

REVIEWED

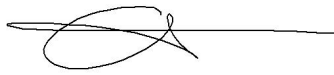
By Amber Gerheart at 10:22 am, Jun 27, 2022



6/17/2022









Worklist: 5997

<u>LAB CASE</u>	<u>ITEM</u>	<u>ITEM TYPE</u>	<u>DESCRIPTION</u>	
C2022-1085	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1090	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1179	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1185	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1206	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1254	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1282	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1283	3	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1284	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1287	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1305	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1314	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-1314	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	



6/17/2022

Worklist: 5998

<u>LAB CASE</u>	<u>ITEM</u>	<u>ITEM TYPE</u>	<u>DESCRIPTION</u>	
C2022-1178	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1204	2	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1207	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1315	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1318	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1319	3	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-1324	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
M2022-2071	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	

AM# 25: Multi-Drug Screen in Blood and Urine by LC-MS/MS

Extraction Date: 6/15/22 Analyst: Anne Nord
Plate lot#: 211015 Plate retest date: 04/15/22

Mobile phase A: 10mM Ammonium Formate
0.5M Ammonium Hydroxide
Mobile phase B: 0.1% Formic Acid in MeOH
Ethyl Acetate LC 20% Methanol
Blank Blood Lot: 22B52020 **Blank Urine lot:** 21522 **Column:** Phenomenex Phenyl Hexyl (4.6x50mm, 2.6um)
LCMS-QQQ ID: 69679

Pre-Analytic:

- 1. Check levels of mobile phases and needle wash refill as needed. Ensure waste is not full.
- 2. Ensure correct column is installed and begin mobile phase flow allow to equilibrate ~ 30 minutes.

Analytic:

- 1. Remove standards, plate, controls, and samples from cold storage. Allow to reach room temperature.
- 2. Urine hydrolysis pipette: 250 ul urine in blank well, add 40 ul BG Turbo, add 100 ul 500 mm sodium phosphate buffer mix for at least five minutes ambient temperature.
Pipette 250 µL blood (calibrated pipette) or 250 ul urine in wells of analytical (standards) plate. **Pipette ID: 390993**
- 3. Pipette 250 µL of 0.5 M ammonium hydroxide in wells of analytical plate.
- 4. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
- 5. Transfer 300 µL of blood or urine+base mixture to corresponding wells of SLE+ plate.
- 6. Apply positive pressure for approx. 10-15 seconds (or until no liquid remains on top of sorbent).
(Load at 85-100 PSI- Selector to the right) Manifold ID: 66792
- 7. Wait 5 minutes.
- 8. Add 900 µL ethyl acetate.
- 9. Wait 5 minutes.
- 10. Apply positive pressure for approx. 10-15 seconds. *(12-15 PSI- Selector to the left).*
- 11. Add 900 µL ethyl acetate.
- 12. Wait 5 minutes.
- 13. Apply positive pressure for approx. 10-15 seconds. *(12-15 PSI- Selector to the left).*
- 14. Remove plate containing eluate. add 50 ul 1% HCl in MeOH Place on SPE Dry and evaporate to dryness at approx. 35°C.
SPE Dry ID: 66819
- 15. Reconstitute in 100 µL 20% LC MeOH in LC Water and heat seal plate with foil. Place in autosampler and run worklist.

Post-Analytic

- 1. Open quantitation software and create a new quantitation batch.
- 2. Make necessary changes to integration limits
- 3. Evaluate samples, S/N of primary transition >5 and S/N of secondary transition >3 or evaluation of peak symmetry and resolution. Within +/- 2% or 0.1 min RT of administrative control. Calculated concentration 5 or greater or 2-5 for discretionary range.
- 4. Did all QCs pass for each analyte? (If no is it described in comments?)
- 5. Central File Packet to include: LIMS Worklist, Method Checklist, Calibration and Control Reports

COMMENTS: *External controls run for plate re-test. Levamisole not evaluated due to peak falling out of acquisition window.*

C2022-1318-1 not evaluated for topiramate due to low IS response

C2022-1207-2 not evaluated for diphenhydramine and brompheniramine due to low IS response; not evaluated for carisoprodol and meprobamate due to shifting or low IS response.

Request for Departure from an Analytical Method or Quality Standard

Deviation Number (assigned by QM): TOX-22-01

Date of Request: **2/3/2022**

Requestor/Discipline: Celena Shrum/Toxicology

Analytical Method/Quality Standard, Revision #: AM #25, AM #28, AM #29, Revision 13

Temporary or Permanent Deviation: Permanent

Scope of Deviation (record specific information, e.g. affected programs, evidence types, expected end date; etc): Deviation will remain in place until the change is made in the next method revision.

Deviation Request (Describe detailed instructions of the changes being made; include reference to specific section number(s) in the method manual): 4.1.4 (Place plate on shaking incubator at approximately 900 rpm for approximately 15 minutes) of AM #25, AM # 28, and AM #29 is being removed. The removal of this step was tested in the validation "Addition of Compounds/Modifications for the MDS" (approved on 2/2/2022) and it was determined that that step is not necessary and can be removed.

Technical Justification for Analytical Method Deviations: Refer to validation "Addition of Compounds/Modifications for the MDS" (approved on 2/2/2022)

Technical Review

Departure approved
Comments:

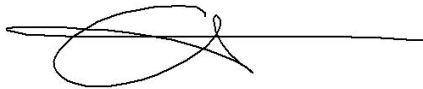
Departure Not Approved
Comments:

Approver: Rachel Cutler
Title: Laboratory Manager

Date: 2/10/2022

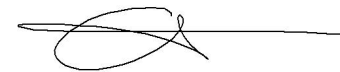
Quality Review

Quality Approver: Jason Crowe
Title: Quality Manager
Date: 2/10/2022



	1	2	3	4	5	6	7	8	9	10	11	12
A			1085-1	1284-1							1318-1	
B	Cal 1		1090-1	1287-1							1315-1	
C			1179-1	1305-1							1207-1	
D			1185-1	1314-1							1204-2	
E			1206-1	1314-2							1178-1	
F			1254-1							M2071-1		
G		negative blood	1282-1							external control urine		
H		external control blood	1283-3							negative urine		

C2022-____-



Toxicology AM method 25/28 urine external control prep

working solution 10000 ng/ml in meoh diphendyramine, methamphetamine, alprazolam, methocarbamol, morphine

Stock solution 1mg/ml 50 ul each in 4750 ul MeOH (Honeywell EA078-US)

ppd 6/25/21: Exp: 6/25/2022 lot 62522 by AMN

Drug	lot	expiration
Methamphetamine	FE03132001	7/1/2025
methocarbamol	FN01212005	1/1/2023
alprazolam	FE06102008	6/1/2025
Diphendyramine	FN02212011	3/1/2025
Morphine	FE03232010	4/1/2025

AM 25/28 control 500 ul working solution (62522) in 4500 ul negative urine (1000ng/mL Expected concentration)

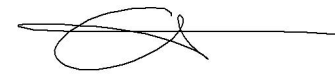
ppd 6/25/21, exp 6/25/22 lot u62522 negative urine 5621 by AMN

ppd 4/26/22, exp 6/25/22 lot u42622 negative urine 22522 by baw

AM 25/28 Blood Control: 50ul working solution (41422) in 4950 ul neg blood (100ng/mL Expected concentration)

ppp 6/25/21, exp 6/25/22 lot b62522 neg blood 21D52496 by AMN

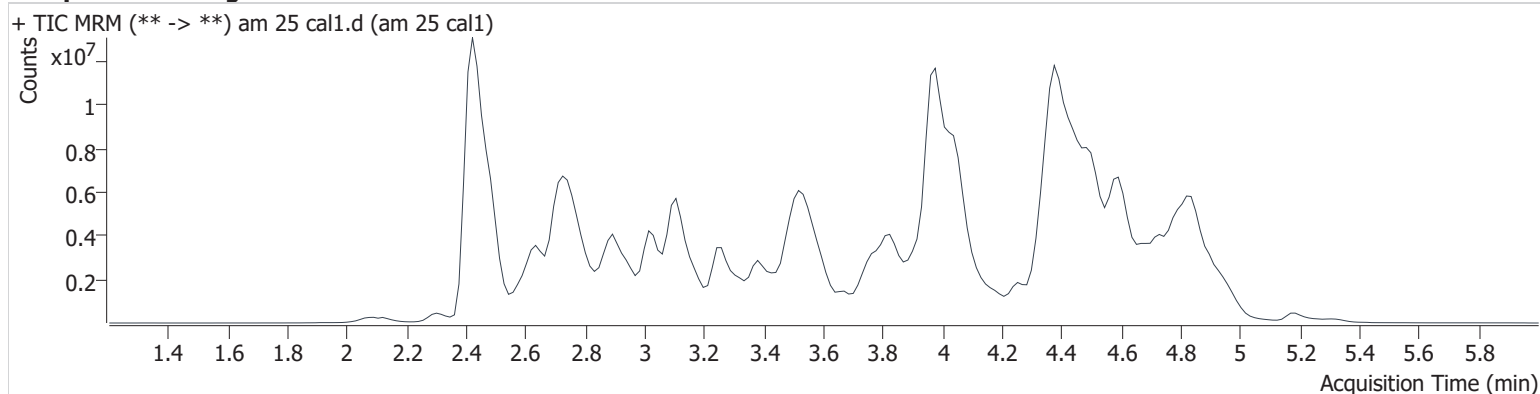
AM #25 Multi-Drug Screen Results



Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\mdq.batch.bin
Calibration Last Update 6/17/2022 11:37:59 AM

