

Astellas BTQ Assay Report

Test Article Report

Approver Signature/Date

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

Astellas KT430 Infectivity Files

First Data File Second Data File

50% L01-240910 & Reference Standard Data

				Accepted	Std						Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Outlier Within Group	Studentized Residuals Between Group
50% L01-240910	13	2	1.797e+10	19656.5	359645621.8	2.0013493063	1.6e+1	1.2041199827	10.254551883	1.552 Ok	0.765 Ok
50% L01-240910	14	2	1.130e+10	20631	235053015.22	2.0794349286	8e+0	0.903089987	10.053220492	1.811 Ok	2.381 Ok
50% L01-240910	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	1.597 Ok	1.099 Ok
50% L01-240910	16	2	2.863e+9	20059	133535135.16	4.6637199832	2e+0	0.3010299957	9.4568630835	1.884 Ok	1.434 Ok
50% L01-240910	17	2	1.555e+10	19717.5	489935793.6	3.1497867731	1.6e+1	1.2041199827	10.191858014	0.362 Ok	-0.503 Ok
50% L01-240910	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	8e+0	0.903089987	9.9503544163	0.322 Ok	0.191 Ok
50% L01-240910	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	4e+0	0.6020599913	9.6479750835	0.060 Ok	-0.314 Ok
50% L01-240910	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	2e+0	0.3010299957	9.3904622856	0.042 Ok	0.053 Ok
50% L01-240910	21	2	1.433e+10	18854	691328511.13	4.8227318281	1.6e+1	1.2041199827	10.156391355	1.395 Ok	-1.245 Ok
50% L01-240910	22	2	7.986e+9	19410.5	272371628.48	3.410460901	8e+0	0.903089987	9.9023487925	1.109 Ok	-0.746 Ok
50% L01-240910	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.376 Ok	-1.732 Ok
50% L01-240910	24	2	2.165e+9	19152	13728570.717	0.6341816577	2e+0	0.3010299957	9.3354116483	1.275 Ok	-1.073 Ok
50% L01-240910	61	2	1.807e+10	18507	67065519.327	0.371135865	1.6e+1	1.2041199827	10.256966367	1.682 Ok	0.816 Ok
50% L01-240910	62	2	1.102e+10	19613.5	190120617.32	1.7258574881	8e+0	0.903089987	10.042024285	1.415 Ok	2.108 Ok
50% L01-240910	63	2	5.159e+9	19546	199264473.2	3.8622715539	4e+0	0.6020599913	9.7125870699	1.342 Ok	0.952 Ok
50% L01-240910	64	2	2.761e+9	19386.5	142914635.79	5.1765314071	2e+0	0.3010299957	9.4410378536	1.207 Ok	1.090 Ok
50% L01-240910	65	2	1.586e+10	19528	426059891.54	2.6857978728	1.6e+1	1.2041199827	10.200397327	0.150 Ok	-0.330 Ok
50% L01-240910	66	2	9.172e+9	19640	381089296.09	4.1548290727	8e+0	0.903089987	9.9624735888	0.137 Ok	0.427 Ok
50% L01-240910	67	2	4.472e+9	20154	205743731.17	4.6005207441	4e+0	0.6020599913	9.6505196182	0.016 Ok	-0.264 Ok
50% L01-240910	68	2	2.420e+9	19772	116728454.59	4.8244854223	2e+0	0.3010299957	9.3837257373	0.180 Ok	-0.082 Ok
50% L01-240910	69	2	1.472e+10	19282.5	392975759.31	2.6697350163	1.6e+1	1.2041199827	10.167897604	1.011 Ok	-0.999 Ok
50% L01-240910	70	2	7.776e+9	19753.5	311276312.65	4.0030128902	8e+0	0.903089987	9.8907590846	1.336 Ok	-0.978 Ok
50% L01-240910	71	2	3.776e+9	19467	89472972.022	2.3697464095	4e+0	0.6020599913	9.5769899896	1.423 Ok	-1.775 Ok
50% L01-240910	72	2	2.148e+9	19516	136835293.16	6.3705683843	2e+0	0.3010299957	9.332019945	1.372 Ok	-1.145 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 Ok	-0.776 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Ok	-0.726 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Ok	-0.674 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Ok	-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 Ok	-0.361 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Ok	0.630 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Ok	0.184 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Ok	-0.475 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Outlier	0.795 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Ok	1.626 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Ok	0.574 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Within Analytical Error	0.195 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 calcular

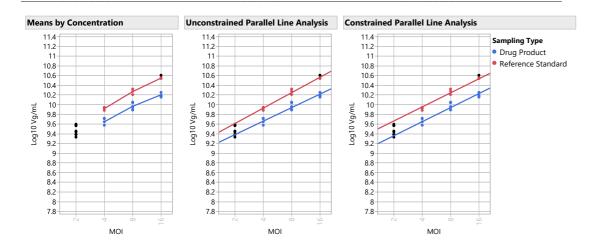
50% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+9
50% L01-240910	2e+0	6	2.47e+9	2.96e+8
50% L01-240910	4e+0	6	4.48e+9	6.35e+8
50% L01-240910	8e+0	6	9.36e+9	1.49e+9
50% L01-240910	1.6e+1	6	1.6e+10	1.6e+9

50% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.876	6.535	0.963	0.056	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.842	1.960	0.980	0.052	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.837	3.546	0.968	0.055	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.908	2.402	0.978	0.057	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.879	0.519	0.978	0.054	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.870	1.812	0.979	0.054	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.849	5.354	0.971	0.053	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.808	6.190	0.961	0.054	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.802	1.006	0.975	0.053	Parallel and Linear	

50% L01-240910 Graphs



50% 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		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.521	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.876	Passed Validity Criteria	
Linearity Ratio		26.3	6.535	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

		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
4.70	9.75	48.3	0	0	48.3	51.6	44.9	150	50	6.7	6.7 Bioassay Results are Reportable Assay is Valid and
		Rela	ative								
Unconstrained I	RI Constrained F	RI Infectivity D	Delta								
49.	.8 48.	.3	1.5								
Infectious	Infectious Particl	le Infectious P	Particle								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								
0.2	0	3	1.0								

