202151-w

Purity Test Report by HPLC-MS/UV (Testosterone Cypionate)

Summary

* We test the purity of Testosterone Cypionate by HPLC-MS and the result is 101.22%.

* We test the purity of Testosterone Cypionate by HPLC-UV and the result it 98.02%

Test Method

HPLC: Agilent 1260

MS: Bruker micrOTOF-Q II

Test solution: Dissolve 93.5 mg of Testosterone Cypionate RS in mobile phase and dilute to 100 mL with the same solvent.

Column:

— *size*: *l* = 0.15 m, Ø = 4.6 mm, spherical end-capped dodecylsilyl silica gel for chromatography R (4 µm)

Mobile phase (water : acetonitrile = 30 : 70).

Flow rate 2 mL/min.

Detection Spectrophotometer at 242 nm.

Injection 10 µL.

MS: ESI, positive ion detection, m/z=413.3050±0.01

Test Result

HPLC-MS

Standard curve R=0.999614

Y=75065.587086x+845824.794509

Result=101.22%

For more details, please see the attachments

HPLC-UV/

N.O.	R.T（min）	Concentration（mg/10mL）	Area of UV
1	40.34	2.48375	2254.30
2	40.07	4.9675	4493.74
3	38.66	9.935	8343.32
4	38.36	19.87	7641.36
5	37.18	39.74	34186.17
S1	40.45	9.68	8470.52
S2	40.30	9.86	8620.44
S3	38.01	9.81	8573.97

y=859.96488x+140.96375，R=0.99939

Result = 98.02%

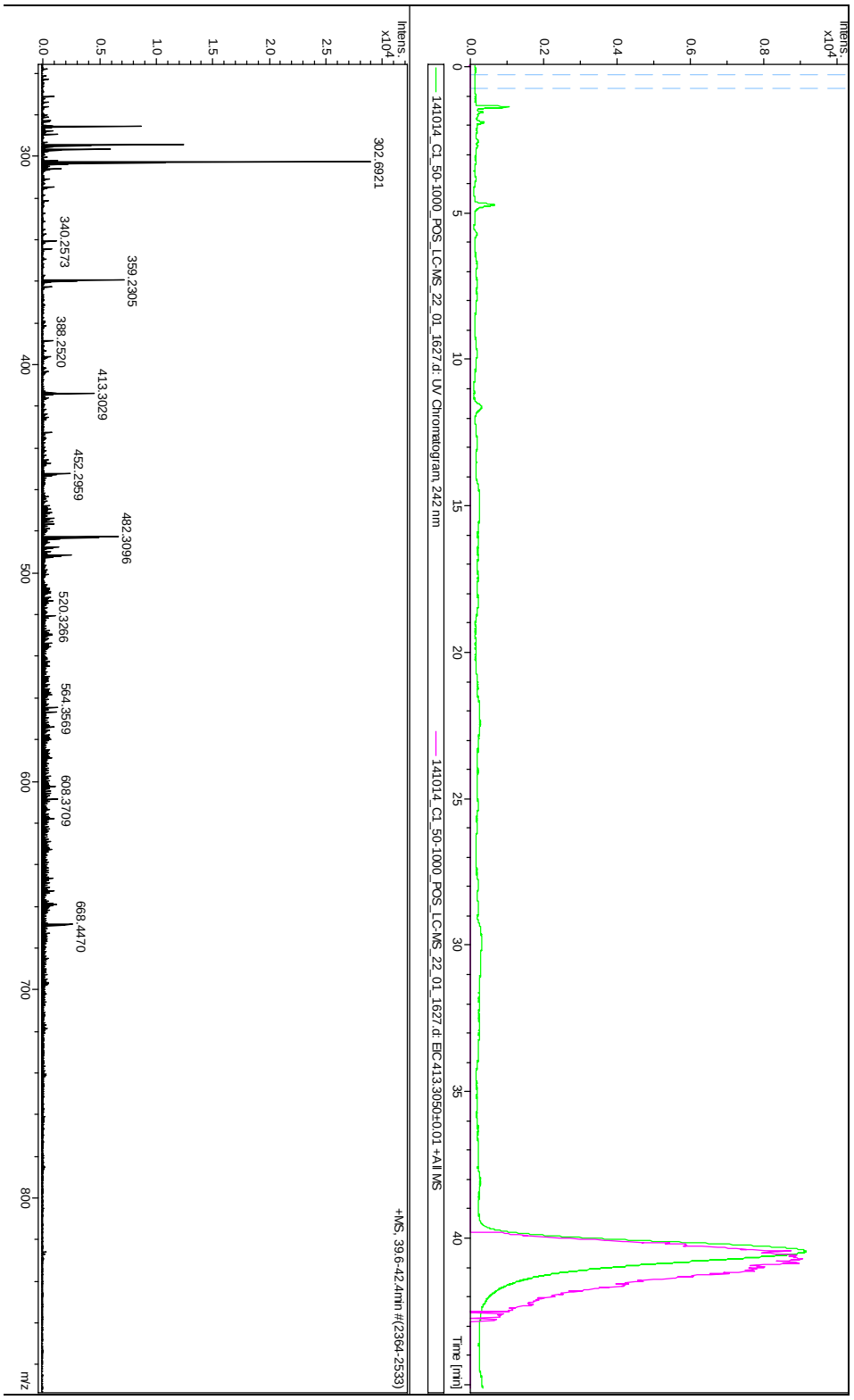
For more details, please see the attachments