Instrument	69679	Data File	am 25 cal1.d
Type	Cal	Sample	am 25 cal1
Acq. Method	mds713.m	Operator	Anne Nord
Sample Position	P2-B1	Comment	
Injection Volume	2.5		
Acq. Date-Time	6/15/2022 1:41:02 PM		

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.542	848026	914.1	98.7	829646	10.000
6-MAM	2.800	23934	55.1	35.5	1002619	10.000
7-aminoclonazepam	3.355	449638	347.3	111.3	1931382	10.000
7-aminoflunitrazepam	3.584	868230	558.1	137.0	1931382	10.000
9-Hydroxyrisperidone	3.958	2338321	380.2	37.1	1931382	10.000
Acetyl Fentanyl	4.101	300815	97.1	245086.7	12782904	10.000
Acetyl Norfentanyl	2.641	220483	1343.8	176.9	12782904	10.000
a-hydroxyalprazolam	4.378	67902	80.4	17.1	1931382	10.000
alpha-hydroxymidazolam	4.454	1306273	337.7	95.4	1931382	10.000
alpha-PHP	3.848	2167986	213.0	281.7	6219910	10.000
alpha-PVP	3.513	2719323	413.4	128.9	6219910	10.000
Alprazolam	4.473	1014425	220.5	129.4	5685230	10.000
Amitriptyline	4.523	1409953	177.3	137.9	7395086	10.000
Amphetamine	2.631	2541152	516.9	560.5	6219910	10.000
Benzoylcegonine	3.123	94056	217.6	21.7	156454	10.000
Brompheniramine	4.009	68189	29.0	102.5	43856632	10.000
Buprenorphine	5.197	14760	164.4	236.5	1547190	10.000
Bupropion	3.834	2811450	1077.8	295.8	10389304	10.000
Carbamazepine	4.049	4370818	639.9	987.0	30951	10.000
Carisoprodol	4.047	522972	1370.5	63.6	2941106	10.000
Chlordiazepoxide	4.597	496840	121.6	270.3	5685230	10.000
Chlorpheniramine	3.906	3192042	3507.6	18.2	5558228	10.000
Chlorpromazine	4.824	2360994	1947.8	659.6	15055984	10.000
Citalopram	4.008	1885646	1171.2	1149.7	5558228	10.000
Clomipramine	4.778	2512927	697.8	572.0	5558228	10.000
Clonazepam	4.286	221072	266.8	199.4	5685230	10.000
clonazolam	4.206	484614	323.2	25219.2	5685230	10.000
clozapine	4.608	3693563	1884.7	2984.4	10203474	10.000
Cocaehtylene	3.733	3094392	478.3	574.5	15089119	10.000
Cocaine	3.505	2623615	738.1	81.4	15089119	10.000
Codeine	2.711	235163	181.8	284.8	4688564	10.000
Cyclobenzaprine	4.399	2263990	200.0	21.9	7395086	10.000
Desipramine	4.339	4407189	1252.4	311.6	7395086	10.000
Dextromethorphan	4.076	1677430	334.0	122.9	8802630	10.000

AM #25 Multi-Drug Screen Results

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextrophan	3.234	1777441	2382.3	812.3	8802630	10.000
Diazepam	4.721	685182	278.2	236.5	5685230	10.000
Dihydrocodeine	2.558	688278	447.2	385.2	2540490	10.000
Diphenhydramine	3.985	5547486	1865.5	236.9	43856632	10.000
Doxepin	4.183	1482092	75.8	24.6	13706662	10.000
Doxylamine	3.540	5443876	∞	∞	1423836	10.000
Duloxetine	4.289	86983	30.2	534.6	13209540	10.000
EDDP	3.983	1088858	102.5	32.6	2540490	10.000
Estazolam	4.382	1651638	340.1	528.6	5685230	10.000
Etizolam	4.499	33155	5592.7	3499.1	5685230	10.000
Fentanyl	4.361	257983	35.4	42874.8	12782904	10.000
Flualprazolam	4.331	493543	94866.4	1371.8	5685230	10.000
Flunitrazepam	4.411	829874	112.4	96.3	5685230	10.000
Fluoxetine	4.257	2977689	441.1	29690.0	4702660	10.000
Flurazepam	4.405	606351	154.7	46591.8	5685230	10.000
Hydrocodone	3.000	632591	84.2	191.0	4688564	10.000
Hydromorphone	2.289	590496	89.9	177.0	4688564	10.000
hydroxyzine	4.682	2010294	473.9	162302.3	8802630	10.000
Imipramine	4.445	4927489	25610.1	686.5	7395086	10.000
Ketamine	3.757	2097471	337.7	91.5	13209540	10.000
Lamotrigine	3.419	173577	151.1	168.9	5558228	10.000
Levetireacetam	2.310	424536	135.7	176.9	5558228	10.000
Lorazepam	4.270	33738	117.3	∞	5685230	10.000
Maprotiline	4.523	728860	126.0	98.7	7395086	10.000
MDA	2.765	1517863	241.6	443.3	19255656	10.000
MDEA	3.039	3013263	797.2	1655.1	19255656	10.000
MDMA	2.856	3500772	389.6	255.0	19255656	10.000
Meperidine	3.558	1595877	212.6	316.9	8802630	10.000
Meprobamate	3.437	118583	74.5	8.2	2941106	10.000
Methadone	4.365	3949737	647.9	112.0	2540490	10.000
Methamphetamine	2.752	6373231	∞	∞	19255656	10.000
Methocarbamol	3.343	120564	137.8	109.3	2540490	10.000
Methylphenidate	3.390	5393766	697.6	∞	13209540	10.000
Metoprolol	3.250	511297	549.0	2863.3	8802630	10.000
Midazolam	4.655	450307	286.9	1104.4	5685230	10.000
Mirtazapine	4.416	3795149	853.9	339.4	8802630	10.000
Mitragynine	4.405	285175	156.1	425.9	8802630	10.000
Morphine	2.062	146441	229.2	227.8	186750	10.000
Norbuprenorphine	3.744	23455	23.9	8167.3	186750	10.000
Nordiazepam	4.555	536855	195.0	113.8	5685230	10.000
Norfentanyl	3.129	3737372	3185.0	∞	19114109	10.000
norhydrocodone	2.697	23849	23.0	10124.3	4688564	10.000
norketamine	3.820	473829	52.0	561.8	13209540	10.000
Normeperidine	3.451	1835175	9210.3	2114.5	5558228	10.000
Noroxycodone	2.634	729965	86.6	217.4	5788887	10.000
Nortriptyline	4.386	1463593	200.0	79.8	7395086	10.000
O-desmethyl-tramadol	2.655	4910401	550.2	100.4	5558228	10.000
o-Desmethylvenlafaxine	3.019	1186625	318.4	5681.7	5558228	10.000
Olanzapine	3.949	717119	301.0	140.2	30951	10.000
Oxazepam	4.367	170041	15.7	14.7	829646	10.000
Oxycodone	2.740	927598	136.0	143.5	5788887	10.000
Oxymorphone	2.074	685265	334.2	334.8	186750	10.000
Paroxetine	4.315	104959	155.0	5878.5	4702660	10.000
Phenazepam	4.499	548293	491.7	25755.0	5685230	10.000
Phencyclidine	3.833	3366350	7620.6	100.5	8802630	10.000
Phentermine	2.919	1272337	∞	∞	13209540	10.000
Phenytoin	3.940	57929	15.4	12.1	30951	10.000
primidone	3.222	120712	195.5	24.9	7395086	10.000
Promethazine	4.506	6087953	549.6	268.8	5558228	10.000
Pseudoephedrine	2.431	62030657	15389.4	1327.2	19255656	10.000



