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

BQT Infectivity_13Nov2024-14-12-06

Astellas BQT Infectivity Files

First Data File	Second Data File
18OCT2024_Plate03_KL-S3	18OCT2024_Plate03_KL-S4

50% L01-240910_1 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
50% L01-240910_1	13	2	1.846e+10	19212	1046797271.2	5.669173539	1.6e+1	1.2041199827	10.26634283	2.307	Pass	0.785	Ok
50% L01-240910_1	14	2	1.154e+10	20496	133015616.6	1.1528235451	8e+0	0.903089987	10.062139794	2.656	Pass	2.386	Ok
50% L01-240910_1	15	2	5.404e+9	20282	177405513.34	3.2830346726	4e+0	0.6020599913	9.7326916431	1.807	Pass	1.102	Ok
50% L01-240910_1	16	2	2.944e+9	19460.5	56060299.031	1.9039125695	2e+0	0.3010299957	9.4690084089	1.996	Pass	1.496	Ok
50% L01-240910_1	17	2	1.643e+10	19077.5	1033162251.4	6.2868996979	1.6e+1	1.2041199827	10.215731998	0.043	Pass	-0.281	Ok
50% L01-240910_1	18	2	9.459e+9	19732.5	188463982.8	1.9924404129	8e+0	0.903089987	9.9758430228	0.112	Pass	0.438	Ok
50% L01-240910_1	19	2	4.726e+9	20131.5	98091321.701	2.075351646	4e+0	0.6020599913	9.6745388925	0.088	Pass	-0.048	Ok
50% L01-240910_1	20	2	2.551e+9	20294	40150072.104	1.5738839181	2e+0	0.3010299957	9.4067136317	0.033	Pass	0.119	Ok
50% L01-240910_1	21	2	1.464e+10	19522	173507016.57	1.1853448318	1.6e+1	1.2041199827	10.165472332	1.958	Pass	-1.391	Ok
50% L01-240910_1	22	2	7.950e+9	19997	155852437.26	1.9603972923	8e+0	0.903089987	9.9003695043	1.733	Pass	-1.041	Ok
50% L01-240910_1	23	2	3.856e+9	20129.5	151481358.05	3.9288780116	4e+0	0.6020599913	9.5860906454	2.526	Pass	-1.906	Ok
50% L01-240910_1	24	2	2.119e+9	20119.5	64724449.5	3.0542138986	2e+0	0.3010299957	9.3261689162	2.259	Pass	-1.666	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-0.758	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-0.805	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.561	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-0.755	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.569	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.549	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.293	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.426	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.287	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	1.464	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	0.834	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.357	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

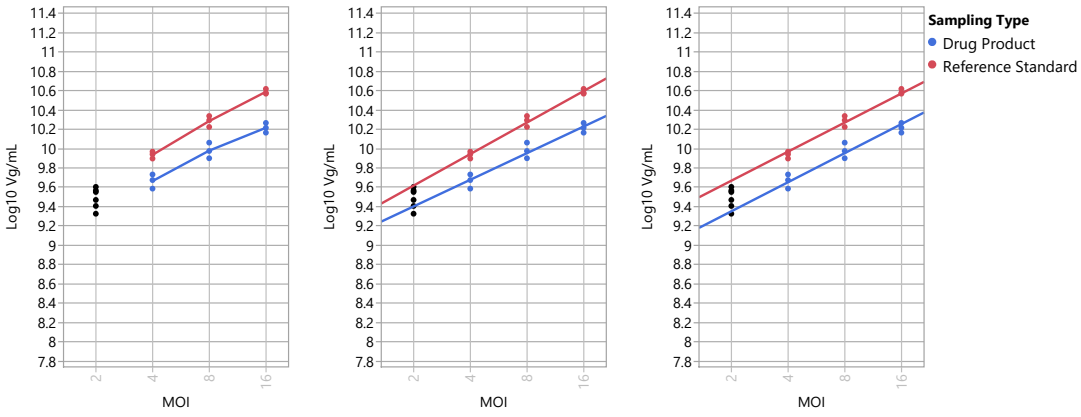
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
50% L01-240910_1	2e+0	3	2.54e+9	4.13e+8
50% L01-240910_1	4e+0	3	4.66e+9	7.76e+8
50% L01-240910_1	8e+0	3	9.65e+9	1.8e+9
50% L01-240910_1	1.6e+1	3	1.7e+10	1.91e+9

50% L01-240910_1 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.845	5.192	0.972	0.056	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.814	2.630	0.983	0.054	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.814	1.501	0.971	0.058	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.887	0.292	0.983	0.058	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.853	2.143	0.984	0.054	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.846	2.283	0.981	0.056	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.813	4.429	0.980	0.053	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.776	1.609	0.974	0.056	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.775	5.410	0.966	0.055	Parallel and Linear	

50% L01-240910_1 Graphs

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



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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.249	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.845	Passed Validity Criteria	
Linearity Ratio	.	26.3	5.192	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

50% L01-240910_1 Relative Infectivity and Infectious Particle Ratio

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
5.56	11.52	48.2	0	0	48.2	53.4	43.1	150	50	10.2	10.2	Bioassay Results are Reportable	Assay is Valid and OOS

