

FIG. 1A

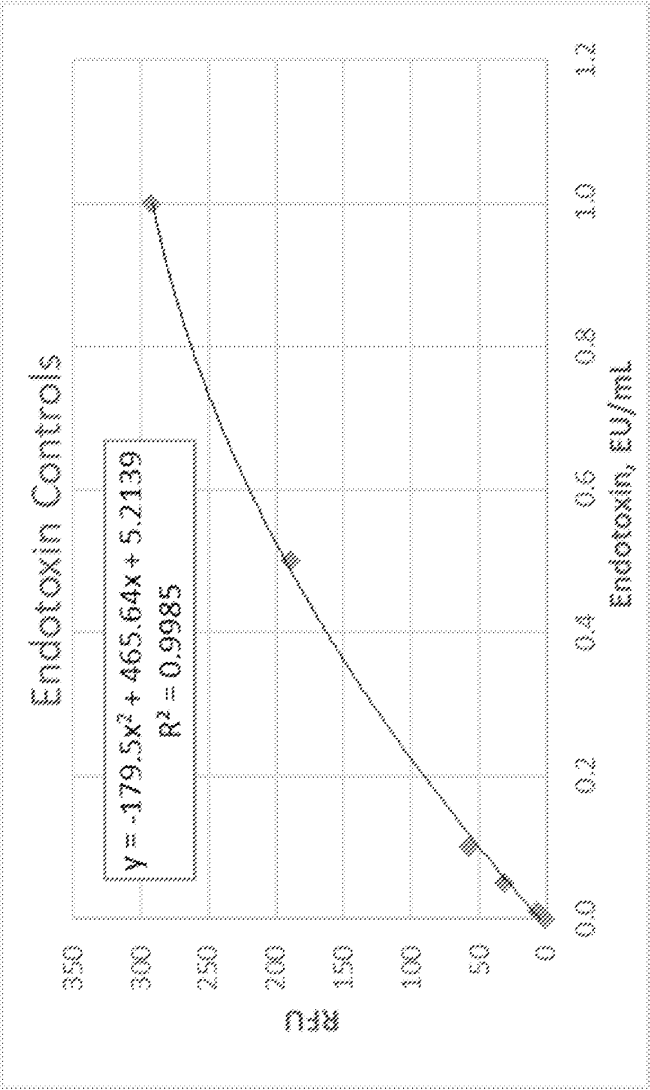


FIG. 1B

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. 2

Sample, 50uL, EU/mL																			
Incubation Reading Time (min)		0	0	0.005	0.005	0.01	0.01	0.05	0.05	0.1	0.1	0.5	0.5	1	1	RSQ	Log RSQ	Z	
1	0	191	179	192	183	188	179	188	184	193	180	193	183	189	180	0.000	0.019	-28.70	
2	5	228	215	234	222	229	218	228	221	234	220	234	223	231	225	0.056	0.114	-24.46	
3	10	468	430	468	430	452	416	462	433	474	432	504	482	549	570	0.840	0.726	-9.47	
4	15	1,469	1,323	1,475	1,313	1,399	1,260	1,530	1,385	1,606	1,443	2,452	2,312	3,528	3,485	0.989	0.839	-8.09	
5	20	4,629	4,161	4,718	4,204	4,471	4,036	5,264	4,746	5,842	5,315	11,665	11,101	17,666	16,723	0.993	0.892	-12.22	
6	25	11,343	10,351	11,692	10,590	11,118	10,275	13,717	12,575	15,599	14,452	30,790	29,687	43,843	41,187	0.985	0.923	-24.86	
7	30	21,361	19,800	22,216	20,662	21,513	20,153	26,449	24,691	30,323	28,735	56,637	54,393	75,699	71,593	0.975	0.938	-23.54	
8	35	34,139	31,413	35,549	33,081	34,446	32,389	41,979	39,939	48,261	45,621	84,831	81,163	109,597	104,126	0.968	0.944	-14.82	
9	40	51,578	47,174	52,057	47,407	49,167	46,073	60,562	55,179	68,706	63,525	113,741	108,702	143,294	136,420	0.963	0.946	-8.06	
10	45	72,442	66,588	71,143	62,871	68,654	59,521	80,879	70,824	89,709	83,407	141,282	138,545	175,866	169,364	0.958	0.936	-4.86	

