	
	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 1, All Doses	1.015	1.719	0.992	0.036	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.956	4.192	0.983	0.041	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	1.048	1.792	0.987	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.997	1.975	0.991	0.037	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.996	3.910	0.990	0.039	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.974	0.777	0.990	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.957	0.694	0.989	0.039	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.047	3.982	0.989	0.039	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.067	0.159	0.991	0.036	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		.		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.		15		0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7		1.4		1.015	Passed Validity Criteria	
Linearity Ratio	.		26.3		1.719	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04		61.8		4.764	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 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
5.71		5.61		Uncorrected	Reference CF							CI Range	of Tolerance	CI Range % of Tolerance	
5.71		5.61		101.7	0	0	101.7	106.3	97.3	150	50	9.0	9.0	Bioassay Results are Reportable	Assay is Valid and Within Limits
Unconstrained RI		Constrained RI		Relative Infectivity Delta											
101.7		101.7		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	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier		Externally Outlier	
				Droplets	Dev(Vg/mL)					Jackknife z	Within Group	Studentized Residuals	Between Group
50% L01-240910_2	61	2	1.836e+10	19242.5	578676092.33	3.1526420738	1.6e+1	1.2041199827	10.263760873	4.977	Pass	0.855	Ok
50% L01-240910_2	62	2	1.146e+10	19672.5	383744830.65	3.3484648371	8e+0	0.903089987	10.059196796	4.500	Pass	2.576	Ok
50% L01-240910_2	63	2	5.320e+9	19670.5	143601825	2.6992944637	4e+0	0.6020599913	9.7259096953	1.665	Pass	1.086	Ok
50% L01-240910_2	64	2	2.844e+9	18932.5	78820891.318	2.771568467	2e+0	0.3010299957	9.45391573	2.285	Pass	1.278	Ok
50% L01-240910_2	65	2	1.572e+10	20668	412066220.06	2.6208869292	1.6e+1	1.2041199827	10.196518729	0.355	Pass	-0.643	Ok
50% L01-240910_2	66	2	9.122e+9	18914	97392479.23	1.0676937726	8e+0	0.903089987	9.9600787117	0.323	Pass	0.211	Ok
50% L01-240910_2	67	2	4.715e+9	20554	235510385.67	4.9945365046	4e+0	0.6020599913	9.673514872	0.136	Pass	-0.007	Ok
50% L01-240910_2	68	2	2.498e+9	15224	.	.	2e+0	0.3010299957	9.3976468856	0.039	Pass	-0.008	Ok
50% L01-240910_2	69	2	1.485e+10	19314.5	496404373.91	3.3426924038	1.6e+1	1.2041199827	10.171739185	1.175	Pass	-1.225	Ok
50% L01-240910_2	70	2	8.250e+9	19914.5	77289525.011	0.9368708507	8e+0	0.903089987	9.9164409116	1.234	Pass	-0.681	Ok
50% L01-240910_2	71	2	3.822e+9	19669.5	76628716.753	2.0047058585	4e+0	0.6020599913	9.5823408932	2.796	Pass	-2.047	Ok
50% L01-240910_2	72	2	2.189e+9	14748	.	.	2e+0	0.3010299957	9.3401609307	1.975	Pass	-1.327	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass	-0.835	Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass	-0.760	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass	-1.323	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass	0.028	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass	-0.303	Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass	0.285	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass	-0.272	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass	-0.163	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass	0.737	Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass	1.699	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass	0.398	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass	0.560	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

