REVIEWED
By Sarah Collins at 8:45 am, Jul 13, 2022

REVIEWED
By Britany Wylie at 9:57 am, Jul 18, 2022

Worklist: 6026

LAB_CASE	ITEM	ITEM_TYPE	DESCRIPTION
C2022-1260	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1373	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1389	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1413	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1418	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1421	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1422	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1423	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1424	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1426	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1427	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1441	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1442	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1462	3	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1464	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1471	2	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1484	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1491	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1516	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1517	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1518	1	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: 07/07/22 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: 22B52016-3 **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.*
C2022-1441-1 did not evaluate 6-mam, phentermine, MDA, MDMA, and MDEA in this sample. This was due to low IS response and shift of IS.

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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

	1	2	3	4	5	6	7	8	9	10	11	12
A					1373-1	1442-2	1518-1		1418-1	7/13/22		
B					1389-2	1462-3	1423-1		1441-1	7/13/22		
C					1413-1	1464-1						
D					1421-1	1471-2						
E					1422-1	1484-1						
F				negative blood	1424-1	1491-1						
G				external control blood	1426-1	1516-1			urine positive control			
H				1260-1	1427-2	1517-1			negative urine			cal 1

C2022-____-_

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)

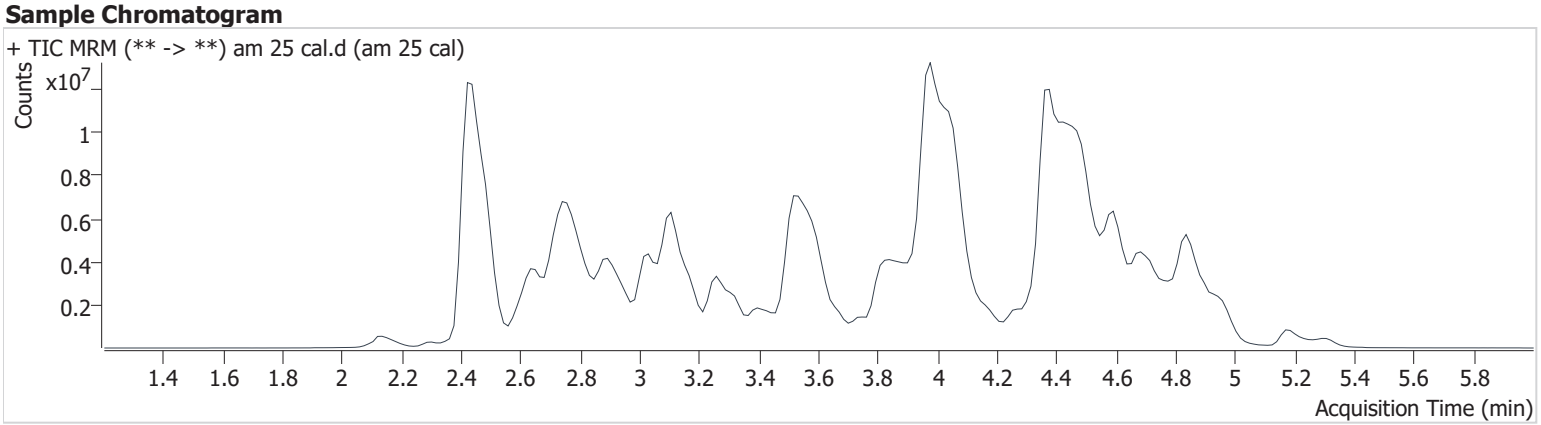
ppp 7/7/22, exp 7/7/23 lot b7722 neg blood 22B52016-3 by AMN

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\mds.batch.bin
Calibration Last Update 7/8/2022 12:51:15 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-H12	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	7/7/2022 5:57:40 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.527	939749	1186.6	34.3	1561681	10.000
6-MAM	2.876	45511	10047.9	6238.4	1462797	10.000
7-aminoclonazepam	3.340	439842	74.7	171.5	1742627	10.000
7-aminoflunitrazepam	3.569	715967	93.5	152.2	1742627	10.000
9-Hydroxyrisperidone	3.973	4435823	186.8	∞	1742627	10.000
Acetyl Fentanyl	4.132	285676	106.2	41567.1	14210100	10.000
Acetyl Norfentanyl	2.641	209658	736.5	391.0	14210100	10.000
a-hydroxyalprazolam	4.378	117349	153.8	64.8	1742627	10.000
alpha-hydroxymidazolam	4.438	2183290	474.1	30215.8	1742627	10.000
alpha-PHP	3.879	2235179	350.0	412.8	6507273	10.000
alpha-PVP	3.559	2951799	1154.9	152.1	6507273	10.000
Alprazolam	4.458	1376055	132.2	210.7	8175770	10.000
Amitriptyline	4.508	884188	85.2	44.8	4828631	10.000
Amphetamine	2.647	2739792	686.8	638.2	6507273	10.000
Benzoylecgonine	3.123	96959	25144.0	88.3	209655	10.000
Brompheniramine	4.040	74718	41.5	8.7	48727227	10.000
Buprenorphine	5.182	107153	34408.7	158428.9	2689279	10.000
Bupropion	3.865	3052734	684.9	7729.3	12388890	10.000
Carbamazepine	4.034	4563598	868.8	385.3	43238	10.000
Carisoprodol	4.032	619244	204.2	85.7	3312006	10.000
Chlordiazepoxide	4.582	550117	43006.6	59.8	8175770	10.000
Chlorpheniramine	3.906	4578034	12903.2	26.5	6172391	10.000
Chlorpromazine	4.809	1002838	116810.7	355.3	2957021	10.000
Citalopram	3.993	2249089	216.7	2301.6	6172391	10.000
Clomimpramine	4.778	1292533	339.2	1238.6	6172391	10.000
Clonazepam	4.271	424186	83.3	34.6	8175770	10.000
Clonazolam	4.190	595866	76962.1	155208.5	8175770	10.000
clozapine	4.608	3834850	7149.5	3168.0	15204578	10.000
Cocaethylene	3.748	3096083	623408.1	38116.8	21116606	10.000
Cocaine	3.535	3760969	361.8	835.9	21116606	10.000
Codeine	2.802	359419	762.1	314.0	5648646	10.000
Cyclobenzaprine	4.400	2070657	1530.4	62.7	4828631	10.000
Desipramine	4.324	3087233	654214.2	675.2	4828631	10.000
Dextromethorphan	4.076	1632289	402.3	241721.4	8723729	10.000