FIG. 3A

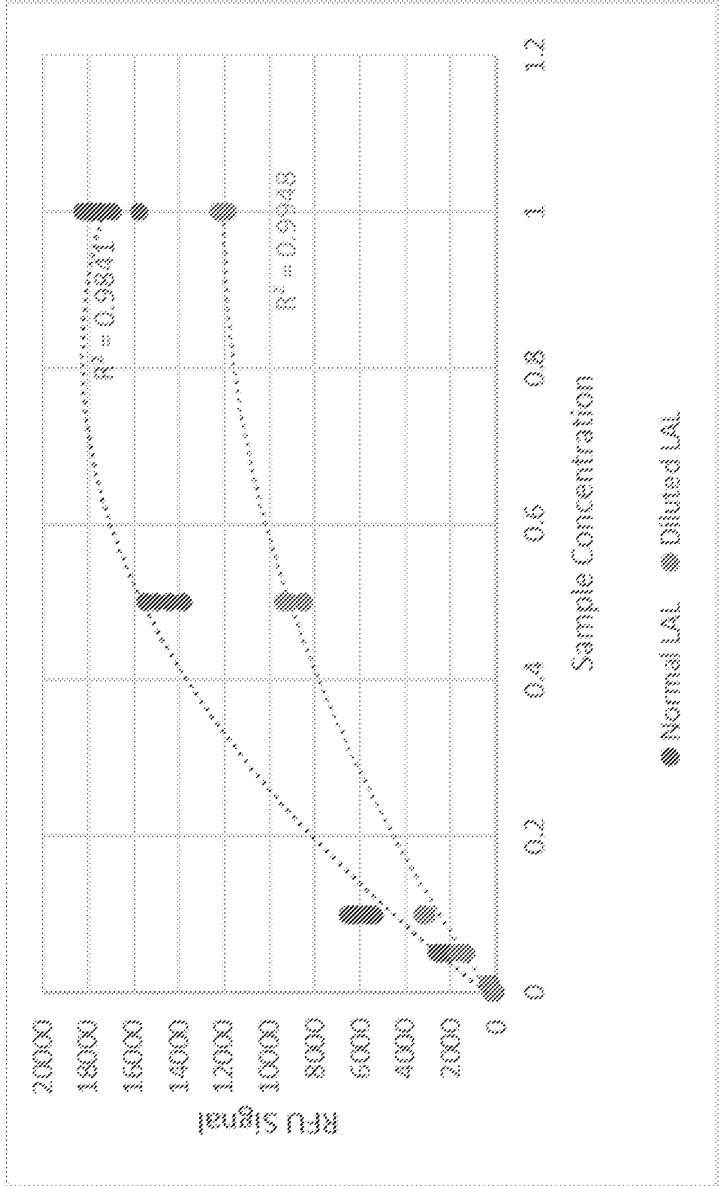


FIG. 3B

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

FIG. 4A

50 µL sample, EU/mL

Incubation time, min)	Incubation Time	0	0.005	0.01	0.05	0.1	0.5	1	RSQ	RSQ #NUM!	Z@.01
0	0	29	28	28	29	28	28	28	0.626*	-32.75*	
5	5	54	54	53	55	55	64	76	0.995	0.804*	-91.21*
10	10	89	90	90	98	105	212	397	0.990	0.839*	-11.18*
15	15	138	140	143	174	216	954	2,541	0.976	0.867*	-3.92*
20	20	198	207	214	315	476	3,701	9,614	0.984	0.907*	-1.82*
25	25	274	296	315	569	1,062	10,018	20,984	0.996	0.949*	-0.36*
30	30	365	407	450	1,019	2,201	19,138	30,711	0.986	0.982	0.17
35	35	471	545	622	1,735	4,126	27,214	37,419	0.961*	0.998	0.38
40	40	593	716	840	2,799	7,082	33,332	42,207	0.941*	0.997	0.60
45	45	732	913	1,107	4,268	11,206	38,008	45,390	0.917*	0.979*	0.75
50	50	888	1,142	1,423	6,227	15,842	41,278	47,657	0.889*	0.955*	0.81
55	55	1,059	1,400	1,790	8,761	20,043	43,941	49,436	0.859*	0.935*	0.84
60	60	1,245	1,689	2,221	12,144	23,762	46,007	50,875	0.828*	0.919*	0.86

