5/25/2022

REVIEWED
By Britany Wylie at 3:04 pm, May 31, 2022

Worklist: 5925

LAB_CASE	ITEM	ITEM_TYPE	DESCRIPTION
C2022-0949	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-0995	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1002	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ
C2022-1024	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1038	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1040	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1041	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1061	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1069	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1075	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1084	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1122	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1151	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by LC-QQQ
C2022-1155	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by LC-QQQ

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

Extraction Date: 5/24/22 Analyst: Anne Nord
Plate lot#: 211015 Plate retest date: 04/15/22

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

Pre-Analytic:

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

Analytic:

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

Post-Analytic

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

COMMENTS: *External controls run for plate re-test.*

	1	2	3	4	5	6	7	8	9	10	11	12
A	Cal 1	1069-1										949-1
B		1075-1										995-1
C	negative blood	1084-1										1002-1
D	1024-1	1122-1										1155-1
E	1038-1	1151-1										
F	1040-1	external control blood										
G	1041-1										external control urine	
H	1061-1										negative urine	

C2022-____-_

Toxicology AM method 25/28 urine external control prep

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

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

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

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

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

ppd 6/25/21, exp 6/25/22 lot u62522	negative urine 5621	by AMN
ppd 4/26/22, exp 6/25/22 lot u42622	negative urine 22522	by baw

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

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

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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

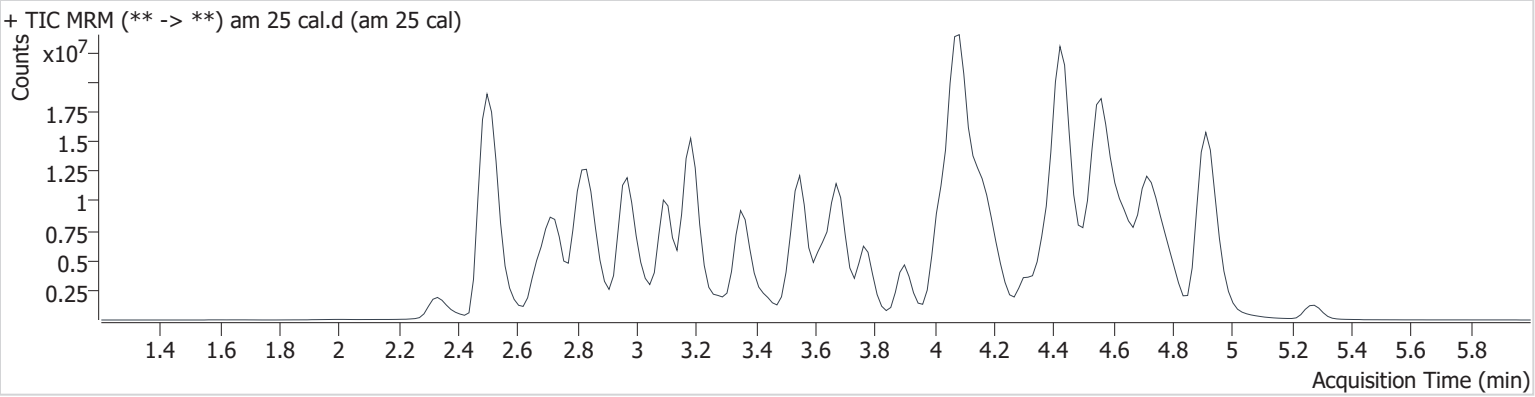
Quality Approver: Jason Crowe
Title: Quality Manager
Date: 2/10/2022

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\mds.batch.bin
Calibration Last Update 5/24/2022 3:07:18 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	5/24/2022 12:05:33 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.557	3540243	57.9	2415.4	7261734	10.000
6-MAM	3.196	70673	300.5	60911.5	2315649	10.000
7-aminoclonazepam	3.370	957314	282.6	1037.9	3690196	10.000
7-aminoflunitrazepam	3.599	1639059	1771.8	252.0	3690196	10.000
9-Hydroxyrisperidone	4.173	6815004	433.4	146.5	3690196	10.000
Acetyl Fentanyl	4.363	510268	287.5	146.5	41233259	10.000
Acetyl Norfentanyl	2.718	597642	1749.8	472.5	41233259	10.000
a-hydroxyalprazolam	4.393	464103	567.0	19946.8	3690196	10.000
alpha-hydroxymidazolam	4.484	3508520	363.7	8528.4	3690196	10.000
alpha-PHP	4.079	3360548	1166.7	432.9	13643591	10.000
alpha-PVP	3.789	4906221	1045.6	1417.7	13643591	10.000
Alprazolam	4.504	2485256	1345.9	600.8	20306296	10.000
Amitriptyline	4.646	1979187	419.7	685.5	10221947	10.000
Amphetamine	2.722	5321905	18310.0	571.0	13643591	10.000
Benzoylecgonine	3.138	267003	7997.8	29.7	536090	10.000
Brompheniramine	4.132	127707	47.3	32.1	53911204	10.000
Buprenorphine	5.273	143248	48498.8	1167.0	3870408	10.000
Bupropion	4.079	4384557	2384.5	721.1	18368159	10.000
Carbamazepine	4.080	6480221	∞	586.0	196250	10.000
Carisoprodol	4.062	1219274	1691.7	47.6	6684588	10.000
Chlordiazepoxide	4.628	1029424	687.3	191.5	20306296	10.000
Chlorpheniramine	4.014	6919098	7742.9	177.7	53911204	10.000
Chlorpromazine	4.960	3591523	3380.1	4056.6	16923488	10.000
Citalopram	4.085	3159283	6110.3	7465.1	53911204	10.000
Clomimpramine	4.900	3833756	2268.4	508.0	11076663	10.000
Clonazepam	4.302	1256522	353.7	283.9	20306296	10.000
Clonazolam	4.221	1482311	2913.4	203761.1	20306296	10.000
clozapine	4.715	5902052	8297.7	6750.1	24779244	10.000
Cocaethylene	3.886	4719943	963.9	7030.8	53911204	10.000
Cocaine	3.703	5756460	11510.0	340.2	33126592	10.000
Codeine	3.168	687871	660.3	1219.6	8189070	10.000
Cyclobenzaprine	4.508	4090627	491.6	175.9	10221947	10.000
Desipramine	4.385	6118502	3105720.6	2432.8	10221947	10.000
Dextromethorphan	4.200	2586882	313.0	4522.9	14192751	10.000

