

Astellas BTQ Assay Report

Test Article Report

Approver Signature/Date

Assay Details	 	
Jser Information		
Jser Name: harding		
Computer Name: DESKTOP-RFHI5SO .ogon Server: \\DESKTOP-RFHI5SO		
Jser Domain: DESKTOP-RFHISSO		
Astellas BTQ Infectivity PLA Script Version 0.1		
MP Version 18.1.0		

Astellas KT430 Infectivity Files

First Data File Second Data File 18OCT2024_Plate01_KL-S3 18OCT2024_Plate01_KL-S4

50% L01-240910 & Reference Standard Data

				Accepted	Std					First Outlier	Analytical	Analytical Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOI	Loa10 Va/mL	Jackknife z Within Group Check	Error Upper	,	Studentized Residuals Between Group
50% L01-240910	13	2	1.797e+10	19656.5		2.0013493063		1.2041199827	J J.	1.552 Pass		-10627646275 Pass	0.774 Ok
50% L01-240910	14	2	1.130e+10	20631	235053015.22		8e+0	0.903089987	10.053220492	1.811 Pass	22301813324	-3577112702 Pass	2.405 Ok
50% L01-240910	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	1.597 Pass	11188841923	-2225172145 Pass	1.111 Ok
50% L01-240910	16	2	2.863e+9	20059	133535135.16			0.3010299957		1.884 Pass	6729036381.8	-1791164373 Pass	1.449 Ok
50% L01-240910	17	2	1.555e+10	19717.5		3.1497867731		1.2041199827		0.362 Pass		-10627646275 Pass	-0.509 Ok
50% L01-240910	18	2	8.920e+9		145520323.79		8e+0		9.9503544163	0.322 Pass	22301813324	-3577112702 Pass	0.193 Ok
50% L01-240910	19	2	4.446e+9		22592759.573		4e+0	0.6020599913		0.060 Pass	11188841923	-2225172145 Pass	-0.317 Ok
50% L01-240910	20	2	2.457e+9	20746.5		0.1458313452		0.3010299957		0.042 Pass	6729036381.8	-1791164373 Pass	0.054 Ok
50% L01-240910	21	2	1.433e+10		691328511.13			1.2041199827		1.395 Pass		-10627646275 Pass	-1.258 Ok
50% L01-240910	22	2	7.986e+9		272371628.48		8e+0		9.9023487925	1.109 Pass	22301813324	-3577112702 Pass	-0.754 Ok
50% L01-240910	23	2	3.792e+9		17206271.137			0.6020599913		1.376 Pass	11188841923	-2225172145 Pass	-1.750 Ok
50% L01-240910	24	2	2.165e+9		13728570.717			0.3010299957		1.275 Pass	6729036381.8	-1791164373 Pass	-1.084 Ok
50% L01-240910	61	2	1.807e+10		67065519.327			1.2041199827		1.682 Pass		-10627646275 Pass	0.824 Ok
50% L01-240910	62	2	1.102e+10		190120617.32		8e+0		10.042024285	1.415 Pass	22301813324	-3577112702 Pass	2.129 Ok
50% L01-240910	63	2	5.159e+9	19546		3.8622715539		0.6020599913		1.342 Pass	11188841923	-2225172145 Pass	0.963 Ok
50% L01-240910	64	2	2.761e+9	19386.5				0.3010299957		1.207 Pass	6729036381.8	-1791164373 Pass	1.102 Ok
50% L01-240910	65	2	1.586e+10		426059891.54			1.2041199827		0.150 Pass		-10627646275 Pass	-0.334 Ok
50% L01-240910	66	2	9.172e+9		381089296.09		8e+0		9.9624735888	0.137 Pass	22301813324	-3577112702 Pass	0.432 Ok
50% L01-240910	67	2	4.472e+9		205743731.17			0.6020599913		0.016 Pass	11188841923	-2225172145 Pass	-0.267 Ok
50% L01-240910	68	2	2.420e+9		116728454.59			0.3010299957		0.180 Pass	6729036381.8	-1791164373 Pass	-0.083 Ok
50% L01-240910	69	2	1.472e+10		392975759.31			1.2041199827		1.011 Pass		-10627646275 Pass	-1.010 Ok
50% L01-240910	70	2	7.776e+9		311276312.65		8e+0		9.8907590846	1.336 Pass	22301813324	-3577112702 Pass	-0.989 Ok
50% L01-240910	71	2	3.776e+9		89472972.022			0.6020599913		1.423 Pass	11188841923	-2225172145 Pass	-1.793 Ok
50% L01-240910	72	2	2.148e+9		136835293.16			0.3010299957		1.372 Pass	6729036381.8	-1791164373 Pass	-1.157 Ok
Ref.Std (L01-240910)	1	2	3.467e+10		587669438.42			1.2041199827		1.175 Pass		8695471254.7 Pass	-0.929 Ok
Ref.Std (L01-240910)	2	2	1.622e+10		463230896.97		8e+0		10.210103028	2.499 Pass		5787178834.6 Pass	-0.820 Ok
Ref.Std (L01-240910)	3	2	7.657e+9	19803.5		3.0296105469		0.6020599913		3.606 Pass		1607676880.9 Pass	-0.705 Ok
Ref.Std (L01-240910)	4	2	3.761e+9		94431706.818			0.3010299957		0.366 Pass		-531978791.1 Pass	-0.260 Ok
Ref.Std (L01-240910)	5	2	3.614e+10		2238782751.2			1.2041199827	10.55804215	0.356 Pass		8695471254.7 Pass	-0.525 Ok
Ref.Std (L01-240910)	6	2	1.892e+10		282808622.15		8e+0		10.276827009	0.083 Pass		5787178834.6 Pass	0.534 Ok
Ref.Std (L01-240910)	7	2	8.450e+9		81272179.859	0.96178488		0.6020599913		0.243 Pass		1607676880.9 Pass	0.162 Ok
Ref.Std (L01-240910)	8	2	3.695e+9		10054551.433			0.3010299957		1.157 Pass		-531978791.1 Pass	-0.428 Ok
Ref.Std (L01-240910)	9	2	4.060e+10		2841771707.6			1.2041199827		4.985 Outlier		8695471254.7 Pass	0.581 Ok
Ref.Std (L01-240910)	10	2	2.104e+10		443443222.92		8e+0		10.3230886	1.823 Pass		5787178834.6 Pass	1.516 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066		1.2784101859		0.6020599913	9.9463114	1.397 Pass		1607676880.9 Pass	0.556 Ok
Ref.Std (L01-240910)	12	2	3.968e+9		132165288.52			0.3010299957		5.157 Outlier		-531978791.1 Pass	0.247 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 calcula

