Astellas BQT Assay Report

Test Article Report

Assay Details

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

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Analyst Signature/Date

_____
Approver Signature/Date

BQT Infectivity_18Nov2024-12-16-01

Astellas BQT Infectivity Files

First Data File	Second Data File
Astellas BQT Test File - 01	Astellas BQT Test File - 02

AC & 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
AC	13	2	3.726e+10	19835	1018233764.9	2.7327798307	1.24e+1	1.0934216852	10.571242851	0.325	Pass	-0.368	Ok
AC	14	2	2.397e+10	20895	127279220.61	0.5309938282	6.18e+0	0.7909884751	10.379668034	2.233	Pass	2.571	Outlier
AC	15	2	9.765e+9	21194	21213203.436	0.2172371064	3.09e+0	0.4899584794	9.9896722476	0.851	Pass	-0.371	Ok
AC	16	2	4.938e+9	20749	313955410.85	6.3579467567	1.54e+0	0.1875207208	9.6935510856	0.722	Pass	-0.551	Ok
AC	17	2	3.888e+10	19902	1781909088.6	4.5830995077	1.24e+1	1.0934216852	10.589726256	4.525	Pass	0.145	Ok
AC	18	2	2.110e+10	19579	1294005409.6	6.131274151	6.18e+0	0.7909884751	10.324385356	0.027	Pass	0.800	Ok
AC	19	2	9.675e+9	21184	148492424.05	1.5348054165	3.09e+0	0.4899584794	9.9856509737	0.577	Pass	-0.476	Ok
AC	20	2	6.081e+9	20805	453962553.52	7.4652615281	1.54e+0	0.1875207208	9.7839750034	134.00	Pass	2.207	Ok
AC	21	2	3.666e+10	18765	1187939392.4	3.2404238745	1.24e+1	1.0934216852	10.564192461	1.231	Pass	-0.567	Ok
AC	22	2	1.845e+10	19234	636396103.07	3.4493013716	6.18e+0	0.7909884751	10.26599637	2.018	Pass	-0.716	Ok
AC	23	2	8.790e+9	18692	127279220.61	1.4480002345	3.09e+0	0.4899584794	9.9439888751	14.614	Pass	-1.649	Ok
AC	24	2	4.950e+9	18572	84852813.742	1.7141982574	1.54e+0	0.1875207208	9.6946051989	0.692	Pass	-0.521	Ok
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-1.565	Ok
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	1.811	Ok
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.346	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.037	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.029	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	1.373	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.054	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		2.440	Ok
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.280	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.053	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-0.828	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.245	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

AC Test Sample & Reference Standard Summary Statistics

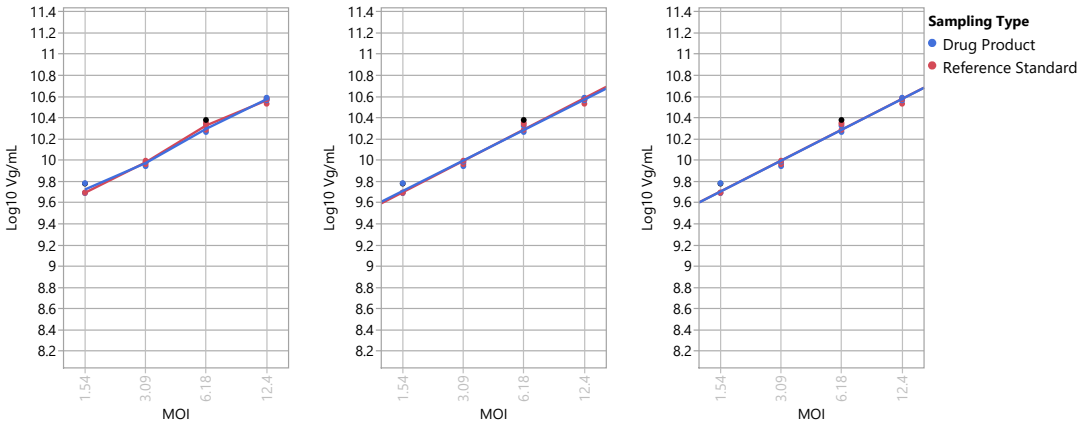
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std (L01-240910)	1.24e+1	3	3.7e+10	2.37e+9
AC	1.54e+0	3	5.32e+9	6.56e+8
AC	3.09e+0	3	9.41e+9	5.39e+8
AC	6.18e+0	2	2e+10	1.88e+9
AC	1.24e+1	3	3.8e+10	1.15e+9

AC Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.971	0.470	0.990	0.035	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.030	6.914	0.986	0.034	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.885	5.649	0.983	0.036	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.982	0.143	0.988	0.037	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.018	3.621	0.991	0.032	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.967	2.868	0.984	0.041	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.956	1.544	0.987	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.942	1.751	0.993	0.027	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.899	3.103	0.991	0.033	Parallel and Linear	

AC Graphs

Means by Concentration | **Unconstrained Parallel Line Analysis** | **Constrained Parallel Line Analysis**



AC 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.012	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.971	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.470	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

AC 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	CI Range % of Tolerance Check	OOS Validity
4.50	4.52	99.7	1	2	102.7	108.1	97.6	150	50	10.5	10.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
99.7	99.7	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
1.9	0.3	1.0

