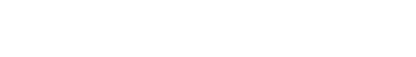


**REVIEWED**

By Sarah Collins at 12:16 pm, Nov 22, 2022

1/17/2022

**Worklist: 6168**

<u>LAB CASE</u>	<u>ITEM</u>	<u>ITEM TYPE</u>	<u>DESCRIPTION</u>	
C2022-2469	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2487		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2489		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2490		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2492		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2493		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2512	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2514		UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-2515		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2516		UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ	
C2022-2517		AVK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2526	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2528		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	
C2022-2556		BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ	

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

Extraction Date: 11/17/22 Analyst: Anne Nord

Plate lot#: 220315 Plate retest date: 09/15/22

**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:** 22B52016-1 **Blank Urine lot:** 7722 **Column:** Agilent Phenyl Hexyl (4.6x50mm, 2.7um)  
**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 QC's 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: *Ran external controls for re-test.*

  
**Idaho State Police  
Forensic Services**

**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

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**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**

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Departure approved

Comments:

Departure Not Approved

Comments:

Approver: Rachel Cutler  
Title: Laboratory Manager



Date: 2/10/2022

**Quality Review**

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





	1	2	3	4	5	6	7	8	9	10	11	12
A								2493-1				
B								negative blood	2469-2		2514-1	
C								2391-1	2512-2		2516-1	
D								Positive control blood	2515-1			
E								2487-1	2517-1	urine control		
F								2489-1	2526-2	negative urine		
G								2490-1	2528-1			cal 1
H								2492-1	2556-1			

C2022-\_\_\_\_\_-

plate position 2

  
Toxicology AM method 25/28 urine external control prep

working solution 10000 ng/ml in meoh diphenhydramine, methamphetamine, alprazolam, , morphine  
Stock solution 1mg/ml 50 ul each in 4800 ul MeOH (VWR 21050767)

ppd 7/7/22: Exp: 7/7/23 lot 7722 by AMN

Drug	lot	expiration
Methamphetamine	FE03132001	7/1/2025
alprazolam	FE06102008	6/1/2025
Diphenhydramine	FN02212011	3/1/2025
Morphine	FE03232010	4/1/2025

**AM 25/28 control 500 ul working solution (7722) in 4500 ul negative urine (1000ng/mL Expected concentration)**

ppd 7/7/22, exp 7/7/23 lot u7722 negative urine 21522 by AMN

**AM 25/28 Blood Control: 50ul working solution (7722) in 4950 ul neg blood (100ng/mL Expected concentration)**

ppp 7/7/22, exp 7/7/23 lot b7722 neg blood 22B52016-3 by AMN

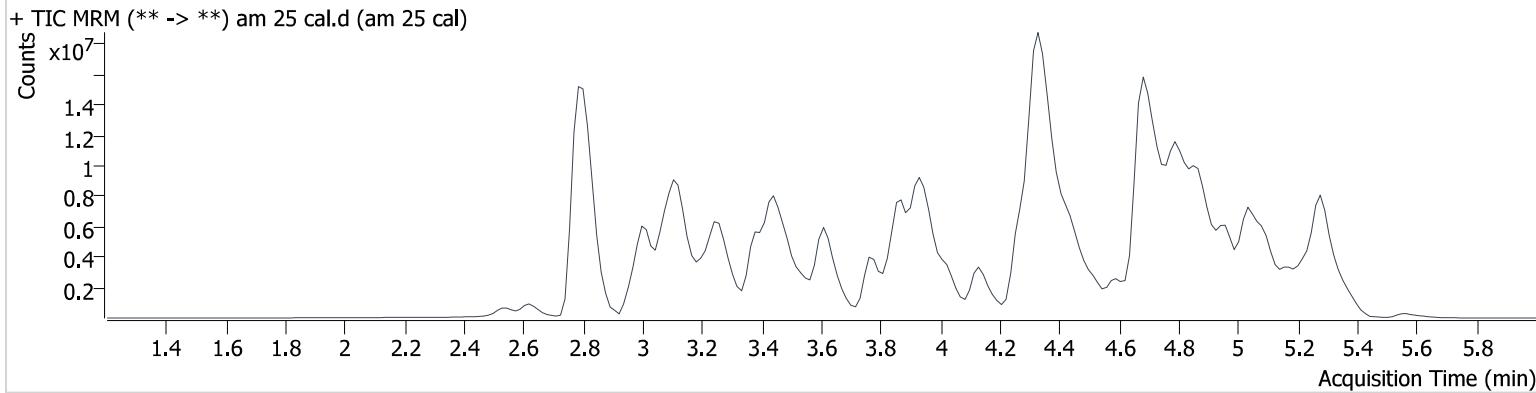
# AM #25 Multi-Drug Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\mds.batch.bin  
**Calibration Last Update** 11/21/2022 1:06:42 PM

<b>Instrument</b>	69679	<b>Data File</b>	am 25 cal.d
<b>Type</b>	Cal	<b>Sample</b>	am 25 cal
<b>Acq. Method</b>	mds713.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P2-G12	<b>Comment</b>	
<b>Injection Volume</b>	2.5		
<b>Acq. Date-Time</b>	11/17/2022 11:39:45 AM		

**Sample Info.**

**Sample Chromatogram**



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.878	2403204	5249.2	147.4	6738931	10.000
6-MAM	3.332	53176	57.3	206.3	1375961	10.000
7-aminoclonazepam	3.643	509540	134.5	198.4	1874986	10.000
7-aminoflunitrazepam	3.874	505184	365.2	1636.6	1874986	10.000
9-Hydroxyrisperidone	4.480	4773593	415.9	49088.6	1874986	10.000
Acetyl Fentanyl	4.593	472161	104.1	33850.4	18085038	10.000
Acetyl Norfentanyl	2.960	250494	1581.9	170.1	18085038	10.000
a-hydroxyalprazolam	4.715	351249	∞	1139.8	1874986	10.000
alpha-hydroxymidazolam	4.775	2038697	449.5	448.7	1874986	10.000
alpha-PHP	4.278	2631138	1147584.7	946.7	8517208	10.000
alpha-PVP	3.972	4137714	456.3	488.6	8517208	10.000
Alprazolam	4.794	1807975	617.9	374.4	6738931	10.000
Amitriptyline	4.905	1915107	∞	1593.2	8307594	10.000
Amphetamine	3.025	3120358	1287.8	4560.2	8517208	10.000
Benzoylecgonine	3.474	133346	189.3	45.8	231070	10.000
Brompheniramine	4.394	126752	387.4	31.3	51622505	10.000
Buprenorphine	5.560	38641	21244.8	466.0	1081625	10.000
Bupropion	4.325	3526517	385.2	488.5	13653344	10.000
Carbamazepine	4.371	6231941	1496.6	∞	67123	10.000
Carisoprodol	4.308	1189710	105640.8	306.5	4456055	10.000
Chlordiazepoxide	4.980	626904	79923.4	1273.7	10689531	10.000
Chlorpheniramine	4.275	6521924	2517959.7	∞	5855145	10.000
Chlorpromazine	5.282	2511506	435394.0	1661.8	9832369	10.000
Citalopram	4.392	2806912	132.5	655008.6	5855145	10.000
Clomipramine	5.220	3246660	504135.4	2678.9	5855145	10.000
Clonazepam	4.655	779383	320.7	58574.1	10689531	10.000
Clonazolam	4.544	979503	444889.6	135034.0	10689531	10.000
clozapine	5.035	5645611	1460652.6	1055455. 7	18024106	10.000
Cocaethylene	4.132	3923204	17386.3	42753.5	25325534	10.000
Cocaine	3.964	5132506	701.4	221.7	25325534	10.000
Codeine	3.320	402126	1130.8	390.7	6744043	10.000
Cyclobenzaprine	4.783	3658878	2594.8	107.2	8307594	10.000
Desipramine	4.692	6315645	1194972.4	959.1	8307594	10.000

