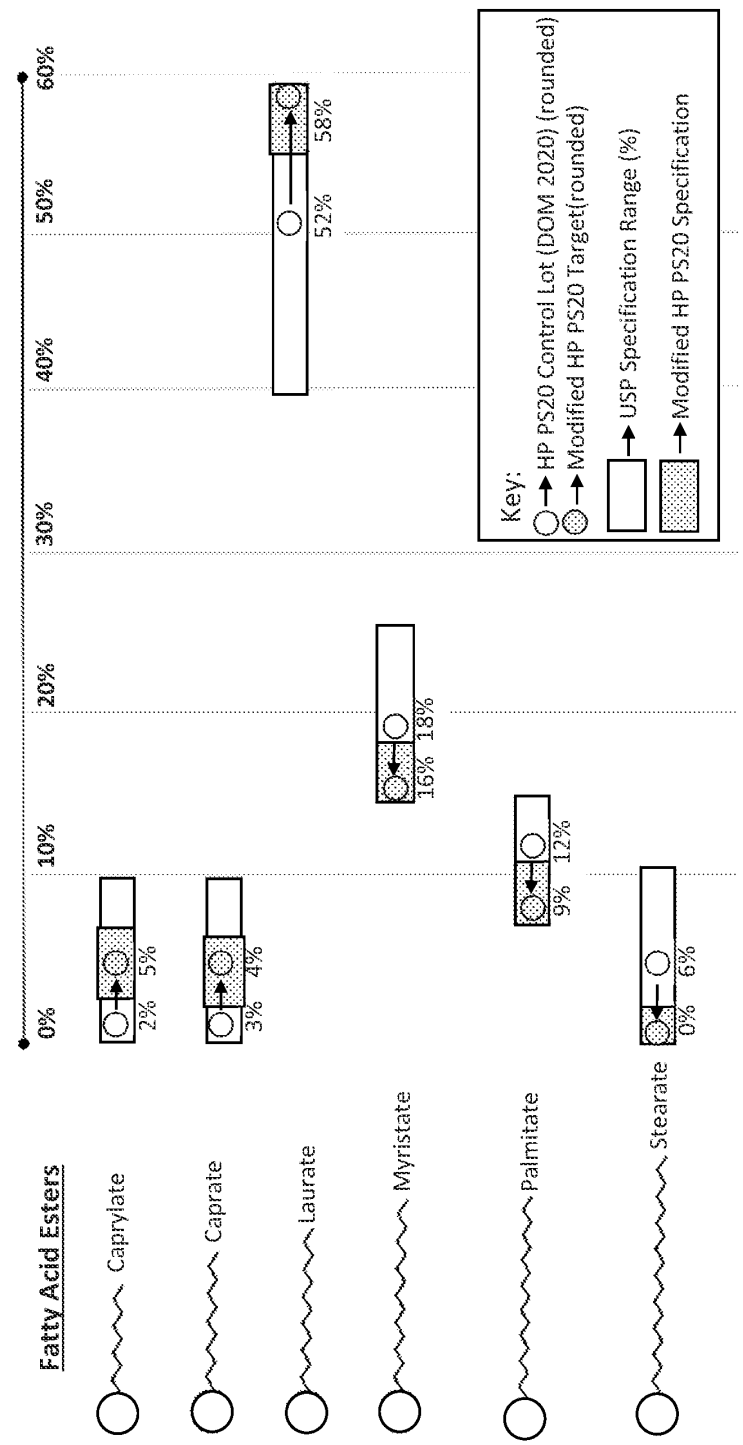

Fatty Acid Esters
Caprylate
Caprate
Laurate
Myristate
Palmitate
Stearate
0%
10%
20%
30%
40%
50%
60%
2%
5%
3%
4%
16%
18%
9%
12%
0%
6%
52%
58%
Key:
HP PS20 Control Lot (DOM 2020) (rounded)
Modified HP PS20 Target(rounded)
USP Specification Range (%)
Modified HP PS20 Specification

Fig. 1

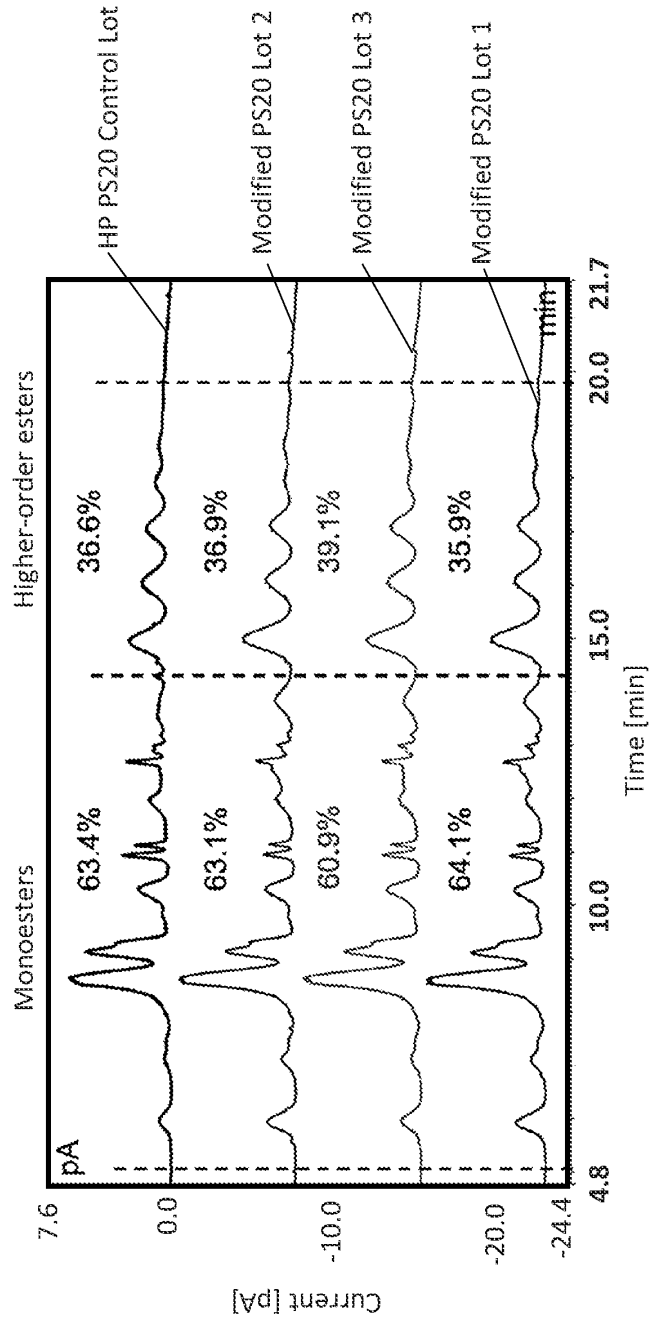

HP PS20 Control Lot
Modified PS20 Lot 2
Modified PS20 Lot 3
Modified PS20 Lot 1
Higher-order esters
Monoesters
36.6%
36.9%
39.1%
35.9%
63.4%
63.1%
60.9%
64.1%
pA
min
7.6
0.0
-10.0
-20.0
-24.4
4.8
10.0
15.0
20.0
21.7
Current [pA]
Time [min]

