

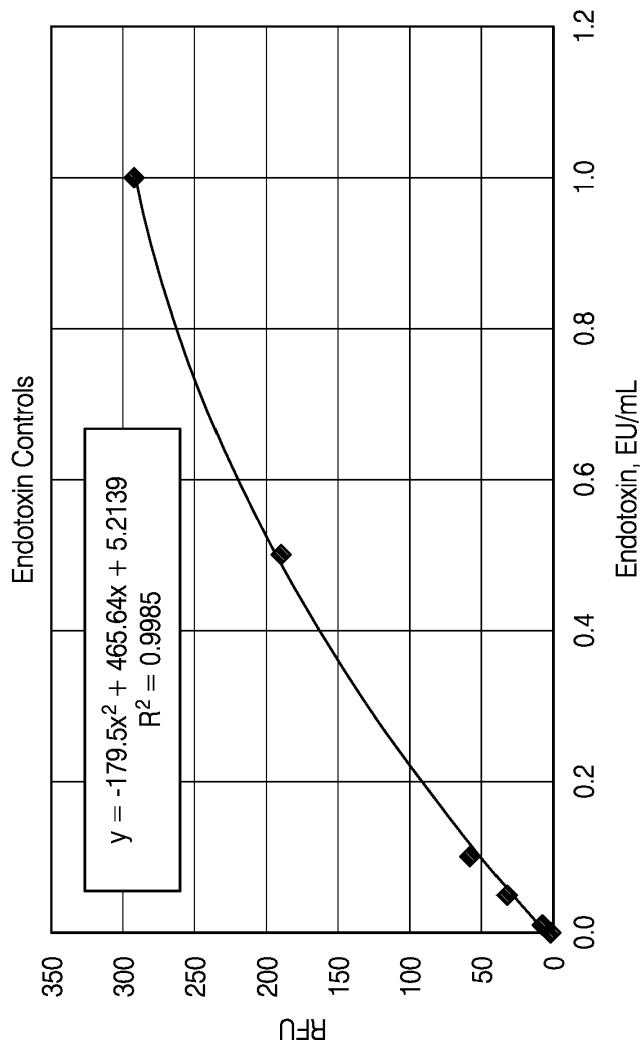


FIG. 1A

QC Test	Test Value	Target Value
RSQ	0.99997	≥0.980
Log RSQ	0.995	≥0.980
Quantitation 0.5EU/mL	1%	≤20%
Quantitation 0.05EU/mL	0%	≤20%
CV Average	12%	≤15%
Signal to Background, Assay	156.4	≥40
Signal to Background, 0.01 EU/mL	4.0	≥1.5
Z Score, 0.01EU/mL	0.57	≥0.0
Z Score, 0.005EU/mL	0.68	≥0.0

FIG. 1B

3/33

Sample, 50uL, EU/mL																
Reading	Incubation Time (min)	Raw Data														
		0	0	0.005	0.005	0.01	0.01	0.01	0.05	0.05	0.1	0.1	0.5	0.5	1	1
1	0	191	179	192	183	188	179	188	184	193	180	180	193	183	189	180
2	5	228	215	234	222	229	218	228	221	234	220	225	234	223	231	225
3	10	468	430	468	430	452	416	462	433	474	432	570	504	482	549	570
4	15	1,469	1,323	1,475	1,313	1,399	1,260	1,530	1,385	1,606	1,443	3,485	2,452	2,312	3,528	3,485
5	20	4,629	4,161	4,718	4,204	4,471	4,026	5,264	4,746	5,842	5,315	16,723	11,665	11,101	17,666	16,723
6	25	11,343	10,351	11,692	10,590	11,118	10,275	13,717	12,575	15,599	14,452	41,187	30,790	29,687	43,843	41,187
7	30	21,361	19,800	22,216	20,662	21,513	20,153	26,449	24,891	30,323	28,735	71,593	56,637	54,393	75,669	71,593
8	35	34,139	31,413	35,549	33,081	334,446	32,389	41,979	39,939	28,261	45,621	104,126	84,831	81,163	109,597	104,126
9	40	51,578	47,174	52,057	47,407	49,167	46,073	60,562	55,179	68,706	63,525	136,420	113,741	108,702	143,294	136,420
10	45	72,442	66,588	71,143	62,871	68,654	59,521	80,879	70,824	89,709	83,407	169,364	141,282	138,545	175,866	169,364

