

Astellas BQT Assay Report

Test Article Report

Assay Details	
User Information	
User Name: harding	
Computer Name: DESKTOP-RFHI5SO	
Logon Server: \\DESKTOP-RFHISSO	
User Domain: DESKTOP-RFHI5SO Astellas BQT Infectivity PLA Script Version 0.1	
JMP Version 18.1.0	
Analyst Signature/Date	_
Approver Signature/Date	_

Astellas BQT Infectivity Files

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

50% L01-240910_1 & Reference Standard Data

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

Within Group Jackknife z Outlier Limit (≥): 4

Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

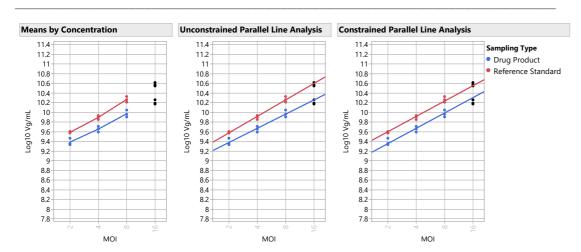
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

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

50% L01-240910_1 Model Selection

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

50% L01-240910_1 Graphs



50% L01-240910_1 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.178	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.860	Passed Validity Criteria	
Linearity Ratio		26.3	4.467	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Check OOS Validity
3.05	5.24	58.3	0	0	58.3	63.8	53.0	150	50	10.8	10.8 Bioassay Results are Reportable Assay is Valid and Within Limits
	RI Constrained		elta								
58 Infectious	3.2 58 Infectious Partic		0.2 article								
	Ratio Lower Lim										
0.7	0	.3	1.0								

150% L01-240910_1 & Reference Standard Data

				Accepted	Std					Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Within Group	Studentized Residuals Between Group
150% L01-240910_1	25	2	4.328e+10	19590	656185083.84	1.516157548	1.6e+1	1.2041199827	10.636282022	0.797 Pass	0.207 Ok
150% L01-240910_1	26	2	2.548e+10	19257.5	127422942.19	0.5001095848	8e+0	0.903089987	10.406182451	6.439 Pass	1.342 Ok
150% L01-240910_1	27	2	1.235e+10	20620.5	95067106.961	0.7697030114	4e+0	0.6020599913	10.091707092	3.487 Pass	-0.123 Ok
150% L01-240910_1	28	2	7.267e+9	19589.5	124780027.36	1.7170178963	2e+0	0.3010299957	9.8613702547	0.645 Pass	1.073 Ok
150% L01-240910_1	29	2	4.320e+10	20041.5	479922826.41	1.1109143873	1.6e+1	1.2041199827	10.635490815	0.622 Pass	0.181 Ok
150% L01-240910_1	30	2	2.319e+10	19921	669588345.21	2.8877311629	8e+0	0.903089987	10.365251126	0.427 Pass	0.071 Ok
150% L01-240910_1	31	2	1.108e+10	20170	136112012.44	1.2281117402	4e+0	0.6020599913	10.044658572	1.427 Pass	-1.617 Ok
150% L01-240910_1	32	2	7.305e+9	19580.5	228548830.67	3.1286225929	2e+0	0.3010299957	9.8636258265	0.772 Pass	1.152 Ok
150% L01-240910_1	33	2	4.196e+10	19967	98481352.962	0.2346842141	1.6e+1	1.2041199827	10.622870128	22.921 Pass	-0.224 Ok
150% L01-240910_1	34	2	2.262e+10	19692	154114236.92	0.681261223	8e+0	0.903089987	10.35452909	1.056 Pass	-0.247 Ok
150% L01-240910_1	35	2	1.151e+10	19410.5	203413827.77	1.7671798668	4e+0	0.6020599913	10.061099717	0.230 Pass	-1.059 Ok
150% L01-240910_1	36	2	6.446e+9	20595.5	356693271.03	5.5331329205	2e+0	0.3010299957	9.8093238133	31.380 Pass	-0.634 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363 Pass	-1.247 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692 Pass	-1.131 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625 Pass	-2.044 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343 Pass	0.040 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259 Pass	-0.444 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126 Pass	0.418 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107 Pass	-0.398 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198 Pass	-0.238 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754 Pass	1.095 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737 Pass	2.731 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750 Pass	0.585 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780 Pass	0.826 Ok

Within Group Jackknife z Outlier Limit (≥): 4

Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

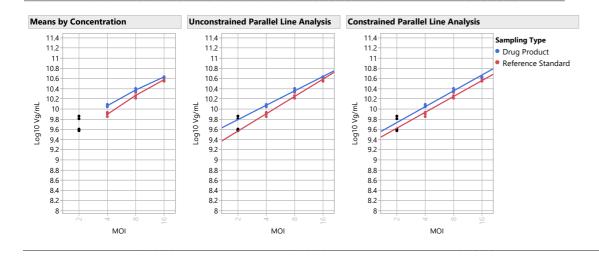
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
150% L01-240910_1	2e+0	3	7.01e+9	4.85e+8
150% L01-240910_1	4e+0	3	1.2e+10	6.45e+8
150% L01-240910_1	8e+0	3	2.4e+10	1.51e+9
150% L01-240910_1	1.6e+1	3	4.3e+10	7.38e+8

150% L01-240910_1 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	,	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.830	4.608	0.985	0.037	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.799	1.120	0.992	0.035	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.780	6.227	0.984	0.039	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.846	0.886	0.992	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.831	0.547	0.992	0.035	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.794	1.617	0.989	0.038	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.785	2.954	0.991	0.035	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.784	0.775	0.987	0.037	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.779	1.659	0.982	0.041	Parallel and Linear	

150% L01-240910_1 Graphs



150% L01-240910_1 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.270	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.830	Passed Validity Criteria	
Linearity Ratio		26.3	4.608	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %	
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Che	ck OOS Validity
9.04	7.08	127.6	0	0	127.6	137.0	119.1	150	50	17.9	17.9 Bioassay Results are Reportab	ole Assay is Valid and Within Limi
		Rela	ative									
Unconstrained I	RI Constrained	RI Infectivity D	Pelta									
127.	.9 127	'.6	0.3									
Infectious	Infectious Partio	le Infectious P	article									
Particle Ratio	Ratio Lower Lin	nit Ratio Uppe	r Limit									
1.7	(1.3	1.0									

