

MB-102 Iohexol

FIG. 1

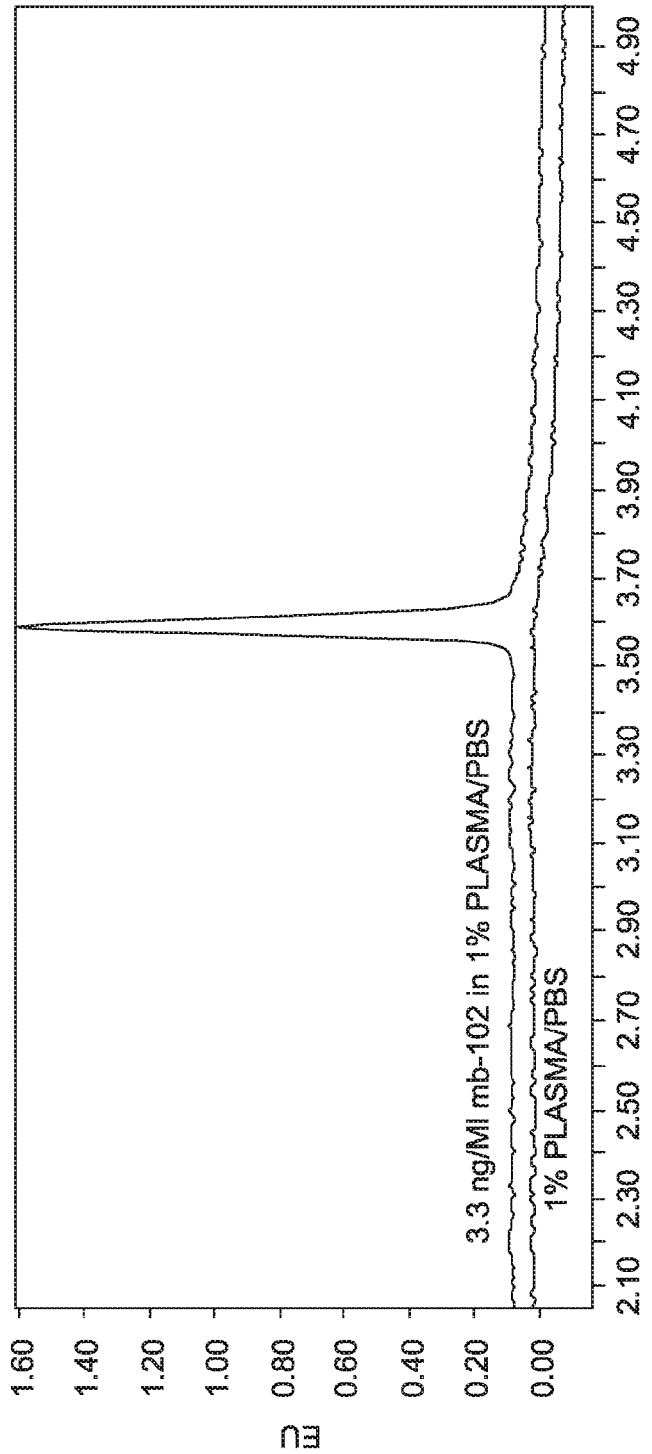

HPLC CHROMATOGRAMS OF MB-102 IN 1% PLASMA/PBS
3.3 ng/Ml mb-102 in 1% PLASMA/PBS
1% PLASMA/PBS
EU
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
2.10
2.30
2.50
2.70
2.90
3.10
3.30
3.50
3.70
3.90
4.10
4.30
4.50
4.70
4.90
MINUTES

FIG. 2

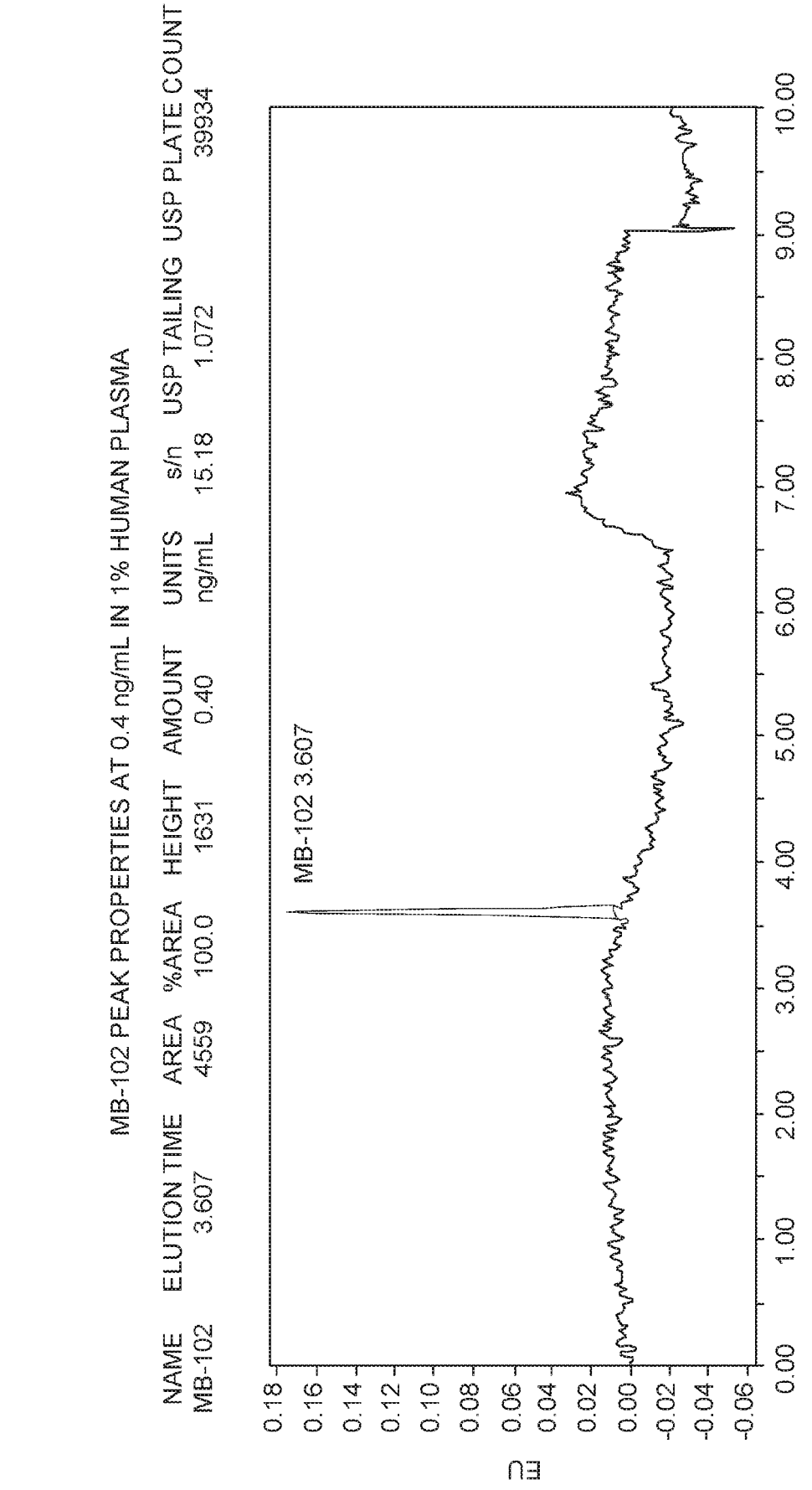

MB-102 PEAK PROPERTIES AT 0.4 ng/mL IN 1% HUMAN PLASMA
NAME ELUTION TIME AREA %AREA HEIGHT AMOUNT UNITS s/n USP TAILING USP PLATE COUNT
MB-102 3.607 4559 100.0 1631 0.40 ng/mL 15.18 1.072 39934
MB-102 3.607
0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
-0.02
-0.04
-0.06
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
8.00
9.00
10.00
MINUTES