# AM #25 Multi-Drug Screen Results

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextromethorphan	4.368	2196672	1165.5	63218.8	10893186	10.000
Dextrorphan	3.554	2474730	3431.3	3724.2	10893186	10.000
Diazepam	5.072	1079950	692.9	912.7	10689531	10.000
Dihydrocodeine	2.983	1044058	923.3	332.7	51622505	10.000
Dimethyltryptamine	3.130	2157966	3072.0	215.6	22836828	10.000
Diphenhydramine	4.354	9106361	10582.8	231.2	51622505	10.000
Doxepin	4.598	2355724	3361.2	50.0	20466854	10.000
Doxylamine	3.860	9162774	14541.0	253.0	2976820	10.000
Duloxetine	4.628	82218	22126.8	440.8	5583250	10.000
EDDP	4.290	250306	255.7	36453.0	504313	10.000
Estazolam	4.704	3793408	3701.6	3785.7	10689531	10.000
Etizolam	4.774	194169	306650.6	237883.8	10689531	10.000
Fentanyl	4.806	355595	166.4	87680.0	18085038	10.000
Flualprazolam	4.623	847729	213543.5	79984.9	10689531	10.000
Flunitrazepam	4.763	1440174	547.1	850.4	10689531	10.000
Fluorofentanyl	4.865	380823	82675.1	623.8	18085038	10.000
Fluoxetine	4.595	3320308	411.0	83140.1	5583250	10.000
Flurazepam	4.834	3226711	892829.0	302373.8	10689531	10.000
Hydrocodone	3.550	1289835	406.2	804.1	6744043	10.000
Hydromorphone	2.819	903620	289.8	127.4	6744043	10.000
hydroxyzine	5.170	4957906	2281.5	1094.2	10893186	10.000
Imipramine	4.828	6576862	26710.3	∞	8307594	10.000
Ketamine	4.325	2665483	704.1	75.6	10893186	10.000
Lamotrigine	3.770	235067	149.1	27022.6	5855145	10.000
Levamisole	3.497	2244309	556.7	173.0	10893186	10.000
Levetiracetam	2.628	897413	1035.4	565.9	5855145	10.000
Lorazepam	4.609	228887	227.3	∞	10689531	10.000
Maprotiline	4.706	793788	889.5	30.3	8307594	10.000
MDA	3.145	2699585	640.6	212.7	22836828	10.000
MDEA	3.389	4101203	6145.5	1891.8	22836828	10.000
MDMA	3.236	4495926	710.6	588.7	22836828	10.000
Meperidine	3.955	2375628	231.2	444.8	10893186	10.000
Meprobamate	3.742	549604	821.8	67.5	4456055	10.000
Methadone	4.672	6017086	534.7	628.9	504313	10.000
Methamphetamine	3.131	8490094	∞	∞	22836828	10.000
Methocarbamol	3.694	356205	399.9	102.7	51622505	10.000
Methylphenidate	3.772	9950115	26713.1	4095.3	10893186	10.000
Metoprolol	3.584	759145	9519.0	7871.7	10893186	10.000
Midazolam	4.944	719536	164830.2	1970.3	10689531	10.000
Mirtazapine	4.800	3075248	3243.3	1034.8	10893186	10.000
Mitragynine	4.863	467016	238529.1	260955.0	10893186	10.000
Morphine	2.623	281951	897.5	1632.8	179267	10.000
Norpurprenorphine	4.035	51513	12238.0	15743.0	1081625	10.000
Nordiazepam	4.921	820903	226667.8	209705.5	10689531	10.000
Norfentanyl	3.464	4482511	692.3	308.9	20236916	10.000
Norhydrocodone	3.061	123120	80.6	57.9	6744043	10.000
norketamine	4.279	529947	870.8	8973.1	10893186	10.000
Normeperidine	3.772	2256702	619.4	842.4	5855145	10.000
Noroxycodone	3.014	1346061	159.2	283.5	8642554	10.000
Nortriptyline	4.739	2190896	775382.6	476.1	8307594	10.000
O-desmethyl-tramadol	3.020	6961236	12572.0	291.9	5855145	10.000
O-Desmethylvenlafaxine	3.385	1698083	684.2	220.8	5855145	10.000
Olanzapine	4.410	1442370	330647.0	398.8	67123	10.000
Oxazepam	4.720	1242646	572.8	205.0	6738931	10.000
Oxycodone	3.256	2057213	33.3	957.3	8642554	10.000
Oxymorphone	2.529	1317753	253.2	3502.7	179267	10.000
Paroxetine	4.653	585647	203.4	58221.2	5583250	10.000
Phenazepam	4.835	1299936	453.0	1447323. 9	10689531	10.000
Phencyclidine	4.140	4833280	459.3	819.2	10893186	10.000

# AM #25 Multi-Drug Screen Results

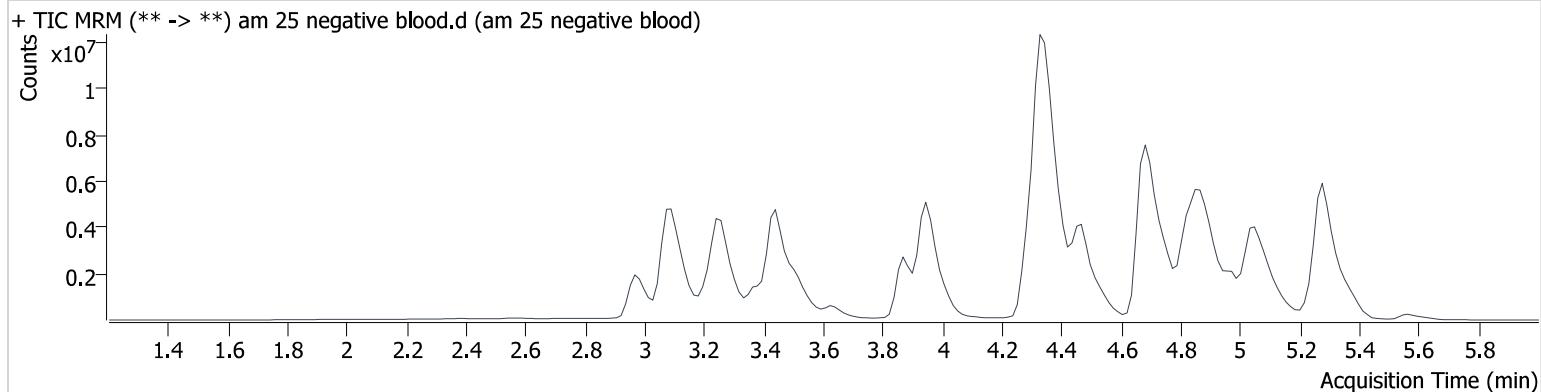
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Phentermine	3.284	1412727	∞	∞	14791919	10.000
Phenytoin	4.262	120005	510.8	16.4	67123	10.000
primidone	3.542	457162	315.1	98.4	8307594	10.000
Promethazine	4.966	8674711	424.5	1169.9	5855145	10.000
Pseudoephedrine	2.795	60422828	12310.6	31263.4	22836828	10.000
Quetiapine	5.094	5697679	1375408.2	992026.6	35027504	10.000
Risperidone	4.741	5627159	1052.7	208.1	649673	10.000
Sertraline	4.994	1198285	∞	∞	5583250	10.000
Sufentanil	5.230	377926	1458.5	426.3	20236916	10.000
Tapentadol	3.619	4777297	2582.6	2077.0	6744043	10.000
Temazepam	4.872	2698633	807.6	79.5	10689531	10.000
Topiramate	3.944	40402	16723.2	9957.8	155290	10.000
Tramadol	3.615	7336823	388.0	29.7	5855145	10.000
Trazodone	5.293	4582745	894.0	1961.2	20466854	10.000
Venlafaxine	4.028	6408062	835.9	280.3	5583250	10.000
Zaleplon	4.519	1408895	273818.9	393.8	35027504	10.000
Zolpidem	4.688	7799874	16115.8	806.4	35027504	10.000
Zopiclone	4.772	661177	417187.5	230859.9	2976820	10.000