150% L01-240910 & Reference Standard Data

				Accepted	Std						Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Outlier Within Group	Studentized Residuals Between Group
150% L01-240910	25	2	4.333e+10	19449.5	1415326191.4	3.2663094426	1.6e+1	1.2041199827	10.636799217	0.616 Ok	0.128 Ok
150% L01-240910	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	1.547 Ok	1.463 Ok
150% L01-240910	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	0.931 Ok	-0.465 Ok
150% L01-240910	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.738 Ok	0.977 Ok
150% L01-240910	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.857 Ok	-0.076 Ok
150% L01-240910	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.714 Ok	-0.089 Ok
150% L01-240910	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.258 Ok	-1.730 Ok
150% L01-240910	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.408 Ok	0.792 Ok
150% L01-240910	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	2.957 Ok	-0.220 Ok
150% L01-240910	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.982 Ok	-0.267 Ok
150% L01-240910	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.803 Ok	-1.490 Ok
150% L01-240910	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	1.929 Ok	-0.363 Ok
150% L01-240910	73	2	4.346e+10	20242.5	164290989.13	0.3780442877	1.6e+1	1.2041199827	10.638071064	1.003 Ok	0.175 Ok
150% L01-240910	74	2	2.554e+10	19859.5	172756060.68	0.6764341882	8e+0	0.903089987	10.407207743	2.014 Ok	1.643 Ok
150% L01-240910	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	2.756 Ok	0.032 Ok
150% L01-240910	76	2	6.956e+9	20033.5	95618993.904	1.3746652481	2e+0	0.3010299957	9.8423472161	0.395 Ok	0.785 Ok
150% L01-240910	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	1.6e+1	1.2041199827	10.635012399	0.148 Ok	0.063 Ok
150% L01-240910	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.520 Ok	0.051 Ok
150% L01-240910	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.555 Ok	-1.342 Ok
150% L01-240910	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.393 Ok	1.274 Ok
150% L01-240910	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.994 Ok	0.174 Ok
150% L01-240910	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.698 Ok	-0.078 Ok
150% L01-240910	83	2	1.151e+10	19997.5	194500111.81	1.690454602	4e+0	0.6020599913	10.060916343	0.190 Ok	-1.111 Ok
150% L01-240910	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	1.464 Ok	-0.215 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 Ok	-1.446 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Ok	-1.348 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Ok	-1.249 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Ok	-0.563 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Ok	-0.659 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Ok	1.164 Ok
Ref.Std (L01-240910)	7	2	8.450e+9		81272179.859	0.96178488	4e+0	0.6020599913		0.243 Ok	0.334 Ok
Ref.Std (L01-240910)	8	2	3.695e+9		10054551.433	0.2720908438			9.5676487726	1.157 Ok	-0.872 Ok
Ref.Std (L01-240910)	9	2	4.060e+10		2841771707.6			1.2041199827		4.985 Outlier	1.446 Ok
Ref.Std (L01-240910)	10	2	2.104e+10		443443222.92		8e+0		10.3230886		3.314 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066		1.2784101859		0.6020599913	9.9463114	1.397 Ok	1.058 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52			0.3010299957		5.157 Within Analytical Error	

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

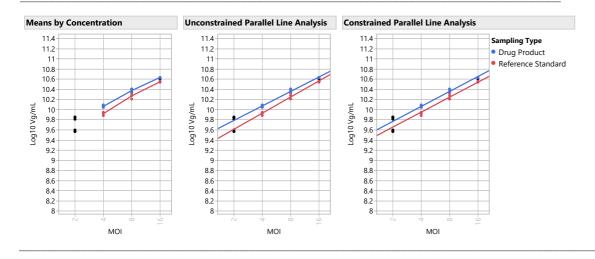
150% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+9
150% L01-240910	2e+0	6	6.85e+9	2.82e+8
150% L01-240910	4e+0	6	1.2e+10	4.93e+8
150% L01-240910	8e+0	6	2.4e+10	1.31e+9
150% L01-240910	1.6e+1	6	4.3e+10	4.28e+8

150% L01-240910 Model Selection

	Davallaliana	Lincosite			Validit.	
Model	Parallelism Slope Ratio	,	R2	RMSE	Validity Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.898		0.989	0.029	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.825	0.245	0.993	0.029	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.782	4.825	0.988	0.031	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.869	4.292	0.994	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.852	1.202	0.991	0.029	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.849	4.438	0.984	0.033	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.827	3.653	0.994	0.027	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.822	0.200	0.989	0.032	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.785	1.865	0.994	0.028	Parallel and Linear	

150% L01-240910 Graphs



150% 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		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.830	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.898	Passed Validity Criteria	
Linearity Ratio		26.3	4.785	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

		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 C	I Range % of Tolerance Check	OOS Validity
9.36	7.18	130.4	0	0	130.4	135.2	125.8	150	50	9.4	9.4 E	Bioassay Results are Reportable	Assay is Valid and Within Lim
		Rela	tive										
Unconstrained RI	Constrained F	RI Infectivity D	elta										
128.5	130.	4	1.8										

Particle Ratio Ratio Lower Limit Ratio Upper Limit 0.4 0.3 1.0

Infectious Infectious Particle Infectious Particle

200% L01-240910 & Reference Standard Data

				Accepted	Std						Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Outlier 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 Ok	0.475 Ok
200% L01-240910	38	2	3.009e+10	18845.5	740491509.11	2.4607466152	8e+0	0.903089987	10.478453187	4.857 Outlier	1.614 Ok
200% L01-240910	39	2	1.408e+10	20251	818244555.34	5.809870213	4e+0	0.6020599913	10.148716693	1.385 Ok	-0.185 Ok
200% L01-240910	40	2	1.053e+10	20253.5	125817445.28	1.1943429664	2e+0	0.3010299957	10.022611806	50.409 Outlier	5.402 Outlier
200% L01-240910	41	2	5.709e+10	18423.5	293737605.16	0.5145218197	1.6e+1	1.2041199827	10.756555753	6.187 Outlier	1.940 Ok
200% L01-240910	42	2	2.693e+10	20411.5	185825277.73	0.6899810404	8e+0	0.903089987	10.430267633	0.348 Ok	0.000 Ok
200% L01-240910	43	2	1.372e+10	20586.5	612192672.69	4.4622681989	4e+0	0.6020599913	10.137332458	0.249 Ok	-0.557 Ok
200% L01-240910	44	2	8.036e+9	19101.5	405078446.6	5.0406160629	2e+0	0.3010299957	9.9050555168	0.668 Ok	0.991 Ok
200% L01-240910	45	2	5.331e+10	19763	1654979461.6	3.1046232995	1.6e+1	1.2041199827	10.726783696	0.417 Ok	0.786 Ok
200% L01-240910	46	2	2.585e+10	20229.5	2807020.1741	0.0108568237	8e+0	0.903089987	10.412542748	1.189 Ok	-0.581 Ok
200% L01-240910	47	2	1.296e+10	19746.5	194907960.04	1.5039726731	4e+0	0.6020599913	10.112589631	3.656 Ok	-1.439 Ok
200% L01-240910	48	2	7.965e+9	19460	83629922.415	1.0499404243	2e+0	0.3010299957	9.9011970368	0.747 Ok	0.839 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 Ok	-1.290 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Ok	-1.199 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Ok	-1.108 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Ok	-0.494 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Ok	-0.579 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Ok	1.031 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Ok	0.293 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Ok	-0.768 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Outlier	1.286 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Ok	3.231 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Ok	0.935 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Within Analytical Error	0.312 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

