

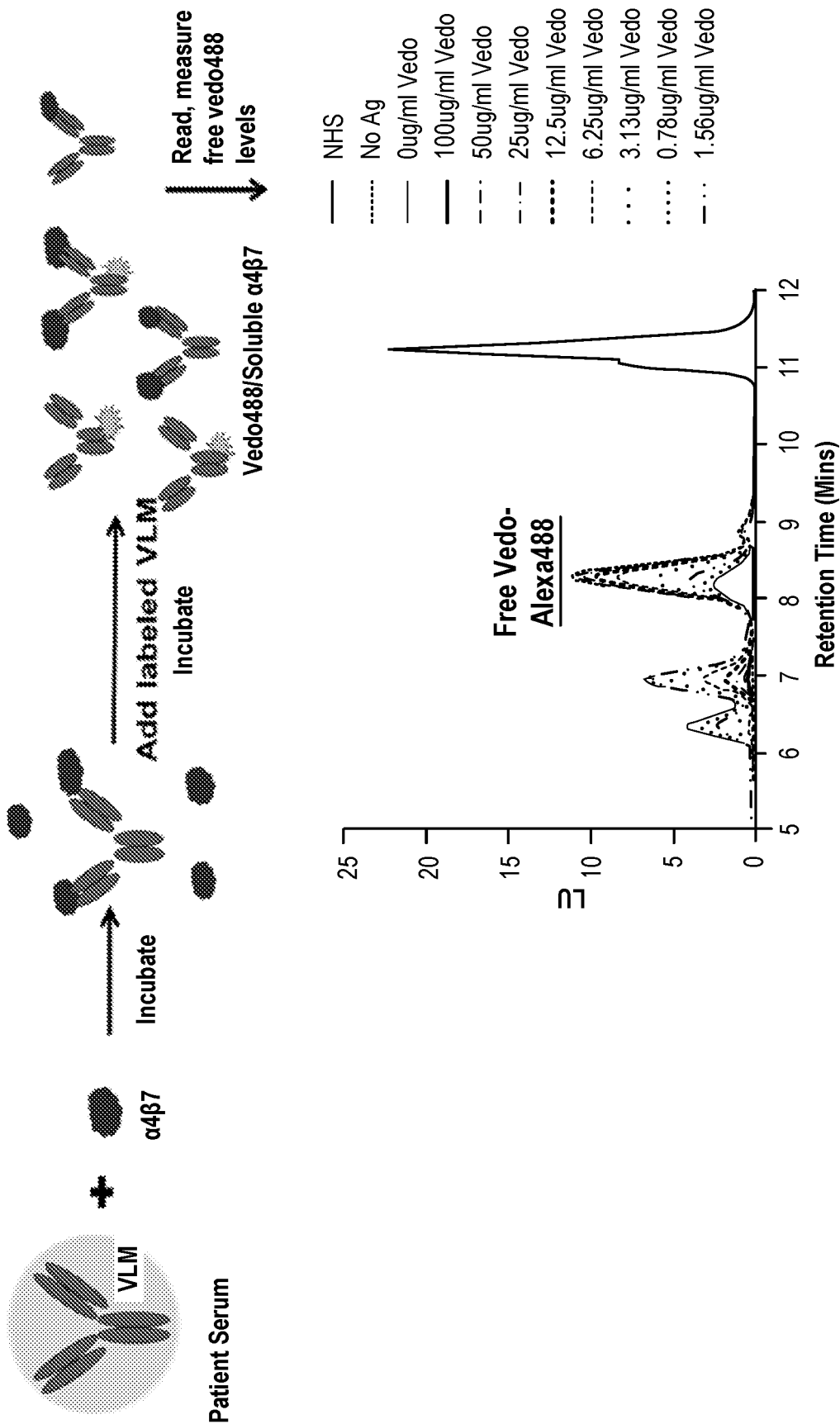


FIG. 1

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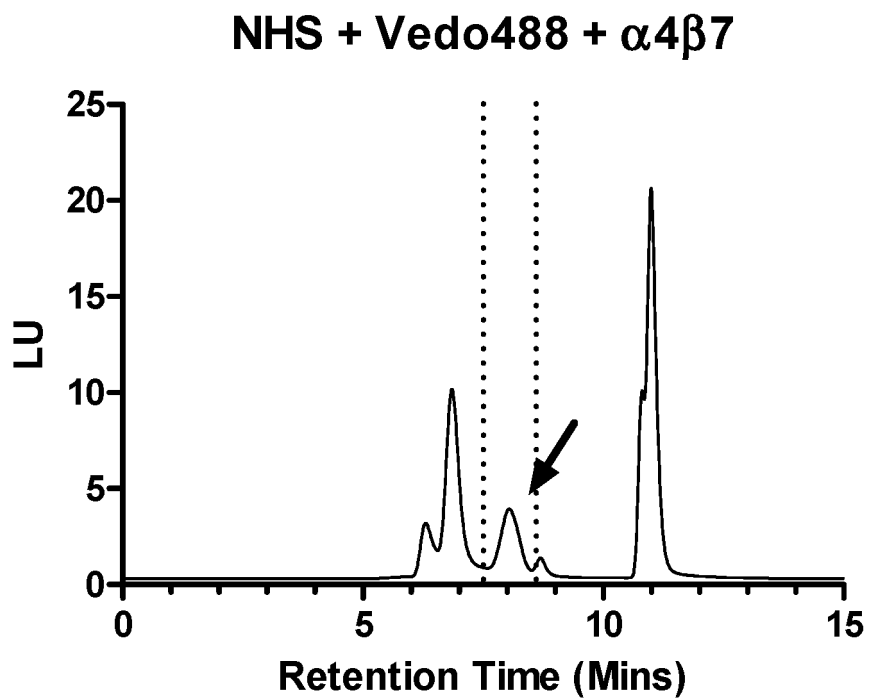
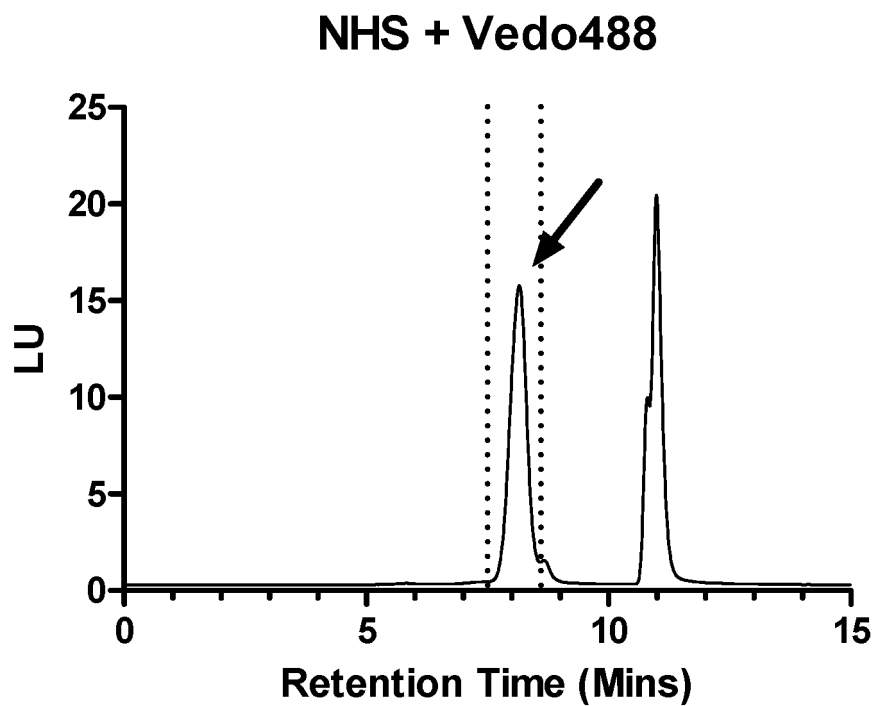