FIG. 2

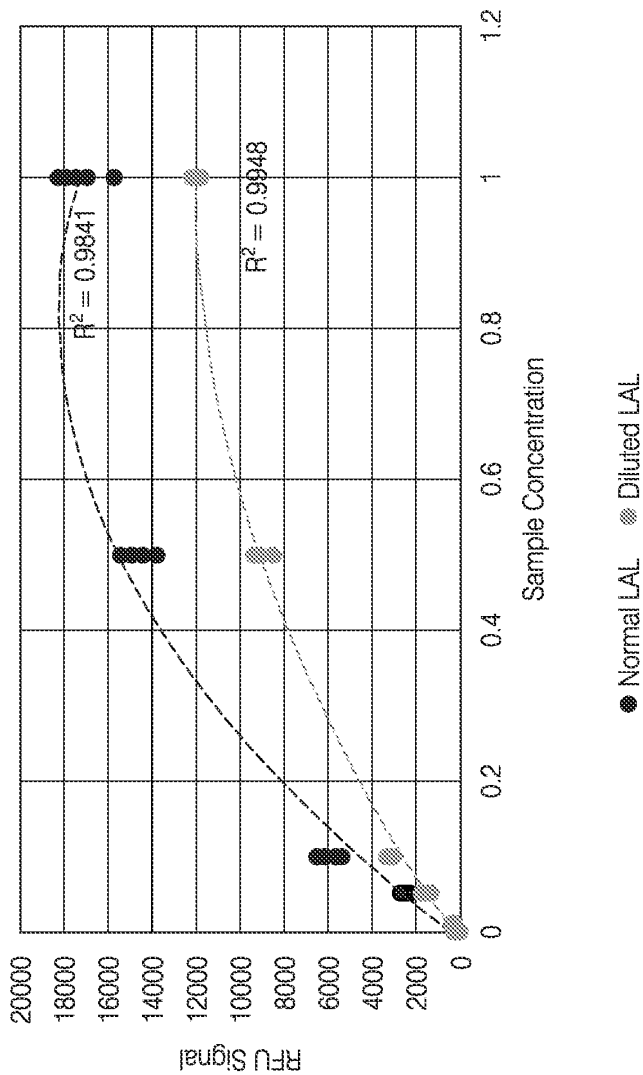


FIG. 3A

	LAL	Diluted LAL
RSQ	0.900	0.947
Log RSQ	0.931	0.986
Z-Score	0.70	0.55

FIG. 3B

50µL sample, EU/mL										
Incubation Time (min)	0	0.005	0.01	0.05	0.1	0.5	1	RSQ	RSQ	Z@0.1
0	29	28	28	29	28	28	28	0.626	#NUM!*	-32.75*
5	54	54	53	55	55	64	76	0.995	0.804*	-91.21*
10	89	90	90	98	105	212	397	0.990	0.839*	-11.18*
15	138	140	143	174	216	954	2,541	0.976	0.867*	-3.92*
20	198	207	241	315	476	3,701	9,614	.0984	0.907*	-1.82*
25	274	296	315	569	1,062	10,018	20,984	0.996	0.949*	-.036*
30	365	407	450	1,019	2,201	19,138	30,711	0.986	0.982	0.17
35	471	545	622	1,735	4,126	27,214	37,419	0.961*	0.998	0.38
40	593	716	840	2,799	7,082	33,332	42,207	0.941*	0.997	0.60
45	732	913	1,107	4,268	11,206	38,008	45,390	0.917*	0.979*	0.75
50	888	1,142	1,423	6,227	15,842	41,278	47,657	0.889*	0.955*	0.81
55	1,059	1,400	1,790	8,761	20,043	39,491	29,436	0.859*	0.935*	0.84
60	1,245	1,689	2,221	12,144	23,762	46,007	50,875	0.828*	0.919*	0.86

Incubation time, min)

FIG. 4A

Metric Target Value	Curve Quality Score, r2 0.98	Quantitation 0.5EU/mL 20%	Quantitation 0.5EU/mL 20%	CV Average 10%	Signal to Background, Assay 40	Signal to Background, 0.01 EU/mL 1.5	Z Score, 0.01EU/mL 0	Z Score, 0.005EU/mL 0
10.0	0.858*	19%	32%	3%	8	1.05	-1.18*	-1.23*
11.0	0.875*	12%	25%	3%	12	1.07	0.12	-0.75*
12.0	0.894*	6%	16%	4%	17	1.09	0.45	-0.73*
13.0	0.915*	1%	6%	4%	23	1.12	0.39	-0.69*
14.0	0.936*	6%	3%	4%	30	1.15	0.49	-0.74*
15.0	0.954*	11%	9%	4%	36	1.20	0.45	-0.67*
16.0	0.970*	14%	14%	5%	42	1.26	0.37	-0.53*
17.0	0.983	15%	16%	5%	47	1.30	0.57	-0.49*
18.0	0.992	15%	18%	5%	51	1.36	0.54	-0.41*
19.0	0.997	15%	19%	5%	54	1.44	0.60	-0.29*
20.0	0.999	14%	18%	5%	55	1.52	0.60	-0.22*
21.0	0.999	12%	17%	5%	56	1.61	0.62	-0.14*
22.0	0.998	7%	15%	5%	58	1.71	0.63	-0.09*
23.0	0.996	7%	14%	5%	58	1.80	0.64	-0.03*
24.0	0.995	4%	12%	5%	57	1.90	0.65	0.02
25.0	0.993	4%	11%	4%	55	1.99	0.67	0.06
26.0	0.991	1%	10%	4%	53	2.09	0.67	0.10
27.0	0.988	4%	9%	4%	50	2.17	0.68	0.13
28.0	0.987	2%	8%	4%	47	2.27	0.68	0.16
29.0	0.986	1%	6%	4%	44	2.33	0.69	0.20
30.0	0.983	2%	6%	4%	41	2.39	0.70	0.22
31.0	0.982	0%	6%	4%	39	2.44	0.71	0.24
32.0	0.979*	5%	8%	4%	36	2.48	0.72	0.27
33.0	0.976*	6%	9%	4%	33	2.51	0.72	0.29
34.0	0.975*	6%	8%	4%	31	2.53	0.73	0.32
35.0	0.975*	7%	6%	4%	29	2.54	0.73	0.32

Incubation time, min)