# AM #25 Multi-Drug Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\mds.batch.bin  
**Calibration Last Update** 11/21/2022 1:06:42 PM

<b>Instrument</b>	69679	<b>Data File</b>	am 25 negative blood.d
<b>Type</b>	Sample	<b>Sample</b>	am 25 negative blood
<b>Acq. Method</b>	mds713.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P2-B8	<b>Comment</b>	
<b>Injection Volume</b>	2.5		
<b>Acq. Date-Time</b>	11/17/2022 11:46:37 AM		
<b>Sample Info.</b>			

## Sample Chromatogram

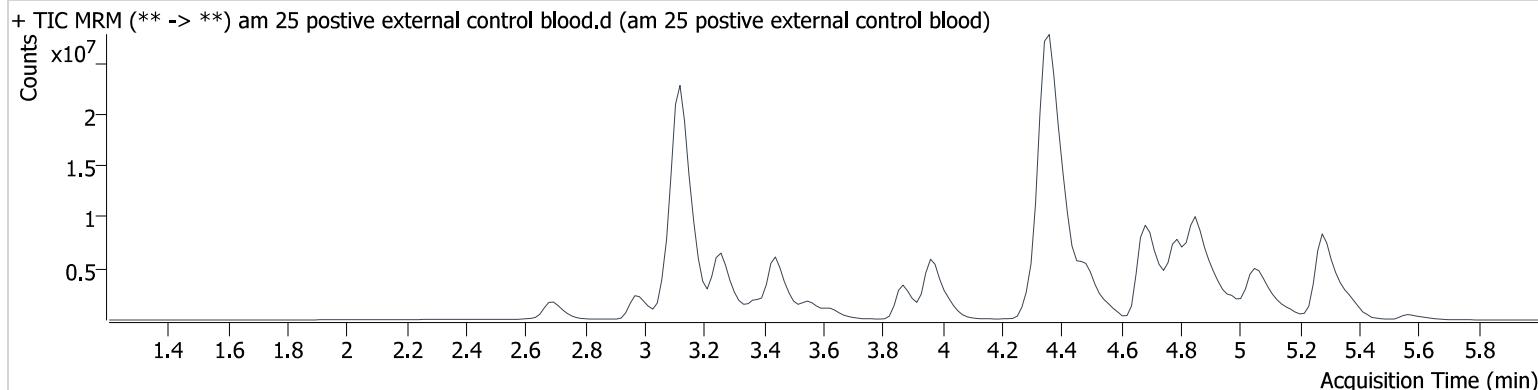


# AM #25 Multi-Drug Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\mds.batch.bin  
**Calibration Last Update** 11/21/2022 1:06:42 PM

<b>Instrument</b>	69679	<b>Data File</b>	am 25 postive external control blood.d
<b>Type</b>	Sample	<b>Sample</b>	am 25 postive external control blood
<b>Acq. Method</b>	mds713.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P2-D8	<b>Comment</b>	
<b>Injection Volume</b>	2.5		
<b>Acq. Date-Time</b>	11/17/2022 12:00:19 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



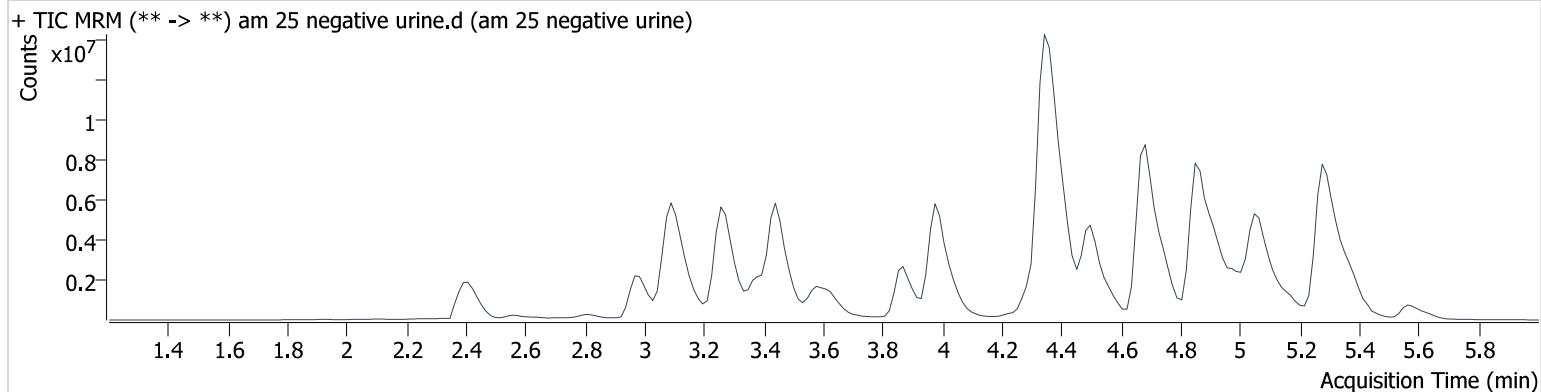
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.794	14706246	1365.4	2000.2	10848082	50.530
Diphenhydramine	4.369	60813858	18487.3	30653.8	52891932	65.179
Methamphetamine	3.131	43333658	$\infty$	$\infty$	23953930	48.660
Morphine	2.698	2362891	1296.1	4437.1	227330	66.087

# AM #25 Multi-Drug Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\mds.batch.bin  
**Calibration Last Update** 11/21/2022 1:06:42 PM

<b>Instrument</b>	69679	<b>Data File</b>	am 25 negative urine.d
<b>Type</b>	Sample	<b>Sample</b>	am 25 negative urine
<b>Acq. Method</b>	mds713.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P2-F10	<b>Comment</b>	
<b>Injection Volume</b>	2.5		
<b>Acq. Date-Time</b>	11/17/2022 1:29:16 PM		
<b>Sample Info.</b>			

## Sample Chromatogram

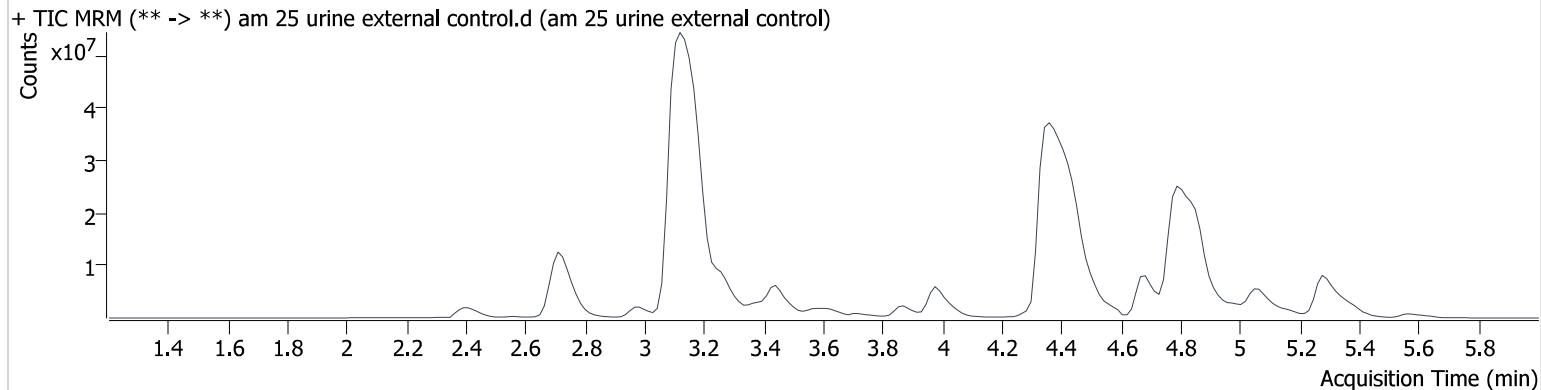


# AM #25 Multi-Drug Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\mds.batch.bin  
**Calibration Last Update** 11/21/2022 1:06:42 PM