200% L01-240910 & Reference Standard Data

				Accepted	Std					Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Within Group	Studentized Residuals Between Group
200% L01-240910	37	2	5.122e+10	19992	783580839.19	1.5299807737	1.6e+1	1.2041199827	10.709397834	0.859 Pass	-0.097 Ok
200% L01-240910	38	2	3.003e+10	19829.5	1181939524.2	3.9352547599	8e+0	0.903089987	10.477622403	5.054 Pass	0.751 Ok
200% L01-240910	39	2	1.444e+10	20205	633969738.98	4.3888702708	4e+0	0.6020599913	10.159715785	0.986 Pass	-0.496 Ok
200% L01-240910	40	2	1.053e+10	20592.5	698524091.26	6.6343484073	2e+0	0.3010299957	10.022383114	43.028 Pass	3.687 Ok
200% L01-240910	41	2	5.692e+10	19740.5	1139795369.6	2.0023037825	1.6e+1	1.2041199827	10.755296921	13.863 Pass	1.130 Ok
200% L01-240910	42	2	2.738e+10	19903.5	659314495.92	2.4079566923	8e+0	0.903089987	10.437443953	0.360 Pass	-0.222 Ok
200% L01-240910	43	2	1.421e+10	19306.5	662221857.73	4.6616125322	4e+0	0.6020599913	10.152467339	0.474 Pass	-0.675 Ok
200% L01-240910	44	2	7.868e+9	19962	351032941.35	4.4612955036	2e+0	0.3010299957	9.8958868825	0.754 Pass	-0.470 Ok
200% L01-240910	45	2	5.177e+10	20033.5	375780825.57	0.7258769233	1.6e+1	1.2041199827	10.714071626	0.570 Pass	0.024 Ok
200% L01-240910	46	2	2.652e+10	18917.5	798069096.51	3.0096351073	8e+0	0.903089987	10.42352665	1.167 Pass	-0.560 Ok
200% L01-240910	47	2	1.299e+10	20733.5	142190222.08	1.0943764268	4e+0	0.6020599913	10.113703003	7.882 Pass	-1.714 Ok
200% L01-240910	48	2	7.954e+9	20191	372262329.4	4.6799330306	2e+0	0.3010299957	9.9006094522	0.661 Pass	-0.346 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363 Pass	-0.995 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692 Pass	-0.904 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625 Pass	-1.594 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343 Pass	0.033 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259 Pass	-0.359 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126 Pass	0.337 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107 Pass	-0.322 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198 Pass	-0.193 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754 Pass	0.876 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737 Pass	2.073 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750 Pass	0.472 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780 Pass	0.664 Ok

Within Group Jackknife z Outlier Limit (≥): 4

Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

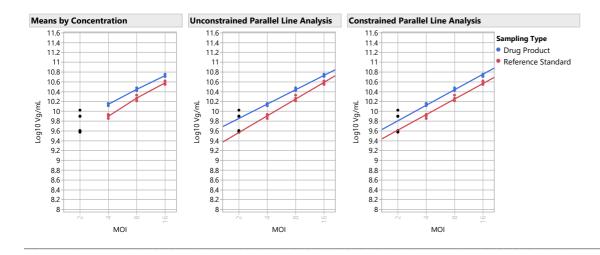
200% L01-240910 Test Sample & Reference Standard Summary Statistics

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

200% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
		,		D1 465	,	61 . 144 11
Model	Slope Ratio	Ratio	R2	KIVISE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.858	3.391	0.986	0.037	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.797	2.449	0.988	0.043	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.744	6.919	0.978	0.047	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.874	0.376	0.993	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.859	2.265	0.993	0.035	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.783	5.194	0.987	0.045	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.782	3.036	0.980	0.046	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.758	1.895	0.984	0.045	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.744	2.542	0.971	0.048	Parallel and Linear	

200% L01-240910 Graphs



200% L01-240910 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.374	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.858	Passed Validity Criteria	
Linearity Ratio		26.3	3.391	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

200% L01-240910 Relative Infectivity and Infectious Particle Ratio

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %	b	
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance	e CI Range % of Tolerance Check	OOS Validity
9.85	6.49	151.7	0	0	151.7	162.5	142.1	150	50	20.4	20.4	Bioassay Results are Reportable	Assay is Valid and OOS
		Rela											
Unconstrained I	RI Constrained	RI Infectivity D	elta										
152.	.1 151	.7	0.4										
Infectious	Infectious Partic	le Infectious P	article										
Particle Ratio	Ratio Lower Lim	it Ratio Upper	r Limit										
20	0	3	1.0										

100% L01-240910 & Reference Standard Data

				Accepted	Std					Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Within Group	Studentized Residuals Between Group
100% L01-240910	49	2	3.677e+10	19203	117861205.29	0.320544712	1.6e+1	1.2041199827	10.565482261	0.792 Pass	-1.083 Ok
100% L01-240910	50	2	1.712e+10	18946	389600987.9	2.276366175	8e+0	0.903089987	10.233377926	2.164 Pass	-0.782 Ok
100% L01-240910	51	2	7.957e+9	20068	202754799.3	2.5482781986	4e+0	0.6020599913	9.9007243042	10.649 Pass	-0.591 Ok
100% L01-240910	52	2	3.687e+9	19366	179490548.5	4.8680635883	2e+0	0.3010299957	9.5666853422	0.134 Pass	-0.479 Ok
100% L01-240910	53	2	3.701e+10	19265	1405677694.6	3.7978791033	1.6e+1	1.2041199827	10.568344618	0.627 Pass	-0.989 Ok
100% L01-240910	54	2	1.924e+10	18664	1497416004.4	7.7830217781	8e+0	0.903089987	10.284194225	0.011 Pass	0.668 Ok
100% L01-240910	55	2	8.908e+9	19092.5	465543327.06	5.226167867	4e+0	0.6020599913	9.9497767506	0.908 Pass	0.809 Ok
100% L01-240910	56	2	3.572e+9	20039	153217941.95	4.2888527325	2e+0	0.3010299957	9.5529684905	1.672 Pass	-0.914 Ok
100% L01-240910	57	2	4.107e+10	18741	112923026.09	0.2749478765	1.6e+1	1.2041199827	10.613532138	24.314 Pass	0.416 Ok
100% L01-240910	58	2	2.130e+10	20008	537971703.31	2.5254998667	8e+0	0.903089987	10.328412083	2.080 Pass	2.118 Ok
100% L01-240910	59	2	8.789e+9	19365.5	327411500.51	3.7250523238	4e+0	0.6020599913	9.9439615528	0.531 Pass	0.639 Ok
100% L01-240910	60	2	3.855e+9	19808	168024878.86	4.3584371279	2e+0	0.3010299957	9.5860428055	2.780 Pass	0.114 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363 Pass	-1.182 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692 Pass	-1.072 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625 Pass	-1.924 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343 Pass	0.038 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259 Pass	-0.422 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126 Pass	0.397 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107 Pass	-0.379 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198 Pass	-0.227 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754 Pass	1.038 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737 Pass	2.550 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750 Pass	0.556 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780 Pass	0.785 Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