AM #25 Multi-Drug Screen Results

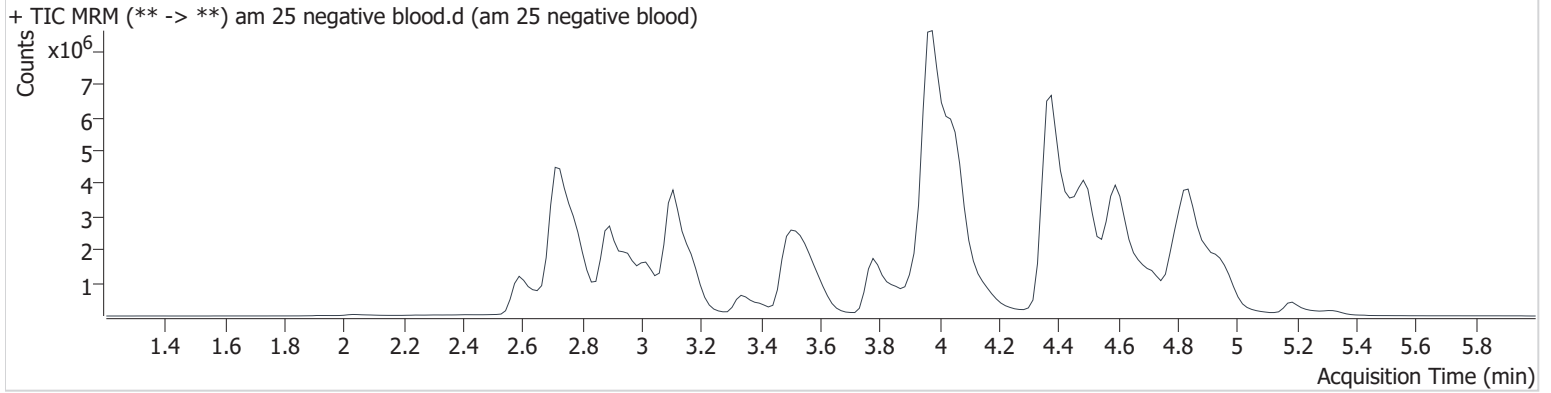
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Quetiapine	4.682	1797139	354.3	500.0	28893501	10.000
Risperidone	4.250	3003643	541.3	343.7	10101994	10.000
Sertraline	4.596	918224	∞	∞	4702660	10.000
Sufentanil	4.850	174299	606.2	220.1	19114109	10.000
Tapentadol	3.268	3246282	714.5	77.5	2540490	10.000
Temazepam	4.521	965277	459.9	23.2	5685230	10.000
Topiramate	3.638	9225	1660.9	3.3	27187	10.000
Tramadol	3.265	5543118	1521.7	37.1	5558228	10.000
Trazodone	4.851	2305947	372.9	257.3	13706662	10.000
Venlafaxine	3.676	4448904	2126.4	360.2	4702660	10.000
Zaleplon	4.196	917853	221728.9	885.4	28893501	10.000
Zolpidem	4.396	4471353	2856.0	1055.2	28893501	10.000
Zopiclone	4.374	194977	133132.9	104528.7	1423836	10.000

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\mdq.batch.bin
Calibration Last Update 6/17/2022 11:37:59 AM

Instrument	69679	Data File	am 25 negative blood.d
Type	Sample	Sample	am 25 negative blood
Acq. Method	mds713.m	Operator	Anne Nord
Sample Position	P2-G2	Comment	
Injection Volume	2.5		
Acq. Date-Time	6/15/2022 1:47:48 PM		
Sample Info.			

Sample Chromatogram

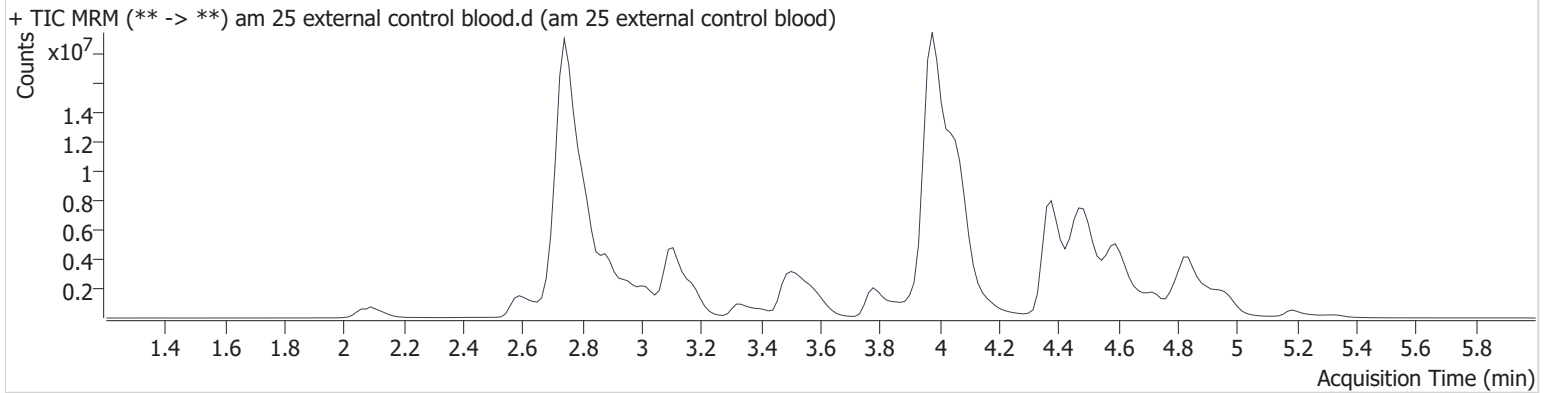


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\mdq.batch.bin
Calibration Last Update 6/17/2022 11:37:59 AM

Instrument	69679	Data File	am 25 external control blood.d
Type	Sample	Sample	am 25 external control blood
Acq. Method	mds713.m	Operator	Anne Nord
Sample Position	P2-H2	Comment	
Injection Volume	2.5		
Acq. Date-Time	6/15/2022 1:54:33 PM		
Sample Info.			

Sample Chromatogram



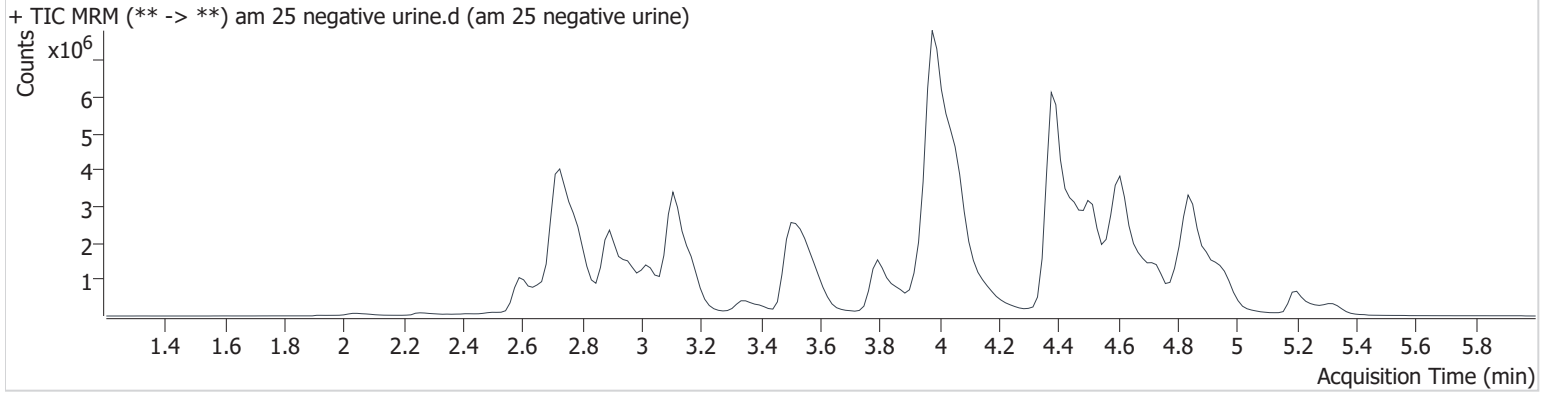
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.473	9846986	1677.5	392.0	7529839	73.290
Diphenhydramine	3.985	50487332	8644.6	9174.8	50768379	78.619
Methamphetamine	2.752	40732828	∞	31176.5	22025385	55.875
Methocarbamol	3.328	898627	1810.5	1156.5	3144297	60.222
Morphine	2.062	1574386	2187.7	5163.0	256270	78.345

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\mdq.batch.bin
Calibration Last Update 6/17/2022 11:37:59 AM

Instrument	69679	Data File	am 25 negative urine.d
Type	Sample	Sample	am 25 negative urine
Acq. Method	mds713.m	Operator	Anne Nord
Sample Position	P2-H10	Comment	
Injection Volume	2.5		
Acq. Date-Time	6/15/2022 3:28:57 PM		
Sample Info.			