FIG. 3A

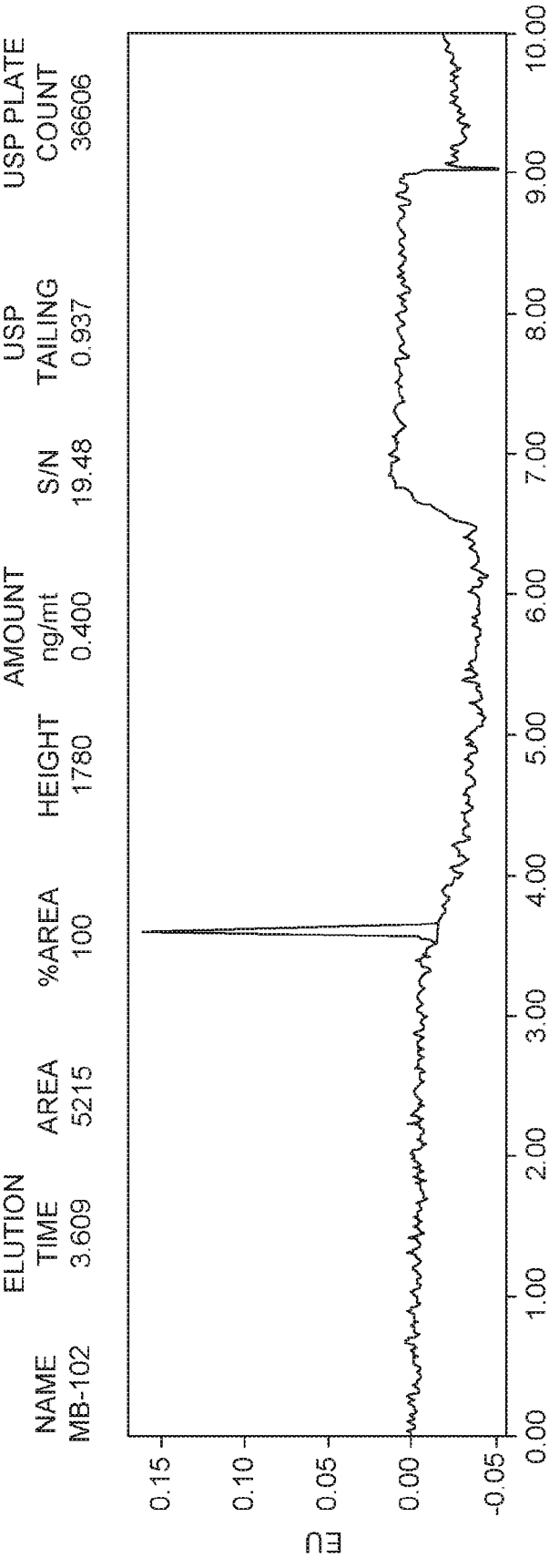

NAME
MB-102
ELUTION TIME
3.609
AREA
5215
%AREA
100
HEIGHT
1780
AMOUNT
ng/ml
0.400
S/N
19.48
USP TAILING
0.937
USP PLATE COUNT
36606
0.15
0.10
0.05
0.00
-0.05
EU
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
8.00
9.00
10.00
MINUTES

FIG. 3B

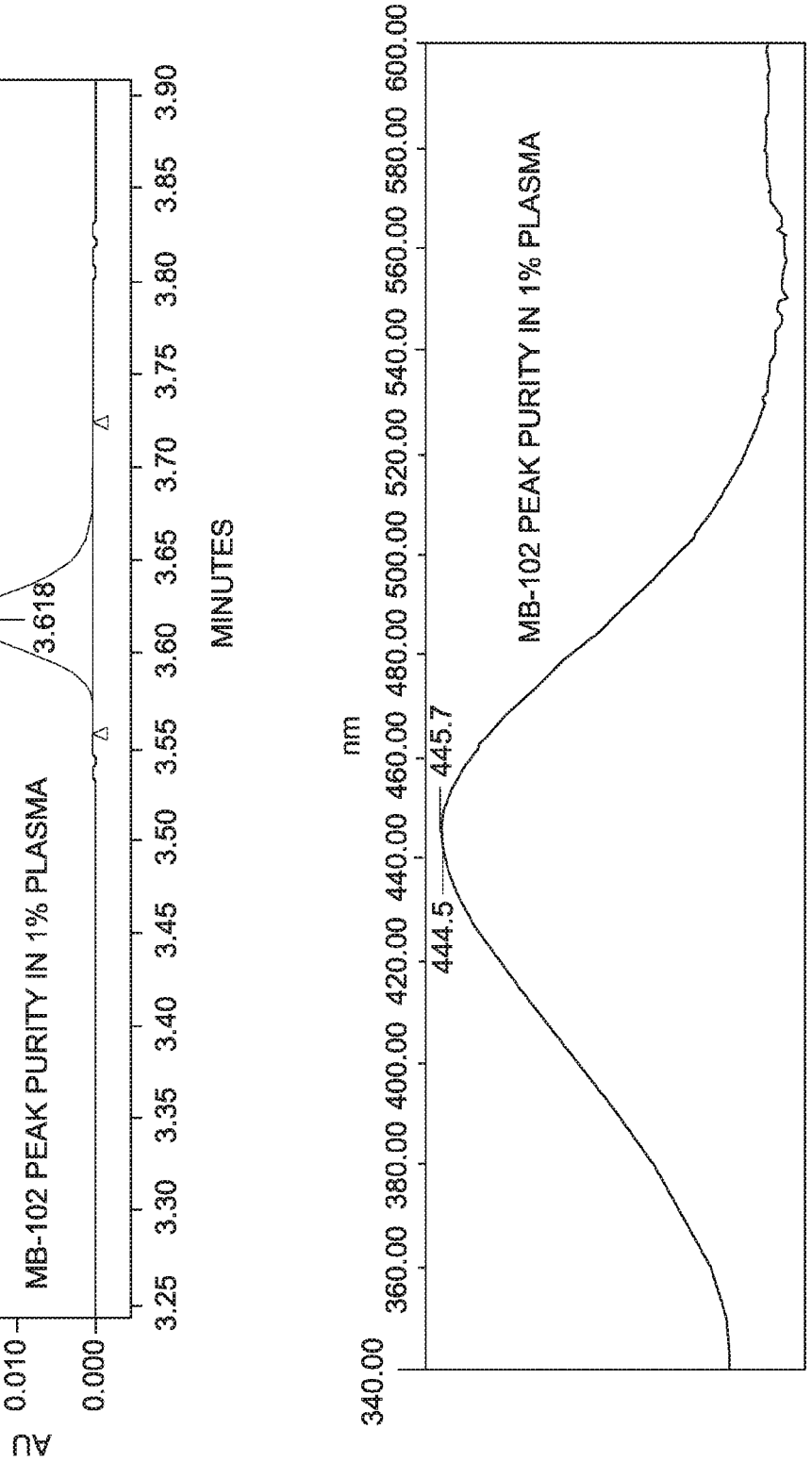
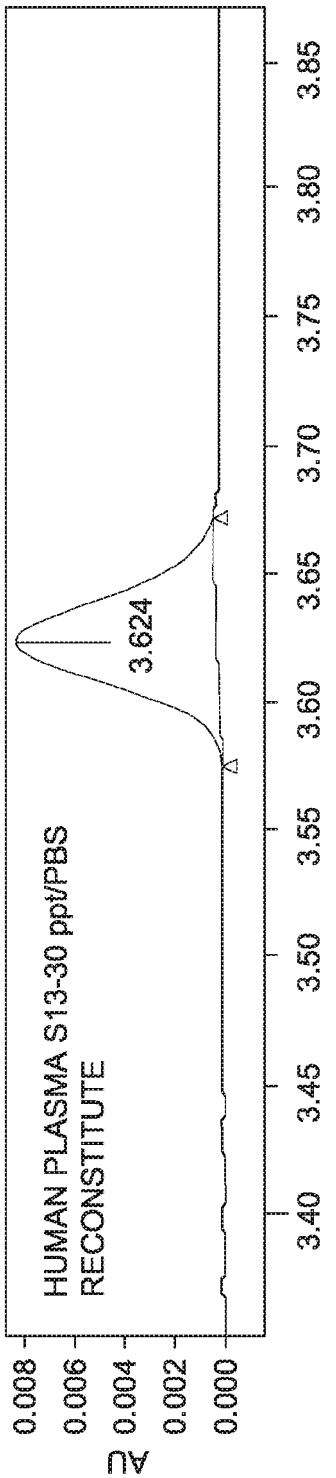