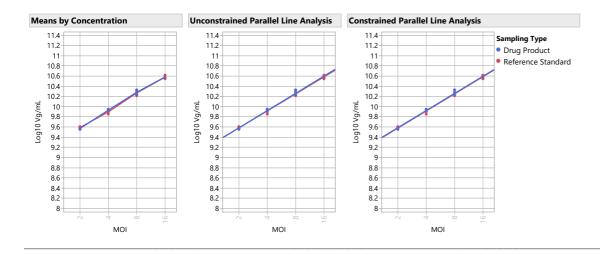
100% L01-240910 Test Sample & Reference Standard Summary Statistics

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

100% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 1, All Doses	1.015	1.719	0.992	0.036	Parallel and Linear	Model 1, All Doses
Model 2, Low Standard and Test Doses Excluded	0.956	4.192	0.983	0.041	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	1.048	1.792	0.987	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.997	1.975	0.991	0.037	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.996	3.910	0.990	0.039	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.974	0.777	0.990	0.038	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.957	0.694	0.989	0.039	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.047	3.982	0.989	0.039	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.067	0.159	0.991	0.036	Parallel and Linear	

100% L01-240910 Graphs



100% L01-240910 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.015	Passed Validity Criteria	
Linearity Ratio		26.3	1.719	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

100% L01-240910 Relative Infectivity and Infectious Particle Ratio

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %	
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Check	OOS Validity
5.71	5.61	101.7	0	0	101.7	106.3	97.3	150	50	9.0	9.0 Bioassay Results are Reportable	Assay is Valid and Within L
		Rela	ative									
Unconstrained	RI Constrained	RI Infectivity D	elta									
101	1.7	1.7	0.0									
Infectious	Infectious Parti	cle Infectious P	article									
Particle Ratio	Ratio Lower Lir	nit Ratio Uppe	r Limit									
1.3	(0.3	1.0									

50% L01-240910_2 & Reference Standard Data

				Accepted	Std					Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Within Group	Studentized Residuals Between Group
50% L01-240910_2	61	2	1.836e+10	19242.5	578676092.33	3.1526420738	1.6e+1	1.2041199827	10.263760873	4.977 Pass	0.855 Ok
50% L01-240910_2	62	2	1.146e+10	19672.5	383744830.65	3.3484648371	8e+0	0.903089987	10.059196796	4.500 Pass	2.576 Ok
50% L01-240910_2	63	2	5.320e+9	19670.5	143601825	2.6992944637	4e+0	0.6020599913	9.7259096953	1.665 Pass	1.086 Ok
50% L01-240910_2	64	2	2.844e+9	18932.5	78820891.318	2.771568467	2e+0	0.3010299957	9.45391573	2.285 Pass	1.278 Ok
50% L01-240910_2	65	2	1.572e+10	20668	412066220.06	2.6208869292	1.6e+1	1.2041199827	10.196518729	0.355 Pass	-0.643 Ok
50% L01-240910_2	66	2	9.122e+9	18914	97392479.23	1.0676937726	8e+0	0.903089987	9.9600787117	0.323 Pass	0.211 Ok
50% L01-240910_2	67	2	4.715e+9	20554	235510385.67	4.9945365046	4e+0	0.6020599913	9.673514872	0.136 Pass	-0.007 Ok
50% L01-240910_2	68	2	2.498e+9	15224			2e+0	0.3010299957	9.3976468856	0.039 Pass	-0.008 Ok
50% L01-240910_2	69	2	1.485e+10	19314.5	496404373.91	3.3426924038	1.6e+1	1.2041199827	10.171739185	1.175 Pass	-1.225 Ok
50% L01-240910_2	70	2	8.250e+9	19914.5	77289525.011	0.9368708507	8e+0	0.903089987	9.9164409116	1.234 Pass	-0.681 Ok
50% L01-240910_2	71	2	3.822e+9	19669.5	76628716.753	2.0047058585	4e+0	0.6020599913	9.5823408932	2.796 Pass	-2.047 Ok
50% L01-240910_2	72	2	2.189e+9	14748			2e+0	0.3010299957	9.3401609307	1.975 Pass	-1.327 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363 Pass	-0.835 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692 Pass	-0.760 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625 Pass	-1.323 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343 Pass	0.028 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259 Pass	-0.303 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126 Pass	0.285 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107 Pass	-0.272 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198 Pass	-0.163 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754 Pass	0.737 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737 Pass	1.699 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750 Pass	0.398 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780 Pass	0.560 Ok

Within Group Jackknife z Outlier Limit (≥): 4
Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

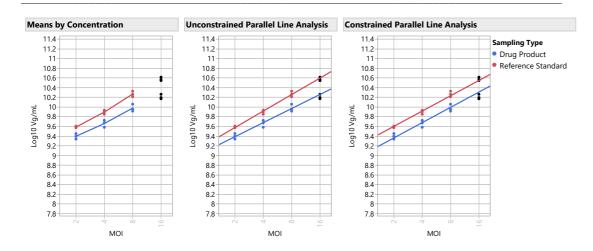
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