<b>Instrument</b>	69679	<b>Data File</b>	am 25 urine external control.d
<b>Type</b>	Sample	<b>Sample</b>	am 25 urine external control
<b>Acq. Method</b>	mds713.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P2-E10	<b>Comment</b>	
<b>Injection Volume</b>	2.5		
<b>Acq. Date-Time</b>	11/17/2022 1:36:06 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.794	78312317	113233.8	31209.6	2993160	975.212
Diphenhydramine	4.385	143700826	26198.9	20569.9	38718518	210.395
Methamphetamine	3.131	124700191	$\infty$	$\infty$	18307040	183.220
Morphine	2.713	18735034	40157.9	68475.0	230149	517.574

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

Extraction Date: 11/17/22 Analyst: Anne Nord

Plate lot#: 220802

Plate retest date: 2/02/23

**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:** 22B52016-1 **Urine Blank:** 7722

**Column:** Agilent Phenyl Hexyl (4.6x50mm: 2.7 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: I41142J**  
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 QC's pass for each analyte? Yes
- 5. Central File Packet to include: LIMS Worklist, Method Checklist, Calibration and Control Reports

COMMENTS:

  
**Idaho State Police  
Forensic Services**

**Request for Departure from an Analytical Method or Quality Standard**

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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

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**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 ToxBox 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 for 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**

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Departure approved

Comments:

Departure Not Approved

Comments:



Approver: Rachel Cutler

Date: 3/2/22

Title: Lab Manager

### **Quality Review**

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Quality Approver: Jason Crowe



Title: Quality Manager

Date: 3/2/2022

	1	2	3	4	5	6
a	cal 1	Internal control urine	2512-2	2516-1		
b	cal 2	negative blood	2515-1			
c	cal 3	2487-1	2517-1			
d	cal 4	2489-1	2526-2			
e	Cal 5	2490-1	2528-1			
f	cal 6	2492-1	2556-1			
g	cal 7	2493-1	negative urine			
h	Internal control (blood)	2469-2	2514-1			

Plate position 3

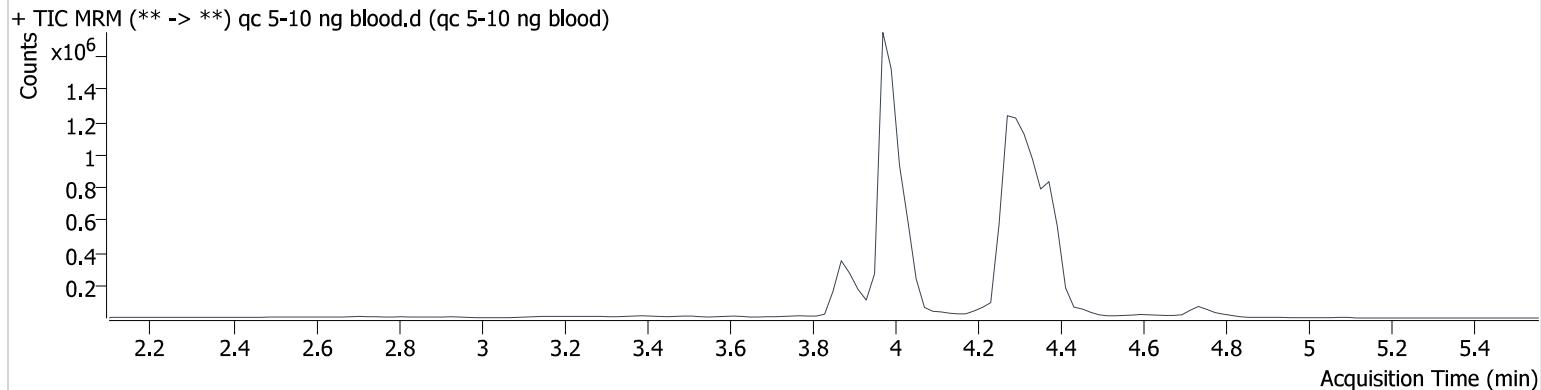
c2022-\_\_\_\_\_-

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	qc 5-10 ng blood.d
<b>Type</b>	QC	<b>Sample</b>	qc 5-10 ng blood
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-H1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 3:10:22 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



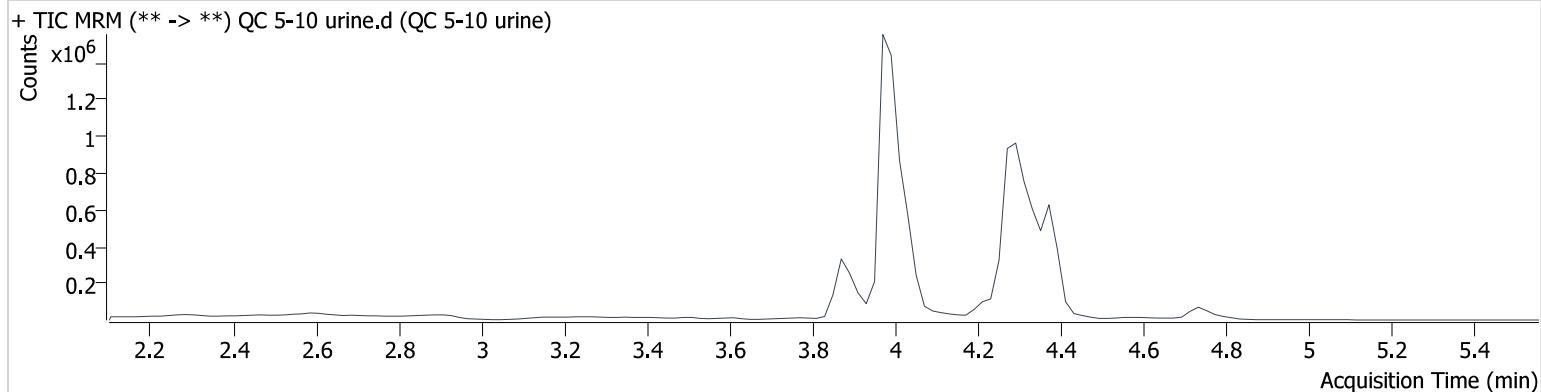
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	50371	1170443	4.955 ng/ml
THC-COOH	3.892	157950	858609	14.166 ng/ml
THC-OH	3.979	50680	5926756	4.670 ng/ml

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	QC 5-10 urine.d
<b>Type</b>	Sample	<b>Sample</b>	QC 5-10 urine
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-A2	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 3:16:58 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



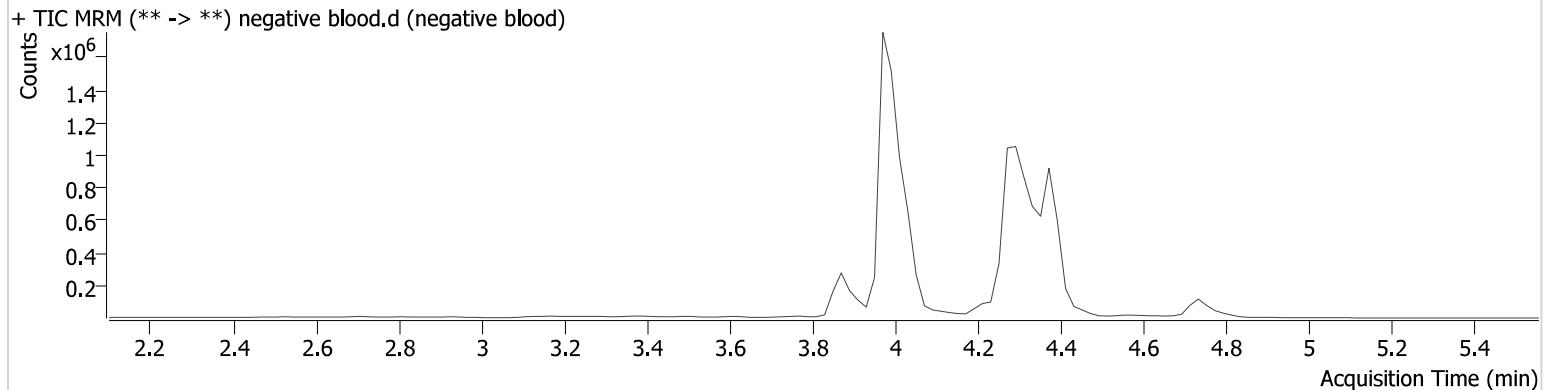
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	47561	1129104	4.855 ng/ml
THC-COOH	3.892	149715	790112	14.588 ng/ml
THC-OH	3.979	47327	5543416	4.663 ng/ml