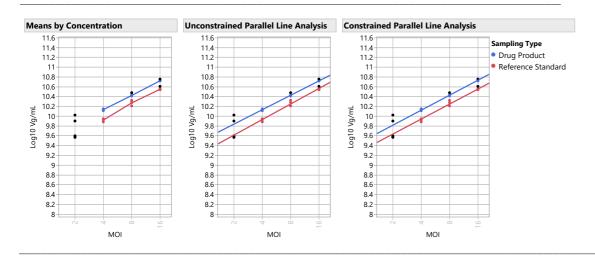
200% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+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	2	2.6e+10	7.62e+8
200% L01-240910	1.6e+1	2	5.3e+10	6.9e+8

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	0.927	2.841	0.989	0.033	Parallel and Linear	Model 2, Low Standard and Test Doses Exclude
Model 1, All Doses	0.841	0.139	0.993	0.032	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.752	2.796	0.990	0.031	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.898	2.847	0.994	0.031	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.868	2.334	0.988	0.034	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.854	1.479	0.995	0.029	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.816	1.169	0.983	0.035	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.800	3.955	0.994	0.031	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.790	2.129	0.991	0.032	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		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	0.242	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.927	Passed Validity Criteria	
Linearity Ratio		26.3	2.841	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

	RI		Reference	Relative Infectivity	Assay RI	Assay RI	Upper	Lower		CI Range as %		
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
5.86	150.7	0	0	150.7	160.9	141.5	150	50	19.4	19.4	Bioassay Results are Reportable	Assay is Valid and O
	Relat	tive										
onstrained P	RI Infectivity De	elta										
150.	7	0.2										
150.	/	0.2										
	5.86 onstrained F	EC50 Test Uncorrected 5.86 150.7 Relationstrained RI Infectivity Do	ECS0 Test Uncorrected Reference CF 5.86 150.7 0 Relative onstrained RI Infectivity Delta	ECS0 Test Uncorrected Reference CF Stability CF 5.86 150.7 0 0 0 Relative onstrained RI Infectivity Delta	ECS0 Test Uncorrected Reference CF Stability CF Reportable Result 5.86 150.7 0 0 150.7 150.7 Relative Constrained RI Infectivity Delta	ECS0 Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% 5.86 150.7 0 0 150.7 160.9 Relative onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% 5.86 150.7 0 0 0 150.7 160.9 141.5 Relative Onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% Spec Limit 5.86 150.7 0 0 150.7 160.9 141.5 150 Relative onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% Spec Limit Spec Limit 5.86 150.7 0 0 150.7 160.9 141.5 150 50 Relative Onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% Spec Limit Spec Limit CI Range 5.86 150.7 0 0 150.7 160.9 141.5 150 50 19.4 Relative Onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% Spec Limit Spec Limit CI Range of Tolerance 5.86 150.7 0 0 150.7 160.9 141.5 150 50 19.4 19.4 Relative Onstrained RI Infectivity Delta	ECSO Test Uncorrected Reference CF Stability CF Reportable Result Upper 95% Lower 95% Spec Limit Spec Limit Cl Range of Tolerance Cl

Particle Ratio Ratio Lower Limit Ratio Upper Limit 0.3

0.5

100% L01-240910 & Reference Standard Data

				Accepted	Std						Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Outlier 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 Ok	-0.941 Ok
100% L01-240910	50	2	1.644e+10	18226.5	20350893.08	0.1237600509	8e+0	0.903089987	10.216002993	2.888 Ok	-0.964 Ok
100% L01-240910	51	2	7.608e+9	19725	256471113.81	3.3709586709	4e+0	0.6020599913	9.8812850299	2.601 Ok	-0.965 Ok
100% L01-240910	52	2	3.716e+9	17735.5	289685040.08	7.7950422058	2e+0	0.3010299957	9.570107597	0.049 Ok	-0.287 Ok
100% L01-240910	53	2	3.690e+10	19450	1728233892.7	4.6832199996	1.6e+1	1.2041199827	10.567057958	0.413 Ok	-0.500 Ok
100% L01-240910	54	2	1.888e+10	18863.5	258789690.42	1.3710651781	8e+0	0.903089987	10.27588887	0.151 Ok	0.854 Ok
100% L01-240910	55	2	8.320e+9	18746	56525600.254	0.6793927511	4e+0	0.6020599913	9.9201242741	0.102 Ok	0.198 Ok
100% L01-240910	56	2	3.593e+9	12685.5			2e+0	0.3010299957	9.5554301725	1.940 Ok	-0.766 Ok
100% L01-240910	57	2	4.094e+10	18744	1870104954.7	4.5675232426	1.6e+1	1.2041199827	10.612185215	6.103 Outlier	1.034 Ok
100% L01-240910	58	2	2.045e+10	20813.5	573367617.57	2.8035032798	8e+0	0.903089987	10.310732093	1.624 Ok	2.097 Ok
100% L01-240910	59	2	8.852e+9	19702.5	137595150.53	1.5544659683	4e+0	0.6020599913	9.9470219092	1.763 Ok	1.014 Ok
100% L01-240910	60	2	3.858e+9	19416	144262472.04	3.7393203403	2e+0	0.3010299957	9.586360698	2.330 Ok	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 Ok	-1.175 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Ok	-1.094 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Ok	-1.013 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Ok	-0.455 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Ok	-0.533 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Ok	0.944 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Ok	0.270 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Ok	-0.706 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Outlier	1.183 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Ok	2.755 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Ok	0.857 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Within Analytical Error	0.288 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