Fig. 2

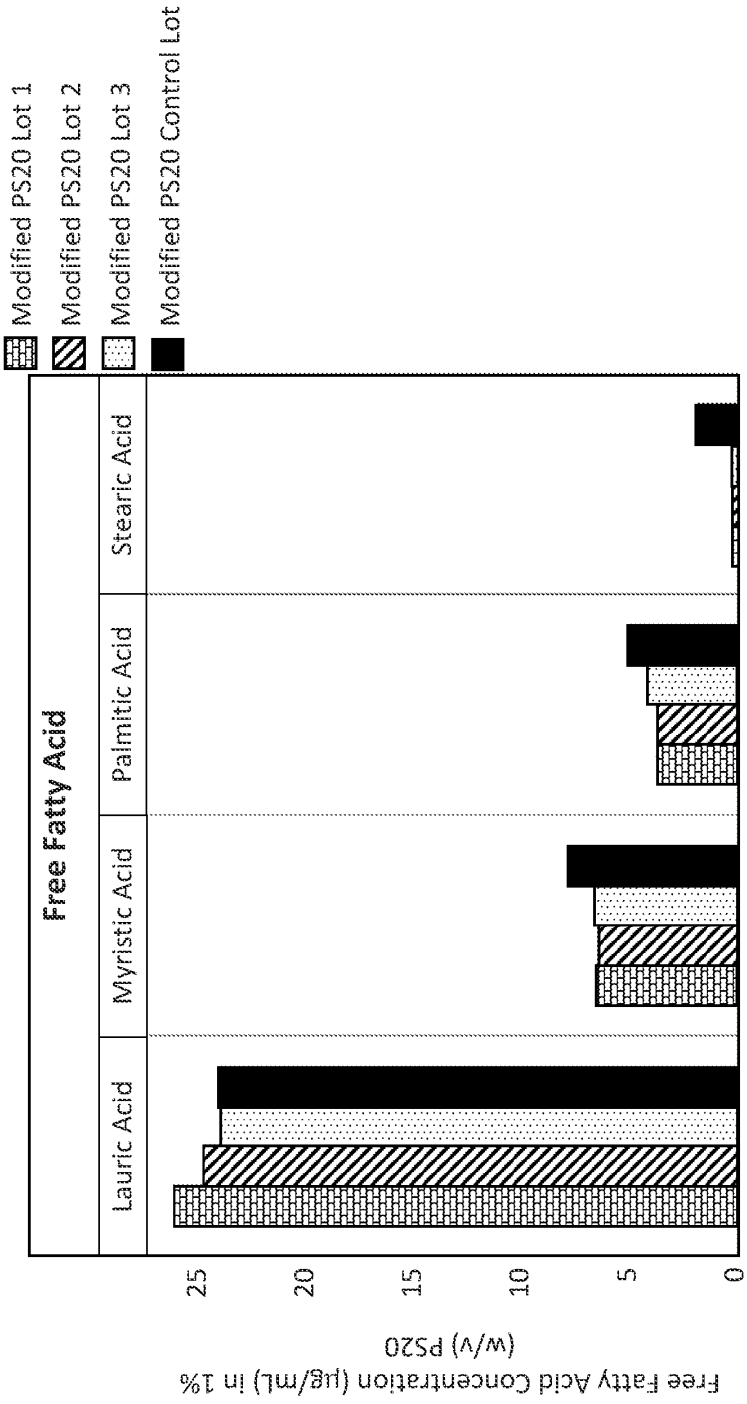

Modified PS20 Lot 1
Modified PS20 Lot 2
Modified PS20 Lot 3
Modified PS20 Control Lot
Free Fatty Acid
Lauric Acid
Myristic Acid
Palmitic Acid
Stearic Acid
0
5
10
15
20
25
Free Fatty Acid Concentration (µg/mL) in 1% (w/v) PS20

