REVIEWED
By Sarah Collins at 11:55 am, Aug 08, 2022

8/8/2022

REVIEWED
By Britany Wylie at 1:39 pm, Aug 10, 2022

Worklist: 6052

LAB_CASE	ITEM	ITEM_TYPE	DESCRIPTION
C2022-1528	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1535	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1538	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1561	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1564	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1565	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1566	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1568	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1569	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1584	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1596	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1598	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1598	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1611	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1612	2	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1621	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1625	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1632	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1634	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1635	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1636	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ

added to list 8/8/22

added to worklist 8/8/22

Worklist: 6052

LAB_CASE	ITEM	ITEM_TYPE	DESCRIPTION
C2022-1660	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1661	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1667	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1679	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1680	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1700	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1707	2	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: 08/03/22 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 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: *Primidone not evaluated – not seen in calibrator, likely outside acquisition window.*
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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

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 Date: 2/10/2022
Title: Laboratory Manager

Quality Review

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

Toxicology AM method 25/28 urine external control prep

working solution 10000 ng/ml in meoh diphendydramine, 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
Diphendydramine	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

	1	2	3	4	5	6	7	8	9	10	11	12
A	cal 1	1569-1	1679-1	1621-1								1612-2
B		1584-2	1680-1	1625-1								1700-1
C	negative blood	1596-1	1707-2	1660-1								
D	1528-1	1611-1	1561-1	1661-1								
E	1535-1	1632-1	1566-1	1667-1								urine control
F	1538-1	1634-1	1568-1									negative urine
G	1564-1	1635-1	1598-1									
H	1565-1	1636-1	1598-2									

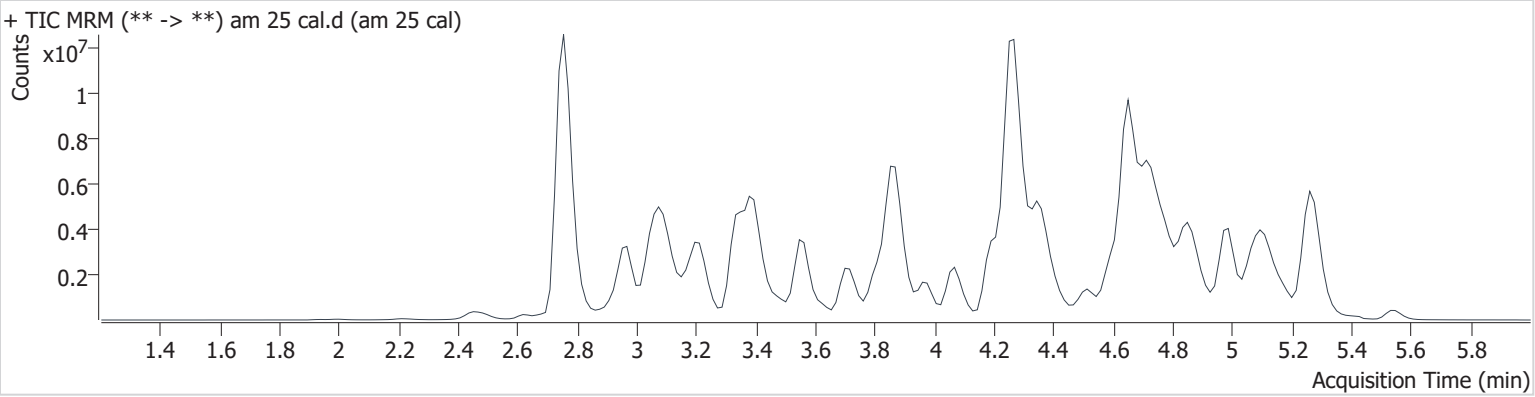
C2022-____-_

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\mds.batch.bin
Calibration Last Update 8/5/2022 4:22:33 PM

Instrument	69679	**Data File**	am 25 cal.d
Type	Cal	**Sample**	am 25 cal
Acq. Method	mds713.m	**Operator**	Anne Nord
Sample Position	P2-A1	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	8/3/2022 3:54:16 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.878	361277	918.2	104.6	664540	10.000
6-MAM	3.210	24540	10067.3	51.6	737875	10.000
7-aminoclonazepam	3.644	239664	433.5	454.8	918021	10.000
7-aminoflunitrazepam	3.858	364965	2084.1	78782.4	918021	10.000
9-Hydroxyrisperidone	4.388	3149534	800.1	37301.0	918021	10.000
Acetyl Fentanyl	4.500	232307	110.1	1991.7	8938297	10.000
Acetyl Norfentanyl	2.931	175142	5666.7	336.4	8938297	10.000
a-hydroxyalprazolam	4.700	52848	30704.2	262754.5	918021	10.000
alpha-hydroxymidazolam	4.759	878586	283.7	834.0	918021	10.000
alpha-PHP	4.201	1550496	598.5	1620.7	3244474	10.000
alpha-PVP	3.880	2477699	∞	327.6	3244474	10.000
Alprazolam	4.778	682412	266.8	242.1	3339397	10.000
Amitriptyline	4.813	865237	886.9	81.2	4002929	10.000
Amphetamine	2.980	1408242	659.0	2830.8	3244474	10.000
Benzoylecgonine	3.459	64465	214.1	24.8	99087	10.000
Brompheniramine	4.332	57303	10585.4	13042.8	31145804	10.000
Buprenorphine	5.545	48227	85439.2	585.3	1261606	10.000
Bupropion	4.248	2081255	598.2	605.1	7599472	10.000
Carbamazepine	4.371	3428682	1518.7	240.8	13098	10.000
Carisoprodol	4.308	338851	197709.9	63.6	1305203	10.000
Chlordiazepoxide	4.964	369612	212.2	80.1	3339397	10.000
Chlorpheniramine	4.213	3613157	∞	11772.9	3460933	10.000
Chlorpromazine	5.158	1410795	426963.7	578.8	4950013	10.000
Citalopram	4.331	1614763	1117.9	385.7	3460933	10.000
Clomimpramine	5.097	1663607	245.5	1910.8	3460933	10.000
Clonazepam	4.640	131518	37044.9	10235.2	3339397	10.000
Clonazolam	4.528	270814	96628.0	38920.5	3339397	10.000
clozapine	4.989	3126230	850902.5	710638.5	9657652	10.000
Cocaethylene	4.070	2561918	608236.9	672630.3	13663683	10.000
Cocaine	3.887	2943052	194.3	326.9	13663683	10.000
Codeine	3.182	226003	40978.2	3766.8	3012961	10.000
Cyclobenzaprine	4.691	1657276	3256.0	∞	4002929	10.000
Desipramine	4.615	2783328	645770.9	836.0	4002929	10.000
Dextromethorphan	4.306	1186543	146649.9	226401.5	5565232	10.000