Unconstrained RI	Constrained RI	Relative Infectivity Delta
48.0	48.2	0.2

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
0.7	0.3	1.0

150% L01-240910_1 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Outlier Jackknife z	Outlier Within Group	Externally Studentized Residuals	Outlier Between Group
150% L01-240910_1	25	2	4.418e+10	19996	1117564494.5	2.5297475867	1.6e+1	1.2041199827	10.645195405	6.522	Pass	0.335	Ok
150% L01-240910_1	26	2	2.550e+10	20365.5	562893082.9	2.2074702976	8e+0	0.903089987	10.406531043	80.472	Pass	1.318	Ok
150% L01-240910_1	27	2	1.230e+10	20080.5	129517198.73	1.0529509883	4e+0	0.6020599913	10.089919286	5.187	Pass	-0.117	Ok
150% L01-240910_1	28	2	7.105e+9	20666.5	120860492.39	1.7010399847	2e+0	0.3010299957	9.851569837	0.478	Pass	0.937	Ok
150% L01-240910_1	29	2	4.324e+10	19797	760109575.1	1.7580116665	1.6e+1	1.2041199827	10.635854451	0.430	Pass	0.031	Ok
150% L01-240910_1	30	2	2.298e+10	20092.5	31656665.012	0.1377308391	8e+0	0.903089987	10.361433967	0.682	Pass	-0.088	Ok
150% L01-240910_1	31	2	1.094e+10	20710	52721619.976	0.4817384535	4e+0	0.6020599913	10.039177432	1.154	Pass	-1.765	Ok
150% L01-240910_1	32	2	7.215e+9	20526	88293615.492	1.2237302372	2e+0	0.3010299957	9.8582436097	0.981	Pass	1.173	Ok
150% L01-240910_1	33	2	4.301e+10	19822.5	1751865687.7	4.073324556	1.6e+1	1.2041199827	10.633551791	1.051	Pass	-0.044	Ok
150% L01-240910_1	34	2	2.294e+10	20557	341864810.14	1.49026602	8e+0	0.903089987	10.3605906	0.732	Pass	-0.113	Ok
150% L01-240910_1	35	2	1.127e+10	20848	21155586.254	0.1877249333	4e+0	0.6020599913	10.051903106	0.368	Pass	-1.310	Ok
150% L01-240910_1	36	2	6.536e+9	20632	262772342.09	4.0203525339	2e+0	0.3010299957	9.8153155151	8.021	Pass	-0.260	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-1.207	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-1.286	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.886	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-1.203	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.898	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.866	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.458	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.669	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.449	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	2.491	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	1.336	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.558	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

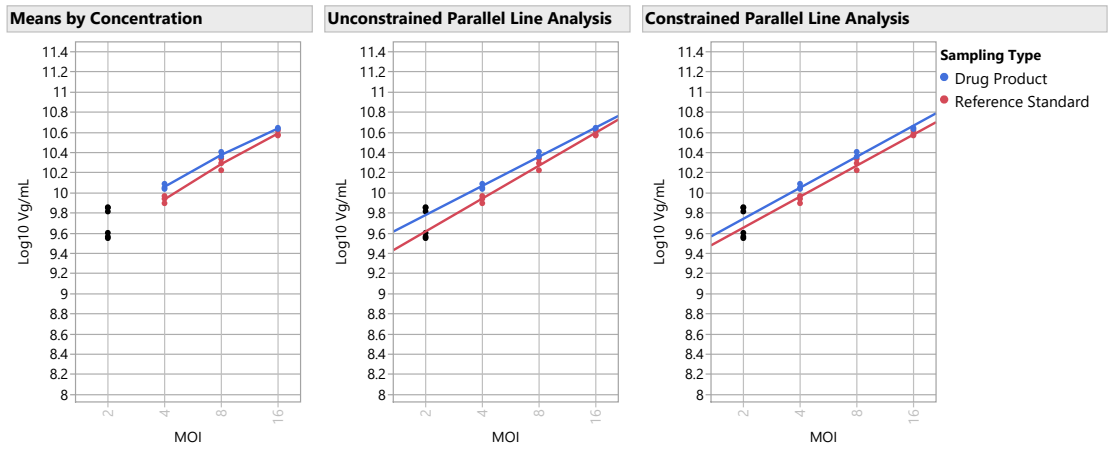
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
150% L01-240910_1	2e+0	3	6.95e+9	3.64e+8
150% L01-240910_1	4e+0	3	1.2e+10	7.08e+8
150% L01-240910_1	8e+0	3	2.4e+10	1.47e+9
150% L01-240910_1	1.6e+1	3	4.3e+10	6.19e+8

150% L01-240910_1 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.886	4.074	0.987	0.034	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.797	0.476	0.992	0.034	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.751	3.401	0.985	0.037	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.852	3.917	0.993	0.034	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.829	1.506	0.988	0.035	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.819	3.211	0.984	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.812	3.858	0.993	0.033	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.788	1.405	0.989	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.761	2.010	0.992	0.034	Parallel and Linear	

150% L01-240910_1 Graphs



150% L01-240910_1 Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.090	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.886	Passed Validity Criteria	
Linearity Ratio	.	26.3	4.074	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

150% L01-240910_1 Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI 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
8.84	7.24	122.0	0	0	122.0	129.5	115.1	150	50	14.5	14.5	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
122.1	122.0	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
1.7	0.3	1.0

BQT Infectivity_13Nov2024-14-12-06

200% L01-240910 & 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
200% L01-240910	37	2	5.344e+10	19290.5	80196876.213	0.1500625229	1.6e+1	1.2041199827	10.727885209	2.668	Pass	-0.062	Ok
200% L01-240910	38	2	3.096e+10	19264.5	154005481.06	0.4974087484	8e+0	0.903089987	10.490822758	6.431	Pass	0.664	Ok
200% L01-240910	39	2	1.470e+10	20635	560906281.84	3.8146779658	4e+0	0.6020599913	10.167432423	1.692	Pass	-0.785	Ok
200% L01-240910	40	2	1.091e+10	20539	257568089.92	2.3602328346	2e+0	0.3010299957	10.03793721	7.404	Pass	3.723	Ok
200% L01-240910	41	2	5.776e+10	19541.5	249954306.34	0.4327798418	1.6e+1	1.2041199827	10.7615936	1.727	Pass	0.861	Ok
200% L01-240910	42	2	2.763e+10	20939.5	269194304.26	0.9743799903	8e+0	0.903089987	10.44133751	1.057	Pass	-0.577	Ok
200% L01-240910	43	2	1.404e+10	19917	594811930.38	4.2353940345	4e+0	0.6020599913	10.14748585	2.738	Pass	-1.325	Ok
200% L01-240910	44	2	8.118e+9	19609.5	102821370.74	1.2666382592	2e+0	0.3010299957	9.9094307874	1.006	Pass	-0.633	Ok
200% L01-240910	45	2	5.595e+10	19982	932086203.29	1.6659818239	1.6e+1	1.2041199827	10.747785821	0.115	Pass	0.476	Ok
200% L01-240910	46	2	2.829e+10	19188	978378731.34	3.4586506089	8e+0	0.903089987	10.451600311	0.427	Pass	-0.318	Ok
200% L01-240910	47	2	1.443e+10	20530.5	91625658.209	0.6348367112	4e+0	0.6020599913	10.159355074	0.127	Pass	-0.998	Ok
200% L01-240910	48	2	8.605e+9	20956.5	277911220.03	3.2296461072	2e+0	0.3010299957	9.9347511442	0.461	Pass	0.055	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-0.990	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-1.053	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.730	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-0.987	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.740	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.714	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.379	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.553	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.372	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	1.969	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	1.093	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.462	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