FIG. 4B

Metric	Curve Quality		Quantitation		Signal to Background			Z Score	
	Score, r2	0.5EU/mL	0.05EU/mL	CV Average	Assay	Background, 6.01 EU/mL	0.01EU/mL	0.005EU/mL	
Target Value	0.98	20%	20%	10%	40	1.5	0	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)

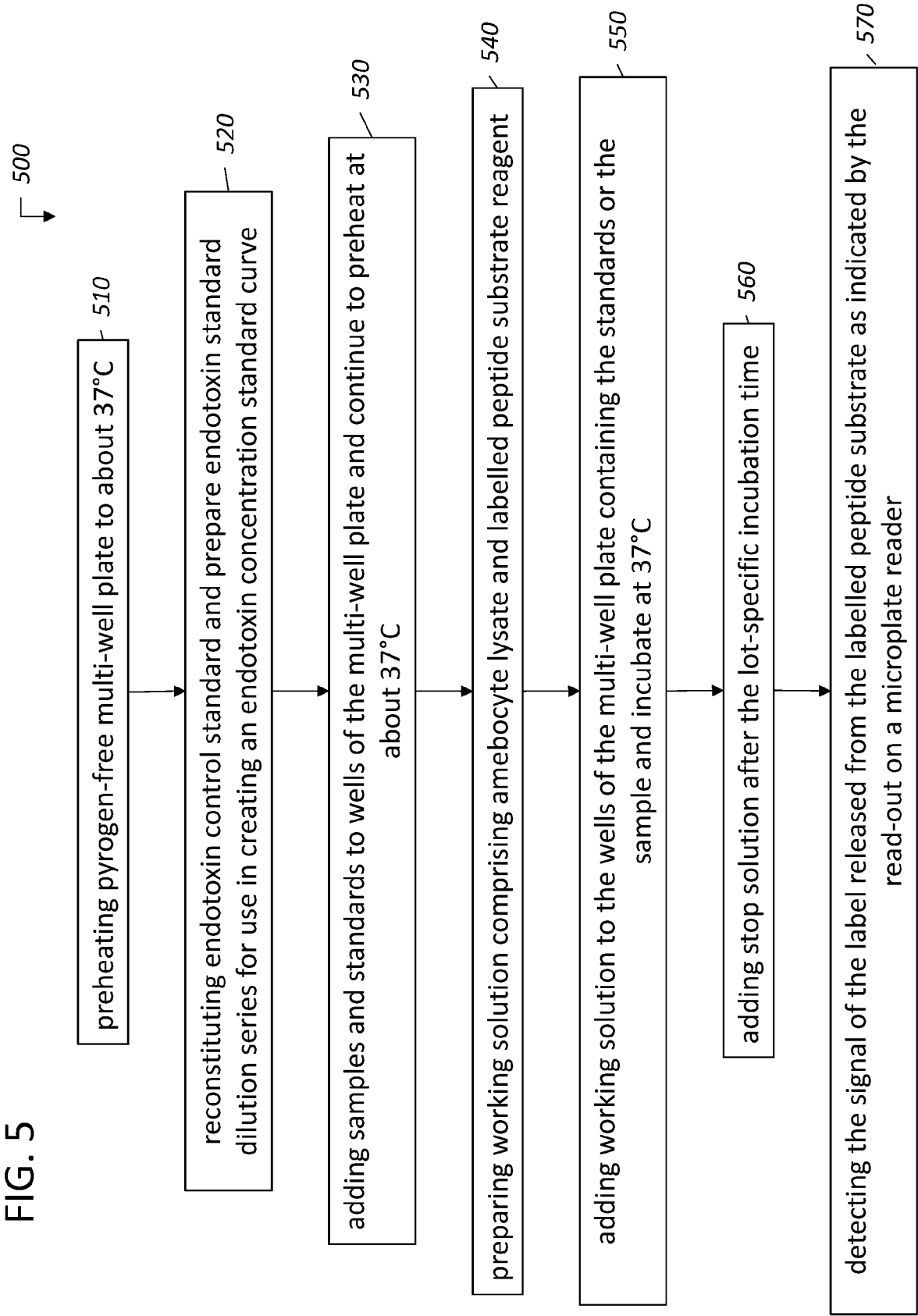


FIG. 6A

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. 6B

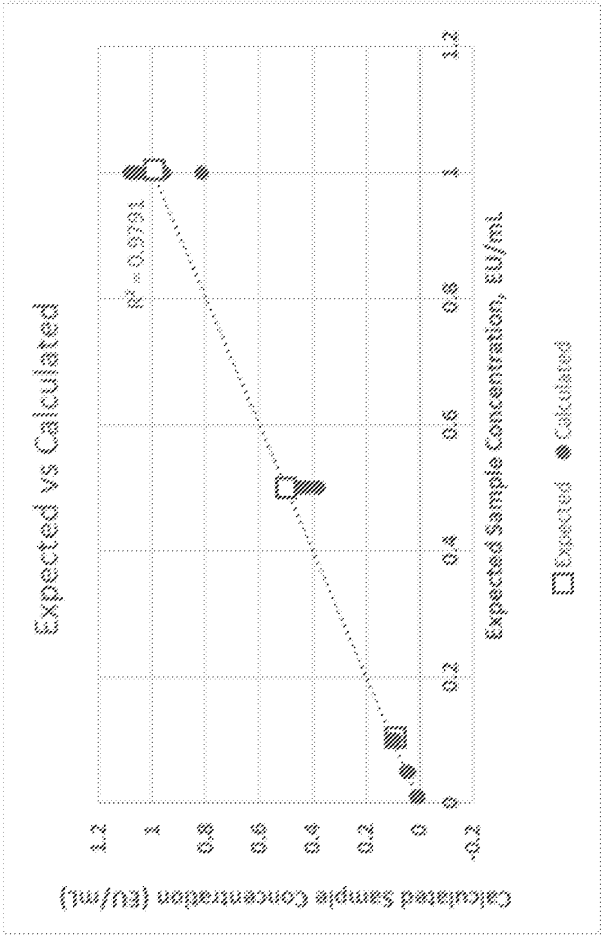
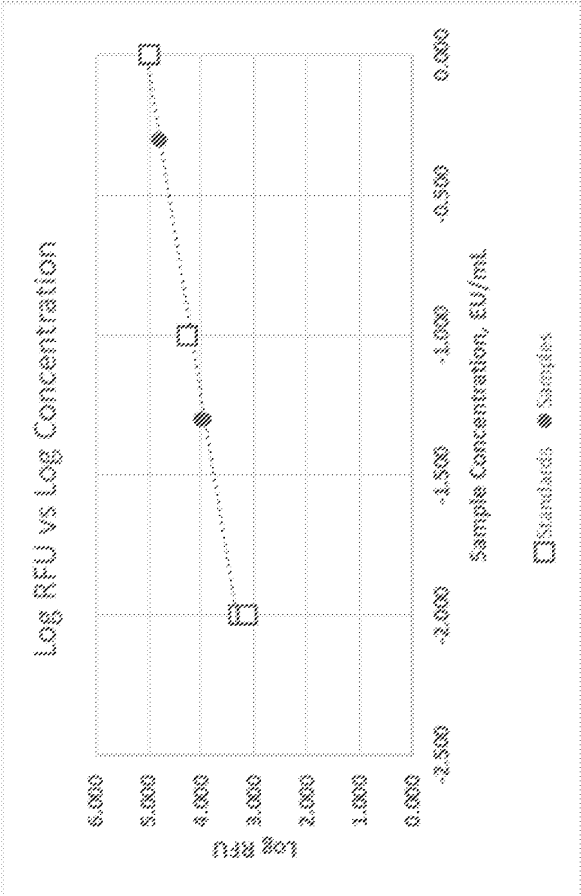