BQT Infectivity_18Nov2024-12-16-01

S1 & 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	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-2.451	Outlier
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	2.926	Outlier
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.502	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.054	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.043	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	2.109	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.077	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		3.528	Outlier
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.406	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.076	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-1.223	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.355	Ok
S1	25	2	4.881e+10	19804	9206530291	18.861975601	1.24e+1	1.0934216852	10.688508808	4.233	Pass	-0.995	Ok
S1	26	2	2.787e+10	19667	1315218613	4.71911953	6.18e+0	0.7909884751	10.445136969	3.024	Pass	0.950	Ok
S1	27	2	1.360e+10	19118	742462120.25	5.4572739452	3.09e+0	0.4899584794	10.133698546	2.230	Pass	0.182	Ok
S1	28	2	7.050e+9	20209	381837661.84	5.4161370474	1.54e+0	0.1875207208	9.848189117	0.463	Pass	0.486	Ok
S1	29	2	5.154e+10	18903	84852813.742	0.1646348734	1.24e+1	1.0934216852	10.712144414	0.302	Pass	-0.022	Ok
S1	30	2	2.672e+10	19260	1124299782.1	4.2084962833	6.18e+0	0.7909884751	10.426755179	0.171	Pass	0.248	Ok
S1	31	2	1.340e+10	20687	700035713.37	5.226097151	3.09e+0	0.4899584794	10.126942718	0.026	Pass	-0.068	Ok
S1	32	2	6.258e+9	19576	25455844.123	0.4067728367	1.54e+0	0.1875207208	9.7964355588	7.495	Pass	-1.715	Ok
S1	33	2	5.264e+10	16903	1887975105.8	3.5869195512	1.24e+1	1.0934216852	10.721274627	1.274	Pass	0.344	Ok
S1	34	2	2.601e+10	19636	636396103.07	2.4467362671	6.18e+0	0.7909884751	10.415140352	1.570	Pass	-0.182	Ok
S1	35	2	1.320e+10	20618	254558441.23	1.9284730396	3.09e+0	0.4899584794	10.120573931	2.020	Pass	-0.304	Ok
S1	36	2	7.215e+9	18540	148492424.05	2.0581070554	1.54e+0	0.1875207208	9.8582363354	1.002	Pass	0.905	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S1 Test Sample & Reference Standard Summary Statistics

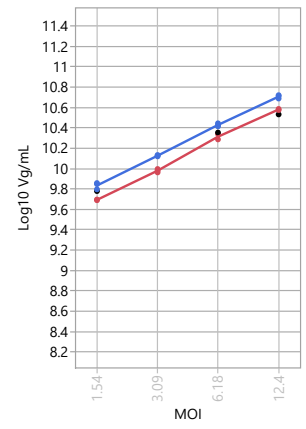
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	2	2.1e+10	1.78e+9
Ref.Std (L01-240910)	1.24e+1	2	3.8e+10	6.89e+8
S1	1.54e+0	3	6.84e+9	5.12e+8
S1	3.09e+0	3	1.3e+10	2.03e+8
S1	6.18e+0	3	2.7e+10	9.39e+8
S1	1.24e+1	3	5.1e+10	1.97e+9

S1 Model Selection

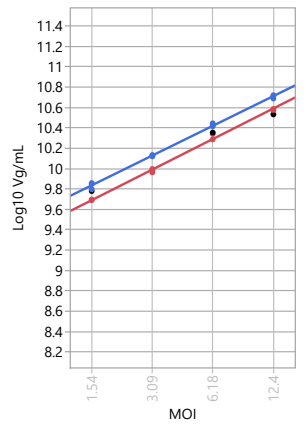
Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.973	0.871	0.997	0.021	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.959	3.577	0.995	0.021	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.959	2.295	0.994	0.022	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.991	0.414	0.996	0.022	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.983	2.714	0.994	0.023	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.967	1.246	0.997	0.019	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.966	1.706	0.996	0.022	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.941	0.041	0.997	0.021	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.935	1.094	0.997	0.019	Parallel and Linear	

S1 Graphs

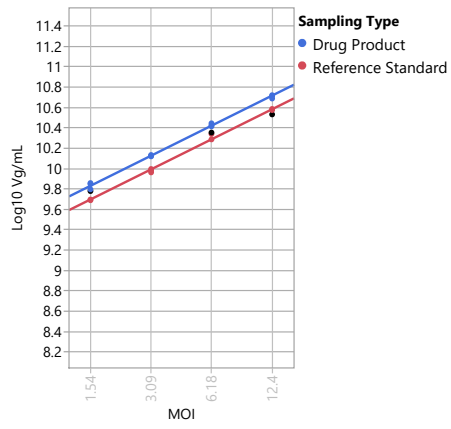
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S1 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.211	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.973	Passed Validity Criteria	
Linearity Ratio	.	26.3	0.871	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

S1 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	CI Range % of Tolerance Check	OOS Validity
5.15	3.75	137.1	1	2	140.1	144.3	136.1	150	50	8.2	8.2	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
136.9	137.1	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.6	0.3	1.0

BQT Infectivity_18Nov2024-12-16-01

S2: & 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
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-1.832	Ok
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	2.141	Ok
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.395	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.043	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.034	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	1.598	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.061	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		2.787	Outlier
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.320	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.060	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-0.951	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.280	Ok
S2:	37	2	4.419e+10	9225.5	2757716446.6	6.2405893791	1.24e+1	1.0934216852	10.645324002	.		-1.647	Ok
S2:	38	2	2.538e+10	18286	84852813.742	0.3343294474	6.18e+0	0.7909884751	10.404491618	3.253	Pass	-0.225	Ok
S2:	39	2	1.420e+10	20357	615182899.63	4.3307490294	3.09e+0	0.4899584794	10.152441238	0.562	Pass	0.605	Ok
S2:	40	2	7.200e+9	20076	424264068.71	5.8925565099	1.54e+0	0.1875207208	9.8573324964	0.047	Pass	0.219	Ok
S2:	41	2	5.136e+10	17904	1697056274.8	3.3042372953	1.24e+1	1.0934216852	10.710625015	0.000	Pass	0.570	Ok
S2:	42	2	2.619e+10	20119	296984848.1	1.1339627648	6.18e+0	0.7909884751	10.418135498	0.202	Pass	0.178	Ok
S2:	43	2	1.146e+10	20155	424264068.71	3.7021297444	3.09e+0	0.4899584794	10.059184618	13.031	Pass	-2.475	Outlier
S2:	44	2	6.447e+9	18381	123036579.93	1.9084315174	1.54e+0	0.1875207208	9.8093576702	2.321	Pass	-1.373	Ok
S2:	45	2	4.743e+10	19699	1824335495.5	3.8463746478	1.24e+1	1.0934216852	10.676053125	0.000	Pass	-0.587	Ok
S2:	46	2	2.664e+10	20634	1951614716.1	7.3258810663	6.18e+0	0.7909884751	10.42553422	1.493	Pass	0.399	Ok
S2:	47	2	1.452e+10	19991	1103086578.7	7.5970150045	3.09e+0	0.4899584794	10.161966616	0.869	Pass	0.897	Ok
S2:	48	2	7.860e+9	18582	593969696.2	7.5568663638	1.54e+0	0.1875207208	9.895422546	1.947	Pass	1.520	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