Attachments:

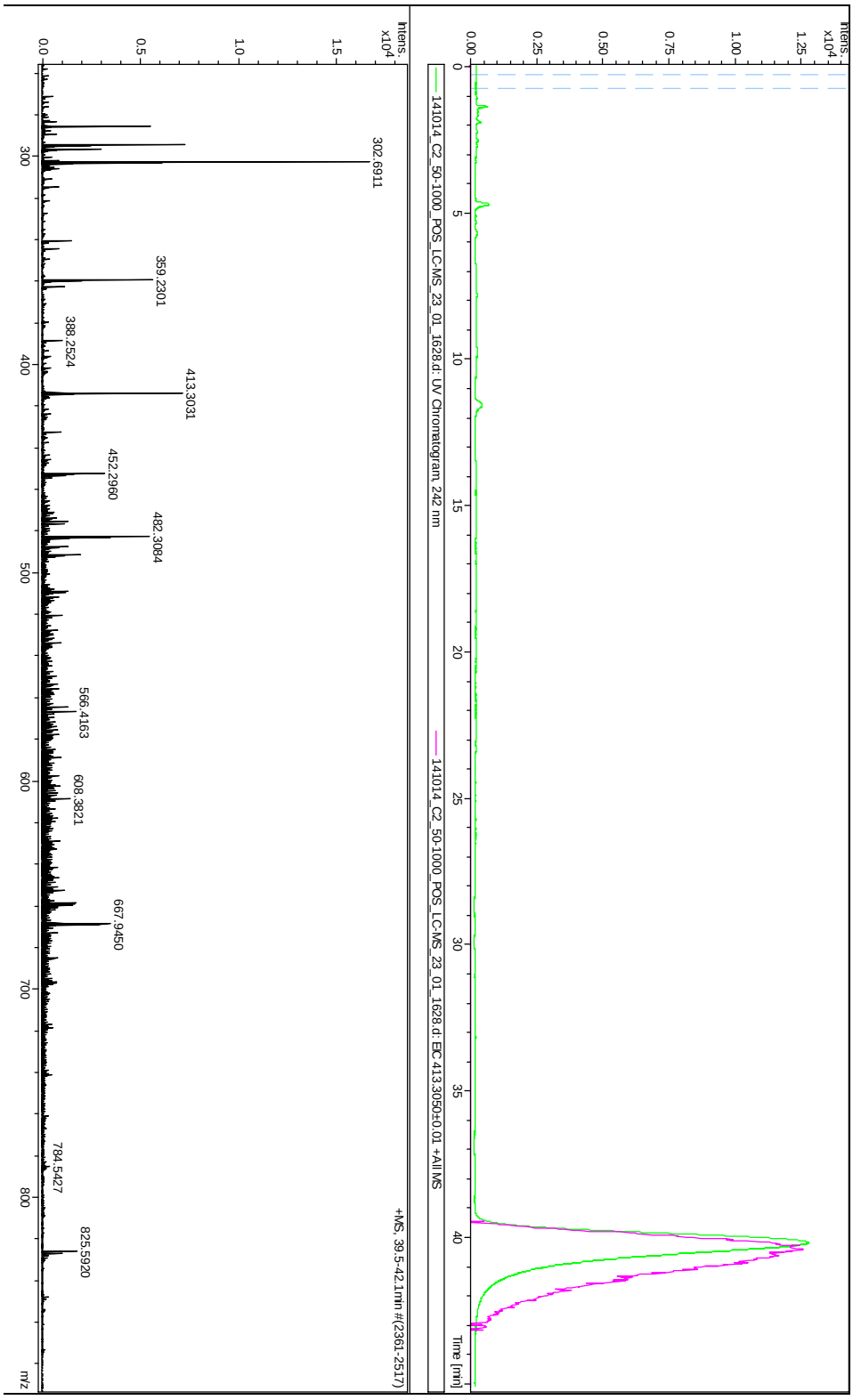
RED: HPLC-MS chromatogram

GREEN: HPLC-UV chromatogram

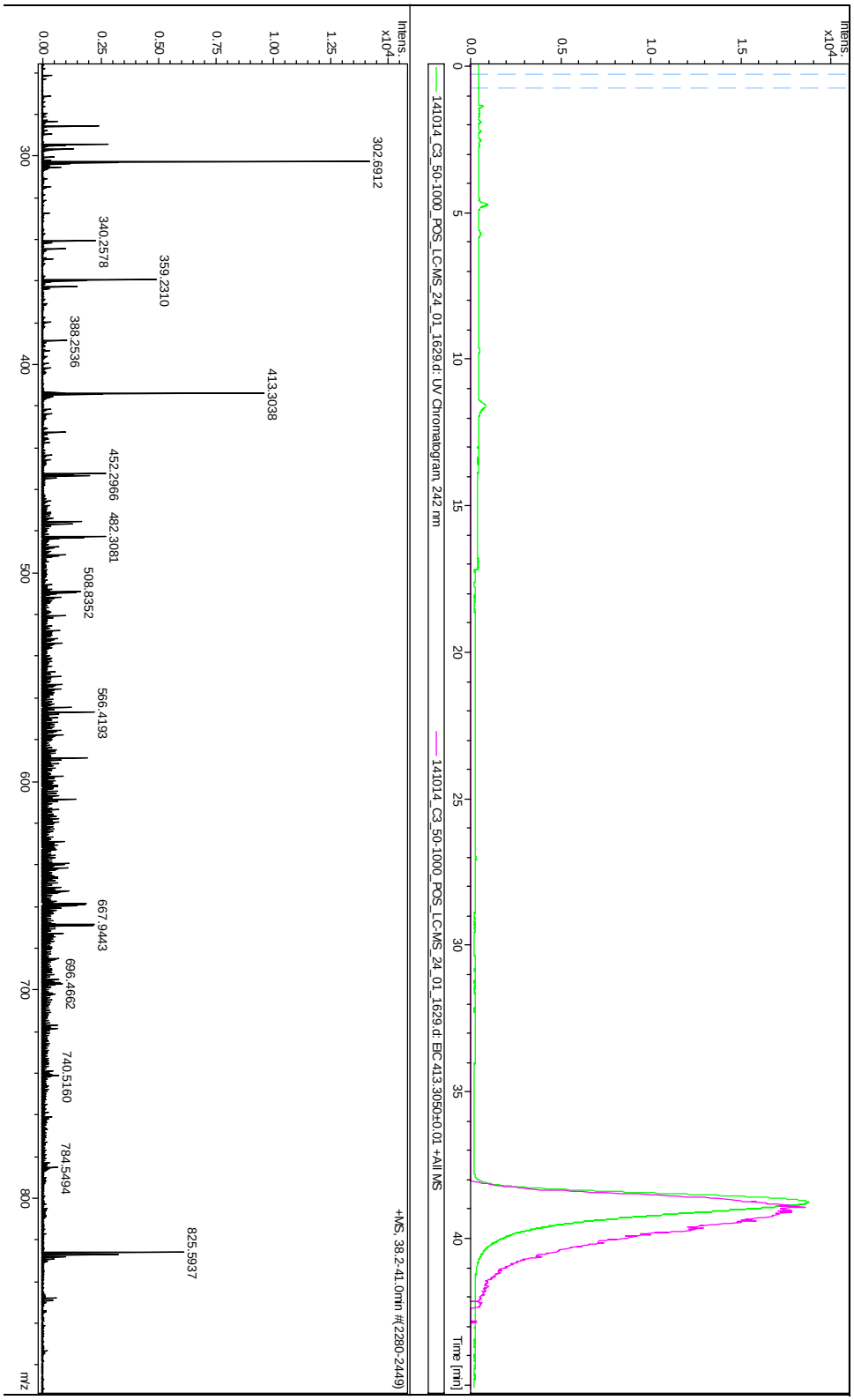
HPLC-UV/MS 1：


Intens.
x10^4
141014_CL_50-1000_POS_LC-MS_22_01_1627.d: UV Chromatogram, 242 nm
141014_CL_50-1000_POS_LC-MS_22_01_1627.d: EIC 413.3050±0.01 +All MS
Time [min]
Intens.
x10^4
302.6921
340.2573
359.2305
388.2520
413.3029
452.2959
482.3096
520.3266
564.3569
608.3709
668.4470
+MS, 39.6-42.4min #(2364-2533)
m/z