Fig. 3A

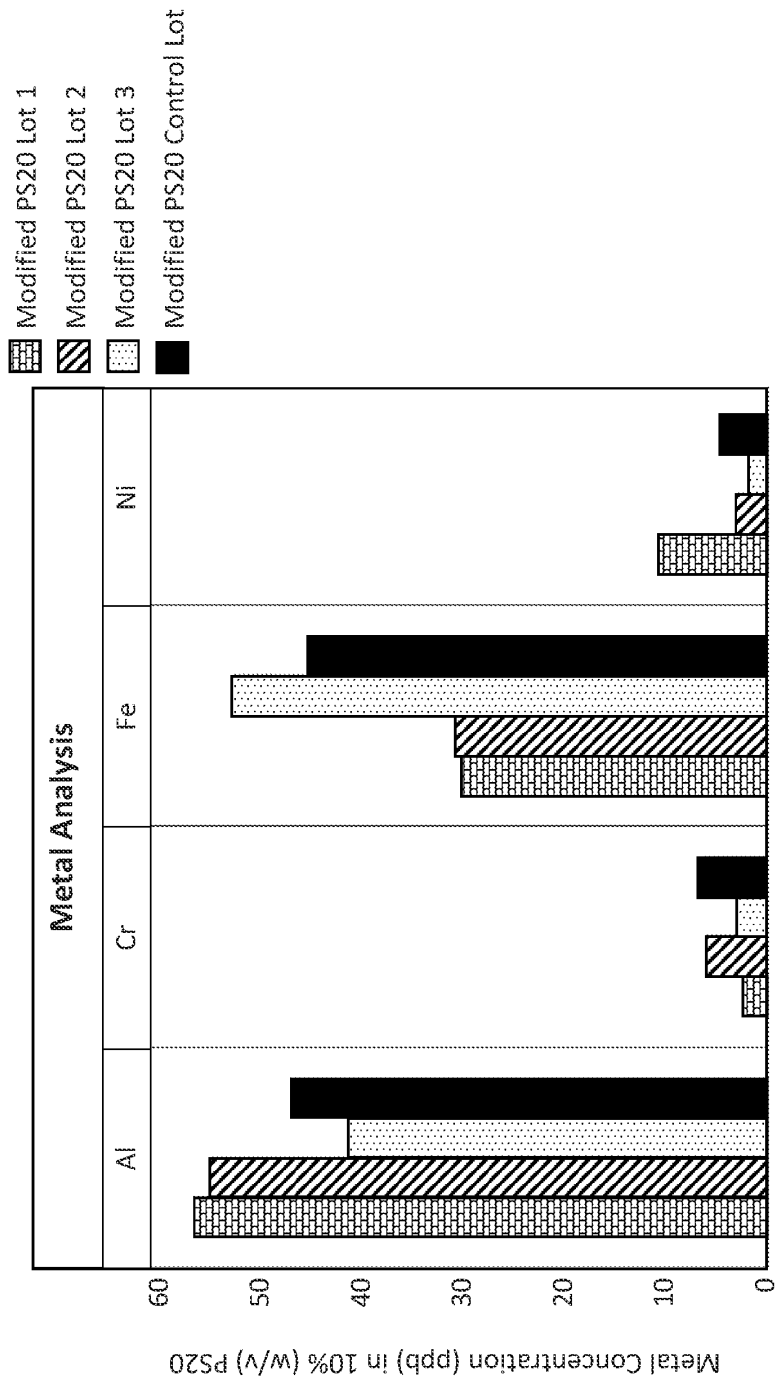

Modified PS20 Lot 1
Modified PS20 Lot 2
Modified PS20 Lot 3
Modified PS20 Control Lot
Metal Analysis
Al
Cr
Fe
Ni
0
10
20
30
40
50
60
Metal Concentration (ppb) in 10% (w/v) PS20

Fig. 3B

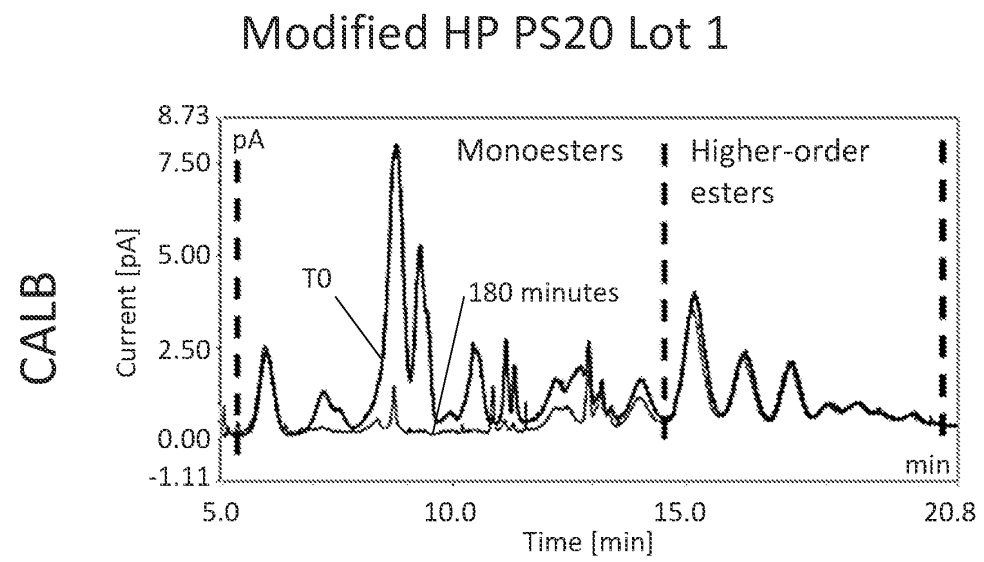

Modified HP PS20 Lot 1
CALB
8.73
7.50
5.00
2.50
0.00
-1.11
pA
Current [pA]
Monoesters
Higher-order esters
T0
180 minutes
min
5.0
10.0
15.0
20.8
Time [min]

Fig. 4A

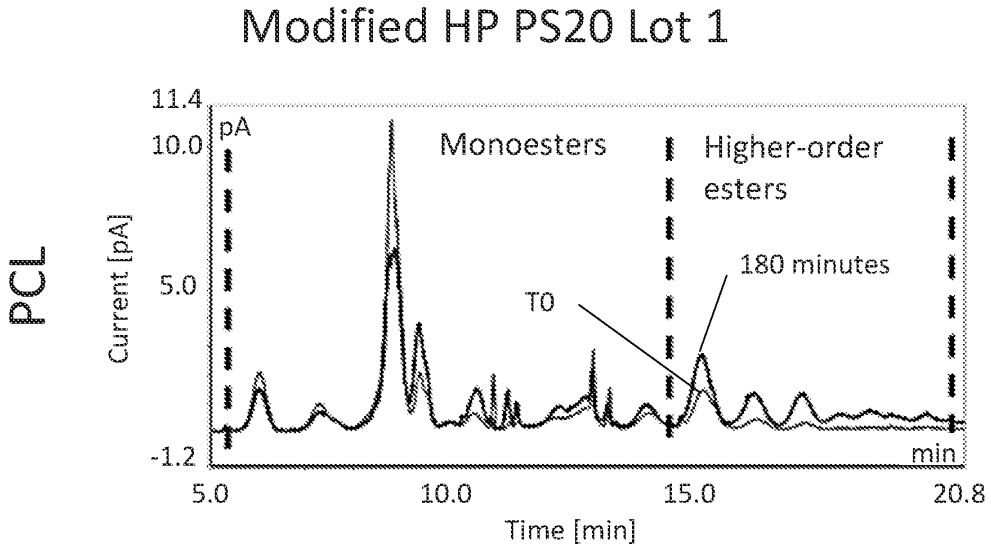

Modified HP PS20 Lot 1
PCL
11.4
10.0
5.0
-1.2
pA
Current [pA]
Monoesters
Higher-order esters
180 minutes
T0
min
5.0
10.0
15.0
20.8
Time [min]