MB-102 PEAK PURITY IN 1% PLASMA
3.618
AU
0.010
0.000
3.25 3.30 3.35 3.40 3.45 3.50 3.55 3.60 3.65 3.70 3.75 3.80 3.85 3.90
MINUTES
MB-102 PEAK PURITY IN 1% PLASMA
444.5
445.7
nm
340.00 360.00 380.00 400.00 420.00 440.00 460.00 480.00 500.00 520.00 540.00 560.00 580.00 600.00

FIG. 4


HUMAN PLASMA S13-30 ppt/PBS
RECONSTITUTE
3.624
AU
0.008
0.006
0.004
0.002
0.000
3.40
3.45
3.50
3.55
3.60
3.65
3.70
3.75
3.80
3.85

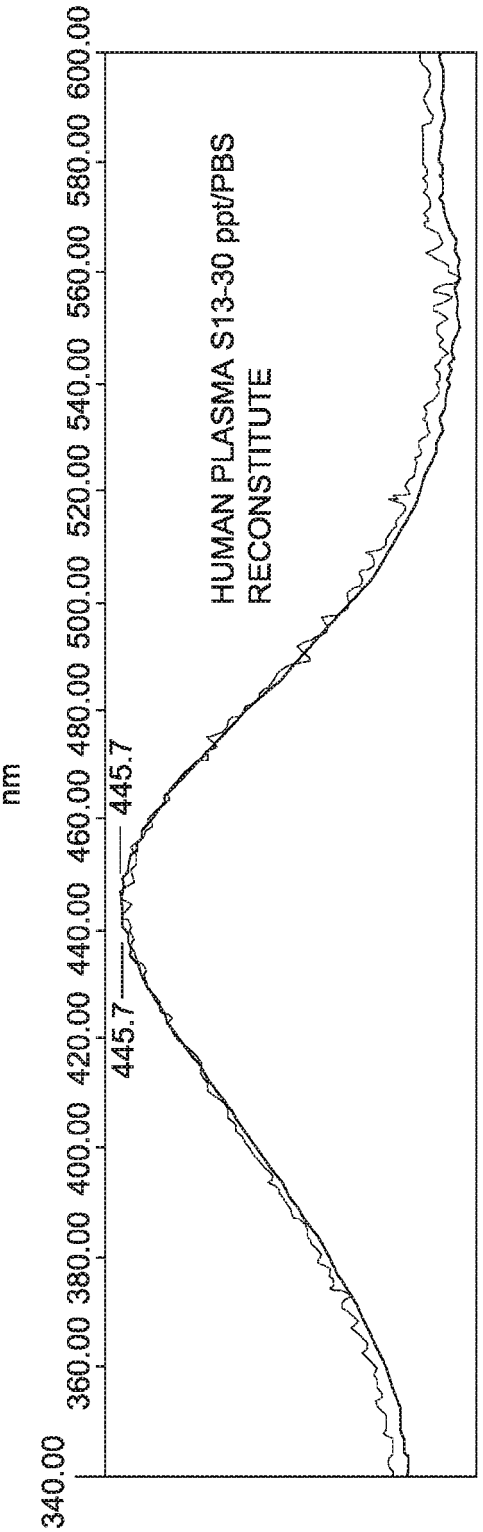

HUMAN PLASMA S13-30 ppt/PBS
RECONSTITUTE
445.7
445.7
nm
340.00
360.00
380.00
400.00
420.00
440.00
460.00
480.00
500.00
520.00
540.00
560.00
580.00
600.00