AM #25 Multi-Drug Screen Results

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextrorphan	3.358	2695807	683.1	3440.9	14192751	10.000
Diazepam	4.751	1271950	477.2	476.0	20306296	10.000
Dihydrocodeine	2.862	1732432	416.3	297.9	4014509	10.000
Diphenhydramine	4.108	9800279	874.7	448.9	53911204	10.000
Doxepin	4.322	2613933	396.8	200.7	31316080	10.000
Doxylamine	3.631	9906634	∞	∞	4296188	10.000
Duloxetine	4.351	836342	1002.3	37533.5	25607821	10.000
EDDP	4.045	1794178	461.0	2917.9	4014509	10.000
Estazolam	4.398	4997526	1226.7	869.9	20306296	10.000
Etizolam	4.515	252486	119563.7	777.2	20306296	10.000
Fentanyl	4.577	397261	99.3	68.2	26738209	10.000
Flualprazolam	4.362	807644	262.5	512.2	20306296	10.000
Flunitrazepam	4.442	2050176	1148.6	1358.7	20306296	10.000
Fluoxetine	4.303	3512474	525.2	704.8	7204977	10.000
Flurazepam	4.590	3801523	1047028.0	414202.6	20306296	10.000
Hydrocodone	3.444	1728777	233.2	81.6	8189070	10.000
Hydromorphone	2.743	2220577	235.7	318.3	534655	10.000
hydroxyzine	4.805	5302175	1417.6	2425.2	14192751	10.000
Imipramine	4.568	6807682	737.9	782.4	10221947	10.000
Ketamine	4.080	3137437	1596.2	113.9	25607821	10.000
Lamotrigine	3.450	287943	758.8	373.2	53911204	10.000
Levamisole	3.285	2520769	584.7	215.6	14192751	10.000
Levetireacetam	2.325	1356729	990.2	510.0	11076663	10.000
Lorazepam	4.301	425739	∞	123.4	20306296	10.000
Maprotiline	4.645	1057005	672.8	85.3	10221947	10.000
MDA	2.841	3313697	520.2	80.1	35420909	10.000
MDEA	3.115	4801066	602.5	372.9	35420909	10.000
MDMA	2.963	6059839	28156.7	238.4	35420909	10.000
Meperidine	3.771	3023518	175.4	413.1	14192751	10.000
Meprobamate	3.453	670363	935.1	43.8	6684588	10.000
Methadone	4.411	6398351	5022.8	519.2	4014509	10.000
Methamphetamine	2.858	9598594	∞	4909.9	35420909	10.000
Methocarbamol	3.343	301400	90.2	347.6	4014509	10.000
Methylphenidate	3.543	10241016	3188.4	1784.3	25607821	10.000
Metoprolol	3.326	836989	708.9	4444.0	14192751	10.000
Midazolam	4.685	785169	3776.4	5242.0	20306296	10.000
Mirtazapine	4.601	3777000	1405.8	2517.6	14192751	10.000
Mitragynine	4.574	596053	179821.2	1136911.2	14192751	10.000
Morphine	2.471	486068	117.0	2472.1	534655	10.000
Norbuprenorphine	3.851	112533	45469.4	34850.1	534655	10.000
Nordiazepam	4.585	1106975	769.4	1473.1	20306296	10.000
Norfentanyl	3.206	8747613	892.6	1083.5	41233259	10.000
Norhydrocodone	2.834	112801	134.0	57.2	8189070	10.000
norketamine	4.004	689191	453.2	1732.4	25607821	10.000
Normeperidine	3.513	3047294	1728.5	1120.7	53911204	10.000
Noroxycodone	2.726	2737780	50.8	616.4	15913170	10.000
Nortriptyline	4.448	2358413	663002.5	987.8	10221947	10.000
O-desmethyl-tramadol	2.746	9302936	2372.6	159.9	53911204	10.000
o-Desmethylvenlafaxine	3.095	2306823	367.7	∞	11076663	10.000
Olanzapine	4.179	1824199	1706.0	785.8	196250	10.000
Oxazepam	4.383	1742276	357.7	172.7	7261734	10.000
Oxycodone	3.044	3417023	395.6	32.6	15913170	10.000
Oxymorphone	2.346	2374961	110.3	6531.0	534655	10.000
Paroxetine	4.377	503289	263.6	7483.5	7204977	10.000
Phenazepam	4.515	1848224	668.2	411580.0	20306296	10.000
Phencyclidine	3.910	5217263	9932.9	∞	14192751	10.000
Phentermine	2.995	71725	∞	∞	25607821	10.000
Phenytoin	3.955	319925	317.2	419.6	196250	10.000
primidone	3.237	1294884	1600.2	94.7	10221947	10.000