FIG. 4B

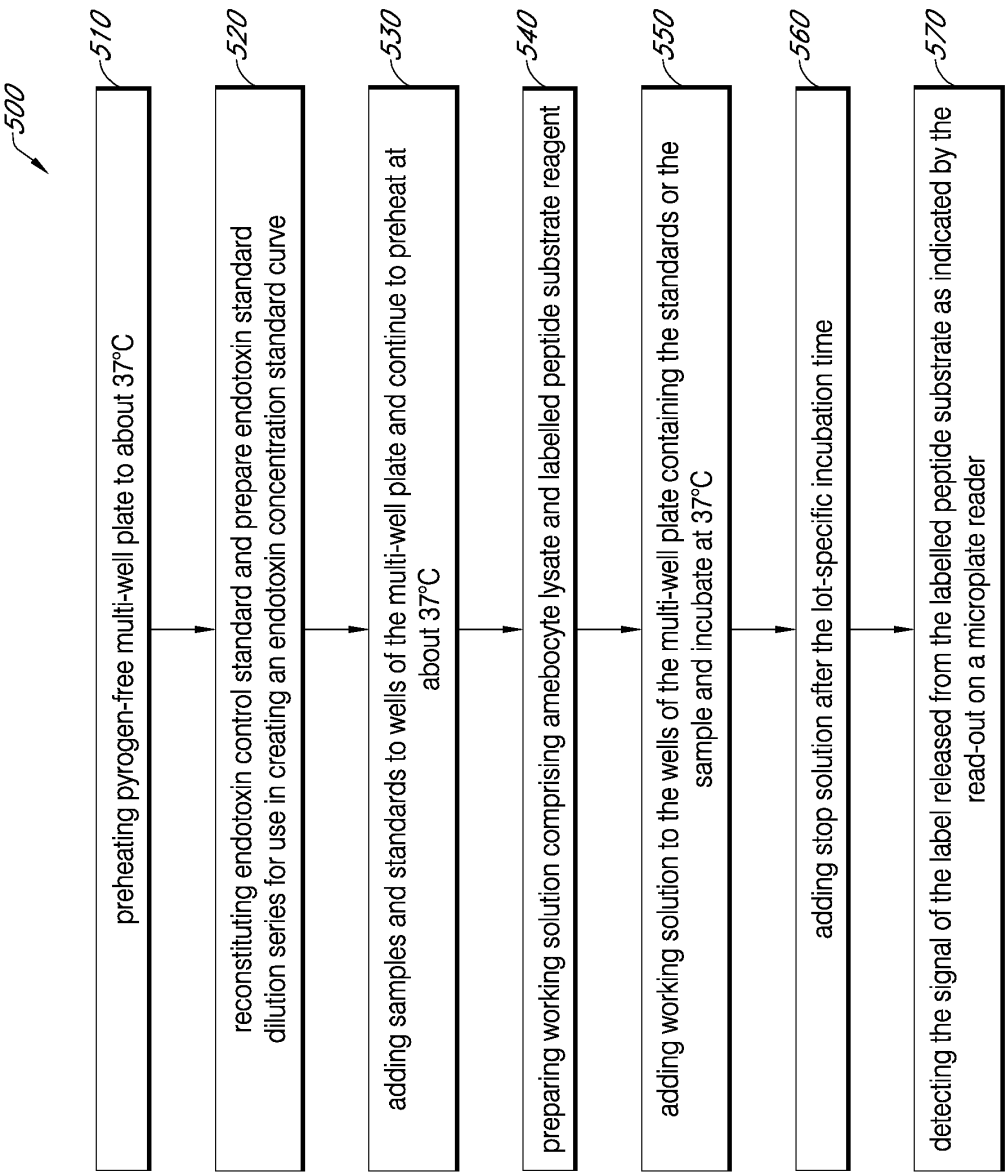


FIG. 5

T = 24min, Quant=iT

Expected EU/mL	0.01	0.05	0.1	0.5	1
Calculated EU/mL (n=6)	0.008	0.043	0.090	0.38	0.82
	0.009	0.047	0.096	0.38	1.08
	0.010	0.051	0.098	0.45	0.96
	0.011	0.049	0.108	0.42	1.06
	0.012	0.050	0.106	0.46	1.07
	0.011	0.049	0.104	0.45	1.05
Average Calculated	0.010	0.048	0.100	0.42	1.01
CV	15%	6%	7%	8%	10%
Error	1%	4%	0%	15%	1%

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r	≥0.980	0.9991	PASS
CV Average (Conc)	≤10%	9.2%	PASS
Accuracy, avg rel error	≤25%	4.2%	PASS
Z Score, 0.01EU/mL (RFU)	≥0	0.21	PASS