AM #25 Multi-Drug Screen Results

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextrorphan	3.235	1889858	237.7	1806.7	8723729	10.000
Diazepam	4.721	938136	203.6	250.0	8175770	10.000
Dihydrocodeine	2.619	866321	624.6	235.4	2755079	10.000
Diphenhydramine	3.985	6274634	2375.9	702.1	48727227	10.000
Doxepin	4.198	1441972	101.4	35.2	12082356	10.000
Doxylamine	3.540	6224462	∞	∞	3787514	10.000
Duloxetine	4.274	37791	9228.8	254.7	2144030	10.000
EDDP	3.983	1264237	52.1	1408.1	2755079	10.000
Estazolam	4.367	2413010	1829.6	185.0	8175770	10.000
Etizolam	4.484	147751	25533.9	169232.4	8175770	10.000
Fentanyl	4.377	223565	78.4	721.7	14210100	10.000
Flualprazolam	4.316	332280	58855.5	87353.8	8175770	10.000
Flunitrazepam	4.395	1181900	70.1	8564.7	8175770	10.000
Fluoxetine	4.257	1347549	5509.3	88886.0	2144030	10.000
Flurazepam	4.421	2467795	431508.9	69150.7	8175770	10.000
Hydrocodone	3.092	910800	165.1	60.4	5648646	10.000
Hydromorphone	2.379	893838	472.4	119.6	5648646	10.000
hydroxyzine	4.682	3012459	856.1	474408.7	8723729	10.000
Imipramine	4.446	3885483	1087.6	343.9	4828631	10.000
Ketamine	3.834	2299898	359.0	76.3	2755079	10.000
Lamotrigine	3.419	187817	1244.3	119.1	6172391	10.000
Levamisole	2.948	1485359	94.2	396.0	8723729	10.000
Levetireacetam	2.310	447890	165.3	1761.8	6172391	10.000
Lorazepam	4.255	49526	46.0	∞	8175770	10.000
Maprotiline	4.507	511322	271.6	75.3	4828631	10.000
MDA	2.765	1630816	122.1	84.2	18873691	10.000
MDEA	3.039	2849911	2857.1	2061.8	18873691	10.000
MDMA	2.872	3316327	4755.2	453.1	18873691	10.000
Meperidine	3.588	1888921	571.5	148.0	8723729	10.000
Meprobamate	3.422	118891	28909.8	13.7	3312006	10.000
Methadone	4.349	4334440	944.0	4661.3	2755079	10.000
Methamphetamine	2.767	7088054	∞	∞	18873691	10.000
Methocarbamol	3.328	113815	554.9	506.9	2755079	10.000
Methylphenidate	3.405	6156323	275.8	363.9	8723729	10.000
Metoprolol	3.250	545685	261.0	2162.2	8723729	10.000
Midazolam	4.655	505250	728.0	74932.5	8175770	10.000
Mirtazapine	4.448	2625795	696.2	488.4	8723729	10.000
Mitragynine	4.389	354824	37477.4	163876.4	8723729	10.000
Morphine	2.138	236628	4388.6	588.0	241629	10.000
Norbuprenorphine	3.760	63972	5320.5	11741.0	241629	10.000
Nordiazepam	4.555	412049	478708.6	365.0	8175770	10.000
Norfentanyl	3.129	3961843	3436.5	447.4	20396930	10.000
Norhydrocodone	2.713	36853	6885.6	4765.8	5648646	10.000
norketamine	3.866	439675	144.8	558.5	2755079	10.000
Normeperidine	3.452	1760911	951.5	94.3	6172391	10.000
Noroxycodone	2.634	918811	212.8	165.5	8182435	10.000
Nortriptyline	4.370	920229	246.8	104.0	4828631	10.000
O-desmethyl-tramadol	2.655	5006803	3366.0	123.7	6172391	10.000
o-Desmethylvenlafaxine	3.034	1360765	678.3	2756.2	6172391	10.000
Olanzapine	3.979	967233	1281.8	313.5	43238	10.000
Oxazepam	4.337	377265	44.6	26.1	1561681	10.000
Oxycodone	2.786	1658183	179.5	340.0	8182435	10.000
Oxymorphone	2.119	932516	175.0	86.7	241629	10.000
Paroxetine	4.299	232186	153.3	391.2	2144030	10.000
Phenazepam	4.484	1072481	235063.0	90386.1	8175770	10.000
Phencyclidine	3.833	3333553	2518.3	301.1	8723729	10.000
Phentermine	2.919	1302371	∞	∞	14168023	10.000
Phenytoin	3.940	68274	110.9	11.3	43238	10.000
primidone	3.207	136976	56327.8	25.4	4828631	10.000
Promethazine	4.522	4551885	845.6	166.5	6172391	10.000

AM #25 Multi-Drug Screen Results

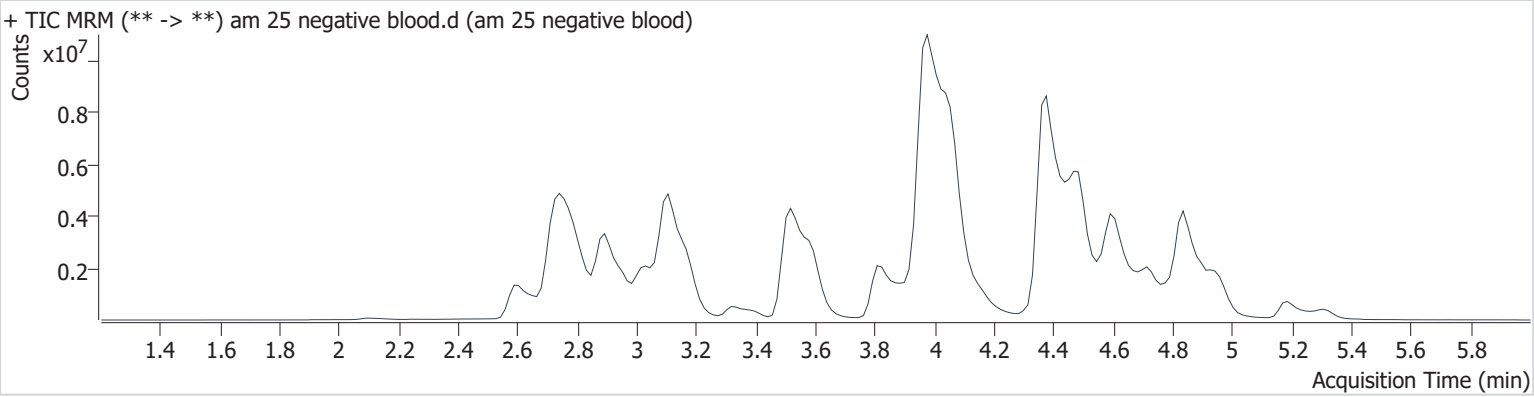
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Pseudoephedrine	2.447	60776877	970.2	2811.3	18873691	10.000
Quetiapine	4.682	4146926	754202.6	912.6	34332549	10.000
Risperidone	4.266	4646049	1168099.6	176.1	4470914	10.000
Sertraline	4.597	383229	107124.4	36283.8	2144030	10.000
Sufentanil	4.850	132075	93375.5	202.9	20396930	10.000
Tapentadol	3.268	3435100	3788.2	124.9	2755079	10.000
Temazepam	4.521	1543272	489.3	129.3	8175770	10.000
Topiramate	3.608	11287	839.9	1835.2	48226	10.000
Tramadol	3.265	5456456	2565.3	35.7	6172391	10.000
Trazodone	4.851	2755169	13306.7	495.4	12082356	10.000
Venlafaxine	3.676	4227864	417.5	54.7	2144030	10.000
Zaleplon	4.181	944834	443.5	56407.0	34332549	10.000
Zolpidem	4.381	6316005	1488.3	720.4	34332549	10.000
Zopiclone	4.390	673979	191416.7	19905.4	3787514	10.000

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\mds.batch.bin
Calibration Last Update 7/8/2022 12:51:15 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-F4	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	7/7/2022 6:04:27 PM		
Sample Info.			