FIG. 2
SUBSTITUTE SHEET (RULE 26)

Vedolizumab Drug Assay

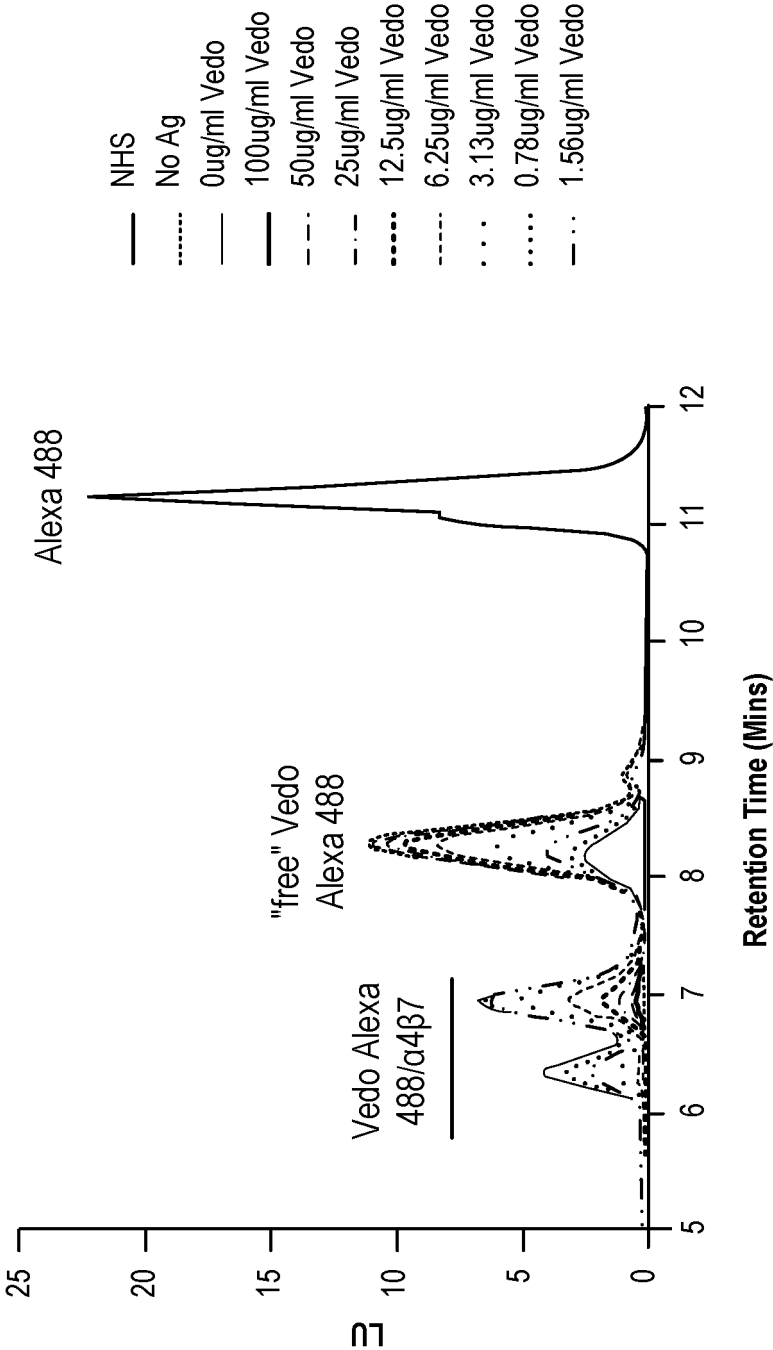
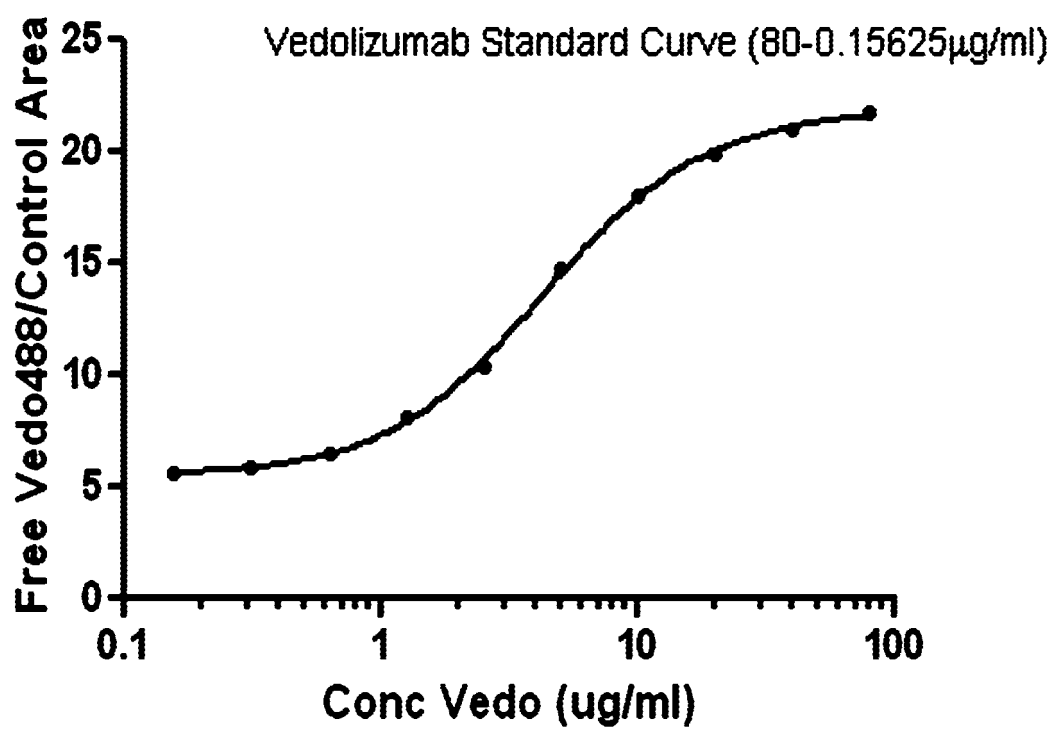


FIG. 3

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Vedolizumab Drug Assay – Validation Specs

Assay parameters (n=30)		Calculated (µg/ml)
Limit of Blank (LOB)		0.054
Limit of Detection (LOD)		0.35
Lower limit of quantitation (LLOQ)		0.625
Upper limit of quantitation (ULOQ)		14