FIG. 6C

FIG. 7A

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. 7B

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. 7C

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. 7D

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. 8

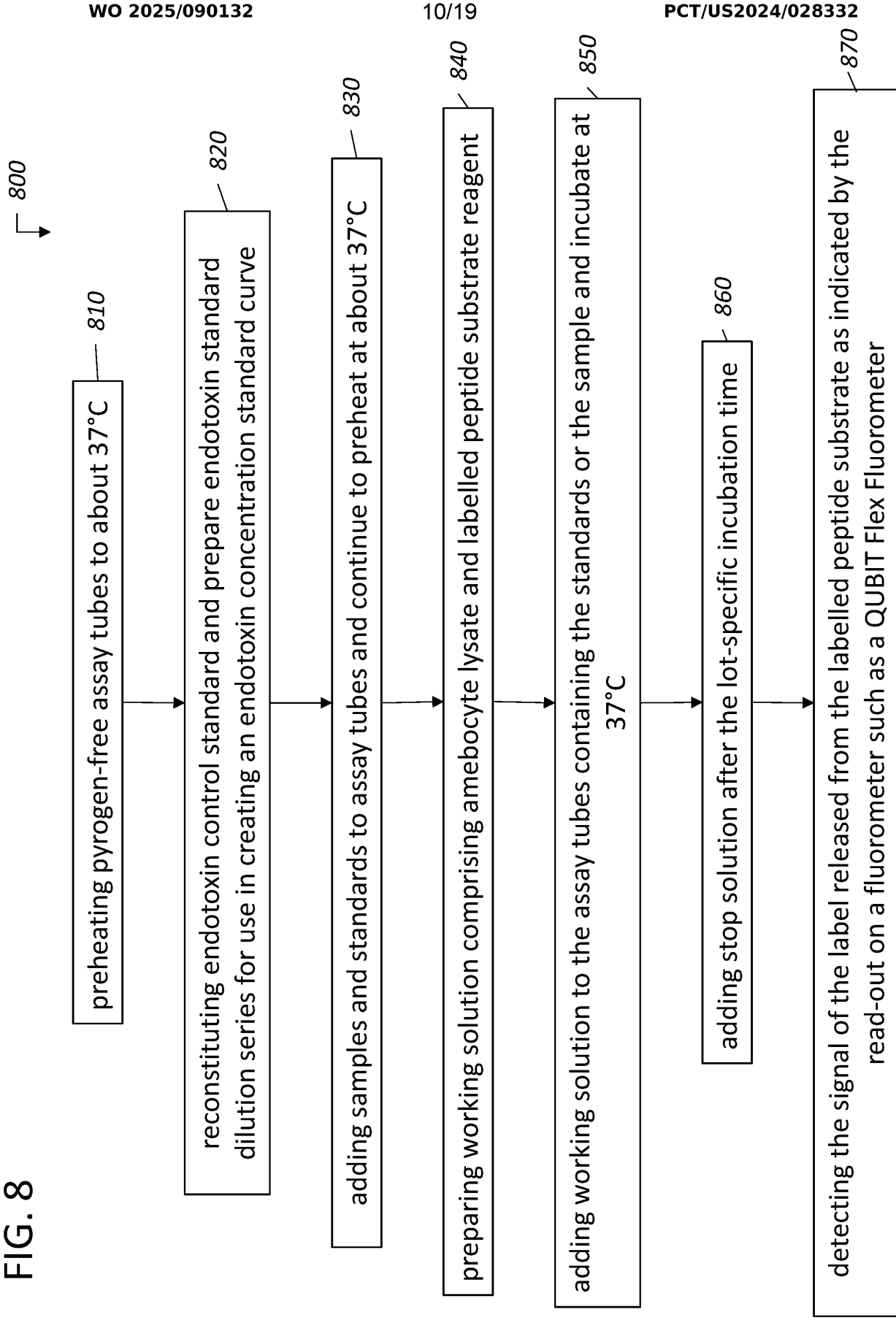


FIG. 9A