Sample Chromatogram

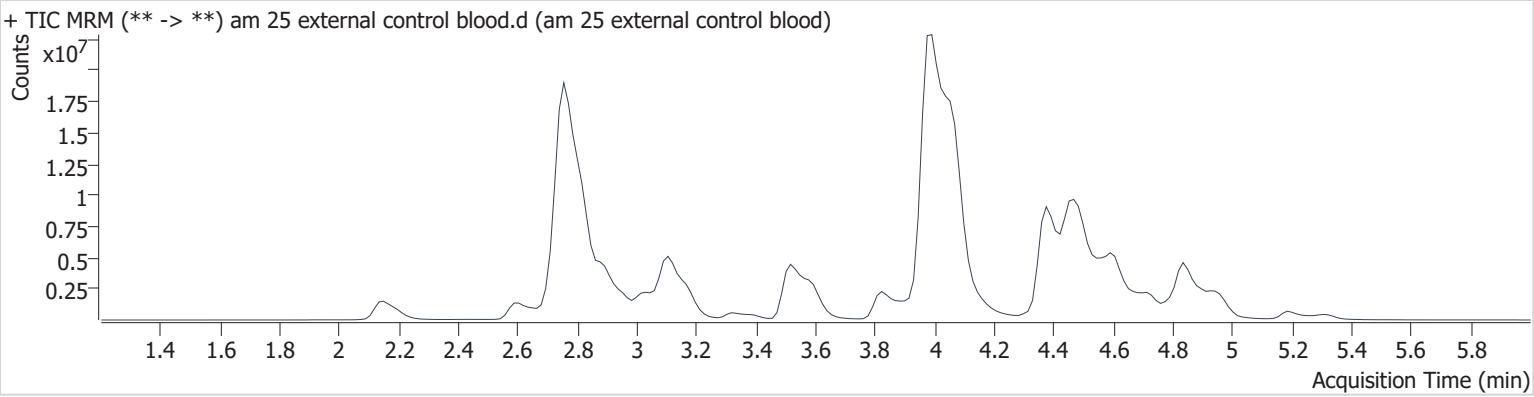


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\mds.batch.bin
Calibration Last Update 7/8/2022 12:51:15 PM

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-G4	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	7/7/2022 6:11:12 PM		
Sample Info.			

Sample Chromatogram



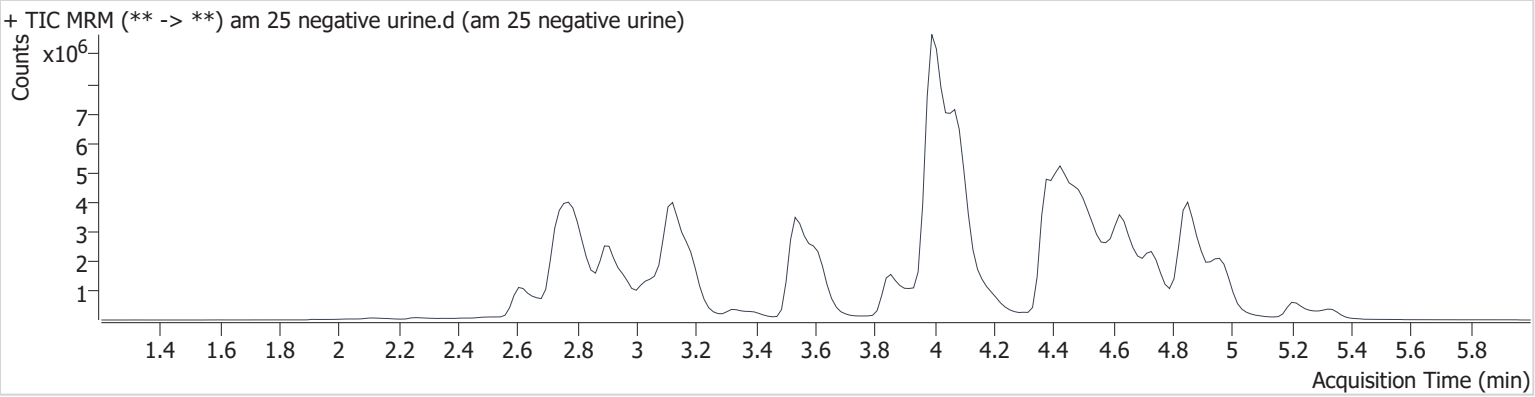
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.458	13837802	5498.9	1932.3	12107898	67.903
Diphenhydramine	4.001	65523850	19513.9	1025.8	55218916	92.150
Methamphetamine	2.767	40732304	∞	∞	20987723	51.678
Morphine	2.153	2492291	10421.0	1016.0	265030	96.025

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\mds.batch.bin
Calibration Last Update 7/8/2022 12:51:15 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-H9	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	7/7/2022 8:26:02 PM		
Sample Info.			

Sample Chromatogram

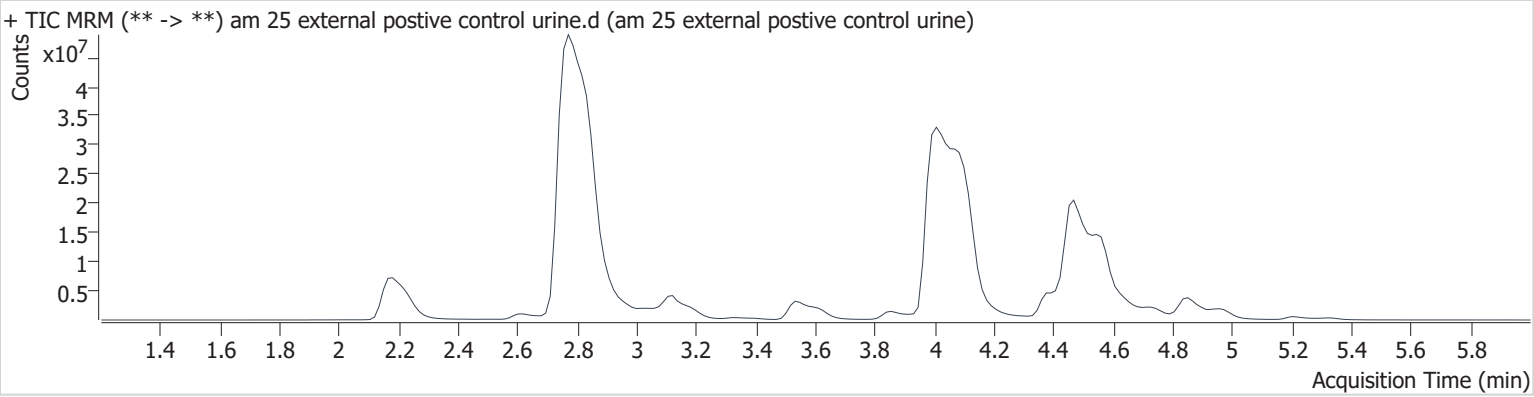


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\mds.batch.bin
Calibration Last Update 7/8/2022 12:51:15 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-G9	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	7/7/2022 8:32:47 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.473	68213599	2278.7	∞	5841857	693.766
Diphenhydramine	4.032	155813050	24818.7	8998.7	32433945	373.067
Methamphetamine	2.783	125455667	5171771015889010.0	∞	12768648	261.623
Morphine	2.183	14171788	80765.1	1496.0	204426	707.898

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

Extraction Date: 07/07/22 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: 22B52016-3 **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 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:

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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.

echnical J stifica ion or Analy ical Method Devia ions:

Internal controls serve the same purpose as external controls but also helps to av id 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	1413-1	1464-1	1517-1	
b	cal 2	negative blood	1421-1	1471-2	1518-1	
c	cal 3	1206-1	1422-1	1484-1	1423-1	
d	cal 4	1314-1	1424-1	1491-1	1427-2 *	
e	Cal 5	1314-2	1426-1	negative urine	1516-1 *	
f	cal 6	1260-1	1427-2 SLE well clogged	1418-1		
g	cal 7	1373-1	1442-2	1441-1		
h	Internal control (blood)	1389-2	1462-3	1516-1 SLE well clogged		

