

Astellas BQT Assay Report

Test Article Report

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

Astellas KT430 Infectivity Files

First Data File Second Data File 18OCT2024_Plate01_KL-S3 18OCT2024_Plate01_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	1.797e+10	19656.5	359645621.8	2.0013493063	1.6e+1	1.2041199827	10.254551883	3.508 Pass	0.907 Ok
50% L01-240910_1	14	2	1.130e+10	20631	235053015.22	2.0794349286	8e+0	0.903089987	10.053220492	4.319 Pass	2.695 Ok
50% L01-240910_1	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	2.437 Pass	1.122 Ok
50% L01-240910_1	16	2	2.863e+9	20059	133535135.16	4.6637199832	2e+0	0.3010299957	9.4568630835	2.669 Pass	1.503 Ok
50% L01-240910_1	17	2	1.555e+10	19717.5	489935793.6	3.1497867731	1.6e+1	1.2041199827	10.191858014	0.233 Pass	-0.493 Ok
50% L01-240910_1	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	8e+0	0.903089987	9.9503544163	0.309 Pass	0.207 Ok
50% L01-240910_1	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	4e+0	0.6020599913	9.6479750835	0.071 Pass	-0.371 Ok
50% L01-240910_1	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	2e+0	0.3010299957	9.3904622856	0.115 Pass	-0.038 Ok
50% L01-240910_1	21	2	1.433e+10	18854	691328511.13	4.8227318281	1.6e+1	1.2041199827	10.156391355	1.421 Pass	-1.326 Ok
50% L01-240910_1	22	2	7.986e+9	19410.5	272371628.48	3.410460901	8e+0	0.903089987	9.9023487925	1.261 Pass	-0.779 Ok
50% L01-240910_1	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.863 Pass	-1.937 Ok
50% L01-240910_1	24	2	2.165e+9	19152	13728570.717	0.6341816577	2e+0	0.3010299957	9.3354116483	1.726 Pass	-1.302 Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175 Pass	-0.944 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-0.832 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-0.714 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.262 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.530 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.540 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.164 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.432 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.587 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	1.566 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.562 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.249 Ok

Within Group Jackknife z Outlier Limit (≥): 4

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

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

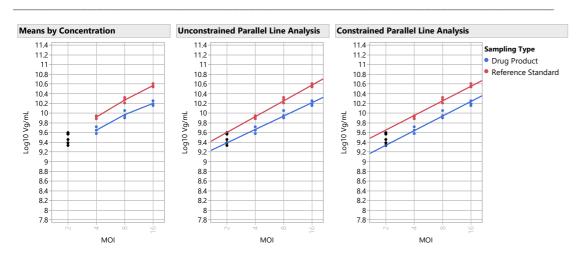
50% L01-240910_1 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
50% L01-240910_1	2e+0	3	2.5e+9	3.51e+8
50% L01-240910_1	4e+0	3	4.49e+9	7.28e+8
50% L01-240910_1	8e+0	3	9.4e+9	1.71e+9
50% L01-240910 1	1.6e+1	3	1.6e+10	1.85e+9

50% L01-240910_1 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.850	5.806	0.973	0.055	Parallel and Linear	Model 2, Low Standard and Test Doses Exclude
Model 3, High Standard and Test Doses Excluded	0.833	3.064	0.974	0.054	Parallel and Linear	
Model 1, All Doses	0.826	1.923	0.984	0.051	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.884	0.797	0.984	0.056	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.866	0.938	0.985	0.051	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.843	2.128	0.982	0.054	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.832	3.632	0.981	0.051	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.801	4.537	0.967	0.053	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.795	0.948	0.976	0.053	Parallel and Linear	

50% L01-240910_1 Graphs



50% L01-240910_1 Validity Report

			Validity		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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.233	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.850	Passed Validity Criteria	
Linearity Ratio		26.3	5.806	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %		
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range S	% of Tolerance Check	OOS Validity
5.57	11.48	48.6	0	0	48.6	53.6	43.5	150	50	10.1	10.1 Bioassay F	Results are Reportable	Assay is Valid and OOS
		Rela	ative										
Unconstrained	RI Constrained	RI Infectivity D	elta										
4	8.3 4	8.6	0.2										
Infectious	Infectious Parti	cle Infectious P	article										
Particle Ratio	Ratio Lower Lir	nit Ratio Uppe	r Limit										
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	4.333e+10	19449.5	1415326191.4	3.2663094426	1.6e+1	1.2041199827	10.636799217	2.752 Pass	0.227 Ok
150% L01-240910_1	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	13.343 Pass	1.472 Ok
150% L01-240910_1	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	7.469 Pass	-0.323 Ok
150% L01-240910_1	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.935 Pass	1.067 Ok
150% L01-240910_1	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.129 Pass	0.030 Ok
150% L01-240910_1	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.565 Pass	0.017 Ok
150% L01-240910_1	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.003 Pass	-1.490 Ok
150% L01-240910_1	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.511 Pass	0.884 Ok
150% L01-240910_1	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	1.685 Pass	-0.107 Ok
150% L01-240910_1	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.865 Pass	-0.146 Ok
150% L01-240910_1	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.463 Pass	-1.266 Ok
150% L01-240910_1	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	9.472 Pass	-0.232 Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175 Pass	-1.563 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-1.365 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-1.162 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.419 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.855 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.871 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.261 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.693 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.949 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	2.789 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.908 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.398 Ok