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	negative blood.d
<b>Type</b>	Sample	<b>Sample</b>	negative blood
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-B2	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 3:23:37 PM		
<b>Sample Info.</b>			

## Sample Chromatogram

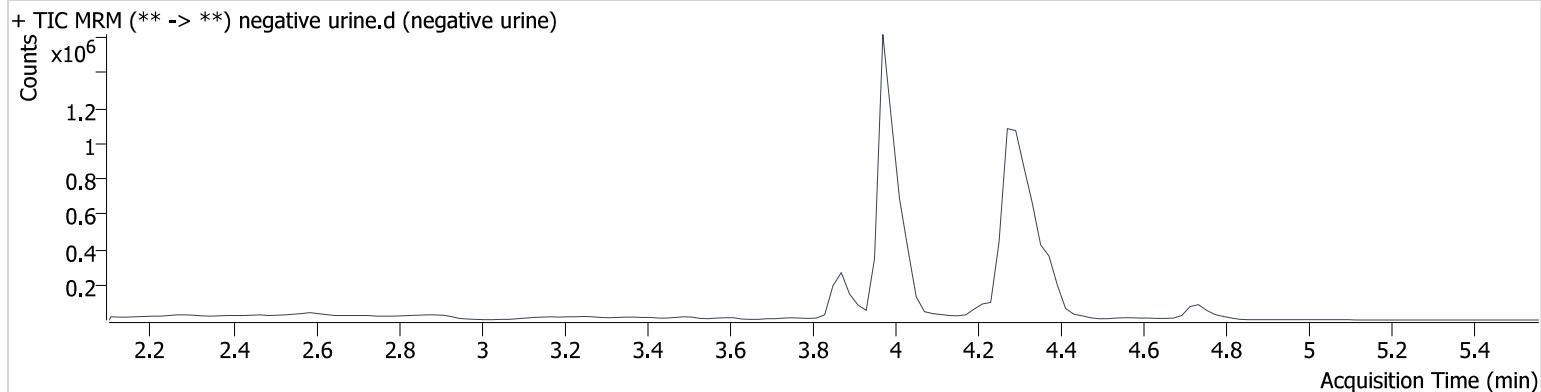


# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	negative urine.d
<b>Type</b>	Sample	<b>Sample</b>	negative urine
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-G3	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 4:49:46 PM		
<b>Sample Info.</b>			

## Sample Chromatogram





## Compound Calibration Report

 Agilent | Trusted Answers**Batch results**

D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin

**Last Cal. Update**

11/18/2022 8:40 AM

**Analyst Name**

ISP\datastor

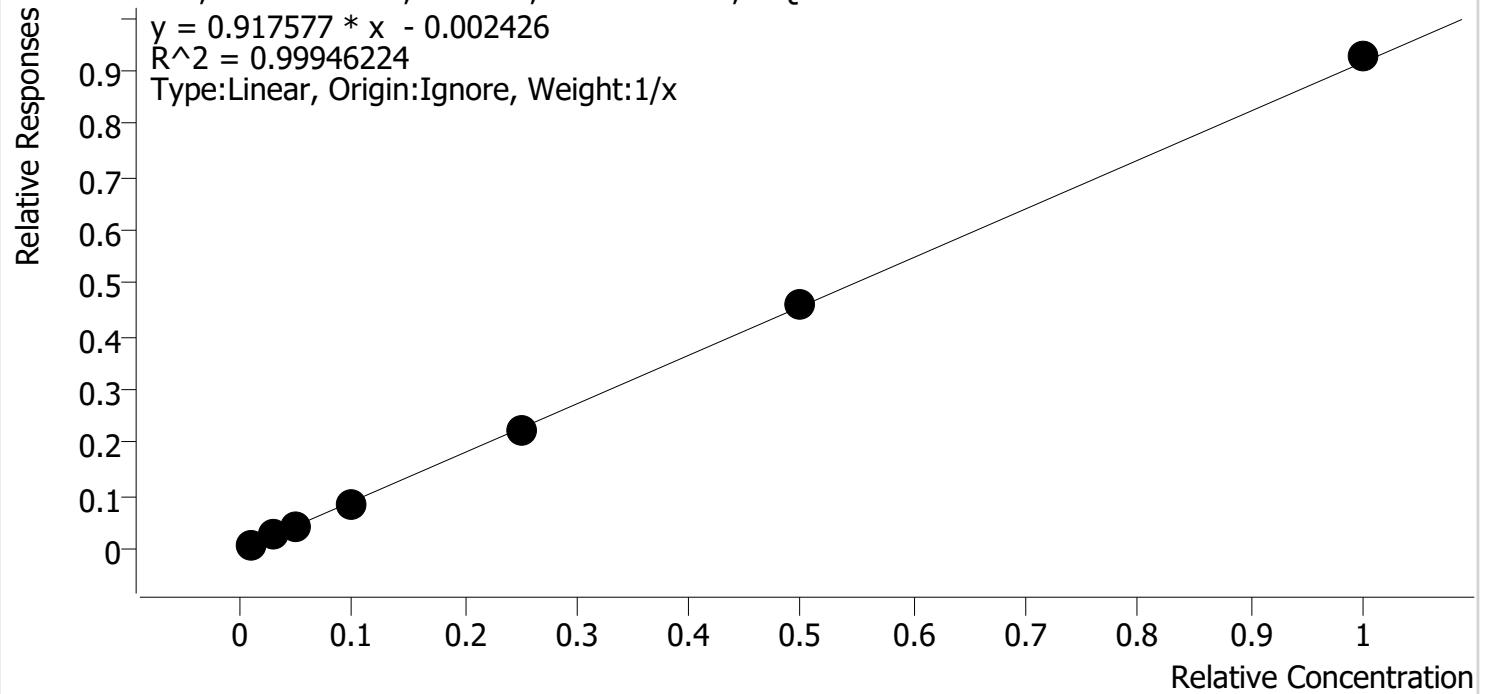
**Analyte**

THC

**Internal Standard**

THC-d3

THC - 7 Levels, 7 Levels Used, 7 Points, 7 Points Used, 0 QC's



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	1.0	1.1	113.7
cal 2	2	✓	3.0	2.9	98.1
cal 3	3	✓	5.0	4.7	93.8
cal 4	4	✓	10.0	9.5	95.4
cal 5	5	✓	25.0	24.4	97.6
cal-6	6	✓	50.0	50.1	100.2
cal-7	7	✓	100.0	101.2	101.2