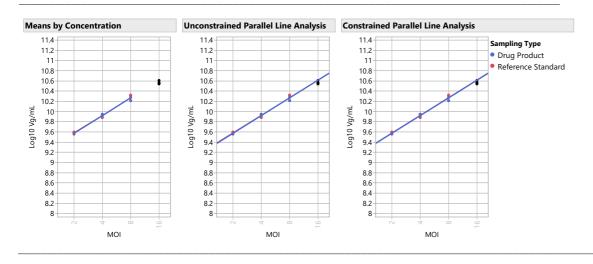
100% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+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	2	3.6e+10	7.49e+8

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 Exclude
Model 1, All Doses	1.019	3.047	0.992	0.035	Parallel and Linear	
Model 2, Low Standard and Test Doses Excluded	1.021	4.978	0.981	0.040	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.989	3.757	0.990	0.037	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.970	2.144	0.991	0.034	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	1.052	3.664	0.990	0.037	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.941	2.400	0.989	0.037	Parallel and Linear	
Model 7, Test High Dose Only Excluded	1.062	2.580	0.991	0.035	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	1.097	3.519	0.989	0.038	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		31600673338	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	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

		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 Limit
Unconstrained F			elta								
99.	.0 99	.0	0.0								
Infectious	Infectious Partic	le Infectious P	article								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								

50% L01-240910 & Reference Standard Data

0.4 0.3 1.0

	C !!		., , ,	Accepted	Std	0.00.7.10					a de Marde C	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	-			Outlier Within Group	Studentized Residuals Between Group
50% L01-240910	13	2	1.797e+10	19656.5		2.0013493063		1.2041199827		1.552 (0.765 Ok
50% L01-240910	14	2	1.130e+10	20631	235053015.22		8e+0		10.053220492	1.811 (2.381 Ok
50% L01-240910	15	2	5.246e+9	20620.5		6.2090657061		0.6020599913		1.597 (1.099 Ok
50% L01-240910	16	2	2.863e+9		133535135.16			0.3010299957		1.884 (1.434 Ok
50% L01-240910	17	2	1.555e+10	19717.5		3.1497867731		1.2041199827		0.362		-0.503 Ok
50% L01-240910	18	2	8.920e+9		145520323.79		8e+0		9.9503544163	0.322		0.191 Ok
50% L01-240910	19	2	4.446e+9		22592759.573			0.6020599913		0.060		-0.314 Ok
50% L01-240910	20	2	2.457e+9	20746.5		0.1458313452		0.3010299957		0.042		0.053 Ok
50% L01-240910	21	2	1.433e+10		691328511.13			1.2041199827		1.395 (-1.245 Ok
50% L01-240910	22	2	7.986e+9		272371628.48		8e+0	0.903089987	9.9023487925	1.109 (-0.746 Ok
50% L01-240910	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.376	Ok	-1.732 Ok
50% L01-240910	24	2	2.165e+9		13728570.717			0.3010299957		1.275 (-1.073 Ok
50% L01-240910	61	2	1.807e+10	18507	67065519.327	0.371135865	1.6e+1	1.2041199827	10.256966367	1.682	Ok	0.816 Ok
50% L01-240910	62	2	1.102e+10	19613.5	190120617.32	1.7258574881	8e+0	0.903089987	10.042024285	1.415 (2.108 Ok
50% L01-240910	63	2	5.159e+9	19546	199264473.2	3.8622715539	4e+0	0.6020599913	9.7125870699	1.342 (Ok	0.952 Ok
50% L01-240910	64	2	2.761e+9	19386.5	142914635.79	5.1765314071	2e+0	0.3010299957	9.4410378536	1.207	Ok	1.090 Ok
50% L01-240910	65	2	1.586e+10	19528	426059891.54	2.6857978728	1.6e+1	1.2041199827	10.200397327	0.150	Ok	-0.330 Ok
50% L01-240910	66	2	9.172e+9	19640	381089296.09	4.1548290727	8e+0	0.903089987	9.9624735888	0.137	Ok	0.427 Ok
50% L01-240910	67	2	4.472e+9	20154	205743731.17	4.6005207441	4e+0	0.6020599913	9.6505196182	0.016	Ok	-0.264 Ok
50% L01-240910	68	2	2.420e+9	19772	116728454.59	4.8244854223	2e+0	0.3010299957	9.3837257373	0.180	Ok	-0.082 Ok
50% L01-240910	69	2	1.472e+10	19282.5	392975759.31	2.6697350163	1.6e+1	1.2041199827	10.167897604	1.011	Ok	-0.999 Ok
50% L01-240910	70	2	7.776e+9	19753.5	311276312.65	4.0030128902	8e+0	0.903089987	9.8907590846	1.336	Ok	-0.978 Ok
50% L01-240910	71	2	3.776e+9	19467	89472972.022	2.3697464095	4e+0	0.6020599913	9.5769899896	1.423 (Ok	-1.775 Ok
50% L01-240910	72	2	2.148e+9	19516	136835293.16	6.3705683843	2e+0	0.3010299957	9.332019945	1.372 (Ok	-1.145 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 (Ok	-0.776 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 (Ok	-0.726 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606	Ok	-0.674 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366	Ok	-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	Ok	-0.361 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083	Ok	0.630 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243	Ok	0.184 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 (Ok	-0.475 Ok
Ref.Std (L01-240910)	9	2	4.060e+10		2841771707.6			1.2041199827		4.985 (0.795 Ok
Ref.Std (L01-240910)	10	2	2.104e+10		443443222.92		8e+0	0.903089987	10.3230886	1.823 (1.626 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066		1.2784101859		0.6020599913	9.9463114	1.397 (0.574 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52		2e+∩	0.3010299957	9.5985241259	5 157 \	Within Analytical Error	0.195 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

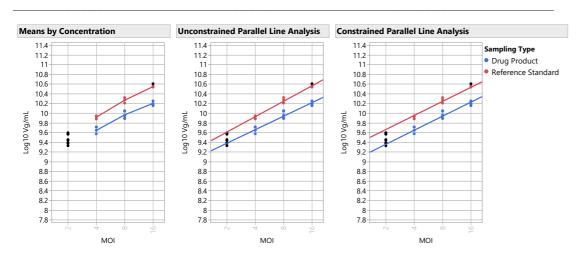
50% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+9
50% L01-240910	2e+0	6	2.47e+9	2.96e+8
50% L01-240910	4e+0	6	4.48e+9	6.35e+8
50% L01-240910	8e+0	6	9.36e+9	1.49e+9
50% L01-240910	1.6e+1	6	1.6e+10	1.6e+9

50% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.876	6.535	0.963	0.056	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.842	1.960	0.980	0.052	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.837	3.546	0.968	0.055	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.908	2.402	0.978	0.057	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.879	0.519	0.978	0.054	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.870	1.812	0.979	0.054	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.849	5.354	0.971	0.053	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.808	6.190	0.961	0.054	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.802	1.006	0.975	0.053	Parallel and Linear	

50% L01-240910 Graphs



50% 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		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.521	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.876	Passed Validity Criteria	
Linearity Ratio		26.3	6.535	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	
Number of Wells that railed Accepted Droplets (< 10000)		ر	0.000	rassed validity Criteria	

50% 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
4.70	9.75	48.3	0	0	48.3	51.6	44.9	150	50	6.7	6.7 Bioassay Results are Reportable Assay is Valid and OC
		Rela	itive								
Inconstrained R	RI Constrained I	RI Infectivity D	elta								
49.8	8 48	3	1.5								
Infectious I	nfectious Partic	e Infectious P	article								
Dantiela Datie	Ratio Lower Lim	it Ratio Uppe	r Limit								
Particle Ratio											

150% L01-240910 & Reference Standard Data

Group	Sampling	N Rows	Vg/mL	Accepted Droplets	Std Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Log10 Vg/mL	Jackknife z Outlier Within Group	Externally Outlier Studentized Residuals Between Group
150% L01-240910	25	2	4.333e+10	19449.5	1415326191.4	3.2663094426	1.6e+1	_		0.616 Ok	0.128 Ok
150% L01-240910	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	1.547 Ok	1.463 Ok
150% L01-240910	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	0.931 Ok	-0.465 Ok
150% L01-240910	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.738 Ok	0.977 Ok
150% L01-240910	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.857 Ok	-0.076 Ok
150% L01-240910	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.714 Ok	-0.089 Ok
150% L01-240910	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.258 Ok	-1.730 Ok
150% L01-240910	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.408 Ok	0.792 Ok
150% L01-240910	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	2.957 Ok	-0.220 Ok
150% L01-240910	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.982 Ok	-0.267 Ok
150% L01-240910	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.803 Ok	-1.490 Ok
150% L01-240910	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	1.929 Ok	-0.363 Ok
150% L01-240910	73	2	4.346e+10	20242.5	164290989.13	0.3780442877	1.6e+1	1.2041199827	10.638071064	1.003 Ok	0.175 Ok
150% L01-240910	74	2	2.554e+10	19859.5	172756060.68	0.6764341882	8e+0	0.903089987	10.407207743	2.014 Ok	1.643 Ok
150% L01-240910	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	2.756 Ok	0.032 Ok
150% L01-240910	76	2	6.956e+9	20033.5	95618993.904	1.3746652481	2e+0	0.3010299957	9.8423472161	0.395 Ok	0.785 Ok
150% L01-240910	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	1.6e+1	1.2041199827	10.635012399	0.148 Ok	0.063 Ok
150% L01-240910	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.520 Ok	0.051 Ok
150% L01-240910	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.555 Ok	-1.342 Ok
150% L01-240910	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.393 Ok	1.274 Ok
150% L01-240910	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.994 Ok	0.174 Ok
150% L01-240910	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.698 Ok	-0.078 Ok
150% L01-240910	83	2	1.151e+10	19997.5	194500111.81	1.690454602	4e+0	0.6020599913	10.060916343	0.190 Ok	-1.111 Ok
150% L01-240910	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	1.464 Ok	-0.215 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 Ok	-1.446 Ok
Ref.Std (L01-240910)	2	2	1.622e+10	19311.5	463230896.97	2.8555810473	8e+0	0.903089987	10.210103028	2.499 Ok	-1.348 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5	231970536.3	3.0296105469	4e+0	0.6020599913	9.8840460225	3.606 Ok	-1.249 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818	2.5108464532	2e+0	0.3010299957	9.5752976845	0.366 Ok	-0.563 Ok
Ref.Std (L01-240910)	5	2	3.614e+10	19200	2238782751.2	6.1939800559	1.6e+1	1.2041199827	10.55804215	0.356 Ok	-0.659 Ok
Ref.Std (L01-240910)	6	2	1.892e+10	19002.5	282808622.15	1.4950841497	8e+0	0.903089987	10.276827009	0.083 Ok	1.164 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Ok	0.334 Ok
Ref.Std (L01-240910)	8	2	3.695e+9	18885.5	10054551.433	0.2720908438	2e+0	0.3010299957	9.5676487726	1.157 Ok	-0.872 Ok
Ref.Std (L01-240910)	9	2	4.060e+10	18942	2841771707.6	7.0001149946	1.6e+1	1.2041199827	10.608484012	4.985 Outlier	1.446 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Ok	3.314 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Ok	1.058 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Within Analytical Error	0.356 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

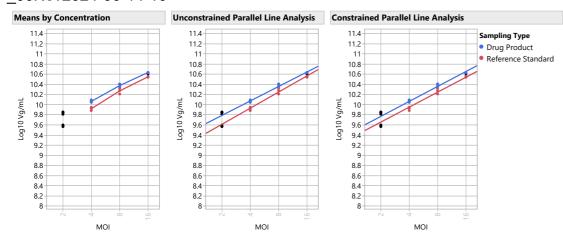
150% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	2	3.5e+10	1.04e+9
150% L01-240910	2e+0	6	6.85e+9	2.82e+8
150% L01-240910	4e+0	6	1.2e+10	4.93e+8
150% L01-240910	8e+0	6	2.4e+10	1.31e+9
150% L01-240910	1.6e+1	6	4.3e+10	4.28e+8

150% L01-240910 Model Selection

	Parallelism	Linearity			Validity	
Model	Slope Ratio	Ratio	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.898	4.785	0.989	0.029	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.825	0.245	0.993	0.029	Parallel and Linear	
Model 3, High Standard and Test Doses Excluded	0.782	4.825	0.988	0.031	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.869	4.292	0.994	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.852	1.202	0.991	0.029	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.849	4.438	0.984	0.033	Parallel and Linear	
Model 9, Standard High Dose and Test Low Dose Excluded	0.827	3.653	0.994	0.027	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.822	0.200	0.989	0.032	Parallel and Linear	
Model 5, Standard High Dose Only Excluded	0.785	1.865	0.994	0.028	Parallel and Linear	

150% L01-240910 Graphs



150% 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		31600673338	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.830	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.898	Passed Validity Criteria	
Linearity Ratio		26.3	4.785	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.906	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