Sample Chromatogram

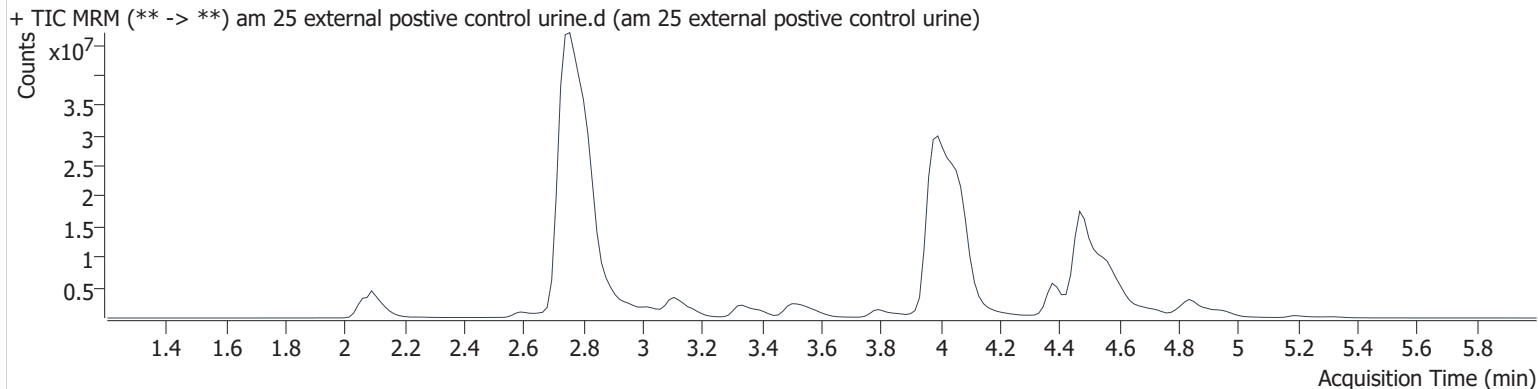


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\mdq.batch.bin
Calibration Last Update 6/17/2022 11:37:59 AM

Instrument	69679	Data File	am 25 external postive control urine.d
Type	Sample	Sample	am 25 external postive control urine
Acq. Method	mds713.m	Operator	Anne Nord
Sample Position	P2-G10	Comment	
Injection Volume	2.5		
Acq. Date-Time	6/15/2022 3:35:41 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.473	47805588	∞	1255.9	4672216	573.434
Diphenhydramine	4.048	129891675	16418.1	9225.8	25629228	400.668
Methamphetamine	2.767	113299067	∞	495194.5	12029000	284.574
Methocarbamol	3.343	5156167	2676.6	2193.4	2024226	536.746
Morphine	2.077	8941078	11686.0	4177.2	167902	679.096



AM# 26: THC and Metabolites Screen in Blood by LC-MS/MS

Extraction Date: 6/15/22 Analyst: Anne Nord

Plate lot#: 220309 Plate retest date: 9/09/22

Mobile phase A: 10mM Ammonium Formate
0.1% Formic Acid in Water

Mobile phase B: 0.1% Formic acid in MeOH
MTBE Hexane

Blank Blood Lot: 22B52020 **Urine Blank:** 21522 **Column:** Phenomenex Phenyl Hexyl (4.6x50mm: 2.6 um)
LCMS-QQQ ID: 69679

Pre-Analytic:

- 1. Check levels of mobile phases and needle wash refill as needed. Ensure waste is not full.
- 2. Ensure correct column is installed and begin mobile phase flow allow to equilibrate ~ 30 minutes.

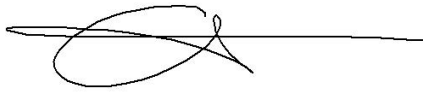
Analytic:

- 1. Remove standards, plate, controls, and samples from cold storage. Allow to reach room temperature.
- 2. Urine hydrolysis: add 1.5 ml urine to blank plate, add 250 ul 1N KOH mix and incubate at 40 degrees for 15 minutes.
Pipette 1000 µL blood (calibrated pipette) in wells of analytical (standards) plate. Pipette ID: K52558g
Pipette 1000 ul urine to analytical (standards) plate.
- 3. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
- 4. Pipette 500 µL 0.1% formic acid in blood wells 500 ul saturated phosphate buffer in urine wells of analytical plate.
- 5. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
- 6. Transfer 800 µL of blood acid or urine acid mixture to corresponding wells of SLE+ plate.
- 7. Apply positive pressure for approx. 10-15 seconds (or until no liquid remains on top of sorbent).
(Load at 85-100 PSI- Selector to the right) Manifold ID: 66792
- 8. Wait 5 minutes.
- 9. Add 2.25 mL MTBE (add in 3 increments of 750 µL).
- 10. Wait 5 minutes.
- 11. Apply positive pressure for approx. 10-15 seconds. (12-15 PSI- Selector to the left).
- 12. Add 2.25 mL hexane (add in 3 increments of 750 µL).
- 13. Wait 5 minutes.
- 14. Apply positive pressure for approx. 10-15 seconds. (12-15 PSI- Selector to the left).
- 15. Remove plate containing eluate. Place on SPE Dry and evaporate to dryness at approx. 35°C.
SPE Dry ID: 66819
- 16. Reconstitute in 100 µL 100% LCMS MeOH and heat seal plate with foil. Place in autosampler and run worklist.

Post-Analytic

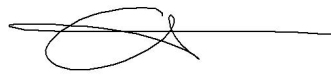
- 1. Create batch and process data.
- 2. Calculated sample concentration of 3 ng/mL or greater for THC and THC-OH, a calculated sample concentration of 10 ng/mL or greater for Carboxy-THC.
- 3. Retention time within +/- 2% or +/-0.100 min whichever is greater of the average retention time of the calibrators.
- 4. Did all QCs pass for each analyte? Yes
- 5. Central File Packet to include: LIMS Worklist, Method Checklist, Calibration and Control Reports

COMMENTS:



	1	2	3	4	5	6
a	cal 1	Internal urine	1282-1	1178-1		
b	cal 2	negative blood	1283-3	1204-2		
c	cal 3	1085-1	1284-1	1207-1		
d	cal 4	1090-1	1287-1	1315-1		
e	Cal 5	1179-1	1305-1	1318-1		
f	cal 6	1185-1	1314-1	1319-3		
g	cal 7	1206-1	1314-2	1324-1		
h	Internal control (blood)	1254-1	negative urine	m2071-1		

c2022-____-__



Request for Departure from an Analytical Method or Quality Standard

Deviation Number (assigned by QM): TOX-22-02

Date of Request:
03/02/2022

Requestor/Discipline:
Celena Shrum/Toxicology

Analytical Method/Quality Standard, Revision #:
Toxicology AM #25, AM #26, and AM #27, Revision 13

Temporary or Permanent Deviation:
Permanent

Scope of Deviation (record specific information, e.g. affected programs, evidence types, expected end date; etc):

Deviation will remain in place until the change is made in the next method revision.

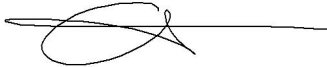
Deviation Request (Describe detailed instructions of the changes being made; include reference to specific section number(s) in the method manual):

Toxicology AM #25 3.3.1.1 Internal standards are prepared by the ToxBBox plate manufacturer and contained on the 96 well plate. If the run contains urine samples, a positive external urine control must also be run.

Toxicology AM #26 3.3.2 A negative control will be run with each extraction. If the run contains urine samples, a negative urine control and external positive urine control must also be included.

Toxicology AM #27 3.3.2 A negative control will be run with each extraction. If the run contains urine samples, a negative urine control and positive external urine control will also be included in the run.

The deviation is to include the option of using an internal urine control in lieu of an external urine control.



Technical Justification or Analytical Method Deviations:

Internal controls serve the same purpose as external controls but also helps to avoid the possible issues that can occur with using external controls (incorrect spiking, incorrect preparation, evaporation of compounds, etc.). If these errors occur, runs need to be repeated and this wastes time, sample, and supplies.

Technical Review

Departure approved
Comments:

Departure Not Approved
Comments:



Approver: Rachel Cutler
Title: Lab Manager

Date: 3/2/22

Quality Review

Quality Approver: Jason Crowe
Title: Quality Manager
Date: 3/2/2022

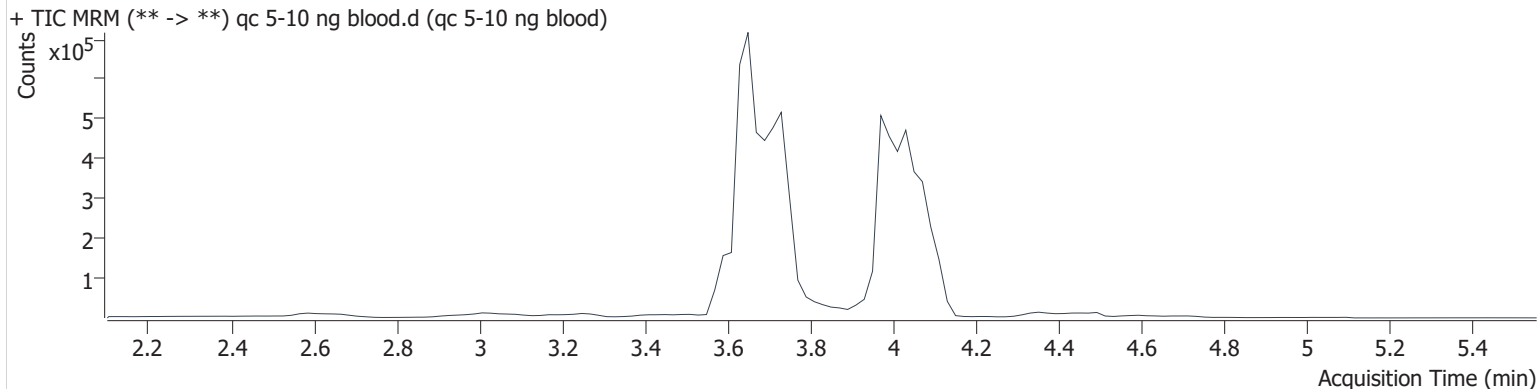


AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	qc 5-10 ng blood.d
Type	QC	Sample	qc 5-10 ng blood
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-H1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:36:16 PM		
Sample Info.			