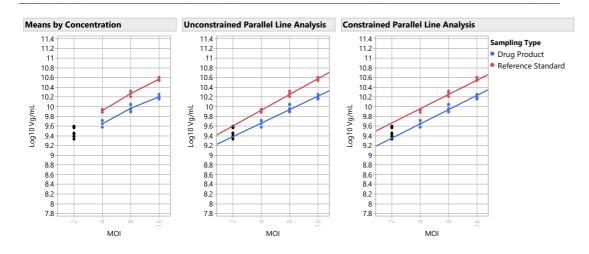
50% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	3	3.7e+10	3.08e+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	0.857	5.929	0.968	0.055	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 3, High Standard and Test Doses Excluded	0.837	3.546	0.968	0.055	Parallel and Linear	
Model 1, All Doses	0.833	1.642	0.982	0.052	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.888	2.902	0.981	0.056	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.870	0.047	0.982	0.053	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.851	1.647	0.981	0.054	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.840	4.355	0.974	0.052	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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.614	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.857	Passed Validity Criteria	
Linearity Ratio		26.3	5.929	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.614	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
4.89	10.23	47.8	0	0	47.8	51.2	44.5	150	50	6.7	6.7 Bioassay Results are Reportable Assay is Valid
		Rela	tive								
Unconstrained	RI Constrained F	RI Infectivity D	elta								
49	9.4 47.	8	1.6								
Infectious	Infectious Particl	e Infectious Pa	article								
Particle Ratio	Ratio Lower Lim	it Ratio Upper	r Limit								
0.2	0.	3	1.0								

150% L01-240910 & Reference Standard Data

				Accepted	Std					First Outlier	Analytical	Analytical 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 Check	Error Upper	Error Lower 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 Pass	69807338810	16381062070 Pass	0.128 Ok
150% L01-240910	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	1.547 Pass	36675079467	10796153441 Pass	1.459 Ok
150% L01-240910	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	0.931 Pass	18299766051	4885751984.1 Pass	-0.464 Ok
150% L01-240910	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.738 Pass	11113846219	2593645464.8 Pass	0.975 Ok
150% L01-240910	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.857 Pass	69807338810	16381062070 Pass	-0.076 Ok
150% L01-240910	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.714 Pass	36675079467	10796153441 Pass	-0.089 Ok
150% L01-240910	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.258 Pass	18299766051	4885751984.1 Pass	-1.725 Ok
150% L01-240910	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.408 Pass	11113846219	2593645464.8 Pass	0.791 Ok
150% L01-240910	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	2.957 Pass	69807338810	16381062070 Pass	-0.219 Ok
150% L01-240910	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.982 Pass	36675079467	10796153441 Pass	-0.267 Ok
150% L01-240910	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.803 Pass	18299766051	4885751984.1 Pass	-1.486 Ok
150% L01-240910	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	1.929 Pass	11113846219	2593645464.8 Pass	-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 Pass	69807338810	16381062070 Pass	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 Pass	36675079467	10796153441 Pass	1.638 Ok
150% L01-240910	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	2.756 Pass	18299766051	4885751984.1 Pass	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 Pass	11113846219	2593645464.8 Pass	0.784 Ok
150% L01-240910	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	1.6e+1	1.2041199827	10.635012399	0.148 Pass	69807338810	16381062070 Pass	0.063 Ok
150% L01-240910	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.520 Pass	36675079467	10796153441 Pass	0.050 Ok
150% L01-240910	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.555 Pass	18299766051	4885751984.1 Pass	-1.339 Ok
150% L01-240910	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.393 Pass	11113846219	2593645464.8 Pass	1.271 Ok
150% L01-240910	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.994 Pass	69807338810	16381062070 Pass	0.174 Ok
150% L01-240910	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.698 Pass	36675079467	10796153441 Pass	-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 Pass	18299766051	4885751984.1 Pass	-1.109 Ok
150% L01-240910	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	1.464 Pass	11113846219	2593645464.8 Pass	-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 Pass	62121747995	8695471254.7 Pass	-1.723 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	31666104861	5787178834.6 Pass	-1.510 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	15021690948	1607676880.9 Pass	-1.290 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	7988221963.3	-531978791.1 Pass	-0.468 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	62121747995	8695471254.7 Pass	-0.952 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	31666104861	5787178834.6 Pass	0.970 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	15021690948	1607676880.9 Pass	0.292 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	7988221963.3	-531978791.1 Pass	-0.774 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	62121747995	8695471254.7 Pass	1.056 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	31666104861	5787178834.6 Pass	2.981 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	15021690948	1607676880.9 Pass	1.011 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Outlier	7988221963.3	-531978791.1 Pass	0.445 Ok

Within Group Jackknife z Outlier Limit (≥):

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

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

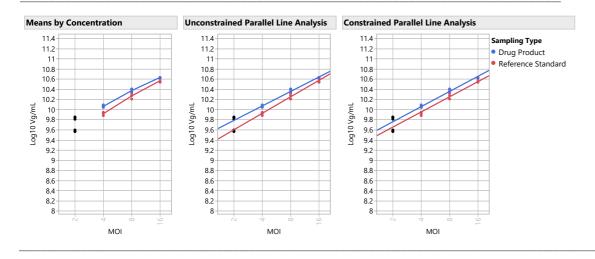
150% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	3	3.7e+10	3.08e+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	Linoarity			Validity	
Model	Slope Ratio	,	R2	RMSE	Evaluation	Selected Model
Model 2, Low Standard and Test Doses Excluded	0.878	4.235	0.988	0.029	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.816	0.474	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	0.860	3.392	0.994	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.833	1.319	0.991	0.030	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.830	4.872	0.985	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	0.813	0.722	0.990	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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.202	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.878	Passed Validity Criteria	
Linearity Ratio		26.3	4.235	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.614	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

		RI			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
9.41	7.38	127.6	0	0	127.6	132.5	123.0	150	50	9.5	9.5 Bioassay Results are Reportable Assay is Valid and Within Limit
Unconstrained	RI Constrained I	Rela RI Infectivity D									
126	.4 127.	6	1.2								
Infectious	Infectious Partic	e Infectious P	article								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								
0.4	0.	3	1.0								