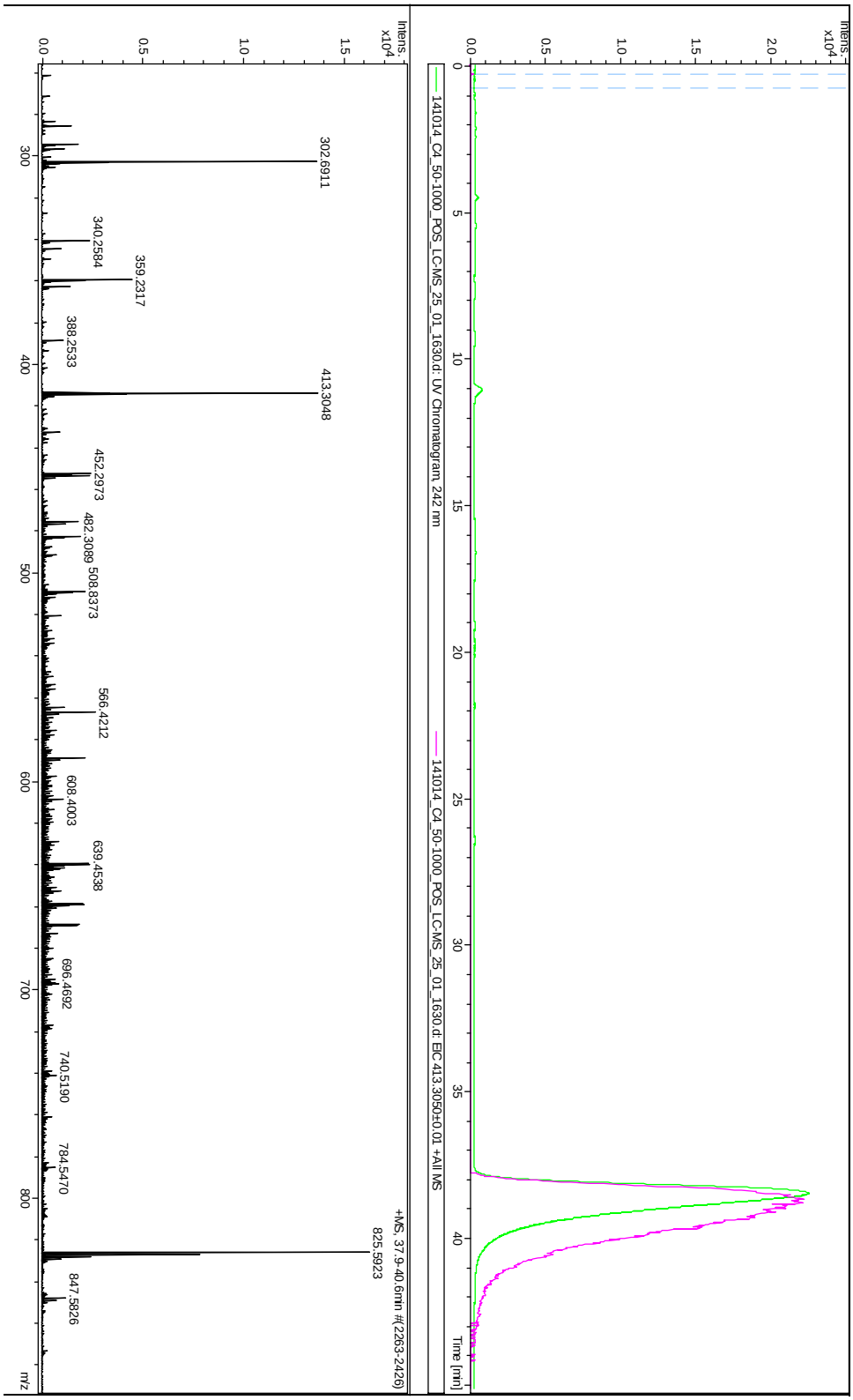
HPLC-UV/MS 2：


Intens.
x10⁴
1.25
1.00
0.75
0.50
0.25
0.00
0
5
10
15
20
25
30
35
40
Time [min]
141014_C2_50-1000_POS_LC-MS_23_01_1628.d: UV Chromatogram, 242 nm
141014_C2_50-1000_POS_LC-MS_23_01_1628.d: EIC 413.3050±0.01 +All MS
Intens.
x10⁴
1.5
1.0
0.5
0.0
300
400
500
600
700
800
m/z
302.6911
359.2301
388.2524
413.3031
452.2960
482.3084
566.4163
608.3821
667.9450
784.5427
825.5920
+MS, 39.5-42.1min #(2361-2517)