FIG. 5

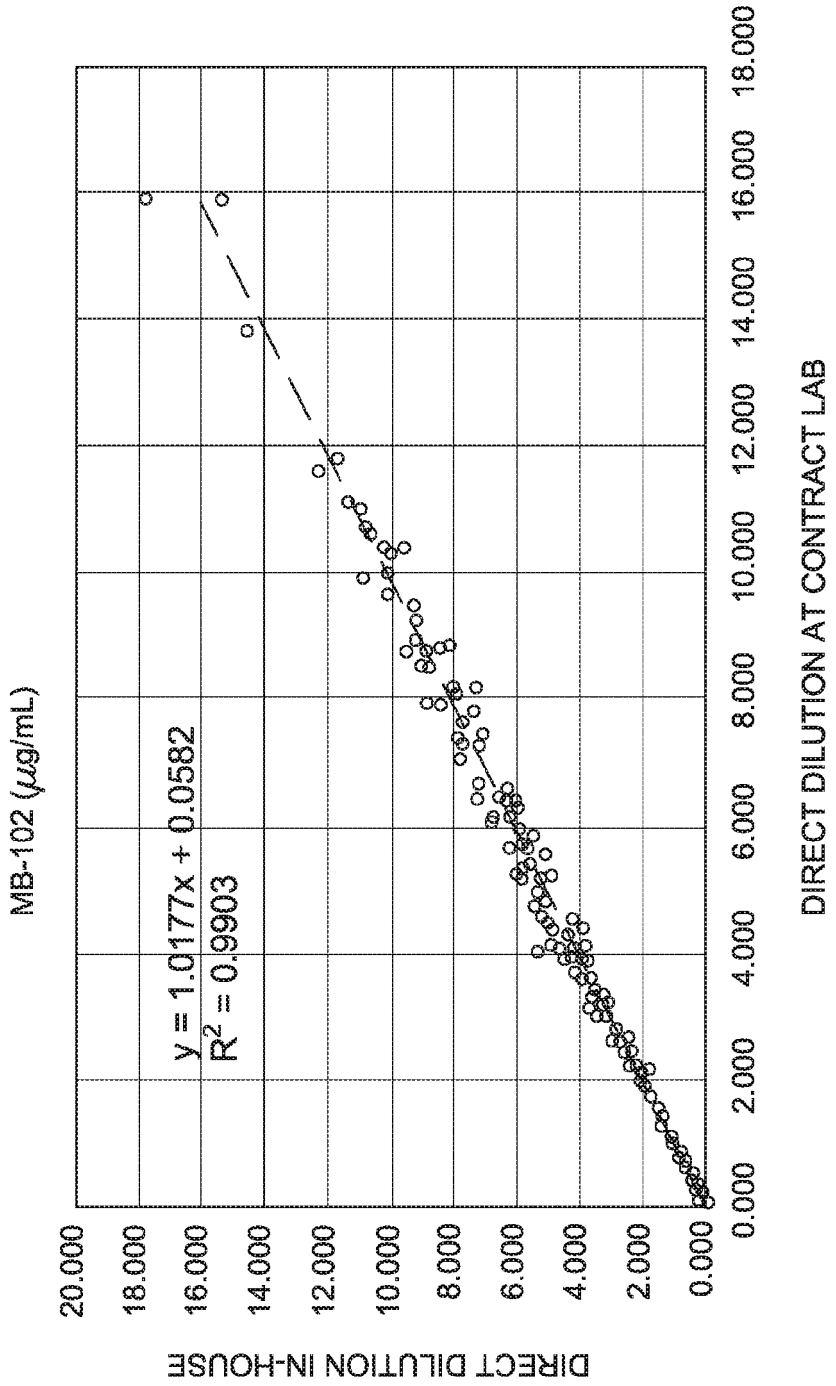

MB-102 (μg/mL)
y = 1.0177x + 0.0582
R2 = 0.9903
DIRECT DILUTION AT CONTRACT LAB
DIRECT DILUTION IN-HOUSE
0.000
2.000
4.000
6.000
8.000
10.000
12.000
14.000
16.000
18.000
20.000

FIG. 6

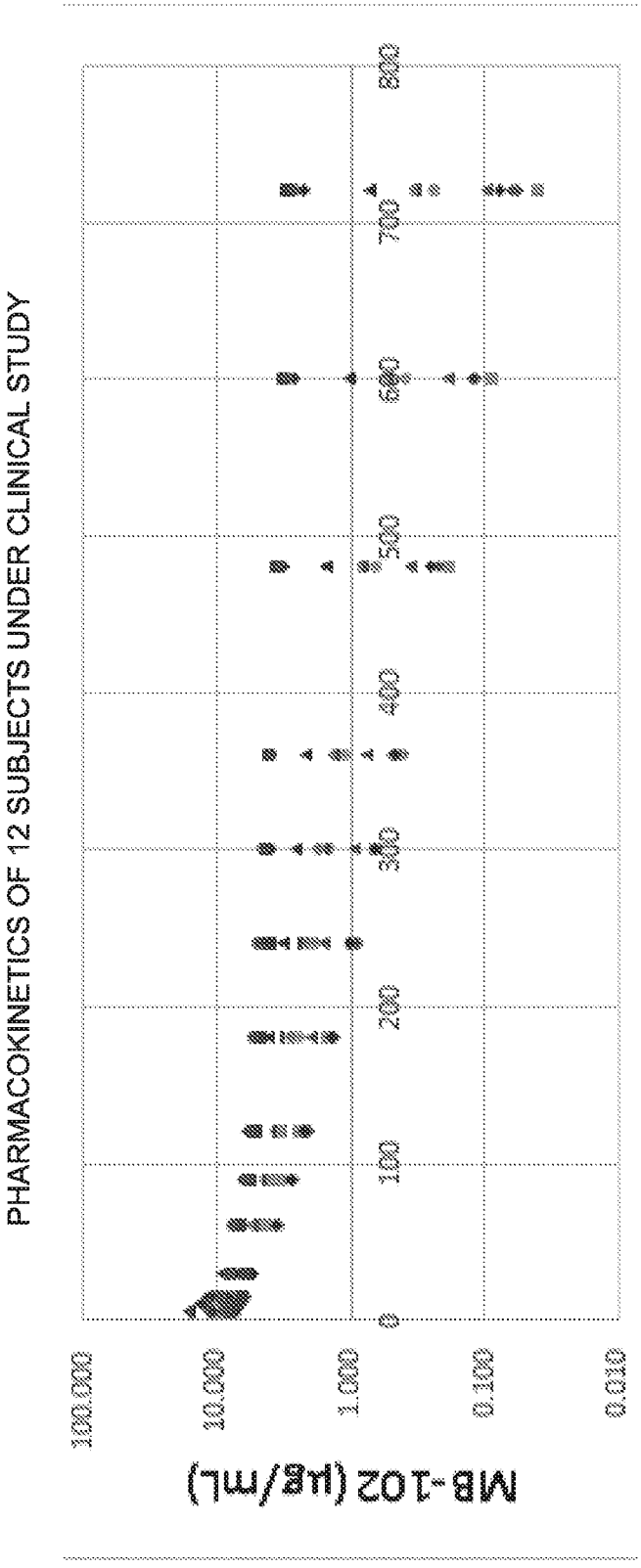

PHARMACOKINETICS OF 12 SUBJECTS UNDER CLINICAL STUDY
MB-102 (µg/mL)
100.000
10.000
1.000
0.100
0.010
0
100
200
300
400
500
600
700
800
TIME