200% L01-240910 & Reference Standard Data

				Accepted	Std					First Outlier	Analytical	Analytical	Outlier	Externally Outlier
Group	Sampling	N Rows	Vg/mL	Droplets	Dev(Vg/mL)	CV(Vg/mL)	MOI	Log10 MOL	Log10 Vg/ml	Jackknife z Within Group Check	Error Upper	,		Studentized Residuals Between Group
200% L01-240910	37	14 10.003	5.233e+10		3273703267.4	, 3. ,	1.6e+1	1.2041199827	3 3	1.072 Pass		26105717830		0.105 Ok
200% L01-240910	38	2	3.009e+10			2.4607466152	8e+0		10.478453187	4.857 Outlier				0.769 Ok
200% L01-240910 200% L01-240910	39	2	1.408e+10		818244555.34	5.809870213				1.385 Pass		6880511277.1		-0.719 Ok
200% L01-240910 200% L01-240910		2	1.406e+10		125817445.28			0.3010299957	10.146716693	50.409 Outlier		3740647074.9		-0.719 Ok 3.861 Ok
200% L01-240910 200% L01-240910	40	2	5.709e+10		293737605.16				10.756555753	6.187 Outlier		26105717830		1.114 Ok
	41	2					1.6e+1							
200% L01-240910	42	2	2.693e+10		185825277.73		8e+0			0.348 Pass		13453953430		-0.390 Ok
200% L01-240910	43	2	1.372e+10		612192672.69			0.6020599913		0.249 Pass		6880511277.1		-1.006 Ok
200% L01-240910	44	2	8.036e+9	19101.5		5.0406160629		0.3010299957		0.668 Pass		3740647074.9		-0.139 Ok
200% L01-240910	45	2	5.331e+10		1654979461.6		1.6e+1	1.2041199827		0.417 Pass		26105717830		0.313 Ok
200% L01-240910	46	2	2.585e+10		2807020.1741		8e+0		10.412542748	1.189 Pass		13453953430		-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	20294525344	6880511277.1	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	12260847829	3740647074.9	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	62121747995	8695471254.7	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	31666104861	5787178834.6	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	15021690948	1607676880.9	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	7988221963.3	-531978791.1	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	62121747995	8695471254.7	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	31666104861	5787178834.6	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	15021690948	1607676880.9	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	7988221963.3	-531978791.1	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 Outlier	62121747995	8695471254.7	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	31666104861	5787178834.6	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	15021690948	1607676880.9	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 Outlier	7988221963.3	-531978791.1	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

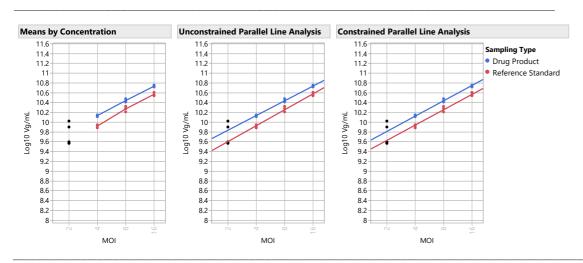
200% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	16.614	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

EC50 Ref	EC50 Test	RI Uncorrected	Reference CF	Relative Infectivity Reportable Result	Assay RI Upper 95%	Assay RI Lower 95%	Upper Spec Limit	Lower Spec Limit	CI Range	CI Range as % of Tolerance CI Range % of Tolerance Check OOS Validity
9.80		150.1	0	150.1	158.9	142.0	150	50	17.0	
Unconstrained	RI Constrained		ative							
150			0.1							
150	0.2 150	• • •	0.1							
Infectious	Infectious Partic	le Infectious P	article							
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit							
0.5	0	.3	1.0							

100% L01-240910 & Reference Standard Data

				Accepted	Std					First Outlier	Analytical	Analytical 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 Check	Error Upper	,	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	63086257877	9659981135.9 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	31529709596	5650783569.6 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	14966965453	1552951385.9 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	7982445576.7	-537755177.7 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	63086257877	9659981135.9 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	31529709596	5650783569.6 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	14966965453	1552951385.9 Pass	0.171 Ok
100% L01-240910	56	2	3.593e+9	12685.5			2e+0	0.3010299957	9.5554301725	1.940 Pass	7982445576.7	-537755177.7 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 Outlier	63086257877	9659981135.9 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	31529709596	5650783569.6 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	14966965453	1552951385.9 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	7982445576.7	-537755177.7 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	62121747995	8695471254.7 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	31666104861	5787178834.6 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	15021690948	1607676880.9 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	7988221963.3	-531978791.1 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	62121747995	8695471254.7 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	31666104861	5787178834.6 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	15021690948	1607676880.9 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	7988221963.3	-531978791.1 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 Outlier	62121747995	8695471254.7 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	31666104861	5787178834.6 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	15021690948	1607676880.9 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 Outlier	7988221963.3	-531978791.1 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

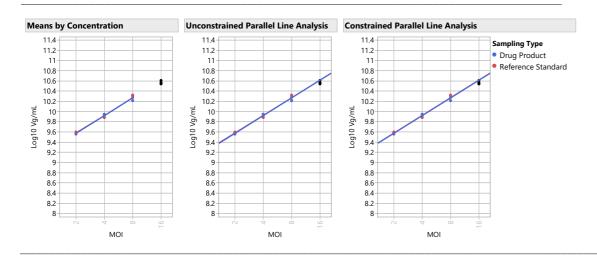
100% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	16.614	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed Validity Criteria	

5650 D (5050 T .	RI	D (Relative Infectivity	Assay RI	Assay RI	Upper	Lower	61.5	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
		Rela	ntive								
Unconstrained	RI Constrained F	RI Infectivity D	elta								
99	.0 99.	0	0.0								
Infactious	Infectious Particl	o Infactious B	articla								
illiectious	illiectious Faitici	e illiectious r	article								
Particle Ratio	Ratio Lower Lim	it Ratio Uppe	r Limit								
0.4	0.	2	1.0								