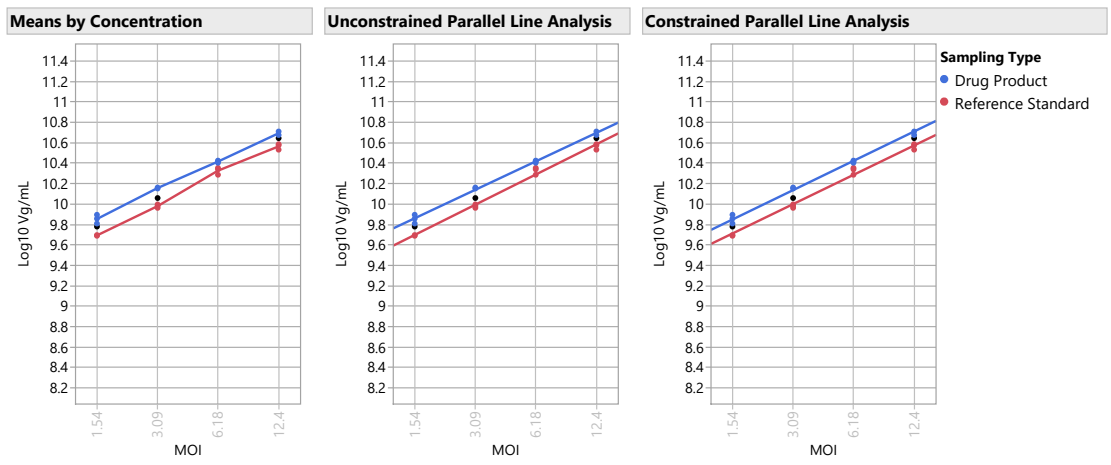
S2: Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std (L01-240910)	1.24e+1	3	3.7e+10	2.37e+9
S2:	1.54e+0	3	7.17e+9	7.07e+8
S2:	3.09e+0	2	1.4e+10	2.23e+8
S2:	6.18e+0	3	2.6e+10	6.39e+8
S2:	1.24e+1	2	4.9e+10	2.78e+9

S2: Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.942	2.564	0.992	0.031	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.917	4.619	0.987	0.031	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.880	1.228	0.991	0.028	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.961	10.799	0.986	0.035	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.953	3.754	0.989	0.033	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.951	3.766	0.990	0.032	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.907	2.748	0.993	0.029	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.872	0.002	0.994	0.027	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.839	5.137	0.996	0.023	Parallel and Linear	

S2: Graphs



S2: 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.058	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.942	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.564	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

S2: 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	CI Range % of Tolerance Check	OOS Validity
5.20	3.73	139.4	1	2	142.4	149.7	135.4	150	50	14.3	14.3	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
139.4	139.4	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.7	0.3	1.0

BQT Infectivity_18Nov2024-12-16-01

S3 & 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
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-1.143	Ok
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	1.312	Ok
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.259	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.028	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.022	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	1.009	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.040	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		1.834	Ok
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.210	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.040	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-0.617	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.184	Ok
S3	49	2	4.080e+10	18004	1697056274.8	4.159451654	1.24e+1	1.0934216852	10.610660163	17.678	Pass	0.618	Ok
S3	50	2	1.803e+10	19345	212132034.36	1.1765503847	6.18e+0	0.7909884751	10.255995727	0.773	Pass	-0.968	Ok
S3	51	2	1.311e+10	21015	466690475.58	3.5598053057	3.09e+0	0.4899584794	10.117602692	1.046	Pass	1.866	Ok
S3	52	2	6.255e+9	18400	21213203.436	0.339139943	1.54e+0	0.1875207208	9.796227314	1.948	Pass	0.935	Ok
S3	53	2	3.666e+10	19275	678822509.94	1.8516707854	1.24e+1	1.0934216852	10.564192461	0.598	Pass	-0.369	Ok
S3	54	2	1.833e+10	18666	1060660171.8	5.7864712045	6.18e+0	0.7909884751	10.263162465	0.644	Pass	-0.819	Ok
S3	55	2	1.286e+10	19344	106066017.18	0.8250954273	3.09e+0	0.4899584794	10.109072081	0.434	Pass	1.655	Ok
S3	56	2	5.307e+9	19435	4242640.6871	0.0799442376	1.54e+0	0.1875207208	9.7248490876	0.046	Pass	-0.578	Ok
S3	57	2	3.632e+10	18713	7360981592.2	20.26981025	1.24e+1	1.0934216852	10.560086048	0.825	Pass	-0.457	Ok
S3	58	2	2.478e+10	21070	1103086578.7	4.4515196879	6.18e+0	0.7909884751	10.394101302	31.113	Outlier	1.774	Ok
S3	59	2	1.179e+10	19272	42426406.871	0.3598507792	3.09e+0	0.4899584794	10.071513805	6.614	Pass	0.830	Ok
S3	60	2	4.227e+9	19743	301227488.79	7.1262713221	1.54e+0	0.1875207208	9.6260322478	2.318	Pass	-3.411	Outlier

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

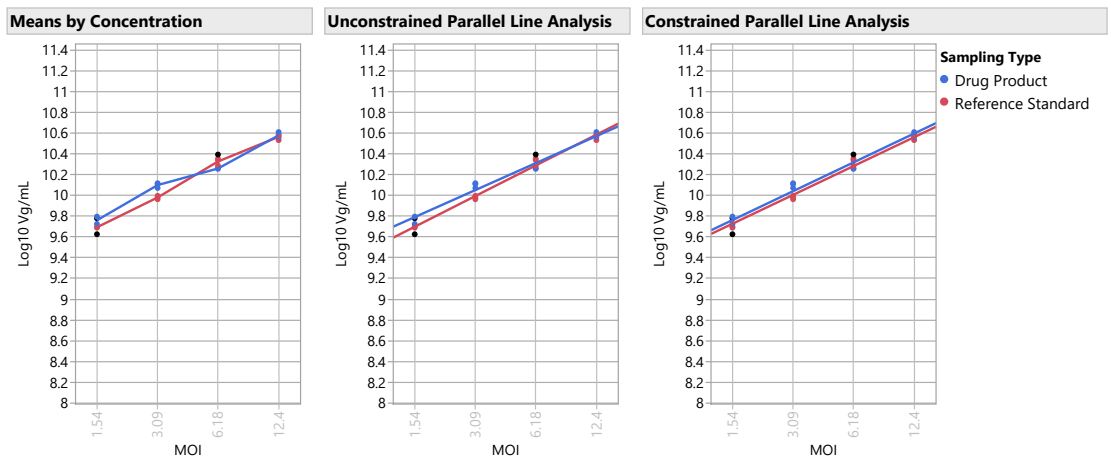
S3 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std (L01-240910)	1.24e+1	3	3.7e+10	2.37e+9
S3	1.54e+0	2	5.78e+9	6.7e+8
S3	3.09e+0	3	1.3e+10	7e+8
S3	6.18e+0	2	1.8e+10	2.12e+8
S3	1.24e+1	3	3.8e+10	2.5e+9