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

50% L01-240910_2 Model Selection

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

50% L01-240910_2 Graphs



50% L01-240910_2 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.193	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.854	Passed Validity Criteria	
Linearity Ratio		26.3	4.636	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Check OOS Validity
3.08	5.20	59.2	0	0	59.2	64.8	53.6	150	50	11.2	11.2 Bioassay Results are Reportable Assay is Valid and Within Limit
Unconstrained	RI Constrained		ative Jelta								
59		,	0.2								
Infectious	Infectious Partic	e Infectious P	article								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								
0.7	0	3	1.0								

150% L01-240910_2 & Reference Standard Data

				Accepted	Std					Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Within Group	Studentized Residuals Between Group
150% L01-240910_2	73	2	4.400e+10	19227.5	1011785905.7	2.2997680598	1.6e+1	1.2041199827	10.643404587	18.815 Pass	0.338 Ok
150% L01-240910_2	74	2	2.553e+10	19561	1022989391.8	4.0075911691	8e+0	0.903089987	10.406987719	8.130 Pass	1.259 Ok
150% L01-240910_2	75	2	1.243e+10	19720	215002496.86	1.7291133125	4e+0	0.6020599913	10.094620049	8.448 Pass	-0.152 Ok
150% L01-240910_2	76	2	7.210e+9	15797	460290519.99	6.3836280682	2e+0	0.3010299957	9.8579644548	0.278 Pass	0.815 Ok
150% L01-240910_2	77	2	4.318e+10	19239	1153369528.8	2.6708724835	1.6e+1	1.2041199827	10.63531532	0.605 Pass	0.077 Ok
150% L01-240910_2	78	2	2.311e+10	19181	16052321.661	0.0694549112	8e+0	0.903089987	10.363834893	0.481 Pass	-0.074 Ok
150% L01-240910_2	79	2	1.140e+10	20626	323785549.92	2.839103811	4e+0	0.6020599913	10.05707619	0.489 Pass	-1.326 Ok
150% L01-240910_2	80	2	7.430e+9	15294.5	318946741.85	4.2927946804	2e+0	0.3010299957	9.8709780529	1.323 Pass	1.271 Ok
150% L01-240910_2	81	2	4.312e+10	19919	212901108.44	0.4937427852	1.6e+1	1.2041199827	10.63467716	0.818 Pass	0.056 Ok
150% L01-240910_2	82	2	2.265e+10	20149	1046904735.2	4.6217208411	8e+0	0.903089987	10.355103454	0.977 Pass	-0.335 Ok
150% L01-240910_2	83	2	1.122e+10	20629	168546177.42	1.5026815525	4e+0	0.6020599913	10.049851952	0.965 Pass	-1.578 Ok
150% L01-240910_2	84	2	6.707e+9	17865	246301164.67	3.6724316625	2e+0	0.3010299957	9.8265127424	3.955 Pass	-0.213 Ok
Ref.Std (L01-240910)	1	2	3.522e+10	18487.5	495102496.28	1.4057743302	1.6e+1	1.2041199827	10.546779507	1.363 Pass	-1.254 Ok
Ref.Std (L01-240910)	2	2	1.633e+10	18938.5	455484403.59	2.789532588	8e+0	0.903089987	10.212942071	1.692 Pass	-1.137 Ok
Ref.Std (L01-240910)	3	2	7.131e+9	19419.5	655734182.36	9.195593152	4e+0	0.6020599913	9.8531480751	2.625 Pass	-2.056 Ok
Ref.Std (L01-240910)	4	2	3.825e+9	19172.5	243220466.59	6.3579511491	2e+0	0.3010299957	9.5826829306	0.343 Pass	0.040 Ok
Ref.Std (L01-240910)	5	2	3.719e+10	17967.5	688805051.03	1.8522753561	1.6e+1	1.2041199827	10.570390775	0.259 Pass	-0.446 Ok
Ref.Std (L01-240910)	6	2	1.836e+10	19003.5	106995643.39	0.5826329245	8e+0	0.903089987	10.263971072	0.126 Pass	0.420 Ok
Ref.Std (L01-240910)	7	2	7.985e+9	19497.5	650271627.62	8.143657325	4e+0	0.6020599913	9.9022753147	0.107 Pass	-0.400 Ok
Ref.Std (L01-240910)	8	2	3.750e+9	19094	169086574.24	4.5092360866	2e+0	0.3010299957	9.5740061513	1.198 Pass	-0.240 Ok
Ref.Std (L01-240910)	9	2	4.143e+10	19174	588327175	1.4201622691	1.6e+1	1.2041199827	10.617280939	3.754 Pass	1.101 Ok
Ref.Std (L01-240910)	10	2	2.129e+10	19244.5	525609422.63	2.4691932446	8e+0	0.903089987	10.328108062	2.737 Pass	2.750 Ok
Ref.Std (L01-240910)	11	2	8.615e+9	20665.5	71422360.234	0.8290586492	4e+0	0.6020599913	9.9352489434	1.750 Pass	0.587 Ok
Ref.Std (L01-240910)	12	2	4.043e+9	20878	192367657.71	4.7575982235	2e+0	0.3010299957	9.6067442937	4.780 Pass	0.831 Ok

Within Group Jackknife z Outlier Limit (≥): 4

Between Group Externally Studentized Residuals Outlier Limit (≥): 4

Accepted Droplets: Invalid wells with < 10,000 accepted droplets excluded from all calculations

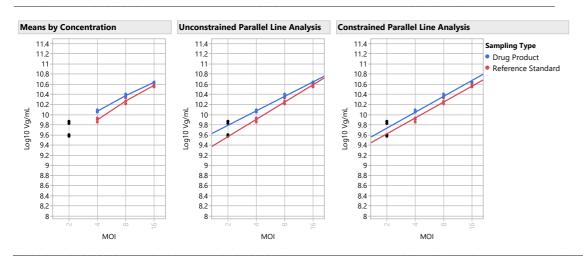
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.87e+9	1.52e+8
Ref.Std (L01-240910)	4e+0	3	7.91e+9	7.45e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.49e+9
Ref.Std (L01-240910)	1.6e+1	3	3.8e+10	3.17e+9
150% L01-240910_2	2e+0	3	7.12e+9	3.71e+8
150% L01-240910_2	4e+0	3	1.2e+10	6.56e+8
150% L01-240910_2	8e+0	3	2.4e+10	1.54e+9
150% L01-240910_2	1.6e+1	3	4.3e+10	4.88e+8

