

Buffer number	1	2	3	4	5	6	7	8	9	10
Sample number	3	9	15	21	27	33	39	45	51	57
Concentration	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL	1mg/mL
Temperature	37C	37C	37C	37C	37C	37C	37C	37C	37C	37C
Visual scoring	0	0	0	0	3	1	0	1	0	0
Est pH @ 37C	7.25	7.26	7.54	8.12	6.73	7.2	7.7	6.64	7.22	7.65
Actual pH @ 4C	7.25	7.26	7.54	8.12	7.59	8.06	8.56	7.5	8.08	8.51

FIG.1

Buffer number	1	2	3	4	5	6	7	8	9	10
Sample number	6	12	18	24	30	36	42	48	54	60
Concentration	10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL 10mg/mL									
Temperature	37C	37C	37C	37C	37C	37C	37C	37C	37C	37C
Visual scoring	5		5		4		3		5	
Est pH @ 37C	7.25	7.26	7.54	8.12	6.73	7.2	7.7	6.64	7.22	7.65
Actual pH @ 4C	7.25	7.26	7.54	8.12	7.59	8.06	8.56	7.5	8.08	8.51

FIG.2

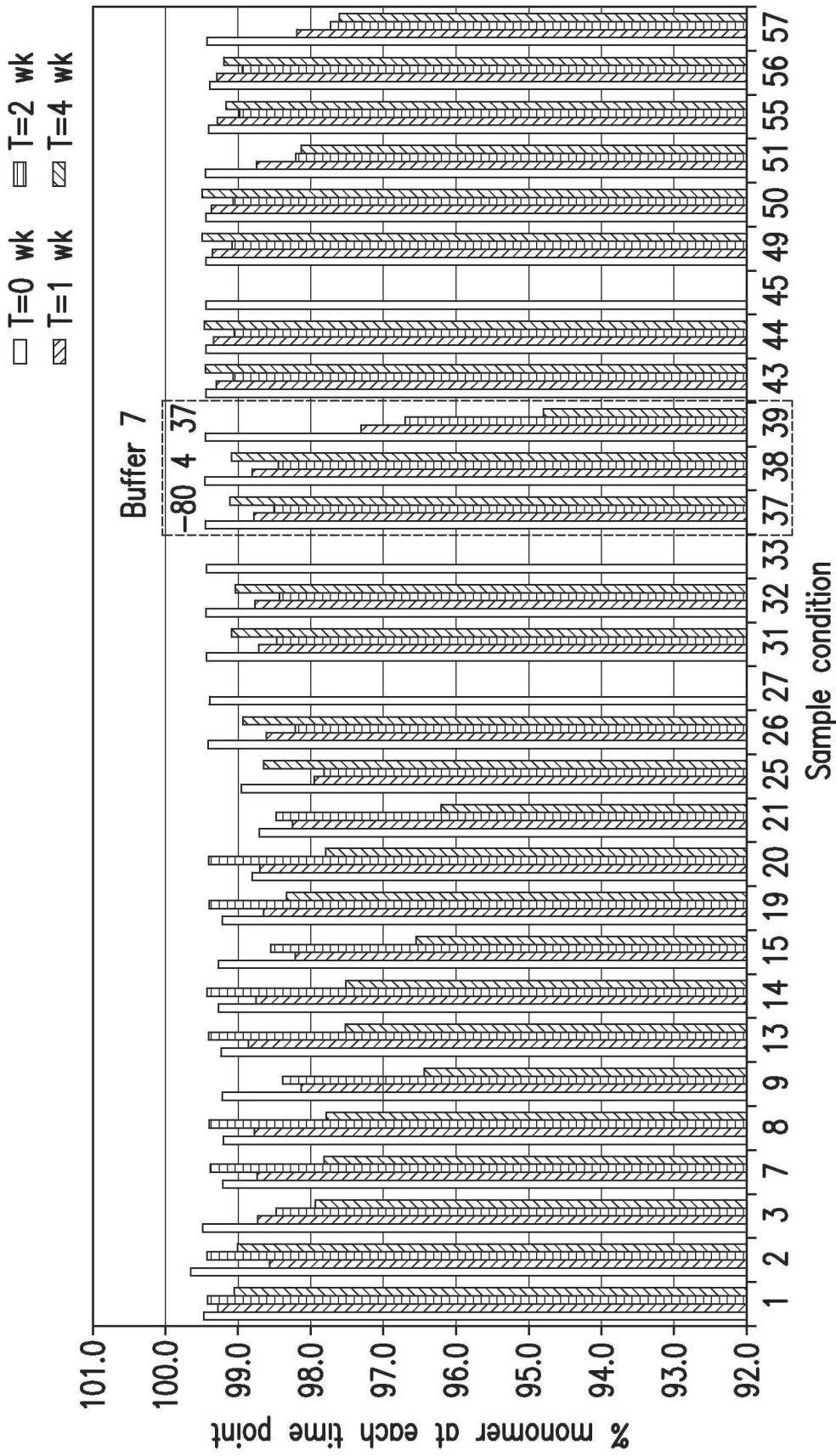


FIG.3

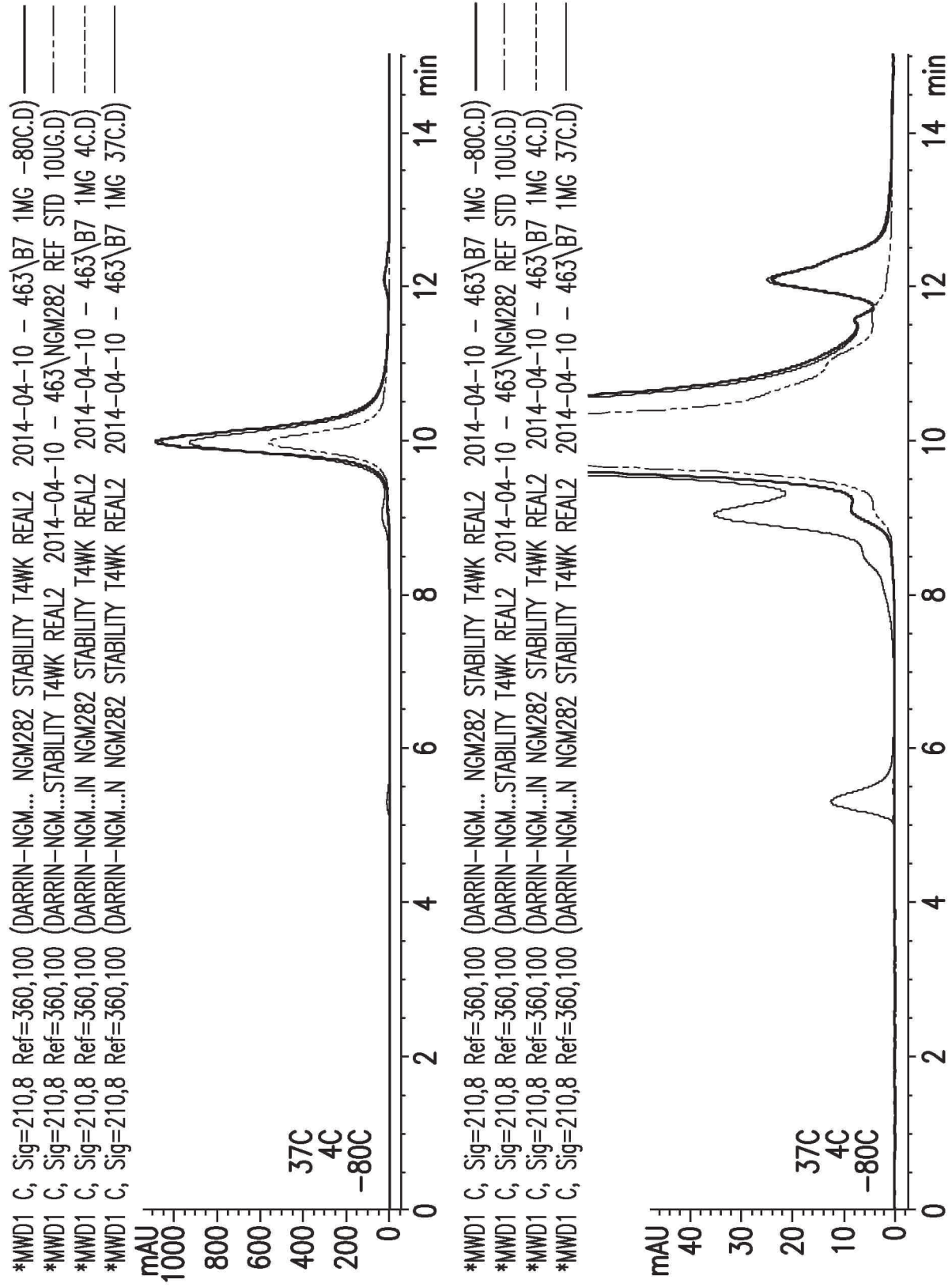


FIG.4

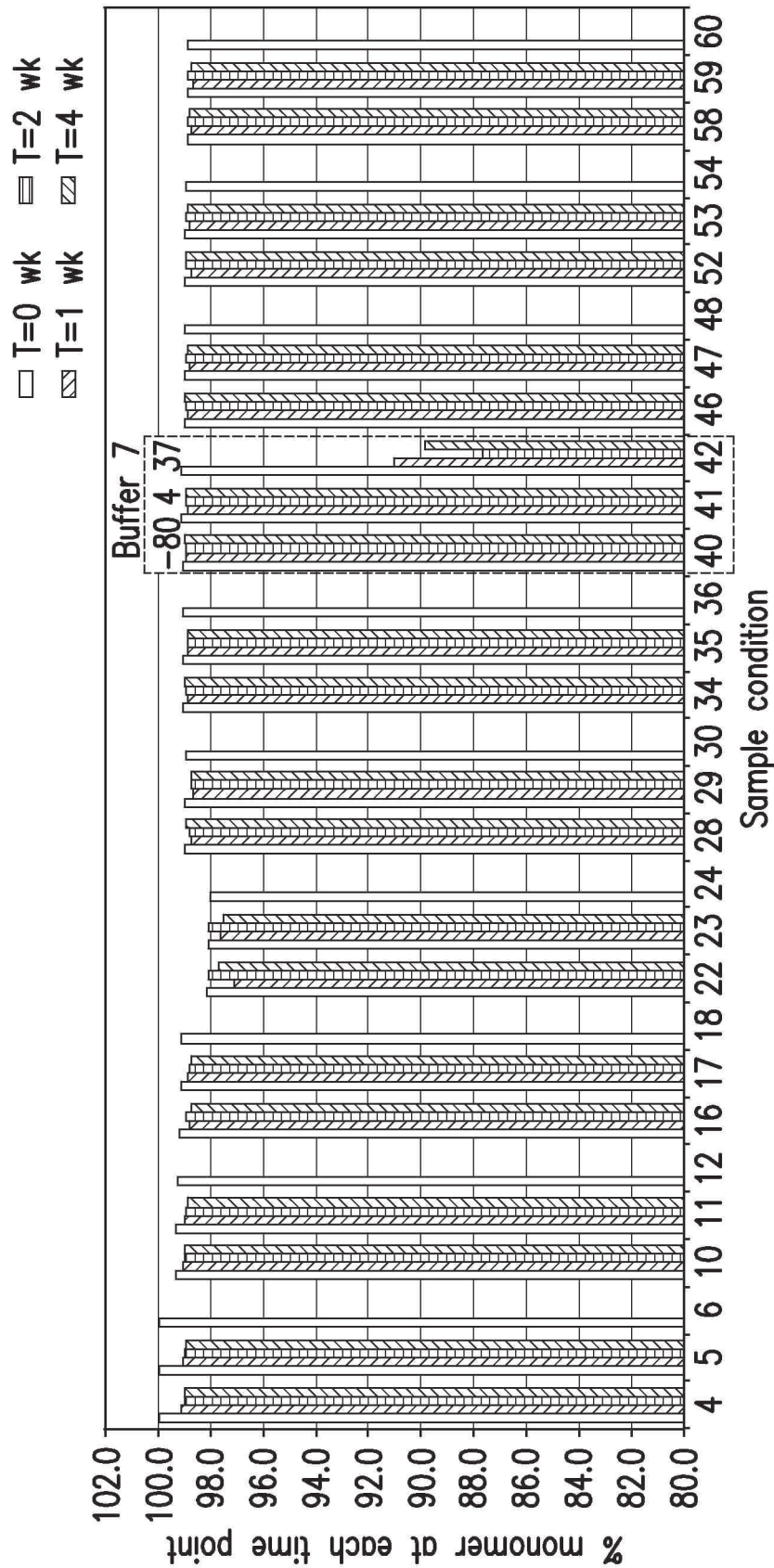