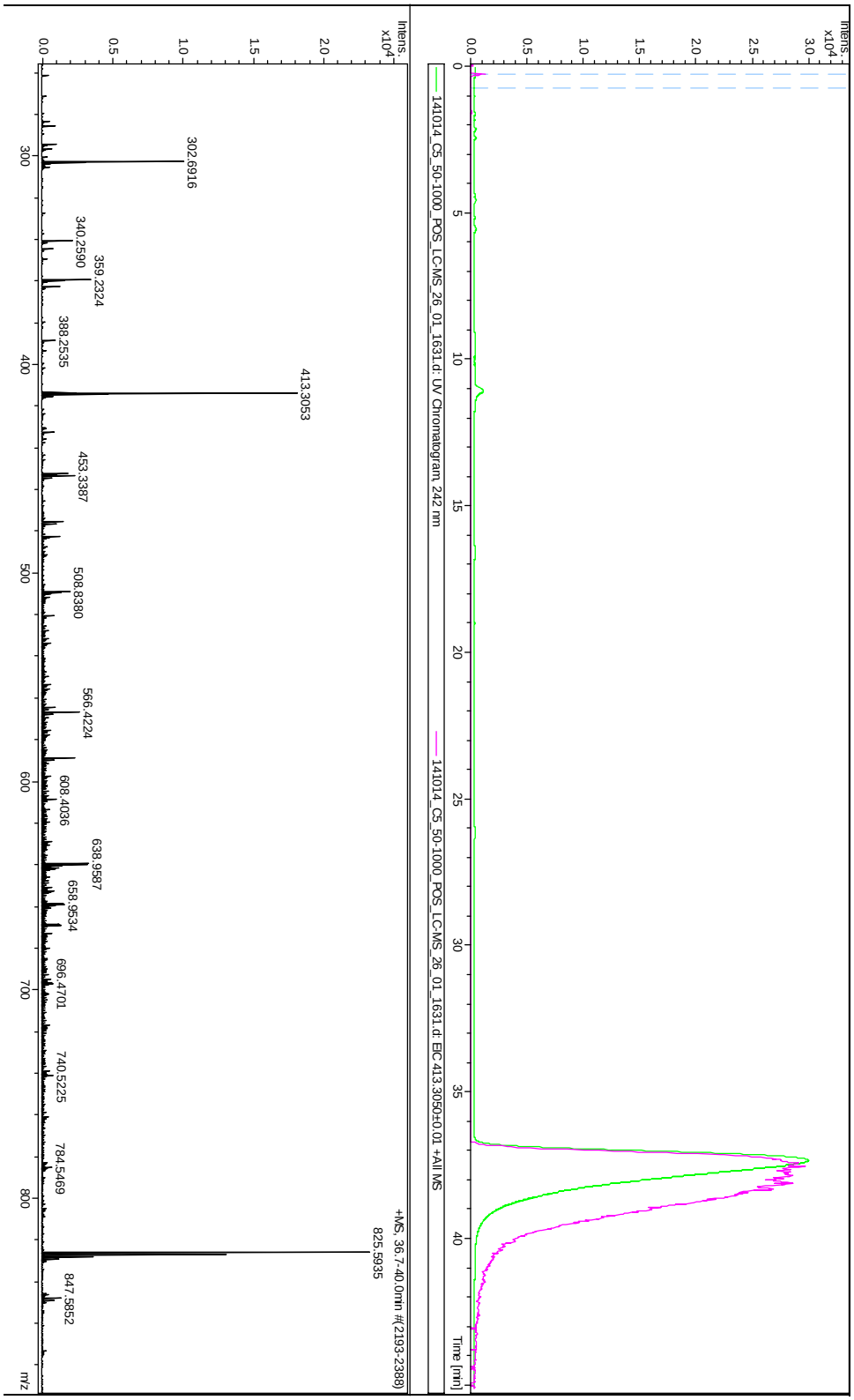
HPLC-UV/MS 3:


Intens.
x10⁴
141014_C3_50-1000_POS_LC-MS_24_01_1629.d: UV Chromatogram, 242 nm
141014_C3_50-1000_POS_LC-MS_24_01_1629.d: EIC 413.3050±0.01 +All MS
Time [min]
Intens.
x10⁴
302.6912
340.2578
359.2310
388.2536
413.3038
452.2966
482.3081
508.8352
566.4193
667.9443
696.4662
740.5160
784.5494
825.5937
+MS, 38.2-41.0min #(2280-2449)
m/z