FIG. 6A

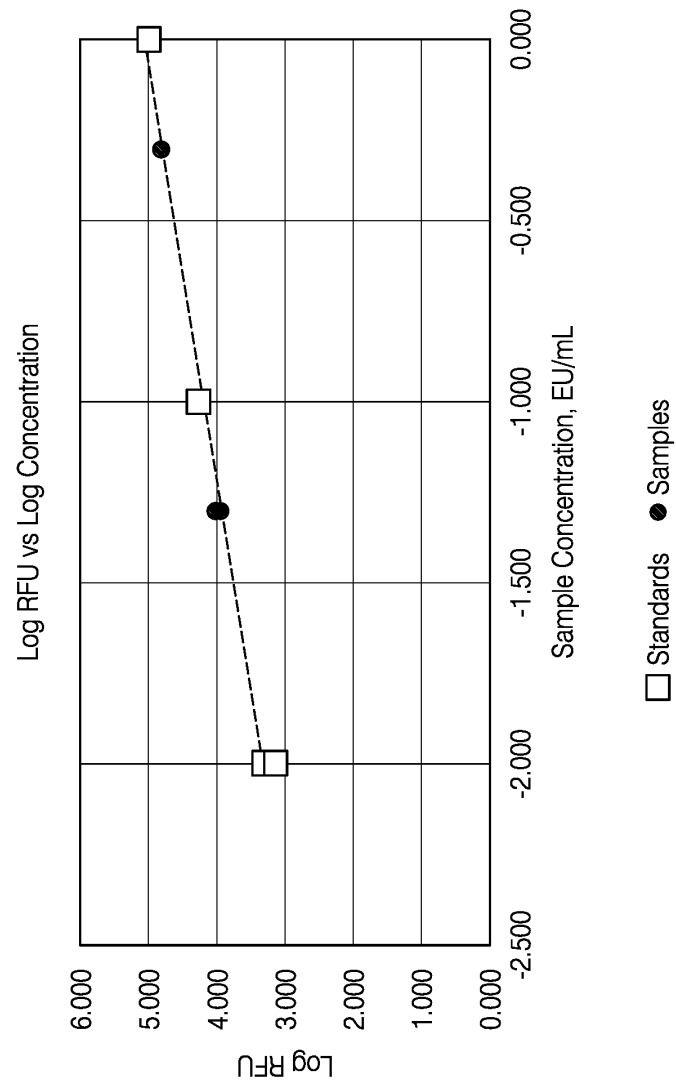


FIG. 6B

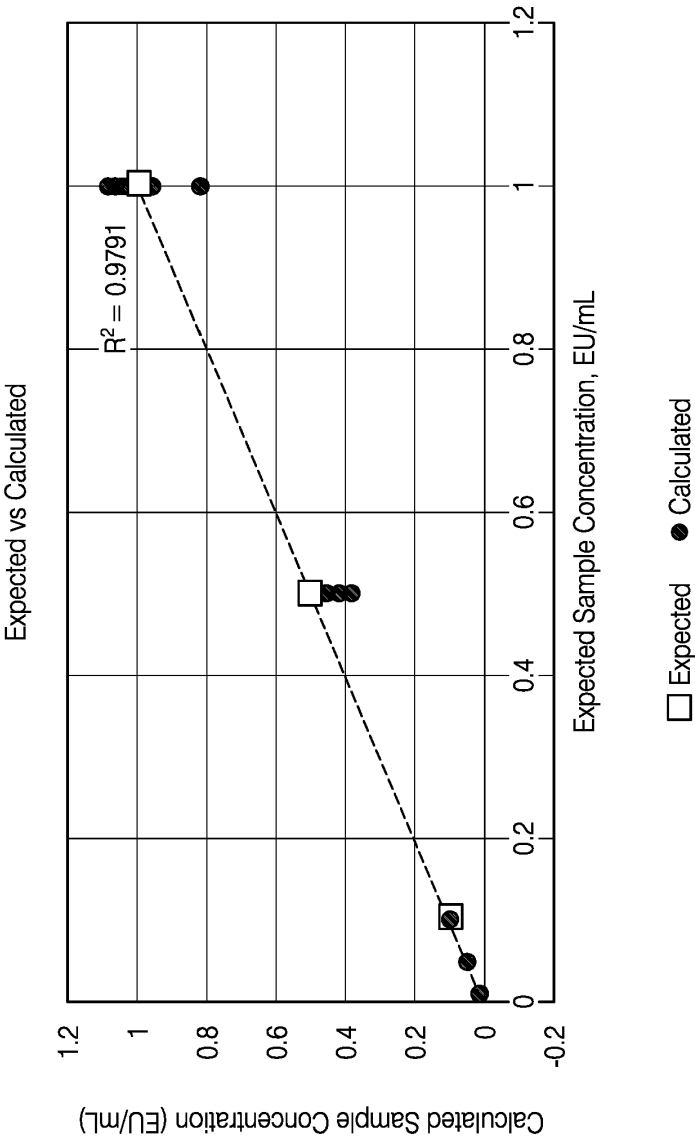


FIG. 6C

Expected EU/mL	Average Observed, EU/mL	Relative Error	Variation (CV)
0.01	0.010	2%	2%
0.05	0.047	7%	2%
0.1	0.102	2%	2%
0.5	0.563	13%	8%
1	0.918	8%	1%
Curve Quality	0.997	Agilent BIOTEK	
Z Score	0.64		

FIG. 7A

Expected EU/mL	Average Observed, EU/mL	Relative Error	Variation (CV)
0.01	0.010	3%	8%
0.05	0.043	15%	3%
0.1	0.113	13%	1%
0.5	0.534	7%	2%
1	0.940	6%	1%
Curve Quality	0.996	SPECTRAMAX	
Z Score	0.63		

FIG. 7B

Expected EU/mL	Average Observed, EU/mL	Relative Error	Variation (CV)
0.01	0.010	1%	7%
0.05	0.046	7%	5%
0.1	0.106	6%	7%
0.5	0.519	4%	3%
1	0.963	4%	3%
Curve Quality	0.998	VARIOSKAN LUX	
Z Score	0.58		

FIG. 7C

Expected EU/mL	Average Observed, EU/mL	Relative Error	Variation (CV)
0.01	0.098	2%	5%
0.05	0.045	11%	2%
0.1	0.099	1%	8%
5.0	4.96	6%	6%
10.0	10.0	10%	10%
Curve Quality	0.996	QUBIT Flex	
Z Score	0.88		