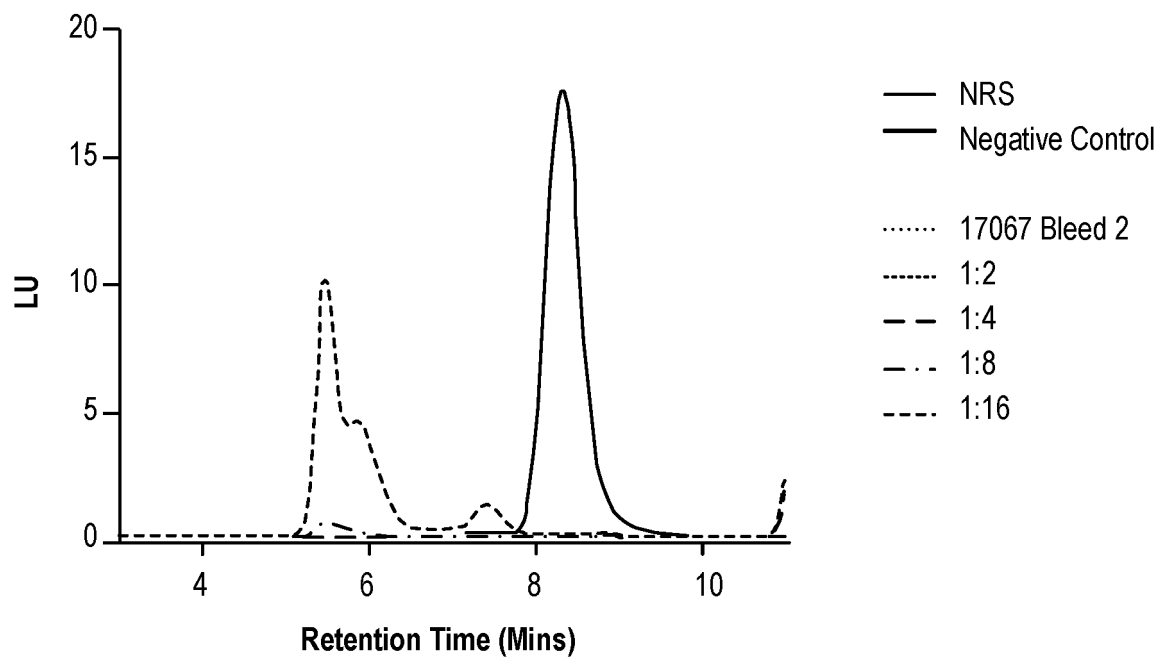
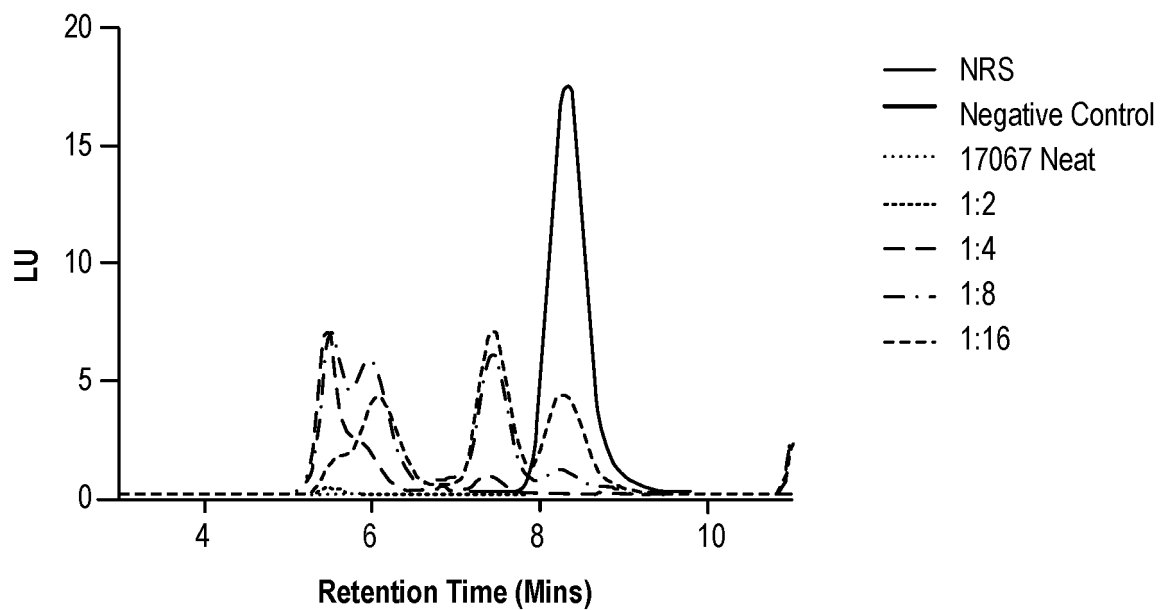


VLM: Validation: Intra-assay Precision & Accuracy

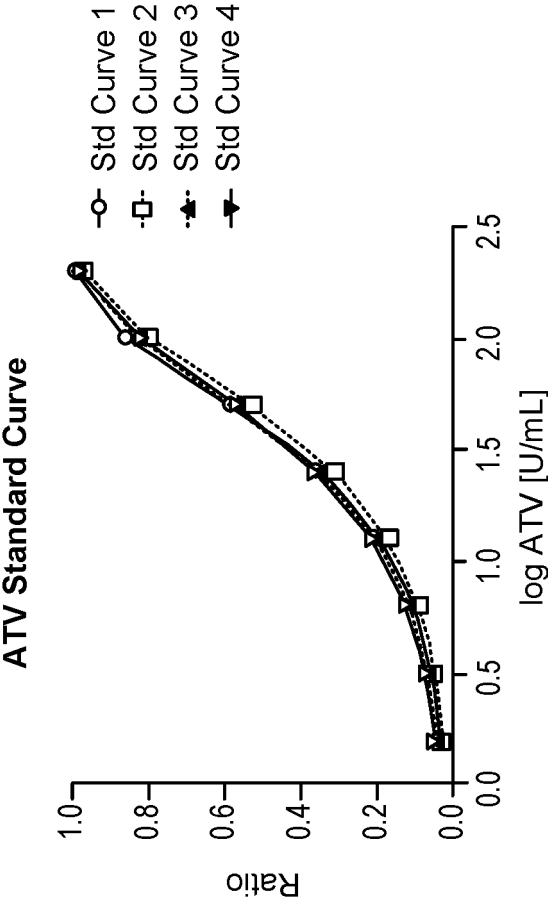
		Average(n=10)	SD	%CV	% Error
High Control	16 µg/mL	15.66	1.05	6.73	-2.08
Med Control	4 µg/mL	4.11	0.17	4.30	2.91
Low Control	1 µg/mL	1.24	0.033	2.73	24.08

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Anti-Vedolizumab (ATV) Assay



ATV : Validation: Standard Curve (200U/mL-1.56U/mL)



ATV U/mL	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8
Experiment	200	100	50	25	13	6	3.13	1.56
1	192	104	49	25	13.1	6.6	3.04	1.05
2	191	103	49	25	12.6	6.3	3.16	1.53
3	193	102	50	25	12.5	6.3	3.16	1.54
4	192	103	49	25	12.4	6.3	3.15	1.55
AVERAGE	192.2	103.1	49.3	24.8	12.7	6.4	3.1	1.4
STDEV	0.7	0.8	0.6	0.2	0.3	0.1	0.1	0.2
%CV	0.4	0.8	1.3	0.8	2.5	2.2	1.8	17.2
%RECOVERY	96.1	103.1	98.7	99.3	101.4	102.2	100.0	90.7

FIG. 8

ATV : Validation: LOB & LOD, LLOQ & ULOQ

Limits of Detection

	Mean (n=25)	SD	1.65SD	Mean +1.65SD	(LOB) Interpolated Value
LOB	0.00828	0.00013	0.00022	0.00850	Too low to interpolate
LOD	LOB + 1.65SD (low conc sample) : could not be determined as LOB has no value				

LOD = LLOQ =3.13

Limits of Quantitation

	Average (n=36)	SD	% CV	% Error
LLOQ	3.13 (U/mL)	0.08	2.14	-17.57
ULOQ	150 (U/mL)	2.67	1.69	-5.29