150% L01-240910_2 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.838	4.285	0.985	0.036	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.798	1.493	0.992	0.035	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.769	6.442	0.984	0.038	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.854	0.751	0.993	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.838	1.003	0.992	0.034	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.784	3.585	0.991	0.035	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.783	1.704	0.989	0.037	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.783	1.409	0.987	0.037	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.768	1.937	0.982	0.040	Parallel and Linear	

150% L01-240910_2 Graphs



150% L01-240910_2 Validity Report

			Validity		Overall
Validity Criteria	LSL	USL	Results	Assay Validity	Validity
Dose Response Test		0.05	0.000	Passed Validity Criteria	Assay is Valid
Reference Standard Curve Depth	2720000000		34071437681	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.251	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.838	Passed Validity Criteria	
Linearity Ratio		26.3	4.285	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.764	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		1	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Check OOS Validity
9.06	7.06	128.2	0	0	128.2	137.4	119.9	150	50	17.6	17.6 Bioassay Results are Reportable Assay is Valid and Within Lim
Inconstrained I	RI Constrained	Rela RI Infectivity D									
128.	.5 128	2	0.3								
Infectious	Infectious Partic	e Infectious P	article								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								
1.7	0	3	1.0								

Relative Infectivity All Samples

			Infectious			
Sample Name	EC50 Standard	EC50 Test	Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910_1	3.0549767736	5.2373556939	0.7	58.3	53.0	63.8
150% L01-240910_1	9.0383279923	7.0809556872	1.7	127.6	119.1	137.0
200% L01-240910	9.8546761029	6.4943788443	2.0	151.7	142.1	162.5
100% L01-240910	5.7055441357	5.6085798723	1.3	101.7	97.3	106.3
50% L01-240910_2	3.0767007171	5.2003758152	0.7	59.2	53.6	64.8
150% L01-240910_2	9.0593997682	7.0644856875	1.7	128.2	119.9	137.4

	Overall		
Sample Name	Validity	OOS	Reportable
50% L01-240910_1	Assay is Valid	Within Limits	Reportable
150% L01-240910_1	Assay is Valid	Within Limits	Reportable
200% L01-240910	Assay is Valid	oos	Reportable
100% L01-240910	Assay is Valid	Within Limits	Reportable
50% L01-240910_2	Assay is Valid	Within Limits	Reportable
150% L01-240910 2	Assay is Valid	Within Limits	Reportable

Astellas BQT Infectivity Bioassay Materials and Reference Standard Report

Assay Details

		Date Assay		Bioassay	Analyst				Instrument	Bioassay preparation	Bioassay review
Assay	Site:	Initiated:	Purpose:	Run Number	Name:	Signal	Method	Instrument ID	internal no.	(date_operator)	(date_reviewer)
Astellas BQT Infectivity			PLA	BQT Test Run 2		Vg/mL	KT430				

Notes Assay Range Check

Materials

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

Reference Details

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

Input Files - Configuration File and Plate File(s)

		Location of Sample										
System Suitability and Limits	Limit Colum	in 3 on Extracted DNA plate	Column 5	1	2	3	4	. 5	6	7	8	9
Lower Specification Limit (≥)	50.00	1	A	1	5	9	13	17	21	25	29	33
Upper Specification Limit (≤)	150.00	E	В	2	6	10	14	18	22	26	30	34
Reference Standard Curve Depth (≥)	2720000000.00		c	3	7	11	15	19			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					77	81
% Relative Potency Delta (Constrained – Unconstrained) (≤)	15.00		F	50	54	58	62			74	78	82
Within Group Jackknife z Outlier Limit (<)	4.00		G	51	55	59			71		79	83
Between Group Studentized Residuals Outlier Limit (<)	4.00		Н	52	56	60			72		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		4	3000	3000	3000					3000	3000
fixed position for ec50	10.00		В	3000	3000	3000			3000		3000	3000
ec50 reference concentration target	4.74		C	3000	3000	3000					3000	3000
fixed position for Test article for Infectious Particles Ratio Equation	10.00		D	3000	3000	3000					3000	3000
Infectious Particles Ratio Lower Specification Limit (≥)	0.30		E	3000	3000	3000					3000	3000
Infectious Particles Ratio Upper Specification Limit (≤)	1.00		F	3000	3000	3000					3000	3000
Failed Accepted Droplets Upper Limit (≤)	5.00		G	3000	3000	3000					3000	3000
railed Accepted Dioplets Opper Limit (5)	3.00		H	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)			Α	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 1 (25-36)		E	В	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
Sample 5 (73-84)			F	6000	6000	6000	6000	6000	6000	6000	6000	6000
			G	6000	6000	6000					6000	6000
Total Number of Plates	2.00		Н	6000	6000	6000			6000		6000	6000
MOI Concentrations												
16												
8												
4												
2												