AM #25 Multi-Drug Screen Results

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextrorphan	3.493	1314308	328732.5	121730.1	5565232	10.000
Diazepam	5.056	549655	910.5	1160.0	3339397	10.000
Dihydrocodeine	2.892	601692	1153.2	1093.3	447050	10.000
Diphenhydramine	4.277	5061311	292.8	306.3	31145804	10.000
Doxepin	4.521	1143014	107.7	169.8	16704157	10.000
Doxylamine	3.814	4906800	∞	∞	1019329	10.000
Duloxetine	4.566	29041	217.6	917.7	2041154	10.000
EDDP	4.228	201110	29387.3	24520.8	447050	10.000
Estazolam	4.689	1249954	12604.6	358027.1	3339397	10.000
Etizolam	4.759	88946	35198.1	180779.1	3339397	10.000
Fentanyl	4.729	176904	92.4	34886.9	8938297	10.000
Flualprazolam	4.607	279705	125821.9	123606.7	3339397	10.000
Flunitrazepam	4.747	520605	∞	83507.2	3339397	10.000
Fluoxetine	4.533	1132161	1105944.5	32086.6	2041154	10.000
Flurazepam	4.757	1761375	414.6	336.7	3339397	10.000
Hydrocodone	3.427	486309	118.4	29.6	3012961	10.000
Hydromorphone	2.683	511243	1028.5	146.2	3012961	10.000
hydroxyzine	5.108	2787109	2551.9	661256.6	5565232	10.000
Imipramine	4.736	3303035	772248.2	1259.5	4002929	10.000
Ketamine	4.263	1573413	505.2	34.3	447050	10.000
Lamotrigine	3.754	119561	542.4	61085.1	3460933	10.000
Levamisole	3.374	1648602	6900.5	473.4	5565232	10.000
Levetireacetam	2.629	256355	94.6	375.8	3460933	10.000
Lorazepam	4.609	22901	60.8	50.7	3339397	10.000
Maprotiline	4.629	324908	204.2	162.5	4002929	10.000
MDA	3.100	992143	907.6	148.5	12347152	10.000
MDEA	3.344	2205002	167.9	1686.7	12347152	10.000
MDMA	3.191	2534773	428.1	521.4	12347152	10.000
Meperidine	3.878	1269777	342.4	∞	5565232	10.000
Meprobamate	3.728	55860	193.5	50.8	1305203	10.000
Methadone	4.594	3087981	5043.8	2808.1	447050	10.000
Methamphetamine	3.101	4832808	∞	5515.9	12347152	10.000
Methocarbamol	3.694	52471	193.7	365.1	447050	10.000
Methylphenidate	3.710	5350616	22549.8	519.3	5565232	10.000
Metoprolol	3.539	425362	3284.3	25359.2	5565232	10.000
Midazolam	4.928	372502	78541.3	152199.4	3339397	10.000
Mirtazapine	4.738	1884199	1153.0	1395676.9	5565232	10.000
Mitragynine	4.771	292864	173.7	119432.4	5565232	10.000
Morphine	2.502	162971	∞	1683.4	104121	10.000
Norbuprenorphine	3.973	27056	10632.0	10206.9	1261606	10.000
Nordiazepam	4.906	296437	85956.8	61329.8	3339397	10.000
Norfentanyl	3.419	2530650	586.0	314.2	11529116	10.000
Norhydrocodone	3.016	52989	65.5	158.2	3012961	10.000
norketamine	4.249	224373	83.6	275511.5	447050	10.000
Normeperidine	3.726	1337206	319.5	480.6	3460933	10.000
Noroxycodone	2.953	527947	138.1	50.3	4124552	10.000
Nortriptyline	4.662	865168	2052.3	75.7	4002929	10.000
O-desmethyl-tramadol	2.975	4430077	17112.3	103.4	3460933	10.000
o-Desmethylvenlafaxine	3.340	1091978	129.6	2935.2	3460933	10.000
Olanzapine	4.333	452800	130217.4	58655.2	13098	10.000
Oxazepam	4.704	104147	65.1	24.7	664540	10.000
Oxycodone	3.165	978724	630.6	3044.7	4124552	10.000
Oxymorphone	2.452	498987	211.9	276.1	104121	10.000
Paroxetine	4.576	192469	63.5	540.2	2041154	10.000
Phenazepam	4.820	302612	102510.7	2308.0	3339397	10.000
Phencyclidine	4.078	2600615	11861.8	430.7	5565232	10.000
Phentermine	3.238	774206	∞	∞	7508345	10.000
Phenytoin	4.247	24534	18768.9	10.7	13098	10.000
Promethazine	4.858	4308121	859563.1	246.2	3460933	10.000

AM #25 Multi-Drug Screen Results

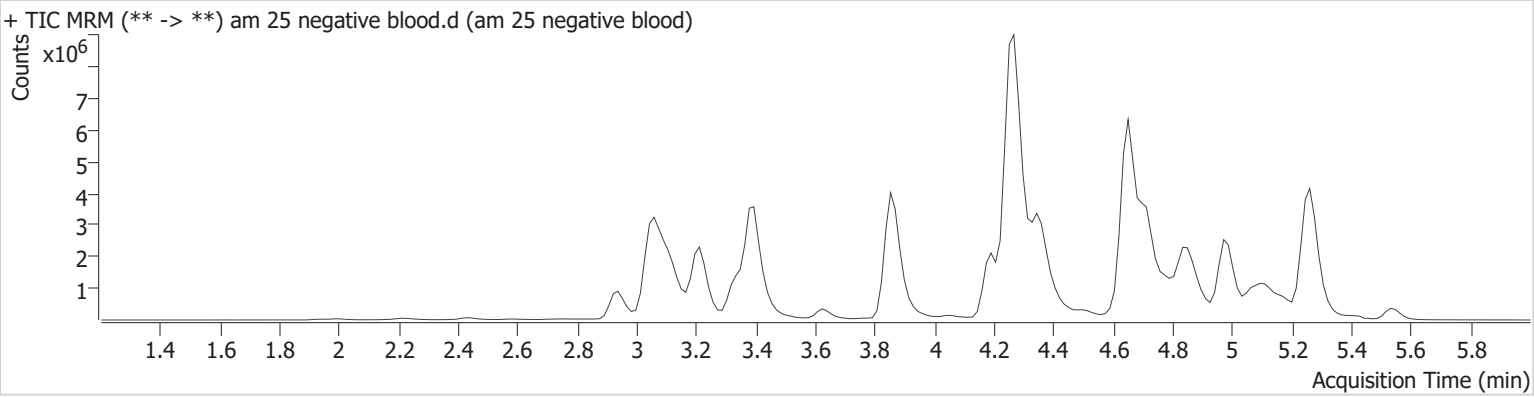
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Pseudoephedrine	2.765	41081949	13965.2	1656.5	12347152	10.000
Quetiapine	5.062	3422819	3432763.7	1467197.9	21651062	10.000
Risperidone	4.649	2939442	440413.6	68487.0	344702	10.000
Sertraline	4.901	447383	129070.8	304875.1	2041154	10.000
Sufentanil	5.183	180670	44290.0	37993.4	11529116	10.000
Tapentadol	3.573	2728970	2008.1	3369.9	447050	10.000
Temazepam	4.856	854041	224789.7	35.7	3339397	10.000
Topiramate	3.944	2994	30886.5	547.2	13210	10.000
Tramadol	3.554	4362464	734.6	59.9	3460933	10.000
Trazodone	5.277	4022625	15898.4	3958.9	16704157	10.000
Venlafaxine	3.982	3762820	1001.6	126.4	2041154	10.000
Zaleplon	4.504	369782	117811.7	217746.9	21651062	10.000
Zolpidem	4.672	4574264	1458089.3	1018.5	21651062	10.000
Zopiclone	4.726	222267	163611.6	57668.7	1019329	10.000

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\mds.batch.bin
Calibration Last Update 8/4/2022 1:39:07 PM

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-C1	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	8/3/2022 4:01:02 PM		
Sample Info.			