FIG. 7

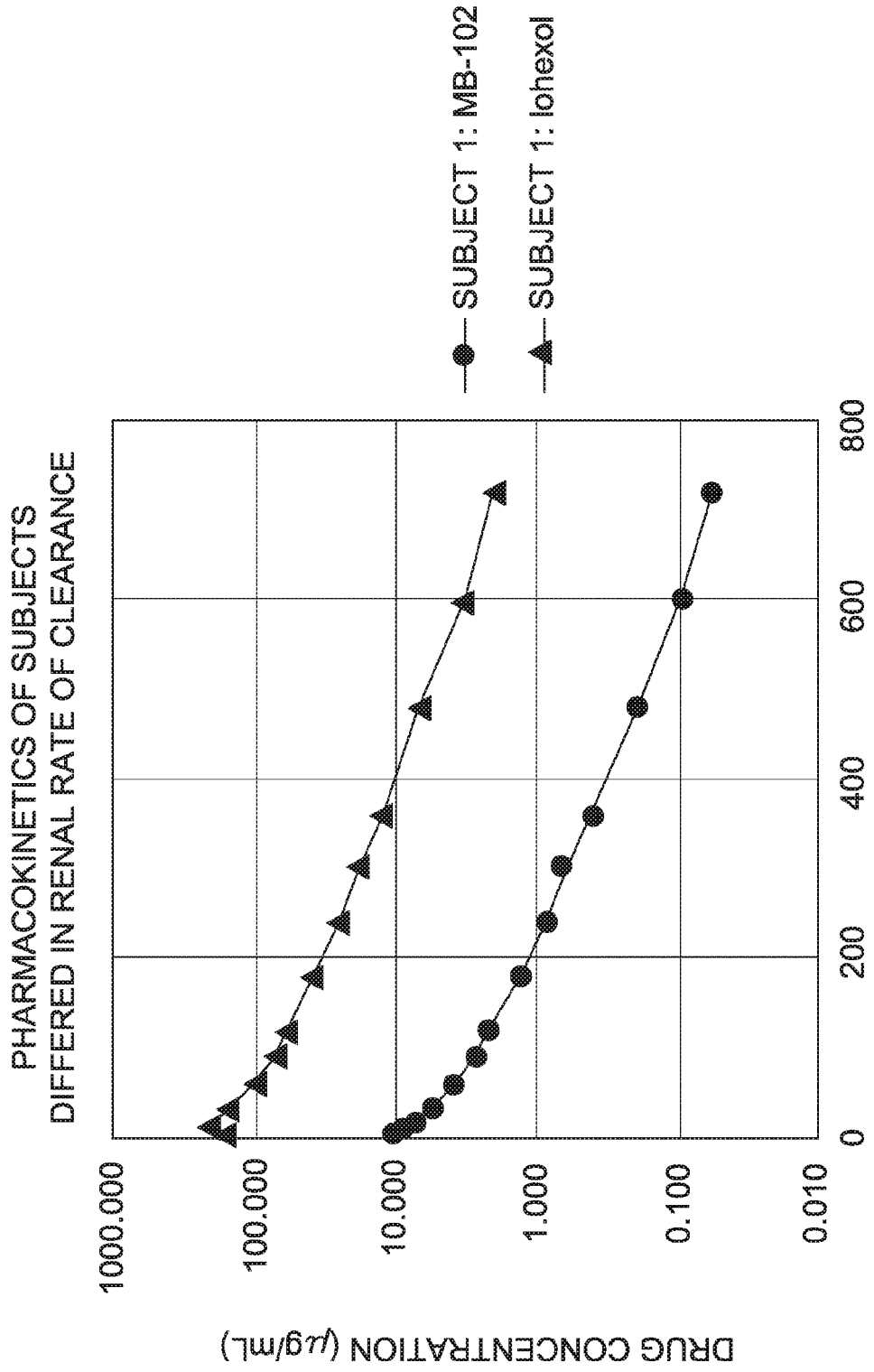

PHARMACOKINETICS OF SUBJECTS
DIFFERED IN RENAL RATE OF CLEARANCE
SUBJECT 1: MB-102
SUBJECT 1: Iohexol
1000.000
100.000
10.000
1.000
0.100
0.010
DRUG CONCENTRATION (μg/mL)
0
200
400
600
800
TIME

FIG. 8A

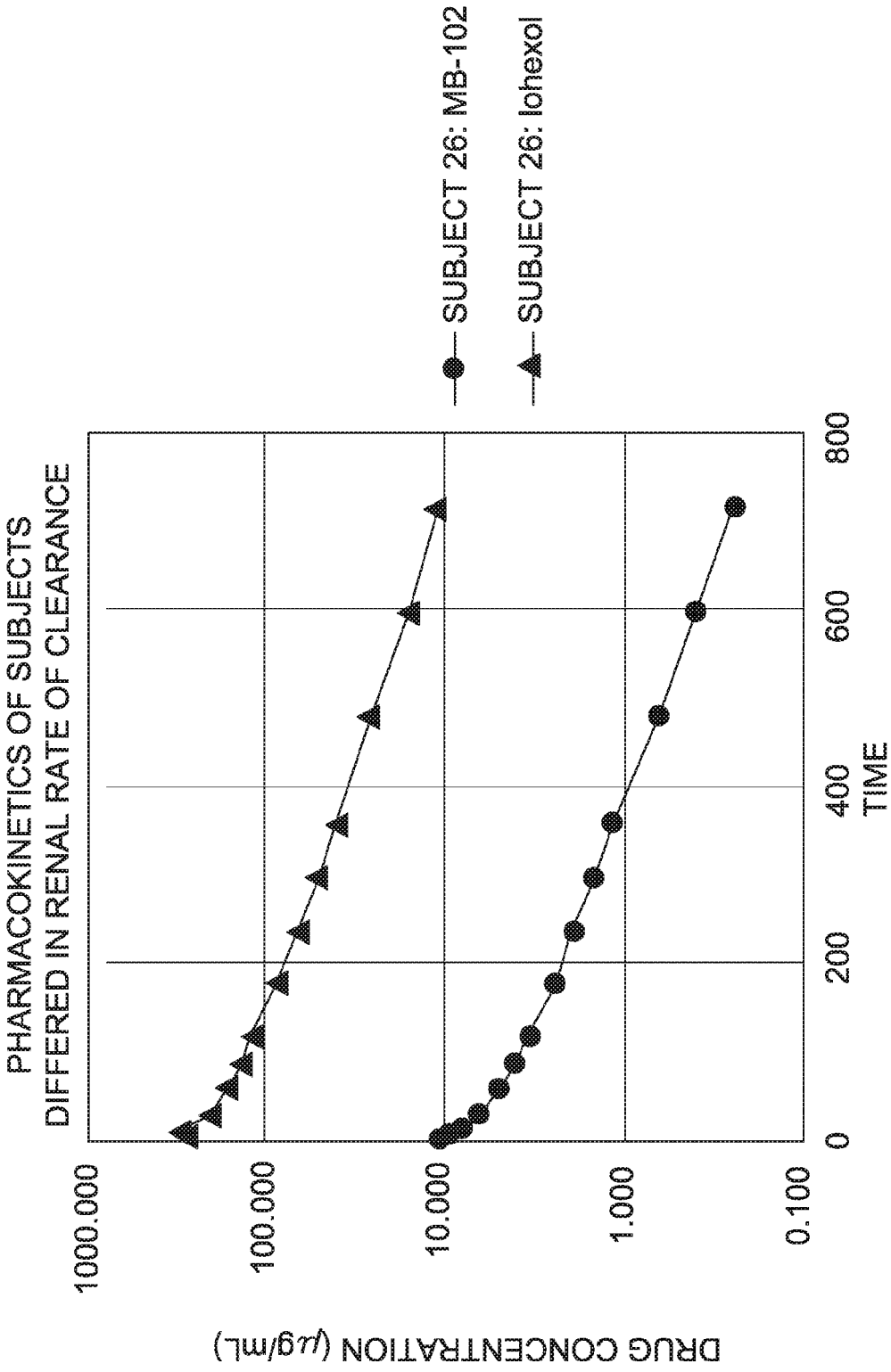

PHARMACOKINETICS OF SUBJECTS
DIFFERED IN RENAL RATE OF CLEARANCE
SUBJECT 26: MB-102
SUBJECT 26: Iohexol
1000.000
100.000
10.000
1.000
0.100
0
200
400
600
800
TIME
DRUG CONCENTRATION (μg/mL)