c2022-____-_

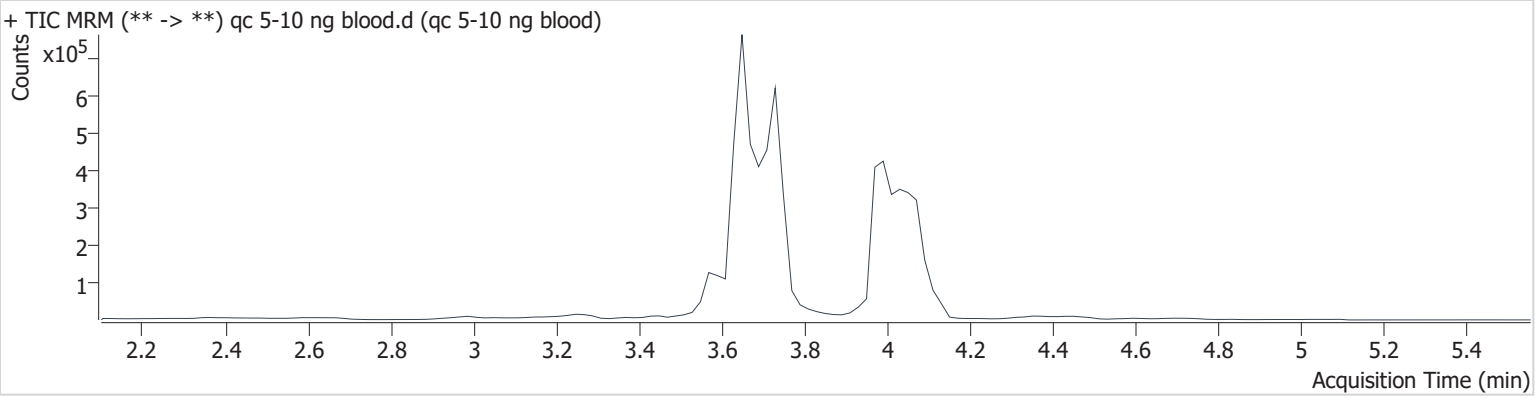
* The SLE well clogged another aloquot was taken and placed here.

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 10:13:18 PM		
Sample Info.			

Sample Chromatogram



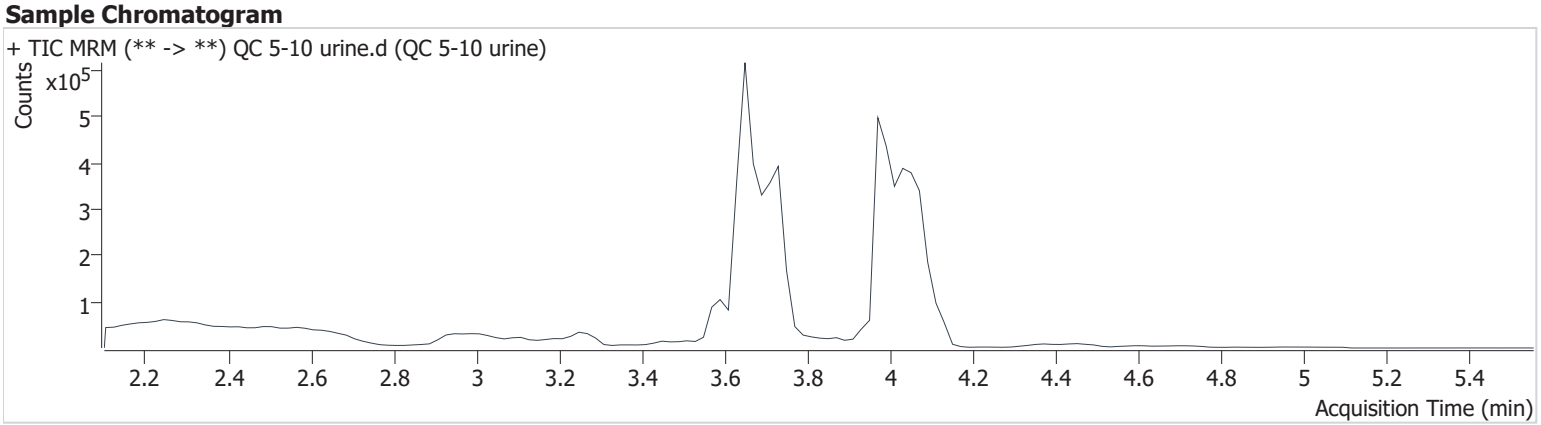
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	7136	194616	4.849 ng/ml
THC-COOH	3.589	148039	417434	16.989 ng/ml
THC-OH	3.739	30505	3792833	4.854 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 PM

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	7/7/2022 10:19:54 PM		
Sample Info.			

Sample Chromatogram



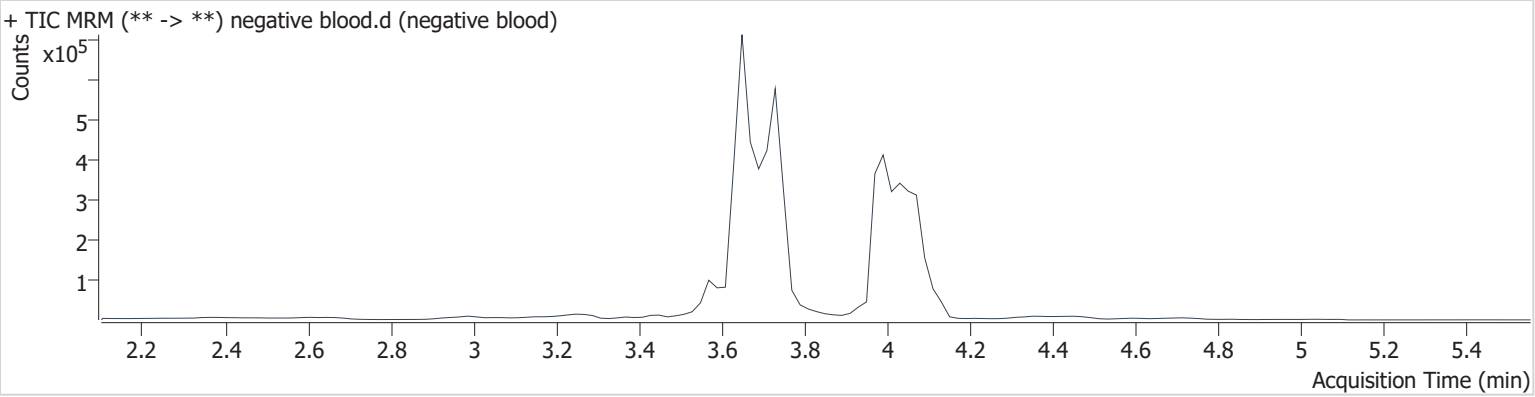
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	10519	280303	4.962 ng/ml
THC-COOH	3.589	87183	308662	13.032 ng/ml
THC-OH	3.739	20498	2803114	4.412 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 10:26:30 PM		
Sample Info.			