Within Group Jackknife z Outlier Limit (≥): 4

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

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

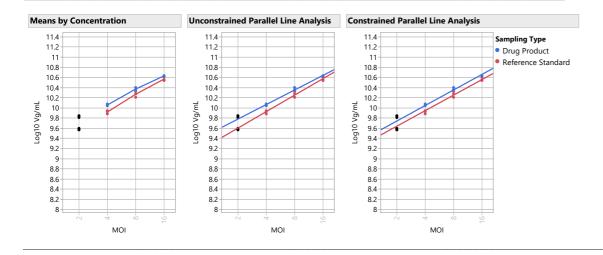
150% L01-240910_1 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
150% L01-240910_1	2e+0	3	6.82e+9	3.05e+8
150% L01-240910_1	4e+0	3	1.1e+10	4.78e+8
150% L01-240910_1	8e+0	3	2.4e+10	1.45e+9
150% L01-240910_1	1.6e+1	3	4.3e+10	4.72e+8

150% L01-240910_1 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.883	4.382	0.987	0.034	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.817	0.158	0.993	0.032	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.781	4.157	0.988	0.034	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.865	3.013	0.993	0.032	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.834	0.935	0.989	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.832	2.539	0.994	0.030	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.829	2.378	0.984	0.037	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.813	0.526	0.990	0.034	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.786	2.021	0.993	0.031	Parallel and Linear	

150% L01-240910_1 Graphs



150% L01-240910_1 Validity Report

			Validity		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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.113	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.883	Passed Validity Criteria	
Linearity Ratio		26.3	4.382	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	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 Check	OOS Validity
8.98	7.13	125.9	0	0	125.9	133.7	118.6	150	50	15.1	15.1	Bioassay Results are Reportable	Assay is Valid and Within Lim
		Rela	tive										
Unconstrained F	RI Constrained	RI Infectivity D	elta										
126.	.0 125	i.9	0.1										
Infectious	Infectious Partic	le Infectious P	article										
Particle Ratio	Ratio Lower Lim	nit Ratio Uppe	r Limit										
1.7	0	0.3	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	5.233e+10	18878	3273703267.4	6.2557892386	1.6e+1	1.2041199827	10.718757203	1.072 Pass	0.105	Ok
200% L01-240910	38	2	3.009e+10	18845.5	740491509.11	2.4607466152	8e+0	0.903089987	10.478453187	4.857 Pass	0.769	Ok
200% L01-240910	39	2	1.408e+10	20251	818244555.34	5.809870213	4e+0	0.6020599913	10.148716693	1.385 Pass	-0.719	Ok
200% L01-240910	40	2	1.053e+10	20253.5	125817445.28	1.1943429664	2e+0	0.3010299957	10.022611806	50.409 Pass	3.861	Ok
200% L01-240910	41	2	5.709e+10	18423.5	293737605.16	0.5145218197	1.6e+1	1.2041199827	10.756555753	6.187 Pass	1.114	Ok
200% L01-240910	42	2	2.693e+10	20411.5	185825277.73	0.6899810404	8e+0	0.903089987	10.430267633	0.348 Pass	-0.390	Ok
200% L01-240910	43	2	1.372e+10	20586.5	612192672.69	4.4622681989	4e+0	0.6020599913	10.137332458	0.249 Pass	-1.006	Ok
200% L01-240910	44	2	8.036e+9	19101.5	405078446.6	5.0406160629	2e+0	0.3010299957	9.9050555168	0.668 Pass	-0.139	Ok
200% L01-240910	45	2	5.331e+10	19763	1654979461.6	3.1046232995	1.6e+1	1.2041199827	10.726783696	0.417 Pass	0.313	Ok
200% L01-240910	46	2	2.585e+10	20229.5	2807020.1741	0.0108568237	8e+0	0.903089987	10.412542748	1.189 Pass	-0.825	Ok
200% L01-240910	47	2	1.296e+10	19746.5	194907960.04	1.5039726731	4e+0	0.6020599913	10.112589631	3.656 Pass	-1.681	Ok
200% L01-240910	48	2	7.965e+9	19460	83629922.415	1.0499404243	2e+0	0.3010299957	9.9011970368	0.747 Pass	-0.239	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175 Pass	-1.118	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-0.983	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-0.842	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.308	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.624	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.635	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.192	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.507	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.691	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	1.883	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.662	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.292	Ok

Within Group Jackknife z Outlier Limit (≥): 4

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

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

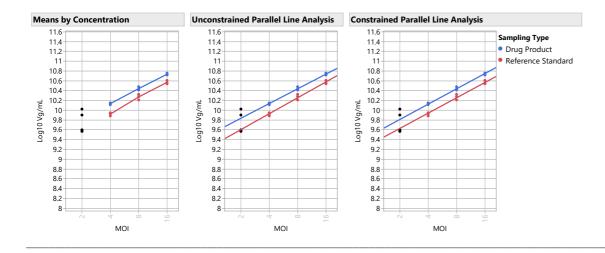
200% L01-240910 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
200% L01-240910	2e+0	3	8.85e+9	1.46e+9
200% L01-240910	4e+0	3	1.4e+10	5.74e+8
200% L01-240910	8e+0	3	2.8e+10	2.2e+9
200% L01-240910	1.6e+1	3	5.4e+10	2.51e+9

200% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.925	2.639	0.988	0.034	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.808	1.999	0.988	0.043	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.721	5.475	0.980	0.045	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.906	2.252	0.994	0.032	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.872	0.092	0.995	0.030	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.825	4.700	0.979	0.046	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.778	5.624	0.987	0.044	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.766	4.283	0.970	0.048	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.750	0.030	0.984	0.044	Parallel and Linear	

200% L01-240910 Graphs



200% L01-240910 Validity Report

			Validity		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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.092	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.925	Passed Validity Criteria	
Linearity Ratio		26.3	2.639	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	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 %		
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
9.80	6.53	150.1	0	0	150.1	158.9	142.0	150	50	17.0	17.0	Bioassay Results are Reportable	Assay is Valid and OOS
		Rela	ative										
Unconstrained RI	Constrained	RI Infectivity D	Pelta										
150.2	150	.1	0.1										
Infectious Ir	nfectious Partic	le Infectious P	article										
Particle Ratio F	Ratio Lower Lim	it Ratio Uppe	r Limit										
2.0	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	3.584e+10	18158.5	513669225.3	1.4330867287	1.6e+1	1.2041199827	10.554411073	1.078 Pass	-1.158 Ok
100% L01-240910	50	2	1.644e+10	18226.5	20350893.08	0.1237600509	8e+0	0.903089987	10.216002993	2.888 Pass	-1.099 Ok
100% L01-240910	51	2	7.608e+9	19725	256471113.81	3.3709586709	4e+0	0.6020599913	9.8812850299	2.601 Pass	-1.015 Ok
100% L01-240910	52	2	3.716e+9	17735.5	289685040.08	7.7950422058	2e+0	0.3010299957	9.570107597	0.049 Pass	-0.226 Ok
100% L01-240910	53	2	3.690e+10	19450	1728233892.7	4.6832199996	1.6e+1	1.2041199827	10.567057958	0.413 Pass	-0.720 Ok
100% L01-240910	54	2	1.888e+10	18863.5	258789690.42	1.3710651781	8e+0	0.903089987	10.27588887	0.151 Pass	0.732 Ok
100% L01-240910	55	2	8.320e+9	18746	56525600.254	0.6793927511	4e+0	0.6020599913	9.9201242741	0.102 Pass	0.171 Ok
100% L01-240910	56	2	3.593e+9	12685.5			2e+0	0.3010299957	9.5554301725	1.940 Pass	-0.709 Ok
100% L01-240910	57	2	4.094e+10	18744	1870104954.7	4.5675232426	1.6e+1	1.2041199827	10.612185215	6.103 Pass	0.761 Ok
100% L01-240910	58	2	2.045e+10	20813.5	573367617.57	2.8035032798	8e+0	0.903089987	10.310732093	1.624 Pass	1.927 Ok
100% L01-240910	59	2	8.852e+9	19702.5	137595150.53	1.5544659683	4e+0	0.6020599913	9.9470219092	1.763 Pass	0.999 Ok
100% L01-240910	60	2	3.858e+9	19416	144262472.04	3.7393203403	2e+0	0.3010299957	9.586360698	2.330 Pass	0.301 Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175 Pass	-1.430 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-1.252 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-1.068 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.387 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.787 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.802 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.241 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.639 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.874 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	2.502 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.836 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.367 Ok

Within Group Jackknife z Outlier Limit (≥): 4

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

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

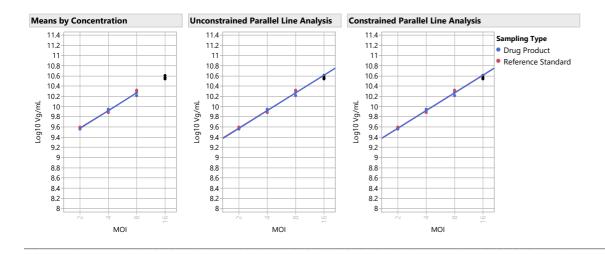
100% L01-240910 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
100% L01-240910	2e+0	3	3.72e+9	1.33e+8
100% L01-240910	4e+0	3	8.26e+9	6.24e+8
100% L01-240910	8e+0	3	1.9e+10	2.02e+9
100% L01-240910	1.6e+1	3	3.8e+10	2.69e+9

100% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 3, High Standard and Test Doses Excluded	1.011	0.658	0.989	0.034	Parallel and Linear	Model 3, High Standard and Test Doses Excluded
Model 1, All Doses	1.017	2.100	0.993	0.034	Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	1.018	3.551	0.983	0.039	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.998	2.586	0.991	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.978	1.465	0.992	0.034	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.038	2.544	0.991	0.037	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.960	1.593	0.990	0.036	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.051	1.789	0.992	0.035	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.073	2.574	0.990	0.037	Parallel and Linear	