FIG. 9

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ATV : Validation: Inter-assay Precision

Inter-assay Precision n=4

		Average(n=4)	SD	%CV	% Error
High Control	50 (U/mL)	50.8	3.9	7.7	1.5
Med Control	25 (U/mL)	25.2	1.3	5.3	0.9
Low Control	12.5 (U/mL)	13.1	0.6	4.7	5.0

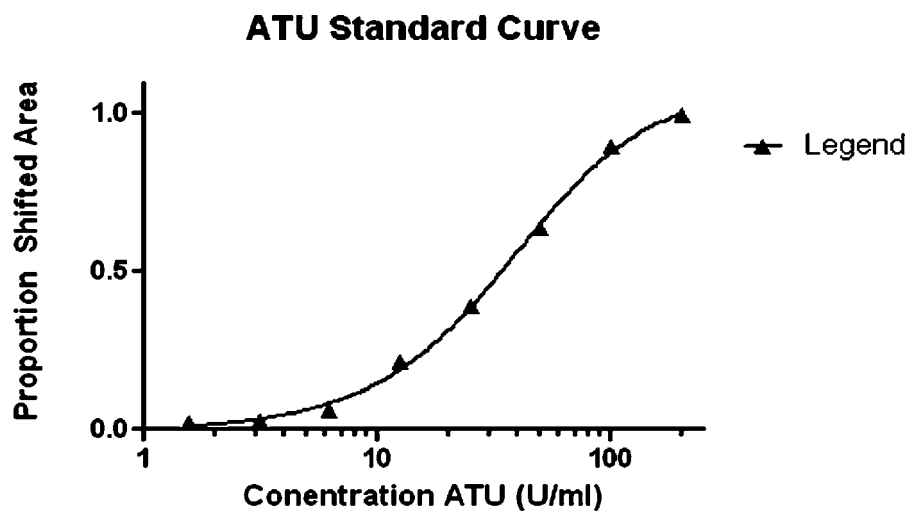


Ustekinumab Drug Assay – Validation Specs

Assay parameters (n=30)		Calculated (µg/ml)
Limit of Blank (LOB)		0.233
Limit of Detection (LOD)		0.147
Lower limit of quantitation (LLOQ)		0.625
Upper limit of quantitation (ULOQ)		8



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Controls (n=1)	SD	%CV	%Error
44.71	NA	NA	-10.58
24.06	NA	NA	-3.76
13.87	NA	NA	-10.96

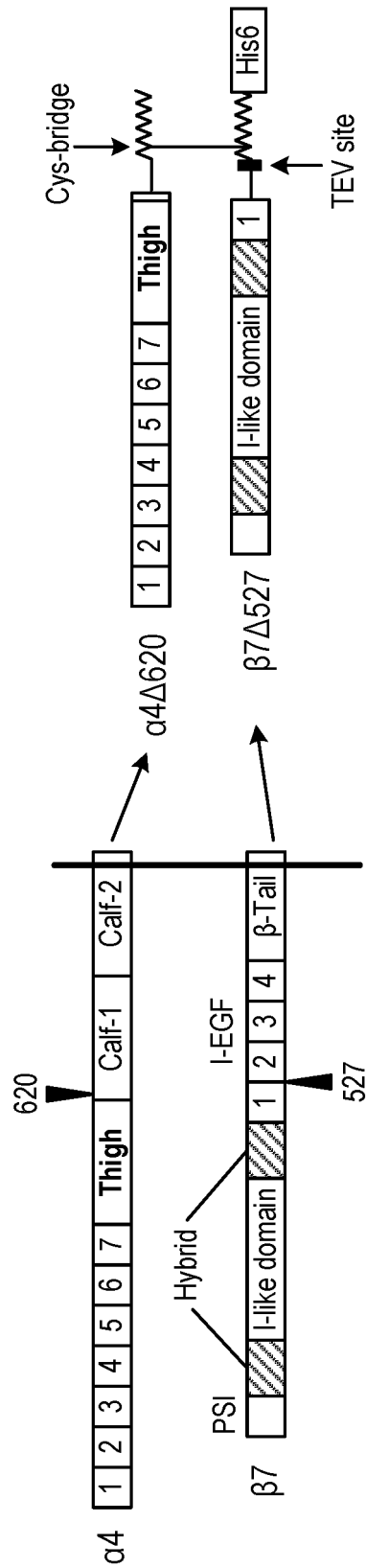
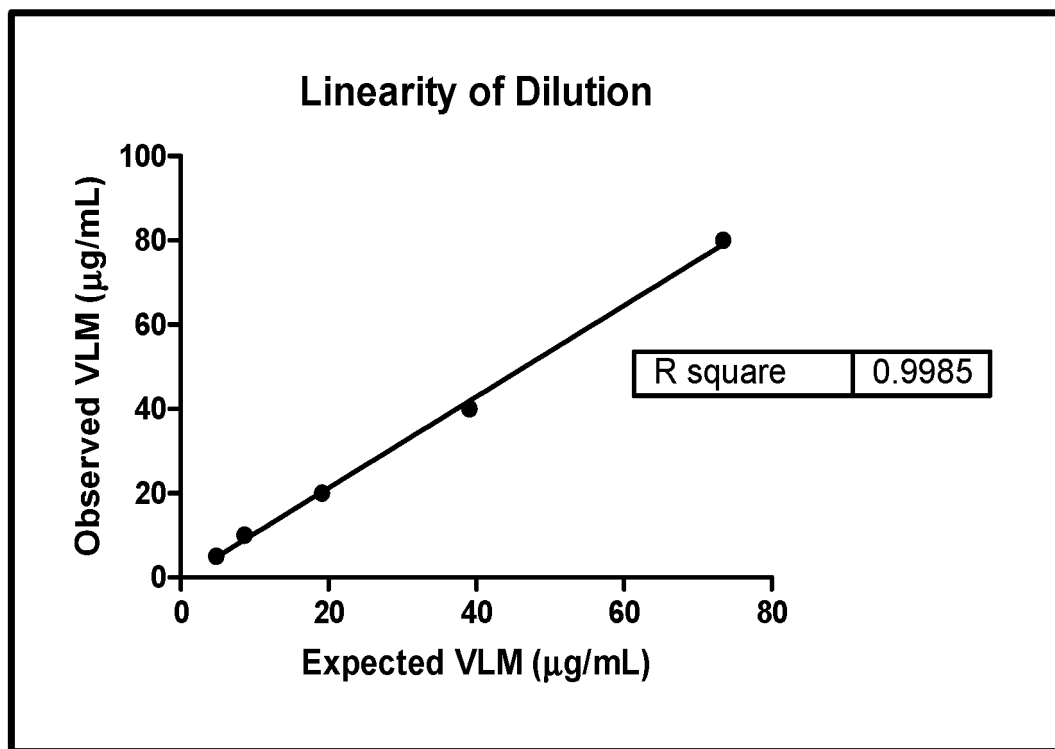
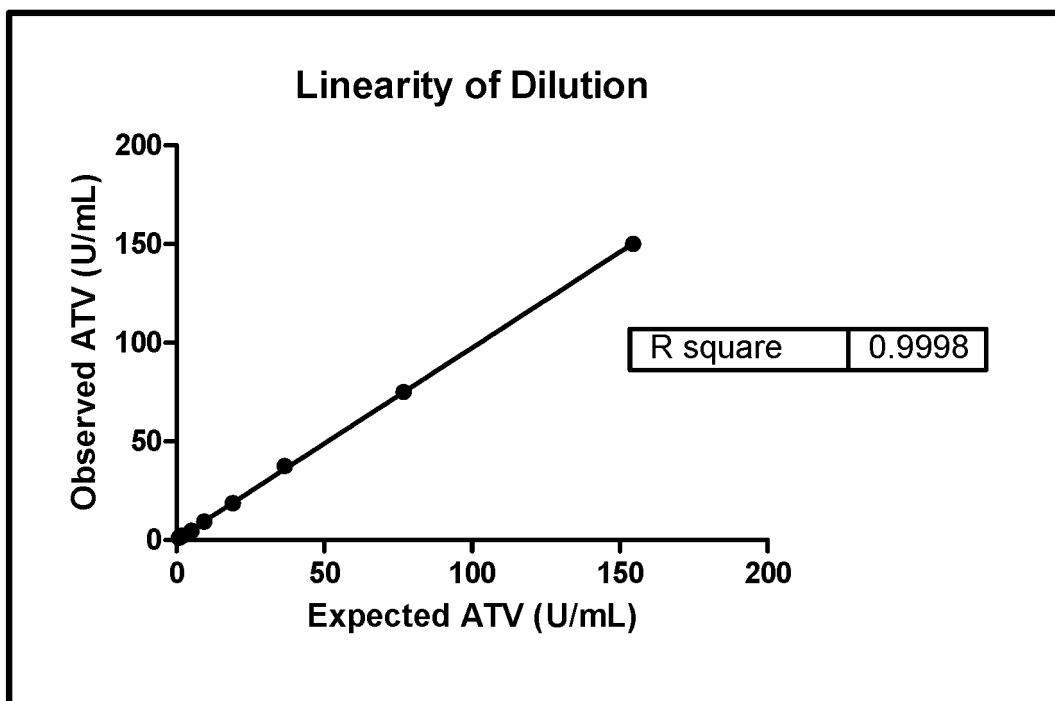