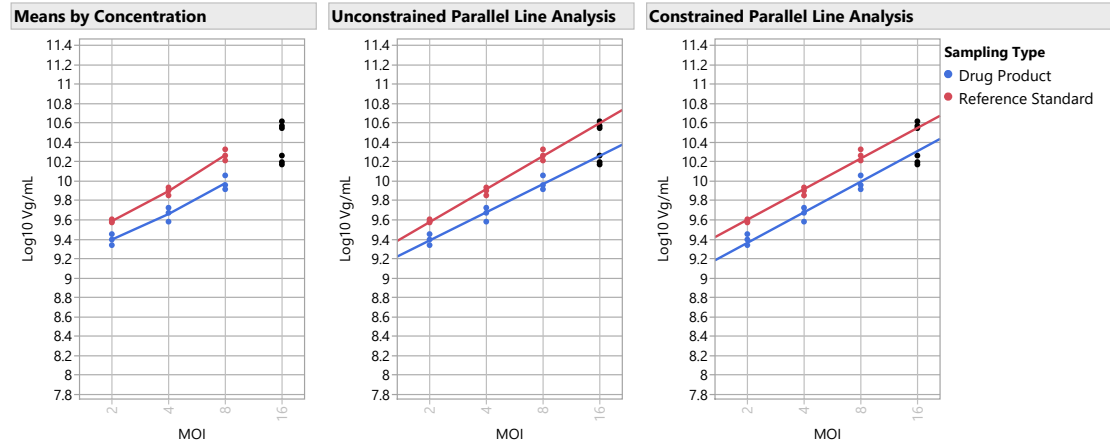
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Std	
			Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
50% L01-240910_2	2e+0	3	2.51e+9	3.28e+8
50% L01-240910_2	4e+0	3	4.62e+9	7.53e+8
50% L01-240910_2	8e+0	3	9.61e+9	1.66e+9
50% L01-240910_2	1.6e+1	3	1.6e+10	1.82e+9

50% L01-240910_2 Model Selection

Model	Parallelism	Linearity	R2	Validity	Selected Model
	Slope Ratio	Ratio		RMSE Evaluation	
Model 3, High Standard and Test Doses Excluded	0.854	4.636	0.972	0.055 Parallel and Linear	Model 3, High Standard and Test Doses Excluded
Model 1, All Doses	0.825	0.938	0.984	0.051 Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	0.807	5.990	0.972	0.056 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.870	0.973	0.985	0.051 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.853	0.416	0.984	0.056 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.823	1.470	0.980	0.051 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.811	0.546	0.975	0.053 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.810	2.694	0.982	0.055 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.808	1.433	0.965	0.055 Parallel and Linear	

50% L01-240910_2 Graphs



50% L01-240910_2 Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.193	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.854	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.636	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	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

EC50 Ref	EC50 Test	RI	Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower	CI Range as %				
		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
3.08	5.20	59.2	0	0	59.2	64.8	53.6	150	50	11.2	11.2	Bioassay Results are Reportable	Assay is Valid and Within Limits

Relative		
Unconstrained RI	Constrained RI	Infectivity Delta
59.0	59.2	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	4.400e+10	19227.5	1011785905.7	2.2997680598	1.6e+1	1.2041199827	10.643404587	18.815	Pass	0.338	Ok
150% L01-240910_2	74	2	2.553e+10	19561	1022989391.8	4.0075911691	8e+0	0.903089987	10.406987719	8.130	Pass	1.259	Ok
150% L01-240910_2	75	2	1.243e+10	19720	215002496.86	1.7291133125	4e+0	0.6020599913	10.094620049	8.448	Pass	-0.152	Ok
150% L01-240910_2	76	2	7.210e+9	15797	460290519.99	6.3836280682	2e+0	0.3010299957	9.8579644548	0.278	Pass	0.815	Ok
150% L01-240910_2	77	2	4.318e+10	19239	1153369528.8	2.6708724835	1.6e+1	1.2041199827	10.63531532	0.605	Pass	0.077	Ok
150% L01-240910_2	78	2	2.311e+10	19181	16052321.661	0.0694549112	8e+0	0.903089987	10.363834893	0.481	Pass	-0.074	Ok
150% L01-240910_2	79	2	1.140e+10	20626	323785549.92	2.839103811	4e+0	0.6020599913	10.05707619	0.489	Pass	-1.326	Ok
150% L01-240910_2	80	2	7.430e+9	15294.5	318946741.85	4.2927946804	2e+0	0.3010299957	9.8709780529	1.323	Pass	1.271	Ok
150% L01-240910_2	81	2	4.312e+10	19919	212901108.44	0.4937427852	1.6e+1	1.2041199827	10.63467716	0.818	Pass	0.056	Ok
150% L01-240910_2	82	2	2.265e+10	20149	1046904735.2	4.6217208411	8e+0	0.903089987	10.355103454	0.977	Pass	-0.335	Ok
150% L01-240910_2	83	2	1.122e+10	20629	168546177.42	1.5026815525	4e+0	0.6020599913	10.049851952	0.965	Pass	-1.578	Ok
150% L01-240910_2	84	2	6.707e+9	17865	246301164.67	3.6724316625	2e+0	0.3010299957	9.8265127424	3.955	Pass	-0.213	Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363	Pass	-1.254	Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692	Pass	-1.137	Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625	Pass	-2.056	Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343	Pass	0.040	Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259	Pass	-0.446	Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126	Pass	0.420	Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107	Pass	-0.400	Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198	Pass	-0.240	Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754	Pass	1.101	Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737	Pass	2.750	Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750	Pass	0.587	Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780	Pass	0.831	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