Sample Chromatogram

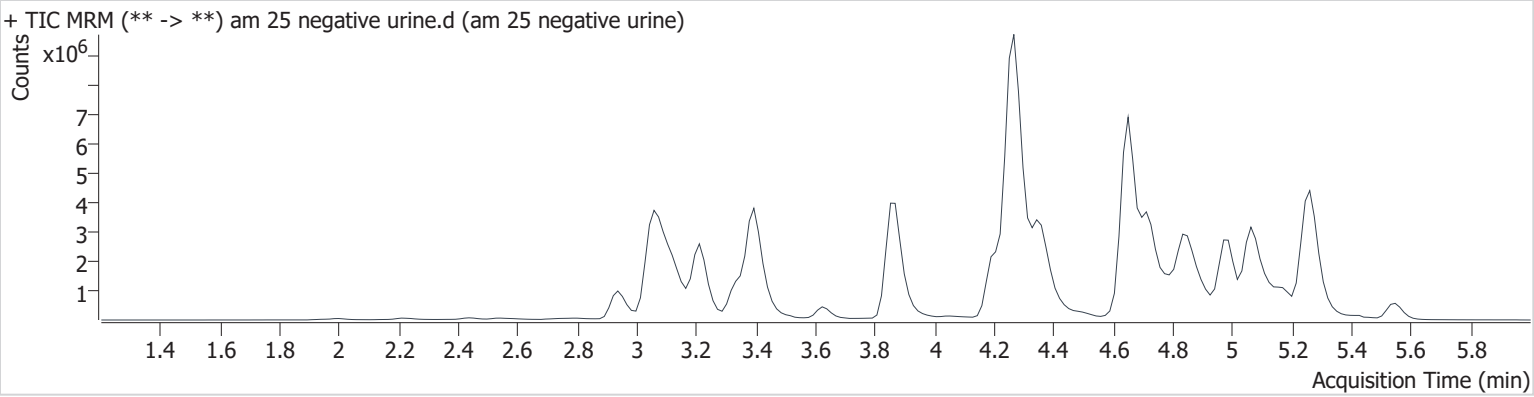


AM #25 Multi-Drug Screen Results

Batch results	D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\mds.batch.bin
Calibration Last Update	8/4/2022 1:39:07 PM

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-F12	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	8/3/2022 7:10:40 PM		
Sample Info.			

Sample Chromatogram

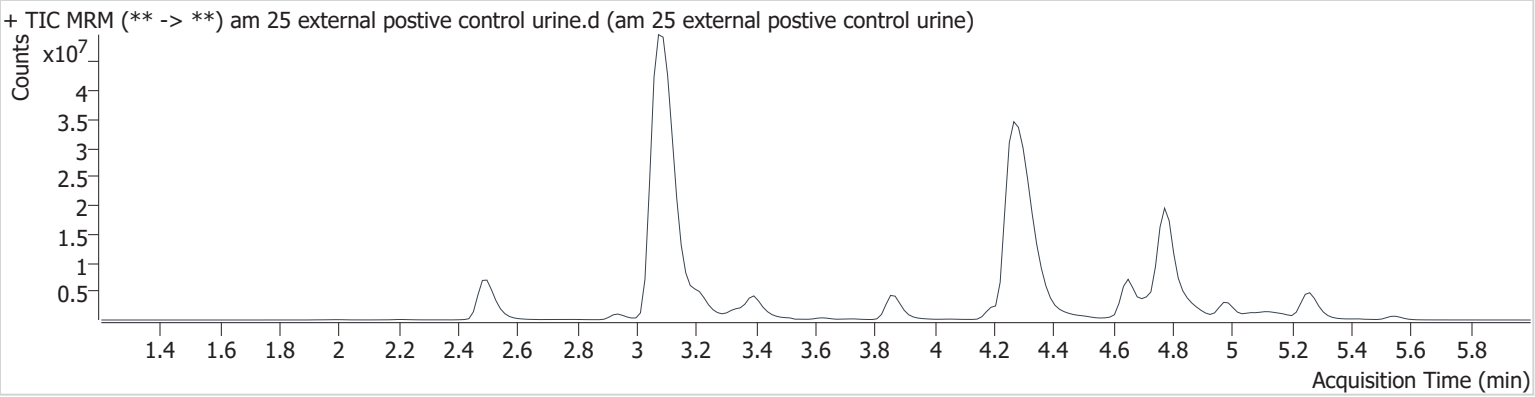


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\mds.batch.bin
Calibration Last Update 8/4/2022 1:39:07 PM

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-E12	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	8/3/2022 7:17:28 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.778	36399093	∞	3488.5	3999148	445.394
Diphenhydramine	4.293	106682603	49969.7	545.6	25664843	255.795
Methamphetamine	3.115	93201873	1655453118805 1200.0	∞	10935460	217.748
Morphine	2.487	8811217	428408.3	3873.4	96607	582.717

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

Extraction Date: 8/3/22 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: 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: 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 8**00 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: *pressure maxed out part way through, changed capillary line leading to column and continued on.*

Idaho State Police
Forensic Services

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 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

☒ Departure approved
Comments:

☐ Departure Not Approved
Comments:

Approver: Rachel Cutler Date: 3/2/22
Title: Lab Manager

Quality Review

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

	1	2	3	4	5	6
a	cal 1	Internal urine	1584-2	1680-1	1625-1	
b	cal 2	negative blood	1596-1	1707-2	1660-1	
c	cal 3	1528-1	1611-1	1561-1	1661-1	
d	cal 4	1535-1	1632-1	1566-1	1667-1	
e	Cal 5	1538-1	1634-1	1568-1	negative urine	
f	cal 6	1564-1	1635-1	1598-1	1612-2	
g	cal 7	1565-1	1636-1	1598-2	1700-1	
h	Internal control (blood)	1569-1	1679-1	1621-1		

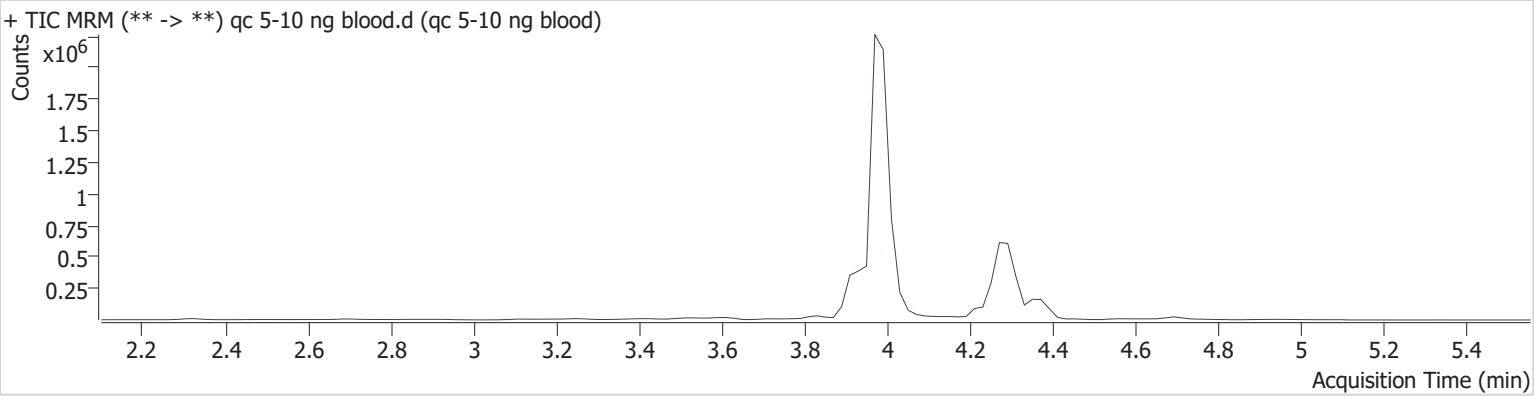
c2022-____-_

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:51:36 PM		
Sample Info.			