FIG. 7D

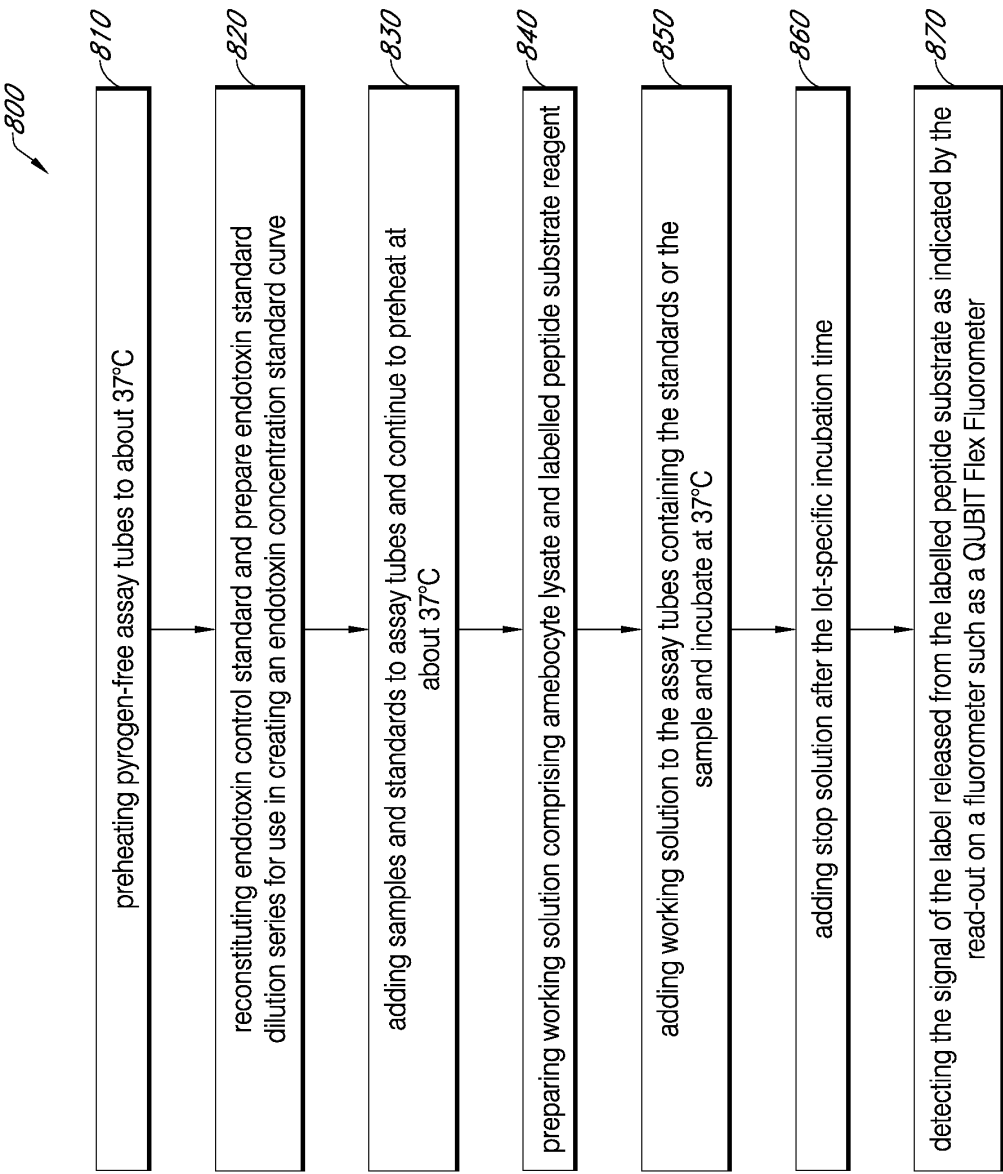


FIG. 8

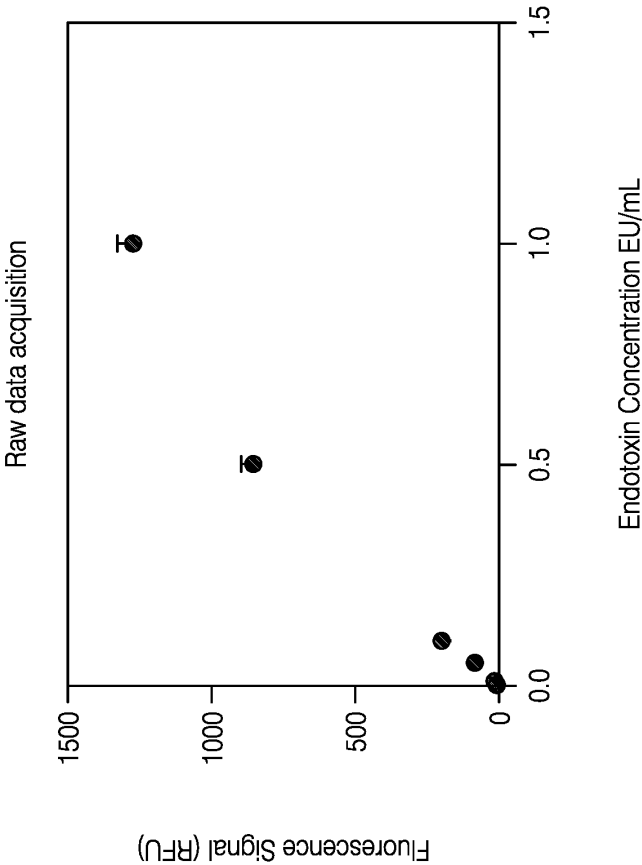


FIG. 9A

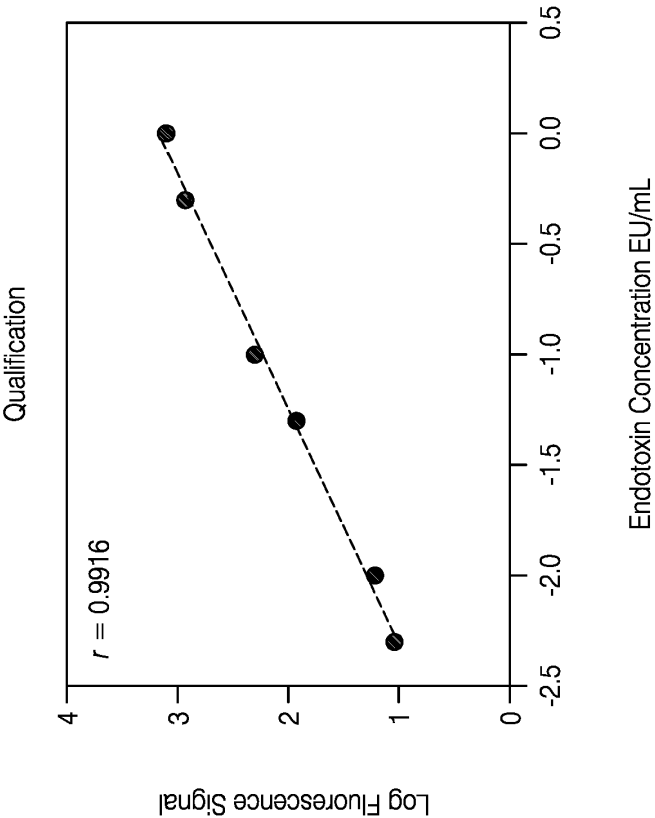


FIG. 9B

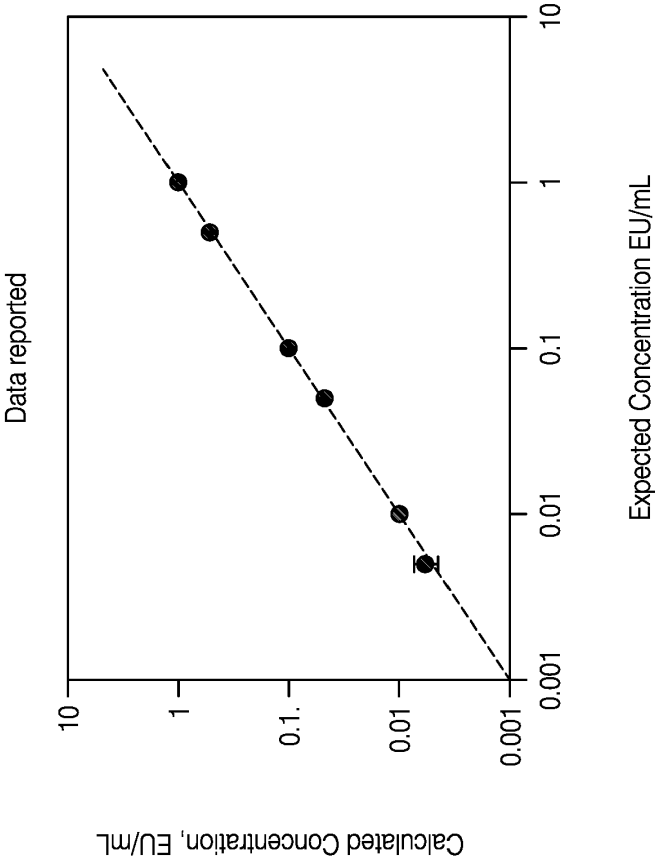


FIG. 9C

Expected EU/mL		0.010	0.050	0.100	0.500	1.00
Calculated EU/mL (n=4)		0.009	0.055	0.099	0.616	0.936
		0.010	0.049	0.103	0.540	0.919
		0.011	0.048	0.106	0.526	1.000
		0.011	0.047	0.109	0.514	1.020
Average Calculated		0.010	0.050	0.104	0.549	0.969
CV		7%	7%	4%	8%	5%
Error		4%	-1%	4%	10%	-3%

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	1.000	PASS
CV Average	≤10%	5%	PASS
Signal to Background, Assay	≥20	54	PASS
Signal to Background, 0.01	≥1.3	1.44	PASS
Z Score, 0.01EU/mL	≥0	0.61	PASS