100% L01-240910 Graphs



100% L01-240910 Validity Report

			Validity		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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.000	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	1.011	Passed Validity Criteria	
Linearity Ratio		26.3	0.658	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	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
3.98	4.02	99.0	0	0	99.0	103.8	94.4	150	50	9.3	9.3 Bioassay Results are Reportable Assay is Valid and Within
		Rela	itive								
Unconstrained	RI Constrained	RI Infectivity D	elta								
99	9.0 99	9.0	0.0								
	Infectious Parti										
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	1.807e+10	18507	67065519.327	0.371135865	1.6e+1	1.2041199827	10.256966367	3.436 Pass	0.879	Ok
50% L01-240910_2	62	2	1.102e+10	19613.5	190120617.32	1.7258574881	8e+0	0.903089987	10.042024285	2.575 Pass	2.469	Ok
50% L01-240910_2	63	2	5.159e+9	19546	199264473.2	3.8622715539	4e+0	0.6020599913	9.7125870699	2.102 Pass	1.105	Ok
50% L01-240910_2	64	2	2.761e+9	19386.5	142914635.79	5.1765314071	2e+0	0.3010299957	9.4410378536	2.485 Pass	1.391	Ok
50% L01-240910_2	65	2	1.586e+10	19528	426059891.54	2.6857978728	1.6e+1	1.2041199827	10.200397327	0.224 Pass	-0.441	Ok
50% L01-240910_2	66	2	9.172e+9	19640	381089296.09	4.1548290727	8e+0	0.903089987	9.9624735888	0.098 Pass	0.463	Ok
50% L01-240910_2	67	2	4.472e+9	20154	205743731.17	4.6005207441	4e+0	0.6020599913	9.6505196182	0.005 Pass	-0.246	Ok
50% L01-240910_2	68	2	2.420e+9	19772	116728454.59	4.8244854223	2e+0	0.3010299957	9.3837257373	0.080 Pass	0.007	Ok
50% L01-240910_2	69	2	1.472e+10	19282.5	392975759.31	2.6697350163	1.6e+1	1.2041199827	10.167897604	1.440 Pass	-1.233	Ok
50% L01-240910_2	70	2	7.776e+9	19753.5	311276312.65	4.0030128902	8e+0	0.903089987	9.8907590846	1.778 Pass	-1.095	Ok
50% L01-240910_2	71	2	3.776e+9	19467	89472972.022	2.3697464095	4e+0	0.6020599913	9.5769899896	2.141 Pass	-1.985	Ok
50% L01-240910_2	72	2	2.148e+9	19516	136835293.16	6.3705683843	2e+0	0.3010299957	9.332019945	1.832 Pass	-1.228	Ok
Ref.Std (L01-240910)	1	2	3.467e+10	18613.5	587669438.42	1.6949040913	1.6e+1	1.2041199827	10.539987978	1.175 Pass	-0.991	Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Pass	-0.872	Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Pass	-0.748	Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Pass	-0.274	Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Pass	-0.555	Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Pass	0.566	Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	0.171	Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Pass	-0.452	Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Pass	0.615	Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	1.649	Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	0.589	Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Pass	0.261	Ok

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

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

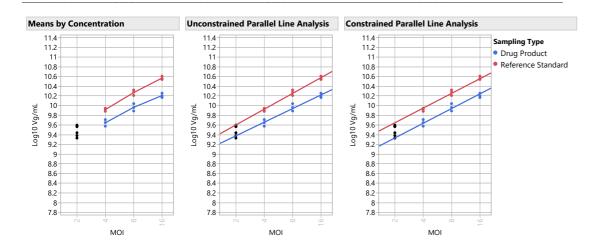
50% L01-240910_2 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
50% L01-240910_2	2e+0	3	2.44e+9	3.07e+8
50% L01-240910_2	4e+0	3	4.47e+9	6.92e+8
50% L01-240910_2	8e+0	3	9.32e+9	1.63e+9
50% L01-240910 2	1.6e+1	3	1.6e+10	1.7e+9

50% L01-240910_2 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.865	5.248	0.975	0.053	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.840	1.767	0.986	0.048	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.840	2.744	0.976	0.052	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.892	0.316	0.985	0.054	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.874	1.070	0.987	0.049	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.858	1.868	0.984	0.052	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.847	3.388	0.982	0.049	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.815	3.758	0.970	0.051	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.808	0.704	0.979	0.050	Parallel and Linear	

50% L01-240910_2 Graphs



50% L01-240910_2 Validity Report

			Validity		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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.185	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.865	Passed Validity Criteria	
Linearity Ratio		26.3	5.248	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	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 Chec	k OOS Validity
5.59	11.44	48.9	0	0	48.9	53.7	44.1	150	50	9.7	9.7 Bioassay Results are Reportab	e Assay is Valid and O
		Rela	ative									
Unconstrained	RI Constrained F	RI Infectivity D	elta									
48	3.7 48.	9	0.2									
Infectious	Infectious Particl	e Infectious P	article									
Particle Ratio	Ratio Lower Lim	it Ratio Upper	r Limit									
0.7	0.	2	1.0									