# Compound Calibration Report

Batch results

D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin

Last Cal. Update

11/18/2022 8:40 AM

Analyst Name

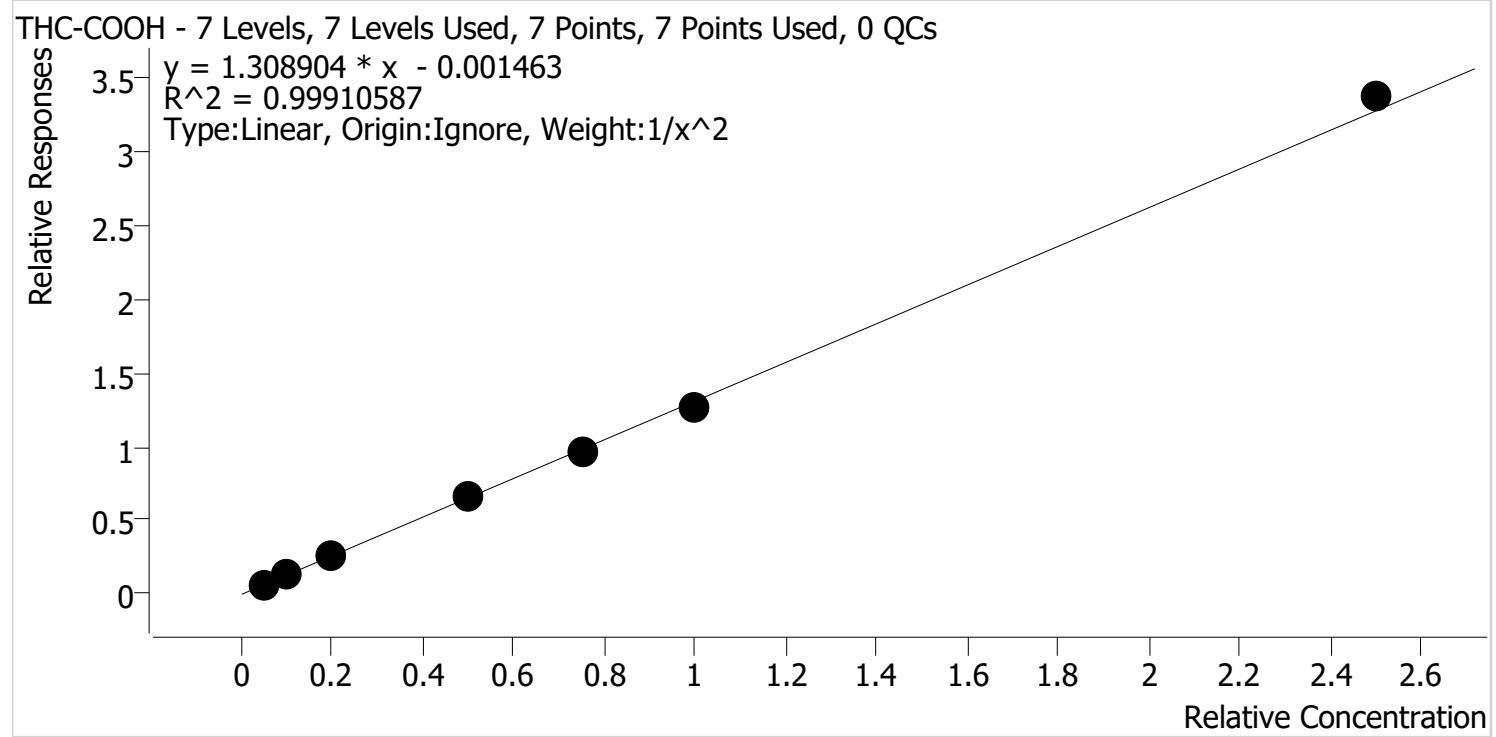
ISP\datastor

Analyte

THC-COOH

Internal Standard

THC-COOH-d9



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	5.0	5.1	101.2
cal 2	2	✓	10.0	9.7	97.2
cal 3	3	✓	20.0	20.1	100.6
cal 4	4	✓	50.0	51.3	102.7
cal 5	5	✓	75.0	73.3	97.8
cal-6	6	✓	100.0	97.6	97.6
cal-7	7	✓	250.0	257.3	102.9