AM #25 Multi-Drug Screen Results

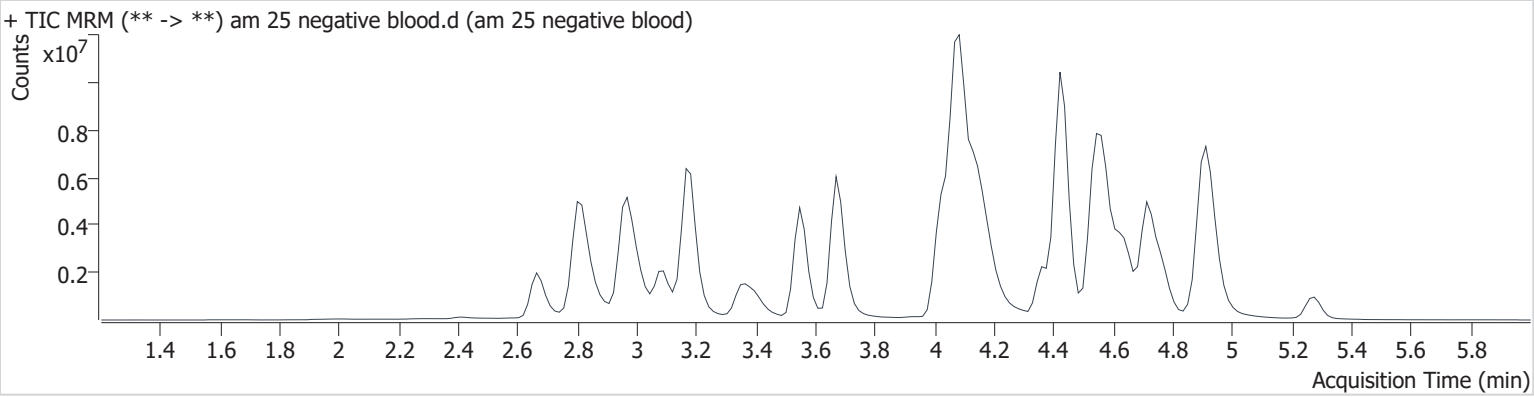
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Promethazine	4.690	8857032	546.4	457.1	53911204	10.000
Pseudoephedrine	2.507	71538108	11399.2	725.4	35420909	10.000
Quetiapine	4.758	6165596	2525.7	1422.0	43786218	10.000
Risperidone	4.451	7476894	2801.8	321.4	9621626	10.000
Sertraline	4.658	1352468	∞	1047.5	7204977	10.000
Sufentanil	4.971	445483	1934.9	1720.2	41233259	10.000
Tapentadol	3.345	4783569	3082.6	587.0	4014509	10.000
Temazepam	4.551	3574531	1050.3	208.9	20306296	10.000
Topiramate	3.653	69072	24715.5	16498.2	366084	10.000
Tramadol	3.372	7311046	2537.7	107.8	53911204	10.000
Trazodone	4.927	6637563	2743.7	283.8	31316080	10.000
Venlafaxine	3.767	6730105	16214.5	∞	7204977	10.000
Zaleplon	4.212	2032765	4428.2	973.8	43786218	10.000
Zolpidem	4.443	9180327	7351.7	3190.7	43786218	10.000
Zopiclone	4.451	748027	15760.8	13810.0	4296188	10.000

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\mds.batch.bin
Calibration Last Update 5/24/2022 3:07:18 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	5/24/2022 12:12:19 PM		
Sample Info.			

Sample Chromatogram



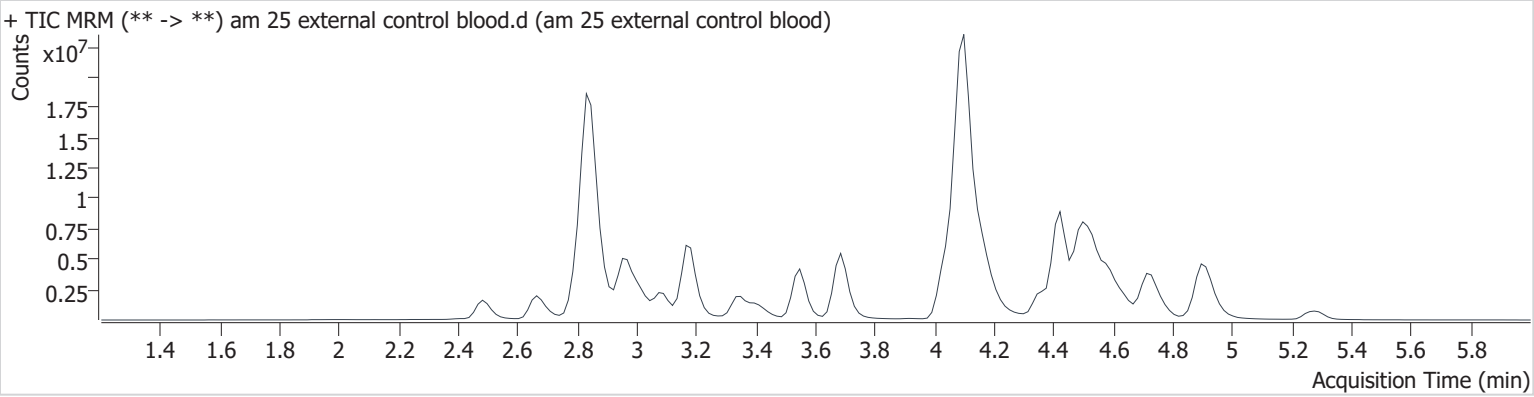
AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\mds.batch.bin
Calibration Last Update 5/24/2022 3:07:18 PM

Instrument 69679
Type Sample
Acq. Method mds713.m
Sample Position P2-F2
Injection Volume 2.5
Acq. Date-Time 5/24/2022 1:33:14 PM
Sample Info.