Fig. 4B

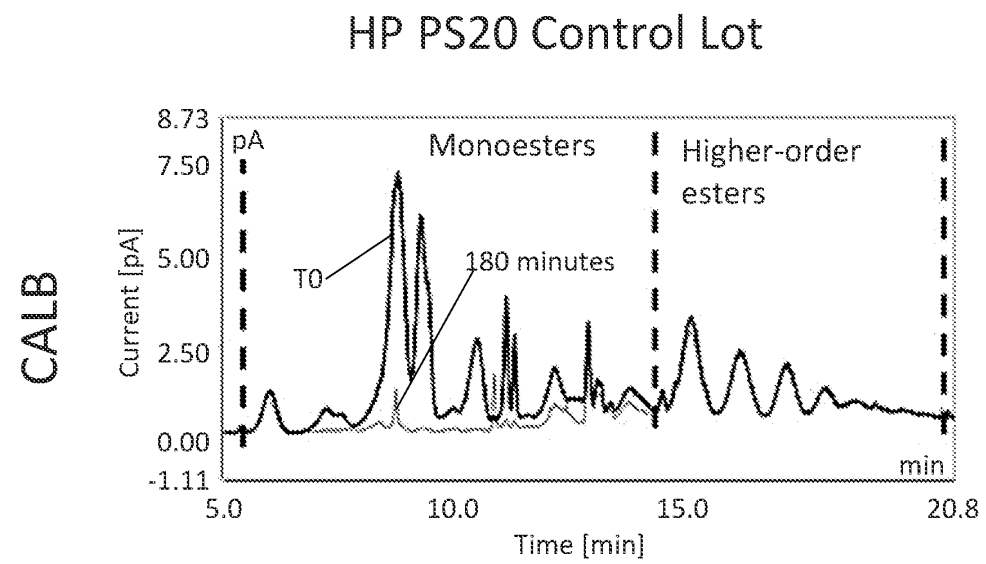

HP PS20 Control Lot
CALB
8.73
7.50
5.00
2.50
0.00
-1.11
pA
Monoesters
Higher-order esters
T0
180 minutes
min
Current [pA]
5.0
10.0
15.0
20.8
Time [min]

Fig. 4C

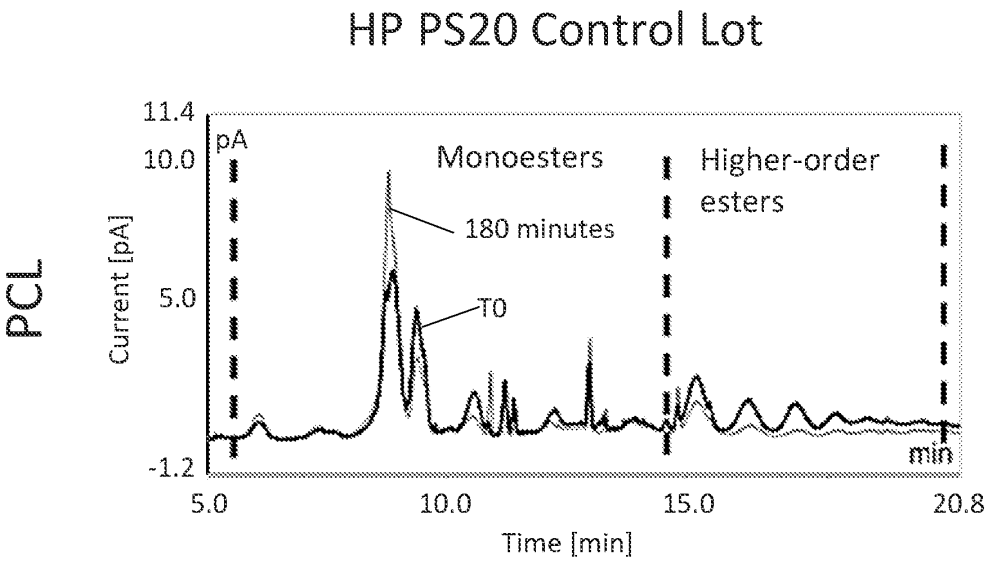

HP PS20 Control Lot
PCL
11.4
10.0
5.0
-1.2
pA
Monoesters
Higher-order esters
180 minutes
T0
min
Current [pA]
5.0
10.0
15.0
20.8
Time [min]