S3 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.879	2.978	0.985	0.042	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.819	0.386	0.974	0.042	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.782	4.741	0.971	0.045	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.889	4.457	0.979	0.045	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.854	20.283	0.972	0.048	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.845	6.655	0.981	0.045	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.814	0.546	0.984	0.042	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.810	0.579	0.985	0.039	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.750	13.826	0.986	0.038	Parallel and Linear	

S3 Graphs



S3 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.052	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.879	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.978	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

S3 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	CI Range % of Tolerance Check	OOS Validity
4.95	4.53	109.3	1	2	112.3	121.0	104.2	150	50	16.8	16.8	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
109.3	109.3	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.1	0.3	1.0

S4 & 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
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-1.397	Ok
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	1.614	Ok
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.311	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.034	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.026	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	1.228	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.048	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		2.199	Ok
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.252	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.047	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-0.743	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.220	Ok
S4	61	2	5.202e+10	18099	1612203461.1	3.0991992716	1.24e+1	1.0934216852	10.716170348	1.241	Pass	1.770	Ok
S4	62	2	2.187e+10	9786	890954544.3	4.0738662291	6.18e+0	0.7909884751	10.339848783	.		-0.778	Ok
S4	63	2	1.113e+10	20116	42426406.871	0.3811896395	3.09e+0	0.4899584794	10.046495164	0.398	Pass	-1.024	Ok
S4	64	2	8.070e+9	18962	42426406.871	0.5257299488	1.54e+0	0.1875207208	9.9068735347	3.691	Pass	3.259	Outlier
S4	65	2	4.764e+10	18922	6873077913.1	14.427115687	1.24e+1	1.0934216852	10.677971753	0.320	Pass	0.602	Ok
S4	66	2	2.230e+10	19293	445477272.15	1.9972081244	6.18e+0	0.7909884751	10.348402228	0.000	Pass	-0.560	Ok
S4	67	2	1.092e+10	19376	0	0	3.09e+0	0.4899584794	10.038222638	1.103	Pass	-1.238	Ok
S4	68	2	6.690e+9	19472	212132034.36	3.1708824268	1.54e+0	0.1875207208	9.8254261178	0.252	Pass	0.495	Ok
S4	69	2	3.603e+10	18628	15825049763	43.921870005	1.24e+1	1.0934216852	10.556664262	4.456	Outlier	-2.737	Outlier
S4	70	2	2.120e+10	19094	190918830.92	0.9007729697	6.18e+0	0.7909884751	10.326233421	0.000	Pass	-1.116	Ok
S4	71	2	1.188e+10	18296	169705627.48	1.4284985479	3.09e+0	0.4899584794	10.074816441	5.758	Pass	-0.341	Ok
S4	72	2	6.036e+9	18454	161220346.11	2.6709798892	1.54e+0	0.1875207208	9.7807492311	1.377	Pass	-0.632	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

S4 Test Sample & Reference Standard Summary Statistics

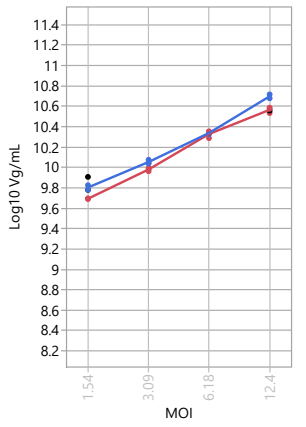
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std (L01-240910)	1.24e+1	3	3.7e+10	2.37e+9
S4	1.54e+0	2	6.36e+9	4.62e+8
S4	3.09e+0	3	1.1e+10	5.05e+8
S4	6.18e+0	2	2.2e+10	7.85e+8
S4	1.24e+1	2	5e+10	3.1e+9

S4 Model Selection

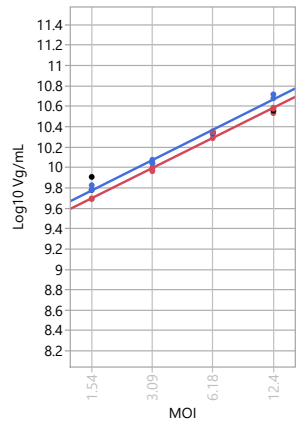
Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	1.006	1.227	0.990	0.036	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.094	2.788	0.986	0.035	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.836	4.144	0.991	0.026	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	1.001	7.941	0.993	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.017	2.991	0.986	0.038	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.931	6.672	0.991	0.033	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.082	1.822	0.991	0.032	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.914	5.883	0.987	0.033	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.904	2.439	0.991	0.031	Parallel and Linear	

S4 Graphs

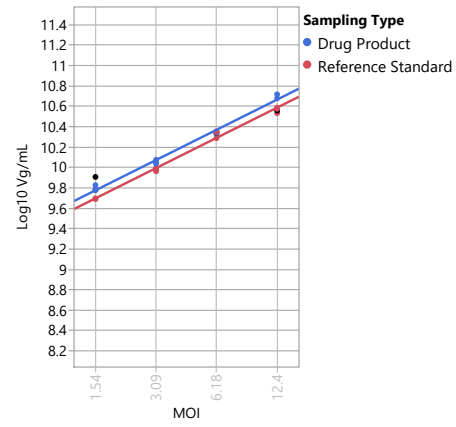
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



S4 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.004	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.006	Passed Validity Criteria	
Linearity Ratio	.	26.3	1.227	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

S4 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	CI Range % of Tolerance Check	OOS Validity
4.92	4.09	120.3	1	2	123.3	130.3	116.6	150	50	13.7	13.7	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
120.3	120.3	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.2	0.3	1.0