150% 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
9.36	7.18	130.4	0	0	130.4	135.2	125.8	150	50	9.4	9.4 Bioassay Results are Reportable Assay is Valid and Within Limi
Inconstrained I	RI Constrained	Rela RI Infectivity D									
128	.5 130	0.4	1.8								
	.5 130 Infectious Partic		1.8								
Infectious		le Infectious P	1.8 article								

Relative Infectivity All Samples

			Infectious			
Sample Name	EC50 Standard	EC50 Test	Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910	4.7038667465	9.7469902675	0.2	48.3	44.9	51.6
150% L01-240910	9.3592156097	7.1792230588	0.4	130.4	125.8	135.2
200% L01-240910	8.8323386383	5.8607726426	0.5	150.7	141.5	160.9
100% L01-240910	3.9797170781	4.0203862953	0.4	99.0	94.4	103.8
50% L01-240910	4.7038667465	9.7469902675	0.2	48.3	44.9	51.6
150% L01-240910	9.3592156097	7.1792230588	0.4	130.4	125.8	135.2
	Overall					

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											

Materials

Assay Range Check

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	Column 3	on Extracted DNA plate		1	2	3	4	5	6	7	8	9
Lower Specification Limit (≥)	50			Α	1	5	9	13	17	21	25	29	33
Upper Specification Limit (≤)	150			В	2	6	10	14	18	22	26	30	34
Reference Standard Curve Depth (≥)	2720000000			С	3	7	11	15	19	23	27	31	35
Unconstrained EC50 Standard Lower Limit (≥)	0.04			D	4	8	12	16	20	24	28	32	36
Unconstrained EC50 Standard Upper Limit (≤)	61.8			E	49	53	57	61	65	69	73	77	81
% Relative Potency Delta (Constrained – Unconstrained) (≤)	15			F	50	54	58	62	66	70	74	78	82
Within Group Jackknife z Outlier Limit (<)	4			G	51	55	59	63	67	71	75	79	83
Between Group Studentized Residuals Outlier Limit (<)	4			Н	52	56	60	64	68	72	76	80	84
Parallelism Slope Ratio Lower Limit (≥)	0.7												
Parallelism Slope Ratio Upper Limit (≤)	1.4												
Linearity Ratio (≤)	26.3		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	10.6			В	3000	3000	3000	3000	3000	3000	3000	3000	3000
fixed position for Test article for Infectious Particles Ratio Equation	n 10.6			С	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Lower Specification Limit (≥)	0.3			D	3000	3000	3000	3000	3000	3000	3000	3000	3000
Infectious Particles Ratio Upper Specification Limit (≤)	1			E	3000	3000	3000	3000	3000	3000	3000	3000	3000
Failed Accepted Droplets Upper Limit (≤)	5			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)	Ref.Std (L01-240910)												
Control (13-24)	50% L01-240910		ddPCR Map - Plate 2		1	2	3	4	5	6	7	8	9
Sample 1 (25-36)	150% L01-240910			Α	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 2 (37-48)	200% L01-240910			В	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 3 (49-60)	100% L01-240910			C	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 4 (61-72)	50% L01-240910			D	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sample 5 (73-84)	150% L01-240910			E	6000	6000	6000	6000	6000	6000	6000	6000	6000
Sumple 5 (75 04)	Ref.Std			F	6000	6000	6000	6000	6000	6000	6000	6000	6000
Total Number of Plates	2			G	6000	6000	6000	6000	6000	6000	6000	6000	6000
Total Number of Flates	2			Н	6000	6000	6000	6000	6000	6000	6000	6000	6000
MOI Concentrations													
16													
8													
4													
2													
									•				
					•		•	•	•	•	•		
										•			
											•		