Data File am 25 external control blood.d
Sample am 25 external control blood
Operator Anne Nord
Comment

Sample Chromatogram



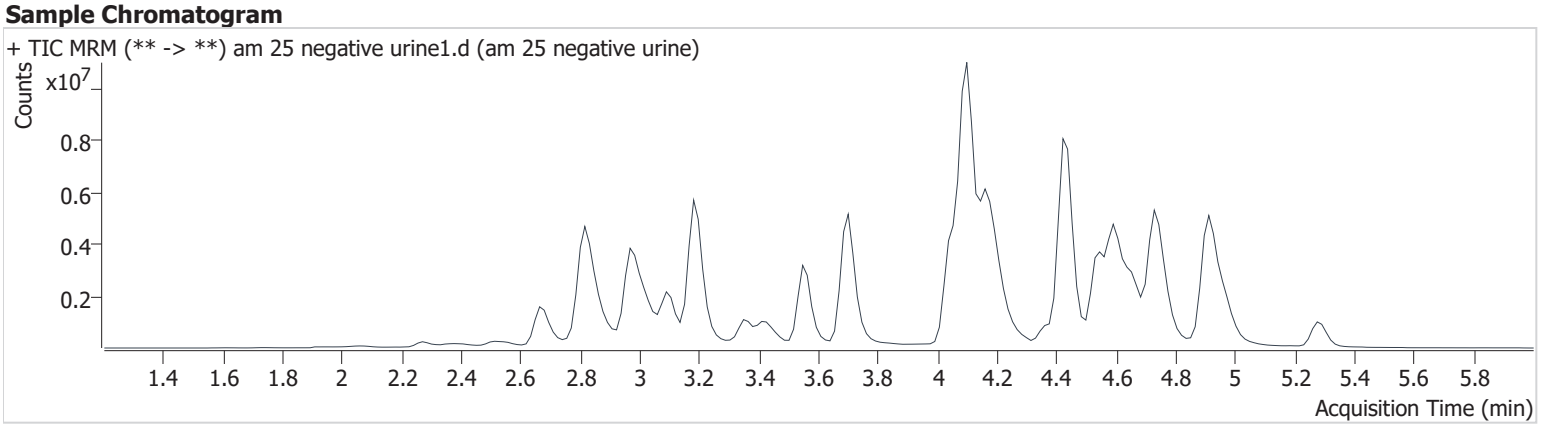
Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.489	12450402	745.8	1885.8	16359292	62.184
Diphenhydramine	4.108	39550768	45870.8	749.2	38633419	56.316
Methamphetamine	2.858	31186539	∞	∞	17202616	66.900
Methocarbamol	3.343	1921834	10867.6	2694.1	2426583	105.490
Morphine	2.486	1808846	8835.5	2868.0	221747	89.726

AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\mds.batch.bin
Calibration Last Update 5/24/2022 3:07:18 PM

Instrument	69679	**Data File**	am 25 negative urine1.d
Type	Sample	**Sample**	am 25 negative urine
Acq. Method	mds713.m	**Operator**	Anne Nord
Sample Position	P2-H11	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	5/24/2022 2:40:19 PM		
Sample Info.			

Sample Chromatogram

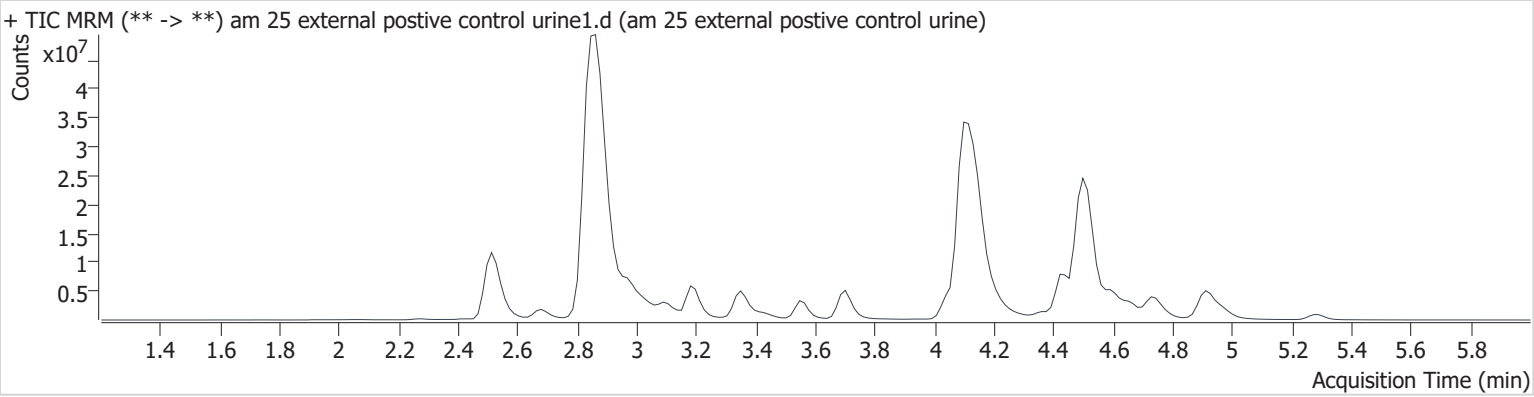


AM #25 Multi-Drug Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\mds.batch.bin
Calibration Last Update 5/24/2022 3:07:18 PM

Instrument	69679	**Data File**	am 25 external postive control urine1.d
Type	Sample	**Sample**	am 25 external postive control urine
Acq. Method	mds713.m	**Operator**	Anne Nord
Sample Position	P2-G11	**Comment**	
Injection Volume	2.5		
Acq. Date-Time	5/24/2022 2:47:05 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Alprazolam	4.504	49395629	1783.9	1777.6	9988901	404.046
Diphenhydramine	4.124	90530990	19081.8	49231.8	29944395	166.312
Methamphetamine	2.873	91112621	∞	∞	13240632	253.935
Methocarbamol	3.359	7367132	6967.6	993.1	2666950	367.936
Morphine	2.517	14294993	∞	5368.3	298284	527.146

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

Extraction Date: 5/24/22 Analyst: Anne Nord

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

Mobile phase A: 10mM Ammonium Formate 0.1% Formic Acid in Water **Mobile phase B:** 0.1% Formic acid in MeOH MTBE Hexane
Blank Blood Lot: 22B52020 **Urine Blank:** 21522 **Column**: Phenomenex Phenyl Hexyl (4.6x50mm: 2.6 um)
LCMS-QQQ ID: 69679