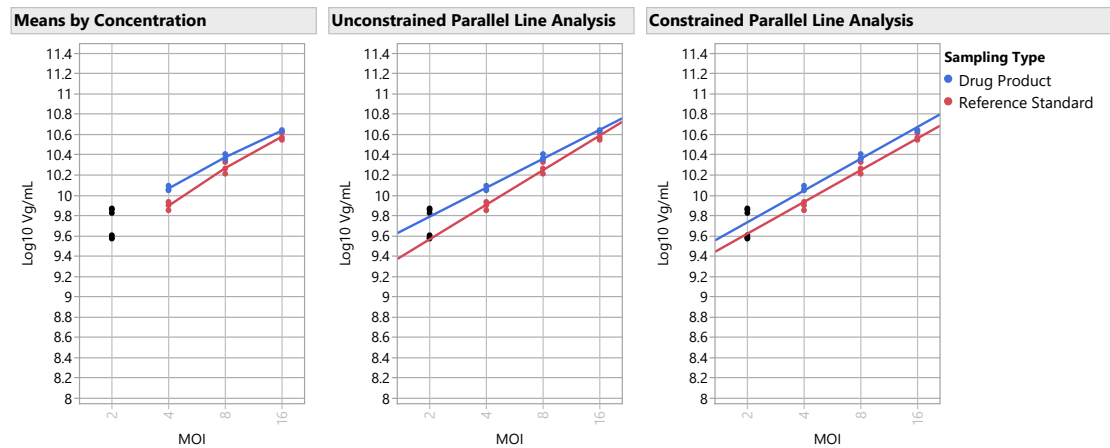
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
150% L01-240910_2	2e+0	3	7.12e+9	3.71e+8
150% L01-240910_2	4e+0	3	1.2e+10	6.56e+8
150% L01-240910_2	8e+0	3	2.4e+10	1.54e+9
150% L01-240910_2	1.6e+1	3	4.3e+10	4.88e+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	0.838	4.285	0.985	0.036 Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.798	1.493	0.992	0.035 Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.769	6.442	0.984	0.038 Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.854	0.751	0.993	0.034 Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.838	1.003	0.992	0.034 Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.784	3.585	0.991	0.035 Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.783	1.704	0.989	0.037 Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.783	1.409	0.987	0.037 Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.768	1.937	0.982	0.040 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	.	34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.251	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.838	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.285	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	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
9.06	7.06	128.2	0	0	128.2	137.4	119.9	150	50	17.6	17.6	Bioassay Results are Reportable Assay is Valid and Within Limits		
		Relative												
Unconstrained RI	Constrained RI	Infectivity Delta												
128.5	128.2	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	3.0549767736	5.2373556939	0.7	58.3	53.0	63.8
150% L01-240910_1	9.0383279923	7.0809556872	1.7	127.6	119.1	137.0
200% L01-240910	9.8546761029	6.4943788443	2.0	151.7	142.1	162.5
100% L01-240910	5.7055441357	5.6085798723	1.3	101.7	97.3	106.3
50% L01-240910_2	3.0767007171	5.2003758152	0.7	59.2	53.6	64.8
150% L01-240910_2	9.0593997682	7.0644856875	1.7	128.2	119.9	137.4
Sample Name	Overall Validity	OOS	Reportable			
50% L01-240910_1	Assay is Valid	Within Limits	Reportable			
150% L01-240910_1	Assay is Valid	Within Limits	Reportable			
200% L01-240910	Assay is Valid	OOS	Reportable			
100% L01-240910	Assay is Valid	Within Limits	Reportable			
50% L01-240910_2	Assay is Valid	Within Limits	Reportable			
150% L01-240910_2	Assay is Valid	Within Limits	Reportable			