S5: & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Droplets	Accepted Dev(Vg/mL)	Std CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
Ref.Std (L01-240910)	1	2	3.408e+10	20296	763675323.68	2.2408313488	1.24e+1	1.0934216852	10.532499586	5.820	Pass	-0.286	Ok
Ref.Std (L01-240910)	2	2	2.260e+10	19198	869741340.86	3.8475617822	6.18e+0	0.7909884751	10.354204511	1.111	Pass	0.324	Ok
Ref.Std (L01-240910)	3	2	9.570e+9	20800	42426406.871	0.4433271355	3.09e+0	0.4899584794	9.9809119378	0.043	Pass	-0.067	Ok
Ref.Std (L01-240910)	4	2	4.974e+9	20320	178190908.86	3.5824469011	1.54e+0	0.1875207208	9.6967057809	0.000	Pass	-0.007	Ok
Ref.Std (L01-240910)	5	2	3.858e+10	19321	.	.	1.24e+1	1.0934216852	10.586362223	1.098	Pass	0.006	Ok
Ref.Std (L01-240910)	6	2	2.188e+10	19099	63639610.307	0.2907909998	6.18e+0	0.7909884751	10.340146551	0.393	Pass	0.254	Ok
Ref.Std (L01-240910)	7	2	9.915e+9	18334	445477272.15	4.4929629062	3.09e+0	0.4899584794	9.9962927185	1.958	Pass	0.010	Ok
Ref.Std (L01-240910)	8	2	6.021e+9	9931.5	156977705.42	2.6071699954	1.54e+0	0.1875207208	9.7796686272	.		0.475	Ok
Ref.Std (L01-240910)	9	2	3.760e+10	19714	487903679.02	1.2974436352	1.24e+1	1.0934216852	10.575245593	0.401	Pass	-0.054	Ok
Ref.Std (L01-240910)	10	2	1.936e+10	21479	403050865.28	2.0813367688	6.18e+0	0.7909884751	10.287017501	5.657	Pass	-0.010	Ok
Ref.Std (L01-240910)	11	2	9.180e+9	10371.5	339411254.97	3.6972903591	3.09e+0	0.4899584794	9.9628426812	2.306	Pass	-0.158	Ok
Ref.Std (L01-240910)	12	2	4.893e+9	21059	462447834.9	9.4512126486	1.54e+0	0.1875207208	9.6895752158	0.000	Pass	-0.048	Ok
S5:	73	2	4.390e+10	20729	233345237.79	0.5314775943	1.24e+1	1.0934216852	10.642513981	0.055	Pass	-0.245	Ok
S5:	74	2	2.409e+10	19375	296984848.1	1.2328138153	6.18e+0	0.7909884751	10.3818368	0.715	Pass	-0.256	Ok
S5:	75	2	9.840e+9	20921	848528137.42	8.6232534291	3.09e+0	0.4899584794	9.9929950984	0.000	Pass	-0.961	Ok
S5:	76	2	6.675e+9	19640	148492424.05	2.2246056037	1.54e+0	0.1875207208	9.82445127	0.354	Pass	-0.553	Ok
S5:	77	2	4.287e+10	20645	127279220.61	0.2968957794	1.24e+1	1.0934216852	10.632153484	2.361	Pass	-0.302	Ok
S5:	78	2	2.452e+10	20971	233345237.79	0.9514586658	6.18e+0	0.7909884751	10.389609016	0.699	Pass	-0.217	Ok
S5:	79	2	9.176e+10	21256	29931830048	32.621470272	3.09e+0	0.4899584794	10.96262974	0.000	Pass	20.105	Outlier
S5:	80	2	5.412e+9	19025	237587878.48	4.3900199275	1.54e+0	0.1875207208	9.7333577879	4.960	Pass	-1.082	Ok
S5:	81	2	4.479e+10	19295	1230365799.3	2.7469653924	1.24e+1	1.0934216852	10.651181062	1.916	Pass	-0.198	Ok
S5:	82	2	9.784e+10	21265	33453221818	34.190016677	6.18e+0	0.7909884751	10.990538638	239.08	Outlier	2.880	Outlier
S5:	83	2	.	19237	.	.	3.09e+0	0.4899584794	.	.		.	
S5:	84	2	7.095e+9	18592	360624458.41	5.0827971586	1.54e+0	0.1875207208	9.8509523998	1.177	Pass	-0.405	Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 2.45
Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

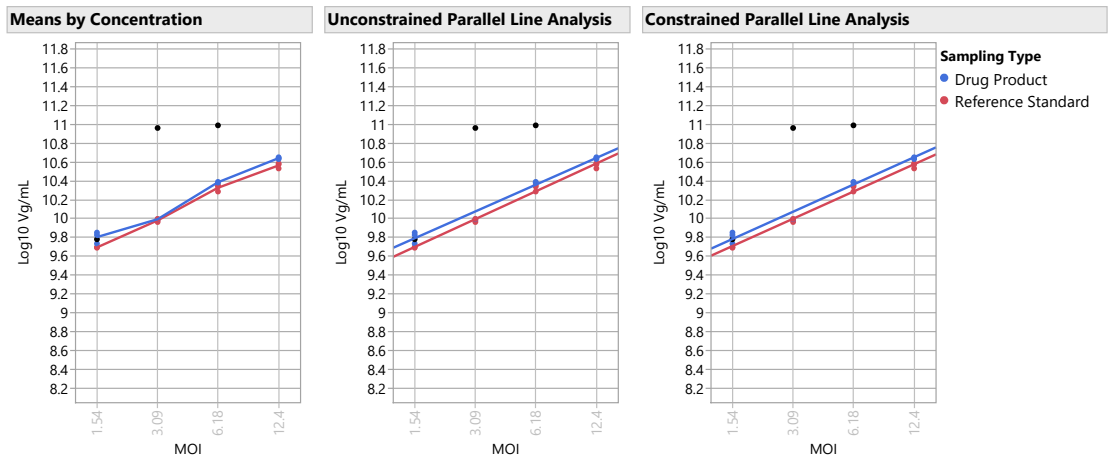
S5: Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	1.54e+0	2	4.93e+9	5.73e+7
Ref.Std (L01-240910)	3.09e+0	3	9.56e+9	3.68e+8
Ref.Std (L01-240910)	6.18e+0	3	2.1e+10	1.7e+9
Ref.Std (L01-240910)	1.24e+1	3	3.7e+10	2.37e+9
S5:	1.54e+0	3	6.39e+9	8.76e+8
S5:	3.09e+0	2	9.84e+9	.
S5:	6.18e+0	2	2.4e+10	3.08e+8
S5:	1.24e+1	3	4.4e+10	9.61e+8

S5: Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	0.962	1.156	0.988	0.041	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	1.063	10.381	0.982	0.039	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.901	8.737	0.977	0.046	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.985	2.430	0.977	0.050	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.974	1.314	0.983	0.046	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.973	1.330	0.984	0.044	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.973	2.022	0.992	0.033	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	1.051	4.716	0.990	0.036	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.891	2.926	0.988	0.041	Parallel and Linear	