Sample Chromatogram



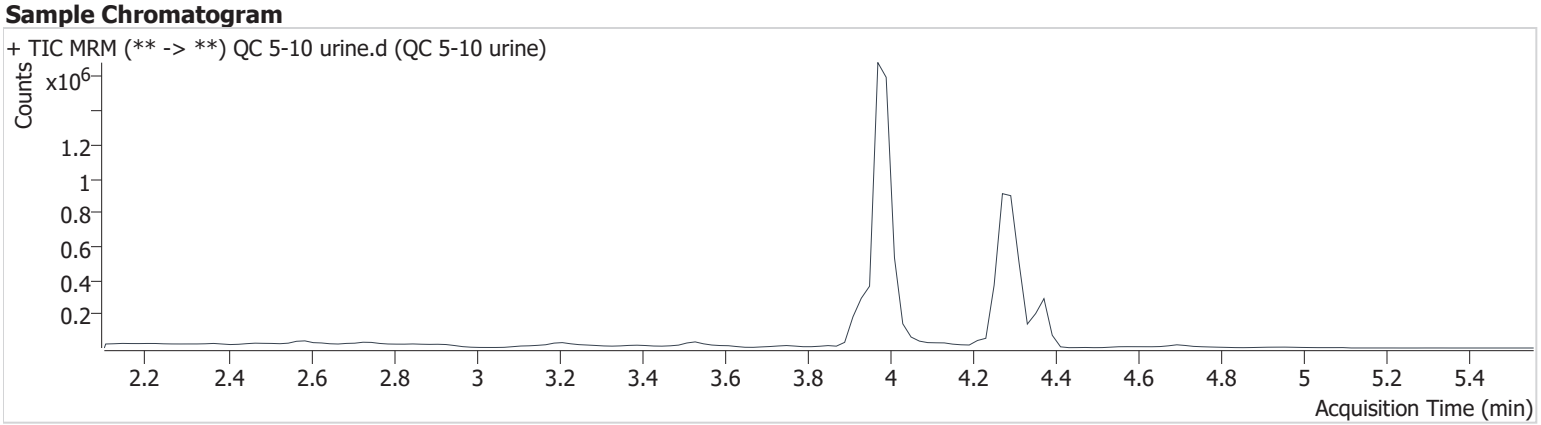
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	11458	339074	4.900 ng/ml
THC-COOH	3.930	264742	798445	14.524 ng/ml
THC-OH	3.999	48947	6464993	4.726 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

Instrument	69679	**Data File**	QC 5-10 urine.d
Type	QC	**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	8/3/2022 8:58:14 PM		
Sample Info.			

Sample Chromatogram



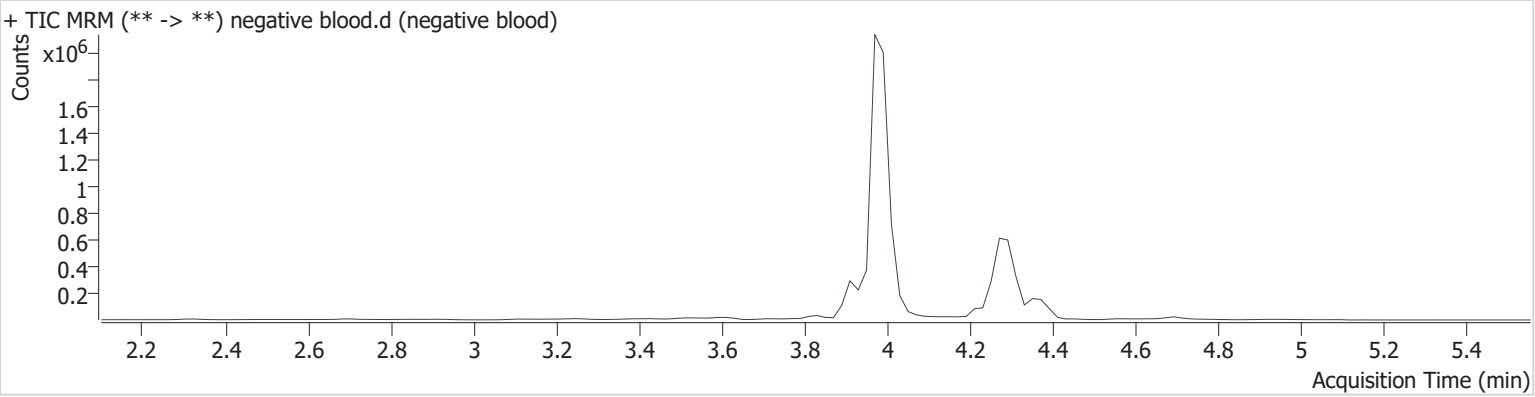
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	18026	535051	4.886 ng/ml
THC-COOH	3.930	151962	533029	12.242 ng/ml
THC-OH	3.999	34693	4778255	4.539 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 9:04:53 PM		
Sample Info.			