FIG. 8B

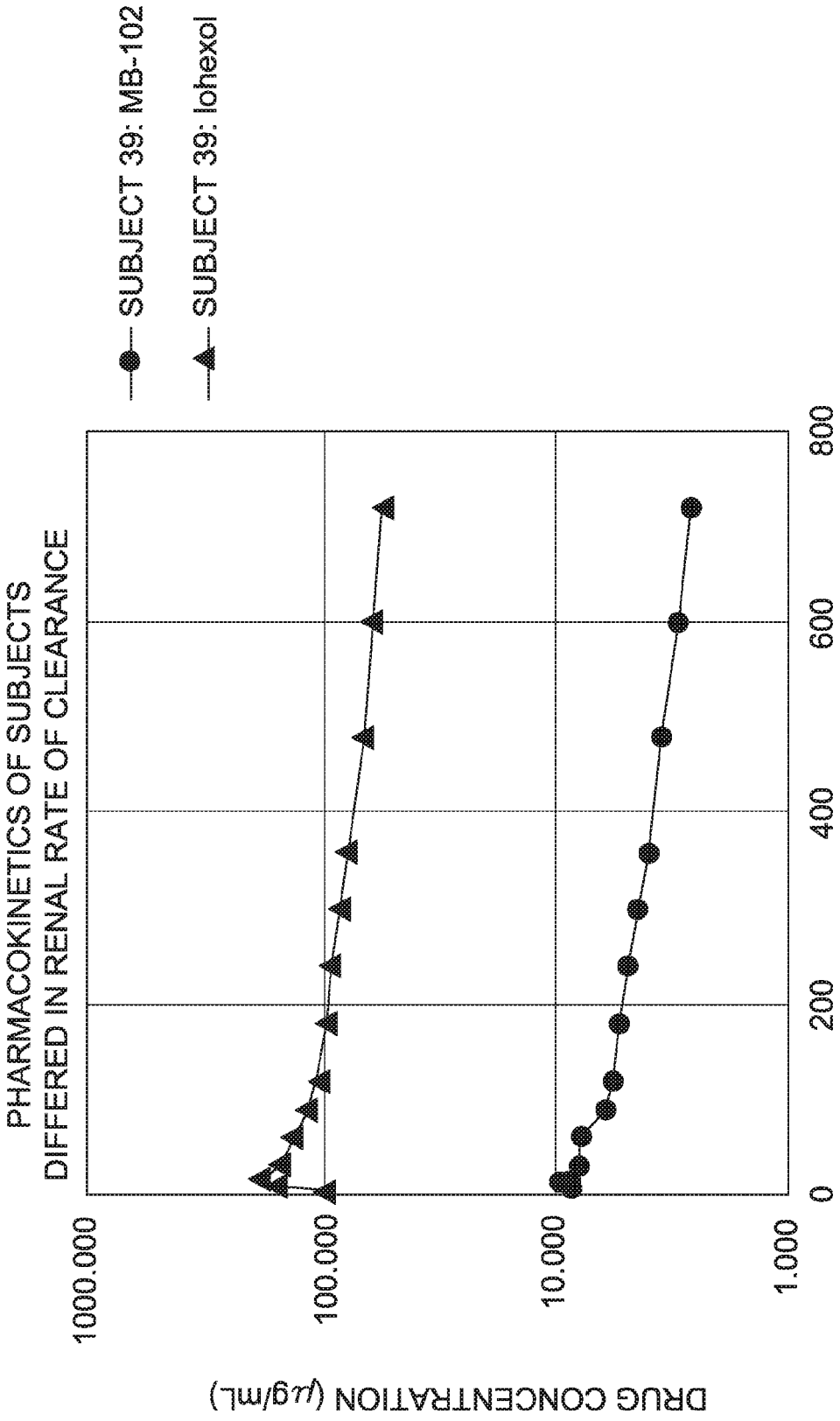

PHARMACOKINETICS OF SUBJECTS
DIFFERED IN RENAL RATE OF CLEARANCE
SUBJECT 39: MB-102
SUBJECT 39: Iohexol
DRUG CONCENTRATION (μg/mL)
1000.000
100.000
10.000
1.000
0
200
400
600
800
TIME