50% L01-240910 & Reference Standard Data

				Accepted	Std					First Outlier	Analytical	Analytical 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 Check	Error Upper	Error Lower 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 Pass	42798630466	-10627646275 Pass	0.774 Ok
50% L01-240910	14	2	1.130e+10	20631	235053015.22	2.0794349286	8e+0	0.903089987	10.053220492	1.811 Pass	22301813324	-3577112702 Pass	2.405 Ok
50% L01-240910	15	2	5.246e+9	20620.5	325698869.5	6.2090657061	4e+0	0.6020599913	9.7197899954	1.597 Pass	11188841923	-2225172145 Pass	1.111 Ok
50% L01-240910	16	2	2.863e+9	20059	133535135.16	4.6637199832	2e+0	0.3010299957	9.4568630835	1.884 Pass	6729036381.8	-1791164373 Pass	1.449 Ok
50% L01-240910	17	2	1.555e+10	19717.5	489935793.6	3.1497867731	1.6e+1	1.2041199827	10.191858014	0.362 Pass	42798630466	-10627646275 Pass	-0.509 Ok
50% L01-240910	18	2	8.920e+9	19954.5	145520323.79	1.6314329748	8e+0	0.903089987	9.9503544163	0.322 Pass	22301813324	-3577112702 Pass	0.193 Ok
50% L01-240910	19	2	4.446e+9	20536.5	22592759.573	0.5081526529	4e+0	0.6020599913	9.6479750835	0.060 Pass	11188841923	-2225172145 Pass	-0.317 Ok
50% L01-240910	20	2	2.457e+9	20746.5	3583547.517	0.1458313452	2e+0	0.3010299957	9.3904622856	0.042 Pass	6729036381.8	-1791164373 Pass	0.054 Ok
50% L01-240910	21	2	1.433e+10	18854	691328511.13	4.8227318281	1.6e+1	1.2041199827	10.156391355	1.395 Pass	42798630466	-10627646275 Pass	-1.258 Ok
50% L01-240910	22	2	7.986e+9	19410.5	272371628.48	3.410460901	8e+0	0.903089987	9.9023487925	1.109 Pass	22301813324	-3577112702 Pass	-0.754 Ok
50% L01-240910	23	2	3.792e+9	19610	17206271.137	0.4537112028	4e+0	0.6020599913	9.5789072595	1.376 Pass	11188841923	-2225172145 Pass	-1.750 Ok
50% L01-240910	24	2	2.165e+9	19152	13728570.717	0.6341816577	2e+0	0.3010299957	9.3354116483	1.275 Pass	6729036381.8	-1791164373 Pass	-1.084 Ok
50% L01-240910	61	2	1.807e+10	18507	67065519.327	0.371135865	1.6e+1	1.2041199827	10.256966367	1.682 Pass	42798630466	-10627646275 Pass	0.824 Ok
50% L01-240910	62	2	1.102e+10	19613.5	190120617.32	1.7258574881	8e+0	0.903089987	10.042024285	1.415 Pass	22301813324	-3577112702 Pass	2.129 Ok
50% L01-240910	63	2	5.159e+9	19546	199264473.2	3.8622715539	4e+0	0.6020599913	9.7125870699	1.342 Pass	11188841923	-2225172145 Pass	0.963 Ok
50% L01-240910	64	2	2.761e+9	19386.5	142914635.79	5.1765314071	2e+0	0.3010299957	9.4410378536	1.207 Pass	6729036381.8	-1791164373 Pass	1.102 Ok
50% L01-240910	65	2	1.586e+10	19528	426059891.54	2.6857978728	1.6e+1	1.2041199827	10.200397327	0.150 Pass	42798630466	-10627646275 Pass	-0.334 Ok
50% L01-240910	66	2	9.172e+9	19640	381089296.09	4.1548290727	8e+0	0.903089987	9.9624735888	0.137 Pass	22301813324	-3577112702 Pass	0.432 Ok
50% L01-240910	67	2	4.472e+9	20154	205743731.17	4.6005207441	4e+0	0.6020599913	9.6505196182	0.016 Pass	11188841923	-2225172145 Pass	-0.267 Ok
50% L01-240910	68	2	2.420e+9	19772	116728454.59	4.8244854223	2e+0	0.3010299957	9.3837257373	0.180 Pass	6729036381.8	-1791164373 Pass	-0.083 Ok
50% L01-240910	69	2	1.472e+10	19282.5	392975759.31	2.6697350163	1.6e+1	1.2041199827	10.167897604	1.011 Pass	42798630466	-10627646275 Pass	-1.010 Ok
50% L01-240910	70	2	7.776e+9	19753.5	311276312.65	4.0030128902	8e+0	0.903089987	9.8907590846	1.336 Pass	22301813324	-3577112702 Pass	-0.989 Ok
50% L01-240910	71	2	3.776e+9	19467	89472972.022	2.3697464095	4e+0	0.6020599913	9.5769899896	1.423 Pass	11188841923	-2225172145 Pass	-1.793 Ok
50% L01-240910	72	2	2.148e+9	19516	136835293.16	6.3705683843	2e+0	0.3010299957	9.332019945	1.372 Pass	6729036381.8	-1791164373 Pass	-1.157 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	62121747995	8695471254.7 Pass	-0.929 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	31666104861	5787178834.6 Pass	-0.820 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	15021690948	1607676880.9 Pass	-0.705 Ok
Ref.Std (L01-240910)	4	2	3.761e+9	19680.5	94431706.818			0.3010299957		0.366 Pass	7988221963.3	-531978791.1 Pass	-0.260 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	62121747995	8695471254.7 Pass	-0.525 Ok
Ref.Std (L01-240910)	6	2	1.892e+10		282808622.15		8e+0	0.903089987	10.276827009	0.083 Pass	31666104861	5787178834.6 Pass	0.534 Ok
Ref.Std (L01-240910)	7	2	8.450e+9		81272179.859	0.96178488	4e+0	0.6020599913		0.243 Pass			0.162 Ok
Ref.Std (L01-240910)	8	2	3.695e+9		10054551.433			0.3010299957		1.157 Pass		-531978791.1 Pass	-0.428 Ok
Ref.Std (L01-240910)	9	2	4.060e+10		2841771707.6			1.2041199827		4.985 Outlier		8695471254.7 Pass	0.581 Ok
Ref.Std (L01-240910)	10	2	2.104e+10		443443222.92		8e+0	0.903089987	10.3230886	1.823 Pass		5787178834.6 Pass	1.516 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066		1.2784101859		0.6020599913	9.9463114	1.397 Pass		1607676880.9 Pass	0.556 Ok
Ref.Std (L01-240910)	12	2	3.968e+9		132165288.52			0.3010299957		5.157 Outlier		-531978791.1 Pass	0.247 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