Sample Chromatogram



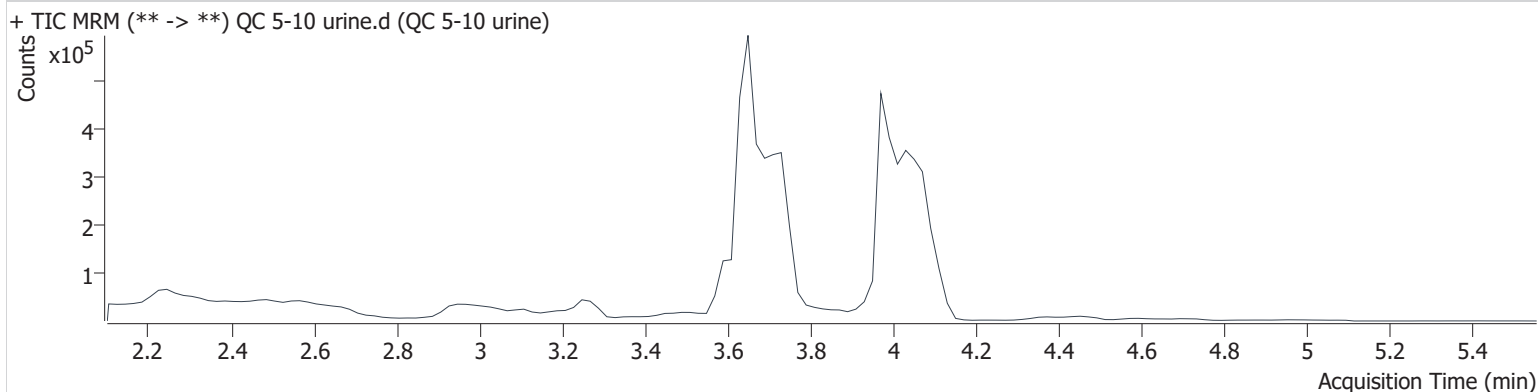
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	22699	623925	4.761 ng/ml
THC-COOH	3.609	136653	569852	15.252 ng/ml
THC-OH	3.658	26628	3869890	4.349 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	QC 5-10 urine.d
Type	Sample	Sample	QC 5-10 urine
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-A2	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:42:54 PM		
Sample Info.			

Sample Chromatogram



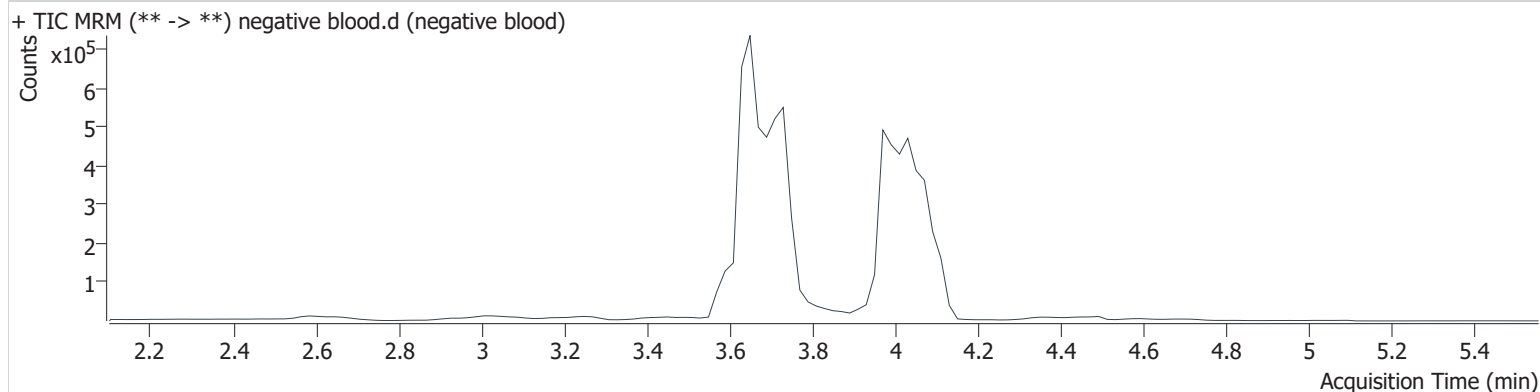
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	11267	308148	4.785 ng/ml
THC-COOH	3.609	96657	372581	16.419 ng/ml
THC-OH	3.658	21691	2788835	4.900 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	negative blood.d
Type	Sample	Sample	negative blood
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-B2	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:49:31 PM		
Sample Info.			

Sample Chromatogram

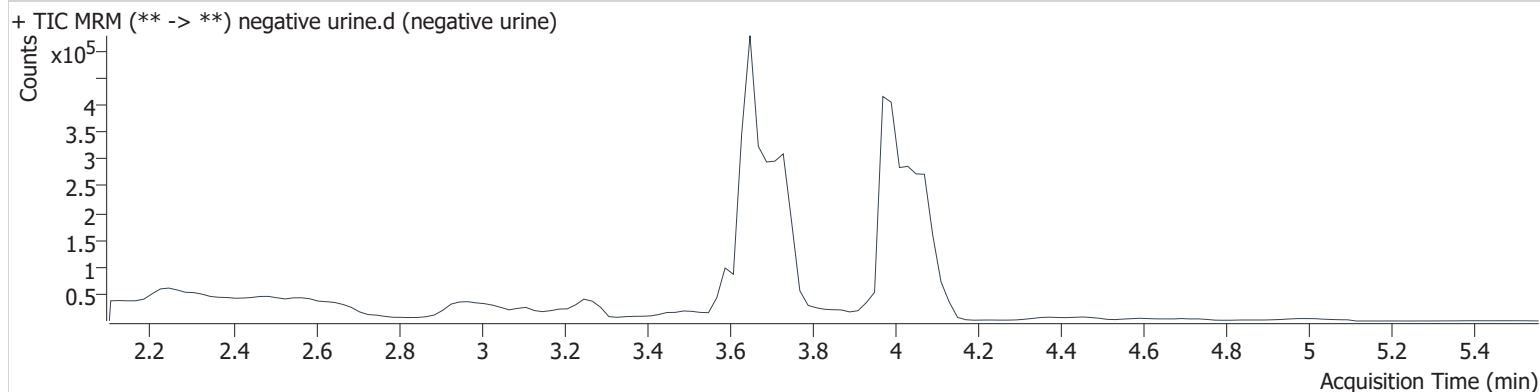


AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	negative urine.d
Type	Sample	Sample	negative urine
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-H3	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 8:22:01 PM		
Sample Info.			