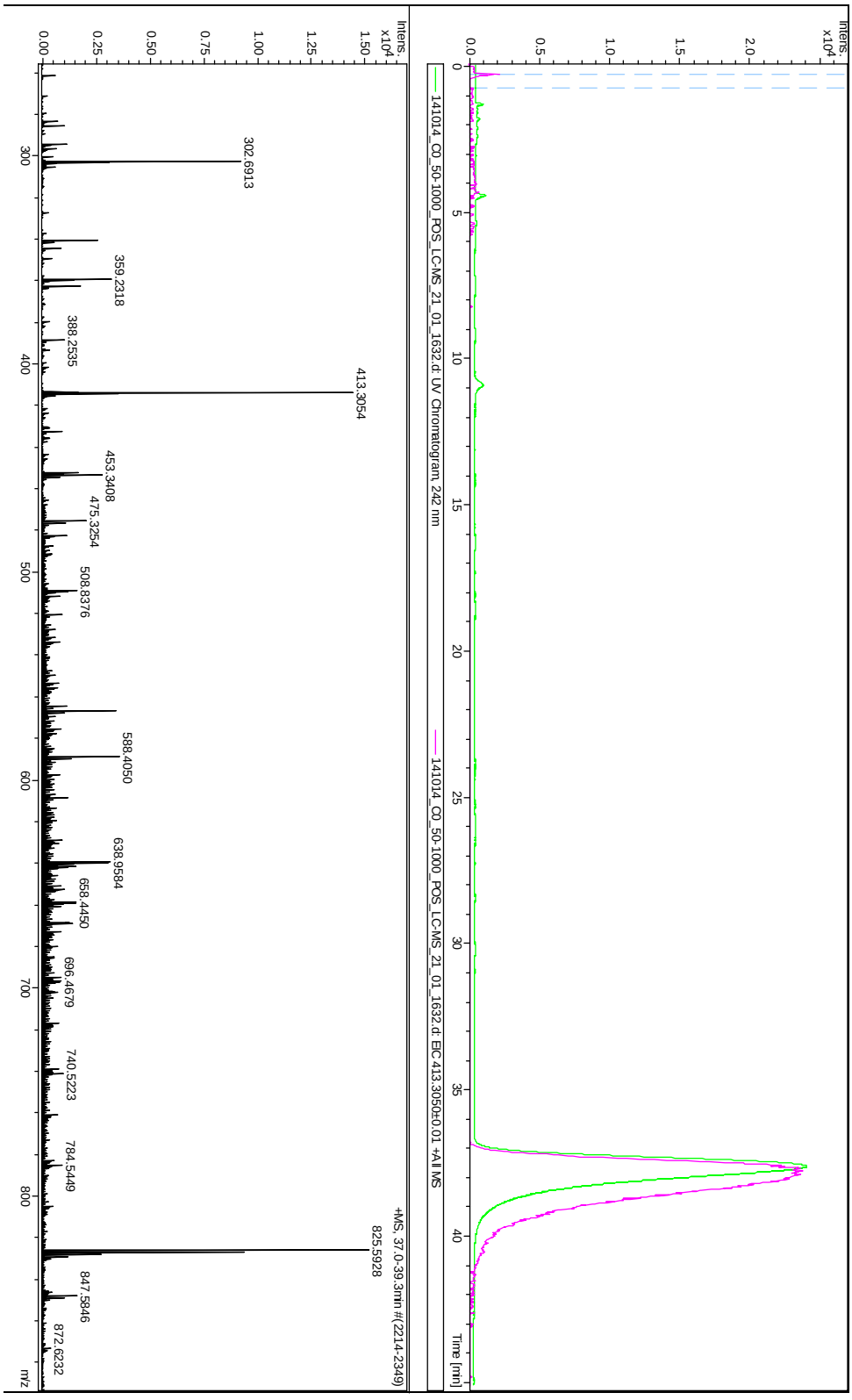
HPLC-UV/MS 4:


Intens.
x10⁴
141014_C4_50-1000_POS_LC-MS_25_01_1630.d: UV Chromatogram, 242 nm
141014_C4_50-1000_POS_LC-MS_25_01_1630.d: EIC 413.3050±0.01 +All MS
Time [min]
+MS, 37.9-40.6min #(2263-2426)
302.6911
340.2584
359.2317
388.2533
413.3048
452.2973
482.3089
508.8373
566.4212
608.4003
639.4538
696.4692
740.5190
784.5470
825.5923
847.5826
m/z

HPLC-UV/MS 5:


Intens.
x10⁴
141014_C5_50-1000_POS_LC-MS_26_01_1631.d: UV Chromatogram, 242 nm
141014_C5_50-1000_POS_LC-MS_26_01_1631.d: EIC 413.3050±0.01 +All MS
Time [min]
Intens.
x10⁴
302.6916
340.2590
359.2324
388.2535
413.3053
453.3387
508.8380
566.4224
608.4036
638.9587
658.9534
696.4701
740.5225
784.5469
825.5935
847.5852
+MS, 36.7-40.0min #(2193-2388)
m/z

HPLC-UV/MS S1:


Intens.
x10⁴
141014_C0_50-1000_POS_LC-MS_21_01_1632.d: UV Chromatogram, 242 nm
141014_C0_50-1000_POS_LC-MS_21_01_1632.d: EIC 413.3050±0.01 +All MS
Time [min]
+MS, 37.0-39.3mn #(2214-2349)
302.6913
359.2318
388.2535
413.3054
453.3408
475.3254
508.8376
588.4050
638.9584
658.4450
696.4679
740.5223
784.5449
825.5928
847.5846
872.6232
m/z

Peak	RT [min]	Peak Height [mAU]	Integral [%]	Peak Area [mAU*s]	HWB [min]	Integral Region [min]
14	1	0.07	0.01	1	0	0.84 - 1.07
20	1.37	1.02	0.16	13.7	0	1.30 - 1.47
21	1.54	0.17	0.02	2	0	1.47 - 1.60
22	1.66	0.11	0.02	1.5	0	1.60 - 1.75
23	1.87	0.41	0.07	6.4	0	1.75 - 2.01
26	2.17	0.22	0.04	3.4	0	2.09 - 2.28
30	2.46	0.18	0.04	3.1	0	2.39 - 2.55
31	2.61	0.07	0.01	1.2	0	2.55 - 2.76
38	3.14	0.04	0.01	0.7	0	3.07 - 3.23
50	3.87	0.03	0.01	0.4	0.0099	3.78 - 3.93
55	4.48	1.37	0.44	38.7	0	4.23 - 4.77
57	5.05	0.08	0.03	2.3	5.1048	4.91 - 5.22
59	5.42	0.27	0.11	9.8	0	5.24 - 5.67
142	10.92	1.05	0.65	57	0	10.63 - 11.32
240	16.32	0.06	0.03	2.8	16.4236	16.21 - 16.63
630	37.56	44.18	98.02	8576	0	36.54 - 40.14

QuantAnalysis Summary Report

Batch Info

Batch	[redacted]TC.btc		
Instrument	micrOTOF-Q II	Operator	BDAL@DE
Acquisition Date	10/15/2014 6:26:55 AM		

Method Parameter

Def. Injection Volume	10.000000	Accuracy Limit (%)	20

Compound	Type	Chromatogram	Ret. Time	Calib.Mode
TC	Target	EIC 413.305±0.02 ±All	37.7 min	Area

File Summary

#	File Name	Vial	Sample Name	Sample Type	CalibLevel	Calib Action
1	141014_C0_50-1000_POS_LC-MS_21_01_1626.d	21	141014_C0_50-1000_POS_LC-MS	Sample		-
2	141014_C1_50-1000_POS_LC-MS_22_01_1627.d	22	141014_C1_50-1000_POS_LC-MS	Calibration	1	New
3	141014_C2_50-1000_POS_LC-MS_23_01_1628.d	23	141014_C2_50-1000_POS_LC-MS	Calibration	2	New
4	141014_C3_50-1000_POS_LC-MS_24_01_1629.d	24	141014_C3_50-1000_POS_LC-MS	Calibration	3	New
5	141014_C4_50-1000_POS_LC-MS_25_01_1630.d	25	141014_C4_50-1000_POS_LC-MS	Calibration	4	New
6	141014_C5_50-1000_POS_LC-MS_26_01_1631.d	26	141014_C5_50-1000_POS_LC-MS	Calibration	5	New
7	141014_C0_50-1000_POS_LC-MS_21_01_1632.d	21	141014_C0_50-1000_POS_LC-MS	Sample		-
8	141014_C0_50-1000_POS_LC-MS_21_01_1633.d	21	141014_C0_50-1000_POS_LC-MS	Sample		-

QuantAnalysis Summary Report

Compound: **TC**

#	Theor. Conc	Area Target Cmpd	Calc. Conc.	Accuracy
1		1622558	10.35	
2	2.5	800218	-0.61	-24.5
3	5.0	1182287	4.48	90.2
4	9.9	1633052	10.49	105.6
5	19.9	2338947	19.89	100.1
6	39.7	3822337	39.65	99.8
7		1657041	10.81	
8		1625963	10.39	

Calibration Block No.: 1