FIG. 10A

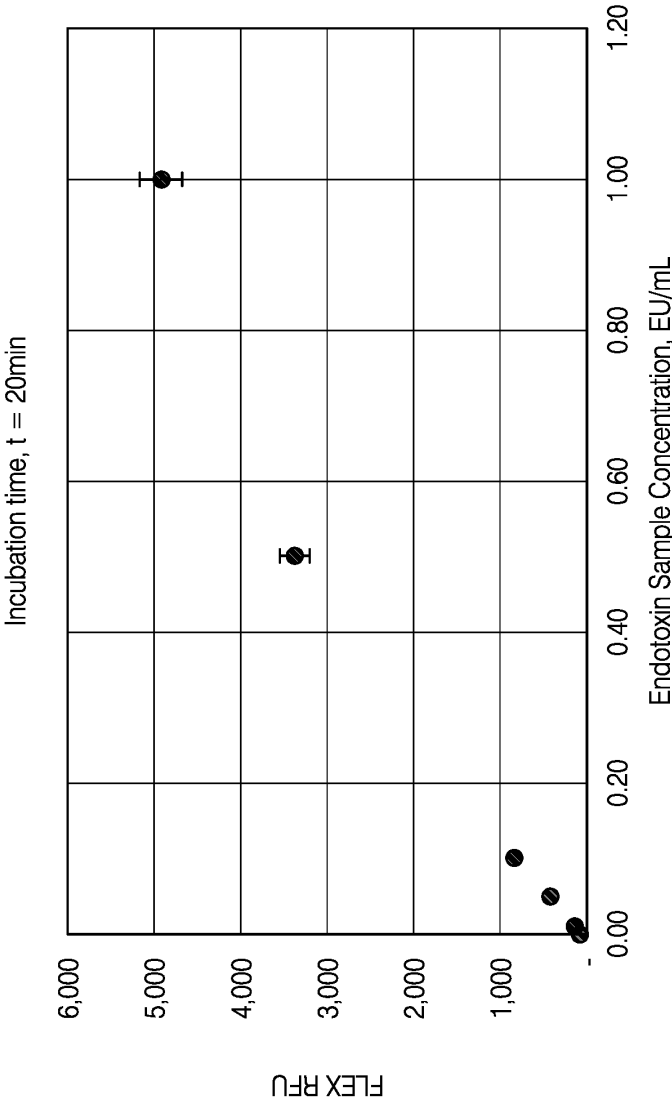


FIG. 10B

Expected EU/mL		0.10	0.50	1.00	5.00	10.0
Calculated EU/mL (n=4)		0.12	0.48	1.06	6.18	10.9
		0.11	0.47	1.08	6.11	10.8
		0.10	0.48	1.04	5.85	10.6
		0.10	0.44	1.01	5.72	10.7
Average Calculated		0.11	0.47	1.05	5.96	10.8
CV		10%	4%	3%	4%	1%
Error		8%	-6%	5%	19%	7%

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.9996	PASS
CV Average	≤10%	3%	PASS
Signal to Background, Assay	≥20	114	PASS
Signal to Background, 0.01	≥1.3	1.59	PASS
Z Score, 0.01EU/mL	≥0	0.54	PASS

FIG. 11A

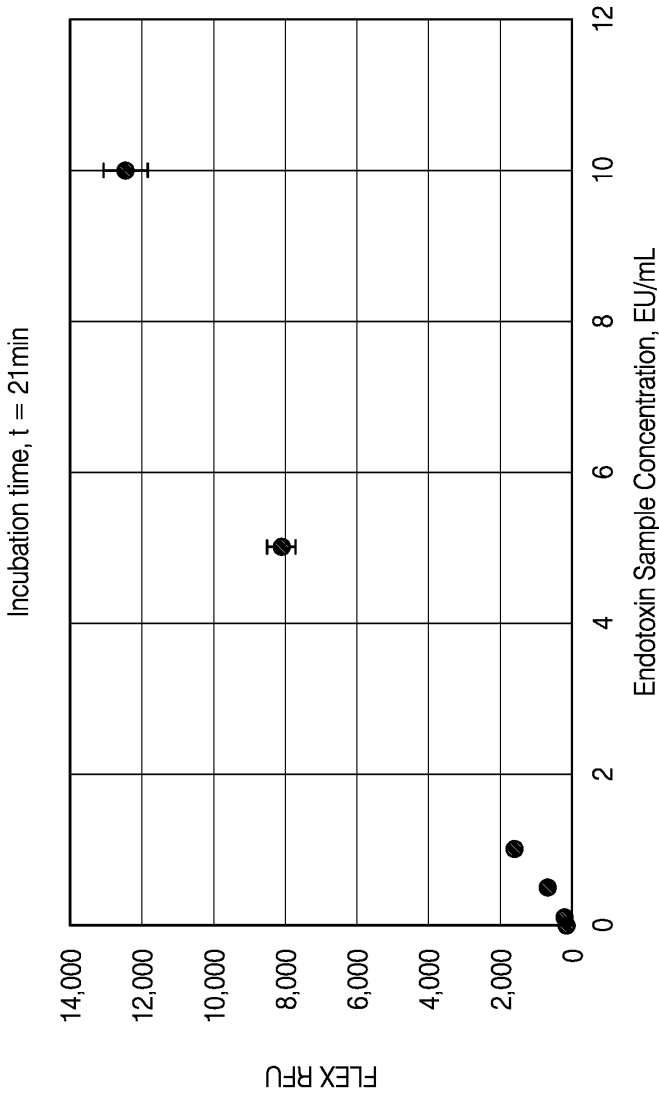


FIG. 11B

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.99998	PASS
CV Average	≤10%	5%	PASS
Signal to Background, Assay	≥20	55	PASS
Signal to Background, 0.01	≥1.3	1.43	PASS
Z Score, 0.01EU/mL	≥0	0.56	PASS

Expected EU/mL	0.010	0.050	0.100	0.500	1.00
Calculated EU/mL	0.010	0.055	0.100	0.612	0.947
	0.011	0.049	0.103	0.525	0.914
	0.011	0.047	0.105	0.512	0.992
	0.011	0.047	0.109	0.502	1.025
Average Calculated	0.011	0.049	0.104	0.538	0.970
CV	6%	7%	4%	9%	5%
Error	8%	-2%	4%	8%	-3%

User #1, Dye lot A
25 EU endotoxin control

FIG. 12A

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.99994	PASS
CV Average	≤10%	3%	PASS
Signal to Background, Assay	≥20	48	PASS
Signal to Background, 0.01	≥1.3	1.49	PASS
Z Score, 0.01EU/mL	≥0	0.57	PASS