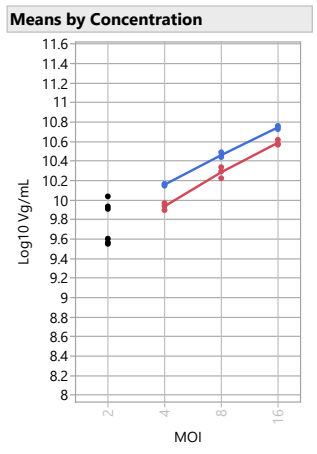
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
200% L01-240910	2e+0	3	9.21e+9	1.49e+9
200% L01-240910	4e+0	3	1.4e+10	3.32e+8
200% L01-240910	8e+0	3	2.9e+10	1.77e+9
200% L01-240910	1.6e+1	3	5.6e+10	2.17e+9

200% L01-240910 Model Selection

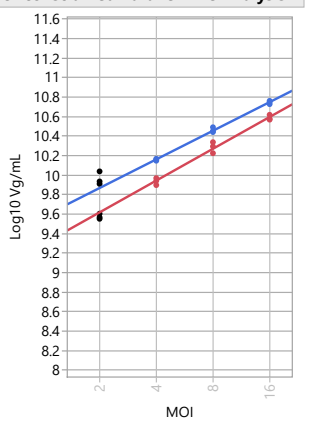
Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.901	2.624	0.989	0.032	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.784	0.875	0.989	0.041	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.704	3.849	0.982	0.044	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.866	3.295	0.994	0.032	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.826	1.798	0.995	0.031	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.815	3.904	0.982	0.043	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.767	3.861	0.974	0.045	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.747	4.273	0.989	0.042	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.738	1.290	0.986	0.043	Parallel and Linear	

200% L01-240910 Graphs

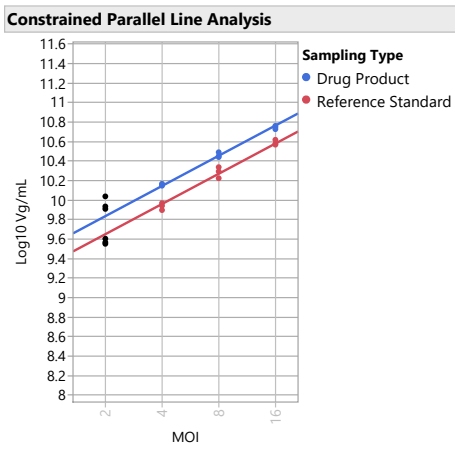
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.172	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.901	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.624	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

200% L01-240910 Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI 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
9.84	6.50	151.3	0	0	151.3	160.1	143.2	150	50	16.8	16.8	Bioassay Results are Reportable	Assay is Valid and OOS

Unconstrained RI	Constrained RI	Relative Infectivity Delta
151.4	151.3	0.2

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

100% L01-240910 & 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
100% L01-240910	49	2	3.683e+10	19073.5	1778869003.2	4.8304881343	1.6e+1	1.2041199827	10.566152948	0.971	Pass	-1.112	Ok
100% L01-240910	50	2	1.680e+10	19201	199492668.93	1.1876932528	8e+0	0.903089987	10.225222651	5.468	Pass	-1.041	Ok
100% L01-240910	51	2	7.499e+9	19370	678147945.98	9.0435733427	4e+0	0.6020599913	9.8749843856	2.185	Pass	-1.352	Ok
100% L01-240910	52	2	3.707e+9	19538	299090113.23	8.0676914922	2e+0	0.3010299957	9.5690527747	0.450	Pass	-0.355	Ok
100% L01-240910	53	2	3.785e+10	18893	3580292594.9	9.459908583	1.6e+1	1.2041199827	10.578031581	0.485	Pass	-0.726	Ok
100% L01-240910	54	2	1.945e+10	18662.5	1149824505.5	5.9125325644	8e+0	0.903089987	10.288858015	0.383	Pass	0.788	Ok
100% L01-240910	55	2	8.368e+9	19716.5	128843280.71	1.5397191217	4e+0	0.6020599913	9.9226202714	0.016	Pass	0.047	Ok
100% L01-240910	56	2	3.646e+9	20386.5	178059200.32	4.8830356341	2e+0	0.3010299957	9.561874525	1.022	Pass	-0.577	Ok
100% L01-240910	57	2	4.332e+10	20021.5	1706528670.2	3.9391021166	1.6e+1	1.2041199827	10.636716349	8.291	Pass	1.104	Ok
100% L01-240910	58	2	2.023e+10	19822.5	2634087129.5	13.017781226	8e+0	0.903089987	10.306093168	1.127	Pass	1.316	Ok
100% L01-240910	59	2	9.200e+9	20137.5	101459939.16	1.1028389063	4e+0	0.6020599913	9.9637825187	2.060	Pass	1.251	Ok
100% L01-240910	60	2	3.981e+9	19947.5	380929556.42	9.5696095024	2e+0	0.3010299957	9.5999504547	7.068	Pass	0.592	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-1.128	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-1.202	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.829	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-1.124	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.841	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.811	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.429	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.627	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.421	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	2.295	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	1.247	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.524	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

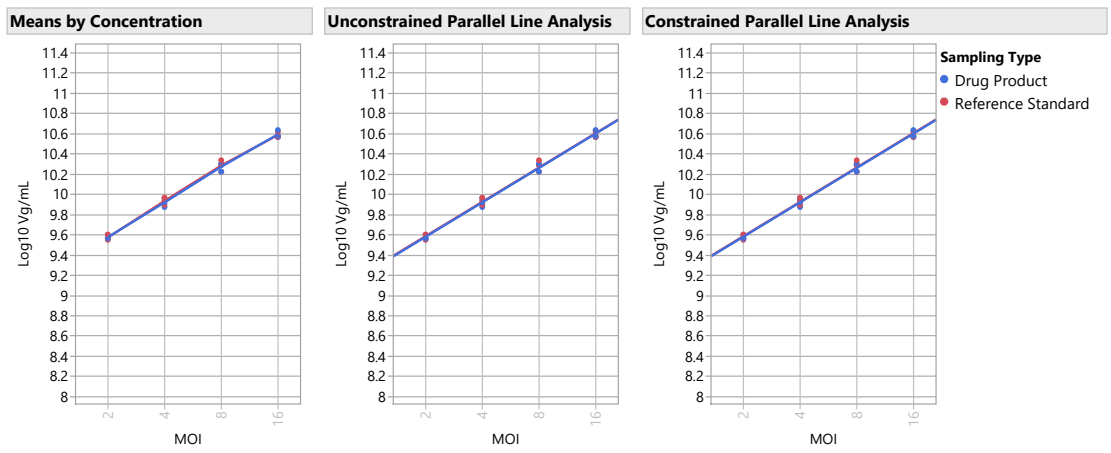
100% L01-240910 Test Sample & Reference Standard Summary Statistics

Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
100% L01-240910	2e+0	3	3.78e+9	1.78e+8
100% L01-240910	4e+0	3	8.36e+9	8.51e+8
100% L01-240910	8e+0	3	1.9e+10	1.8e+9
100% L01-240910	1.6e+1	3	3.9e+10	3.49e+9

100% L01-240910 Model Selection

Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 1, All Doses	1.003	2.267	0.992	0.037	Parallel and Linear	Model 1, All Doses
Model 3, High Standard and Test Doses Excluded	0.979	0.108	0.987	0.037	Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	1.032	2.983	0.983	0.040	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.992	3.308	0.990	0.039	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.026	2.613	0.991	0.037	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.043	1.864	0.991	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.957	1.268	0.991	0.037	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.946	2.446	0.989	0.039	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.067	2.056	0.990	0.038	Parallel and Linear	

100% L01-240910 Graphs



100% L01-240910 Validity Report

Validity Criteria	LSL	USL	Validity Results	Assay Validity	Overall Validity
Dose Response Test	.	0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.003	Passed Validity Criteria	
Linearity Ratio	.	26.3	2.267	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

100% L01-240910 Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI 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
5.63	5.68	99.0	0	0	99.0	103.5	94.8	150	50	8.7	8.7	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
99.0	99.0	0.0

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
1.3	0.3	1.0

BQT Infectivity_13Nov2024-14-12-06

50% 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
50% L01-240910_2	61	2	1.834e+10	19737	203751104.97	1.1111170816	1.6e+1	1.2041199827	10.263340148	2.562	Pass	0.667	Ok
50% L01-240910_2	62	2	1.130e+10	20211	262898579.74	2.3266742485	8e+0	0.903089987	10.053052657	2.246	Pass	2.242	Ok
50% L01-240910_2	63	2	5.357e+9	21162.5	66651202.129	1.2441699278	4e+0	0.6020599913	9.7289282868	2.055	Pass	1.176	Ok
50% L01-240910_2	64	2	2.820e+9	19762	168860802.11	5.9869546674	2e+0	0.3010299957	9.4503228782	1.566	Pass	1.331	Ok
50% L01-240910_2	65	2	1.644e+10	20267.5	452436562.64	2.7520219303	1.6e+1	1.2041199827	10.215905804	0.095	Pass	-0.354	Ok
50% L01-240910_2	66	2	9.639e+9	19391	154759020.72	1.6054847679	8e+0	0.903089987	9.9840497834	0.030	Pass	0.641	Ok
50% L01-240910_2	67	2	4.560e+9	21001	18127.742997	0.000397543	4e+0	0.6020599913	9.6589596546	0.017	Pass	-0.243	Ok
50% L01-240910_2	68	2	2.548e+9	19777.5	91143848.022	3.5773123313	2e+0	0.3010299957	9.4061705006	0.173	Pass	0.331	Ok
50% L01-240910_2	69	2	1.499e+10	19994	579169394.77	3.8628534835	1.6e+1	1.2041199827	10.175897368	1.786	Pass	-1.256	Ok
50% L01-240910_2	70	2	8.114e+9	20973	65816734.103	0.8111860937	8e+0	0.903089987	9.9092158315	2.007	Pass	-0.856	Ok
50% L01-240910_2	71	2	3.723e+9	20849	22105610.024	0.5936871551	4e+0	0.6020599913	9.5709448514	2.191	Pass	-2.218	Ok
50% L01-240910_2	72	2	2.099e+9	20993	13367658.82	0.6368196257	2e+0	0.3010299957	9.3220389135	3.035	Pass	-1.556	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-0.778	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-0.827	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.576	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-0.775	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.584	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.564	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.300	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.437	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.294	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	1.507	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	0.857	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.366	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

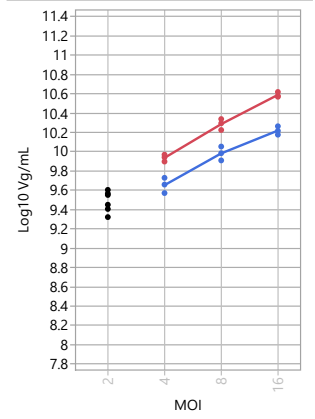
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
50% L01-240910_2	2e+0	3	2.49e+9	3.64e+8
50% L01-240910_2	4e+0	3	4.55e+9	8.17e+8
50% L01-240910_2	8e+0	3	9.68e+9	1.59e+9
50% L01-240910_2	1.6e+1	3	1.7e+10	1.68e+9

50% L01-240910_2 Model Selection

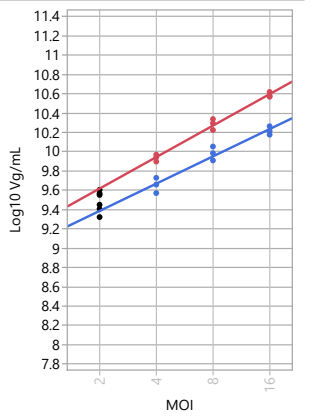
Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.867	5.719	0.974	0.055	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 3, High Standard and Test Doses Excluded	0.828	2.175	0.973	0.056	Parallel and Linear	
Model 1, All Doses	0.827	2.502	0.984	0.052	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.903	1.368	0.984	0.057	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.868	1.822	0.985	0.053	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.860	2.077	0.983	0.055	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.833	4.623	0.981	0.052	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.795	6.189	0.967	0.055	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.789	1.416	0.976	0.054	Parallel and Linear	

50% L01-240910_2 Graphs

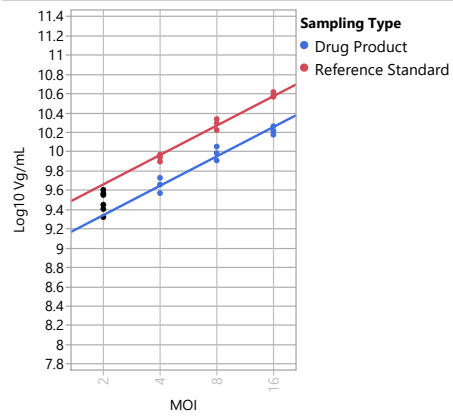
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.180	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.867	Passed Validity Criteria	
Linearity Ratio	.	26.3	5.719	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