Sample Chromatogram

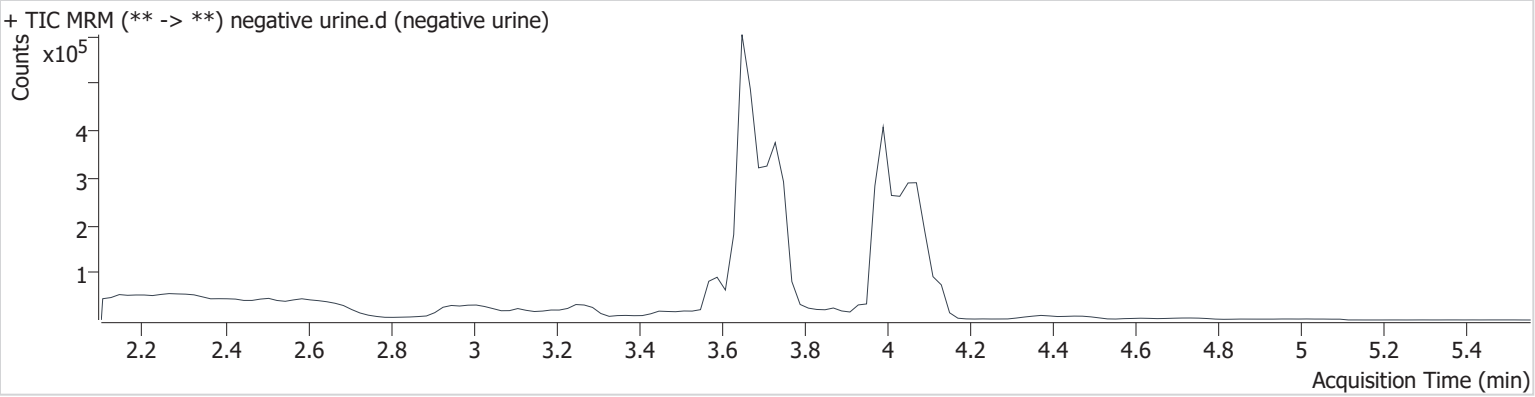


AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 PM

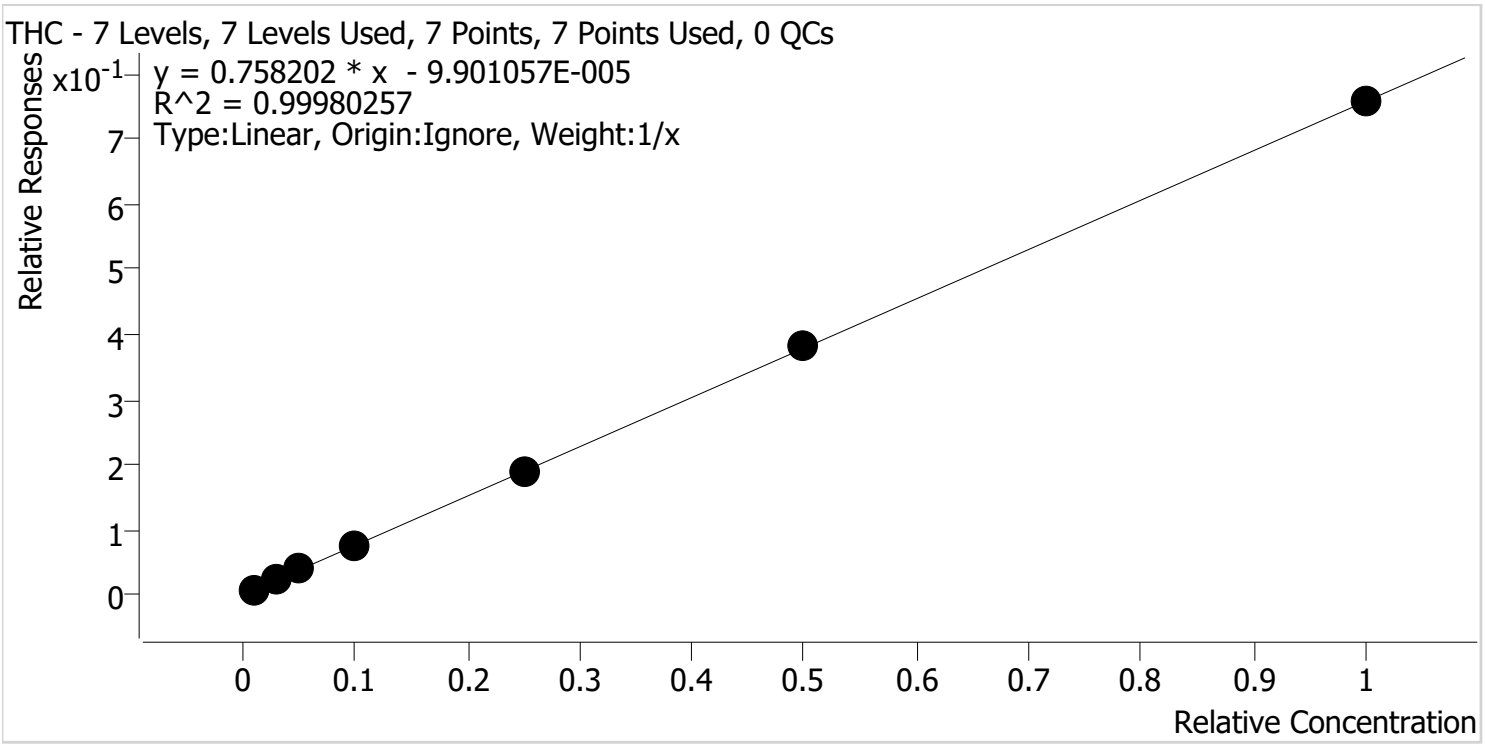
Instrument	69679	**Data File**	negative urine.d
Type	Sample	**Sample**	negative urine
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-E4	**Comment**	
Injection Volume	5		
Acq. Date-Time	7/8/2022 8:39:54 AM		
Sample Info.			

Sample Chromatogram



Compound Calibration Report

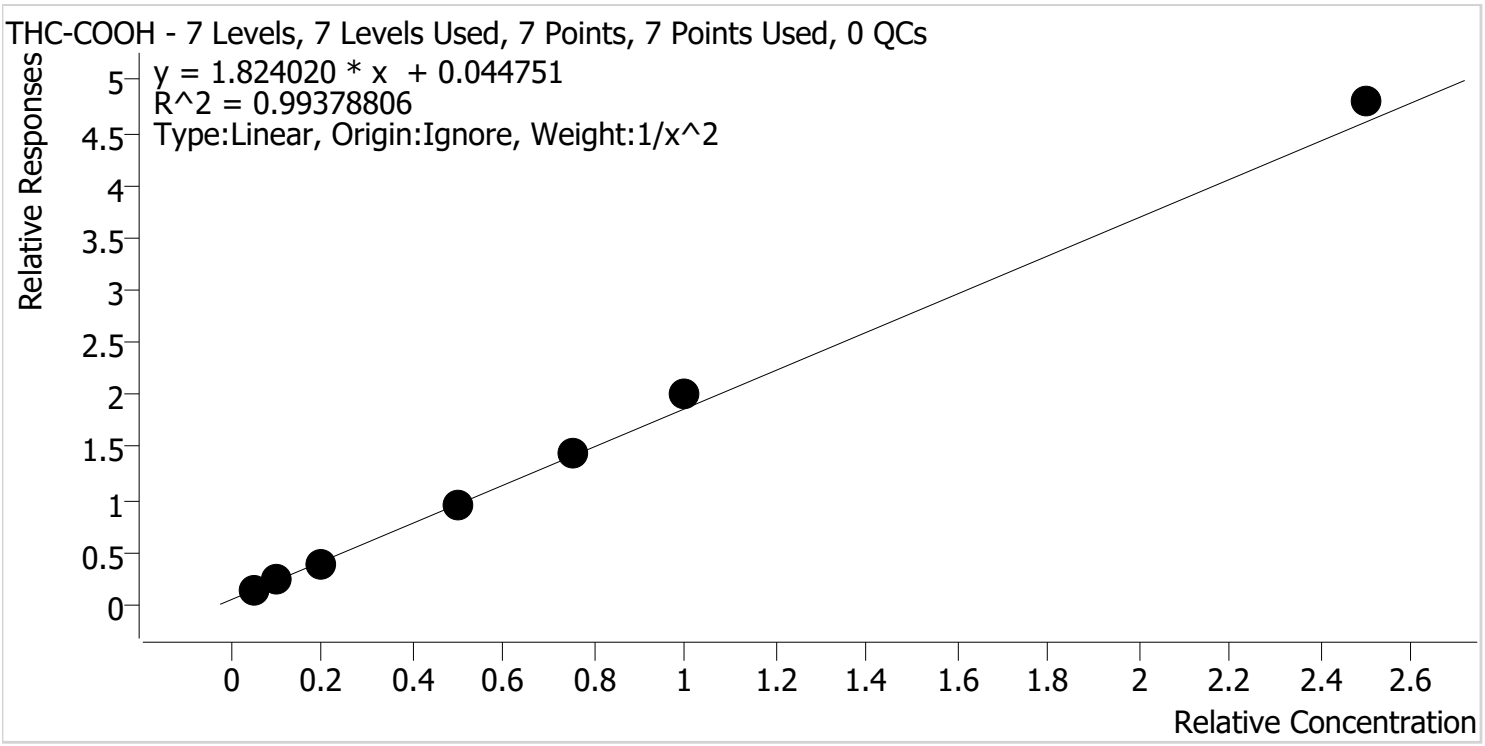
Batch results	D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Last Cal. Update	7/8/2022 12:53 PM
Analyst Name	ISP\datastor
Analyte	THC
Internal Standard	THC-d3