FIG. 13

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A**B**

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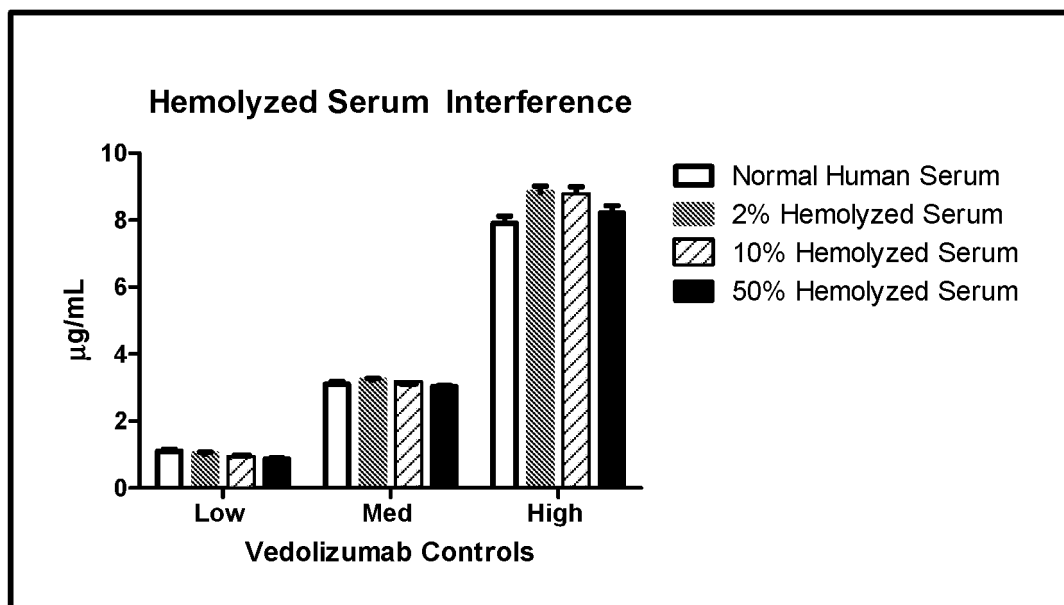
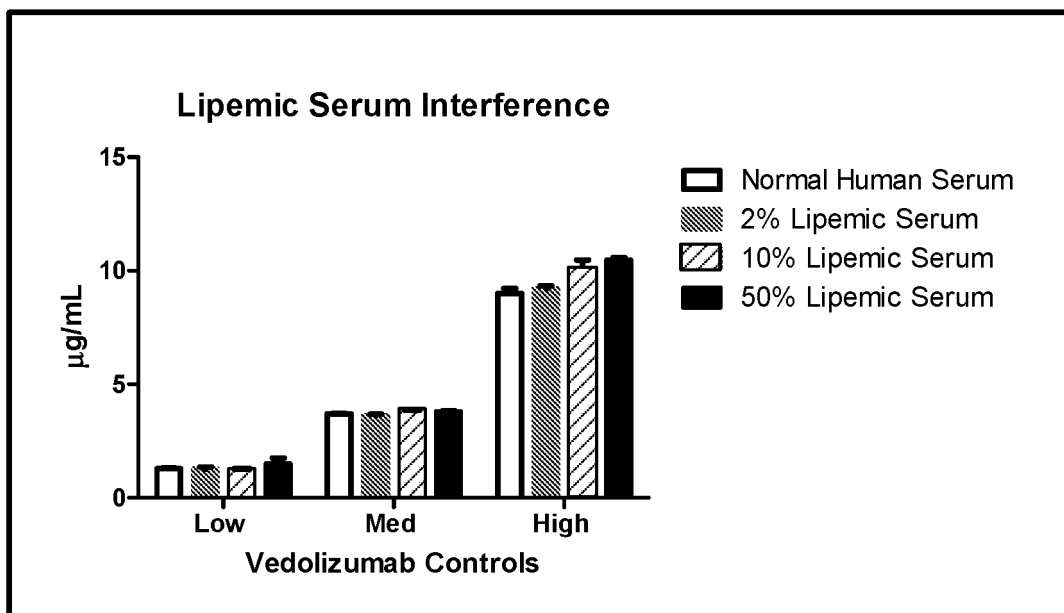
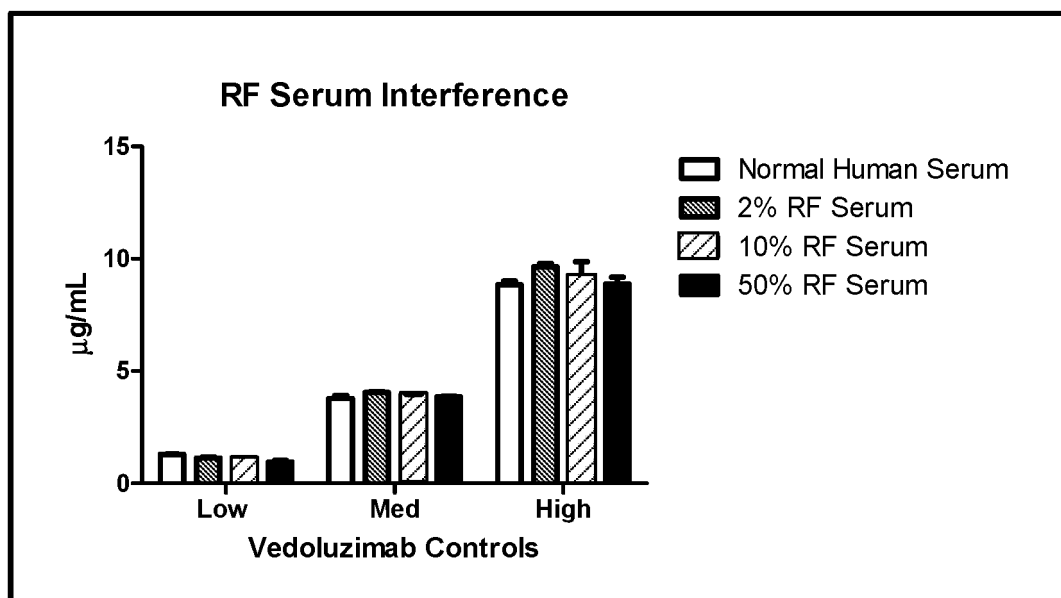
A**B****C**