	Sample	Sample	Sample		Conc(copies/									Accepted		
		description 3 REP1	description 4		μL) 184.5901031			SampleType			fau Duahaa	(Nie dutto)	DyeName(s)	Droplets	Positives 3013	Ne
4	50	REP1		BDNF BDNF	334.3489075		DQ DQ	Unknown	Unknown	ddPCR Supermix				20749 21194	5243	
8	50	REP1			742.4992676		DQ	Unknown	Unknown	ddPCR Supermix				20895	9779	
16		REP1		BDNF	1214.964355		DQ	Unknown	Unknown	ddPCR Supermix				19835	12773	
4	50.2	REP1		BDNF	177.3175049		DQ	Unknown	Unknown	ddPCR Supermix				18962	2653	
8	50.2 50.2	REP1		BDNF BDNF	334.5569763 743.3629761		DQ DQ	Unknown	Unknown	ddPCR Supermix				20116 19571	4979 9167	
16		REP1		BDNF	1207.850952		DQ	Unknown	Unknown	ddPCR Supermix				18099	11616	
2	100.2	REP1		BDNF	234.0956421		DQ	Unknown	Unknown	ddPCR Supermix				18400	3320	
4	100.2	REP1		BDNF	495.1268005	OK	DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	21015	7219	
8		REP1		BDNF	1095.296021		DQ	Unknown	Unknown	ddPCR Supermix				19345	11720	
16		REP1		BDNF	2365.355713		DQ	Unknown	Unknown	ddPCR Supermix		. ,		18004	15593	
4		REP1		BDNF BDNF	467.249176 781.6210327	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix				20209 19118	6624 9280	
8	150	REP1		BDNF	1654.55957	OK	DQ	Unknown	Unknown	ddPCR Supermix				19667	14848	
16	150	REP1		BDNF	2955.455811	ОК	DQ	Unknown	Unknown	ddPCR Supermix				19804	18198	
2		REP1		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix				19640	6347	
4		REP1		BDNF	800.2147217		DQ	Unknown	Unknown	ddPCR Supermix				20921	10324	
16		REP1		BDNF BDNF	1710.758911 2889.464111		DQ DQ	Unknown	Unknown	ddPCR Supermix				19375 20729	14849 18951	
2		REP1		BDNF	708.2276611		DQ	Unknown	Unknown	ddPCR Supermix		. ,		20076	9080	
4		REP1		BDNF	977.4855957		DQ	Unknown	Unknown	ddPCR Supermix				20357	11488	
8	200	REP1		BDNF	2041.050293		DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	18286	15060	
16		REP1		BDNF		ОК	DQ	Unknown	Unknown	ddPCR Supermix				18450	17616	
2	RS	REP1		BDNF	246.2785187		DQ	Unknown	Unknown	ddPCR Supermix		. ,		20320	3838	
8	RS RS	REP1		BDNF BDNF	499.5166321 1059.626343		DQ DQ	Unknown	Unknown	ddPCR Supermix				20800 19198	7196 11398	
16		REP1		BDNF	2283.812012		DQ	Unknown	Unknown	ddPCR Supermix				20296	17398	
2		REP2		BDNF	163.9904785		DQ	Unknown	Unknown	ddPCR Supermix				20805	2707	
4	50	REP2		BDNF	295.3388062		DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	21184	4703	
8		REP2		BDNF	601.5122681		DQ	Unknown	Unknown	ddPCR Supermix				19579	7837	
16		REP2		BDNF	1060.067139		DQ	Unknown	Unknown	ddPCR Supermix				19902	11819	
4		REP2 REP2		BDNF BDNF	166.8026733 307.8444214		DQ DQ	Unknown	Unknown	ddPCR Supermix				19472 19376	2574 4461	
8		REP2		BDNF	629.4448242		DQ	Unknown	Unknown	ddPCR Supermix				19293	7994	
16		REP2		BDNF	1077.647217		DQ	Unknown	Unknown	ddPCR Supermix				18922	11351	
2	100.2	REP2		BDNF	239.5184174	OK	DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	19435	3580	
4		REP2			557.3325195		DQ	Unknown	Unknown	ddPCR Supermix				19344	7299	
8	100.2	REP2		BDNF	1246.139404		DQ	Unknown	Unknown	ddPCR Supermix				18666	12194	
16		REP2 REP2		BDNF	2541.648682 467.5604553		DQ DQ	Unknown	Unknown	ddPCR Supermix				19275 19576	17053 6420	
4		REP2		BDNF	697.5460205		DQ	Unknown	Unknown	ddPCR Supermix				20687	9253	
8		REP2			1459.571045		DQ	Unknown	Unknown	ddPCR Supermix				19260	13690	
16	150	REP2		BDNF	2833.755615	OK	DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	18903	17203	
2		REP2		BDNF	463.5831604		DQ	Unknown	Unknown	ddPCR Supermix				19025	6196	
4		REP2			727.1038818		DQ	Unknown	Unknown	ddPCR Supermix				21256	9799	
16	150.2 150.2	REP2 REP2		BDNF	1474.371826 2850.130615		DQ DQ	Unknown	Unknown	ddPCR Supermix				20971 20645	14982 18814	
2	200	REP2			516.6569824		DQ	Unknown	Unknown	ddPCR Supermix				18381	6533	
4	200	REP2		BDNF	885.7620239	ОК	DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	20155	10662	
8	200	REP2		BDNF	1786.702759		DQ	Unknown	Unknown	ddPCR Supermix				20119	15713	
16	200	REP2		BDNF	3792.115479		DQ	Unknown	Unknown	ddPCR Supermix		. ,		17904	17191	
4	RS RS	REP2 REP2		BDNF BDNF	246.8267822 567.1739502		DQ DQ	Unknown	Unknown	ddPCR Supermix				19862 18334	3759 7013	
8	RS	REP2			1274.391724		DQ	Unknown	Unknown	ddPCR Supermix				19099	12634	
16		REP2		BDNF	2515.170166		DQ	Unknown	Unknown	ddPCR Supermix				19321	17043	
2	50	REP3		BDNF	143.6707916	OK	DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	18572	2135	
4		REP3		BDNF	253.6337738		DQ	Unknown	Unknown	ddPCR Supermix				18692	3625	
16	50	REP3		BDNF	545.2636108		DQ	Unknown	Unknown	ddPCR Supermix				19234	7134	
16		REP3 REP3		BDNF BDNF	988.2422485 136.7447968		DQ DQ	Unknown	Unknown	ddPCR Supermix				18765 18454	10664 2025	
4	50.2	REP3		BDNF	247.4911957		DQ	Unknown	Unknown	ddPCR Supermix				18296	3471	
8	50.2	REP3			533.0770874		DQ	Unknown	Unknown	ddPCR Supermix				19094	6957	
16		REP3		BDNF	999.8353271		DQ	Unknown	Unknown	ddPCR Supermix				18628	10665	
2	100.2	REP3		BDNF	250.3984985		DQ	Unknown	Unknown	ddPCR Supermix				19743	3785	
8	100.2	REP3 REP3		BDNF BDNF	583.6205444 1390.483887		DQ DQ	Unknown	Unknown	ddPCR Supermix				19272 21070	7537 14608	
16		REP3		BDNF	2817.72583	OK	DQ	Unknown	Unknown	ddPCR Supermix				18713	17007	
2	150	REP3			434.8545532		DQ	Unknown	Unknown	ddPCR Supermix				18540	5729	
4		REP3			744.3925781		DQ	Unknown	Unknown	ddPCR Supermix	for Probes	(No dUTP)	FAM	20618	9667	
8		REP3		BDNF	1498.908447		DQ	Unknown	Unknown	ddPCR Supermix				19636	14144	
16	150	REP3		BDNF	2870.013184		DQ	Unknown	Unknown	ddPCR Supermix				16903	15429	
4	150.2 150.2	REP3 REP3		BDNF BDNF	428.2732849 757.883667	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix				18592 19237	5673 9136	
8	150.2	REP3		BDNF	1495.671997		DQ	Unknown	Unknown	ddPCR Supermix				21265	15301	
16		REP3		BDNF	2888.75415	ОК	DQ	Unknown	Unknown	ddPCR Supermix				19295	17639	
2	200	REP3		BDNF	527.0714111		DQ	Unknown	Unknown	ddPCR Supermix				18582	6710	
4		REP3			854.7813721		DQ	Unknown	Unknown	ddPCR Supermix				19991	10324	
16	200	REP3			1723.79187	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix				20634 19699	15867	
16	200 RS	REP3 REP3		BDNF BDNF	3631.812012 270.7347107		DQ	Unknown	Unknown Unknown	ddPCR Supermix				19699 21059	18800 4329	
4	RS	REP3		BDNF	583.8165283		DQ	Unknown	Unknown	ddPCR Supermix				20742	8114	
8	RS	REP3			1423.709229		DQ	Unknown	Unknown	ddPCR Supermix				21479	15075	
16	RS	REP3		BDNF	2840.367188		DQ	Unknown	Unknown	ddPCR Supermix				19714	17951	
NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix				19126	0	
NTC NTC				BDNF BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix				20944 18778	0	
				22141	Cum	C. ILCK	- 4	SINCHOWIT	2	-a. c. sabellilly		(uo ir)		10,70	U	