Sample Chromatogram

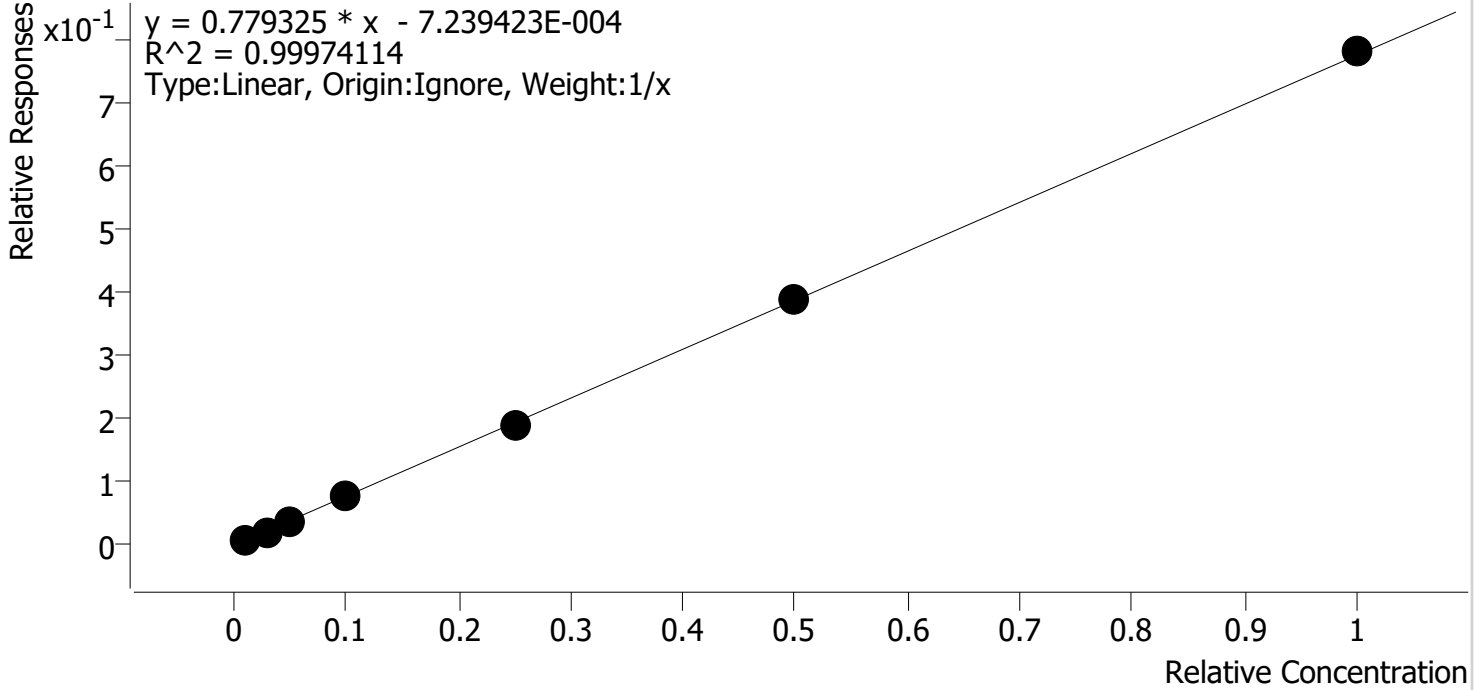


Compound Calibration Report



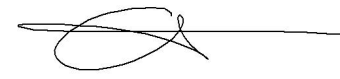
Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Last Cal. Update 6/17/2022 11:36 AM
Analyst Name ISP\datastor
Analyte THC **Internal Standard** THC-d3

THC - 7 Levels, 7 Levels Used, 7 Points, 7 Points Used, 0 QCs



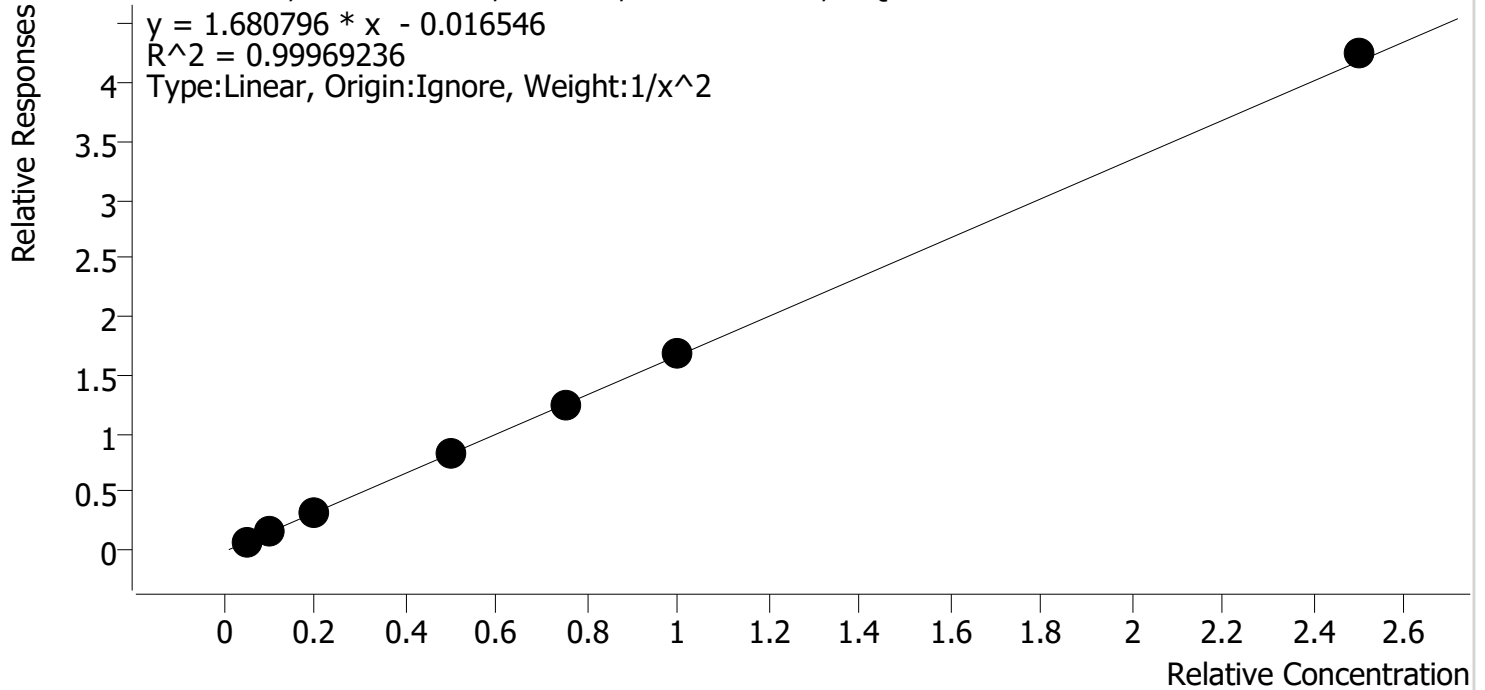
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	1.0	1.1	110.5
cal 2	2	✓	3.0	2.9	95.1
cal 3	3	✓	5.0	4.9	97.4
cal 4	4	✓	10.0	9.8	98.1
cal 5	5	✓	25.0	24.5	97.8
cal-6	6	✓	50.0	50.2	100.4
cal-7	7	✓	100.0	100.7	100.7

Compound Calibration Report



Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Last Cal. Update 6/17/2022 11:36 AM
Analyst Name ISP\datastor
Analyte THC-COOH **Internal Standard** THC-COOH-d9

THC-COOH - 7 Levels, 7 Levels Used, 7 Points, 7 Points Used, 0 QCs



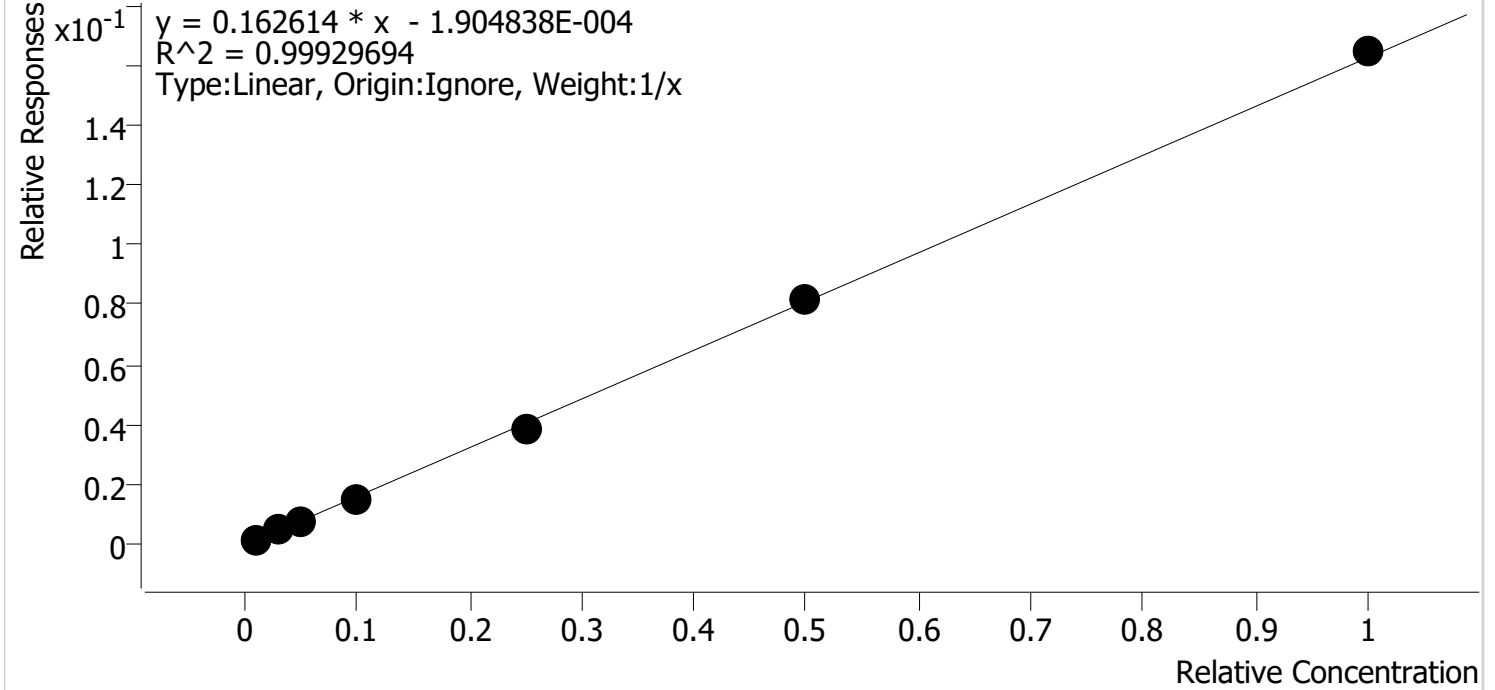
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	5.0	5.1	101.0
cal 2	2	✓	10.0	9.9	99.1
cal 3	3	✓	20.0	19.5	97.3
cal 4	4	✓	50.0	50.4	100.8
cal 5	5	✓	75.0	74.9	99.9
cal-6	6	✓	100.0	100.3	100.3
cal-7	7	✓	250.0	253.9	101.6