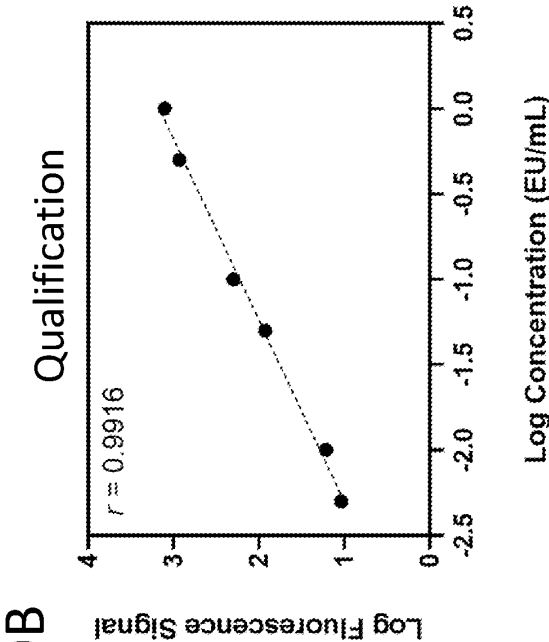
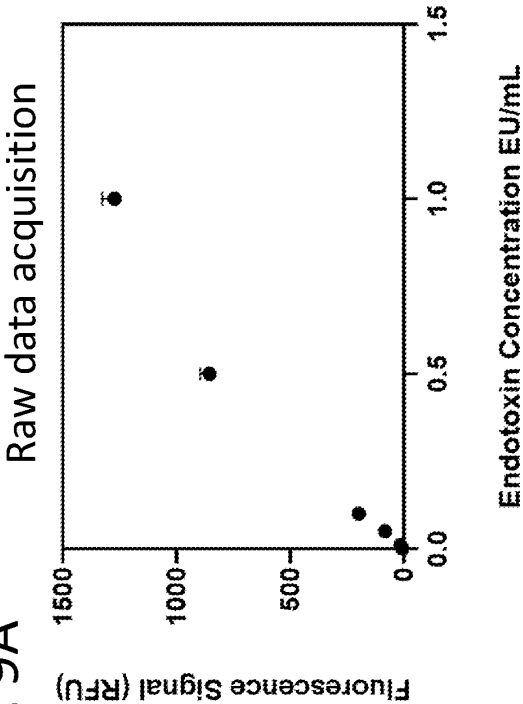


FIG. 9C

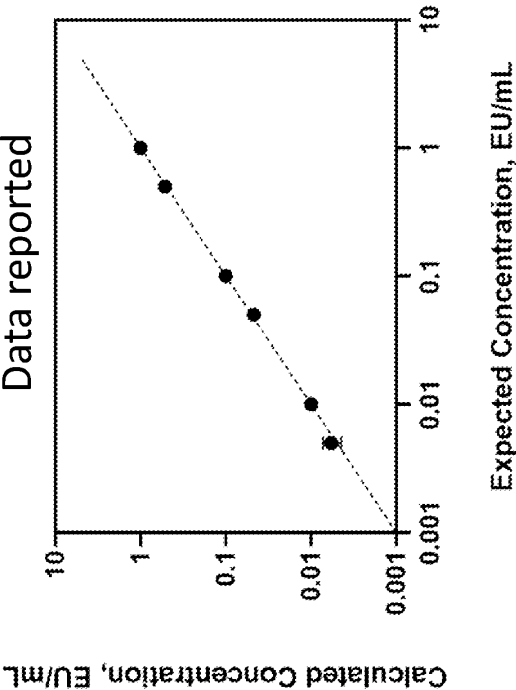


FIG. 10A

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	0.918
	0.011	0.048	0.106	0.526	1.006
	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. 10B