FIG. 8C

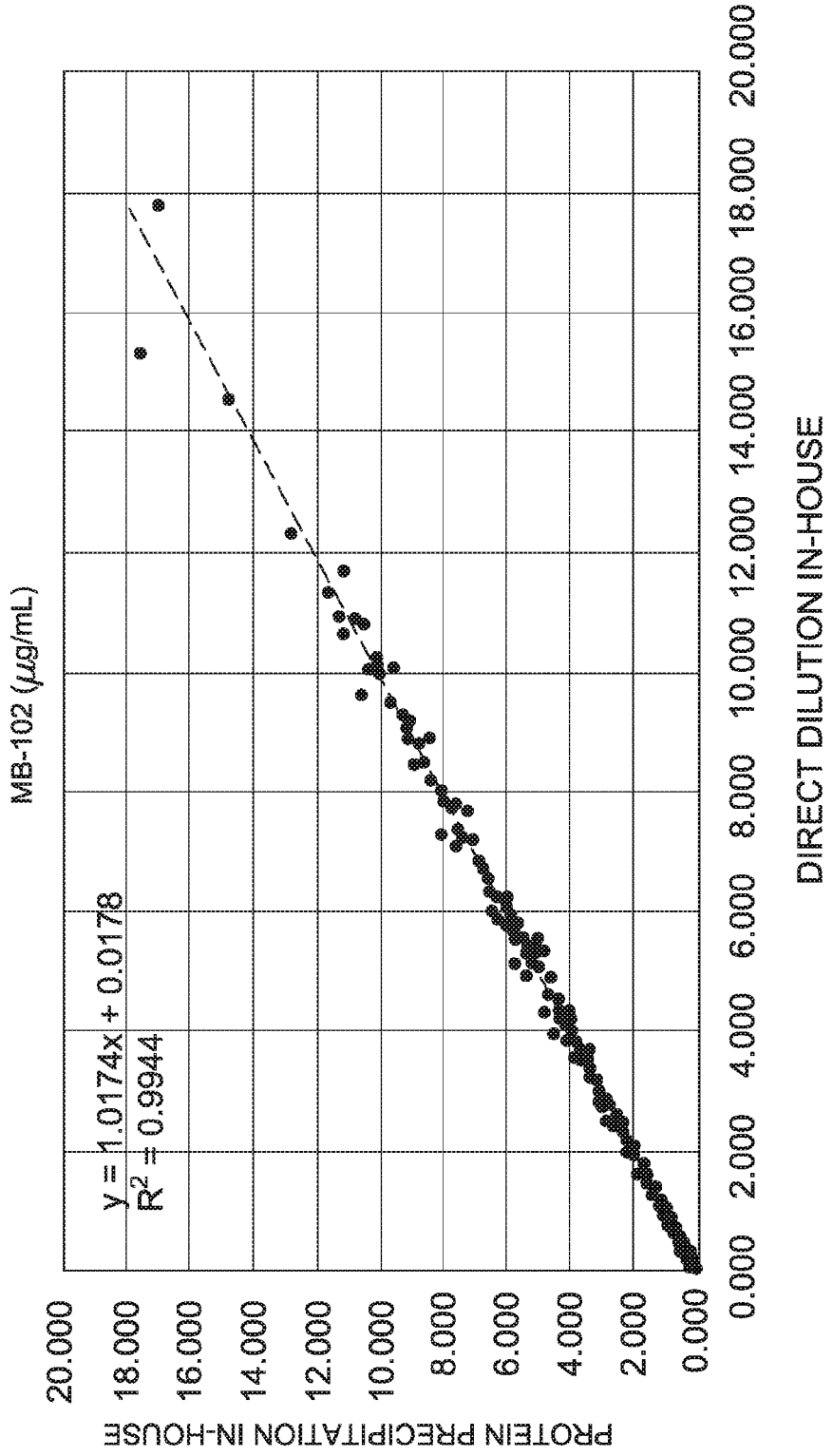

MB-102 (µg/mL)
y = 1.0174x + 0.0178
R² = 0.9944
0.000
2.000
4.000
6.000
8.000
10.000
12.000
14.000
16.000
18.000
20.000
PROTEIN PRECIPITATION IN-HOUSE
DIRECT DILUTION IN-HOUSE

FIG. 9

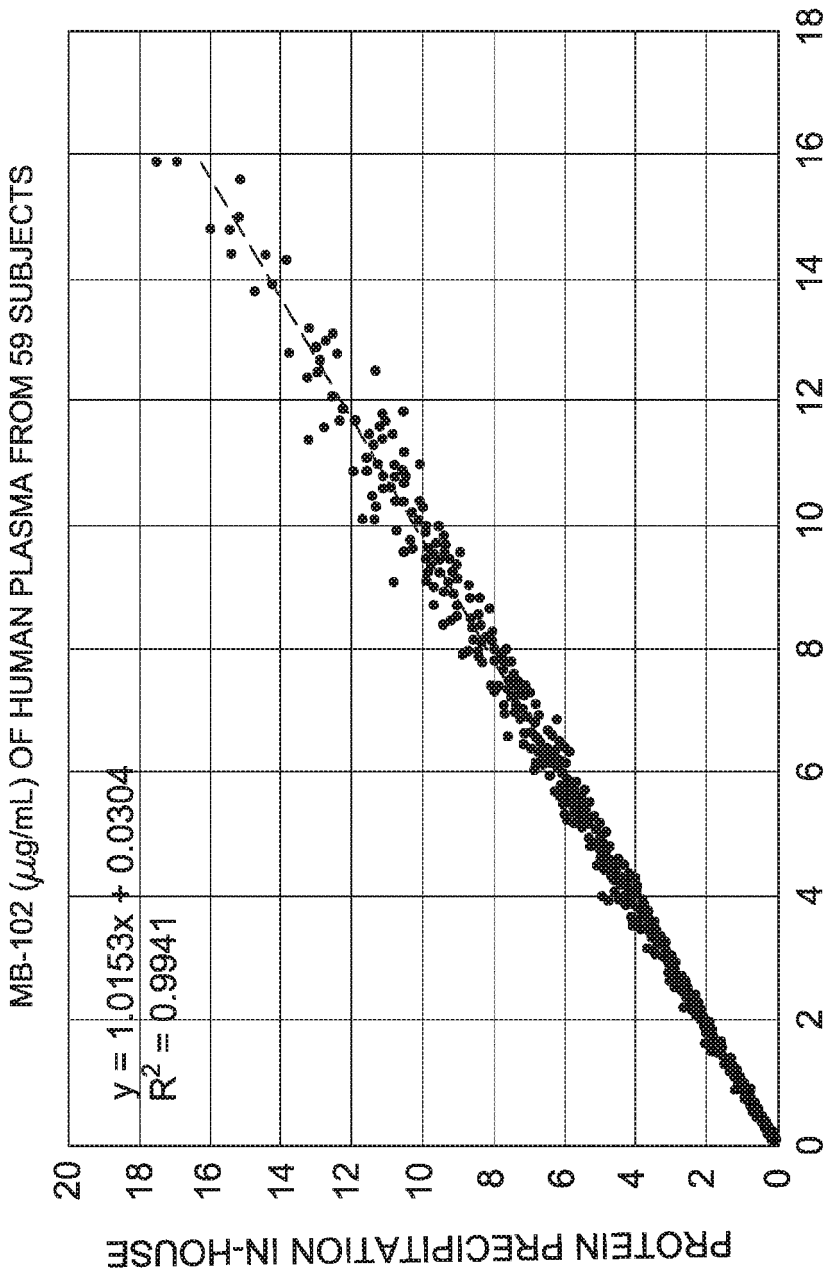

MB-102 (μg/mL) OF HUMAN PLASMA FROM 59 SUBJECTS
y = 1.0153x + 0.0304
R² = 0.9941
PROTEIN PRECIPITATION IN-HOUSE
DIRECT DILUTION AT CONTRACT LAB
0
2
4
6
8
10
12
14
16
18
20