Compound Calibration Report



Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Last Cal. Update 6/17/2022 11:36 AM
Analyst Name ISP\datastor
Analyte THC-OH **Internal Standard** THC-OH-d3

THC-OH - 7 Levels, 7 Levels Used, 7 Points, 7 Points Used, 0 QCs



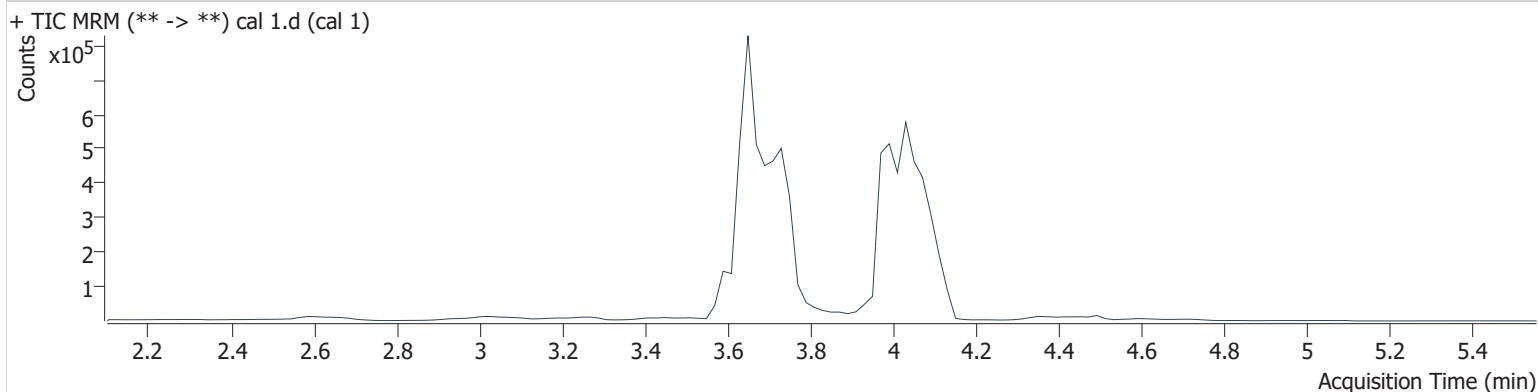
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	1.0	1.1	113.8
cal 2	2	✓	3.0	3.0	100.2
cal 3	3	✓	5.0	4.5	90.4
cal 4	4	✓	10.0	9.7	97.3
cal 5	5	✓	25.0	24.2	96.7
cal-6	6	✓	50.0	50.2	100.4
cal-7	7	✓	100.0	101.2	101.2

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal 1.d
Type	Cal	Sample	cal 1
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-A1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 5:43:30 PM		
Sample Info.			

Sample Chromatogram



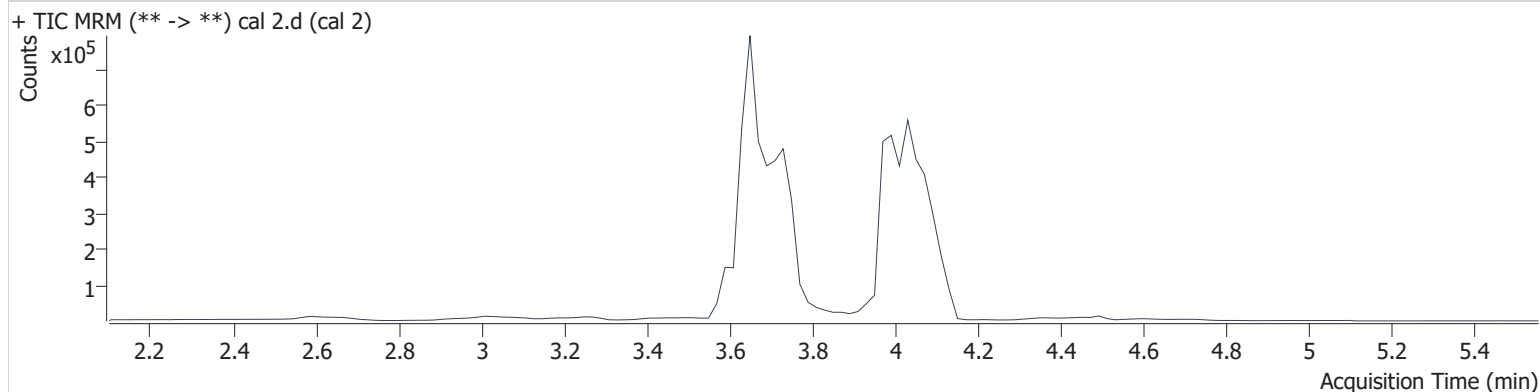
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	6330	802789	1.105 ng/ml Low
THC-COOH	3.609	43769	640378	5.051 ng/ml Low
THC-OH	3.658	7032	4236226	1.138 ng/ml Low

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal 2.d
Type	Cal	Sample	cal 2
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-B1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 5:50:09 PM		
Sample Info.			

Sample Chromatogram



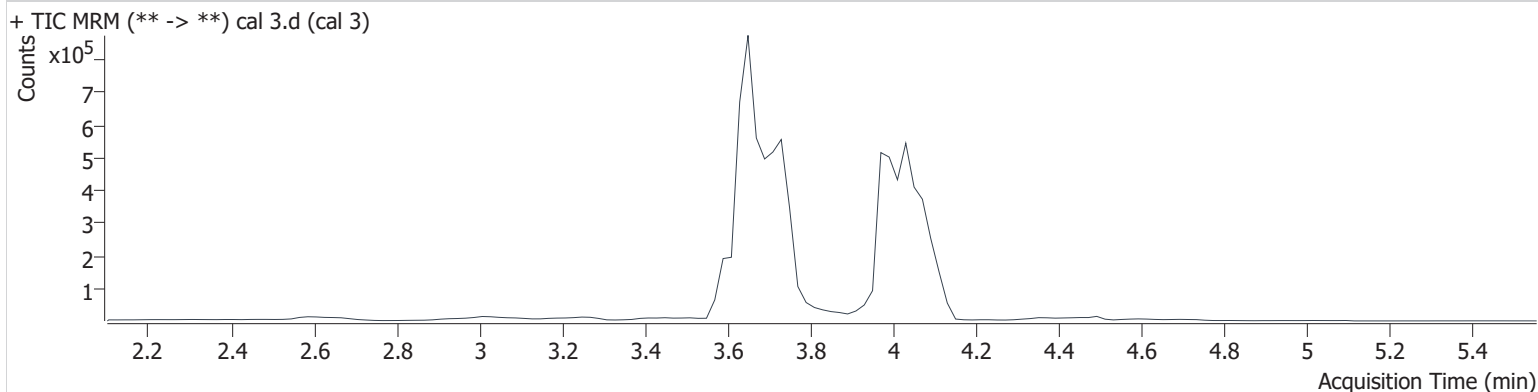
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	16486	766430	2.853 ng/ml Low
THC-COOH	3.609	89863	599239	9.906 ng/ml Low
THC-OH	3.658	18485	3934317	3.006 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal 3.d
Type	Cal	Sample	cal 3
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-C1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 5:56:45 PM		
Sample Info.			