50% L01-240910_2 Relative Infectivity and Infectious Particle Ratio

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Reference Stability CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance	CI Range % of Tolerance Check	OOS Validity
5.57	11.50	48.4	0	0	48.4	53.3	43.5	150	50	9.8	9.8	Bioassay Results are Reportable	Assay is Valid and OOS

Unconstrained RI	Constrained RI	Relative Infectivity Delta
48.2	48.4	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	Droplets	Accepted Droplets	Dev(Vg/mL)	Std CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z	Outlier Within Group	Studentized Residuals	Externally Outlier Between Group
150% L01-240910_2	73	2	4.494e+10	20268.5	1382444686.6	3.0760724392	1.6e+1	1.2041199827	10.652651205	1.953	Pass	0.523	Ok
150% L01-240910_2	74	2	2.566e+10	20858	639666646.59	2.4930803141	8e+0	0.903089987	10.409217437	3.857	Pass	1.344	Ok
150% L01-240910_2	75	2	1.222e+10	20415.5	212403284.41	1.7378576067	4e+0	0.6020599913	10.087147039	5.758	Pass	-0.365	Ok
150% L01-240910_2	76	2	7.248e+9	19921	49605155.379	0.6844349971	2e+0	0.3010299957	9.8601946062	0.933	Pass	1.065	Ok
150% L01-240910_2	77	2	4.381e+10	19580	1157150209.5	2.6411706984	1.6e+1	1.2041199827	10.641593268	0.045	Pass	0.146	Ok
150% L01-240910_2	78	2	2.344e+10	20742.5	482974557.86	2.0600966742	8e+0	0.903089987	10.370036653	0.269	Pass	0.062	Ok
150% L01-240910_2	79	2	1.144e+10	20183	480465980.94	4.1993236748	4e+0	0.6020599913	10.058483293	1.103	Pass	-1.314	Ok
150% L01-240910_2	80	2	7.163e+9	19195	3819839.2688	0.0533236786	2e+0	0.3010299957	9.8551249868	0.513	Pass	0.881	Ok
150% L01-240910_2	81	2	4.253e+10	19371.5	109815609.98	0.2582091481	1.6e+1	1.2041199827	10.628692453	2.312	Pass	-0.291	Ok
150% L01-240910_2	82	2	2.245e+10	20023.5	582856847.74	2.596168258	8e+0	0.903089987	10.351229067	1.342	Pass	-0.529	Ok
150% L01-240910_2	83	2	1.161e+10	20684	214437339.99	1.8466429905	4e+0	0.6020599913	10.064917469	0.398	Pass	-1.090	Ok
150% L01-240910_2	84	2	6.636e+9	19439	77730062.789	1.1713325325	2e+0	0.3010299957	9.821908813	9.576	Pass	-0.260	Ok
Ref.Std (L01-240910)	1	2	3.706e+10	18978	760275303.25	2.0513230621	1.6e+1	1.2041199827	10.56893682	0.993	Pass	-1.263	Ok
Ref.Std (L01-240910)	2	2	1.676e+10	19425	448865633.8	2.6779458075	8e+0	0.903089987	10.224314572	2.677	Pass	-1.346	Ok
Ref.Std (L01-240910)	3	2	7.894e+9	19283	173809988.84	2.2019327821	4e+0	0.6020599913	9.8972706745	2.803	Pass	-0.925	Ok
Ref.Std (L01-240910)	4	2	3.558e+9	19900.5	119963713.77	3.3714963187	2e+0	0.3010299957	9.5512272121	1.253	Pass	-1.258	Ok
Ref.Std (L01-240910)	5	2	3.782e+10	19498	2633987435.9	6.9650394744	1.6e+1	1.2041199827	10.577690117	0.469	Pass	-0.938	Ok
Ref.Std (L01-240910)	6	2	1.968e+10	19161.5	988424708.4	5.0234907393	8e+0	0.903089987	10.293937987	0.116	Pass	0.904	Ok
Ref.Std (L01-240910)	7	2	8.739e+9	19226	368054388.21	4.2113957236	4e+0	0.6020599913	9.9414859483	0.137	Pass	0.477	Ok
Ref.Std (L01-240910)	8	2	3.686e+9	19778.5	16840666.879	0.4568279827	2e+0	0.3010299957	9.5666065868	0.313	Pass	-0.698	Ok
Ref.Std (L01-240910)	9	2	4.155e+10	19128	1958531281.1	4.7134708372	1.6e+1	1.2041199827	10.618589688	7.706	Pass	0.468	Ok
Ref.Std (L01-240910)	10	2	2.177e+10	20050	122498999.17	0.562730193	8e+0	0.903089987	10.337832323	1.723	Pass	2.635	Ok
Ref.Std (L01-240910)	11	2	9.310e+9	19816.5	38582938.215	0.4144158489	4e+0	0.6020599913	9.9689589413	1.661	Pass	1.398	Ok
Ref.Std (L01-240910)	12	2	4.019e+9	20427	40014284.268	0.9957034587	2e+0	0.3010299957	9.6040850374	4.371	Pass	0.583	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

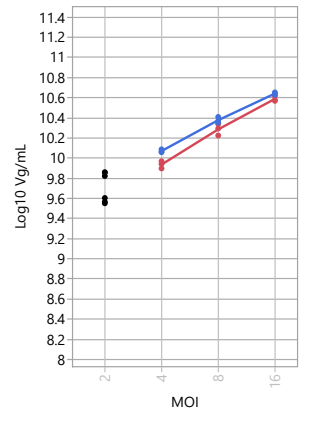
Group	MOI	N Rows	Mean(Vg/mL)	Std Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.75e+9	2.38e+8
Ref.Std (L01-240910)	4e+0	3	8.65e+9	7.13e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.51e+9
Ref.Std (L01-240910)	1.6e+1	3	3.9e+10	2.4e+9
150% L01-240910_2	2e+0	3	7.02e+9	3.31e+8
150% L01-240910_2	4e+0	3	1.2e+10	4.1e+8
150% L01-240910_2	8e+0	3	2.4e+10	1.64e+9
150% L01-240910_2	1.6e+1	3	4.4e+10	1.21e+9