FIG. 10

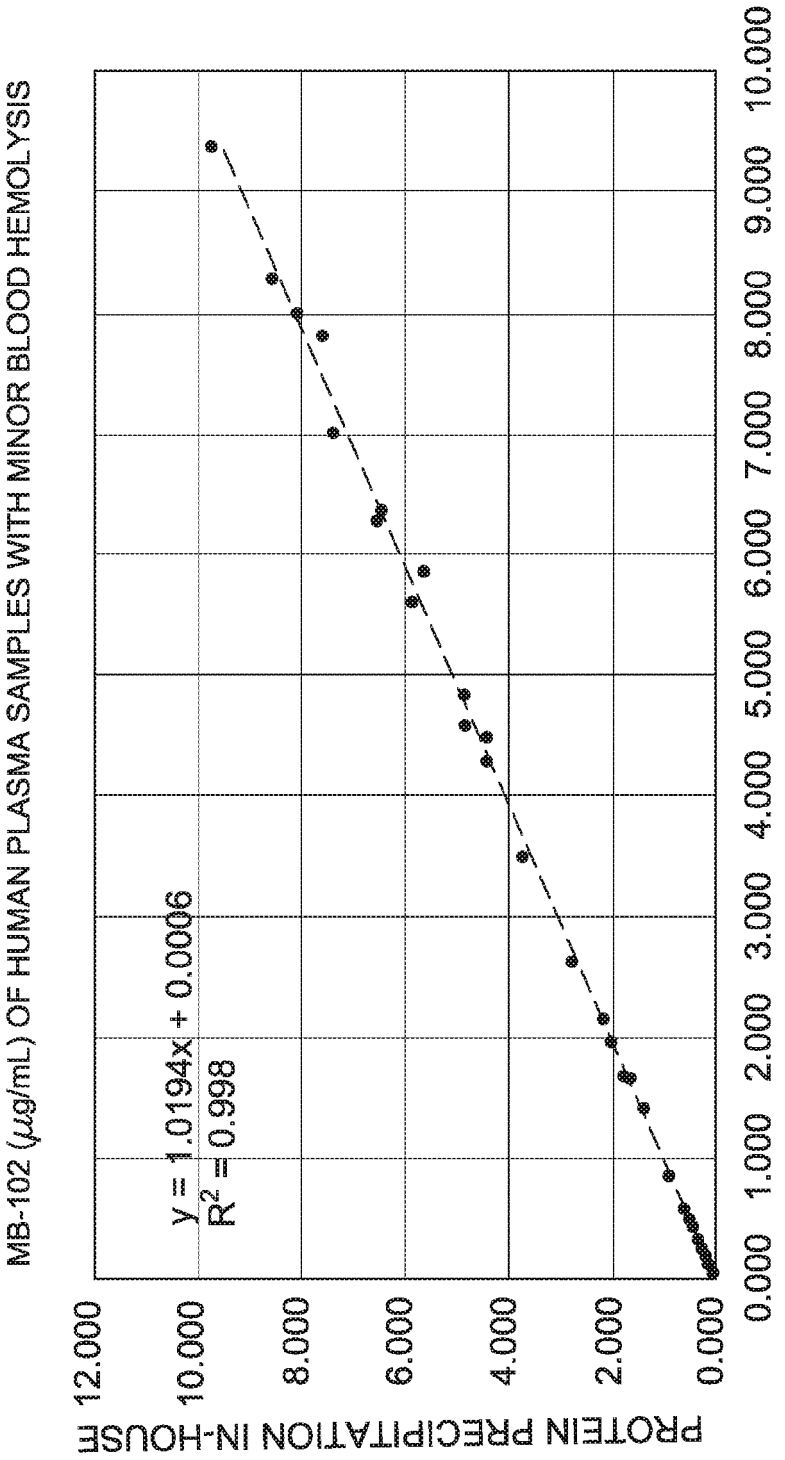

MB-102 (μg/mL) OF HUMAN PLASMA SAMPLES WITH MINOR BLOOD HEMOLYSIS
y = 1.0194x + 0.0006
R² = 0.998
PROTEIN PRECIPITATION IN-HOUSE
DIRECT DILUTION AT CONTRACT LAB
0.000
2.000
4.000
6.000
8.000
10.000
12.000
0.000
1.000
2.000
3.000
4.000
5.000
6.000
7.000
8.000
9.000
10.000

FIG. 11

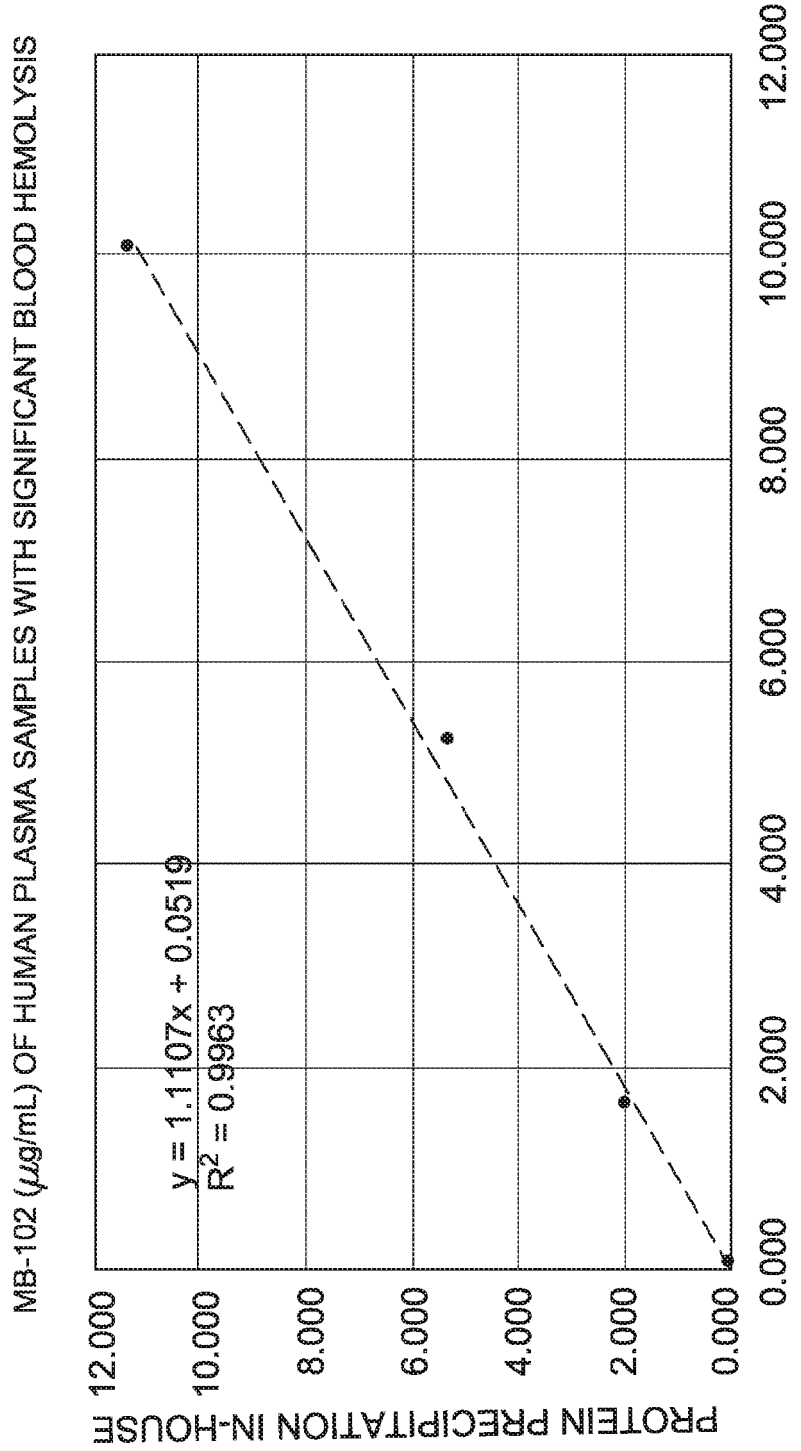

MB-102 (μg/mL) OF HUMAN PLASMA SAMPLES WITH SIGNIFICANT BLOOD HEMOLYSIS
y = 1.1107x + 0.0519
R² = 0.9963
PROTEIN PRECIPITATION IN-HOUSE
DIRECT DILUTION AT CONTRACT LAB
0.000
2.000
4.000
6.000
8.000
10.000
12.000

FIG. 12