Sample Chromatogram

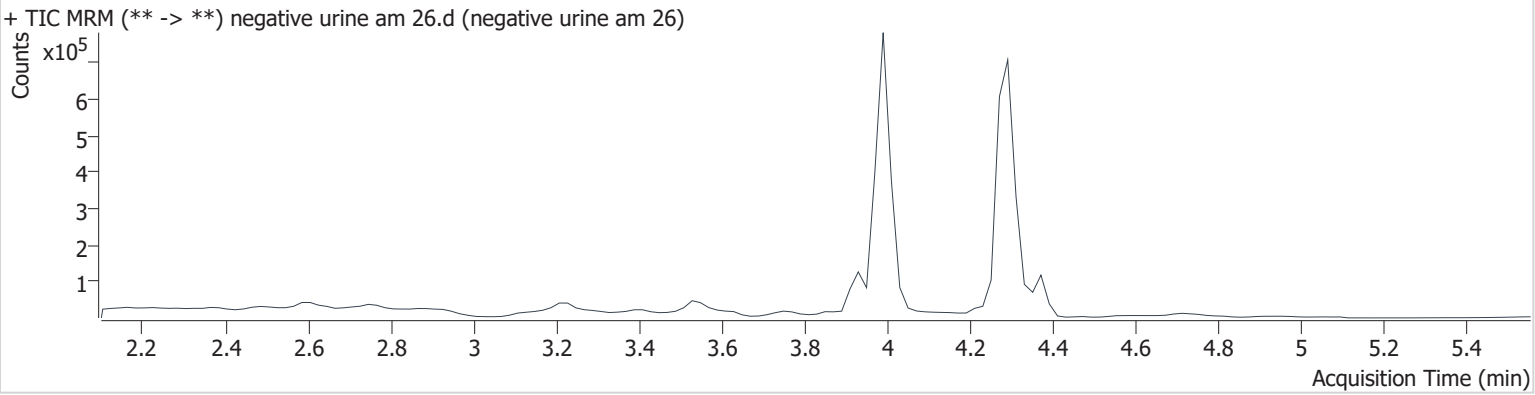


AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

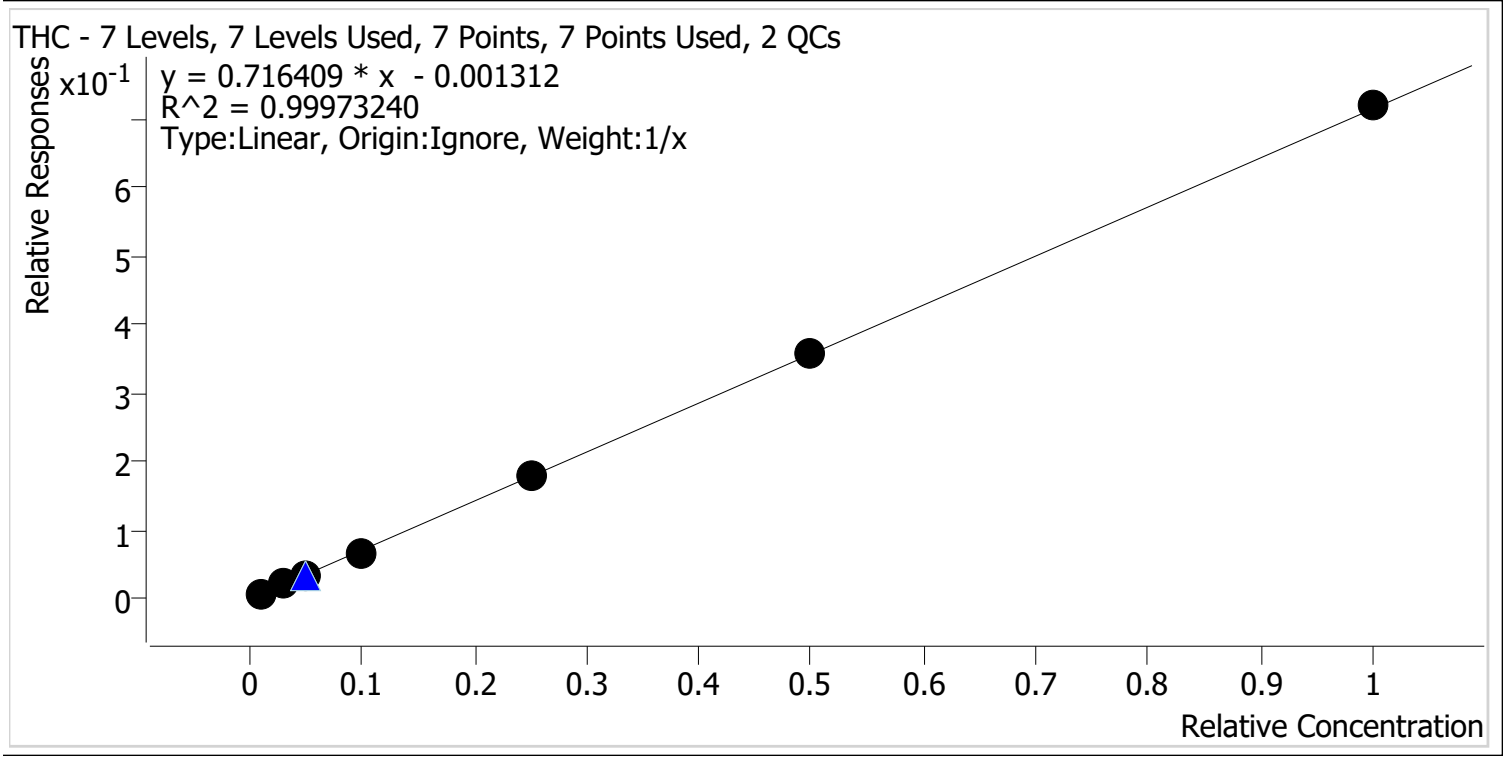
Instrument	69679	**Data File**	negative urine am 26.d
Type	Sample	**Sample**	negative urine am 26
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-E5	**Comment**	
Injection Volume	5		
Acq. Date-Time	8/4/2022 11:19:07 AM		
Sample Info.			

Sample Chromatogram



Compound Calibration Report

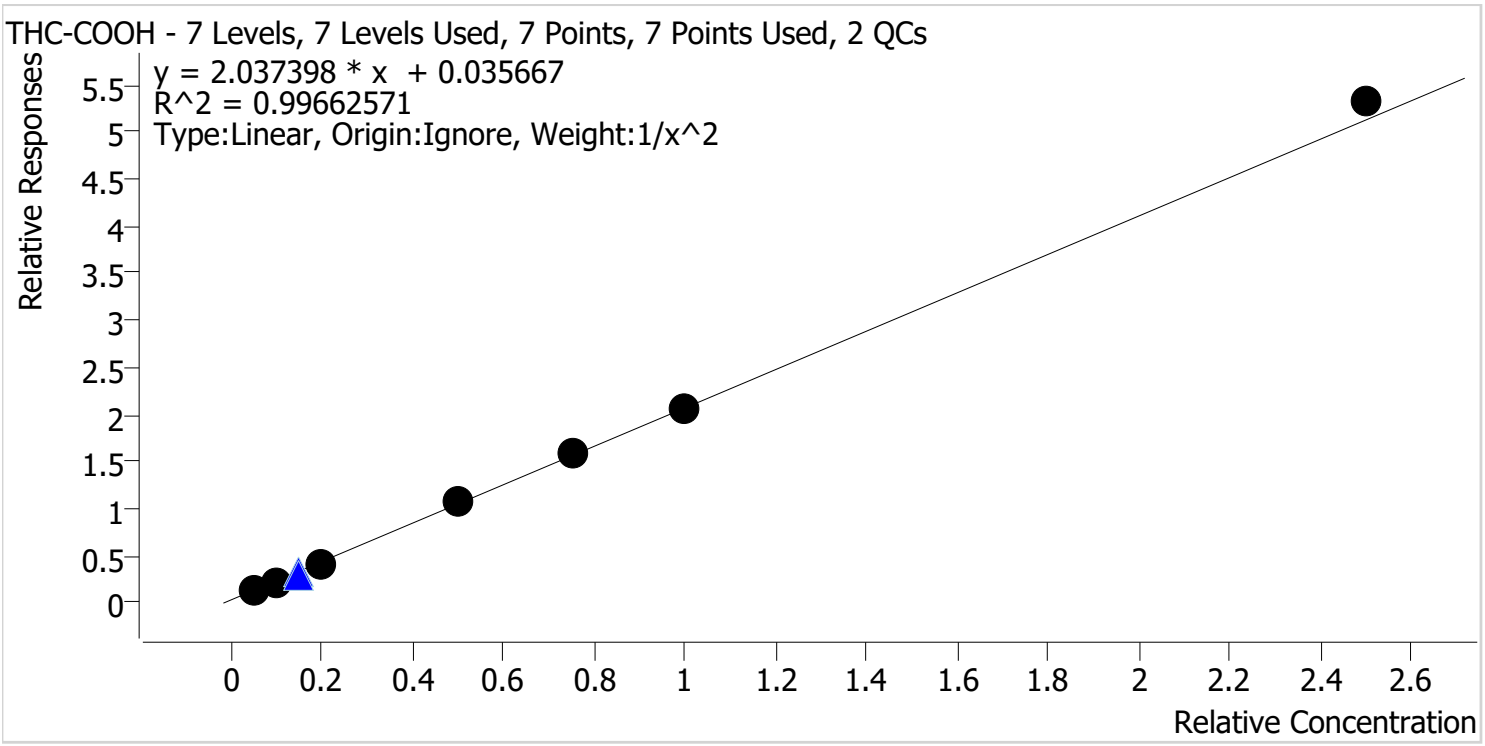
Batch results	D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Last Cal. Update	8/4/2022 1:29 PM
Analyst Name	ISP\datastor
Analyte	THC
Internal Standard	THC-d3