Pre-Analytic:

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

Analytic:

☒ 1. Remove standards, plate, controls, and samples from cold storage. Allow to reach room temperature.
☒ 2. Urine hydrolysis: add 1.5 ml urine to blank plate, add 250 ul 1N KOH mix and incubate at 40 degrees for 15 minutes.
Pipette **1000 µL blood (calibrated pipette)** in wells of analytical (standards) plate. **Pipette ID: K52558g**
Pipette 1000 ul urine to analytical (standards) plate.
☒ 3. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
☒ 4. Pipette **500 µL 0.1% formic acid in blood** wells **500 ul saturated phosphate buffer in urine** wells of analytical plate.
☒ 5. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
☒ 6. Transfer 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: *Curve limits THC-OH 3-100*

	1	2	3	4	5	6
a	cal 1	Internal urine	1075-1	1155-1		
b	cal 2	negative blood	1084-1			
c	cal 3	1024-1	1122-1			
d	cal 4	1038-1	1151-1			
e	Cal 5	1040-1	negative urine			
f	cal 6	1041-1	0949-1			
g	cal 7	1061-1	0995-1			
h	Internal control (blood)	1069-1	1002-1			

c2022-____-_

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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

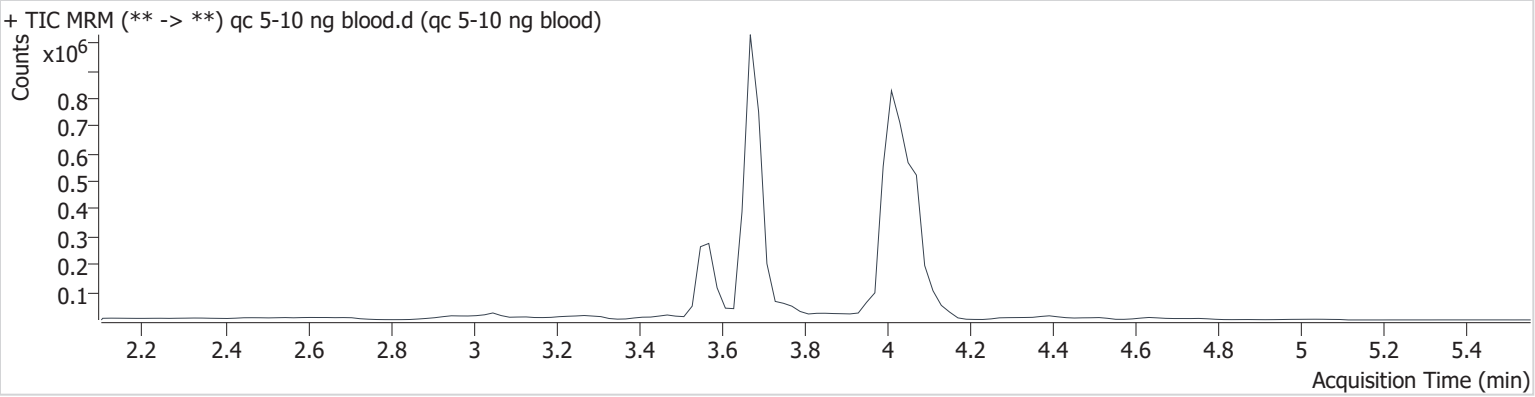
AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	qc 5-10 ng blood.d
Type	QC	**Sample**	qc 5-10 ng blood
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-H1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 4:07:11 PM		
Sample Info.			

concentrations 5ng for THC and THC-OH, 15 ng for THC-COOH

Sample Chromatogram



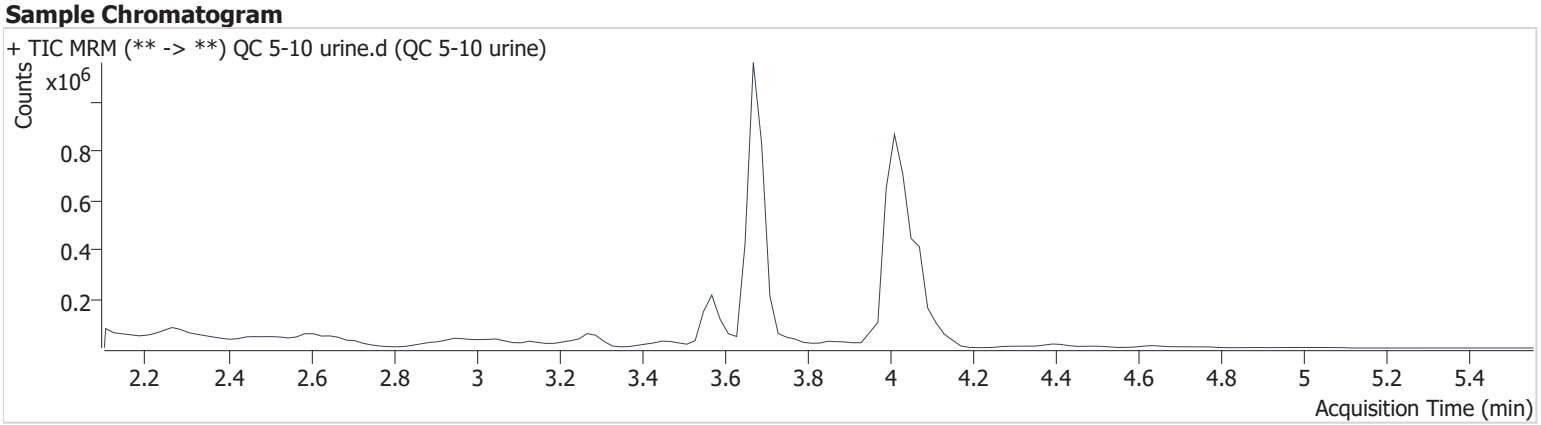
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	33345	886325	4.770 ng/ml
THC-COOH	3.569	173880	639695	15.822 ng/ml
THC-OH	3.679	21223	2844531	4.953 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