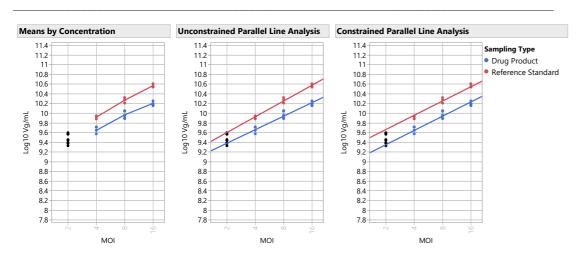
50% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	3	3.7e+10	3.08e+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	0.857	5.929	0.968	0.055	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 3, High Standard and Test Doses Excluded	0.837	3.546	0.968	0.055	Parallel and Linear	
Model 1, All Doses	0.833	1.642	0.982	0.052	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.888	2.902	0.981	0.056	Parallel and Linear	
Model 7, Test High Dose Only Excluded	0.870	0.047	0.982	0.053	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.851	1.647	0.981	0.054	Parallel and Linear	
Model 6, Test Low Dose Only Excluded	0.840	4.355	0.974	0.052	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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.614	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.857	Passed Validity Criteria	
Linearity Ratio		26.3	5.929	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.614	Passed Validity Criteria	
Number of Wells that Failed Accepted Droplets (<10000)		5	0.000	Passed 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
4.89	10.23	47.8	0	0	47.8	51.2	44.5	150	50	6.7	6.7 Bioassay Results are Reportable Assay is Valid and O
		Rela	itive								
Jnconstrained F	RI Constrained F	RI Infectivity D	elta								
49.	4 47.	8	1.6								
Infectious	Infectious Particl	e Infectious P	article								
miccious											
	Ratio Lower Lim	it Ratio Uppe	r Limit								

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	First Outlier Jackknife z Within Group Check	Analytical Error Upper	Analytical Outlier Error Lower 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	1.2041199827		0.616 Pass	69807338810	16381062070 Pass	0.128 Ok
150% L01-240910	26	2	2.527e+10	19744	642816777.6	2.5434988531	8e+0	0.903089987	10.402655657	1.547 Pass	36675079467	10796153441 Pass	1.459 Ok
150% L01-240910	27	2	1.199e+10	19708.5	370403067.43	3.0902382741	4e+0	0.6020599913	10.078682607	0.931 Pass	18299766051	4885751984.1 Pass	-0.464 Ok
150% L01-240910	28	2	7.037e+9	20511	40166095.497	0.5707730578	2e+0	0.3010299957	9.8473961516	0.738 Pass	11113846219	2593645464.8 Pass	0.975 Ok
150% L01-240910	29	2	4.278e+10	19064	380998669.04	0.8906886483	1.6e+1	1.2041199827	10.631197541	0.857 Pass	69807338810	16381062070 Pass	-0.076 Ok
150% L01-240910	30	2	2.291e+10	19624.5	1437202301	6.2733021375	8e+0	0.903089987	10.360021699	0.714 Pass	36675079467	10796153441 Pass	-0.089 Ok
150% L01-240910	31	2	1.109e+10	20716	889172320.19	8.0163895138	4e+0	0.6020599913	10.045007123	1.258 Pass	18299766051	4885751984.1 Pass	-1.725 Ok
150% L01-240910	32	2	6.959e+9	19792	77086896.492	1.1077457191	2e+0	0.3010299957	9.842540481	0.408 Pass	11113846219	2593645464.8 Pass	0.791 Ok
150% L01-240910	33	2	4.239e+10	18382	931314530.59	2.1969287211	1.6e+1	1.2041199827	10.627280412	2.957 Pass	69807338810	16381062070 Pass	-0.219 Ok
150% L01-240910	34	2	2.265e+10	19918.5	228694495.38	1.0098965802	8e+0	0.903089987	10.35497881	0.982 Pass	36675079467	10796153441 Pass	-0.267 Ok
150% L01-240910	35	2	1.125e+10	20499	114153032.32	1.0149997396	4e+0	0.6020599913	10.051021522	0.803 Pass	18299766051	4885751984.1 Pass	-1.486 Ok
150% L01-240910	36	2	6.474e+9	19781.5	69066883.248	1.0668379646	2e+0	0.3010299957	9.8111713961	1.929 Pass	11113846219	2593645464.8 Pass	-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 Pass	69807338810	16381062070 Pass	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 Pass	36675079467	10796153441 Pass	1.638 Ok
150% L01-240910	75	2	1.238e+10	20354	532896929.11	4.304486152	4e+0	0.6020599913	10.092721903	2.756 Pass	18299766051	4885751984.1 Pass	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 Pass	11113846219	2593645464.8 Pass	0.784 Ok
150% L01-240910	77	2	4.315e+10	20507.5	567354794.46	1.3147474299	1.6e+1	1.2041199827	10.635012399	0.148 Pass	69807338810	16381062070 Pass	0.063 Ok
150% L01-240910	78	2	2.312e+10	20364	1420489654.8	6.1439823415	8e+0	0.903089987	10.363988116	0.520 Pass	36675079467	10796153441 Pass	0.050 Ok
150% L01-240910	79	2	1.135e+10	21188.5	621413242.94	5.4769542447	4e+0	0.6020599913	10.054841391	0.555 Pass	18299766051	4885751984.1 Pass	-1.339 Ok
150% L01-240910	80	2	7.162e+9	19824.5	294757875.4	4.1154812625	2e+0	0.3010299957	9.8550447888	1.393 Pass	11113846219	2593645464.8 Pass	1.271 Ok
150% L01-240910	81	2	4.346e+10	19857	175599334.22	0.4040901983	1.6e+1	1.2041199827	10.638044549	0.994 Pass	69807338810	16381062070 Pass	0.174 Ok
150% L01-240910	82	2	2.293e+10	20353	694780318.29	3.0304863146	8e+0	0.903089987	10.36033518	0.698 Pass	36675079467	10796153441 Pass	-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 Pass	18299766051	4885751984.1 Pass	-1.109 Ok
150% L01-240910	84	2	6.534e+9	19613	156104914.68	2.3889408814	2e+0	0.3010299957	9.8152111738	1.464 Pass	11113846219	2593645464.8 Pass	-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 Pass	62121747995	8695471254.7 Pass	-1.723 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	31666104861	5787178834.6 Pass	-1.510 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	15021690948	1607676880.9 Pass	-1.290 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	7988221963.3	-531978791.1 Pass	-0.468 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	62121747995	8695471254.7 Pass	-0.952 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	31666104861	5787178834.6 Pass	0.970 Ok
Ref.Std (L01-240910)	7	2	8.450e+9	18863	81272179.859	0.96178488	4e+0	0.6020599913	9.9268639631	0.243 Pass	15021690948	1607676880.9 Pass	0.292 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	7988221963.3	-531978791.1 Pass	-0.774 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	62121747995	8695471254.7 Pass	1.056 Ok
Ref.Std (L01-240910)	10	2	2.104e+10	20346	443443222.92	2.1074118715	8e+0	0.903089987	10.3230886	1.823 Pass	31666104861	5787178834.6 Pass	2.981 Ok
Ref.Std (L01-240910)	11	2	8.837e+9	20066	112974810.7	1.2784101859	4e+0	0.6020599913	9.9463114	1.397 Pass	15021690948	1607676880.9 Pass	1.011 Ok
Ref.Std (L01-240910)	12	2	3.968e+9	20399	132165288.52	3.3311430456	2e+0	0.3010299957	9.5985241259	5.157 Outlier	7988221963.3	-531978791.1 Pass	0.445 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