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	1.0	1.0	102.7
cal 2	2	✔	3.0	2.9	96.2
cal 3	3	✔	5.0	5.2	104.2
cal 4	4	✔	10.0	9.7	97.3
cal 5	5	✔	25.0	24.6	98.6
cal-6	6	✔	50.0	50.6	101.2
cal-7	7	✔	100.0	99.9	99.9

Compound Calibration Report

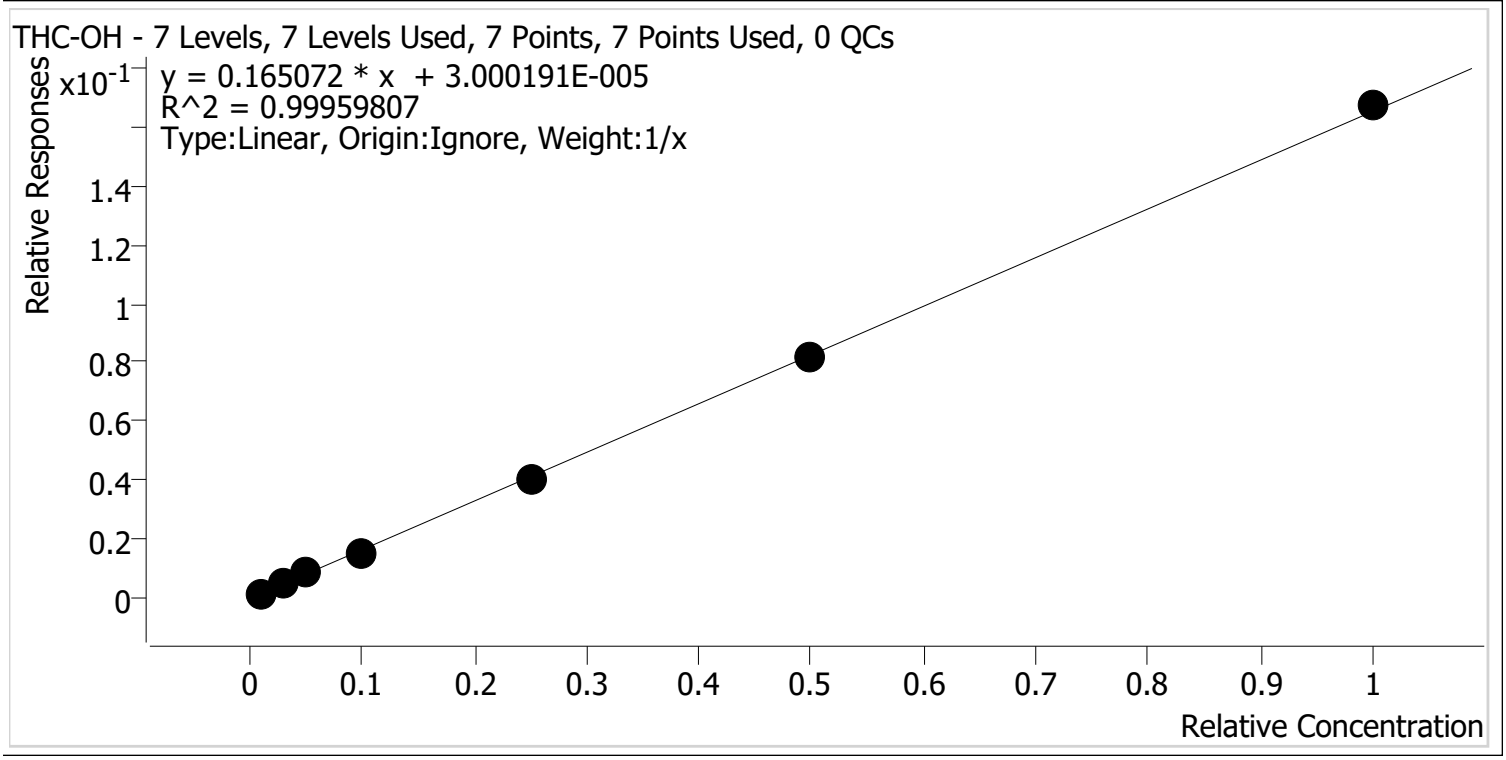
Batch results	D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Last Cal. Update	7/8/2022 12:53 PM
Analyst Name	ISP\datastor
Analyte	THC-COOH
Internal Standard	THC-COOH-d9



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	5.0	5.2	104.0
cal 2	2	✔	10.0	9.7	97.3
cal 3	3	✔	20.0	17.6	88.0
cal 4	4	✔	50.0	48.7	97.3
cal 5	5	✔	75.0	76.0	101.4
cal-6	6	✔	100.0	107.6	107.6
cal-7	7	✔	250.0	260.6	104.3

Compound Calibration Report

Batch results	D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Last Cal. Update	7/8/2022 12:53 PM
Analyst Name	ISP\datastor
Analyte	THC-OH
Internal Standard	THC-OH-d3



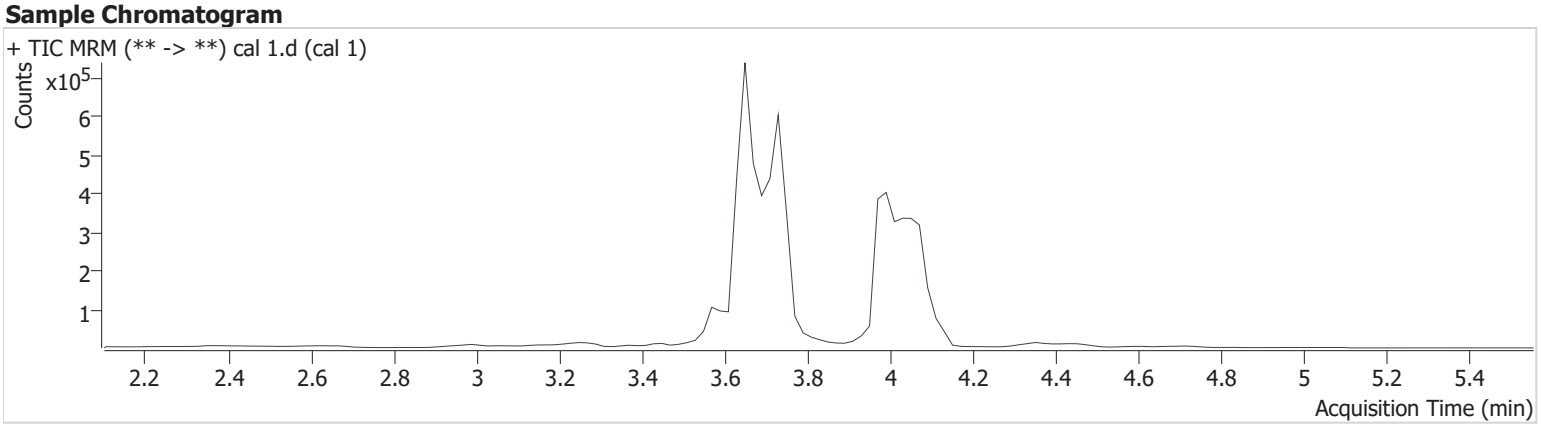
Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✔	1.0	1.0	97.0
cal 2	2	✔	3.0	3.2	105.8
cal 3	3	✔	5.0	5.2	103.5
cal 4	4	✔	10.0	9.6	95.9
cal 5	5	✔	25.0	24.4	97.6
cal-6	6	✔	50.0	49.5	99.1
cal-7	7	✔	100.0	101.2	101.2

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 9:27:01 PM		
Sample Info.			

