



202151-w

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



Summary

* We test the purity of Testosterone Enantate by HPLC-MS and the result is 102.38%.

* We test the purity of Testosterone Enantate by HPLC-UV and the result it 99.20%



Test Method

HPLC: Agilent 1260

MS: Bruker micrOTOF-Q II

Test solution: Dissolve 92.4 mg of Testosterone Enantate RS in mobile phase and dilute to 100 mL with the same solvent.

Column:

— size: $l = 0.15$ m, $\varnothing = 4.6$ mm, spherical end-capped dodecylsilyl silica gel for chromatography R (4 μ m)

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

Flow rate 2 mL/min.

Detection Spectrophotometer at 242 nm.

Injection 10 μ L.

MS: ESI, positive ion detection, $m/z = 401.3050 \pm 0.01$



Test Result

HPLC-MS

Standard curve R=0.987847

Y=193364.567311x+1039938.999190

Result=102.38

For more details, please see the attachments

HPLC-UV

N.O.	R.T (min)	Concentration (mg/10mL)	Area of UV
1	35.79	2.475	2319.00
2	35.51	4.95	4640.93
3	35.57	9.9	9304.69
4	35.46	19.8	18315.17
5	35.23	39.6	35344.95
S1	34.56	9.10	8430.52
S2	35.80	9.07	8404.71
S3	35.79	9.04	8380.26

y=888.79872x+346.33167, R=0.99951

Result = 99.20%

For more details, please see the attachments

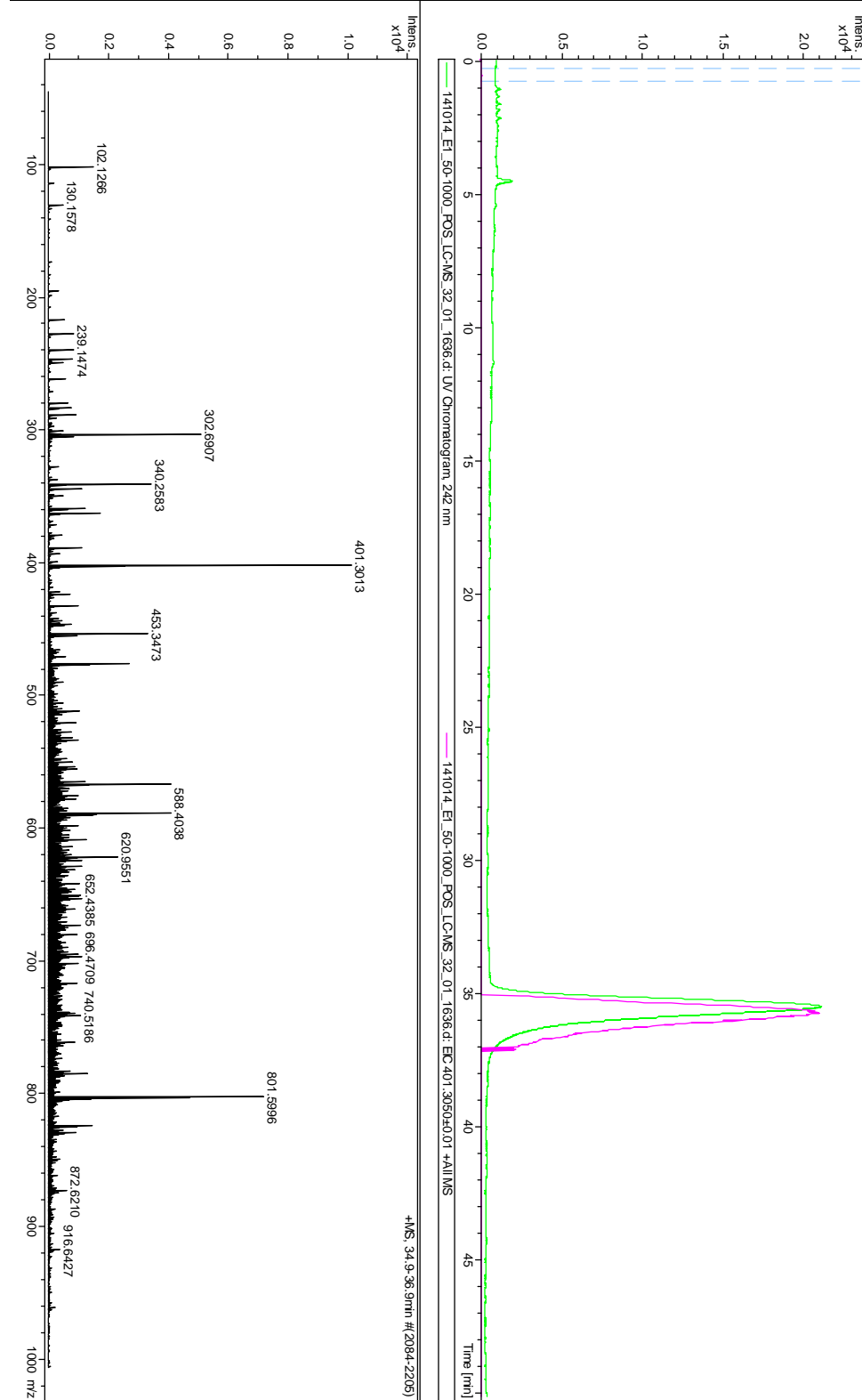
Attachments:

RED: HPLC-MS chromatogram

GREEN: HPLC-UV chromatogram

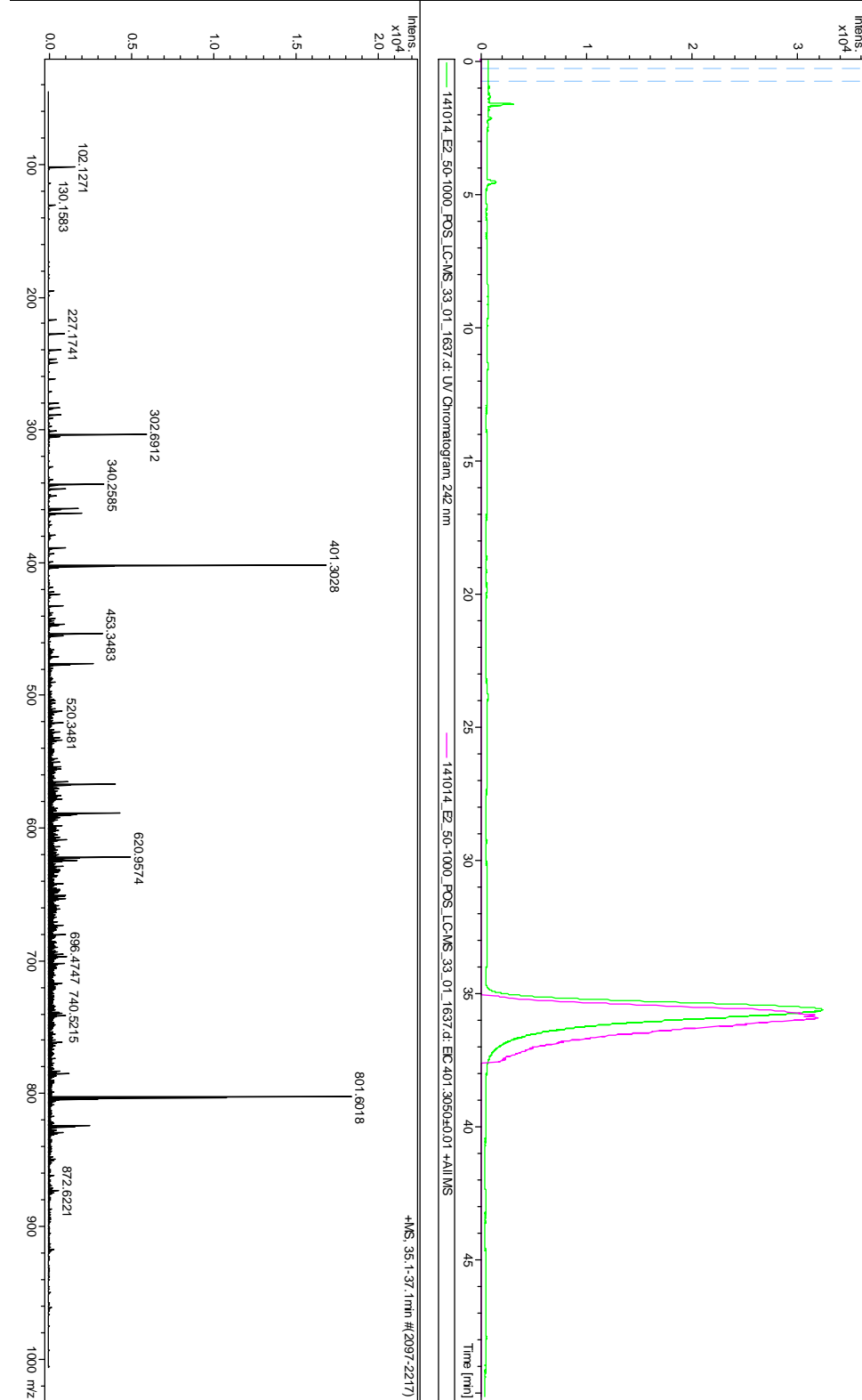


HPLC-UV/MS 1:



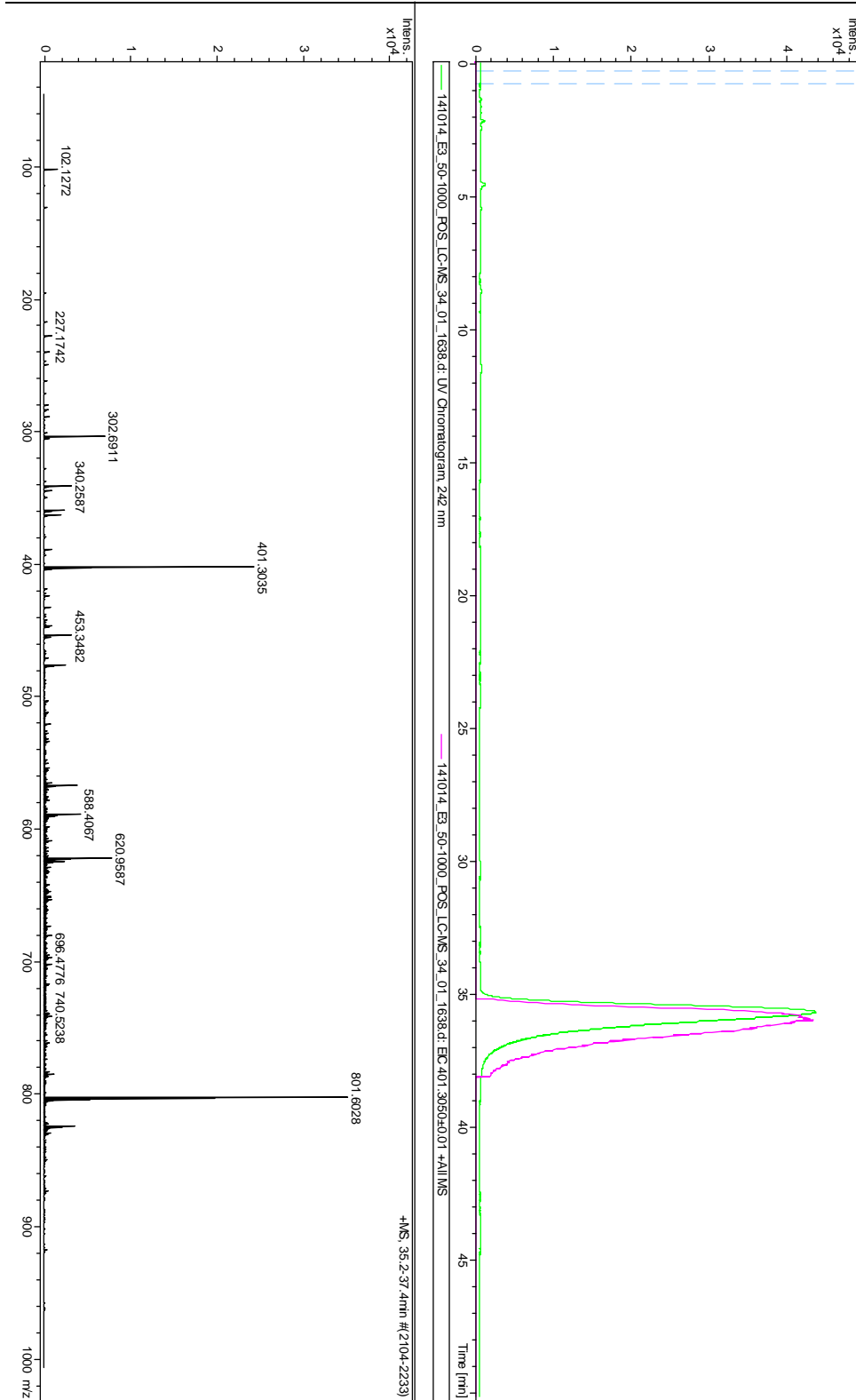


HPLC-UV/MS 2:



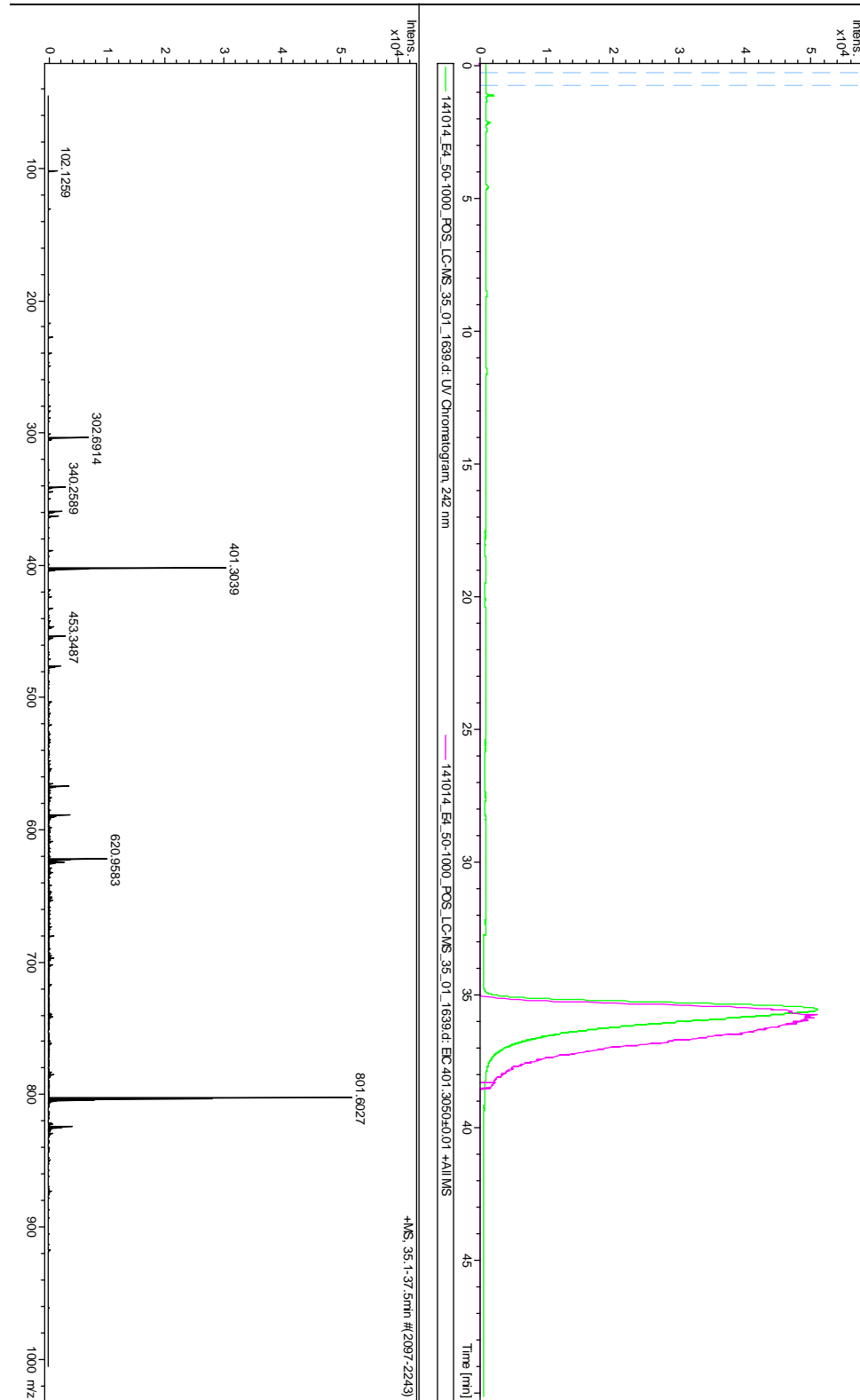


HPLC-UV/MS 3:



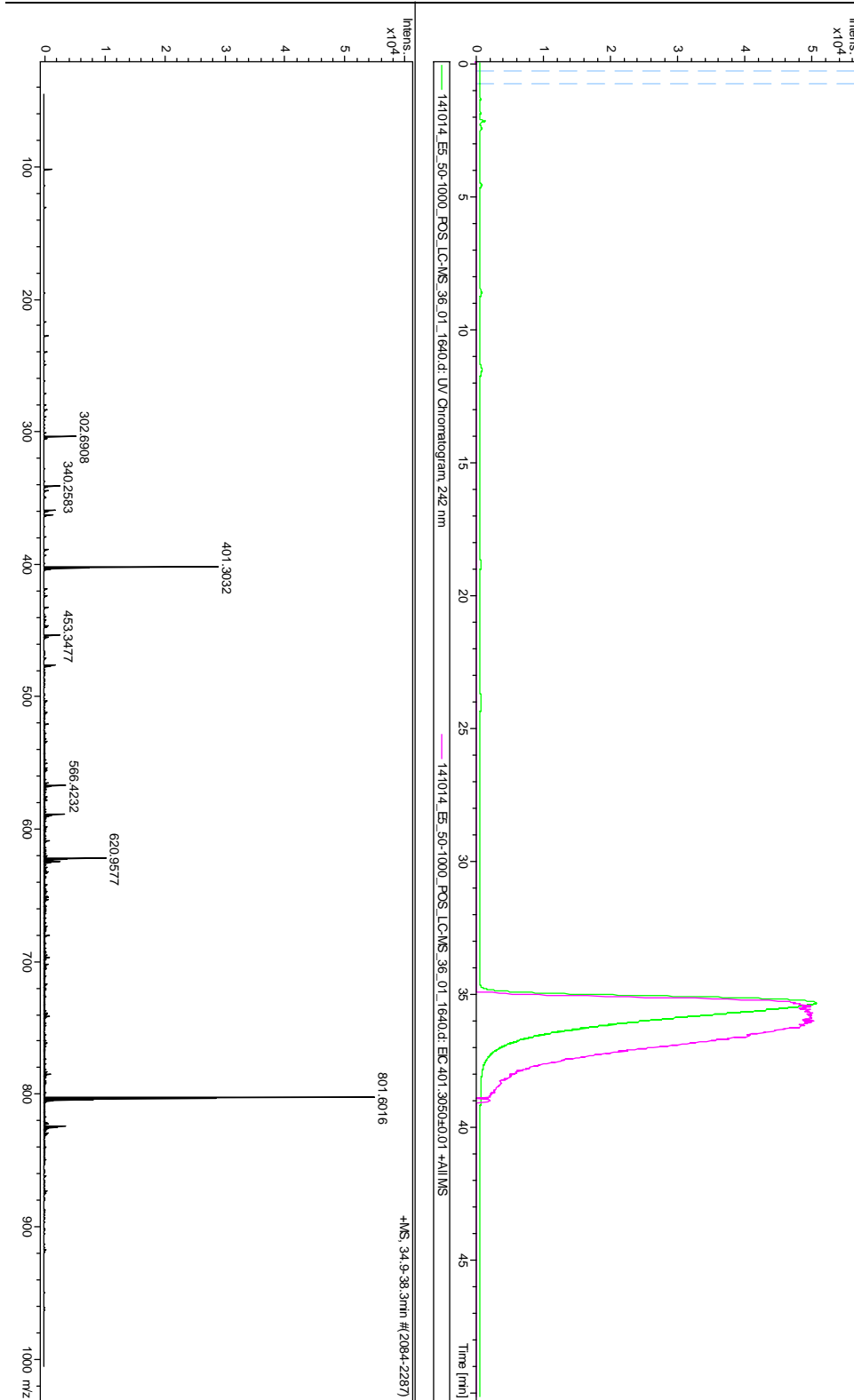


HPLC-UV/MS 4:



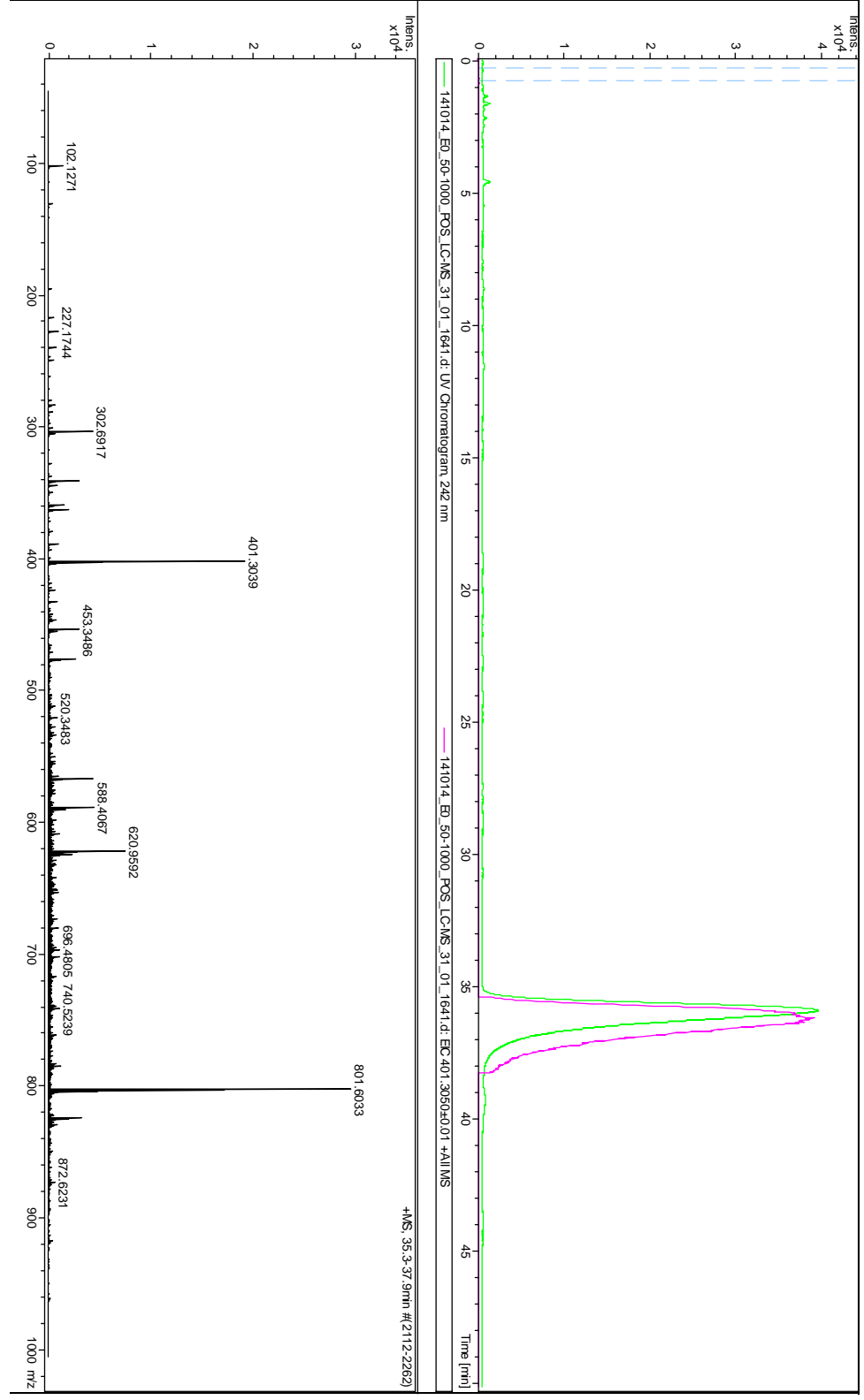


HPLC-UV/MS 5:





HPLC-UV/MS S1:





Peak	RT [min]	Peak Height [mAU]	Integral [%]	Peak Area [mAU*s]	HWB [min]	Integral Region [min]
1	1.4	0.72	0.11	9.7	0	1.34 - 1.51
2	1.57	0.11	0.02	1.3	0	1.51 - 1.62
3	1.69	0.96	0.16	13.2	0	1.62 - 1.82
4	1.91	0.23	0.04	3.3	0	1.84 - 2.01
5	2.22	0.54	0.1	8.6	0	2.15 - 2.36
6	2.51	0.19	0.05	4.6	0	2.38 - 2.62
7	2.69	0.08	0.02	1.4	0	2.62 - 2.80
8	4.63	0	0	0	0	34.95 - 34.97
9	4.63	0.96	0.3	25.6	0	4.49 - 4.87
10	35.86	0	0	0.1	0	38.80 - 38.87
11	35.86	46.19	99.2	8360.5	0	34.97 - 38.09

QuantAnalysis Summary Report

Batch Info

Batch [REDACTED] TE.btc
Instrument micrOTOF-Q II Operator BDAL@DE
Acquisition Date 10/15/2014 3:02:00 PM

Method Parameter

Def. Injection Volume 10.000000 Accuracy Limit (%) 20

Compound Type Chromatogram Ret. Time Calib.Mode

TE Target EIC 401.305±0.02 ±All 36.1 min Area

File Summary

#	File Name	Via I	Sample Name	Sample Type	Calib Level	Calib Action
1	141014_E0_50-1000_POS_LC-MS_31_01_1635.d	31	141014_E0_50-1000_POS_LC-MS	Sample	-	-