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	1.0	1.1	109.8
cal 2	2	✔	3.0	2.9	96.2
cal 3	3	✔	5.0	4.9	98.6
cal 4	4	✔	10.0	9.5	95.0
cal 5	5	✔	25.0	24.9	99.7
cal-6	6	✔	50.0	50.0	100.0
cal-7	7	✔	100.0	100.6	100.6

Compound Calibration Report

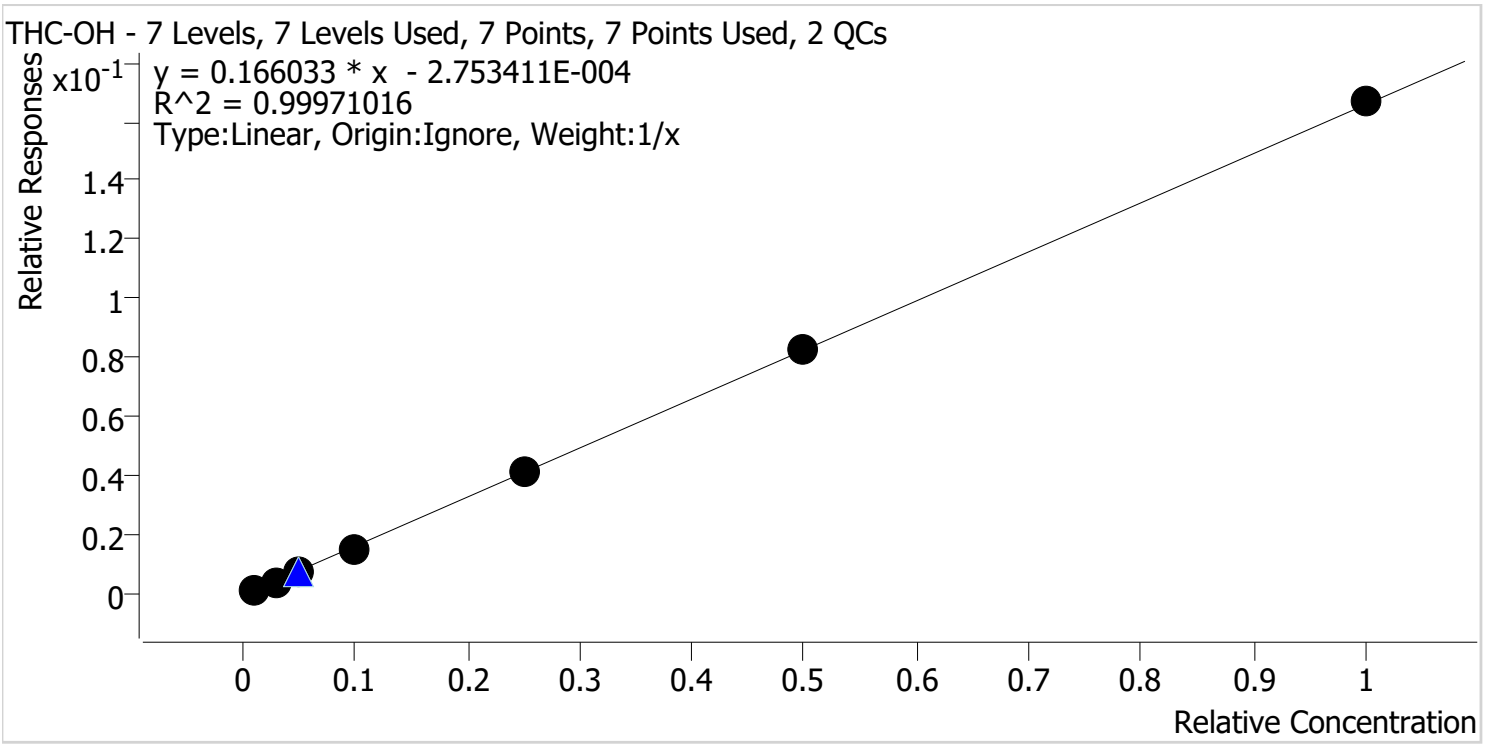
Batch results	D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Last Cal. Update	8/4/2022 1:29 PM
Analyst Name	ISP\datastor
Analyte	THC-COOH
Internal Standard	THC-COOH-d9



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	5.0	5.2	104.9
cal 2	2	✔	10.0	9.1	91.2
cal 3	3	✔	20.0	19.3	96.4
cal 4	4	✔	50.0	50.6	101.2
cal 5	5	✔	75.0	77.0	102.6
cal-6	6	✔	100.0	99.8	99.8
cal-7	7	✔	250.0	259.5	103.8

Compound Calibration Report

Batch results	D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Last Cal. Update	8/4/2022 1:29 PM
Analyst Name	ISP\datastor
Analyte	THC-OH
Internal Standard	THC-OH-d3



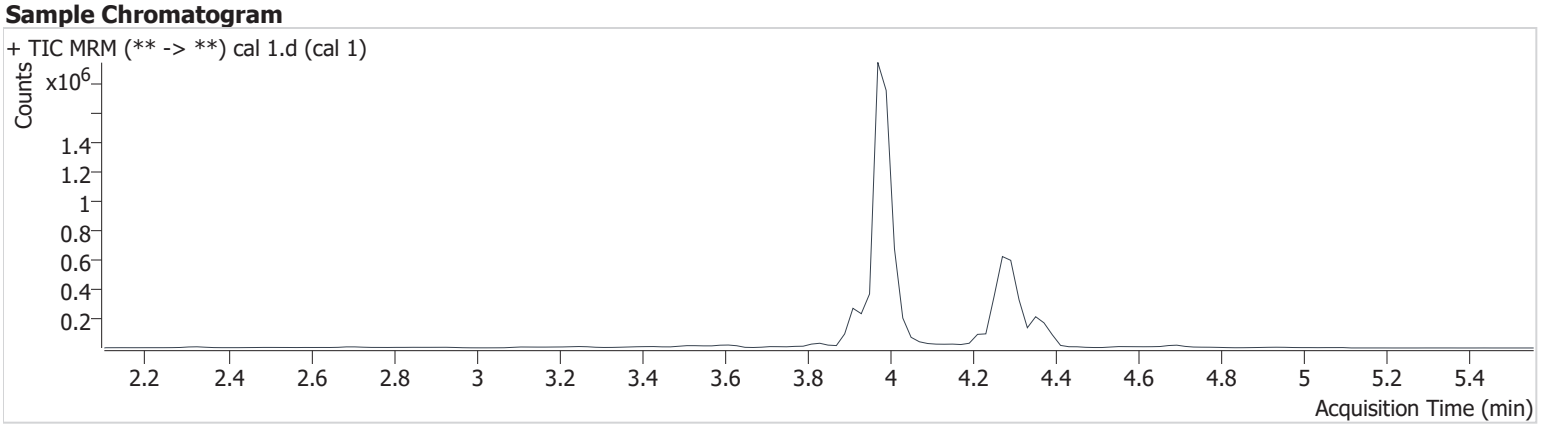
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	1.0	1.1	112.3
cal 2	2	✔	3.0	2.8	94.1
cal 3	3	✔	5.0	4.8	96.8
cal 4	4	✔	10.0	9.6	96.3
cal 5	5	✔	25.0	25.0	99.9
cal-6	6	✔	50.0	50.0	100.1
cal-7	7	✔	100.0	100.6	100.6

AM #26 Cannabinoids Screen Results

Batch results	D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update	8/4/2022 1:29:13 PM

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	8/3/2022 8:05:05 PM		
Sample Info.			