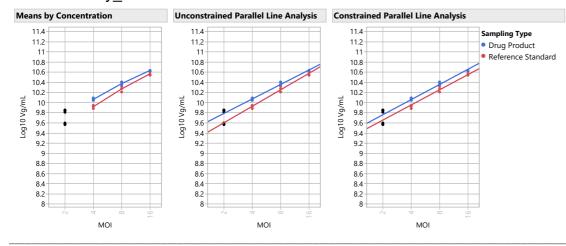
150% L01-240910 Test Sample & Reference Standard Summary Statistics

				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	3	3.7e+10	3.08e+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	0.878	4.235	0.988	0.029	Parallel and Linear	Model 2, Low Standard and Test Doses Excluded
Model 1, All Doses	0.816	0.474	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	0.860	3.392	0.994	0.028	Parallel and Linear	
Model 4, Standard Low Dose Only Excluded	0.833	1.319	0.991	0.030	Parallel and Linear	
Model 8, Standard Low Dose and Test High Dose Excluded	0.830	4.872	0.985	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	0.813	0.722	0.990	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		33329827388	Passed Validity Criteria	
% Relative Infectivity Delta (Constrained - Unconstrained)		15	1.202	Passed Validity Criteria	
Parallelism Slope Ratio	0.7	1.4	0.878	Passed Validity Criteria	
Linearity Ratio		26.3	4.235	Passed Validity Criteria	
Unconstrained EC50 Standard	0.04	61.8	16.614	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
9.41	7.38	127.6	0	0	127.6	132.5	123.0	150	50	9.5	9.5 Bioassay Results are Reportable Assay is Valid and Within Lim
	RI Constrained R	Rela I Infectivity D									
	Infectious Particle	e Infectious P									
Infectious		e Infectious P t Ratio Uppe	article								

Relative Infectivity All Samples

			Infectious			
Sample Name	EC50 Standard	EC50 Test	Ratio	Reportable RI	RI Lower 95	RI Upper 95
50% L01-240910	4.891833482	10.230553902	0.2	47.8	44.5	51.2
150% L01-240910	9.4132022136	7.3750723708	0.4	127.6	123.0	132.5
200% L01-240910	9.8001683441	6.5305000642	0.5	150.1	142.0	158.9
100% L01-240910	3.9797170781	4.0203862953	0.4	99.0	94.4	103.8
50% L01-240910	4.891833482	10.230553902	0.2	47.8	44.5	51.2
150% L01-240910	9.4132022136	7.3750723708	0.4	127.6	123.0	132.5
	Overall					

 Overall

 Sample Name
 Validity
 OOS
 Reportable

 50% L01-240910
 Assay is Valid
 OOS
 Reportable

 150% L01-240910
 Assay is Valid
 Within Limits
 Reportable

 200% L01-240910
 Assay is Valid
 Within Limits
 Reportable

 50% L01-240910
 Assay is Valid
 OOS
 Reportable

 150% L01-240910
 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				
Astends K1450 Infectivity			T DA			¥9/111L	1(1430				

Materials

Notes 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		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
` ,	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	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	BQT Infectivity		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		С	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
	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 Hamber of Flates	_		Н	6000	6000	6000	6000	6000	6000	6000	6000	6000
MOI Concentrations				0000	0000	0000	0000	0000	0000	0000	0000	0000
16												
8												
4												
2												
_									·		•	
				•								
										•	•	•
											•	