## Compound Calibration Report

**Batch results**

D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin

**Last Cal. Update**

11/18/2022 8:40 AM

**Analyst Name**

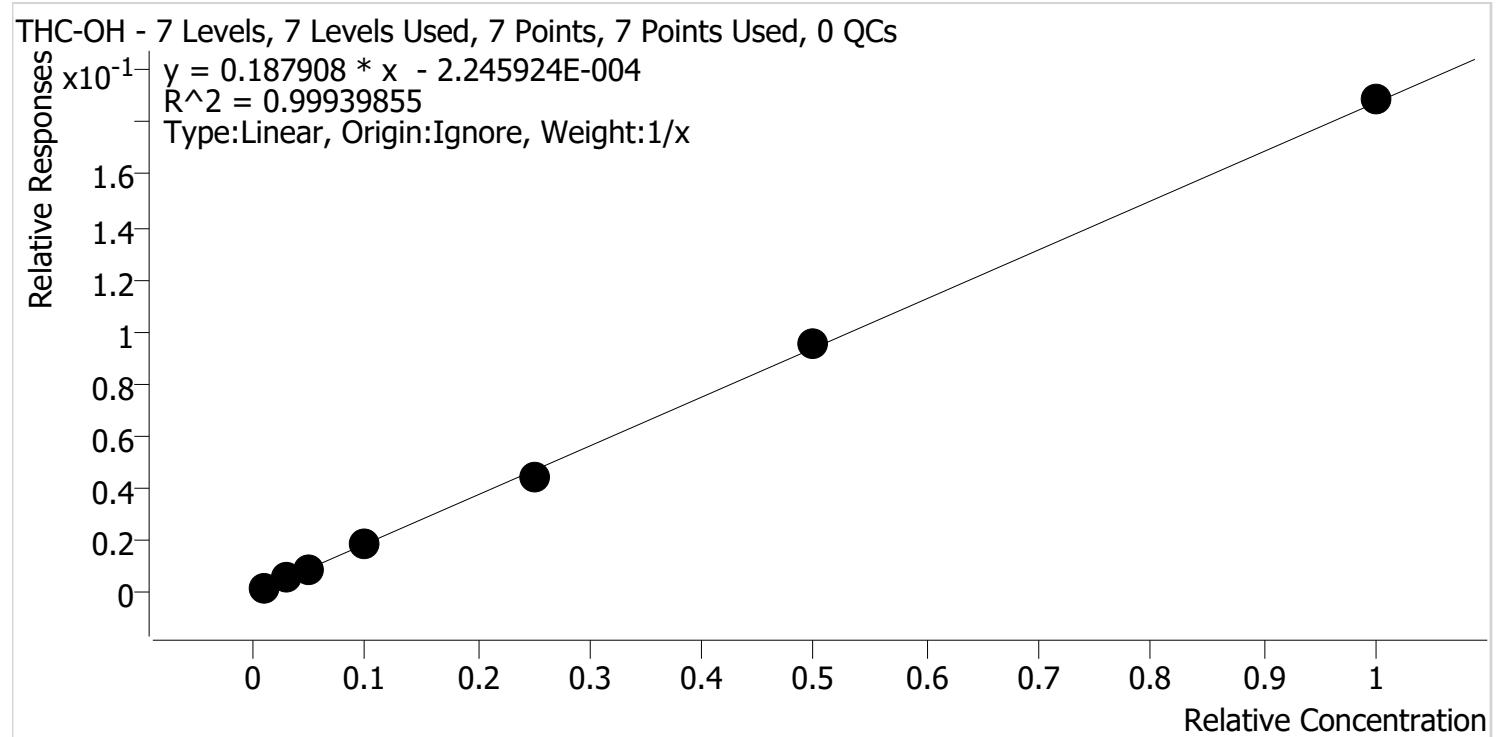
ISP\datastor

**Analyte**

THC-OH

**Internal Standard**

THC-OH-d3



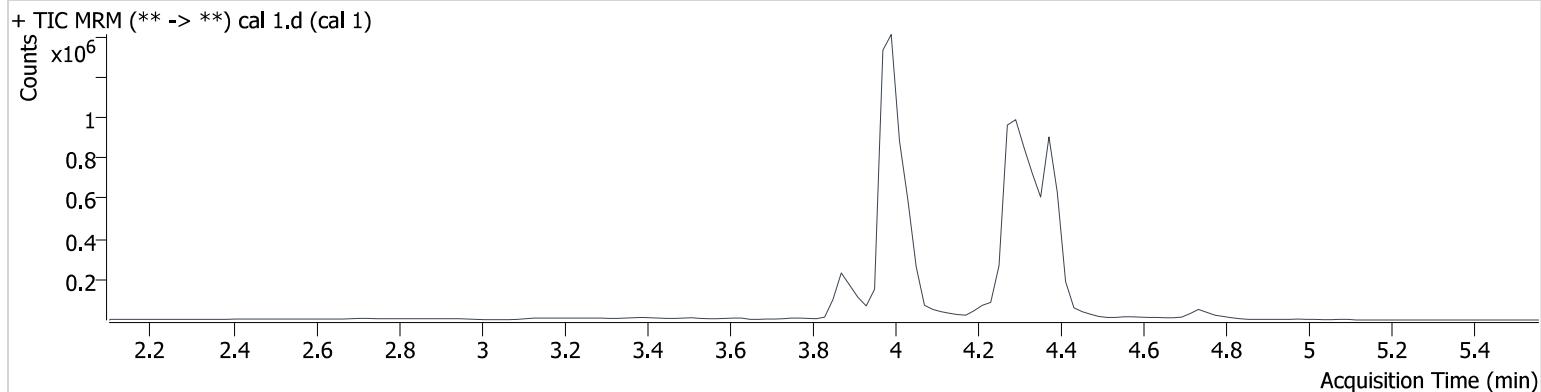
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	1.0	1.1	111.9
cal 2	2	✓	3.0	2.9	96.8
cal 3	3	✓	5.0	4.8	95.4
cal 4	4	✓	10.0	9.8	97.8
cal 5	5	✓	25.0	23.9	95.7
cal-6	6	✓	50.0	50.9	101.8
cal-7	7	✓	100.0	100.6	100.6

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	cal 1.d
<b>Type</b>	Cal	<b>Sample</b>	cal 1
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-A1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 2:24:00 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



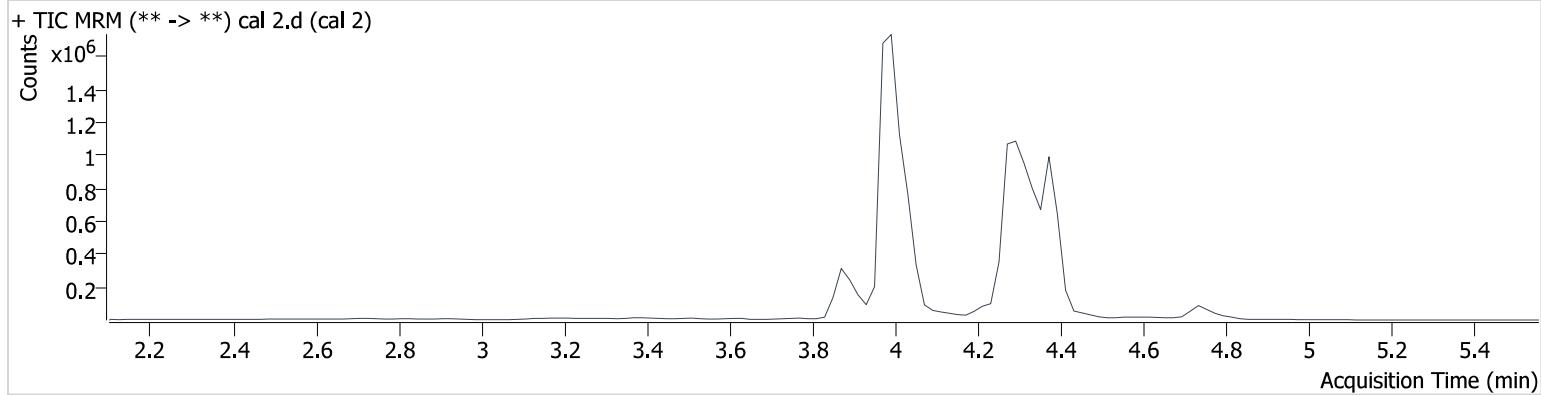
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	14264	1782021	1.137 ng/ml <b>Low</b>
THC-COOH	3.892	44745	690889	5.060 ng/ml <b>Low</b>
THC-OH	3.979	10489	5586395	1.119 ng/ml <b>Low</b>

# AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
Calibration Last Update 11/18/2022 8:40:33 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	11/17/2022 2:30:38 PM		
Sample Info.			

## Sample Chromatogram



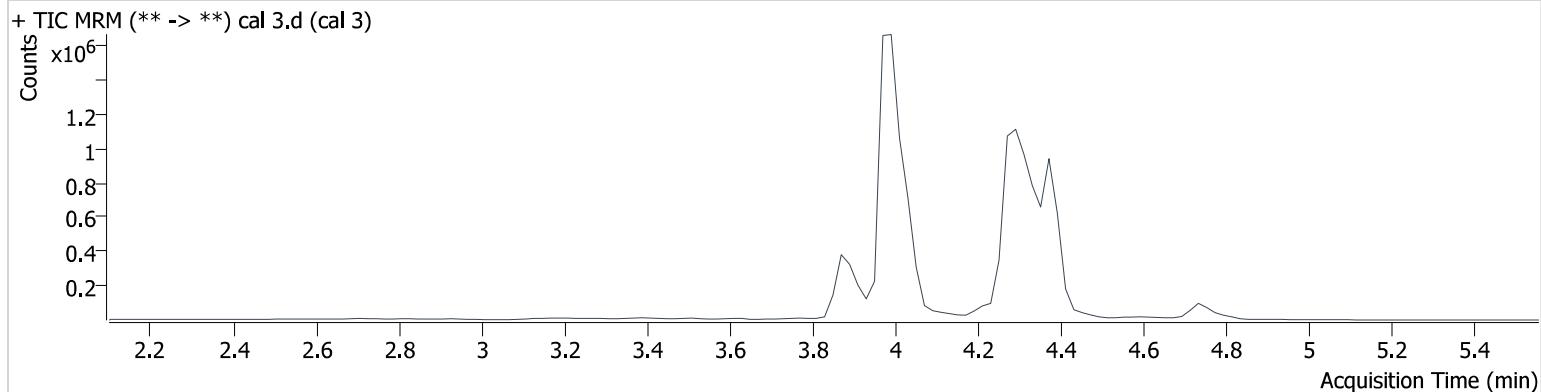
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	43580	1772483	2.944 ng/ml <b>Low</b>
THC-COOH	3.892	108389	862012	9.718 ng/ml <b>Low</b>
THC-OH	3.999	35695	6820356	2.905 ng/ml <b>Low</b>

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	cal 3.d
<b>Type</b>	Cal	<b>Sample</b>	cal 3
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-C1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 2:37:16 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



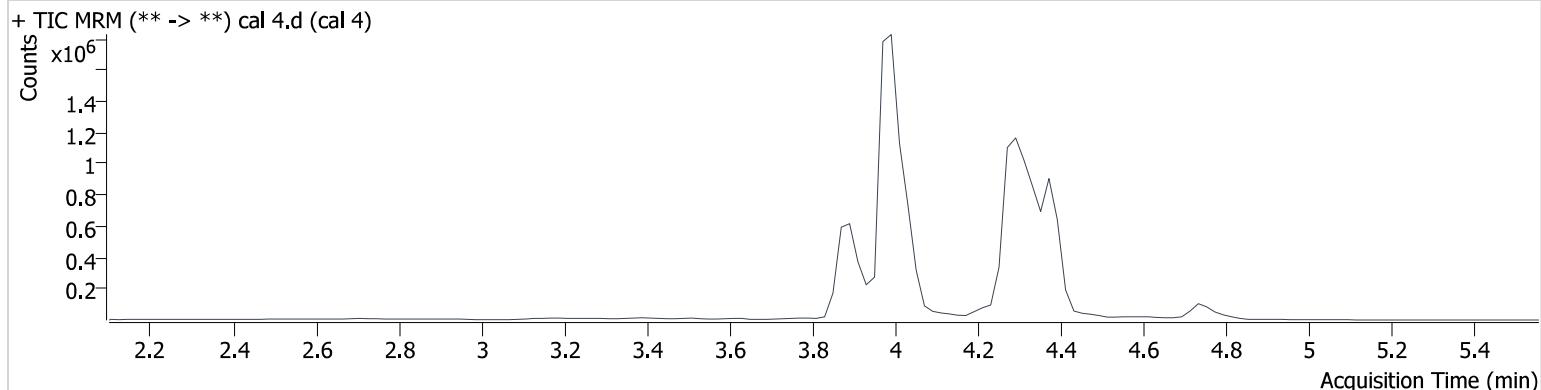
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	69872	1720850	4.689 ng/ml
THC-COOH	3.892	226596	865085	20.124 ng/ml
THC-OH	3.999	55335	6330044	4.772 ng/ml