Sample Chromatogram



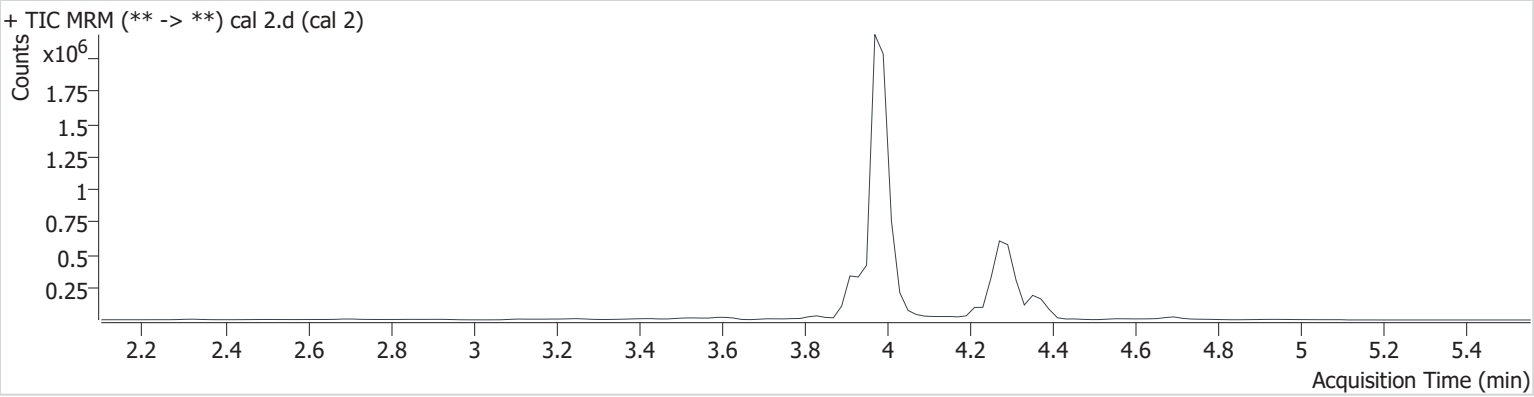
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	2620	399826	1.098 ng/ml **Low**
THC-COOH	3.930	98001	687510	5.246 ng/ml **Low**
THC-OH	3.979	9330	5871169	1.123 ng/ml **Low**

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:11:46 PM		
Sample Info.			

Sample Chromatogram



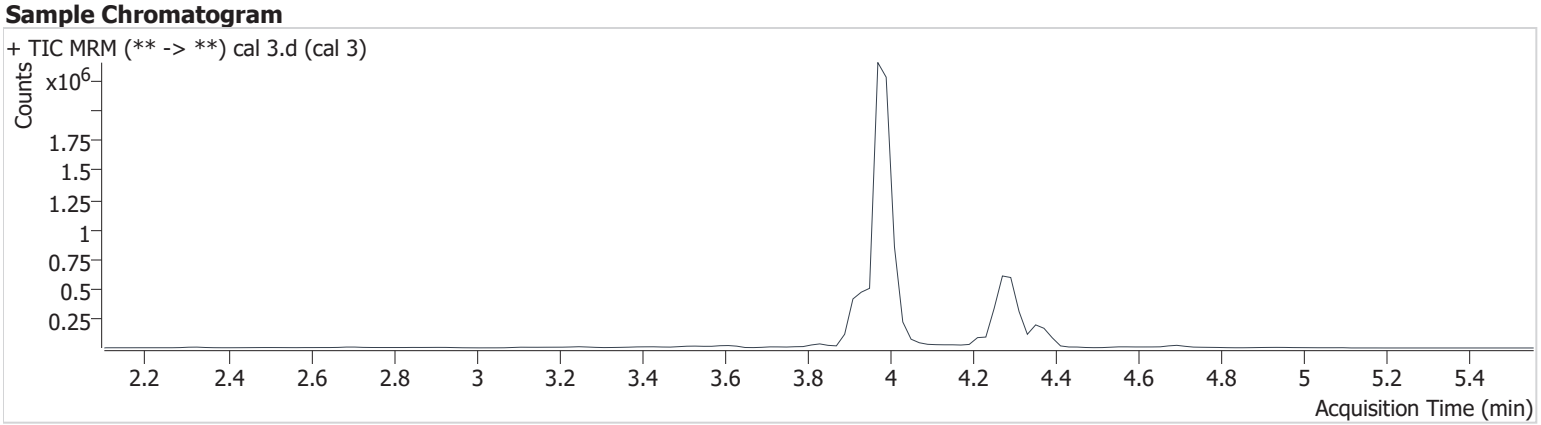
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	6987	360935	2.885 ng/ml **Low**
THC-COOH	3.930	176908	798413	9.125 ng/ml **Low**
THC-OH	3.999	28199	6393716	2.822 ng/ml **Low**

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:18:24 PM		
Sample Info.			

Sample Chromatogram



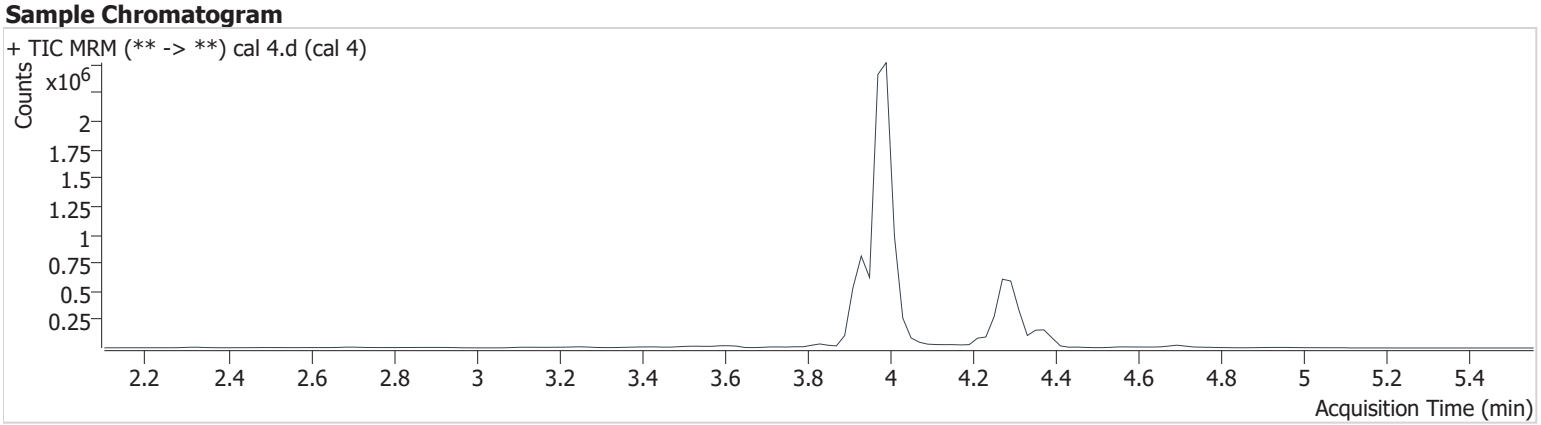
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	12733	374302	4.932 ng/ml
THC-COOH	3.930	367875	858608	19.279 ng/ml
THC-OH	3.999	53305	6868549	4.840 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:25:03 PM		
Sample Info.			