150% L01-240910_2 Model Selection

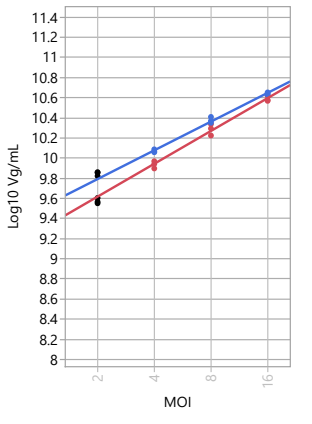
Model	Parallelism Slope Ratio	Linearity Ratio	R2	Validity RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.875	3.634	0.987	0.033	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.794	0.591	0.993	0.033	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.747	2.806	0.987	0.035	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.841	3.746	0.993	0.033	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.825	1.310	0.989	0.033	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.814	2.268	0.985	0.036	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.802	3.215	0.993	0.032	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.783	1.676	0.990	0.035	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.757	1.825	0.992	0.032	Parallel and Linear	

150% L01-240910_2 Graphs

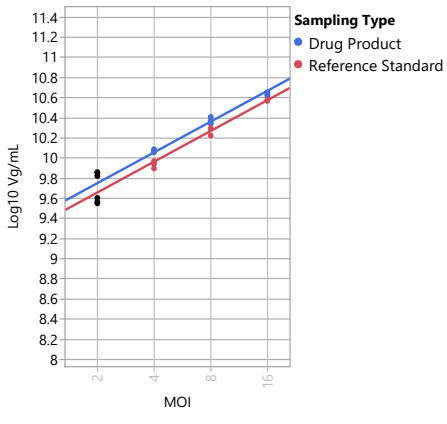
Means by Concentration



Unconstrained Parallel Line Analysis



Constrained Parallel Line Analysis



BQT Infectivity_13Nov2024-14-12-06

150% 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	.	35056142037	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)	.	15	0.116	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.875	Passed Validity Criteria	
Linearity Ratio	.	26.3	3.634	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.650	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)	.	1	0.000	Passed Validity Criteria	

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

EC50 Ref	EC50 Test	RI 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
8.89	7.20	123.4	0	0	123.4	131.0	116.3	150	50	14.7	14.7	Bioassay Results are Reportable	Assay is Valid and Within Limits

Unconstrained RI	Constrained RI	Relative Infectivity Delta
123.5	123.4	0.1

Infectious Particle Ratio	Infectious Particle Ratio Lower Limit	Infectious Particle Ratio Upper Limit
1.7	0.3	1.0

Relative Infectivity All Samples

Sample Name	EC50 Standard	EC50 Test	Infectious Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910_1	5.5557183451	11.51966245	0.7	48.2	43.1	53.4
150% L01-240910_1	8.8373499091	7.2419900375	1.7	122.0	115.1	129.5
200% L01-240910	9.8394470118	6.5044305766	2.1	151.3	143.2	160.1
100% L01-240910	5.6292283576	5.6846157177	1.3	99.0	94.8	103.5
50% L01-240910_2	5.5657610786	11.498876631	0.7	48.4	43.5	53.3
150% L01-240910_2	8.8868731414	7.2016331258	1.7	123.4	116.3	131.0

Sample Name	Overall Validity	OOS	Reportable
50% L01-240910_1	Assay is Valid	OOS	Reportable
150% L01-240910_1	Assay is Valid	Within Limits	Reportable
200% L01-240910	Assay is Valid	OOS	Reportable
100% L01-240910	Assay is Valid	Within Limits	Reportable
50% L01-240910_2	Assay is Valid	OOS	Reportable
150% L01-240910_2	Assay is Valid	Within Limits	Reportable