Fig. 4D

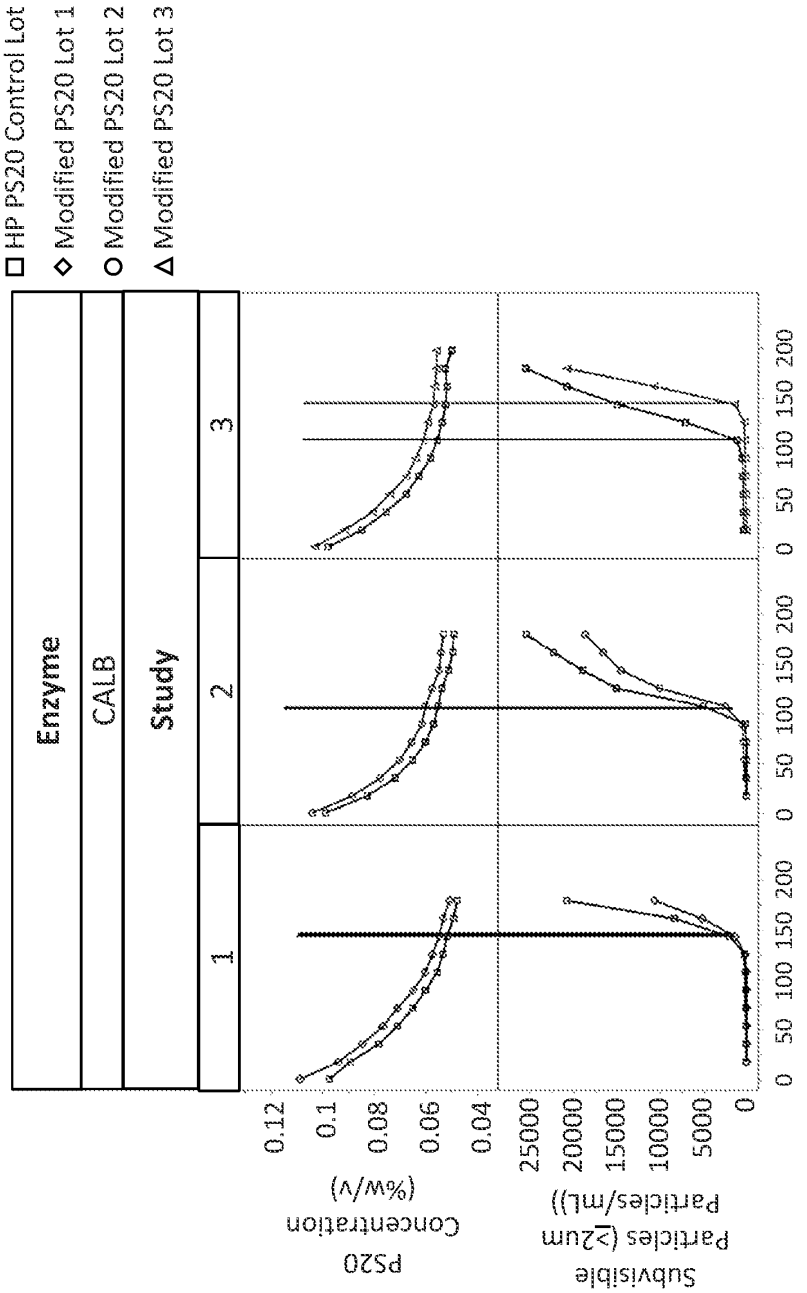

HP PS20 Control Lot
Modified PS20 Lot 1
Modified PS20 Lot 2
Modified PS20 Lot 3
Enzyme
CALB
Study
1
2
3
PS20 Concentration (%w/v)
0.12
0.1
0.08
0.06
0.04
Subvisible Particles (≥2um Particles/mL))
25000
20000
15000
10000
5000
0
0 50 100 150 200
Time [min]

Fig. 5A

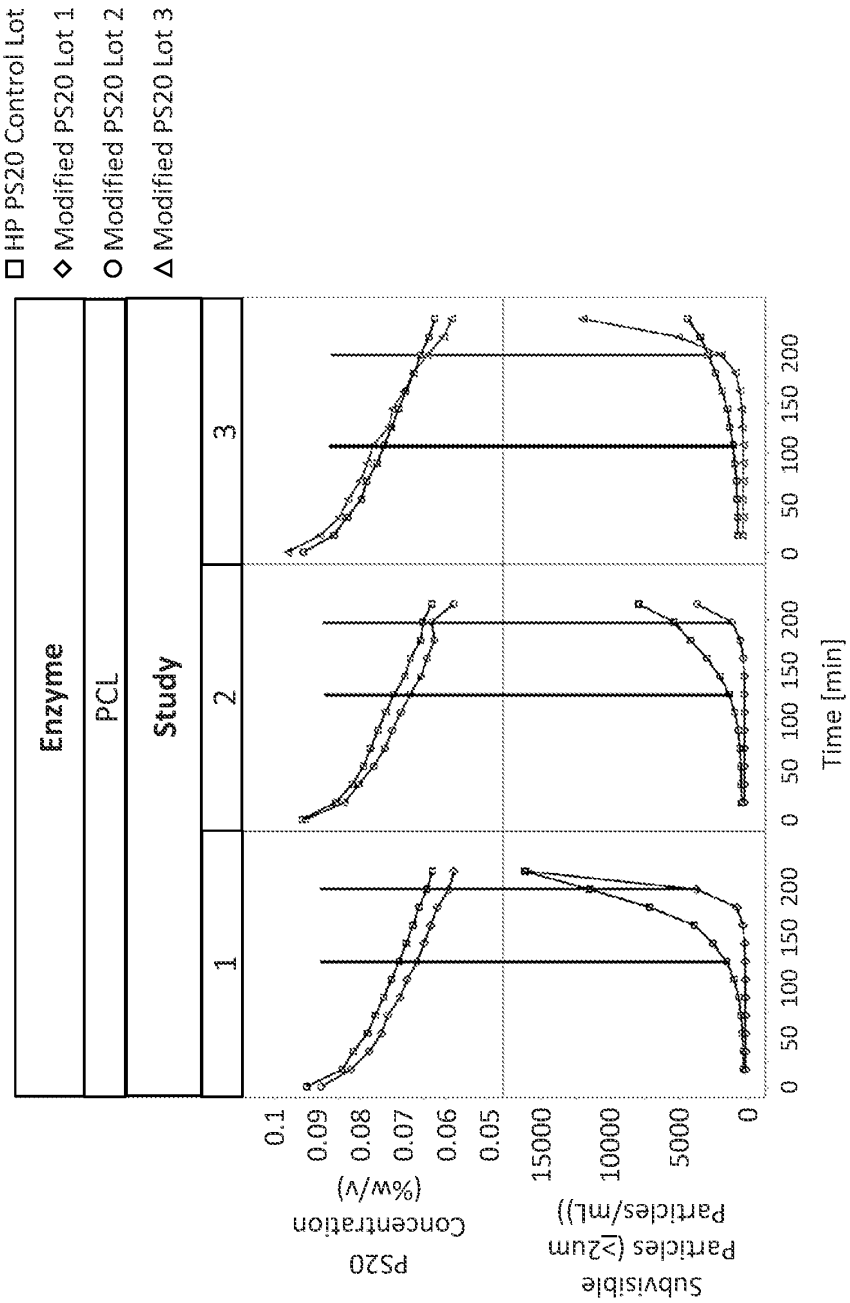

HP PS20 Control Lot
Modified PS20 Lot 1
Modified PS20 Lot 2
Modified PS20 Lot 3
Enzyme
PCL
Study
1
2
3
PS20 Concentration (%w/v)
0.1
0.09
0.08
0.07
0.06
0.05
Subvisible Particles (≥2um Particles/mL))
15000
10000
5000
0
0 50 100 150 200
Time [min]