2	141014_E1_50-1000_POS_LC-MS_32_01_1636.d	32	141014_E1_50-1000_POS_LC-MS	Calibration	1	New
3	141014_E2_50-1000_POS_LC-MS_33_01_1637.d	33	141014_E2_50-1000_POS_LC-MS	Calibration	2	New
4	141014_E3_50-1000_POS_LC-MS_34_01_1638.d	34	141014_E3_50-1000_POS_LC-MS	Calibration	3	New
5	141014_E4_50-1000_POS_LC-MS_35_01_1639.d	35	141014_E4_50-1000_POS_LC-MS	Calibration	4	New
6	141014_E5_50-1000_POS_LC-MS_36_01_1640.d	36	141014_E5_50-1000_POS_LC-MS	Calibration	5	New
7	141014_E0_50-1000_POS_LC-MS_31_01_1641.d	31	141014_E0_50-1000_POS_LC-MS	Sample	-	-
8	141014_E0_50-1000_POS_LC-MS_31_01_1642.d	31	141014_E0_50-1000_POS_LC-MS	Sample	-	-

QuantAnalysis Summary Report

Compound: TE

#	Theor. Conc	Area Target Cmpd	Calc. Conc.	Accuracy
1		2874452	9.49	
2	2.5	1285152	1.27	51.2
3	5.0	2076199	5.36	108.3
4	9.9	3243978	11.40	115.1
5	19.8	4733087	19.10	96.5
6	39.6	6094030	26.14	66.0
7		2957914	9.92	
8		2773976	8.97	

Calibration Block No.: 1