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	cal 4.d
<b>Type</b>	Cal	<b>Sample</b>	cal 4
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-D1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 2:43:55 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



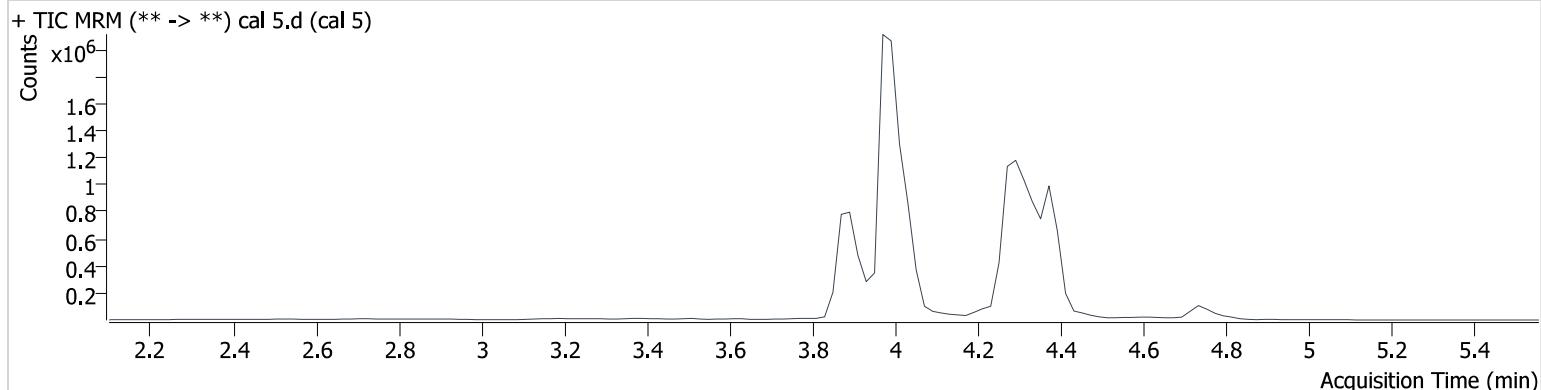
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	125766	1477502	9.541 ng/ml
THC-COOH	3.892	609486	909048	51.335 ng/ml
THC-OH	3.999	113081	6232455	9.775 ng/ml

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	cal 5.d
<b>Type</b>	Cal	<b>Sample</b>	cal 5
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-E1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 2:50:33 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



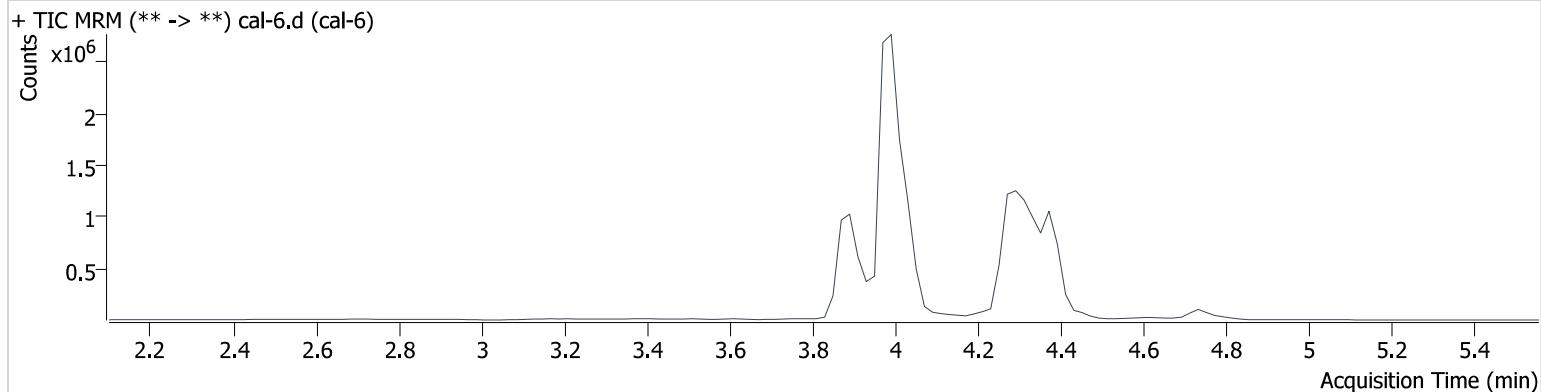
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	314957	1422562	24.393 ng/ml
THC-COOH	3.892	852359	889210	73.345 ng/ml
THC-OH	3.979	264631	5916414	23.923 ng/ml

# AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
Calibration Last Update 11/18/2022 8:40:33 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	11/17/2022 2:57:09 PM		
Sample Info.			

## Sample Chromatogram



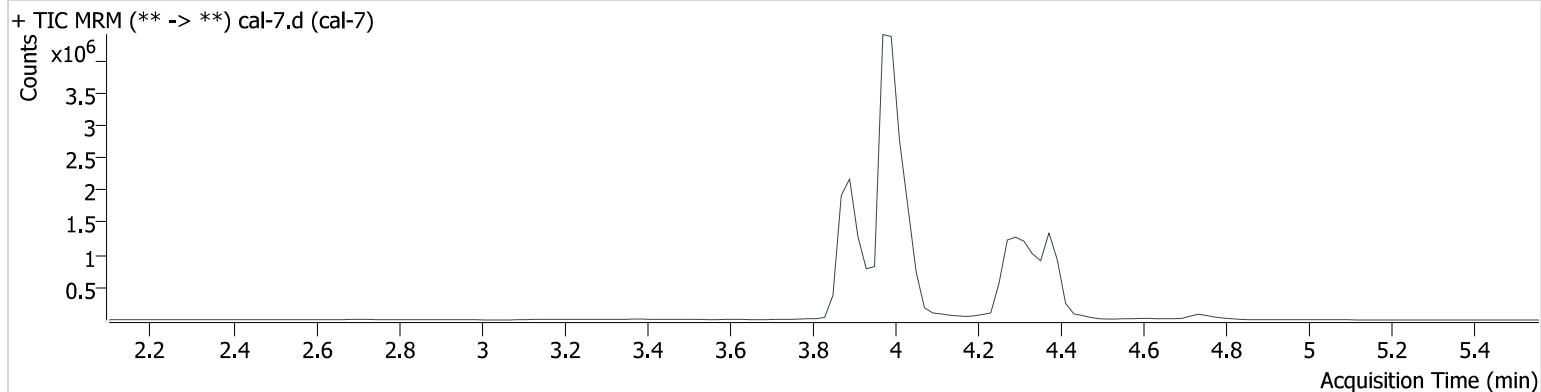
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	546134	1193810	50.121 ng/ml
THC-COOH	3.892	1164004	912150	97.606 ng/ml
THC-OH	3.999	567038	5939905	50.922 ng/ml

# AM #26 Cannabinoids Screen Results

**Batch results** D:\MassHunter\Data\2022\am 25-26\111722\QuantResults\cann.batch.bin  
**Calibration Last Update** 11/18/2022 8:40:33 AM

<b>Instrument</b>	69679	<b>Data File</b>	cal-7.d
<b>Type</b>	Cal	<b>Sample</b>	cal-7
<b>Acq. Method</b>	am 26 cann scr 5-5-20.m	<b>Operator</b>	Anne Nord
<b>Sample Position</b>	P3-G1	<b>Comment</b>	
<b>Injection Volume</b>	5		
<b>Acq. Date-Time</b>	11/17/2022 3:03:45 PM		
<b>Sample Info.</b>			

## Sample Chromatogram



Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	1078452	1164726	101.174 ng/ml
THC-COOH	3.892	2774485	824073	257.334 ng/ml
THC-OH	3.979	1191722	6312697	100.585 ng/ml