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	5/24/2022 4:13:47 PM		
Sample Info.	Concentrations 5 ng for THC and THC-OH, 15 ng for THC-COOH		

Sample Chromatogram



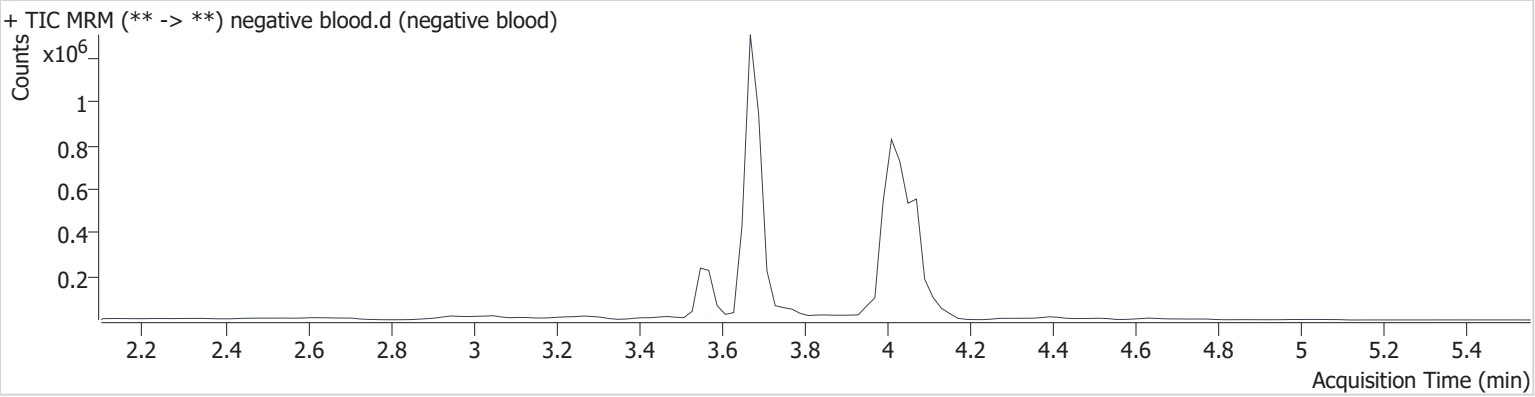
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	22634	603516	4.755 ng/ml
THC-COOH	3.569	114161	399589	16.605 ng/ml
THC-OH	3.679	22428	2982622	4.990 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	negative blood.d
Type	Sample	**Sample**	negative blood
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-B2	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 4:20:23 PM		
Sample Info.			