ell description 4 2 4 4 8 4 4 8 4 16 5 2 5 8 5 16 6 2 6 6 8 6 16 6 16 6 16 6 16 6 16 6 16 6 1	ion i descrin		Sample description 3	Sample description 4	Target	Conc(copies/ µL)	Status	Experiment	SampleType	TargetTvne	Supermix	DyeName(s)	Accepted Droplets	Positives	Negative
44	50		REP1	description 4		188.0128937		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20847	3079	1776
14	50	F	REP1			341.3909912		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18688	4707	1398
15	50		REP1			747.9627075		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21166	9958	1120
55	50		REP1			1209.836426		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21600	13876	772
55 8 56 16 66 4 66 8 66 16 67 4 2 68 8 68 16 69 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 16 60 17 60 17 60 18 60	50 50		REP2 REP2		BDNF	155.0210876 303.0492554		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20801 19587	2568 4448	1823 1513
15	50		REP2		BDNF	617.7595215		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20656	8438	1221
166 2 6 4 6 6 6 6 6 6 6 6	50		REP2			1060.544067		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19011	11293	771
66 8 66 16 67 68 68 69 69 69 69 69 69 69 69 69 69 69 69 69	50		REP3		BDNF	142.6859741		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20321	2321	1800
166 16 16 16 17 18 18 18 18 18 18 18 18 18 18 18 18 18	50	F	REP3		BDNF	260.5404053	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19874	3948	1592
144 2 4 4 4 4 4 4 4 16 15 2 15 5 8 16 16 16 16 16 16 16	50	F	REP3		BDNF	550.8071899	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20339	7604	1273
14	50		REP3		BDNF	1030.301392		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20185	11777	840
4 8 8 4 16 15 15 16 16 16 17 18 16 16 17 18 18 18 18 18 18 18 18 18 18 18 18 18	50.2		REP1		BDNF	193.3096008		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21198	3212	1798
4 16 16 15 2 15 4 16 16 16 16 16 16 16 16 16 16 16 16 16	50.2 50.2		REP1 REP1		BDNF BDNF	347.8956299		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18090 18871	4631 8861	1345 1001
15	50.2		REP1		BDNF	745.9315186 1250.963989		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18818	12320	649
15	50.2		REP2		BDNF	166.5542145		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20802	2746	1805
55 8 56 16 66 26 16 67 4 8 68 16 17 2 67 17 18 68 18 18 18 18 68 18 18 18 18 68 18 18 18 18 68 18 18 18 18 68 18 18 18 18 68 18 18 18 68 18 18 18 68 18 18 18 68 18 18 18 68 18 68 1	50.2		REP2		BDNF	303.2552795		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20834	4734	1610
106	50.2		REP2		BDNF	603.5263062		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18592	7461	1113
166	50.2	F	REP2		BDNF	1067.584717	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20151	12019	813
66 8 66 16 67 16 68 16 69 17 69 18 6	50.2		REP3		BDNF	145.9048309		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19685	2296	1738
66 16 16 11 2 11 1 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1	50.2		REP3		BDNF	258.4417725		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18710	3690	1502
101 2 101 4 101 4 11 16 102 2 102 4 103 3 103 4 103 3 104 3 105 3 107 7 107 7 108 8 108 108 108 108 108 108 108 108 108 108	50.2		REP3		BDNF	553.6269531		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19685	7389	1229
11	50.2 100.2		REP3 REP1			1013.429749 254.2681732		DQ DQ	Unknown	Unknown Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19332 19566	11163 3803	816 1576
1 8 8 1 1 16 16 17 16 17 18 18 18 18 18 18 18 18 18 18 18 18 18	100.2		REP1		BDNF	520.8781128		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20440	7312	1312
1 16 16 12 2 2 12 14 14 15 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 16 17 17 17 17 18 17 16 17 17 17 18 17 16 17 17 16 17 17 17 17 17 17 17 17 17 17 17 17 17	100.2		REP1			1122.636719		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17938	11030	690
22 2 24 4 28 8 31 4 31 8 31 8 31 7 7 8 7 8 7 16 88 8 8 16 99 9 89 9 16 77 4 78 8 88 8 88 16 99 9 90 9 91 9 91 9 91 9 91 9 91 9 91 9	100.2		REP1			2445.713135		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18789	16439	235
2 8 8 9 16 9 16 9 16 9 16 9 16 9 16 9 16	100.2	F	REP2		BDNF	245.3873749	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19733	3715	1601
2 16 16 13 2 13 3 4 16 17 2 17 4 17 16 18 2 18 18 16 19 19 16 19 19 18 18 18 16 19 19 19 18 18 18 18 18 18 18 18 18 18 18 18 18	100.2	F	REP2		BDNF	571.9160156	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18530	7134	1139
33	100.2		REP2			1212.045776		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17763	11423	634
33	100.2		REP2			2533.742676		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18672	16505	216
3 8 8 16 17 2 17 4 18 18 18 18 18 18 18 18 18 18 18 18 18	100.2 100.2		REP3 REP3		BDNF BDNF	264.9316711 601.3974609		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19059 19327	3843	1521 1159
3 16 3 16 7 2 7 8 7 16 8 2 8 4 8 8 16 9 9 16 7 7 8 7 8 7 9 9 16 9 9 9 16 9 9 9 16 9 9 9 16 9 9 9 16 9 9 16 9 2 9 16 9	100.2		REP3			1394.745972		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20312	7735 14105	620
177 2 177 4 178 16 188 2 188 4 18 8 8 199 2 199 4 199 16 177 2 177 4 178 8 188 8 189 9 19 16 10 2 10 2 10 4 11 1 11 1 11 1 11 1 11 1 11 1 11 1	100.2		REP3			2743.370117		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17536	15833	170
77	150		REP1			478.6013184		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18586	6212	1237
17 16 18 2 18 4 19 9 2 19 16 17 4 7 8 7 16 18 2 17 4 18 2 18 4 18 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	150	F	REP1		BDNF	827.8909302	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20277	10245	1003