150% L01-240910_2 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOL	Log10 Vg/mL	lackknife z	Outlier Within Group	Externally Outlier Studentized Residuals Between Grou
150% L01-240910 2	73	2	4.346e+10	20242.5		0.3780442877	1.6e+1	1.2041199827		0.720		0.066 Ok
150% L01-240910_2	74	2	2.554e+10			0.6764341882	8e+0	0.903089987	10.407207743	18.374		1.453 Ok
150% L01-240910_2	75	2	1.238e+10		532896929.11	4.304486152			10.407207743	8.443		-0.076 Ok
150% L01-240910_2	76	2	6.956e+9		95618993.904			0.3010299957		0.242		0.652 Ok
150% L01-240910_2	77	2	4.315e+10			1.3147474299	1.6e+1	1.2041199827		161.86		-0.044 Ok
150% L01-240910_2	78	2	2.312e+10			6.1439823415	8e+0	0.903089987		0.602		-0.044 Ok -0.054 Ok
150% L01-240910_2	70	2	1.135e+10		621413242.94			0.6020599913		0.802		-0.034 Ok -1.398 Ok
	80	2	7.162e+9			4.1154812625			9.8550447888	1.400		1.138 Ok
150% L01-240910_2 150% L01-240910_2	81	2	4.346e+10	19824.5 19857	175599334.22		1.6e+1	1.2041199827	10.638044549	0.695		0.065 Ok
		2										
150% L01-240910_2	82	_	2.293e+10			3.0304863146	8e+0	0.903089987	10.36033518	0.820		-0.175 Ok
150% L01-240910_2	83	2	1.151e+10		194500111.81	1.690454602			10.060916343	0.489		-1.170 Ok
150% L01-240910_2	84	2	6.534e+9						9.8152111738	3.594		-0.330 Ok
Ref.Std (L01-240910)	1	2	3.467e+10		587669438.42				10.539987978	1.175		-1.608 Ok
Ref.Std (L01-240910)	2	2	1.622e+10		463230896.97		8e+0			2.499		-1.403 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3				9.8840460225	3.606		-1.194 Ok
Ref.Std (L01-240910)	4	2	3.761e+9			2.5108464532			9.5752976845	0.366		-0.430 Ok
Ref.Std (L01-240910)	5	2	3.614e+10			6.1939800559		1.2041199827	10.55804215	0.356		-0.877 Ok
Ref.Std (L01-240910)	6	2	1.892e+10		282808622.15		8e+0	0.903089987		0.083		0.894 Ok
Ref.Std (L01-240910)	7	2	8.450e+9		81272179.859	0.96178488		0.6020599913		0.243		0.268 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157	Pass	-0.711 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985	Pass	0.974 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823	Pass	2.890 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397	Pass	0.932 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157	Pass	0.408 Ok

Within Group Jackknife z Outlier Limit (≥): 4

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

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

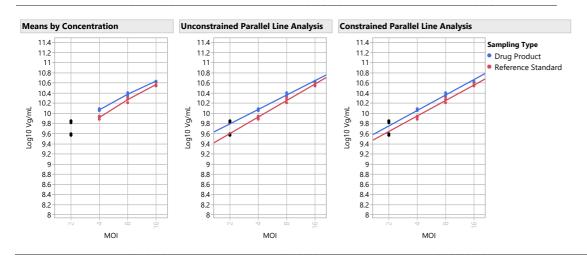
150% L01-240910_2 Test Sample & Reference Standard Summary Statistics

				Std
Group	MOI	N Rows	Mean(Vg/mL)	Dev(Vg/mL)
Ref.Std (L01-240910)	2e+0	3	3.81e+9	1.42e+8
Ref.Std (L01-240910)	4e+0	3	8.31e+9	6.02e+8
Ref.Std (L01-240910)	8e+0	3	1.9e+10	2.42e+9
Ref.Std (L01-240910)	1.6e+1	3	3.7e+10	3.08e+9
150% L01-240910_2	2e+0	3	6.88e+9	3.2e+8
150% L01-240910_2	4e+0	3	1.2e+10	5.57e+8
150% L01-240910_2	8e+0	3	2.4e+10	1.46e+9
150% L01-240910_2	1.6e+1	3	4.3e+10	1.75e+8

150% L01-240910_2 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.873	4.104	0.987	0.033	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.816	0.369	0.993	0.031	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.783	3.583	0.988	0.033	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.856	2.901	0.993	0.031	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.833	0.569	0.990	0.033	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.831	1.490	0.985	0.036	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.823	2.116	0.994	0.030	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.814	0.776	0.991	0.034	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.785	1.670	0.994	0.030	Parallel and Linear	

150% L01-240910_2 Graphs



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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.145	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.873	Passed Validity Criteria	
Linearity Ratio		26.3	4.104	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	4.740	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

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

		RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %
EC50 Ref	EC50 Test	Uncorrected	Reference CF	Stability CF	Reportable Result	Upper 95%	Lower 95%	Spec Limit	Spec Limit	CI Range	of Tolerance CI Range % of Tolerance Check OOS Validity
9.05	7.07	128.1	0	0	128.1	136.2	120.6	150	50	15.7	15.7 Bioassay Results are Reportable Assay is Valid and Within Lin
		Rela	itive								
nconstrained I	RI Constrained F	RI Infectivity D	elta								
neonstranica i	in constrained i	a miceavity D	Cita								
128			0.1								
128		.1	0.1								
128.	.2 128.	le Infectious P	0.1 article								

Relative Infectivity All Samples

			Infectious			
Sample Name	EC50 Standard	EC50 Test	Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910_1	5.5745946199	11.480655431	0.7	48.6	43.5	53.6
150% L01-240910_1	8.9756559112	7.1303981161	1.7	125.9	118.6	133.7
200% L01-240910	9.8001683441	6.5305000642	2.0	150.1	142.0	158.9
100% L01-240910	3.9797170781	4.0203862953	1.3	99.0	94.4	103.8
50% L01-240910_2	5.5944150952	11.439980572	0.7	48.9	44.1	53.7
150% L01-240910_2	9.0531686713	7.0693480177	1.7	128.1	120.6	136.2