S5: Graphs



S5: 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	.	31821500000	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.016	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.962	Passed Validity Criteria	
Linearity Ratio	.	26.3	1.156	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	13.129	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	5	3.000	Passed Validity Criteria	

S5: 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	CI Range % of Tolerance Check	OOS Validity
5.08	4.24	119.6	1	2	122.6	131.2	114.7	150	50	16.5	16.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
119.6	119.6	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
2.3	0.3	1.0

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious Particle Ratio	Reportable RI	RI Lower 95	RI Upper 95
AC	4.5041034334	4.5167958314	1.9	102.7	97.6	108.1
S1	5.1481603204	3.7544361796	2.6	140.1	136.1	144.3
S2:	5.2031025756	3.7338330985	2.7	142.4	135.4	149.7
S3	4.9517864212	4.5320274284	2.1	112.3	104.2	121.0
S4	4.9165415851	4.088031054	2.2	123.3	116.6	130.3
S5:	5.0777640695	4.2445797805	2.3	122.6	114.7	131.2

Sample Name	Overall Validity	OOS	Reportable
AC	Assay is Valid	Within Limits	Reportable
S1	Assay is Valid	Within Limits	Reportable
S2:	Assay is Valid	Within Limits	Reportable
S3	Assay is Valid	Within Limits	Reportable
S4	Assay is Valid	Within Limits	Reportable
S5:	Assay is Valid	Within Limits	Reportable

Astellas BQT Infectivity Bioassay Materials and Reference Standard Report

Assay Details

Assay	Site:	Date Assay Initiated:	Purpose:	Bioassay Run Number	Analyst Name:	Signal	Method	Instrument ID	Instrument internal no.	Bioassay preparation (date_operator)	Bioassay review (date_reviewer)
Astellas BQT Infectivity			PLA	BQT Test Run 1		Vg/mL	KT430				

Notes
Assay Range Check

Materials

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

Reference Details

Reference/Control	Reference Standard (RS)	Description	Lot#	Expiry/ Reevalution	RS Correction Factor	RS Stability Correction Factor
1	Ref.Std	Test	Test	Test	1	2

Input Files - Configuration File and Plate File(s)