Astellas BQT Infectivity Bioassay Materials and Reference Standard Report

Assay Details

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 3		Vg/mL	KT430				
Notes											
Assay Range Check											

Materials

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

Reference Details

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

[illegible]

BQT Infectivity_13Nov2024-11-38-15

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

Well	Sample description 1	Sample description 2	Sample description 3	Sample description 4	Conc(copies/ μL)	Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted	Droplets	Positives	Negatives
D04	2	50	REP1		BDNF	101.0765839	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20637	1699	18938
C04	4	50	REP1		BDNF	172.6802826	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21082	2878	18204
B04	8	50	REP1		BDNF	371.6410217	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19759	5352	14407
A04	16	50	REP1		BDNF	609.3699341	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20103	8127	11976
D05	2	50	REP2		BDNF	75.4953537	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20497	1274	19223
C05	4	50	REP2		BDNF	151.4544525	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20448	2470	17978
B05	8	50	REP2		BDNF	302.6741638	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20199	4582	15617
A05	16	50	REP2		BDNF	502.1239014	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20034	6960	13074
D06	2	50	REP3		BDNF	72.69373322	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21095	1264	19831
C06	4	50	REP3		BDNF	131.8019867	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20588	2182	18406
B06	8	50	REP3		BDNF	262.907135	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19849	3975	15874
A06	16	50	REP3		BDNF	479.9829102	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20062	6721	13341
H04	2	50.2	REP1		BDNF	92.93914795	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	16667	1266	15401
G04	4	50.2	REP1		BDNF	180.7172699	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21251	3026	18243
F04	8	50.2	REP1		BDNF	391.0556641	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20474	5790	14684
E04	16	50.2	REP1		BDNF	598.2029419	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19667	7839	11828
H05	2	50.2	REP2		BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	9646	632	9014
G05	4	50.2	REP2		BDNF	162.7297058	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20274	2619	17655
F05	8	50.2	REP2		BDNF	306.3542786	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19236	4410	14826
E05	16	50.2	REP2		BDNF	514.3673706	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21185	7503	13682
H06	2	50.2	REP3		BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	9811	474	9337
G06	4	50.2	REP3		BDNF	125.6085739	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20629	2089	18540
F06	8	50.2	REP3		BDNF	273.1700134	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20144	4174	15970
E06	16	50.2	REP3		BDNF	483.3141479	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19297	6501	12796
H01	2	100.2	REP1		BDNF	118.672821	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19166	1839	17327
G01	4	100.2	REP1		BDNF	269.9970093	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19696	4039	15657
F01	8	100.2	REP1		BDNF	579.6843262	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19954	7763	12191
E01	16	100.2	REP1		BDNF	1228.412598	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19617	12712	6905
H02	2	100.2	REP2		BDNF	115.4709244	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20345	1902	18443
G02	4	100.2	REP2		BDNF	307.9039307	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19655	4526	15129
F02	8	100.2	REP2		BDNF	676.6117554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19565	8557	11008
E02	16	100.2	REP2		BDNF	1200.607056	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19858	12701	7157
H03	2	100.2	REP3		BDNF	124.5450668	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20557	2065	18492
G03	4	100.2	REP3		BDNF	285.2644043	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19404	4178	15226
F03	8	100.2	REP3		BDNF	722.7332153	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19704	9044	10660
E03	16	100.2	REP3		BDNF	1366.361816	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19946	13702	6244
D07	2	150	REP1		BDNF	245.1828461	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20593	3874	16719