	Overall		
Sample Name	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 KT430 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 KT430 Infectivity			PLA			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)

System Suitability and Limits	Limit Colu	Location of Sample mn 3 on Extracted DNA plate	Column F	1	2	3	4	5	6	7	8	9
Lower Specification Limit (≥)	50.00	IIII 3 OII EXTIACTED DIVA PIATE	A	1	5	9	13	17	21	25	29	33
1 11	150.00		В	2	6	10	14	18	22	26	30	34
Upper Specification Limit (≤)	2720000000.00		С	3	7	11	15	19	23	27	31	35
Reference Standard Curve Depth (≥)			D			12	16	20	24	28	32	36
Unconstrained EC50 Standard Lower Limit (≥)	0.04			4	8							
Unconstrained EC50 Standard Upper Limit (≤)	61.80		E	49	53	57	61	65	69	73	77	81
% Relative Potency Delta (Constrained – Unconstrained) (≤)	15.00			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		Н	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		В	3000	3000	3000	3000	3000	3000	3000	3000	3000
fixed position for Test article for Infectious Particles Ratio Equation	10.00		С	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Lower Specification Limit (≥)	0.30		D	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Upper Specification Limit (≤)	1.00		E	3000	3000	3000	3000	3000	3000	3000	3000	3000
Failed Accepted Droplets Upper Limit (≤)	5.00		F	3000	3000	3000	3000	3000	3000	3000	3000	3000
			G	3000	3000	3000	3000	3000	3000	3000	3000	3000
Report File Name			Н	3000	3000	3000	3000	3000	3000	3000	3000	3000
Ref.Std (1-12)												
Control (13-24)		ddPCR Map - Plate 2		1	2	3	4	5	6	7	8	9
Sample 1 (25-36)			A	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 2 (37-48)			В	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 3 (49-60)			С	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 4 (61-72)			D	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 5 (73-84)			E	6000	6000	6000	6000	6000	6000	6000	6000	6000
			F	6000	6000	6000	6000	6000	6000	6000	6000	6000
Total Number of Plates	2.00		G	6000	6000	6000	6000	6000	6000	6000	6000	6000
			Н	6000	6000	6000	6000	6000	6000	6000	6000	6000
MOI Concentrations												
16												
8												
4												
2												
_					•							•
												•
				•		•					•	
									•			
						-						