Expected EU/mL	0.010	0.050	0.100	0.500	1.00
Calculated EU/mL	0.009	0.053	0.101	0.553	0.957
	0.010	0.051	0.098	0.527	0.940
	0.010	0.049	0.102	0.522	0.979
	0.011	0.047	0.105	0.505	1.034
Average Calculated	0.010	0.050	0.101	0.527	0.977
CV	7%	5%	3%	4%	4%
Error	0%	0%	1%	5%	-2%

User #2, Dye lot B
35 EU endotoxin control

FIG. 12B

User #1, Dye lot A
25 EU endotoxin control

Expected EU/mL	0.010	0.050	0.100	0.500	1.00
Calculated EU/mL	0.011	0.053	0.104	0.661	0.989
	0.011	0.048	0.105	0.556	0.963
	0.011	0.048	0.106	0.556	1.021
	0.013	0.046	0.109	0.543	1.025
Average Calculated	0.011	0.049	0.106	0.579	1.000
CV	7%	6%	2%	10%	3%
Error	15%	-3%	6%	16%	0%

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.99996	PASS
CV Average	≤10%	4%	PASS
Signal to Background, Assay	≥20	79	PASS
Signal to Background, 0.01	≥1.3	1.37	PASS
Z Score, 0.01EU/mL	≥0	0.19	PASS

FIG. 13A

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.9997	PASS
CV Average	≤10%	3%	PASS
Signal to Background, Assay	≥20	72	PASS
Signal to Background, 0.01	≥1.3	1.51	PASS
Z Score, 0.01EU/mL	≥0	0.58	PASS

Expected EU/mL	0.010	0.050	0.100	0.500	1.00
Calculated EU/mL	0.011	0.048	0.101	0.606	0.961
	0.009	0.047	0.119	0.588	0.962
	0.009	0.047	0.104	0.581	1.000
	0.010	0.045	0.115	0.566	1.027
Average Calculated	0.010	0.047	0.110	0.585	0.988
CV	10%	3%	8%	3%	3%
Error	-4%	-6%	10%	17%	-1%

User #2, Dye lot B
35 EU endotoxin control

FIG. 13B

LOT 1 (t=20min)		25 EU endotoxin control				
User #1, Dye lot A	Expected EU/mL	0.010	0.050	0.100	0.500	1.00
	Calculated EU/mL	0.010	0.055	0.100	0.612	0.947
		0.011	0.049	0.103	0.525	0.914
		0.011	0.047	0.105	0.512	0.992
	Average Calculated	0.011	0.047	0.109	0.502	1.025
	CV	0.011	0.049	0.104	0.538	0.970
	Error	6% 8%	7% -2%	4% 4%	9% 8%	5% -3%

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.99998	PASS
CV Average	≤10%	5%	PASS
Signal to Background, Assay	≥20	55	PASS
Signal to Background, 0.01	≥1.3	1.43	PASS
Z Score, 0.01EU/mL	≥0	0.56	PASS

FIG. 14A

LOT 2 (t=21min)		25 EU endotoxin control						
User #1, Dye lot B	Expected EU/mL	0.010	0.050	0.100	0.500	1.00		
	Calculated EU/mL	0.011	0.053	0.104	0.661	0.989		
		0.011	0.048	0.105	0.556	0.963		
		0.011	0.048	0.106	0.556	1.021		
	Average Calculated	0.013	0.046	0.109	0.543	1.025		
	CV	0.011	0.049	0.106	0.579	1.000		
	Error	7% 15%	6% -3%	2% 6%	10% 16%	3% 0%		

Assay Metric	Specification	Result	Pass/Fail
Curve Quality Score, r2	≥0.980	0.99996	PASS
CV Average	≤10%	4%	PASS
Signal to Background, Assay	≥20	79	PASS
Signal to Background, 0.01	≥1.3	1.37	PASS
Z Score, 0.01EU/mL	≥0	0.19	PASS

FIG. 14B

Lot1 (t=20min)						
Instrument Name (Avg of 4 Replicates)	Expected	0.0100	0.0500	0.100	0.500	1.000
	QUBIT-1	0.0106	0.0499	0.105	0.546	0.965
	QUBIT-2	0.0109	0.0492	0.105	0.534	0.963
	QUBIT-3	0.0109	0.0490	0.104	0.533	0.966
	QUBIT-4	0.0104	0.0497	0.104	0.549	0.969
	QUBIT-5	0.0108	0.0492	0.104	0.538	0.970
AVG	0.0107	0.0494	0.104	0.540	0.966	
Error	7%	-1%	4%	8%	-3%	
CV	2%	1%	0%	1%	0%	

FIG. 15A

Lot2 (t=21min)								
Instrument Name (Avg of 4 Replicates)	Expected	0.0100	0.0500	0.100	0.500	1.000		
	QUBIT-1	0.0113	0.0493	0.106	0.583	0.994		
	QUBIT-2	0.0115	0.0486	0.107	0.570	0.985		
	QUBIT-3	0.0115	0.0484	0.106	0.571	0.986		
	QUBIT-4	0.0111	0.0490	0.106	0.585	0.988		
	QUBIT-5	0.0115	0.0487	0.106	0.579	1.000		
AVG		0.0114	0.0488	0.106	0.577	0.990		
Error		14%	-2%	6%	15%	-1%		
CV		2%	1%	0%	1%	1%		