FIG. 15
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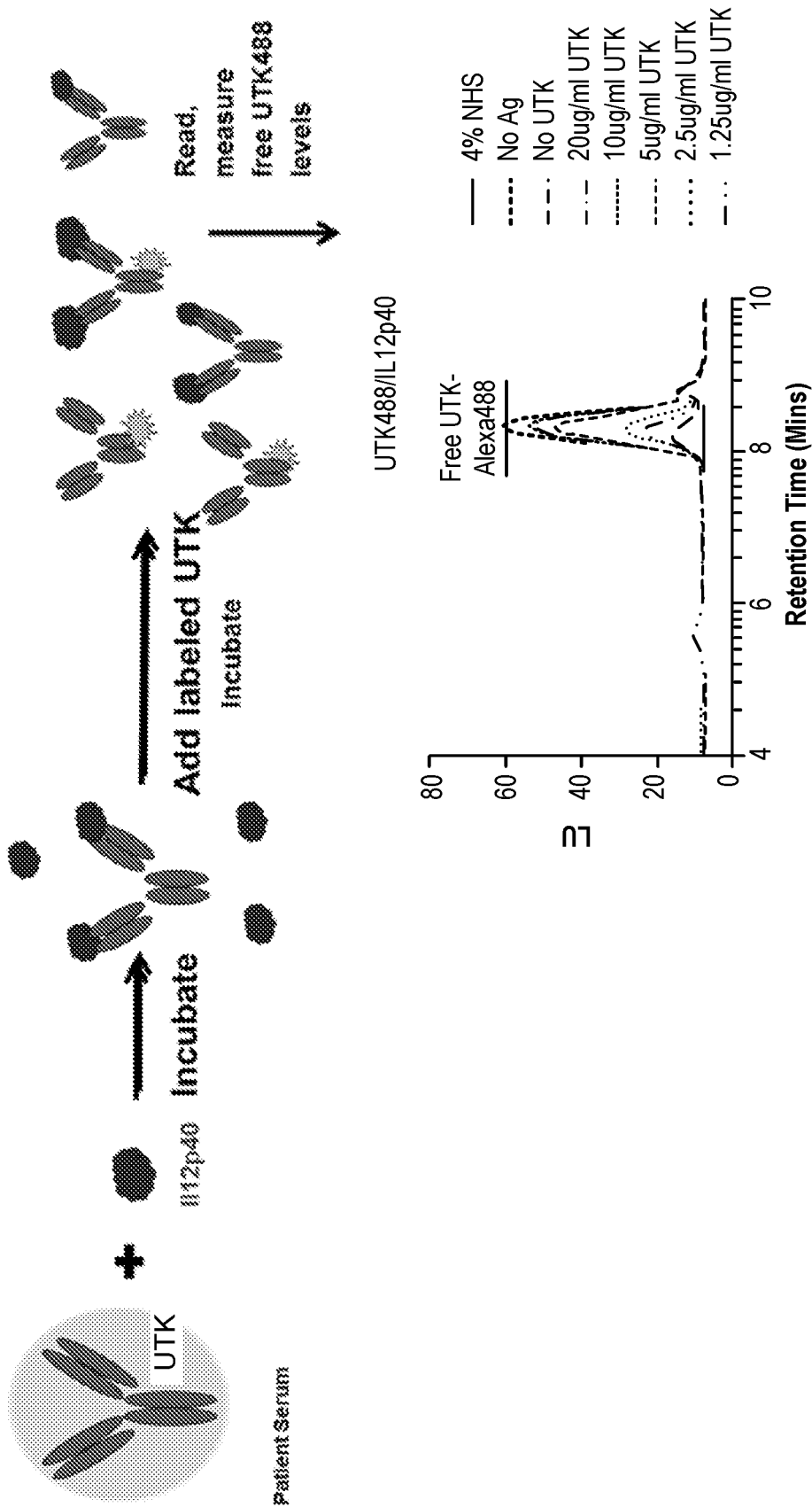


FIG. 16

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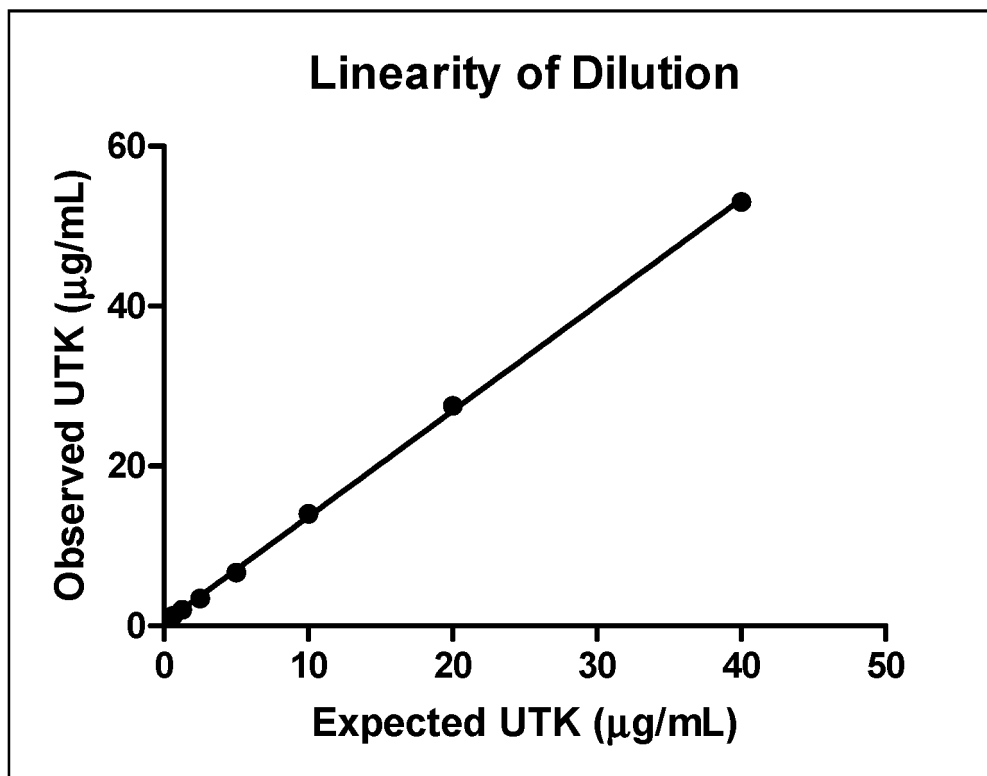
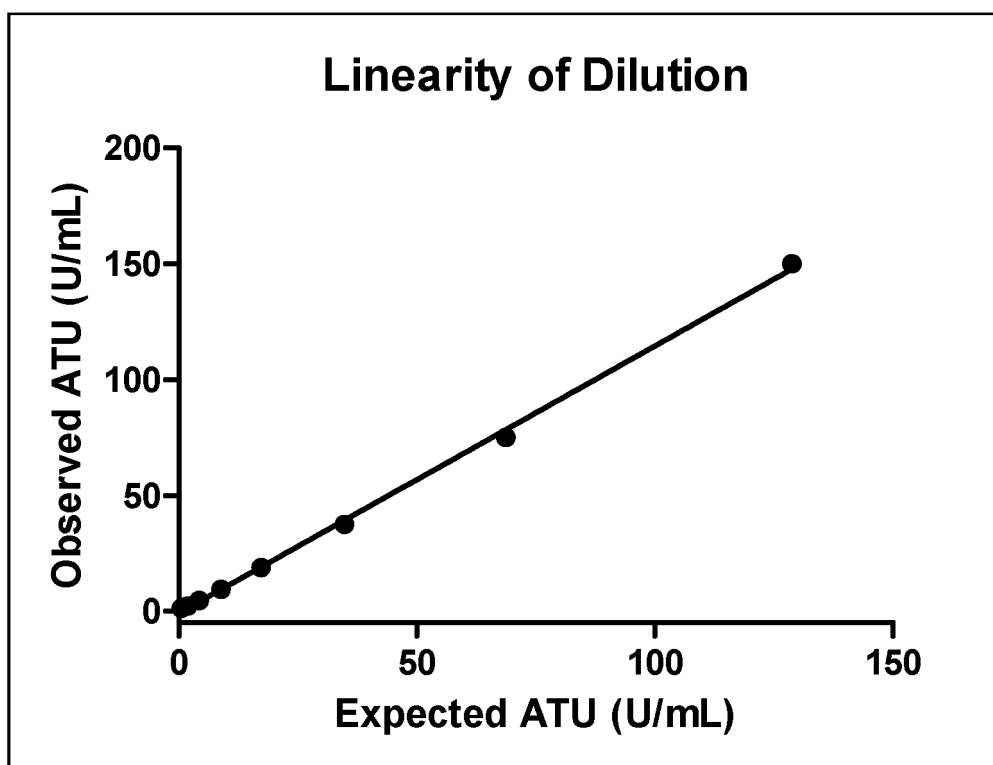
A**B**