(Sample	Sample	Sample	Sample	Conc(copies/							Accepted		
				description 4 Target		Status	Experimen	nt SampleType	TargetType	Supermix	DyeName(s)	Droplets	Positives	Negative
D04 2	•	50	REP1	BDNF			DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20749	3013	1773
C04 4		50	REP1	BDNF	334.3489075		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21194	5243	159
304 8	В	50	REP1	BDNF	742.4992676	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20895	9779	111
104	16	50	REP1	BDNF	1214.964355	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19835	12773	70
104 2	2	50.2	REP1	BDNF	177.3175049	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18962	2653	163
504 4		50.2	REP1	BDNF	334.5569763		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20116	4979	151
04 8		50.2	REP1	BDNF	743.3629761		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19571	9167	104
	16	50.2	REP1	BDNF	1207.850952		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18099	11616	64
101 2		100.2	REP1	BDNF	234.0956421		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18400	3320	150
501 4		100.2	REP1	BDNF	495.1268005		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21015	7219	137
01 8 01 1	16	100.2	REP1	BDNF	1095.296021		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19345	11720	76 24
007 2		100.2 150	REP1	BDNF BDNF	2365.355713 467.249176	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18004 20209	15593 6624	135
207 4		150	REP1	BDNF			DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19118	9280	98
307 8		150	REP1	BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19667	14848	48
A07 1	16	150	REP1	BDNF	2955.455811	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19804	18198	16
107 2	2	150.2	REP1	BDNF	459.212616	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19640	6347	132
307 4	4	150.2	REP1	BDNF	800.2147217	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20921	10324	105
07 8	3	150.2	REP1	BDNF	1710.758911	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19375	14849	45
07 1	16	150.2	REP1	BDNF	2889.464111	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20729	18951	17
010 2	2	200	REP1	BDNF	708.2276611	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20076	9080	109
210 4		200	REP1	BDNF	977.4855957		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20357	11488	88
310 8		200	REP1	BDNF	2041.050293		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18286	15060	32
10 1		200 pc	REP1	BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18450	17616	164
001 2		RS RS	REP1	BDNF	246.2785187 499.5166321		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20320 20800	3838 7196	164 136
01 4 301 8		RS RS	REP1	BDNF BDNF	1059.626343		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19198	11398	78
A01 1		RS	REP1	BDNF	2283.812012		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20296	17383	78 29
005 2		50	REP2	BDNF	163.9904785		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20805	2707	180
05 4		50	REP2	BDNF	295.3388062		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21184	4703	164
305 8	3	50	REP2	BDNF	601.5122681		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19579	7837	117
A05 1	16	50	REP2	BDNF	1060.067139	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19902	11819	80
105 2	2	50.2	REP2	BDNF	166.8026733	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19472	2574	168
305 4	4	50.2	REP2	BDNF	307.8444214	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19376	4461	149
05 8		50.2	REP2	BDNF	629.4448242		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19293	7994	112
	16	50.2	REP2	BDNF	1077.647217		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18922	11351	75
102 2		100.2	REP2	BDNF	239.5184174		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19435	3580	158
302 4		100.2	REP2	BDNF	557.3325195		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19344	7299	120
02 8	16	100.2 100.2	REP2 REP2	BDNF BDNF	1246.139404		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18666 19275	12194 17053	64 ²
02 1		150	REP2	BDNF	2541.648682 467.5604553		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19275	6420	131
208 4		150	REP2	BDNF	697.5460205		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20687	9253	114
808		150	REP2	BDNF	1459.571045		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19260	13690	55
A08 1		150	REP2	BDNF	2833.755615		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18903	17203	17
108 2		150.2	REP2	BDNF	463.5831604		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19025	6196	128
G08 4	4	150.2	REP2	BDNF	727.1038818	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	21256	9799	114
08 8	3	150.2	REP2	BDNF	1474.371826	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20971	14982	59
	16	150.2	REP2	BDNF	2850.130615	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20645	18814	18
011 2		200	REP2	BDNF	516.6569824		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18381	6533	118
211 4		200	REP2	BDNF	885.7620239		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20155	10662	94
311 8		200	REP2	BDNF	1786.702759		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20119	15713	44
A11 1	16	200 RS	REP2 REP2	BDNF BDNF	3792.115479 246.8267822	OK	DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17904 19862	17191 3759	7 161
02 4		RS	REP2	BDNF	567.1739502		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		18334	7013	113
302 8		RS	REP2		1274.391724		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19099	12634	64
102 1		RS	REP2	BDNF	2515.170166		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19321	17043	22
006 2		50	REP3	BDNF	143.6707916		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18572	2135	164
206 4		50	REP3	BDNF	253.6337738		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18692	3625	150
306		50	REP3	BDNF	545.2636108	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19234	7134	121
106		50	REP3	BDNF	988.2422485		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18765	10664	81
106 2		50.2	REP3	BDNF	136.7447968		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18454	2025	164
506 4		50.2	REP3	BDNF	247.4911957		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18296	3471	148
-06		50.2	REP3	BDNF	533.0770874		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19094	6957	121
06 1		50.2	REP3	BDNF	999.8353271		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18628	10665	79
103 2		100.2	REP3	BDNF	250.3984985		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19743	3785	159
03 8		100.2	REP3	BDNF BDNF	1390 483887		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19272	7537	117
03 8		100.2 100.2	REP3	BDNF	1390.483887 2817.72583	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21070 18713	14608 17007	64 17
009 2		150	REP3	BDNF	434.8545532		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18540	5729	128
09 4		150	REP3	BDNF	744.3925781		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20618	9667	109
09 8		150	REP3	BDNF	1498.908447		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19636	14144	54
09 1		150	REP3	BDNF	2870.013184		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		16903	15429	14
109 2	2	150.2	REP3	BDNF	428.2732849	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	18592	5673	129
309 4	4	150.2	REP3	BDNF	757.883667	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19237	9136	101
09 8	3	150.2	REP3	BDNF	1495.671997	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21265	15301	59
09 1		150.2	REP3	BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19295	17639	16
012 2		200	REP3	BDNF	527.0714111		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18582	6710	118
12 4		200	REP3	BDNF	854.7813721		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19991	10324	96
12 8		200	REP3	BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20634	15867	47
112 1		200	REP3	BDNF	3631.812012		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19699	18800	167
003 2		RS	REP3	BDNF	270.7347107		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21059	4329	167
203 4 303 8		RS RS	REP3	BDNF	583.8165283		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20742	8114	126
	,	1/3	REP3	DUNF	1423.709229	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	i Aivi	21479	15075	64