Astellas BQT Infectivity Bioassay Materials and Reference Standard Report

Assay Details

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

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 (<)	4.00			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	3000	3000	3000	3000	3000	3000	3000	3000	3000
fixed position for ec50	10.00			B	3000	3000	3000	3000	3000	3000	3000	3000	3000
ec50 reference concentration target	4.74			C	3000	3000	3000	3000	3000	3000	3000	3000	3000
fixed position for Test article for Infectious Particles Ratio Equation	10.00			D	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Lower Specification Limit (≥)	0.30			E	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Upper Specification Limit (≤)	1.00			F	3000	3000	3000	3000	3000	3000	3000	3000	3000
Failed Accepted Droplets Upper Limit (≤)	5.00			G	3000	3000	3000	3000	3000	3000	3000	3000	3000
	.			H	3000	3000	3000	3000	3000	3000	3000	3000	3000
Report File Name	.				.	.	.	.	.	.	.	.	.
Ref.Std (1-12)	.		ddPCR Map - Plate 2		1	2	3	4	5	6	7	8	9
Control (13-24)	.			A	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 1 (25-36)	.			B	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 2 (37-48)	.			C	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 3 (49-60)	.			D	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 4 (61-72)	.			E	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 5 (73-84)	.			F	6000	6000	6000	6000	6000	6000	6000	6000	6000
	.			G	6000	6000	6000	6000	6000	6000	6000	6000	6000
Total Number of Plates	2.00			H	6000	6000	6000	6000	6000	6000	6000	6000	6000
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MOI Concentrations	.				.	.	.	.	.	.	.	.	.
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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
D01	2	RS	REP1		BDNF	231.5564728	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20060	3584	16476
C01	4	RS	REP1		BDNF	518.0411377	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19347	6891	12456
B01	8	RS	REP1		BDNF	1138.597412	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18820	11670	7150
A01	16	RS	REP1		BDNF	2435.005615	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18595	16248	2347
D10	2	200	REP1		BDNF	715.3798218	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19550	8907	10643
C10	4	200	REP1		BDNF	953.8183594	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20307	11280	9027
B10	8	200	REP1		BDNF	2056.84375	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18401	15198	3203
A10	16	200	REP1		BDNF	3566.601074	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19238	18310	928
H07	2	150.2	REP1		BDNF	485.5121765	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20294	6862	13432
G07	4	150.2	REP1		BDNF	824.8217163	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20329	10245	10084
F07	8	150.2	REP1		BDNF	1740.666382	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21077	16277	4800
E07	16	150.2	REP1		BDNF	3061.294189	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20346	18838	1508
D07	2	150	REP1		BDNF	467.9755249	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20543	6742	13801
C07	4	150	REP1		BDNF	813.9212646	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19772	9873	9899
B07	8	150	REP1		BDNF	1726.499268	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20226	15564	4662
A07	16	150	REP1		BDNF	2997.810303	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20351	18759	1592
H01	2	100.2	REP1		BDNF	233.0512695	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19721	3544	16177
G01	4	100.2	REP1		BDNF	467.9432983	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18920	6209	12711
F01	8	100.2	REP1		BDNF	1110.372437	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20147	12307	7840
E01	16	100.2	REP1		BDNF	2371.200928	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18619	16138	2481
H04	2	50.2	REP1		BDNF	180.0717621	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19567	2777	16790
G04	4	50.2	REP1		BDNF	353.9968262	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21328	5542	15786
F04	8	50.2	REP1		BDNF	740.8954468	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20294	9483	10811
E04	16	50.2	REP1		BDNF	1232.10498	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20166	13090	7076
D04	2	50	REP1		BDNF	193.6558685	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18890	2867	16023
C04	4	50	REP1		BDNF	368.6099854	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20176	5427	14749
B04	8	50	REP1		BDNF	775.4868164	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20366	9831	10535
A04	16	50	REP1		BDNF	1280.328125	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18581	12323	6258
D02	2	RS	REP2		BDNF	244.9684601	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19242	3617	15625
C02	4	RS	REP2		BDNF	599.9827271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18636	7445	11191
B02	8	RS	REP2		BDNF	1358.331665	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18941	12971	5970
A02	16	RS	REP2		BDNF	2645.318359	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19819	17727	2092
D11	2	200	REP2		BDNF	536.3302002	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18041	6605	11436
C11	4	200	REP2		BDNF	908.2162476	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18230	9806	8424
B11	8	200	REP2		BDNF	1854.505981	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20587	16331	4256
A11	16	200	REP2		BDNF	3838.585938	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19827	19068	759
H08	2	150.2	REP2		BDNF	477.3862915	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19158	6390	12768
G08	4	150.2	REP2		BDNF	740.1178589	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18823	8789	10034
F08	8	150.2	REP2		BDNF	1540.183472	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20663	15083	5580
E08	16	150.2	REP2		BDNF	2975.349854	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18712	17220	1492
D08	2	150	REP2		BDNF	476.8458557	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20529	6841	13688
C08	4	150	REP2		BDNF	727.1169434	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20772	9576	11196
B08	8	150	REP2		BDNF	1533.788452	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19575	14260	5315
A08	16	150	REP2		BDNF	2918.29126	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20144	18458	1686
H02	2	100.2	REP2		BDNF	251.4928436	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19801	3811	15990
G02	4	100.2	REP2		BDNF	563.9385986	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19461	7411	12050
F02	8	100.2	REP2		BDNF	1350.686035	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18812	12844	5968
E02	16	100.2	REP2		BDNF	2691.910645	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17781	15977	1804
H05	2	50.2	REP2		BDNF	165.5587921	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19791	2598	17193
G05	4	50.2	REP2		BDNF	303.9955139	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20649	4702	15947
F05	8	50.2	REP2		BDNF	635.3309326	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18923	7896	11027
E05	16	50.2	REP2		BDNF	1117.338135	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20688	12685	8003
D05	2	50	REP2		BDNF	168.1752167	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20255	2698	17557
C05	4	50	REP2		BDNF	310.4753723	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19823	4598	15225
B05	8	50	REP2		BDNF	639.4810791	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19646	8238	11408
A05	16	50	REP2		BDNF	1144.275269	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18755	11664	7091
D03	2	RS	REP3		BDNF	266.0267029	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20002	4048	15954
C03	4	RS	REP3		BDNF	622.4987183	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19064	7833	11231
B03	8	RS	REP3		BDNF	1457.020752	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20871	14822	6049
A03	16	RS	REP3		BDNF	2862.445068	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18686	17046	1640
D12	2	200	REP3		BDNF	586.7678833	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20473	8040	12433
C12	4	200	REP3		BDNF	957.8773193	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20551	11447	9104
B12	8	200	REP3		BDNF	1931.979492	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18439	14870	3569
A12	16	200	REP3		BDNF	3773.816406	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20100	19287	813
H09	2	150.2	REP3		BDNF	446.0667114	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18944	5978	12966
G09	4	150.2	REP3		BDNF	764.0432739	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19830	9472	10358
F09	8	150.2	REP3		BDNF	1469.234375	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19126	13640	5486
E09	16	150.2	REP3		BDNF	2840.490967	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18430	16782	1648
D09	2	150	REP3		BDNF	423.3496094	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20568	6216	14352
C09	4	150	REP3		BDNF	750.3000488	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20841	9827	11014
B09	8	150	REP3		BDNF	1545.439087	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20298	14841	5457
A09	16	150	REP3		BDNF	2949.800537	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20384	18723	1661
H03	2	100.2	REP3		BDNF	247.4173126	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20547	3897	16650
G03	4	100.2	REP3		BDNF	608.5429688	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19485	7869	11616
F03	8	100.2	REP3		BDNF	1224.796753	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19908	12879	7029
E03	16	100.2	REP3		BDNF	2968.63208	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19840	18249	1591
H06	2	50.2	REP3		BDNF	140.5720215	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21008	2366	18642
G06	4	50.2	REP3		BDNF	249.2716827	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20991	4008	16983
F06	8	50.2	REP3		BDNF	544.012085	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20965	7762	13203
E06	16	50.2	REP3		BDNF	1026.855957	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19889	11580	8309
D06	2	50	REP3		BDNF	138.2278748	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18574	2059	16515
C06	4	50	REP3		BDNF	249.8983154	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19930	3814	16116

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BQT Infectivity_13Nov2024-14-12-06

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
B06	8	50	REP3		BDNF	537.3498535	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19064	6990	12074
A06	16	50	REP3		BDNF	984.0247192	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19568	11090	8478
E10	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19747	0	19747
E11	NTC				BDNF	0.34029907	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20746	6	20740
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19958	0	19958
F10	PC				BDNF	1509.848633	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19141	13837	5304
F11	PC				BDNF	1421.419922	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19171	13444	5727
F12	PC				BDNF	1506.818848	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18865	13624	5241