Sample Chromatogram



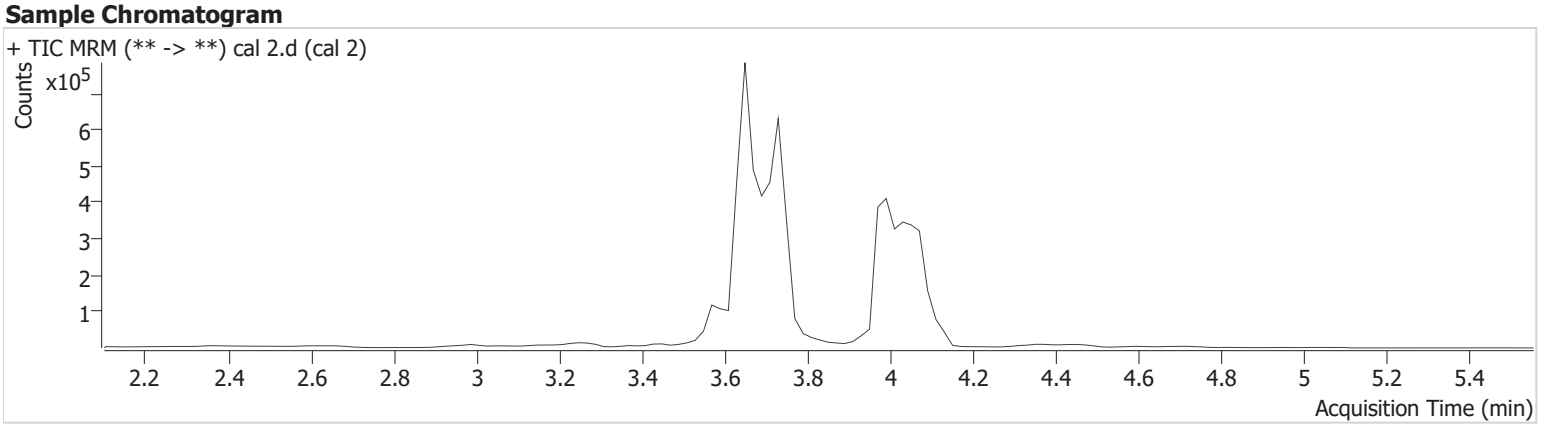
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	1618	210534	1.027 ng/ml **Low**
THC-COOH	3.589	62782	449644	5.201 ng/ml **Low**
THC-OH	3.739	6456	3958785	0.970 ng/ml **Low**

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 9:33:39 PM		
Sample Info.			

Sample Chromatogram



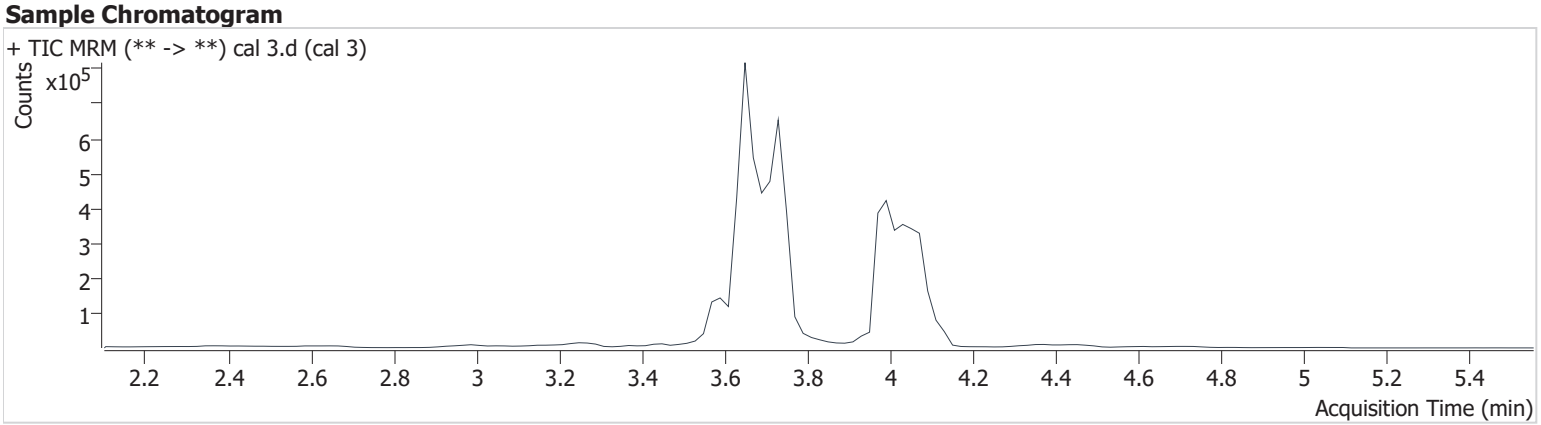
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	4554	209074	2.886 ng/ml **Low**
THC-COOH	3.589	99786	448845	9.735 ng/ml **Low**
THC-OH	3.739	21012	3987791	3.174 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 9:40:16 PM		
Sample Info.			

Sample Chromatogram



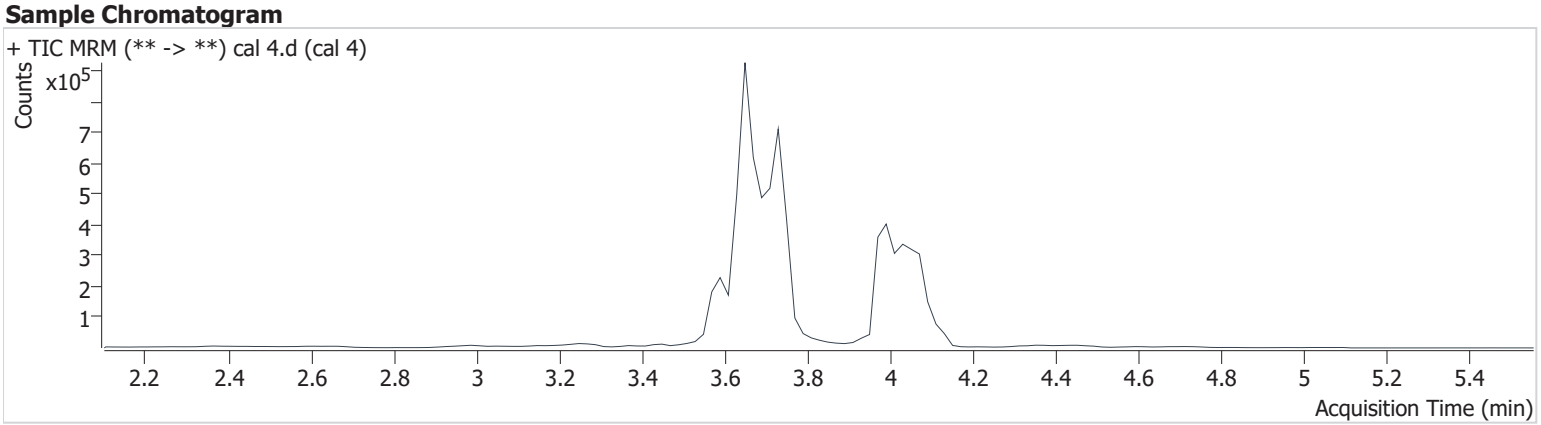
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	8113	205967	5.208 ng/ml
THC-COOH	3.589	168047	459327	17.604 ng/ml
THC-OH	3.739	34392	4011584	5.175 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 9:46:52 PM		
Sample Info.			