No. 188	150	F	REP1		BDNF	1704.607056	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18797	14383	441
88	150		REP1		BDNF	2916.231445		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19417	17789	162
8 8 8 8 8 16 99 4 99 8 99 16 97 2 97 16 98 8 8 8 8 8 16 99 2 99 4 99 8 9 16 99 2 99 4 99 16 99 1	150		REP2			476.2323914		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18718	6231	1248
16	150		REP2			732.4523926		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19860	9204	1065
99 2 99 4 99 8 916 97 2 98 8 98 8 98 8 8 16 99 9 99 16 00 2 00 4 00 8 00 16 11 2 11 4 16 16 11 1	150 150		REP2 REP2		BDNF BDNF	1514.258667 2902.670654		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20075 20008	14533 18311	554 169
99 4 99 8 99 8 16 17 2 17 4 7 8 7 16 18 4 8 8 8 8 16 99 2 99 16 00 2 00 4 00 16 11 2 11 4 11 16 22 2 24 4 28 8 21 1 21 1 4	150		REP3			412.9518127		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20164	5969	1419
99 8 99 16 77 2 77 4 78 8 77 16 88 8 8 16 99 2 99 4 99 16 00 2 00 4 00 16 11 2 11 4 11 16 22 2 24 4 28 8 16 11 2 11 4	150		REP3			757.7874146		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18030	8562	946
77 2 77 4 77 8 78 8 8 8 8 8 8 16 99 9 8 99 16 00 2 00 4 00 8 00 16 11 2 11 4 16 22 2 24 28 11 4	150		REP3			1500.861694		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18562	13379	518
77	150		REP3		BDNF	2792.914063	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20986	19032	195
7 8 8 7 16 9 16 9 16 9 16 9 16 9 16 9 16 9 16	150.2		REP1		BDNF	459.0006714		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21254	6866	1438
7 16 8 2 88 8 8 8 8 8 8 8 16 99 2 90 4 90 16 00 2 00 4 00 8 00 16 11 2 11 4 11 16 2 2 2 4 2 8 11 1 2 11 4	150.2		REP1			839.0861816		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19018	9698	932
08 2 88 4 88 8 8 16 99 2 99 4 99 8 90 16 00 2 00 4 00 8 00 16 11 2 11 8 11 16 22 2 24 4 28 8 11 2 11 4	150.2		REP1			1653.528564		DQ			ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19136	14443	469
88	150.2 150.2		REP1 REP2			2980.70459 480.2857666	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18369 20368	16911 6827	145 1354
8 8 8 8 16 99 4 99 8 99 16 00 2 00 4 8 00 16 11 2 1 4 8 11 16 2 2 2 2 4 2 8 11 2 11 4 1 4 1 16 11 2 11 4 1 16 11 1 1 1 1 1 1 1 1 1 1 1 1 1	150.2		REP2				OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20326	9536	1079
99 2 99 4 99 8 90 2 00 2 00 4 00 8 00 16 11 2 11 4 11 16 12 2 2 4 2 8 8 10 16 11 2 11 4	150.2		REP2			1541.547363		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18077	13201	487
99 4 99 8 99 16 00 2 00 4 00 8 00 16 11 2 11 8 11 16 22 2 2 4 2 8 2 16 11 2	150.2		REP2			2933.253662		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18260	16751	150
9 8 9 16 00 2 00 4 00 8 00 16 11 2 11 14 11 18 11 16 22 2 2 2 2 8 2 2 16 01 2 11 4	150.2		REP3			435.5065613		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20521	6349	1417
9 16 2 3 4 4 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	150.2		REP3			755.7026978		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20475	9704	1077
0 2 0 4 0 8 0 16 1 2 1 4 1 8 1 1 16 2 2 2 2 4 2 8 2 16 11 2 11 4	150.2		REP3		BDNF	1460.770996		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19965	14197	576
0 4 0 8 0 16 1 2 1 4 1 8 1 16 2 2 2 4 2 8 2 16 01 2	150.2		REP3		BDNF	2864.619873		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19805	18070	173
0 8 0 16 1 2 1 4 1 8 1 16 2 2 2 4 2 8 2 16 11 2 11 4	200		REP1 REP1		BDNF BDNF	668.9981079 933.1104736		DQ DQ	Unknown Unknown	Unknown Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20991 18821	9104 10306	1188 851
0 16 1 2 1 4 1 8 1 16 2 2 2 4 2 8 2 16 01 2	200		REP1			1946.592041		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18863	15257	360
1 2 1 4 1 8 1 16 2 2 2 4 2 8 2 16 01 2	200		REP1			3377.400146		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20228	19082	114
1 4 1 8 1 16 2 2 2 4 2 8 2 16 01 2	200		REP2			508.0126953		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19018	6669	1234
1 16 2 2 2 4 2 8 2 16 01 2	200		REP2			915.8394775		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18220	9855	836
2 2 2 4 2 8 2 16 01 2	200		REP2			1794.297119		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18581	14538	404
2 4 2 8 2 16 01 2	200		REP2			3741.216064		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19719	18899	82
2 8 2 16 01 2 11 4	200		REP3			512.7471924		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20576	7269	1330
2 16 01 2 11 4	200		REP3			872.8900757		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20761	10875	988
)1 2 1 4	200		REP3 REP3			1730.187866 3468.99585	OK OK	DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17465 20244	13452 19183	401 106
11 4	RS		REP3			243.5647125		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18930	3540	1539
	RS		REP1				OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18849	6592	1225
1 8	RS		REP1			1110.027832		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18574	11344	723
1 16	RS		REP1			2371.286133		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19566	16959	260
2 2	RS	F	REP2		BDNF	242.0147247	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18426	3426	1500
2 4	RS		REP2		BDNF	562.987915	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18377	6989	1138
2 8	RS		REP2			1219.233521		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18788	12123	666
12 16	RS		REP2			2511.601807		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18493	16306	218
3 4	RS RS		REP3 REP3			260.4902039 577.6918335		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20829 20399	4137 7915	1669 1248