FIG.5

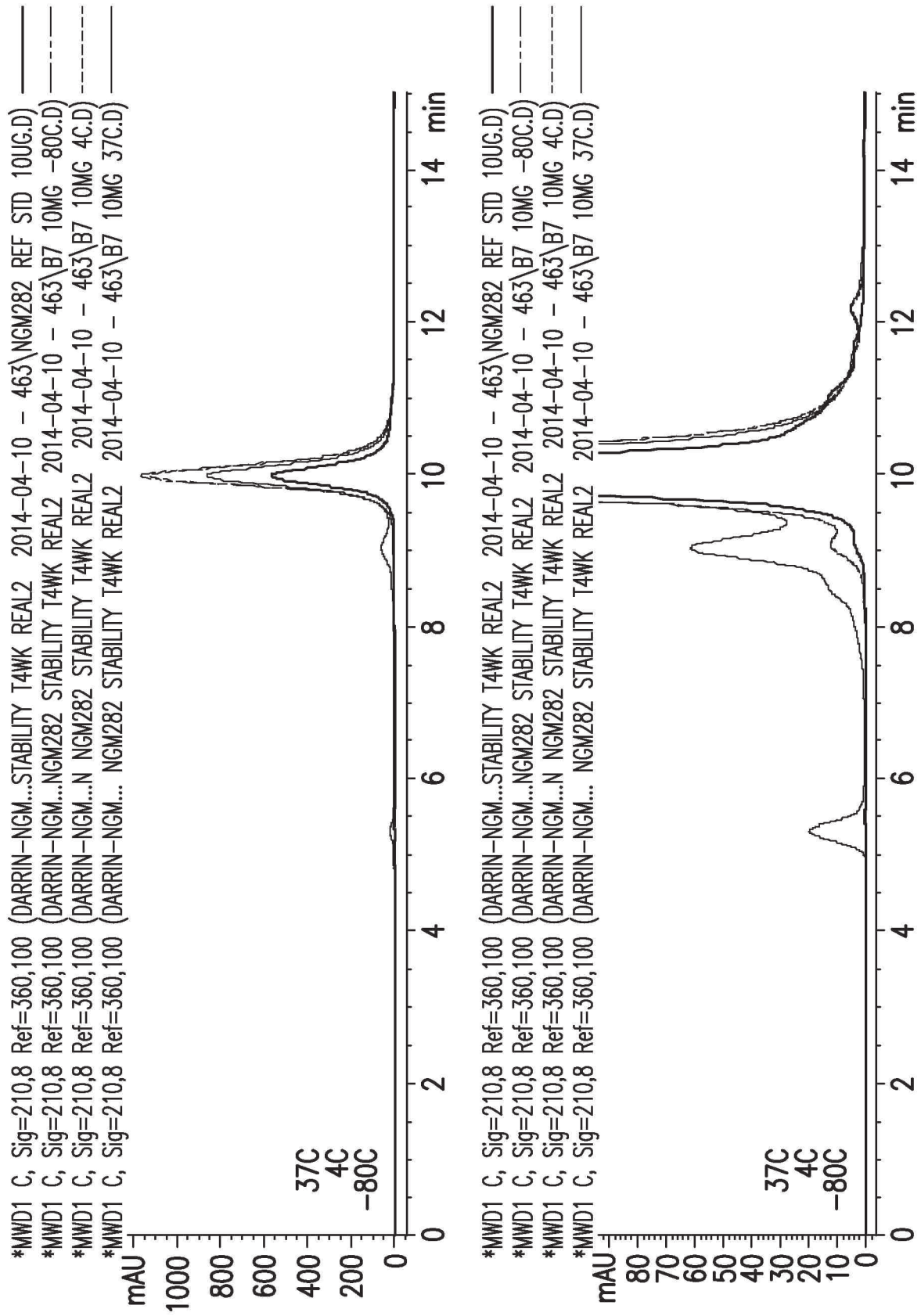


FIG.6

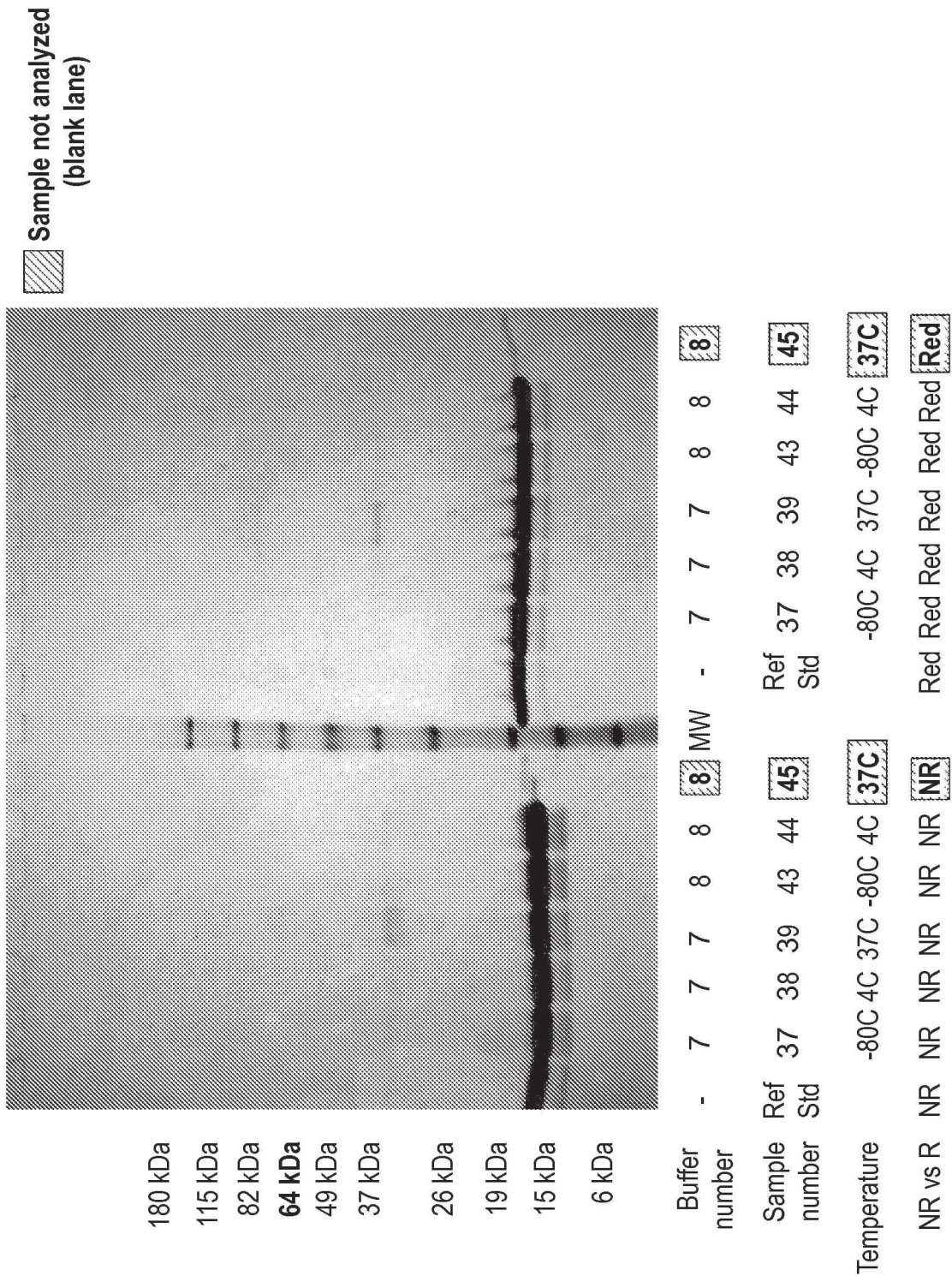


FIG. 7A

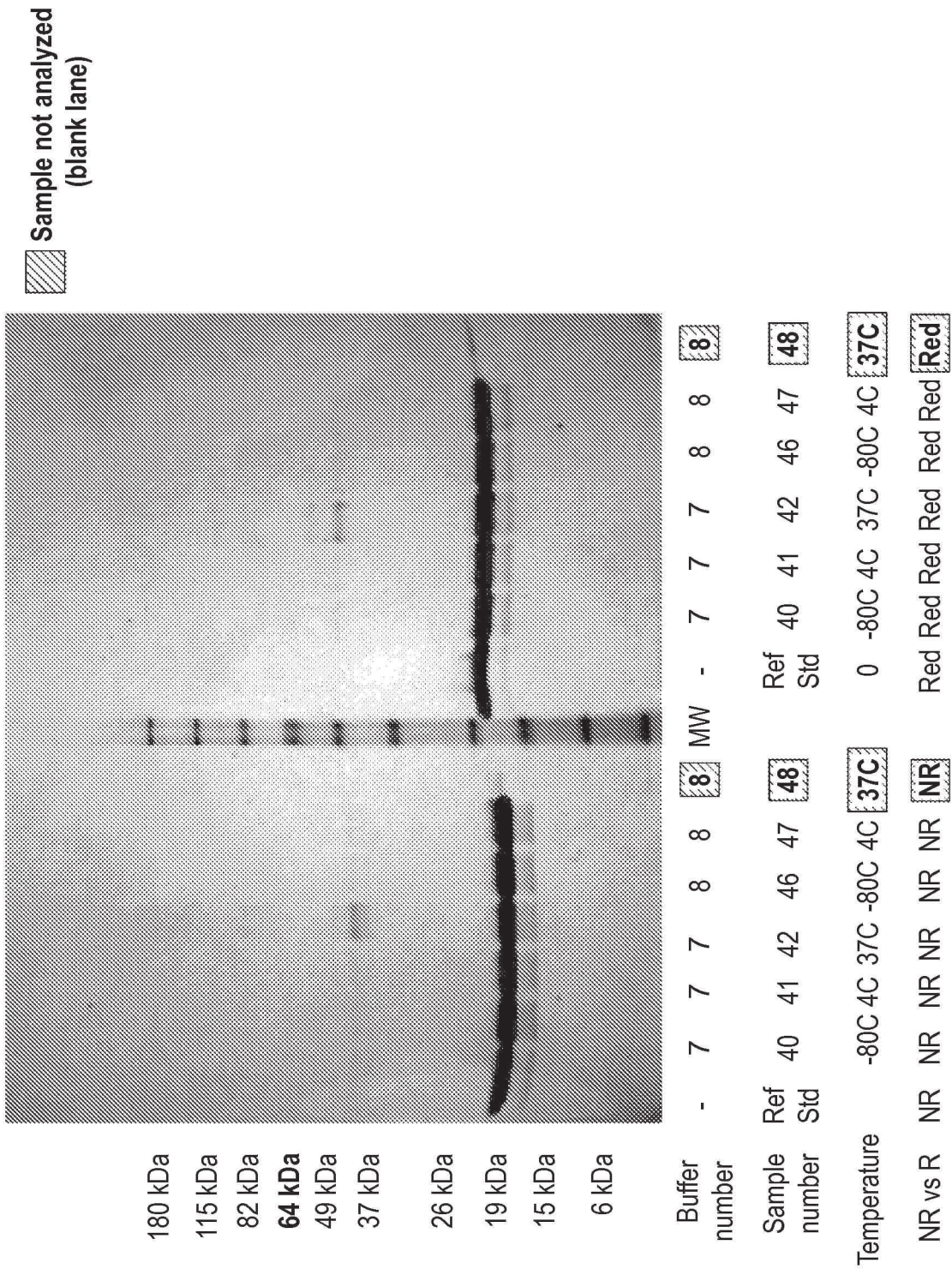


FIG.7B