Sample Chromatogram



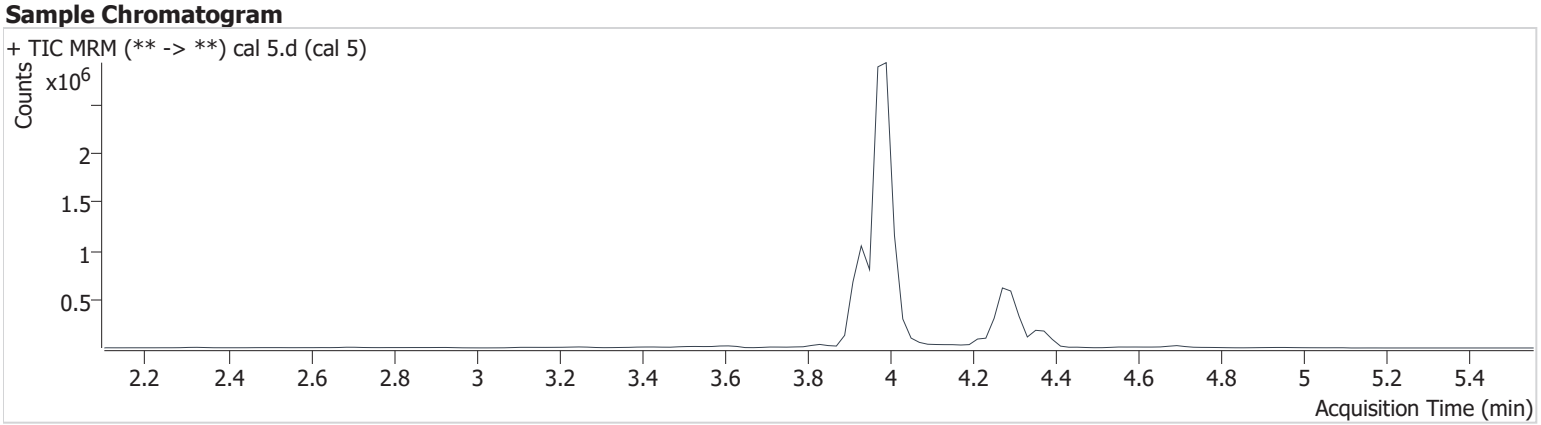
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	21402	320642	9.500 ng/ml
THC-COOH	3.930	889819	834308	50.597 ng/ml
THC-OH	3.999	104979	6681586	9.629 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:31:41 PM		
Sample Info.			

Sample Chromatogram



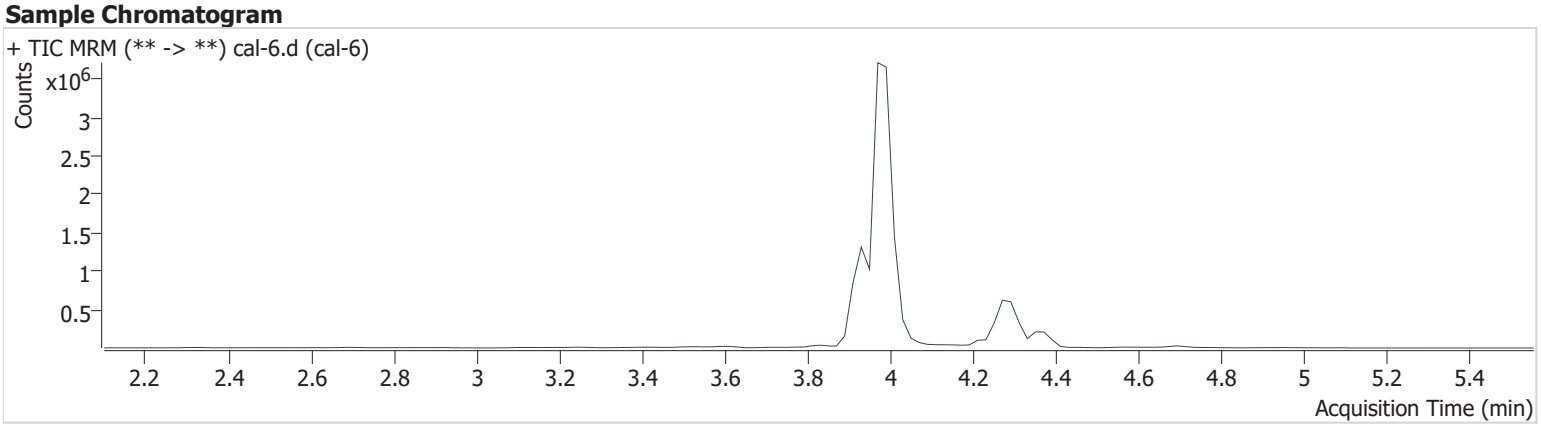
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	58051	327340	24.937 ng/ml
THC-COOH	3.930	1293556	806669	76.956 ng/ml
THC-OH	3.999	273174	6632881	24.971 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:38:19 PM		
Sample Info.			

Sample Chromatogram



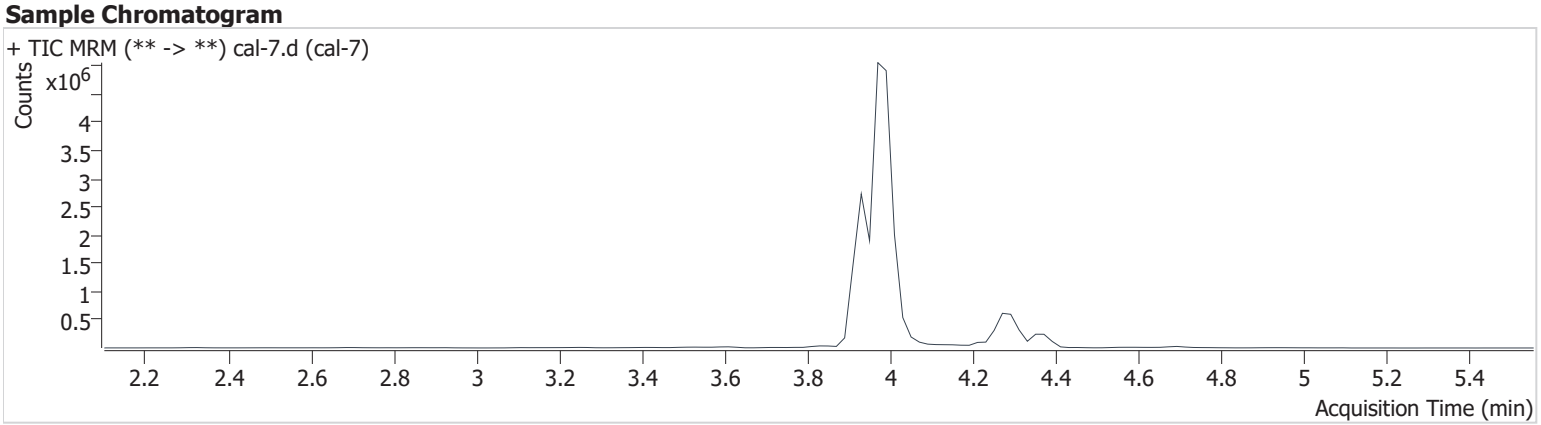
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	120868	338635	50.005 ng/ml
THC-COOH	3.930	1717131	829665	99.833 ng/ml
THC-OH	3.999	543789	6566827	50.041 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\080322\QuantResults\cann.batch.bin
Calibration Last Update 8/4/2022 1:29:13 PM

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	8/3/2022 8:44:57 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.385	225084	312744	100.644 ng/ml
THC-COOH	3.930	3998036	751091	259.513 ng/ml
THC-OH	3.979	1018850	6111485	100.574 ng/ml