10	11	12	Column 18	Column 19
37	41	45		
38	42	46		
39	43	47		
40	44	48		
10	11	12		
3000	3000	3000		
3000	3000	3000		
3000	3000	3000		
3000	3000	3000		
10	11	12		
6000	6000	6000		
6000	6000	6000		
6000	6000	6000		
6000	6000	6000		
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	Sample	Sample	Sample	Sample		Conc(copies/							Accepted		
	description 1			description 4					SampleType			DyeName(s)	Droplets	Positives	Negative
	16 NTC	RS	REP3		BDNF	2840.367188 No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (no dUTP)		19714 19126	17951 0	176 1912
	NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20944	0	2094
	NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		18778	0	1877
F10	PC				BDNF	1280.408691	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	18318	12149	616
	PC				BDNF	1218.153198		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		19227	12400	682
F12	PC				BDNF	1202.61377	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	17535	11226	630
	Sample	Sample	Sample	Sample		Conc(copies/							Accepted		
	description 1			description 4	Target				SampleType	TargetType		DyeName(s)	Droplets	Positives	Negative
	2	RS	REP1		BDNF	127.5908127			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19041	1957	1708
C01		RS	REP1		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18807	3738	1506
B01 A01	16	RS RS	REP1		BDNF	551.6500854 1169.609009		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19425 16931	7271 10666	1215 626
D10		200	REP1		BDNF	348.1827393			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20431	5234	1519
C10		200	REP1		BDNF	450.1703796		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20145	6405	1374
B10	8	200	REP1		BDNF	985.618042	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19405	11009	839
A10	16	200	REP1		BDNF	1667.197388	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19306	14626	468
H07		150.2	REP1		BDNF	234.1138306		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20427	3686	1674
G07 F07	8	150.2	REP1		BDNF	425.228363 847.2356567	OK	DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19787 20344	6002	1378 990
E07		150.2 150.2	REP1		BDNF	1452.476807			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19756	10443 14008	574
D07		150.2	REP1		BDNF	235.5180359		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20813	3776	1703
C07		150	REP1		BDNF	408.2714844		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20299	5952	1434
B07	8	150	REP1		BDNF	857.5824585	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19821	10259	956
A07	16	150	REP1		BDNF	1411.008789		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19095	13340	575
H01		100.2	REP1		BDNF	130.7037048		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17071	1795	1527
G01		100.2	REP1		BDNF	259.6535645			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18435	3651	1478
	16	100.2	REP1		BDNF	548.6073608 1206.892456		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		17108 18313	6376 11748	1073
	2	50.2	REP1		BDNF	95.39581299			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19811	1543	18268
G04		50.2	REP1			176.6719055		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18976	2646	16330
	8	50.2	REP1		BDNF	362.7191162		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19656	5215	1444
	16	50.2	REP1		BDNF	600.7639771		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18915	7564	1135
D04		50	REP1		BDNF	98.58995819		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19369	1557	17812
C04		50	REP1		BDNF	182.5280457		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20047	2881	1716
B04 A04		50	REP1		BDNF	382.3301392 590.5283203		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20367 19478	5651 7687	14716 1179
D02		RS	REP1				OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		17909	1777	16132
C02		RS	REP2		BDNF	279.7557678		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19392	4104	1528
B02		RS	REP2		BDNF	623.8641357			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18906	7781	11125
A02	16	RS	REP2		BDNF	1152.047852	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19079	11913	7166
D11		200	REP2		BDNF	277.4240723		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19822	4164	15658
C11		200	REP2			471.7400513		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21018	6943	14075
B11 A11		200	REP2 REP2		BDNF	902.1112671 1909.904663		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20704 18943	11087 15207	9617 3736
H08		150.2	REP2		BDNF	245.6865997		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20624	3887	16737
G08		150.2	REP2		BDNF		OK		Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21121	5996	15125
	8	150.2	REP2		BDNF	804.1484375		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19757	9783	9974
E08	16	150.2	REP2		BDNF	1451.810669	ОК	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	20370	14440	5930
D08		150	REP2			230.1463165		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20008	3555	16453
	4	150	REP2		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20745	5862	14883
B08		150	REP2			797.5358887 1434.838257		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19989	9841	10148
A08 H02		150	REP2 REP2		BDNF BDNF	No Call	CHECK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19225 5936	13547	5678 5936
G02		100.2	REP2		BDNF	276.0016174			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		18148	3795	14353
F02		100.2	REP2		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19061	7953	11108
E02	16	100.2	REP2		BDNF	1189.354614	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19625	12484	714
H05		50.2	REP2			77.89870453		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20072	1286	18786
G05		50.2	REP2		BDNF	144.2233582		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20932	2415	18517
FO5		50.2	REP2 REP2		BDNF	296.7576904 518.7389526		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19987 20134	4456	15531 12955
E05 D05	16	50.2	REP2				OK	DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20134	7179 1390	19298
C05		50	REP2		BDNF		OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19889	2362	17527
B05		50	REP2		BDNF	293.8962402		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20330	4494	15836
A05	16	50	REP2		BDNF	506.9377747	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19533	6838	12695
D03		RS	REP3		BDNF	129.1370239		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19739	2052	17687
C03		RS	REP3		BDNF	297.2339478			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19390	4329	15061
B03 A03		RS RS	REP3		BDNF	690.9505005 1286.221191		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19213 18170	8534 12081	10679
D12		200	REP3		BDNF	267.4780579		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20338	4136	16202
C12		200	REP3		BDNF	436.5787354		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19502	6046	13456
B12	8	200	REP3		BDNF	861.7636108	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)	FAM	19825	10295	9530
A12		200	REP3			1737.889526		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19827	15301	4526
H09		150.2	REP3		BDNF	221.4954987		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20634	3541	17093
G09 F09	8	150.2 150.2	REP3			388.1106567 780.5882568		DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20758 19441	5833 9428	1492 1001
	16	150.2	REP3		BDNF	1452.654907			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20419	14479	5940
D09		150.2	REP3			214.1714325		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		21023	3499	1752
C09			REP3		BDNF	377.5775146		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20380	5595	1478
B09	8	150	REP3		BDNF	760.2349854	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20201	9615	10586
A09		150	REP3		BDNF	1391.104004			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19861	13773	608
H03		100.2	REP3		BDNF	131.9998474		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19089	2026	17063
G03		100.2	REP3			298.2965698		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20133	4509	15624 11649
	16	100.2	REP3		BDNF	668.2131348 1320.705322		DQ DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		20557 18775	8908 12665	6110
H06		50.2	REP3			74.82287598		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20578	1268	1931
G06		50.2	REP3			127.9633942			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20638	2127	1851
F06	8	50.2	REP3		BDNF	251.8648376	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20413	3934	1647
E06		50.2	REP3		BDNF	481.3926086			Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19937	6695	1324
D06		50	REP3		BDNF	72.48256683		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		19732	1179	1855
C06		50	REP3		BDNF	126.0057755		DQ	Unknown	Unknown	ddPCR Supermix for Probes (No dUTP)		20528	2085	1844
B06 A06	16	50	REP3		BDNF	259.7920837 461.5315857		DQ DQ	Unknown Unknown	Unknown	ddPCR Supermix for Probes (No dUTP) ddPCR Supermix for Probes (No dUTP)		19587 18943	3881 6147	1570 1279
	NTC	50	. (61 3			No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20488	0	2048
	NTC					No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		21273	0	2127
	NTC				BDNF	No Call	CHECK		Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20600	0	20600
	PC				BDNF	1441.094727		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20444	14438	6006
	PC				BDNF	1468.046875		DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)		20465	14589	5876
	PC				BDNF	1419.062134	OK	DQ	Unknown	Unknown	ddPCR Supermix for Probes (no dUTP)	FAM	20950	14679	627