FIG. 17
SUBSTITUTE SHEET (RULE 26)

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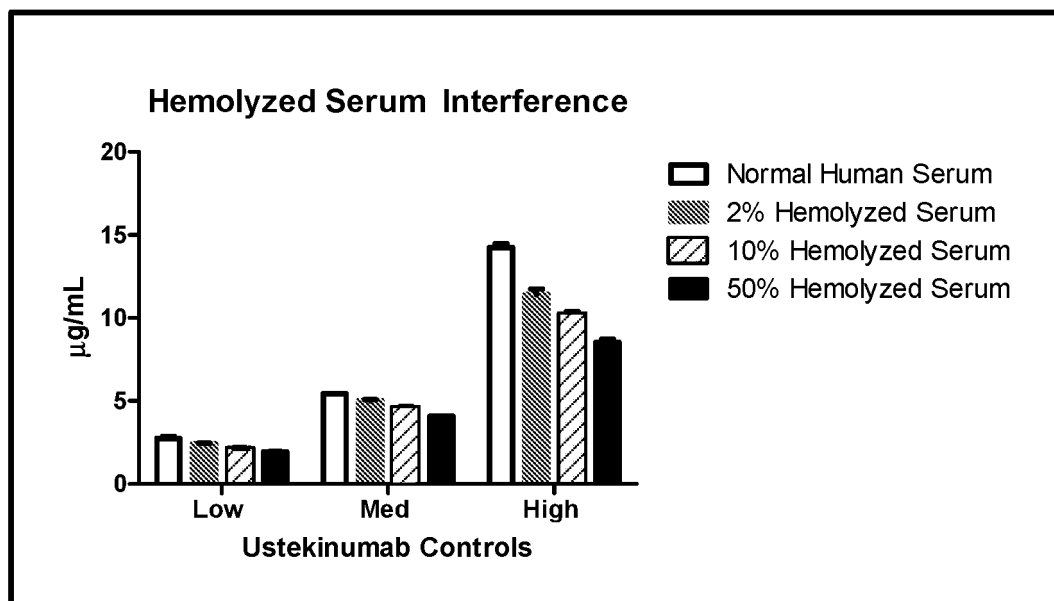
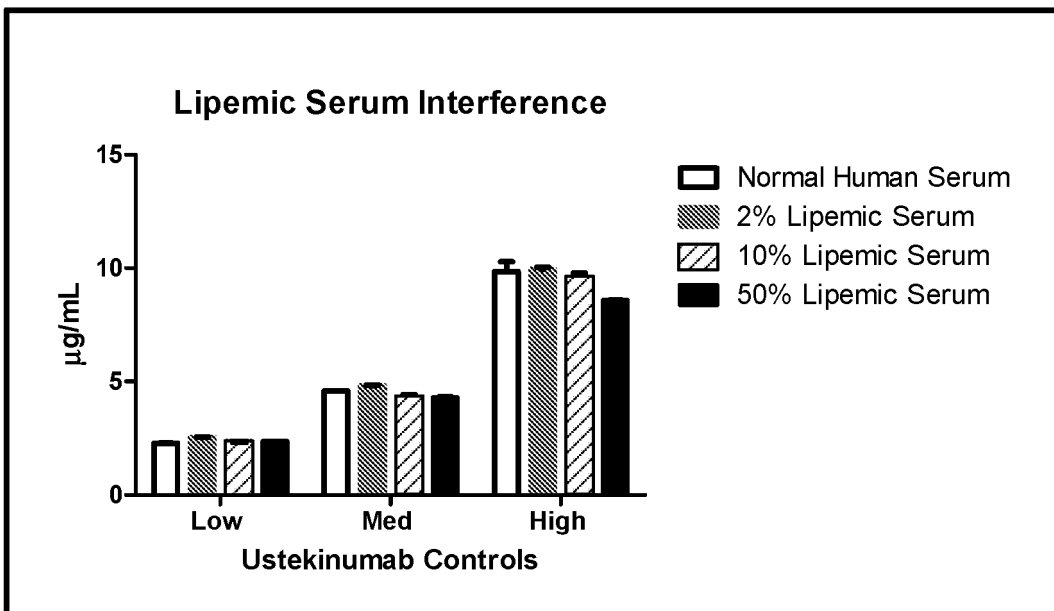
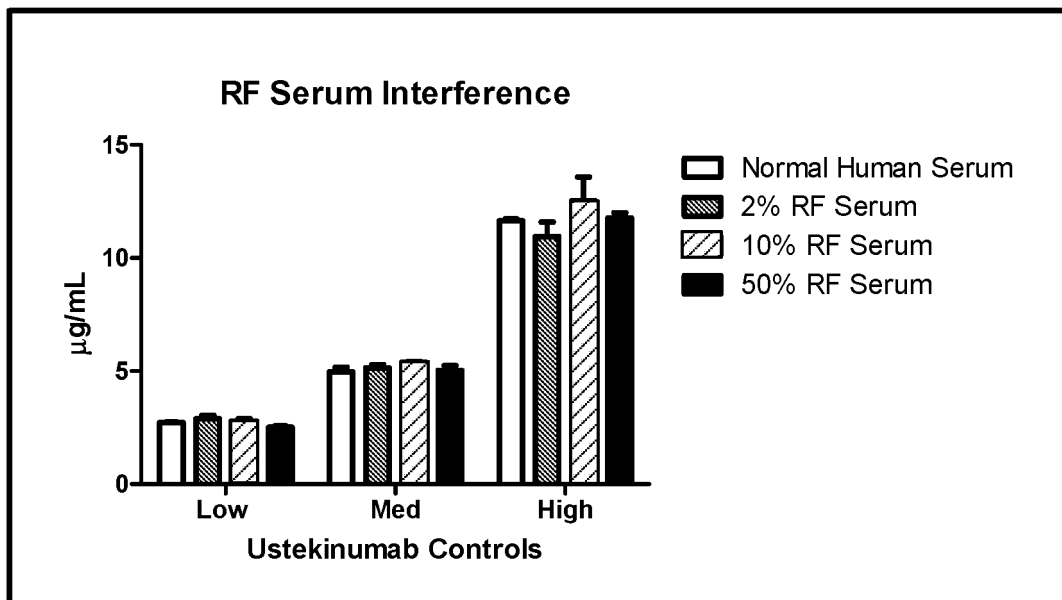
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FIG. 18
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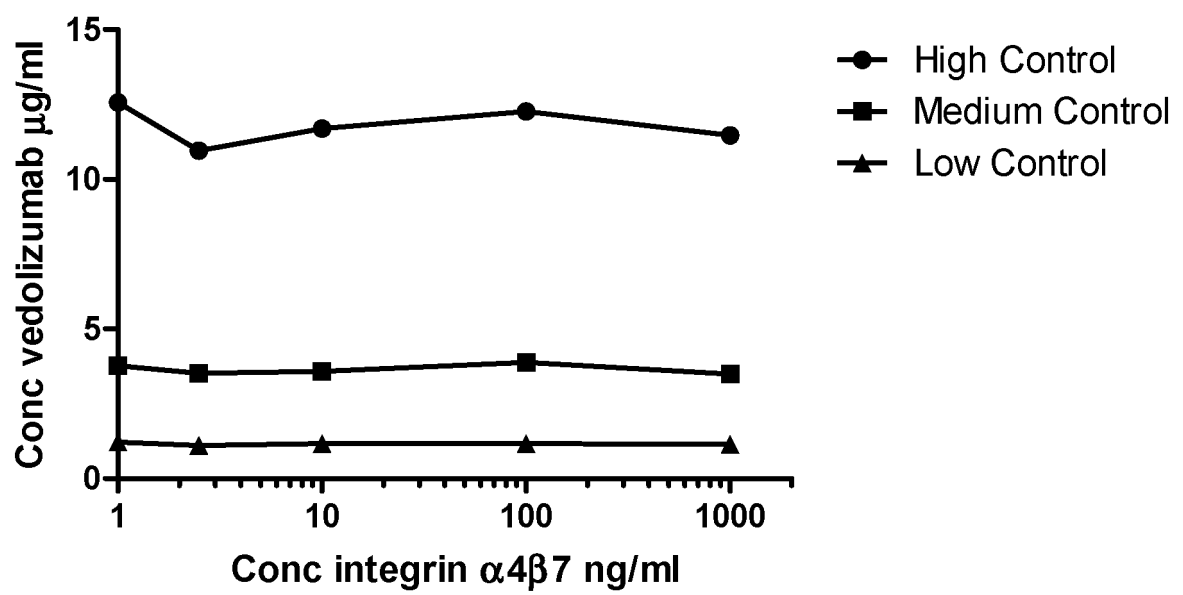