Fig. 5B

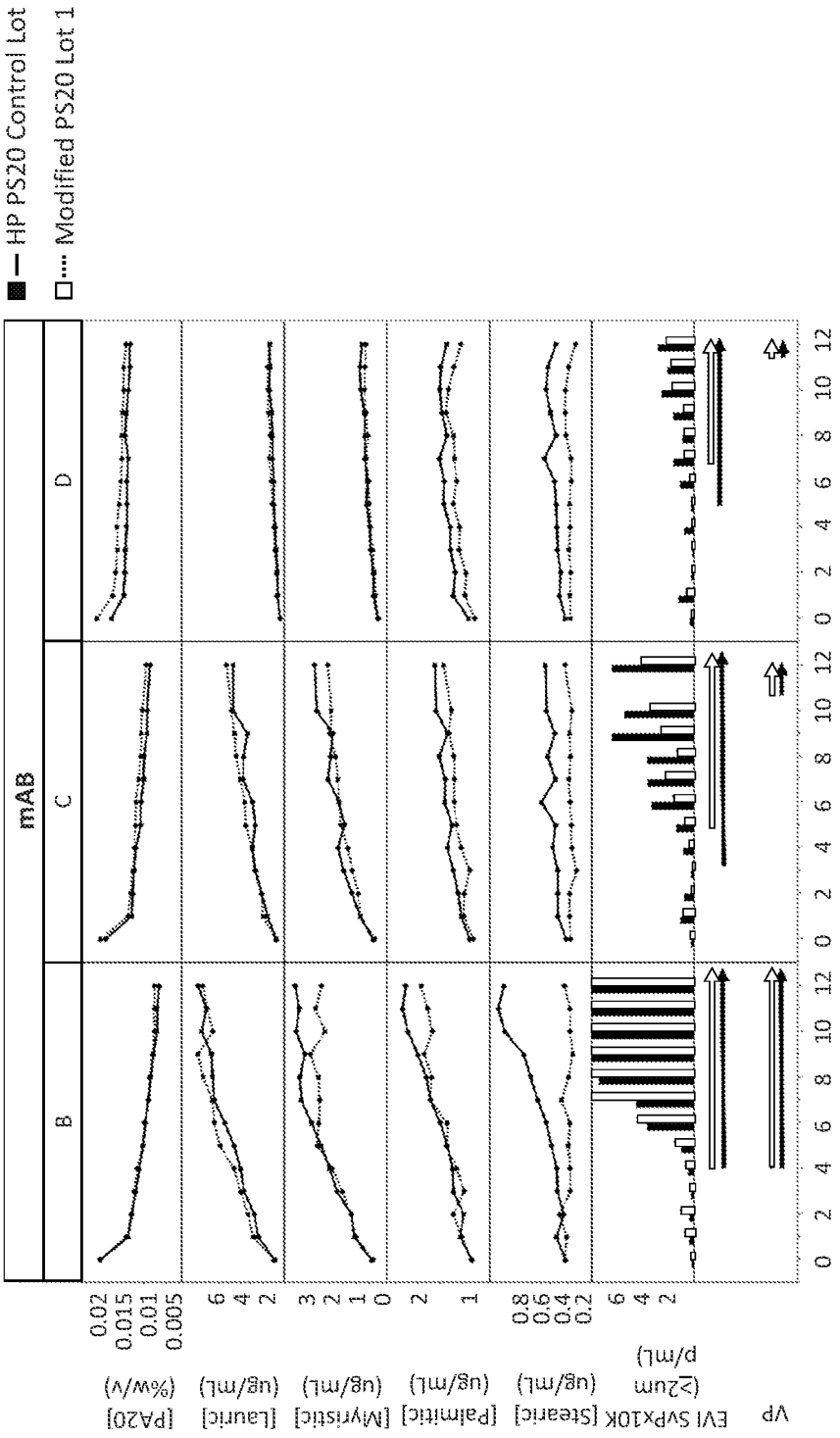

HP PS20 Control Lot
Modified PS20 Lot 1
mAB
B
C
D
[PA20] (%w/v)
[Lauric] (ug/mL)
[Myristic] (ug/mL)
[Palmitic] (ug/mL)
[Stearic] (ug/mL)
EVI SvPx10K (≥2um p/mL)
VP
Time (weeks)