C07	4	150	REP1		BDNF	409.4639587	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20964	6162	14802
B07	8	150	REP1		BDNF	846.2967529	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19718	10114	9604
A07	16	150	REP1		BDNF	1427.182861	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19763	13888	5875
D08	2	150	REP2		BDNF	248.8900909	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20443	3898	16545
C08	4	150	REP2		BDNF	372.6425781	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20480	5560	14920
B08	8	150	REP2		BDNF	788.6940308	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19767	9656	10111
A08	16	150	REP2		BDNF	1428.711548	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20075	14115	5960
D09	2	150	REP3		BDNF	223.2905884	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21027	3635	17392
C09	4	150	REP3		BDNF	388.4827271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20791	5847	14944
B09	8	150	REP3		BDNF	757.6958618	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20822	9887	10935
A09	16	150	REP3		BDNF	1401.099487	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18948	13189	5759
H07	2	150.2	REP1		BDNF	251.1986389	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	10340	1988	8352
G07	4	150.2	REP1		BDNF	409.4077759	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20422	6002	14420
F07	8	150.2	REP1		BDNF	874.9884644	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19986	10486	9500
E07	16	150.2	REP1		BDNF	1442.65625	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20086	14193	5893
H08	2	150.2	REP2		BDNF	255.1781769	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	10221	1993	8228
G08	4	150.2	REP2		BDNF	387.7816467	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20926	5876	15050
F08	8	150.2	REP2		BDNF	770.0169678	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20285	9743	10542
E08	16	150.2	REP2		BDNF	1412.25647	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20218	14131	6087
H09	2	150.2	REP3		BDNF	229.3640289	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	15209	2694	12515
G09	4	150.2	REP3		BDNF	369.9060059	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20783	5607	15176
F09	8	150.2	REP3		BDNF	779.7370605	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20333	9853	10480
E09	16	150.2	REP3		BDNF	1442.346191	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20033	14154	5879
D10	2	200	REP1		BDNF	367.4277954	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20194	5417	14777
C10	4	200	REP1		BDNF	496.4408569	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21589	7432	14157
B10	8	200	REP1		BDNF	1029.013184	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20796	12124	8672
A10	16	200	REP1		BDNF	1725.638428	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19756	15199	4557
D11	2	200	REP2		BDNF	270.5541992	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20906	4295	16611
C11	4	200	REP2		BDNF	489.1371765	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20393	6937	13456
B11	8	200	REP2		BDNF	928.2289429	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21226	11583	9643
A11	16	200	REP2		BDNF	1924.338501	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19762	15912	3850
D12	2	200	REP3		BDNF	273.9222107	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19806	4114	15692
C12	4	200	REP3		BDNF	429.7421265	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20706	6336	14370
B12	8	200	REP3		BDNF	902.715271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20370	10913	9457
A12	16	200	REP3		BDNF	1716.783447	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19823	15216	4607
D01	2	RS	REP1		BDNF	133.247879	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19415	2079	17336
C01	4	RS	REP1		BDNF	222.2429047	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19990	3441	16549
B01	8	RS	REP1		BDNF	533.5421753	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19303	7038	12265
A01	16	RS	REP1		BDNF	1162.303711	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17409	10927	6482
D02	2	RS	REP2		BDNF	128.9781799	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19762	2052	17710
C02	4	RS	REP2		BDNF	250.839859	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20618	3959	16659
B02	8	RS	REP2		BDNF	614.6605835	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19219	7821	11398
A02	16	RS	REP2		BDNF	1223.330322	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17442	11276	6166