System Suitability and Limits	Limit	Column 3	Location of Sample on Extracted DNA plate	Column 5	1	2	3	4	5	6	7	8	9
Lower Specification Limit (≥)	50.00			A	1	5	9	13	17	21	25	29	33
Upper Specification Limit (≤)	150.00			B	2	6	10	14	18	22	26	30	34
Reference Standard Curve Depth (≥)	2720000000.00			C	3	7	11	15	19	23	27	31	35
Unconstrained EC50 Standard Lower Limit (≥)	0.04			D	4	8	12	16	20	24	28	32	36
Unconstrained EC50 Standard Upper Limit (≤)	61.80			E	49	53	57	61	65	69	73	77	81
% Relative Potency Delta (Constrained – Unconstrained) (≤)	15.00			F	50	54	58	62	66	70	74	78	82
Within Group Jackknife z Outlier Limit (<)	4.00			G	51	55	59	63	67	71	75	79	83
Between Group Studentized Residuals Outlier Limit (<)	2.45			H	52	56	60	64	68	72	76	80	84
Parallelism Slope Ratio Lower Limit (≥)	0.70				.	.	.	.	.	.	.	.	.
Parallelism Slope Ratio Upper Limit (≤)	1.40				.	.	.	.	.	.	.	.	.
Linearity Ratio (≤)	26.30		ddPCR Map - Plate 1		1	2	3	4	5	6	7	8	9
Dose Reponse Test (≤)	0.05			A	6000	6000	6000	6000	6000	6000	6000	6000	6000
fixed position for ec50	10.60			B	6000	6000	6000	6000	6000	6000	6000	6000	6000
ec50 reference concentration target	4.74			C	6000	6000	6000	6000	6000	6000	6000	6000	6000
fixed position for Test article for Infectious Particles Ratio Equation	9.90			D	6000	6000	6000	6000	6000	6000	6000	6000	6000
Infectious Particles Ratio Lower Specification Limit (≥)	0.30			E	6000	6000	6000	6000	6000	6000	6000	6000	6000
Infectious Particles Ratio Upper Specification Limit (≤)	1.00			F	6000	6000	6000	6000	6000	6000	6000	6000	6000
Failed Accepted Droplets Upper Limit (≤)	5.00			G	6000	6000	6000	6000	6000	6000	6000	6000	6000
	.			H	6000	6000	6000	6000	6000	6000	6000	6000	6000
Report File Name	.				.	.	.	.	.	.	.	.	.
Ref.Std (1-12)	.		ddPCR Map - Plate 2		1	2	3	4	5	6	7	8	9
Control (13-24)	.			A	12000	12000	12000	12000	12000	12000	12000	12000	12000
Sample 1 (25-36)	.			B	12000	12000	12000	12000	12000	12000	12000	12000	12000
Sample 2 (37-48)	.			C	12000	12000	12000	12000	12000	12000	12000	12000	12000
Sample 3 (49-60)	.			D	12000	12000	12000	12000	12000	12000	12000	12000	12000
Sample 4 (61-72)	.			E	12000	12000	12000	12000	12000	12000	12000	12000	12000
Sample 5 (73-84)	.			F	12000	12000	12000	12000	12000	12000	12000	12000	12000
	.			G	12000	12000	12000	12000	12000	12000	12000	12000	12000
Total Number of Plates	2.00			H	12000	12000	12000	12000	12000	12000	12000	12000	12000
	.				.	.	.	.	.	.	.	.	.
MOI Concentrations	.				.	.	.	.	.	.	.	.	.
12.4	.				.	.	.	.	.	.	.	.	.
6.18	.				.	.	.	.	.	.	.	.	.
3.09	.				.	.	.	.	.	.	.	.	.
1.54	.				.	.	.	.	.	.	.	.	.
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Well	Sample description 1	Sample description 2	Sample description 3	Sample description 4	Target	Conc(copies/µL)	Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted Droplets	Positives	Negatives
A01	16	RS	REP1		BDNF	1118	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20296	17383	2913
A02	16	RS	REP2		BDNF	No Call	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19321	17043	2278
A03	16	RS	REP3		BDNF	1265	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19714	17951	1763
A04	16	50	REP1		BDNF	1266	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19835	12773	7062
A05	16	50	REP2		BDNF	1254	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19902	11819	8083
A06	16	50	REP3		BDNF	1194	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18765	10664	8101
A07	16	150	REP1		BDNF	1844	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19804	18198	1606
A08	16	150	REP2		BDNF	1720	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18903	17203	1700
A09	16	150	REP3		BDNF	1799	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	16903	15429	1474
A10	16	200	REP1		BDNF	1538	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	1	17616	834
A11	16	200	REP2		BDNF	1752	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17904	17191	713
A12	16	200	REP3		BDNF	1624	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19699	18800	899
B01	8	RS	REP1		BDNF	733	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19198	11398	7800
B02	8	RS	REP2		BDNF	731	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19099	12634	6465
B03	8	RS	REP3		BDNF	655	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21479	15075	6404
B04	8	50	REP1		BDNF	802	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20895	9779	11116
B05	8	50	REP2		BDNF	673	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19579	7837	11742
B06	8	50	REP3		BDNF	630	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19234	7134	12100
B07	8	150	REP1		BDNF	898	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19667	14848	4819
B08	8	150	REP2		BDNF	917	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19260	13690	5570
B09	8	150	REP3		BDNF	882	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19636	14144	5492
B10	8	200	REP1		BDNF	848	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18286	15060	3226
B11	8	200	REP2		BDNF	866	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20119	15713	4406
B12	8	200	REP3		BDNF	842	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20634	15867	4767
C01	4	RS	REP1		BDNF	318	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20800	7196	13604
C02	4	RS	REP2		BDNF	341	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18334	7013	11321
C03	4	RS	REP3		BDNF	314	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	1	8114	12628
C04	4	50	REP1		BDNF	325	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21194	5243	15951
C05	4	50	REP2		BDNF	319	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21184	4703	16481
C06	4	50	REP3		BDNF	290	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18692	3625	15067
C07	4	150	REP1		BDNF	471	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19118	9280	9838
C08	4	150	REP2		BDNF	463	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20687	9253	11434
C09	4	150	REP3		BDNF	434	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20618	9667	10951
C10	4	200	REP1		BDNF	459	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20357	11488	8869
C11	4	200	REP2		BDNF	392	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20155	10662	9493
C12	4	200	REP3		BDNF	458	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19991	10324	9667
D01	2	RS	REP1		BDNF	170	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20320	3838	16482
D02	2	RS	REP2		BDNF	197	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19862	3759	16103
D03	2	RS	REP3		BDNF	174	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21059	4329	16730
D04	2	50	REP1		BDNF	172	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20749	3013	17736
D05	2	50	REP2		BDNF	192	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20805	2707	18098
D06	2	50	REP3		BDNF	163	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18572	2135	16437
D07	2	150	REP1		BDNF	226	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20209	6624	13585
D08	2	150	REP2		BDNF	208	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19576	6420	13156
D09	2	150	REP3		BDNF	237	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18540	5729	12811
D10	2	200	REP1		BDNF	230	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20076	9080	10996
D11	2	200	REP2		BDNF	212	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18381	6533	11848
D12	2	200	REP3		BDNF	248	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18582	6710	11872
E01	16	100.2	REP1		BDNF	1400	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18004	15593	2411
E02	16	100.2	REP2		BDNF	1238	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19275	17053	2222
E03	16	100.2	REP3		BDNF	1037	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18713	17007	1706
E04	16	50.2	REP1		BDNF	1772	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18099	11616	6483
E05	16	50.2	REP2		BDNF	1426	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18922	11351	7571
E06	16	50.2	REP3		BDNF	828	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18628	10665	7963
E07	16	150.2	REP1		BDNF	1469	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20729	18951	1778
E08	16	150.2	REP2		BDNF	1432	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20645	18814	1831
E09	16	150.2	REP3		BDNF	1522	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19295	17639	1656
E10	NTC				BDNF	2415	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	752	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18778	0	18778
F01	8	100.2	REP1		BDNF	596	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19345	11720	7625
F02	8	100.2	REP2		BDNF	636	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18666	12194	6472
F03	8	100.2	REP3		BDNF	852	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21070	14608	6462
F04	8	50.2	REP1		BDNF	750	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19571	9167	10404
F05	8	50.2	REP2		BDNF	733	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19293	7994	11299
F06	8	50.2	REP3		BDNF	711	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19094	6957	12137
F07	8	150.2	REP1		BDNF	810	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19375	14849	4526
F08	8	150.2	REP2		BDNF	823	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20971	14982	5989
F09	8	150.2	REP3		BDNF	2473	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21265	15301	5964
F10	PC				BDNF	No Call	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18318	12149	6169
F11	PC				BDNF	386	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19227	12400	6827
F12	PC				BDNF	320	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	17535	11226	6309
G01	4	100.2	REP1		BDNF	448	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21015	7219	13796
G02	4	100.2	REP2		BDNF	431	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19344	7299	12045
G03	4	100.2	REP3		BDNF	394	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19272	7537	11735
G04	4	50.2	REP1		BDNF	370	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20116	4979	15137
G05	4	50.2	REP2		BDNF	364	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19376	4461	14915
G06	4	50.2	REP3		BDNF	400	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18296	3471	14825
G07	4	150.2	REP1		BDNF	348	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20921	10324	10597
G08	4	150.2	REP2		BDNF	2353	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21256	9799	11457
G09	4	150.2	REP3		BDNF	No Call	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19237	9136	10101
H01	2	100.2	REP1		BDNF	209	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18400	3320	15080
H02	2	100.2	REP2		BDNF	177	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19435	3580	15855

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BQT Infectivity_18Nov2024-12-16-01

Well	Sample description 1	Sample description 2	Sample description 3	Sample description 4	Target	Conc(copies/µL)	Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted Droplets	Positives	Negatives
H03	2	100.2	REP3		BDNF	148	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19743	3785	15958
H04	2	50.2	REP1		BDNF	268	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18962	2653	16309
H05	2	50.2	REP2		BDNF	228	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19472	2574	16898
H06	2	50.2	REP3		BDNF	205	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18454	2025	16429
H07	2	150.2	REP1		BDNF	219	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19640	6347	13293
H08	2	150.2	REP2		BDNF	186	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19025	6196	12829
H09	2	150.2	REP3		BDNF	245	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18592	5673	12919