Sample Chromatogram

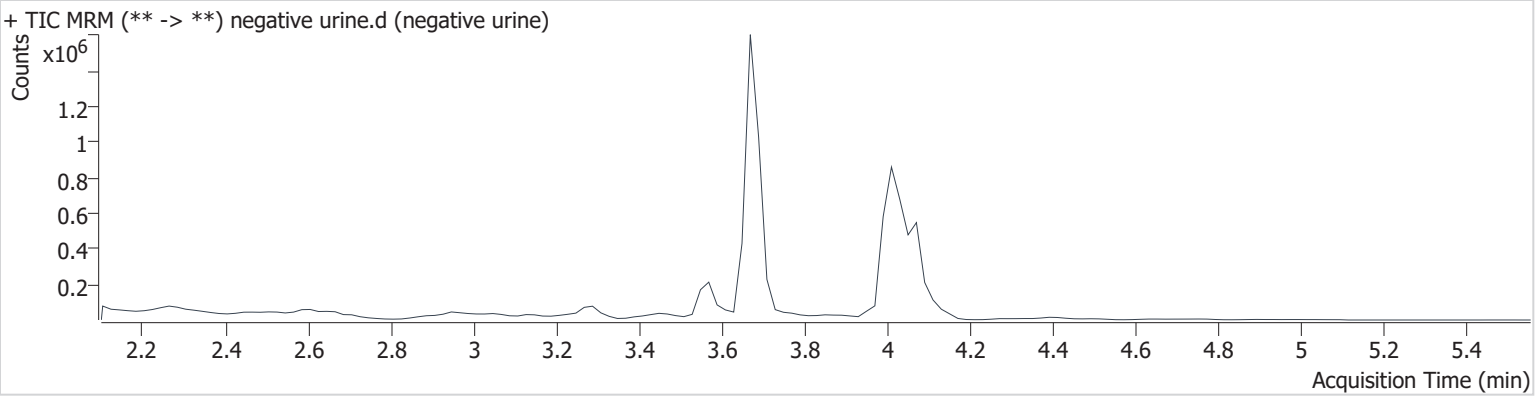


AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

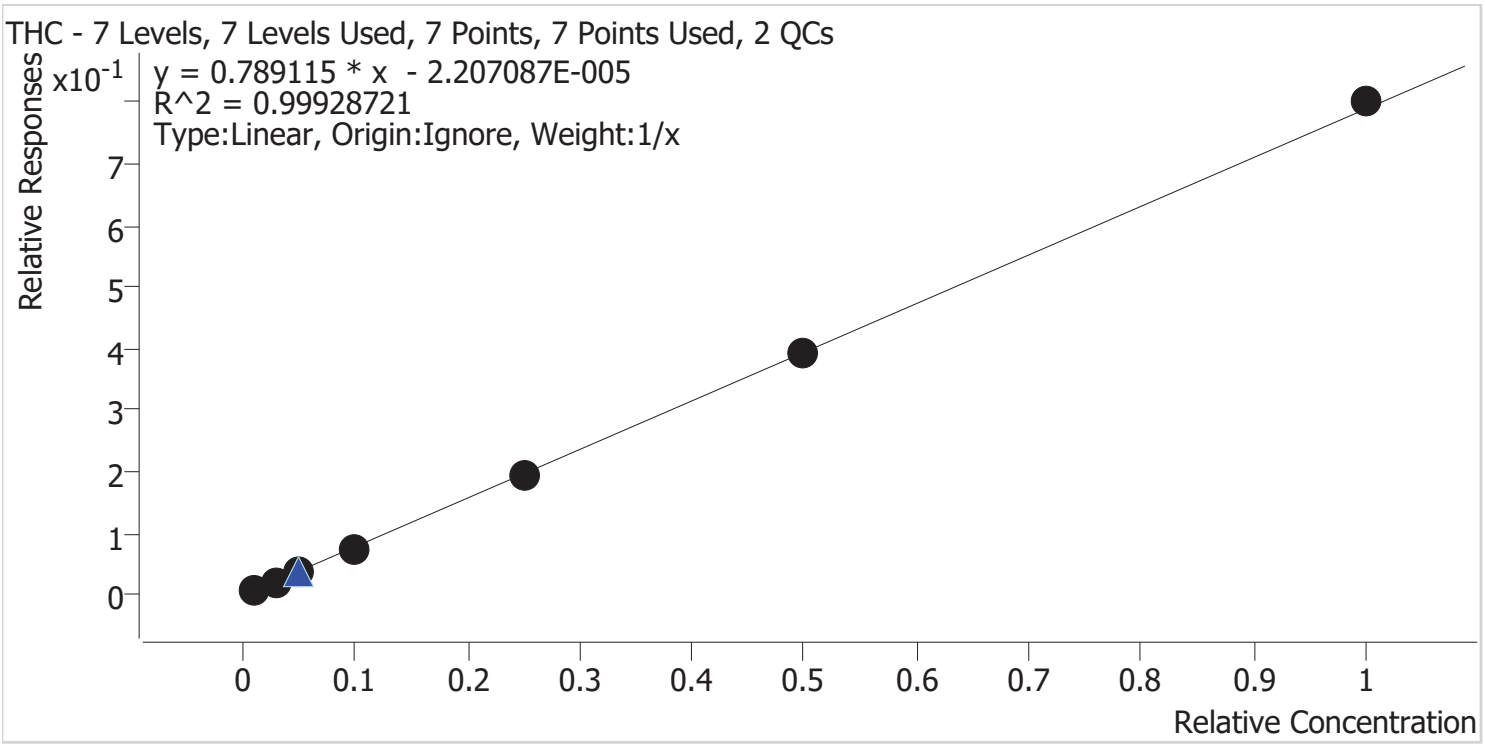
Instrument	69679	**Data File**	negative urine.d
Type	Sample	**Sample**	negative urine
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-E3	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 5:34:22 PM		
Sample Info.			

Sample Chromatogram



Compound Calibration Report

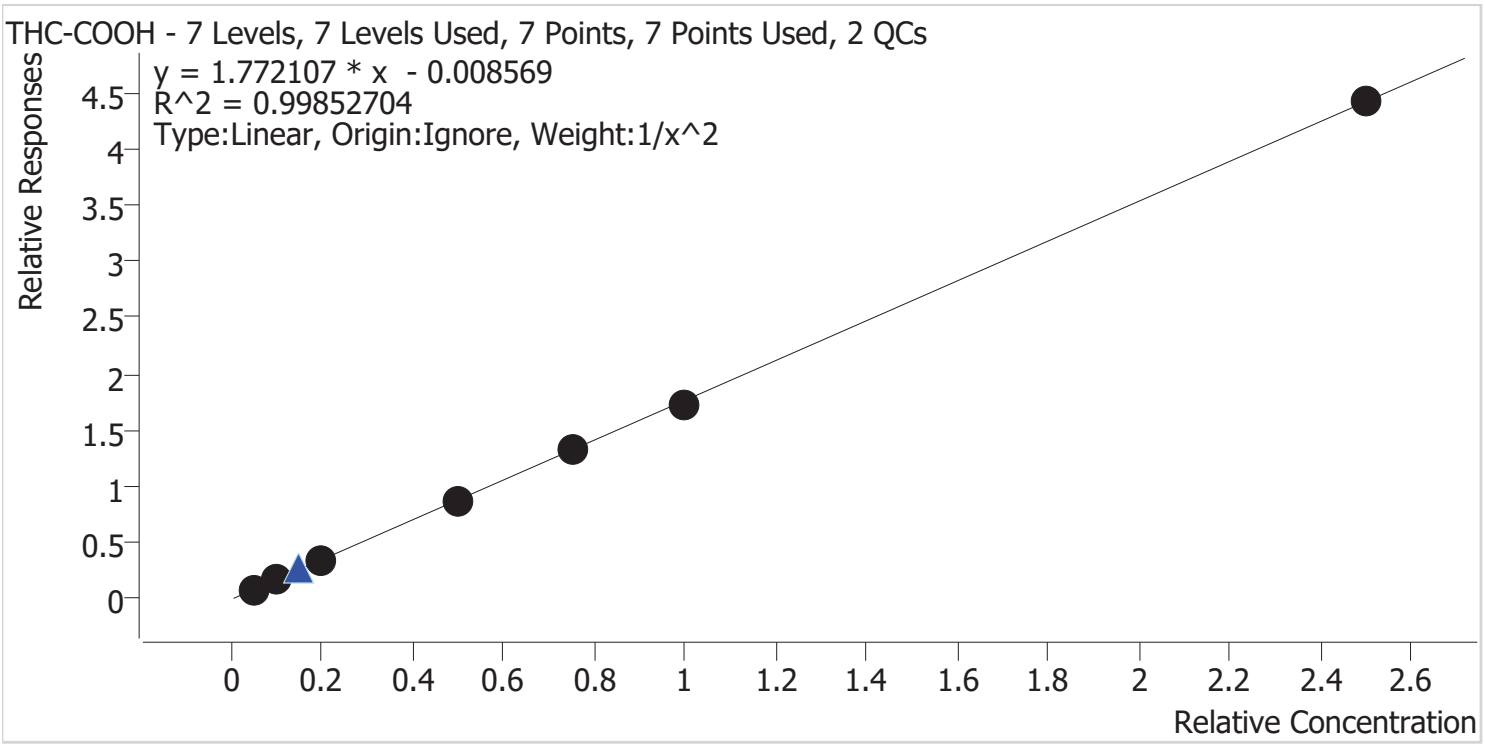
Batch results	D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Last Cal. Update	5/25/2022 7:52 AM
Analyst Name	ISP\datastor
Analyte	THC
Internal Standard	THC-d3