	Sample	Sample	Sample	Sample		Conc(copies/							Accepted		
				description 4					SampleType			DyeName(s)	Droplets	Positives	Negative
	4	50 50	REP1		BDNF BDNF	184.5901031 334.3489075		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20749 21194	3013 5243	1773 1595
304		50	REP1		BDNF	742.4992676		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20895	9779	1111
	16	50	REP1		BDNF	1214.964355		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19835	12773	706
H04	2	50.2	REP1		BDNF	177.3175049		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18962	2653	1630
304		50.2	REP1		BDNF	334.5569763		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20116	4979	1513
	8	50.2	REP1		BDNF	743.3629761		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19571	9167	1040
	16	50.2	REP1		BDNF	1207.850952		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18099	11616	648
	4	100.2 100.2	REP1		BDNF BDNF	234.0956421 495.1268005		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18400 21015	3320 7219	1508 1379
	8	100.2	REP1			1095.296021		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19345	11720	762
	16	100.2	REP1		BDNF	2365.355713		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18004	15593	241
007	2	150	REP1		BDNF	467.249176	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20209	6624	1358
207		150	REP1		BDNF	781.6210327	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19118	9280	983
	8	150	REP1		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19667	14848	481
407		150	REP1		BDNF	2955.455811		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19804	18198	160
H07	2	150.2 150.2	REP1		BDNF BDNF	459.212616 800.2147217	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19640 20921	6347 10324	1329 1059
	8	150.2	REP1		BDNF	1710.758911		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19375	14849	452
	16	150.2	REP1		BDNF	2889.464111		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20729	18951	177
010		200	REP1		BDNF	708.2276611		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20076	9080	1099
210	4	200	REP1		BDNF	977.4855957	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20357	11488	886
310	8	200	REP1		BDNF	2041.050293	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18286	15060	322
410		200	REP1		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18450	17616	83
	2	RS	REP1		BDNF	246.2785187		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20320	3838	1648
201		RS	REP1		BDNF	499.5166321		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20800	7196	1360
301 401	16	RS RS	REP1		BDNF BDNF	1059.626343		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19198 20296	11398	780 291
201		50	REP1 REP2		BDNF	2283.812012 163.9904785		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20296	17383 2707	1809
	4	50	REP2		BDNF	295.3388062		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21184	4703	1648
305		50	REP2		BDNF	601.5122681		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19579	7837	1174
405	16	50	REP2		BDNF	1060.067139	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19902	11819	808
H05	2	50.2	REP2		BDNF	166.8026733	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19472	2574	1689
G05		50.2	REP2		BDNF	307.8444214		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19376	4461	1491
	8	50.2	REP2		BDNF	629.4448242		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19293	7994	1129
	16	50.2	REP2		BDNF	1077.647217		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18922	11351	757
H02		100.2 100.2	REP2 REP2		BDNF BDNF	239.5184174 557.3325195		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19435 19344	3580 7299	1585 1204
	8	100.2	REP2		BDNF	1246.139404		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18666	12194	647
E02		100.2	REP2		BDNF	2541.648682		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19275	17053	222
	2	150	REP2			467.5604553		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19576	6420	1315
208	4	150	REP2		BDNF	697.5460205	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20687	9253	1143
308	8	150	REP2		BDNF	1459.571045	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19260	13690	557
804		150	REP2		BDNF	2833.755615		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18903	17203	170
408		150.2	REP2		BDNF	463.5831604		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19025	6196	1282
308		150.2	REP2		BDNF	727.1038818		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21256	9799	1145
	16	150.2 150.2	REP2 REP2		BDNF BDNF	1474.371826 2850.130615		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20971 20645	14982 18814	598 183
D11		200	REP2		BDNF	516.6569824		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18381	6533	1184
211		200	REP2		BDNF	885.7620239		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20155	10662	949
311	8	200	REP2		BDNF	1786.702759	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20119	15713	440
411	16	200	REP2		BDNF	3792.115479	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17904	17191	71
002	2	RS	REP2		BDNF	246.8267822	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19862	3759	1610
202		RS	REP2		BDNF	567.1739502		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18334	7013	1132
	8	RS	REP2		BDNF	1274.391724		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19099	12634	646
402		RS 50	REP2		BDNF	2515.170166		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19321	17043	227
206		50	REP3		BDNF BDNF	143.6707916 253.6337738		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18572 18692	2135 3625	1643 1506
306		50	REP3		BDNF	545.2636108		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19234	7134	1210
406		50	REP3		BDNF	988.2422485		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18765	10664	810
H06		50.2	REP3			136.7447968		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18454	2025	1642
306		50.2	REP3		BDNF	247.4911957		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18296	3471	1482
-06		50.2	REP3		BDNF	533.0770874		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19094	6957	1213
	16	50.2	REP3		BDNF	999.8353271		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18628	10665	796
103		100.2	REP3		BDNF	250.3984985		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19743	3785	1595
G03 F03	8	100.2 100.2	REP3 REP3		BDNF BDNF	583.6205444 1390.483887		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19272 21070	7537 14608	1173 646
	16	100.2	REP3		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18713	17007	170
009		150	REP3		BDNF	434.8545532		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18540	5729	1281
	4	150	REP3		BDNF	744.3925781		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20618	9667	1095
	8	150	REP3			1498.908447		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19636	14144	549
409	16	150	REP3		BDNF	2870.013184	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	16903	15429	147
109		150.2	REP3		BDNF	428.2732849		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18592	5673	1291
309		150.2	REP3		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19237	9136	1010
	8	150.2	REP3		BDNF	1495.671997		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21265	15301	596
	16	150.2	REP3		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19295	17639	165
D12 C12		200	REP3 REP3		BDNF BDNF	527.0714111 854.7813721		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18582 19991	6710 10324	1187 966
312		200	REP3		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20634	15867	476
412		200	REP3		BDNF	3631.812012		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19699	18800	89
003		RS	REP3		BDNF	270.7347107		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21059	4329	1673
203		RS	REP3		BDNF	583.8165283		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20742	8114	1262
303		RS	REP3			1423.709229		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21479	15075	640

10 11 12 Column 18 Column 19 37 41 45 38 42 46 33 43 47 40 44 48					
38	10	11	12	Column 18	Column 19
39	37	41	45		
40	38	42			
	39	43	47		
10 11 12 3000 3000 3000 3000 3000 3000 3	40	44	48		
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BQT Infectivity 11Nov2024-14-12-23