FIG. 19
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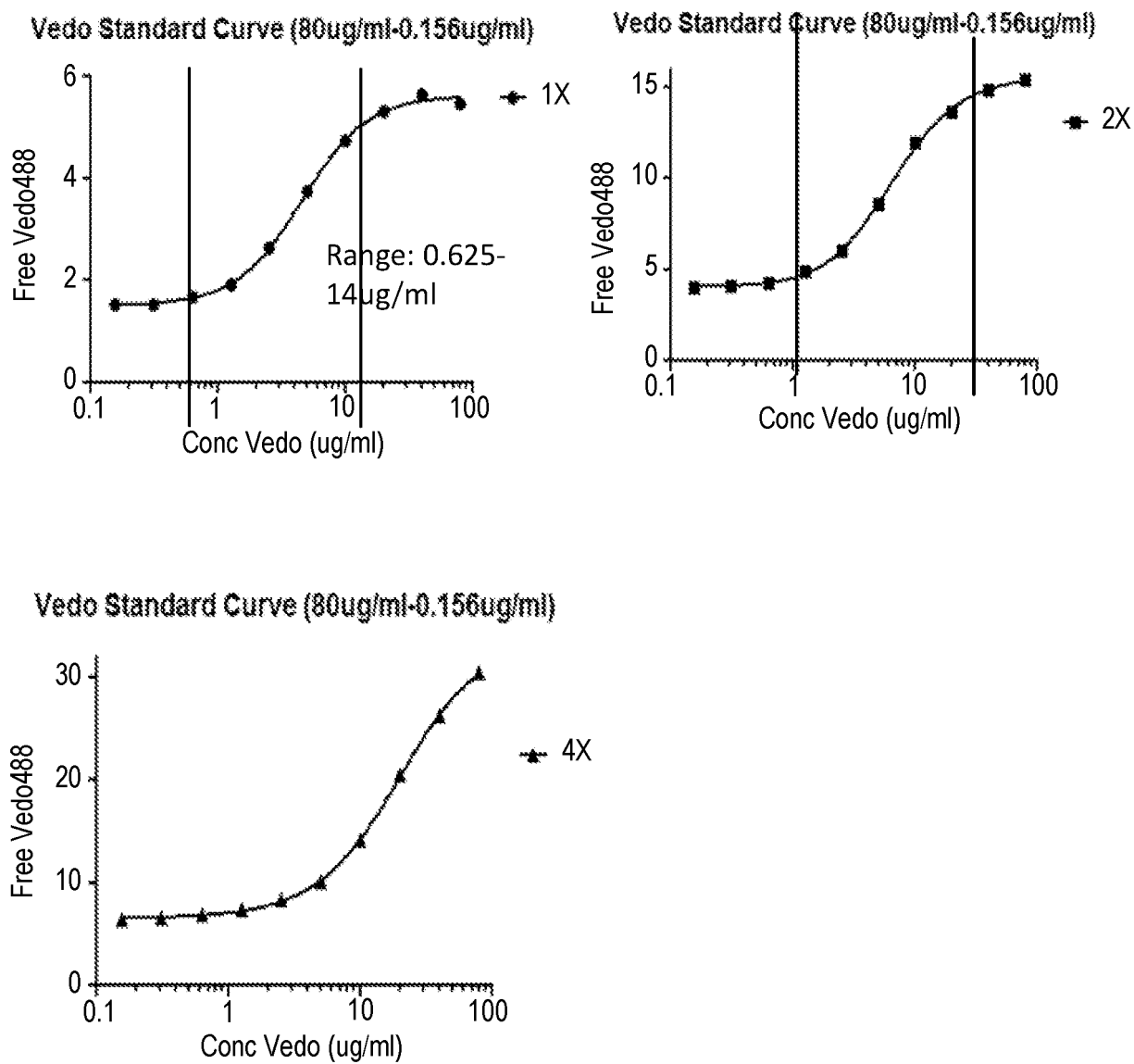


FIG. 20
SUBSTITUTE SHEET (RULE 26)