FIG. 15B

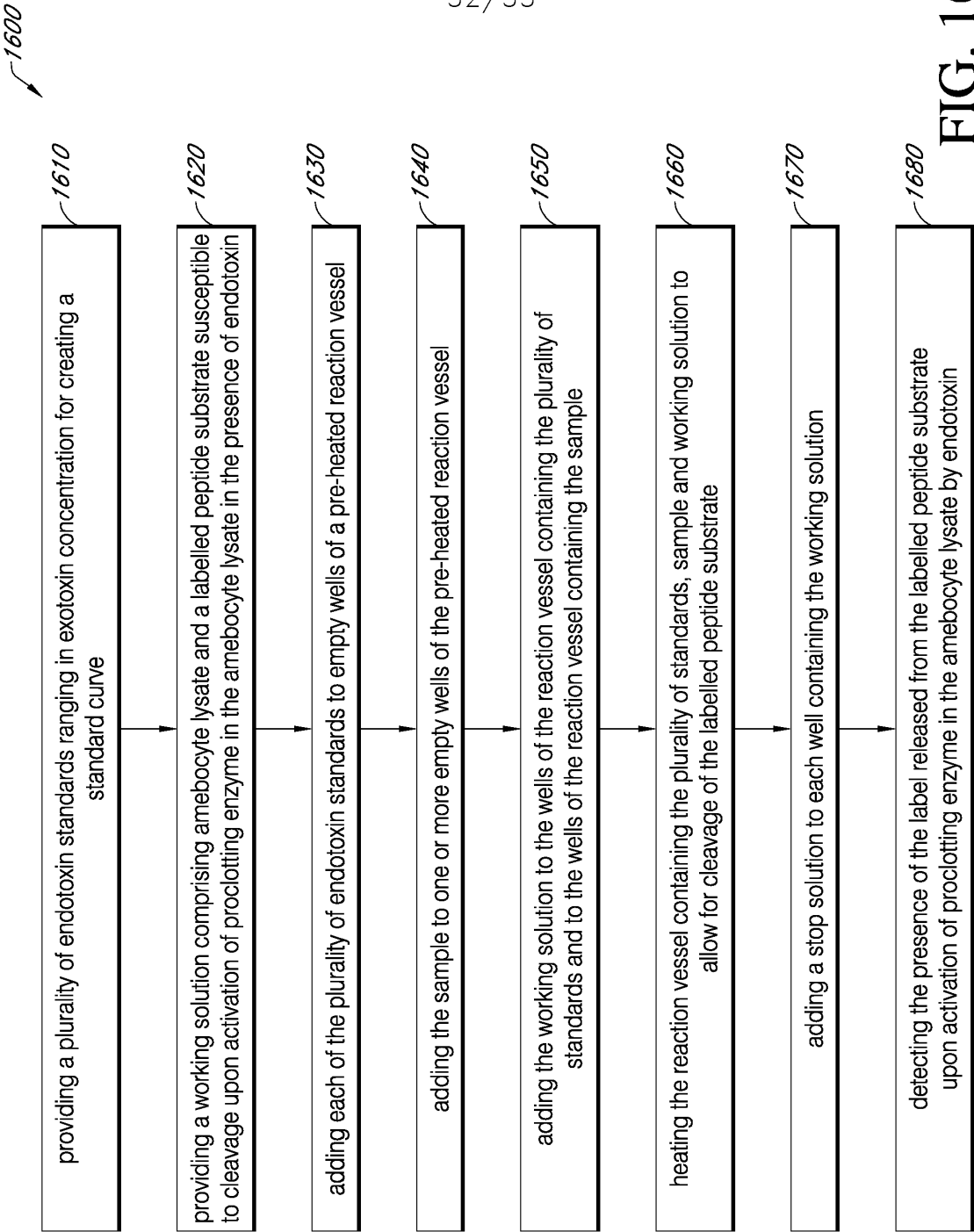


FIG. 16

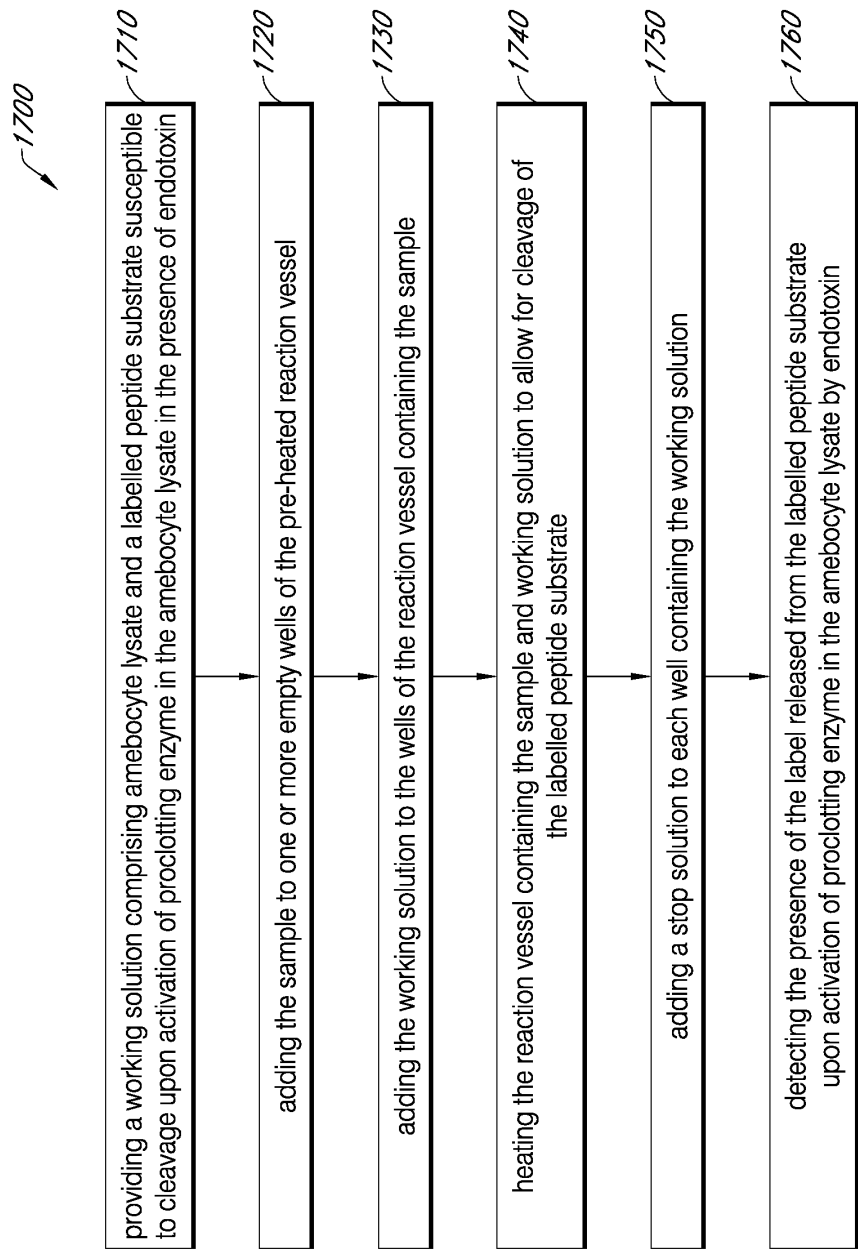


FIG. 17