Fig. 6

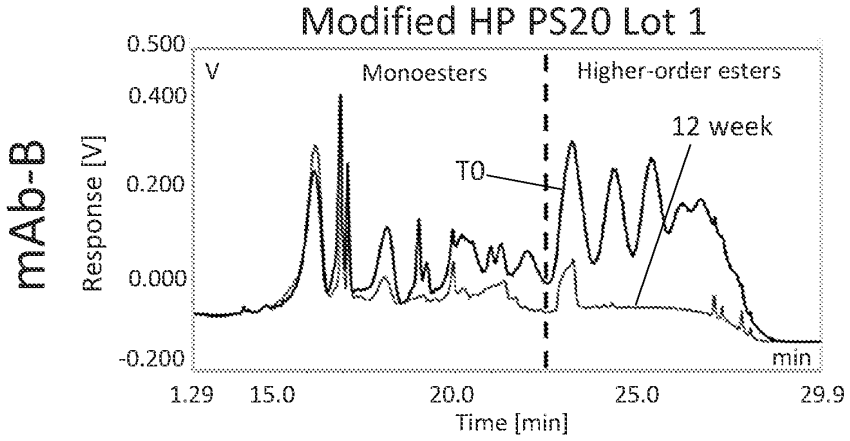


Fig. 7A

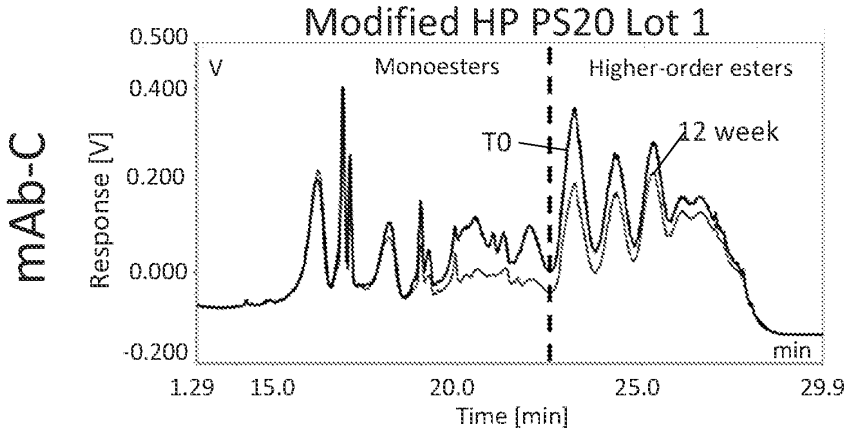


Fig. 7B

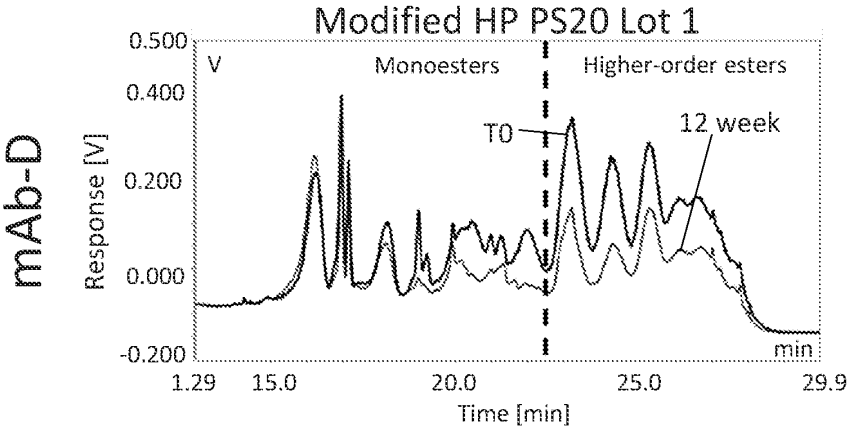


Fig. 7C

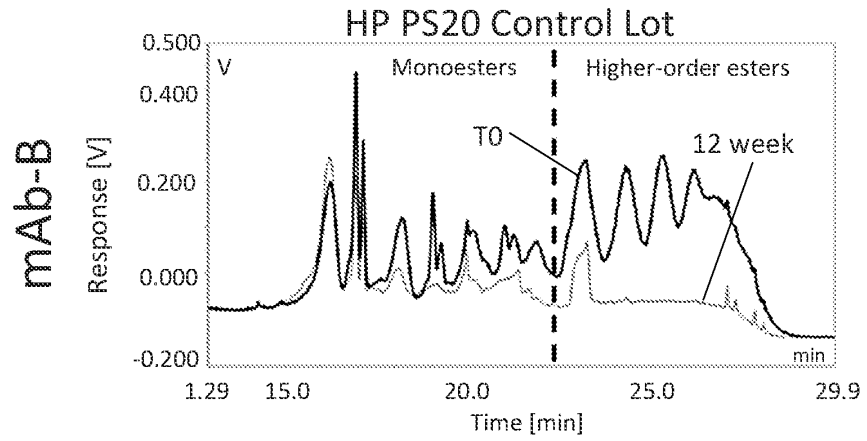


Fig. 7D

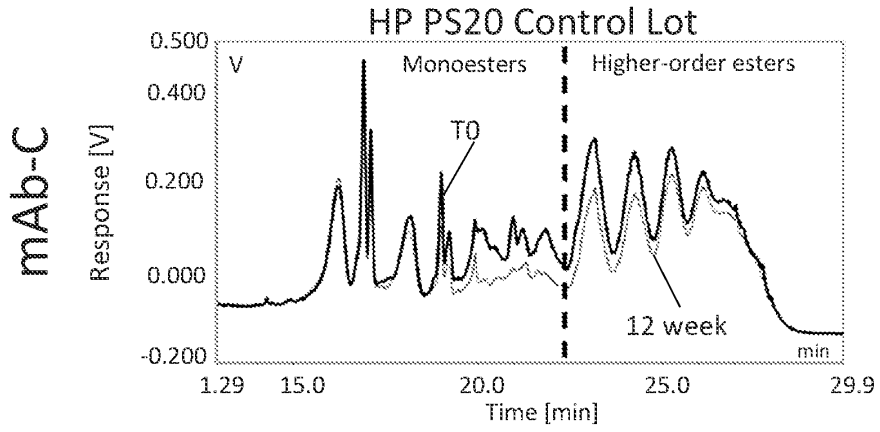


Fig. 7E

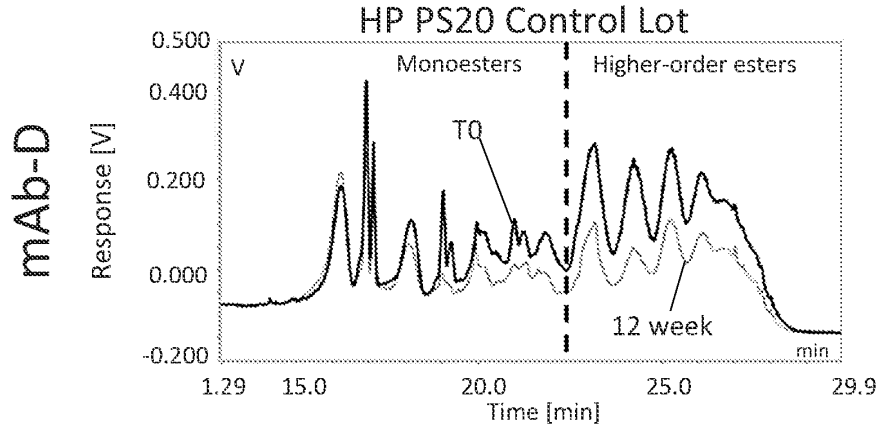


Fig. 7F

Fig. 8A *Fig. 8B*