Sample Chromatogram



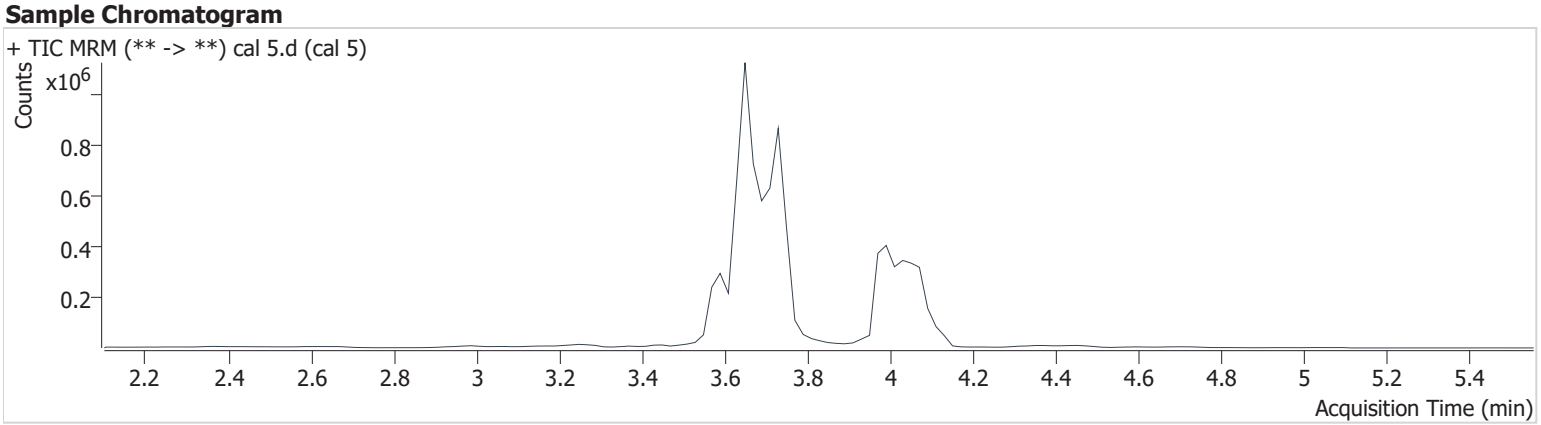
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	15840	214991	9.730 ng/ml
THC-COOH	3.589	420084	450506	48.668 ng/ml
THC-OH	3.658	64096	4040356	9.592 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 9:53:29 PM		
Sample Info.			

Sample Chromatogram



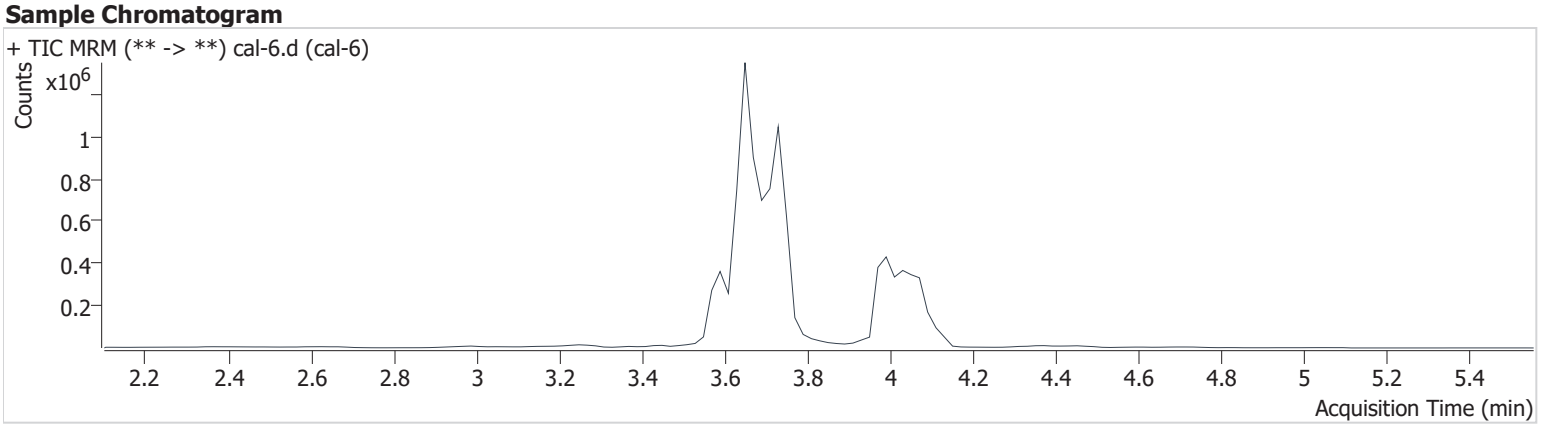
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	40215	215288	24.650 ng/ml
THC-COOH	3.589	636947	444897	76.036 ng/ml
THC-OH	3.739	163585	4059566	24.393 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 10:00:05 PM		
Sample Info.			

Sample Chromatogram



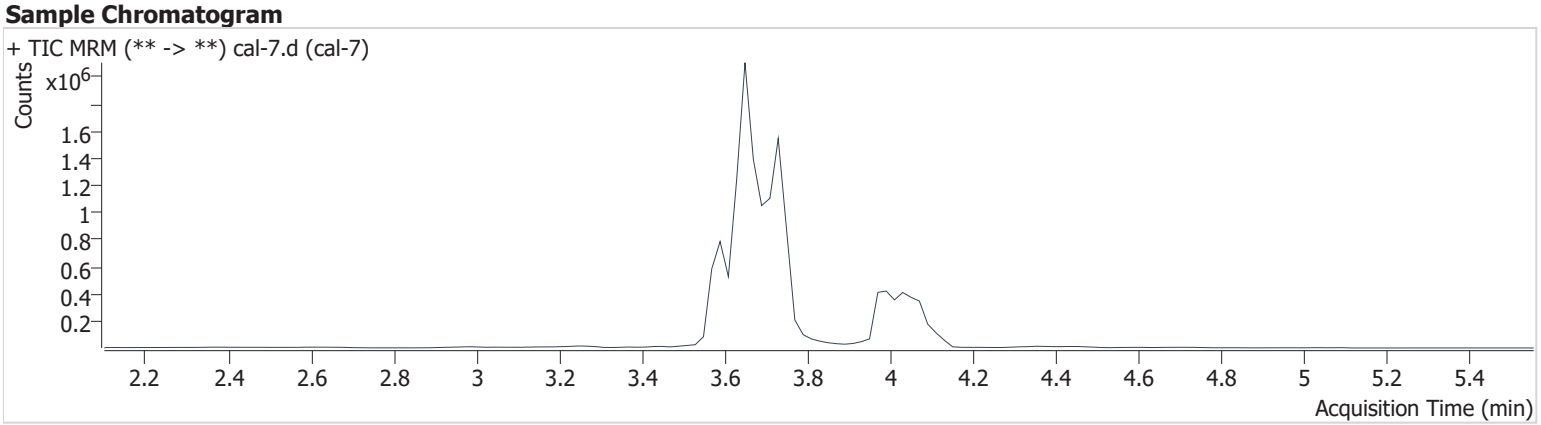
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	80368	209632	50.577 ng/ml
THC-COOH	3.589	833357	415040	107.627 ng/ml
THC-OH	3.739	317036	3876061	49.532 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\070722\QuantResults\cann.batch.bin
Calibration Last Update 7/8/2022 12:53:41 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	7/7/2022 10:06:41 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.044	162497	214513	99.923 ng/ml
THC-COOH	3.589	2116017	440941	260.639 ng/ml
THC-OH	3.739	658040	3939819	101.164 ng/ml