Incubation time, t = 20min

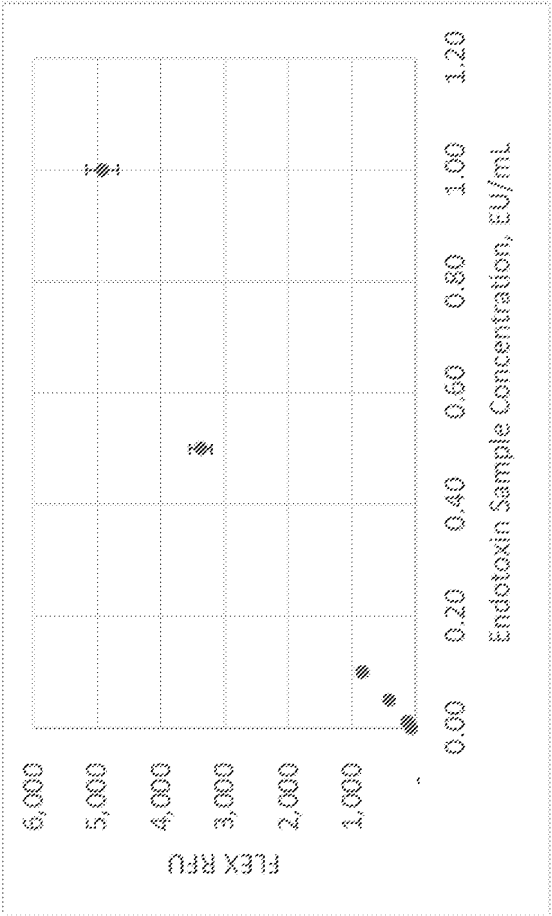


FIG. 11A

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. 11B

Incubation time, t = 21min

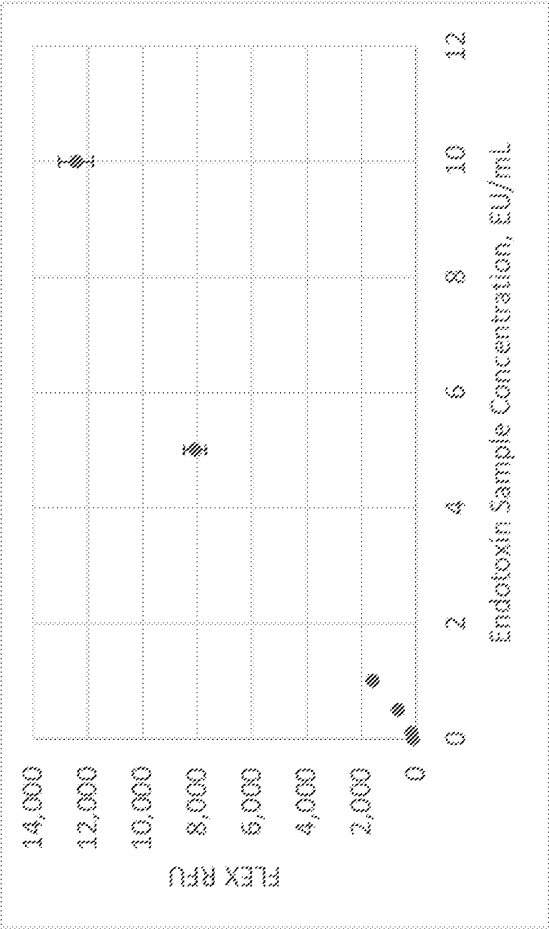


FIG. 12A

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
Average Calculated	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
	0.011	0.049	0.104	0.538	0.970
CV	6%	7%	4%	9%	5%
Error	8%	-2%	4%	8%	-3%

Sample	OD
User #2, Dye lot B	0.00
User #1, Dye lot A	0.00
35 EU endotoxin control	0.00
25 EU endotoxin control	0.00

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	0.978
	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

FIG. 12B

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

Assay Matrix	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

FIG. 13A

Expected EU/mL		0.010	0.050	0.100	0.500	1.00
Calculated EU/mL	Calculated	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	1.003
CV		7%	6%	2%	10%	3%
Error		15%	-3%	6%	16%	0%

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	Calculated	0.011	0.048	0.101	0.606	0.963
		0.009	0.047	0.119	0.588	0.962
		0.009	0.047	0.104	0.581	1.003
		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
25 EU endotoxin control

FIG. 13B

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

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

FIG. 14A

LOT 1 (t=20min)

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
Average Calculated CV	0.011	0.049	0.103	0.525	0.914
Error	0.011	0.047	0.105	0.512	0.992
	0.011	0.047	0.109	0.502	1.025
	0.011	0.049	0.104	0.538	0.970
	6%	7%	4%	9%	5%
	8%	-2%	4%	8%	-3%

25 EU endotoxin control

User #1, Dye lot A

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

LOT 2 (t=21min)

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
Average Calculated CV	0.011	0.048	0.105	0.556	0.963
Error	0.011	0.048	0.106	0.556	1.021
	0.013	0.045	0.109	0.543	1.025
	0.011	0.049	0.105	0.579	1.000
	7%	6%	2%	10%	3%
	15%	-3%	6%	16%	0%