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
D01	2	RS	REP1		BDNF	121.4333801	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19741	1936	17805
C01	4	RS	REP1		BDNF	267.2140503	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19219	3905	15314
B01	8	RS	REP1		BDNF	548.1389771	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20030	7460	12570
A01	16	RS	REP1		BDNF	1253.342529	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19361	12689	6672
D10	2	200	REP1		BDNF	369.8317871	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21528	5807	15721
C10	4	200	REP1		BDNF	503.3505554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20963	7297	13666
B10	8	200	REP1		BDNF	1035.681763	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20128	11782	8346
A10	16	200	REP1		BDNF	1779.52002	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19343	15081	4262
H07	2	150.2	REP1		BDNF	240.4176788	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19548	3613	15935
G07	4	150.2	REP1		BDNF	402.3980713	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20502	5939	14563
F07	8	150.2	REP1		BDNF	840.1790161	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20639	10534	10105
E07	16	150.2	REP1		BDNF	1465.478027	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20191	14381	5810
D07	2	150	REP1		BDNF	239.6851807	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20790	3832	16958
C07	4	150	REP1		BDNF	413.0661316	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20389	6037	14352
B07	8	150	REP1		BDNF	836.7145996	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20505	10436	10069
A07	16	150	REP1		BDNF	1446.222656	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19641	13896	5745
H01	2	100.2	REP1		BDNF	130.6248779	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19355	2034	17321
G01	4	100.2	REP1		BDNF	265.9398499	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19820	4010	15810
F01	8	100.2	REP1		BDNF	564.5903931	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18255	6958	11297
E01	16	100.2	REP1		BDNF	1269.457153	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19528	12890	6638
H04	2	50.2	REP1		BDNF	97.9960556	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19957	1595	18362
G04	4	50.2	REP1		BDNF	180.1403809	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20997	2981	18016
F04	8	50.2	REP1		BDNF	382.8408813	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20128	5591	14537
E04	16	50.2	REP1		BDNF	606.4475708	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19308	7777	11531
D04	2	50	REP1		BDNF	99.47064209	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20031	1624	18407
C04	4	50	REP1		BDNF	175.9420166	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20388	2832	17556
B04	8	50	REP1		BDNF	381.4729919	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20626	5712	14914
A04	16	50	REP1		BDNF	590.8175659	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19843	7834	12009
D02	2	RS	REP2		BDNF	123.2781067	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20315	2021	18294
C02	4	RS	REP2		BDNF	282.6411133	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19816	4232	15584
B02	8	RS	REP2		BDNF	632.5710449	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19382	8061	11321
A02	16	RS	REP2		BDNF	1198.491821	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19177	12253	6924
D11	2	200	REP2		BDNF	273.012146	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21178	4386	16792
C11	4	200	REP2		BDNF	482.1478271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21604	7264	14340
B11	8	200	REP2		BDNF	914.5630493	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21292	11506	9786
A11	16	200	REP2		BDNF	1931.075928	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19256	15526	3730
H08	2	150.2	REP2		BDNF	238.8732147	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19232	3534	15698
G08	4	150.2	REP2		BDNF	392.708313	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21543	6114	15429
F08	8	150.2	REP2		BDNF	792.859375	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20822	10209	10613
E08	16	150.2	REP2		BDNF	1433.126343	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20448	14400	6048
D08	2	150	REP2		BDNF	242.5851288	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20523	3824	16699
C08	4	150	REP2		BDNF	366.0437927	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20648	5521	15127
B08	8	150	REP2		BDNF	765.4019165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20610	9857	10753
A08	16	150	REP2		BDNF	1423.313721	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19450	13649	5801
H02	2	100.2	REP2		BDNF	117.3526306	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20972	1991	18981
G02	4	100.2	REP2		BDNF	275.8955688	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19972	4175	15797
F02	8	100.2	REP2		BDNF	621.1397705	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18513	7594	10919
E02	16	100.2	REP2		BDNF	1177.178711	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20005	12650	7355
H05	2	50.2	REP2		BDNF	87.07595825	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19764	1410	18354
G05	4	50.2	REP2		BDNF	151.9986115	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21353	2588	18765
F05	8	50.2	REP2		BDNF	324.9608765	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19859	4793	15066
E05	16	50.2	REP2		BDNF	537.3410034	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19847	7277	12570
D05	2	50	REP2		BDNF	85.9803009	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20333	1433	18900
C05	4	50	REP2		BDNF	159.8617554	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20440	2597	17843
B05	8	50	REP2		BDNF	310.8562622	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19819	4602	15217
A05	16	50	REP2		BDNF	523.4338989	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19400	6967	12433
D03	2	RS	REP3		BDNF	134.8996429	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20852	2259	18593
C03	4	RS	REP3		BDNF	309.430542	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20569	4757	15812
B03	8	RS	REP3		BDNF	722.7357178	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19229	8826	10403
A03	16	RS	REP3		BDNF	1338.896484	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19570	13299	6271
D12	2	200	REP3		BDNF	280.2830811	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21440	4545	16895
C12	4	200	REP3		BDNF	483.2579346	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20510	6909	13601
B12	8	200	REP3		BDNF	919.8685303	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19937	10815	9122
A12	16	200	REP3		BDNF	1842.969238	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19864	15717	4147
H09	2	150.2	REP3		BDNF	219.3691254	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19934	3391	16543
G09	4	150.2	REP3		BDNF	392.1303101	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21538	6105	15433
F09	8	150.2	REP3		BDNF	762.0933228	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20921	9975	10946
E09	16	150.2	REP3		BDNF	1415.068726	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20313	14212	6101
D09	2	150	REP3		BDNF	224.0620117	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20696	3589	17107
C09	4	150	REP3		BDNF	376.1473083	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20855	5707	15148
B09	8	150	REP3		BDNF	756.6038818	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20816	9874	10942
A09	16	150	REP3		BDNF	1392.316528	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19261	13363	5898
H03	2	100.2	REP3		BDNF	141.6658478	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19348	2195	17153
G03	4	100.2	REP3		BDNF	309.0543518	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20790	4803	15987
F03	8	100.2	REP3		BDNF	736.5704346	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19737	9184	10553
E03	16	100.2	REP3		BDNF	1403.869507	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20203	14077	6126
H06	2	50.2	REP3		BDNF	69.65585327	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20978	1206	19772
G06	4	50.2	REP3		BDNF	123.5937729	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20707	2065	18642
F06	8	50.2	REP3		BDNF	268.9034119	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20981	4287	16694
E06	16	50.2	REP3		BDNF	486.1256714	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20099	6803	13296
D06	2	50	REP3		BDNF	72.16507721	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21665	1289	20376
C06	4	50	REP3		BDNF	132.0900574	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20329	2159	18170
B06	8	50	REP3		BDNF	261.3279724	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20930	4169	16761
A06	16	50	REP3		BDNF	483.8331604	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19476	6567	12909
E10	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	21291	0	21291
E11	NTC				BDNF	0.340020388	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20763	6	20757
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	21116	0	21116
F10	PC				BDNF	1563.026733	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20313	14933	5380
F11	PC				BDNF	1458.765747	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19582	13915	5667
F12	PC				BDNF	1504.456665	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	19833	14312	5521