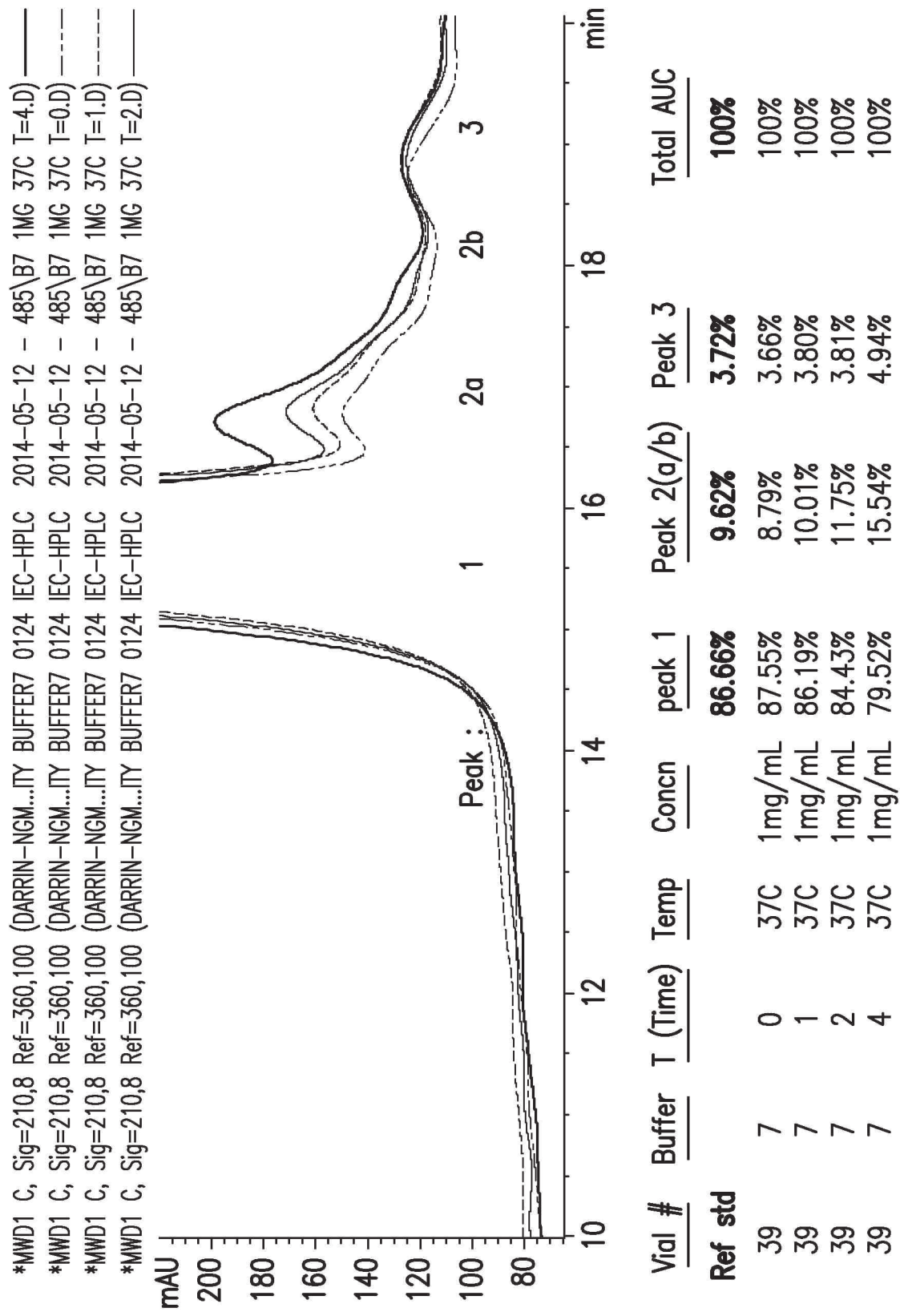


FIG.8

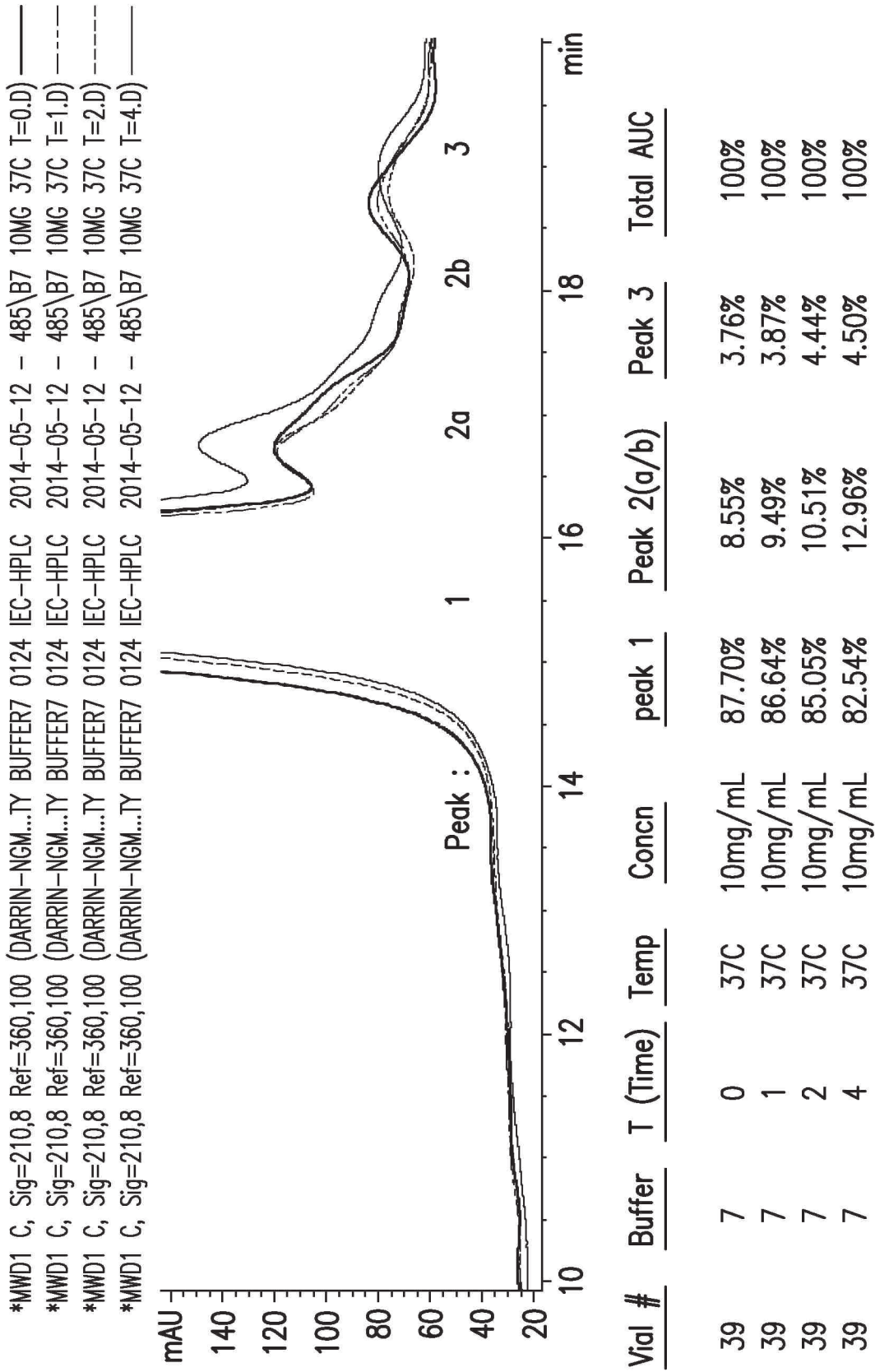


FIG.9

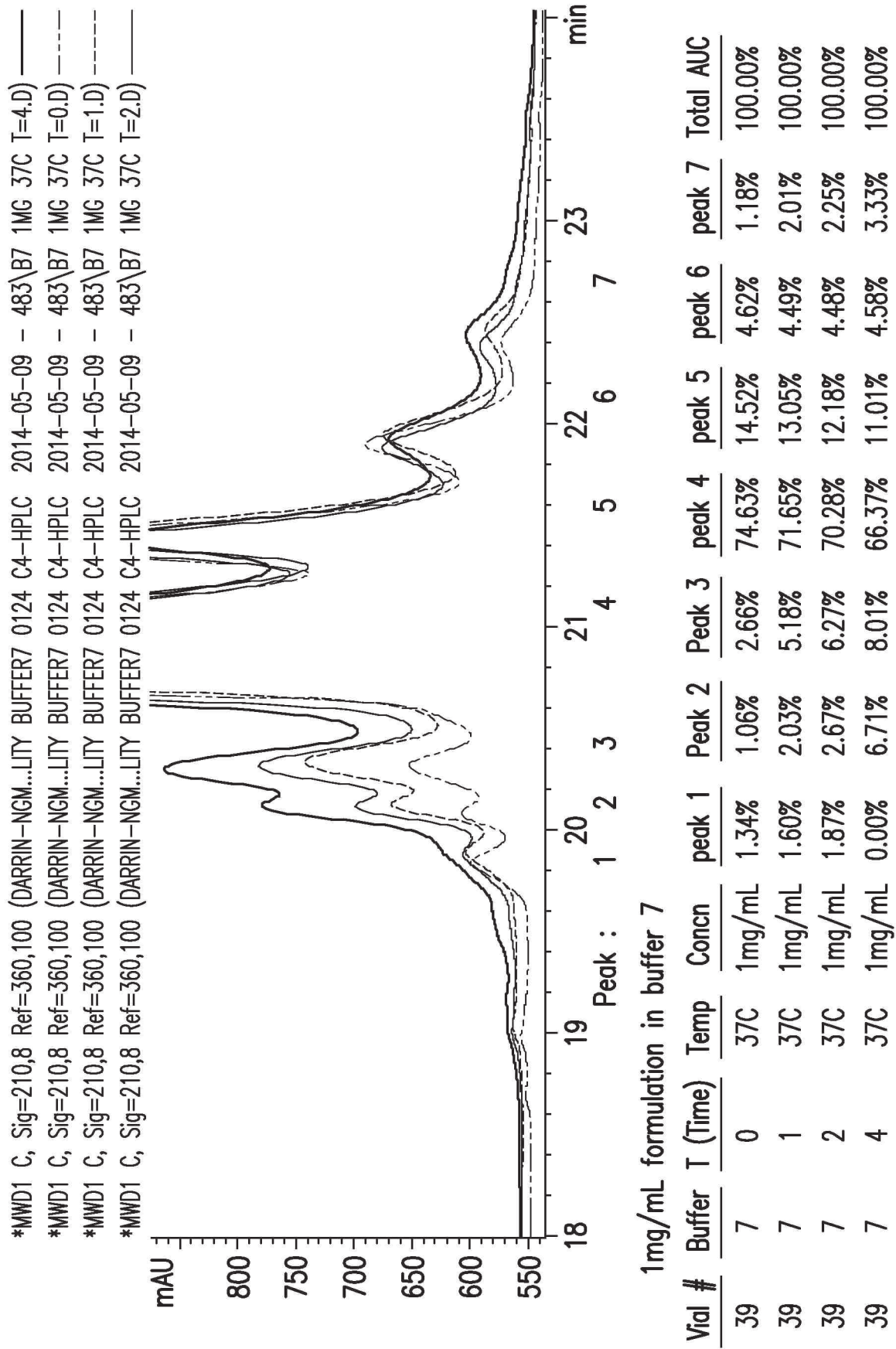
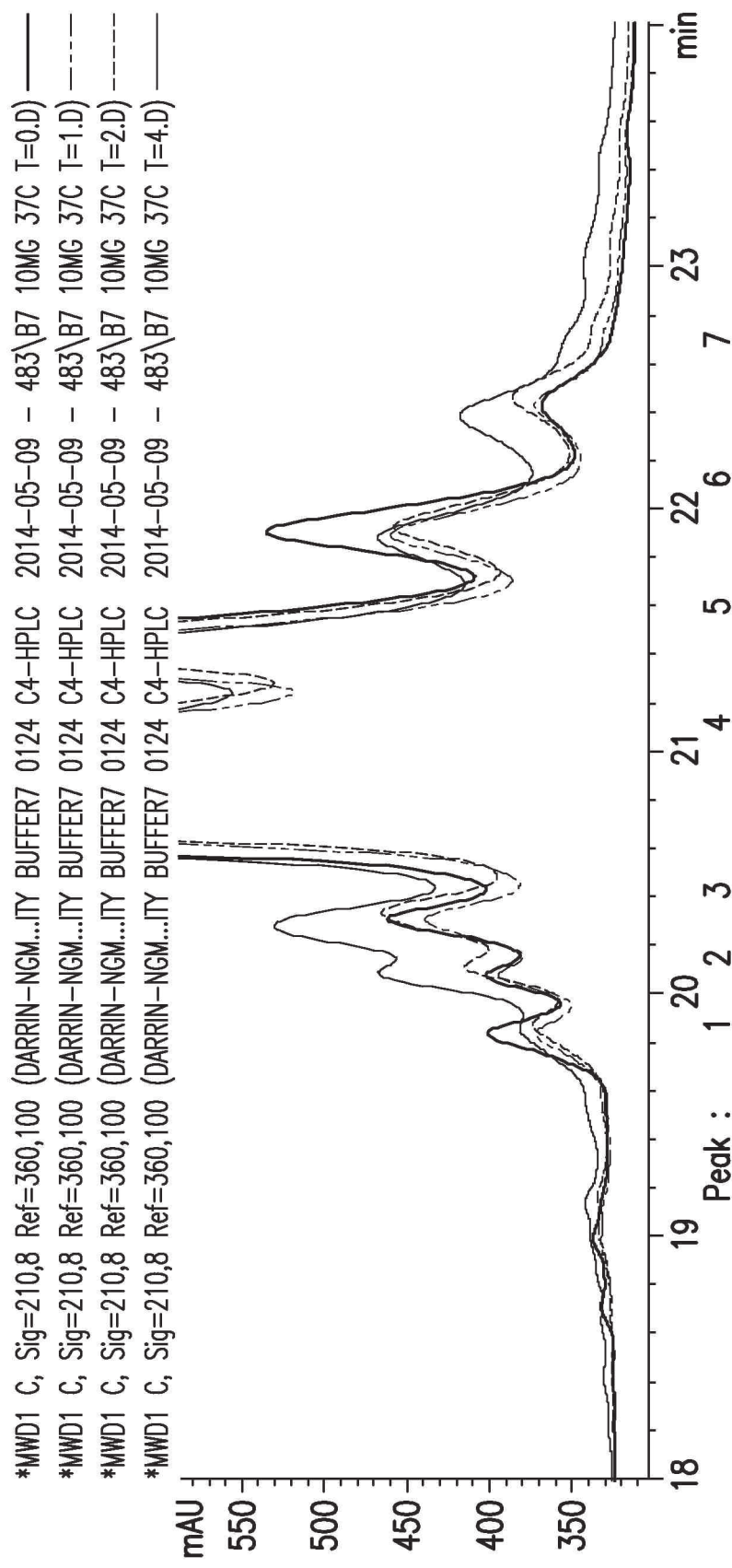