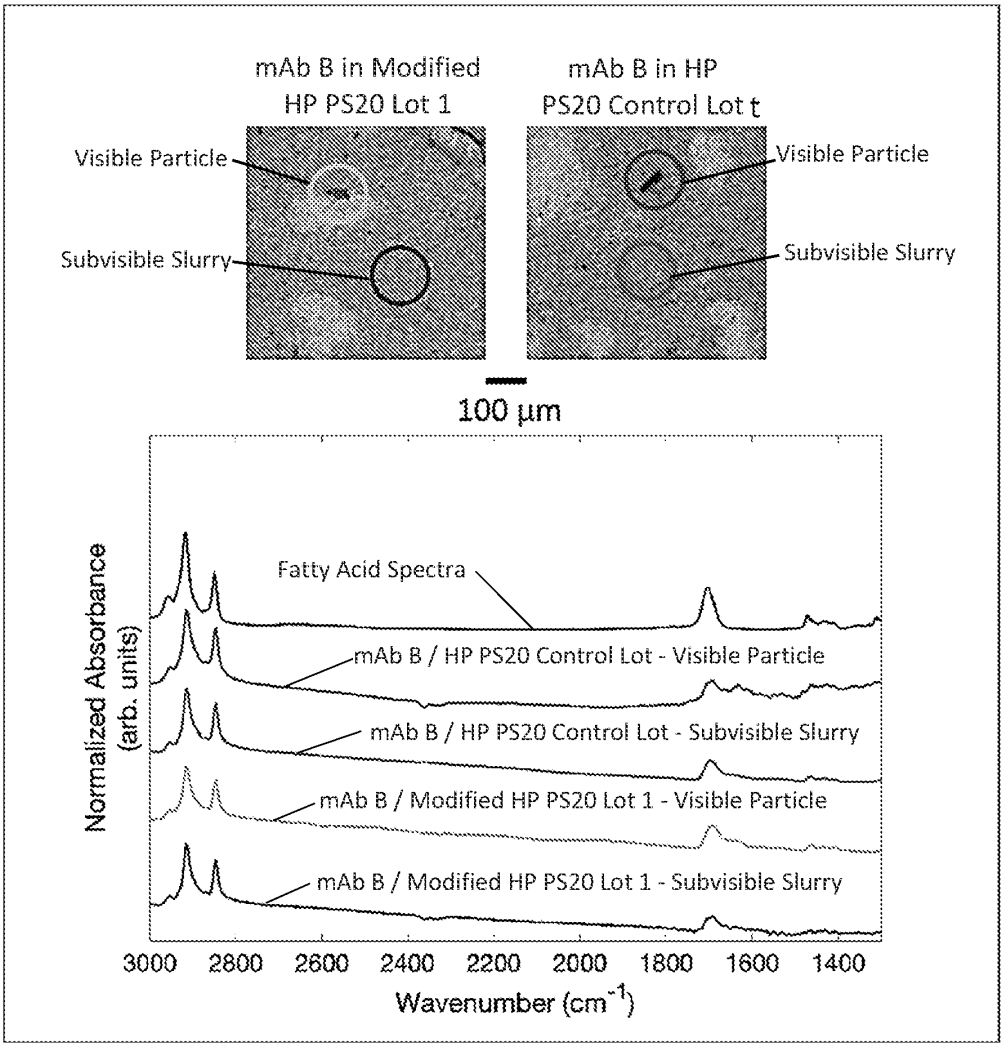


Fig. 8C

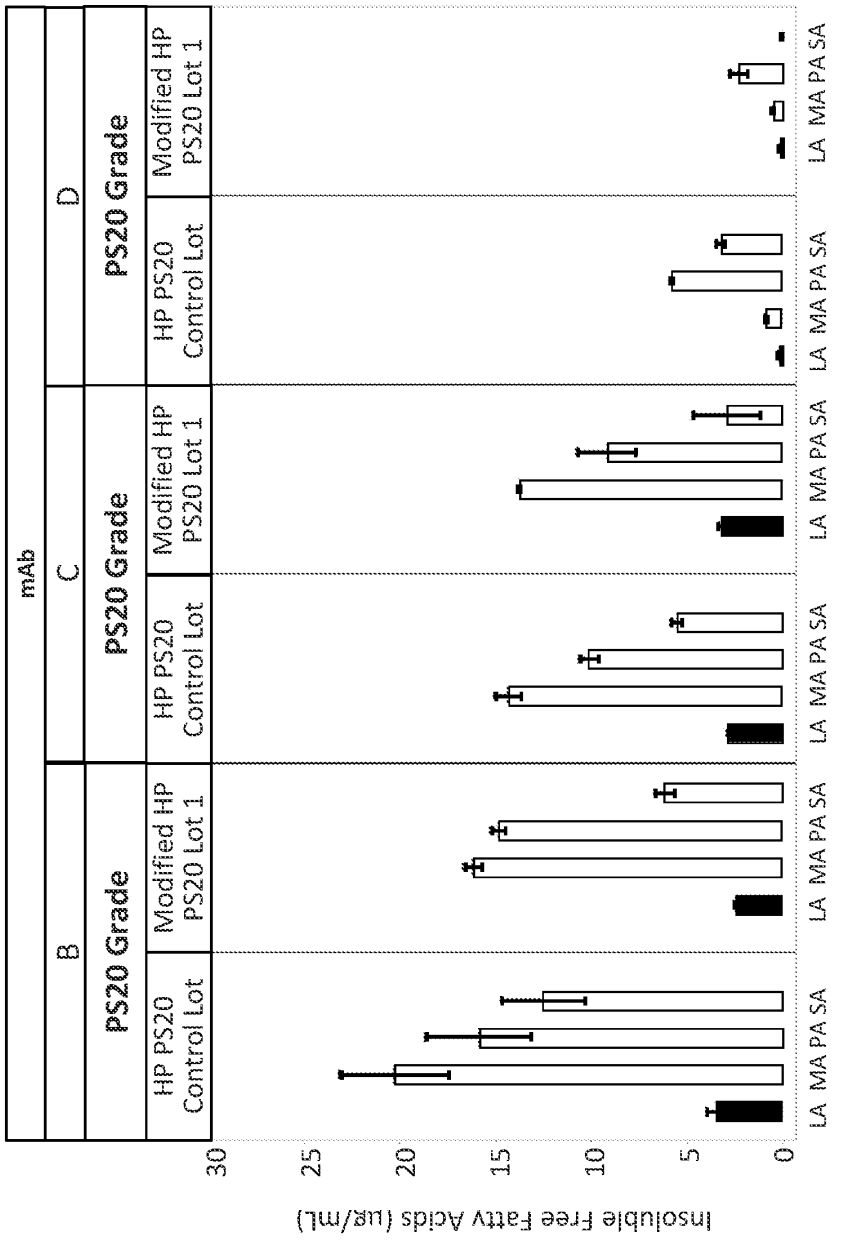

mAb
B
PS20 Grade
HP PS20 Control Lot
Modified HP PS20 Lot 1
C
PS20 Grade
HP PS20 Control Lot
Modified HP PS20 Lot 1
D
PS20 Grade
HP PS20 Control Lot
Modified HP PS20 Lot 1
Insoluble Free Fatty Acids (uR/mL)
0
5
10
15
20
25
30
LA MA PA SA
LA MA PA SA
LA MA PA SA
LA MA PA SA

Fig. 9