Well	Sample description 1	Sample description 2	Sample description 3	Sample description 4	Target	Conc(copies/µL)	Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Accepted Droplets	Positives	Negatives
A01	16	RS	REP1		BDNF	577	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20296	17383	2913
A02	16	RS	REP2		BDNF	643	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19321	17043	2278
A03	16	RS	REP3		BDNF	621	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19714	17951	1763
A04	16	50	REP1		BDNF	609	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19835	12773	7062
A05	16	50	REP2		BDNF	669	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19902	11819	8083
A06	16	50	REP3		BDNF	625	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18765	10664	8101
A07	16	150	REP1		BDNF	705	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19804	18198	1606
A08	16	150	REP2		BDNF	858	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18903	17203	1700
A09	16	150	REP3		BDNF	855	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	16903	15429	1474
A10	16	200	REP1		BDNF	704	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18450	17616	834
A11	16	200	REP2		BDNF	836	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17904	17191	713
A12	16	200	REP3		BDNF	769	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19699	18800	899
B01	8	RS	REP1		BDNF	387	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19198	11398	7800
B02	8	RS	REP2		BDNF	364	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19099	12634	1
B03	8	RS	REP3		BDNF	318	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21479	15075	6404
B04	8	50	REP1		BDNF	398	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20895	9779	11116
B05	8	50	REP2		BDNF	367	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19579	7837	11742
B06	8	50	REP3		BDNF	300	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19234	7134	12100
B07	8	150	REP1		BDNF	480	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19667	14848	4819
B08	8	150	REP2		BDNF	432	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19260	13690	5570
B09	8	150	REP3		BDNF	426	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19636	14144	5492
B10	8	200	REP1		BDNF	422	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18286	15060	3226
B11	8	200	REP2		BDNF	440	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20119	15713	4406
B12	8	200	REP3		BDNF	467	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20634	15867	4767
C01	4	RS	REP1		BDNF	160	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20800	7196	13604
C02	4	RS	REP2		BDNF	160	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18334	7013	11321
C03	4	RS	REP3		BDNF	149	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20742	8114	12628
C04	4	50	REP1		BDNF	163	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21194	5243	15951
C05	4	50	REP2		BDNF	163	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21184	4703	16481
C06	4	50	REP3		BDNF	148	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18692	3625	15067
C07	4	150	REP1		BDNF	218	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19118	9280	9838
C08	4	150	REP2		BDNF	215	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20687	9253	11434
C09	4	150	REP3		BDNF	223	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20618	9667	10951
C10	4	200	REP1		BDNF	244	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20357	11488	8869
C11	4	200	REP2		BDNF	186	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20155	10662	9493
C12	4	200	REP3		BDNF	255	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19991	10324	9667
D01	2	RS	REP1		BDNF	80.8	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20320	3838	16482
D02	2	RS	REP2		BDNF	102.2	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	1	3759	16103
D03	2	RS	REP3		BDNF	76.1	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21059	4329	16730
D04	2	50	REP1		BDNF	78.6	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20749	3013	17736
D05	2	50	REP2		BDNF	106.7	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20805	2707	18098
D06	2	50	REP3		BDNF	83.5	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18572	2135	16437
D07	2	150	REP1		BDNF	122	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20209	6624	13585
D08	2	150	REP2		BDNF	104.6	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19576	6420	13156
D09	2	150	REP3		BDNF	122	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18540	5729	12811
D10	2	200	REP1		BDNF	125	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20076	9080	10996
D11	2	200	REP2		BDNF	108.9	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18381	6533	11848
D12	2	200	REP3		BDNF	138	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18582	6710	11872
E01	16	100.2	REP1		BDNF	660	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18004	15593	2411
E02	16	100.2	REP2		BDNF	603	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19275	17053	2222
E03	16	100.2	REP3		BDNF	692	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18713	17007	1706
E04	16	50.2	REP1		BDNF	848	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18099	11616	6483
E05	16	50.2	REP2		BDNF	875	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18922	11351	7571
E06	16	50.2	REP3		BDNF	787	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18628	10665	7963
E07	16	150.2	REP1		BDNF	729	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20729	18951	1778
E08	16	150.2	REP2		BDNF	713	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20645	18814	1831
E09	16	150.2	REP3		BDNF	732	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19295	17639	1656
E10	NTC				BDNF	2220	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	381	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18778	0	18778
F01	8	100.2	REP1		BDNF	303	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19345	11720	7625
F02	8	100.2	REP2		BDNF	293	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18666	12194	6472
F03	8	100.2	REP3		BDNF	400	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21070	14608	6462
F04	8	50.2	REP1		BDNF	354	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	1	9167	10404
F05	8	50.2	REP2		BDNF	377	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19293	7994	11299
F06	8	50.2	REP3		BDNF	351	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19094	6957	12137
F07	8	150.2	REP1		BDNF	398	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19375	14849	4526
F08	8	150.2	REP2		BDNF	406	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20971	14982	5989
F09	8	150.2	REP3		BDNF	2025	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21265	15301	5964
F10	PC				BDNF	No Call	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18318	12149	6169
F11	PC				BDNF	182	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19227	12400	6827
F12	PC				BDNF	157	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	17535	11226	6309
G01	4	100.2	REP1		BDNF	213	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21015	7219	13796
G02	4	100.2	REP2		BDNF	213	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19344	7299	12045
G03	4	100.2	REP3		BDNF	196	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19272	7537	11735
G04	4	50.2	REP1		BDNF	186	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20116	4979	15137
G05	4	50.2	REP2		BDNF	182	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19376	4461	14915
G06	4	50.2	REP3		BDNF	196	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18296	3471	14825
G07	4	150.2	REP1		BDNF	154	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20921	10324	10597
G08	4	150.2	REP2		BDNF	1882	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21256	9799	11457
G09	4	150.2	REP3		BDNF	No Call	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19237	9136	10101
H01	2	100.2	REP1		BDNF	104	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18400	3320	15080
H02	2	100.2	REP2		BDNF	88.4	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19435	3580	15855
H03	2	100.2	REP3		BDNF	66.9	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19743	3785	15958
H04	2	50.2	REP1		BDNF	135	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18962	2653	16309
H05	2	50.2	REP2		BDNF	109	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19472	2574	16898
H06	2	50.2	REP3		BDNF	98.7	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18454	2025	16429
H07	2	150.2	REP1		BDNF	113	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19640	6347	13293
H08	2	150.2	REP2		BDNF	87.4	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19025	6196	12829
H09	2	150.2	REP3		BDNF	114	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18592	5673	12919