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Mall	Sample	Sample	Sample	Sample	Tare	Conc(copies/	C+-+	Evperire	CamalaT	Target	Cuparmiy	DuoNeres (-)	Accepted	Desition	Nine -+1
	description 1	description 2	description 3	description 4	-	μL) 1202.61377		DQ	SampleType Unknown		ddPCR Supermix for Probes (no dUTP)	DyeName(s)	Droplets 17535	Positives 11226	Negative 630
12	PC				DUNF	1202.01377	UK	DQ	Unknown	Uliknown	darck supermix for Probes (no do re)	PAIVI	17555	11220	030
	Sample	Sample	Sample	Sample		Conc(copies/							Accepted		
				description 4	_				SampleType		· ·	DyeName(s)	Droplets	Positives	Negative
	2 4	RS RS	REP1			127.5908127 260.693512	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19041 18807	1957 3738	1708 1506
01		RS	REP1			551.6500854		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19425	7271	1215
01	16	RS	REP1			1169.609009		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		16931	10666	626
10		200	REP1			348.1827393		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20431	5234	1519
10		200	REP1			450.1703796		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20145	6405	1374
10 10		200	REP1			985.618042 1667.197388		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19405 19306	11009 14626	839 468
107		150.2	REP1			234.1138306		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20427	3686	1674
07		150.2	REP1			425.228363		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19787	6002	1378
07	8	150.2	REP1	1		847.2356567		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20344	10443	990
07	16	150.2	REP1		BDNF	1452.476807	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19756	14008	574
07		150	REP1			235.5180359		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20813	3776	170:
07 07	4	150 150	REP1			408.2714844 857.5824585		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20299 19821	5952 10259	1434
07		150	REP1			1411.008789		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19095	13340	57
	2	100.2	REP1		BDNF	130.7037048		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17071	1795	152
01	4	100.2	REP1		BDNF	259.6535645	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18435	3651	147
01	8	100.2	REP1	1	BDNF	548.6073608	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	17108	6376	107.
	16	100.2	REP1			1206.892456		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18313	11748	65
	2	50.2	REP1			95.39581299		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19811	1543	182
	4 8	50.2 50.2	REP1			176.6719055 362.7191162		DQ DQ	Unknown	Unknown Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18976 19656	2646 5215	163 144
	16	50.2	REP1			600.7639771		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18915	7564	113
	2	50.2	REP1			98.58995819		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19369	1557	178
04		50	REP1		BDNF	182.5280457	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20047	2881	171
	8	50	REP1			382.3301392		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20367	5651	147
	16	50	REP1			590.5283203		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19478	7687	117
02 02		RS RS	REP2 REP2			122.939415 279.7557678		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		17909 19392	1777 4104	161 152
)2		RS	REP2			623.8641357		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18906	7781	111
02		RS	REP2			1152.047852		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19079	11913	71
11		200	REP2	1		277.4240723		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19822	4164	156
11	4	200	REP2	E	BDNF	471.7400513	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21018	6943	140
11		200	REP2			902.1112671		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20704	11087	96
11		200	REP2			1909.904663		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18943	15207	37
08 08	2	150.2 150.2	REP2 REP2			245.6865997 392.8456421		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20624 21121	3887 5996	167 151
	8	150.2	REP2			804.1484375		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19757	9783	99
	16	150.2	REP2		BDNF	1451.810669		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20370	14440	59
08	2	150	REP2		BDNF	230.1463165	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20008	3555	164
	4	150	REP2			390.6889954		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20745	5862	148
80		150	REP2			797.5358887		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19989	9841	1014
.08		150	REP2 REP2			1434.838257 No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19225 5936	13547	56 59
02		100.2	REP2			276.0016174		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18148	3795	143
02		100.2	REP2			635.269165		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19061	7953	1110
02	16	100.2	REP2		BDNF	1189.354614	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19625	12484	714
105		50.2	REP2			77.89870453		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20072	1286	187
05		50.2	REP2			144.2233582		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20932	2415	185
05 05	16	50.2 50.2	REP2 REP2			296.7576904 518.7389526		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19987 20134	4456 7179	155 129
05		50.2	REP2			81.8263092		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20688	1390	192
	4	50	REP2		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19889	2362	175
05	8	50	REP2		BDNF	293.8962402	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20330	4494	158
05	16	50	REP2		BDNF	506.9377747		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19533	6838	126
	2	RS	REP3		BDNF	129.1370239		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19739	2052	176
03		RS	REP3			297.2339478		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19390	4329	150 106
03 03		RS RS	REP3			690.9505005 1286.221191		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19213 18170	8534 12081	60
12		200	REP3			267.4780579		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20338	4136	162
12		200	REP3			436.5787354		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19502	6046	134
12		200	REP3			861.7636108		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19825	10295	95
12		200	REP3			1737.889526		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19827	15301	45
09		150.2	REP3			221.4954987		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20634	3541	170
09 09		150.2 150.2	REP3 REP3			388.1106567 780.5882568		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20758 19441	5833 9428	149 100
	16	150.2	REP3		BDNF	1452.654907		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20419	14479	59
09		150.2	REP3			214.1714325		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21023	3499	175
)9		150	REP3			377.5775146		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20380	5595	147
	8	150	REP3			760.2349854		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20201	9615	105
09		150	REP3			1391.104004		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19861	13773	170
)3		100.2	REP3 REP3			131.9998474 298.2965698		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19089 20133	2026 4509	170 156
)3)3	8	100.2	REP3			668.2131348		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20133	4509 8908	116
)3		100.2	REP3			1320.705322		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18775	12665	61
06		50.2	REP3			74.82287598		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20578	1268	193
06		50.2	REP3			127.9633942		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20638	2127	185
	8	50.2	REP3			251.8648376		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20413	3934	164
	16	50.2	REP3			481.3926086		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19937	6695	132
06 06		50	REP3		BDNF BDNF	72.48256683 126.0057755		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19732 20528	1179 2085	185 184
)6		50	REP3			259.7920837		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19587	3881	157
	16	50	REP3			461.5315857		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18943	6147	127
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20488	0	204
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		21273	0	212
					BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20600	0	206
2	NTC						0''	DO	L Lack	L La La		EAN4	201		
0	NTC PC PC				BDNF BDNF	1441.094727 1468.046875		DQ DQ	Unknown Unknown	Unknown Unknown	ddPCR Supermix for Probes (no dUTP) ddPCR Supermix for Probes (no dUTP)		20444 20465	14438 14589	60 58