Mall	Sample	Sample	Sample	Sample	Target	Conc(copies/	Ctatus	Evporiment	CamplaTupa	TargetTupe	Cuparmiy	DuoNamo(s)	Accepted	Positivos	Nogativo
Weii 403		description 2	REP3	description 4		2840.367188		DQ	SampleType Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	DyeName(s)	Droplets 19714	Positives 17951	Negatives 1763
	NTC	N3	NEFS			No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		19126	0	19126
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20944	0	20944
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		18778	0	18778
	PC PC					1280.408691 1218.153198			Unknown	Unknown	ddPCR Supermix for Probes (no dUTP) ddPCR Supermix for Probes (no dUTP)		18318 19227	12149 12400	6169 6827
F12							OK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		17535	11226	6309
	Sample	Sample	Sample	Sample		Conc(copies/							Accepted		
		description 2		description 4					SampleType			DyeName(s)	Droplets	Positives	Negatives
001 001		RS RS	REP1			127.5908127 260.693512	OK OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19041	1957 3738	17084 15069
	8	RS	REP1			551.6500854			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18807 19425	7271	12154
401	16	RS	REP1			1169.609009		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		16931	10666	6265
010		200	REP1			348.1827393			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20431	5234	15197
C10 B10		200	REP1			450.1703796 985.618042	OK		Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20145 19405	6405 11009	13740 8396
A10		200	REP1			1667.197388			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19306	14626	4680
H07		150.2	REP1			234.1138306	OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20427	3686	16741
307 -07	8	150.2 150.2	REP1			425.228363 847.2356567	OK	-	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19787 20344	6002 10443	13785 9901
F07 E07		150.2	REP1			1452.476807			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19756	14008	5748
D07		150	REP1			235.5180359			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20813	3776	17037
C07		150	REP1			408.2714844			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20299	5952	14347
B07 A07		150 150	REP1			857.5824585 1411.008789			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19821 19095	10259 13340	9562 5755
	2	100.2	REP1				OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17071	1795	15276
G01	4	100.2	REP1		BDNF	259.6535645	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18435	3651	14784
01		100.2	REP1			548.6073608			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17108	6376	10732
E01 H04	16	100.2 50.2	REP1			1206.892456 95.39581299			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18313 19811	11748 1543	6565 18268
G04		50.2	REP1			176.6719055			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18976	2646	16330
F04	8	50.2	REP1		BDNF	362.7191162	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19656	5215	14441
	16	50.2	REP1			600.7639771 98.58995819			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18915	7564	11351
D04 C04	4	50	REP1			182.5280457			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19369 20047	1557 2881	17812 17166
304		50	REP1			382.3301392			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20367	5651	14716
A04		50	REP1			590.5283203			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19478	7687	11791
D02 C02		RS RS	REP2 REP2			122.939415 279.7557678	OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		17909 19392	1777 4104	16132 15288
302		RS	REP2			623.8641357			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18906	7781	11125
402	16	RS	REP2		BDNF	1152.047852	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19079	11913	7166
D11		200	REP2			277.4240723			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19822	4164	15658
211 311		200	REP2 REP2			471.7400513 902.1112671			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		21018 20704	6943 11087	14075 9617
A11		200	REP2			1909.904663			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18943	15207	3736
80H		150.2	REP2			245.6865997			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20624	3887	16737
G08 F08		150.2 150.2	REP2 REP2			392.8456421 804.1484375			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		21121 19757	5996 9783	15125 9974
	16	150.2	REP2			1451.810669			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20370	14440	5930
D08		150	REP2		BDNF	230.1463165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20008	3555	16453
208		150	REP2			390.6889954		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20745	5862	14883
808 A08		150 150	REP2 REP2			797.5358887 1434.838257		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19989 19225	9841 13547	10148 5678
H02		100.2	REP2			No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		5936	0	5936
G02		100.2	REP2			276.0016174			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18148	3795	14353
F02 E02		100.2	REP2 REP2			635.269165 1189.354614	OK		Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19061 19625	7953 12484	11108 7141
H05		50.2	REP2			77.89870453			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20072	1286	18786
3 05		50.2	REP2			144.2233582			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20932	2415	18517
F05 E05	16	50.2	REP2 REP2			296.7576904 518.7389526			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19987 20134	4456 7179	15531 12955
005		50.2	REP2				OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20688	1390	19298
C05		50	REP2				OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19889	2362	17527
305		50	REP2			293.8962402		-	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20330	4494	15836
A05 D03		50 RS	REP2 REP3			506.9377747 129.1370239			Unknown Unknown	Unknown Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19533 19739	6838 2052	12695 17687
203		RS	REP3			297.2339478			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19390	4329	15061
B03	8	RS	REP3			690.9505005			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19213	8534	10679
103		RS	REP3			1286.221191			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18170	12081	6089
D12 C12		200	REP3			267.4780579 436.5787354			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20338 19502	4136 6046	16202 13456
312		200	REP3			861.7636108			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19825	10295	9530
A12		200	REP3			1737.889526			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19827	15301	4526
H09		150.2	REP3 REP3			221.4954987 388.1106567			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20634 20758	3541 5833	17093 14925
309 -09	8	150.2 150.2	REP3			780.5882568			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19441	9428	10013
	16	150.2	REP3			1452.654907			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20419	14479	5940
D09		150	REP3			214.1714325			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21023	3499	17524
C09 B09	8	150	REP3 REP3			377.5775146 760.2349854			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20380 20201	5595 9615	14785 10586
A09		150	REP3			1391.104004			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19861	13773	6088
H03		100.2	REP3			131.9998474			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19089	2026	17063
G03		100.2	REP3			298.2965698			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20133	4509	15624
03		100.2	REP3 REP3			668.2131348 1320.705322			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20557 18775	8908 12665	11649 6110
106		50.2	REP3				OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20578	1268	19310
306		50.2	REP3			127.9633942			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20638	2127	18511
-06 -06		50.2 50.2	REP3			251.8648376 481.3926086			Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20413 19937	3934 6695	16479 13242
006		50.2	REP3			72.48256683			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19732	1179	18553
206	4	50	REP3		BDNF	126.0057755	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20528	2085	18443
306		50	REP3			259.7920837			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19587	3881	15706
406 E10	16 NTC	50	REP3			461.5315857 No Call	OK		Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (no dUTP)		18943 20488	6147 0	12796 20488
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		21273	0	21273
E12	NTC				BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20600	0	20600
	PC					1441.094727			Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20444	14438	6006
F11 F12	PC PC				BDNF	1468.046875 1419.062134			Unknown Unknown	Unknown	ddPCR Supermix for Probes (no dUTP) ddPCR Supermix for Probes (no dUTP)		20465 20950	14589 14679	5876 6271
	. •				22141	5.002 154	5.1	-4	21111104411	2VVII	(ilo do ir)		20330	1-013	0211