10	11	12	Column 18	Column 19
37	41	45		
38	42	46		
39	43	47		
40	44	48		
10	11	12		
3000	3000	3000		
3000	3000	3000		
3000	3000	3000		
3000	3000	3000		
10	11	12		
6000	6000	6000		
6000	6000	6000		
6000	6000	6000		
6000	6000	6000		

BQT Infectivity_13Nov2024-14-11-21

/ell		Sample	Sample	Sample		Conc(copies/							Accepted		
				description 4		μL)			SampleType			DyeName(s)	Droplets	Positives	Negativ
	8	RS	REP3			1394.334961	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18015	12508	55
	16 NTC	RS	REP3		BDNF	2789.517822 No Call	OK CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (no dUTP)		19030 20448	17253 0	17 204
	NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20903	0	209
	NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20513	0	205
10	PC				BDNF	1426.414185	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		18476	12980	54
	PC PC				BDNF BDNF	1468.001953 1407.259521		DQ DQ	Unknown Unknown	Unknown Unknown	ddPCR Supermix for Probes (no dUTP)		19503 19193	13903 13390	56 58
12		Cample	Cample	Cample	DUNF		OK	DQ	UIKIOWII	OTIKITOWIT	ddPCR Supermix for Probes (no dUTP)	FAIVI	Accepted	15550	30
ell	Sample description 1	Sample description 2	Sample description 3	Sample description 4	Target	Conc(copies/ µL)	Status	Experiment	SampleType	TargetType	Supermix	DyeName(s)	Droplets	Positives	Negati
04	2	50	REP1		BDNF	101.0765839	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20637	1699	189
)4	4	50	REP1		BDNF	172.6802826	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21082	2878	18
	8	50	REP1		BDNF	371.6410217		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19759	5352	14
	16	50	REP1 REP2		BDNF	609.3699341	OK OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20103 20497	8127 1274	11 19
5 5		50	REP2		BDNF	75.4953537 151.4544525		DQ DO	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20497	2470	17
5		50	REP2		BDNF	302.6741638		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20199	4582	15
	16	50	REP2		BDNF	502.1239014		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20034	6960	13
)6		50	REP3		BDNF	72.69373322		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21095	1264	19
)6		50	REP3		BDNF	131.8019867		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20588	2182	18
16	16	50	REP3		BDNF	262.907135 479.9829102	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19849 20062	3975 6721	15 13
	2	50.2	REP1		BDNF	92.93914795		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		16667	1266	15
	4	50.2	REP1		BDNF	180.7172699		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21251	3026	18
	8	50.2	REP1		BDNF	391.0556641		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20474	5790	14
14	16	50.2	REP1		BDNF	598.2029419	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19667	7839	11
	2	50.2	REP2		BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		9646	632	9
)5		50.2	REP2		BDNF	162.7297058		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20274	2619	17
5 5	16	50.2 50.2	REP2 REP2		BDNF	306.3542786 514.3673706		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19236 21185	4410 7503	14
	2	50.2	REP3		BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		9811	474	13
	4	50.2	REP3		BDNF	125.6085739		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20629	2089	18
	8	50.2	REP3		BDNF	273.1700134	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20144	4174	1
	16	50.2	REP3		BDNF	483.3141479		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19297	6501	1
	2	100.2	REP1		BDNF	118.672821	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19166	1839	1
1		100.2	REP1		BDNF	269.9970093		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19696	4039	1
	16	100.2	REP1		BDNF	579.6843262 1228.412598		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19954 19617	7763 12712	1
2		100.2	REP2		BDNF	115.4709244		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20345	1902	1
2		100.2	REP2		BDNF	307.9039307		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19655	4526	1
2	8	100.2	REP2		BDNF	676.6117554	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19565	8557	1
2	16	100.2	REP2		BDNF	1200.607056	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19858	12701	
3		100.2	REP3		BDNF	124.5450668		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20557	2065	1
	8	100.2 100.2	REP3 REP3		BDNF	285.2644043 722.7332153		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19404 19704	4178 9044	1
	16	100.2	REP3		BDNF	1366.361816		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19704	13702	1
	2	150	REP1		BDNF	245.1828461		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20593	3874	1
7	4	150	REP1		BDNF	409.4639587		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20964	6162	1-
7	8	150	REP1		BDNF	846.2967529	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19718	10114	!
	16	150	REP1		BDNF	1427.182861		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19763	13888	
	2	150	REP2		BDNF	248.8900909	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20443	3898	16
8		150 150	REP2 REP2		BDNF	372.6425781 788.6940308		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20480 19767	5560 9656	1-
	16	150	REP2		BDNF	1428.711548		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20075	14115	
	2	150	REP3		BDNF	223.2905884		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21027	3635	1
9	4	150	REP3		BDNF	388.4827271	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20791	5847	1-
9		150	REP3		BDNF	757.6958618		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20822	9887	1
	16	150	REP3		BDNF	1401.099487		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18948	13189	
7		150.2	REP1		BDNF	251.1986389		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		10340	1988	
7	8	150.2 150.2	REP1		BDNF	409.4077759 874.9884644		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20422 19986	6002 10486	1
	16	150.2	REP1		BDNF	1442.65625		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20086	14193	
8		150.2	REP2		BDNF	255.1781769		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		10221	1993	
8	4	150.2	REP2		BDNF	387.7816467	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20926	5876	1
	8	150.2	REP2		BDNF	770.0169678		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20285	9743	1
	16	150.2	REP2		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20218	14131	
9 9	2	150.2	REP3		BDNF	229.3640289 369.9060059		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		15209	2694 5607	1.
	8	150.2 150.2	REP3 REP3		BDNF	779.7370605		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20783 20333	9853	1
	16	150.2	REP3		BDNF	1442.346191		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20033	14154	
)		200	REP1		BDNF	367.4277954		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20194	5417	1
	4	200	REP1		BDNF	496.4408569		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21589	7432	1
)		200	REP1		BDNF	1029.013184		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20796	12124	
	16	200	REP1		BDNF	1725.638428		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19756	15199	1
	4	200	REP2 REP2		BDNF	270.5541992 489.1371765		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20906 20393	4295 6937	1
I		200	REP2		BDNF	928.2289429		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21226	11583	'
	16	200	REP2		BDNF	1924.338501		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19762	15912	
2		200	REP3		BDNF	273.9222107		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19806	4114	1
	4	200	REP3		BDNF	429.7421265		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20706	6336	1
	16	200	REP3		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20370	10913	
	16	200 RS	REP3 REP1		BDNF	1716.783447 133.247879	OK OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19823 19415	15216 2079	1
	4	RS	REP1		BDNF	222.2429047		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19990	3441	1
	8	RS	REP1		BDNF	533.5421753		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19303	7038	1
	16	RS	REP1		BDNF	1162.303711		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17409	10927	
	2	RS	REP2		BDNF	128.9781799	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19762	2052	1
	4	RS	REP2		BDNF	250.839859	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20618	3959	1
	8	RS	REP2		BDNF	614.6605835		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19219	7821	1
	16	RS	REP2		BDNF	1223.330322		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17442	11276	
	2	RS	REP3		BDNF	139.3134003		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20927	2337	1
3		RS RS	REP3 REP3		BDNF	285.4790344 721.9449463		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20932 20474	4510 9390	1
	16	RS	REP3		BDNF	1367.024902		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19318	13274	'
	NTC		_		BDNF	0.670353651		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		21066	12	2
	NTC				BDNF	0.281836599		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20874	5	2
2	NTC				BDNF	0.38757062	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	21252	7	2
	PC				BDNF	1510.759277		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20958	15155	
	PC				BDNF	1492.258545	011	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FANA	20631	14828	