25 EU endotoxin control

User #1, Dye lot B

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

FIG. 15B

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. 16

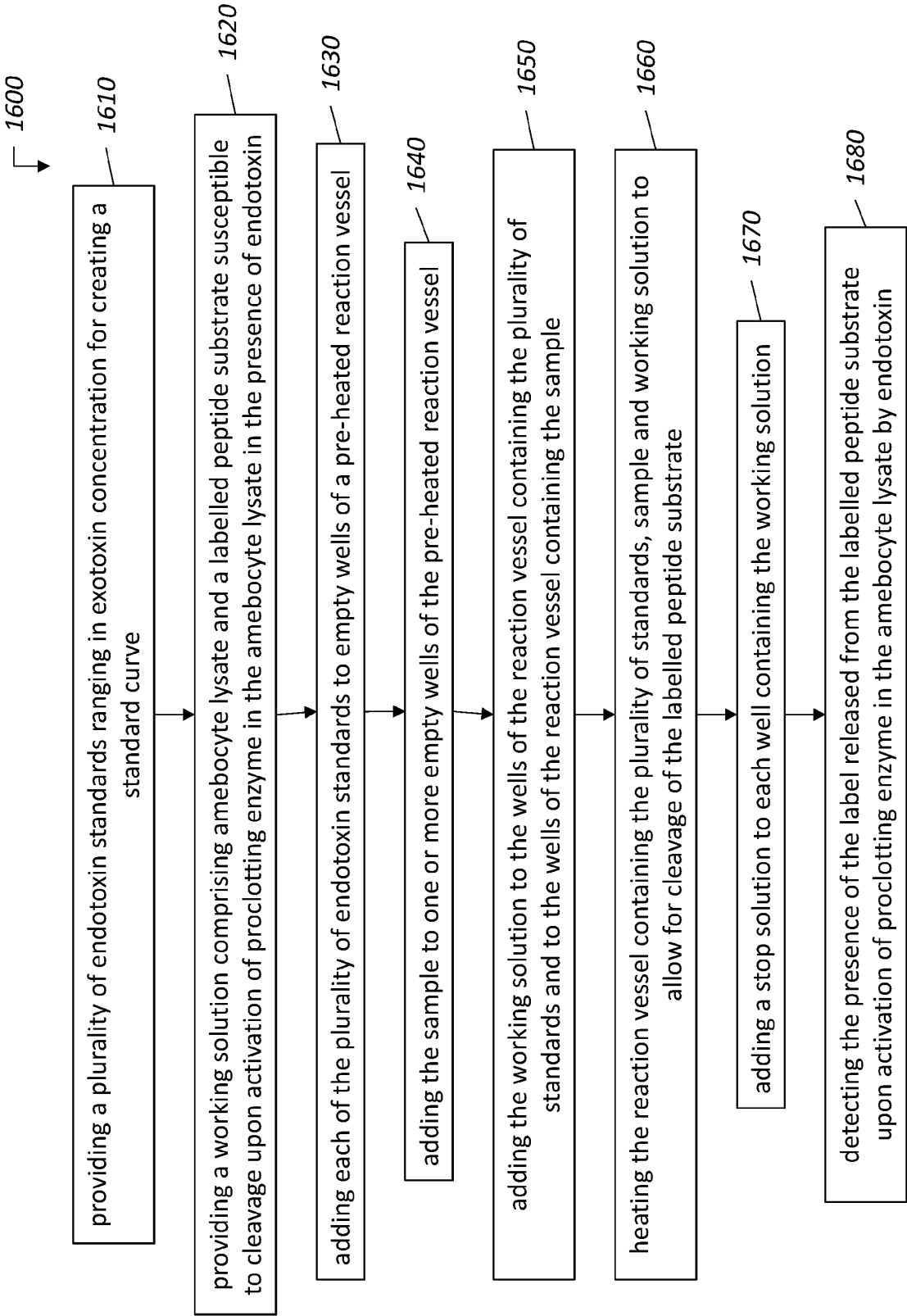


FIG. 17