Sample Chromatogram



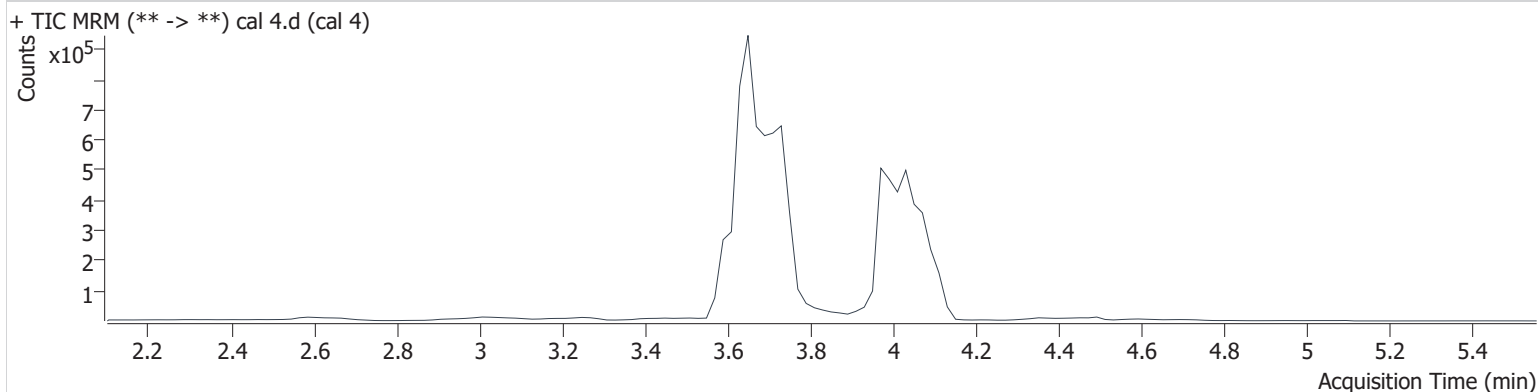
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	26046	699513	4.871 ng/ml
THC-COOH	3.609	198601	639492	19.461 ng/ml
THC-OH	3.658	31063	4340692	4.518 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal 4.d
Type	Cal	Sample	cal 4
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-D1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:03:21 PM		
Sample Info.			

Sample Chromatogram



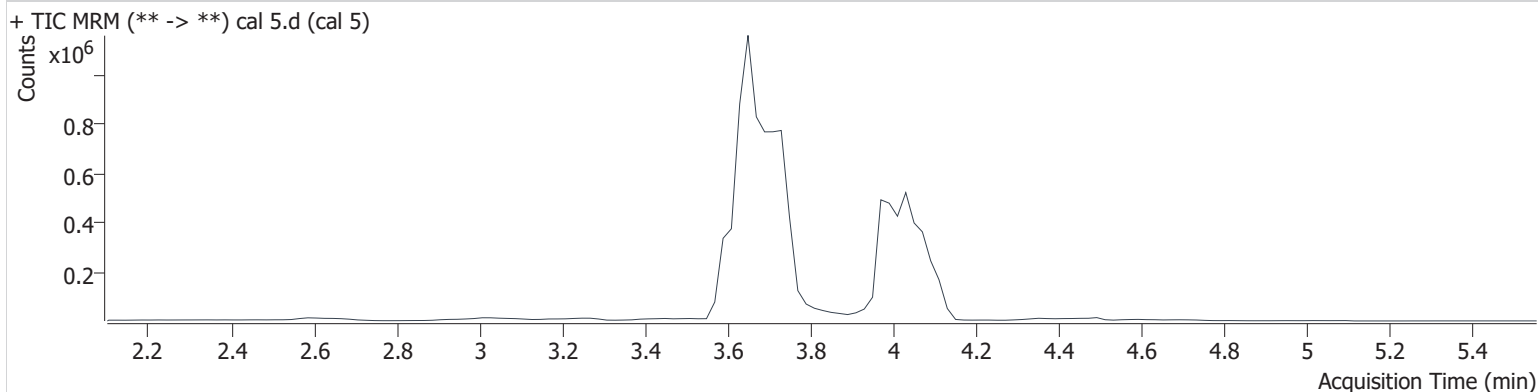
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	50073	661223	9.810 ng/ml
THC-COOH	3.609	512788	617200	50.415 ng/ml
THC-OH	3.658	66927	4281626	9.730 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal 5.d
Type	Cal	Sample	cal 5
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-E1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:09:57 PM		
Sample Info.			

Sample Chromatogram



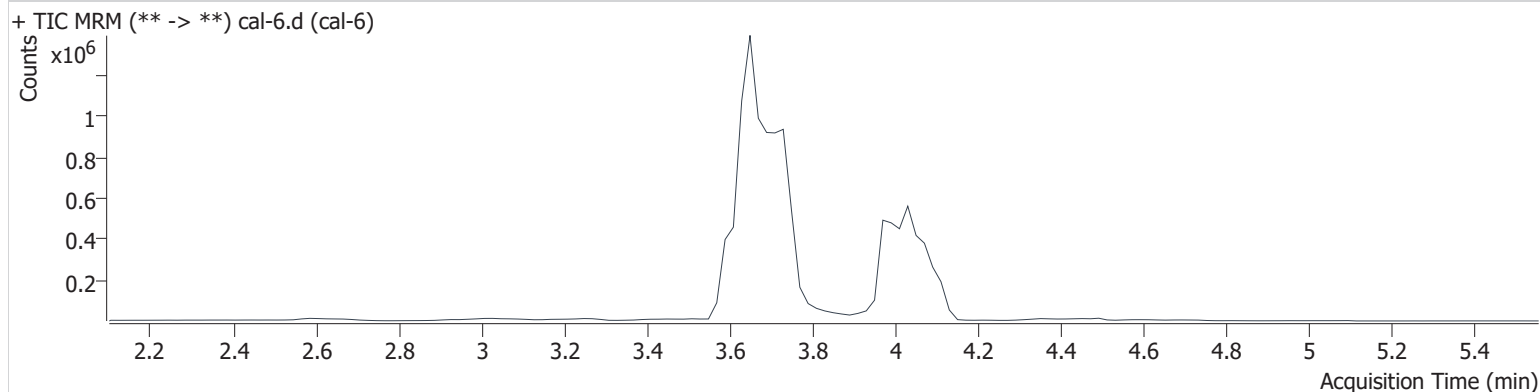
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	122744	646451	24.457 ng/ml
THC-COOH	3.609	770688	619955	74.946 ng/ml
THC-OH	3.658	173504	4435981	24.170 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal-6.d
Type	Cal	Sample	cal-6
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-F1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:16:33 PM		
Sample Info.			

Sample Chromatogram



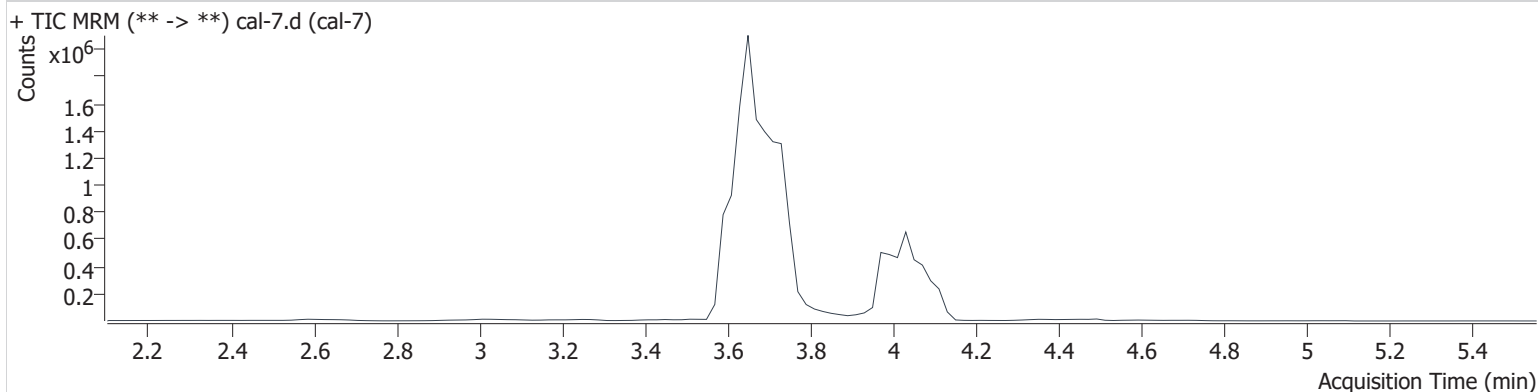
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	247465	633904	50.185 ng/ml
THC-COOH	3.609	1014067	607605	100.280 ng/ml
THC-OH	3.658	355727	4366159	50.220 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\061522\QuantResults\cann.batch.bin
Calibration Last Update 6/17/2022 11:36:58 AM

Instrument	69679	Data File	cal-7.d
Type	Cal	Sample	cal-7
Acq. Method	am 26 cann scr 5-5-20.m	Operator	Anne Nord
Sample Position	P3-G1	Comment	
Injection Volume	5		
Acq. Date-Time	6/15/2022 6:23:10 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	504936	643881	100.719 ng/ml
THC-COOH	3.609	2412924	567541	253.933 ng/ml
THC-OH	3.658	695458	4230150	101.219 ng/ml