FIG.10



10mg/mL formulation in buffer 7

Vial #	Buffer	T (Time)	Temp	Concn	peak 1	Peak 2	Peak 3	peak 4	peak 5	peak 6	peak 7	Total AUC
42	7	0	37C	10mg/mL	1.49%	1.08%	2.38%	71.92%	16.08%	5.23%	1.82%	100.00%
42	7	1	37C	10mg/mL	1.47%	1.32%	2.94%	72.96%	13.71%	4.79%	2.80%	100.00%
42	7	2	37C	10mg/mL	1.62%	1.67%	3.68%	71.54%	12.97%	4.82%	3.71%	100.00%
42	7	4	37C	10mg/mL	1.87%	2.56%	5.03%	68.95%	11.97%	5.06%	4.57%	100.00%

FIG.11

Condition	O	A	B	C	D	E	F
Freeze cycle (n=X) @ -80C for 30 mins	input	1	1	3	3	5	5
Thaw cycle (RT vs 4C) for 1 hour	input	RT	4C	RT	4C	RT	4C
SEC – PBS + 5% ETOH (% main peak)	99.6%	99.6%	99.5%	99.5%	99.5%	99.5%	99.5%
SEC – TTP mobile phase (% main peak)	94.8%	95.3%	95.0%	95.0%	95.3%	95.1%	94.9%
ALEX – Althea SOP (% main peak)	91.3%	91.3%	91.4%	91.5%	91.5%	91.5%	91.7%
RP – Althea SOP (% main peak)	91.0%	91.1%	91.2%	91.1%	91.1%	91.1%	91.1%
DLS measurement	N/A	N/A	N/A	N/A	N/A	N/A	N/A

FIG.12