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	1.0	1.2	117.4
cal 2	2	✓	3.0	2.8	94.5
cal 3	3	✓	5.0	4.7	94.2
cal 4	4	✓	10.0	9.4	94.1
cal 5	5	✓	25.0	24.7	98.9
cal-6	6	✓	50.0	49.6	99.3
cal-7	7	✓	100.0	101.5	101.5

Compound Calibration Report

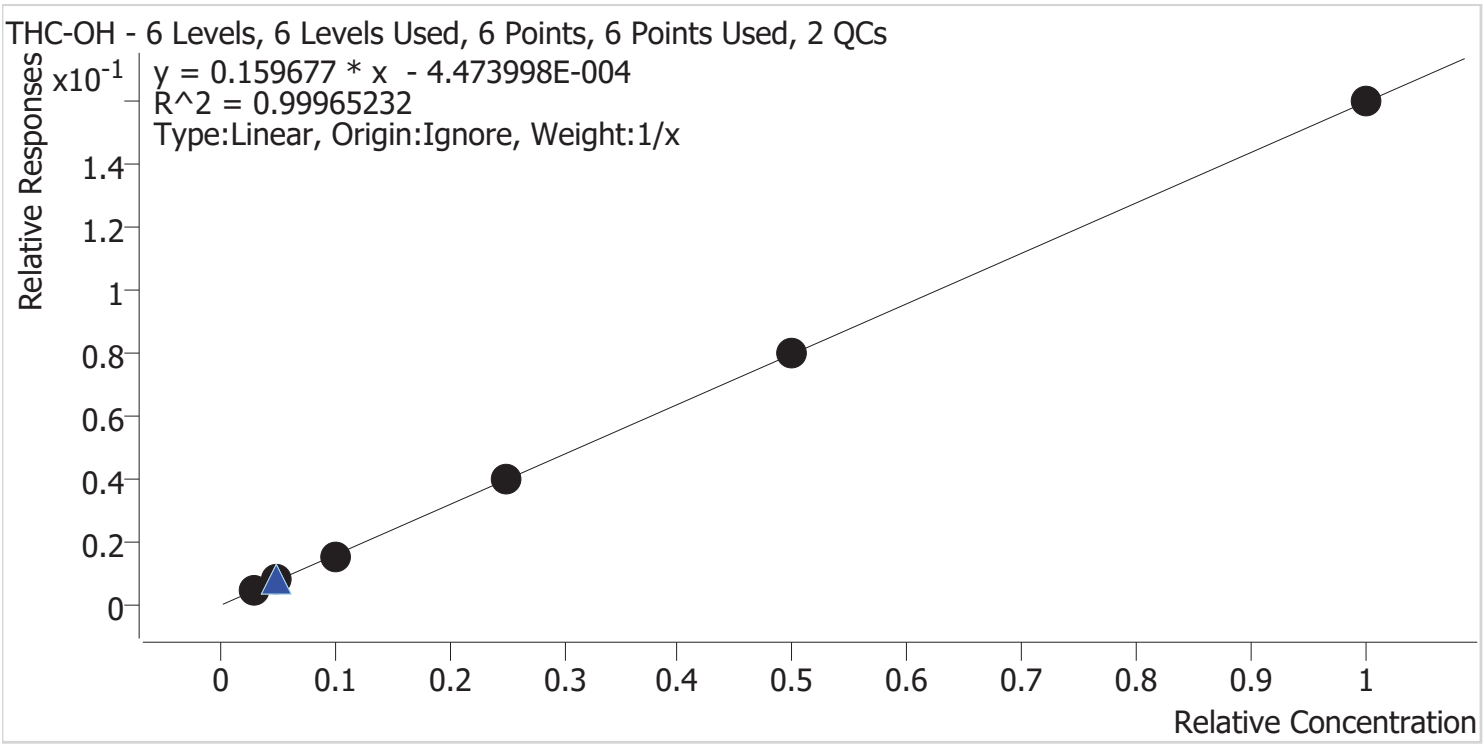
Batch results	D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Last Cal. Update	5/25/2022 7:52 AM
Analyst Name	ISP\datastor
Analyte	THC-COOH
Internal Standard	THC-COOH-d9



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 1	1	✓	5.0	4.8	97.0
cal 2	2	✓	10.0	10.7	106.6
cal 3	3	✓	20.0	20.0	100.0
cal 4	4	✓	50.0	49.0	98.0
cal 5	5	✓	75.0	75.0	100.0
cal-6	6	✓	100.0	98.5	98.5
cal-7	7	✓	250.0	250.0	100.0

Compound Calibration Report

Batch results	D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Last Cal. Update	5/25/2022 7:52 AM
Analyst Name	ISP\datastor
Analyte	THC-OH
Internal Standard	THC-OH-d3



Sample	Level	Enabled	Expected Concentration	Final Concentration	Accuracy
cal 2	2	✓	3.0	3.2	105.8
cal 3	3	✓	5.0	5.0	99.3
cal 4	4	✓	10.0	9.4	94.1
cal 5	5	✓	25.0	25.0	99.9
cal-6	6	✓	50.0	50.4	100.8
cal-7	7	✓	100.0	100.1	100.1

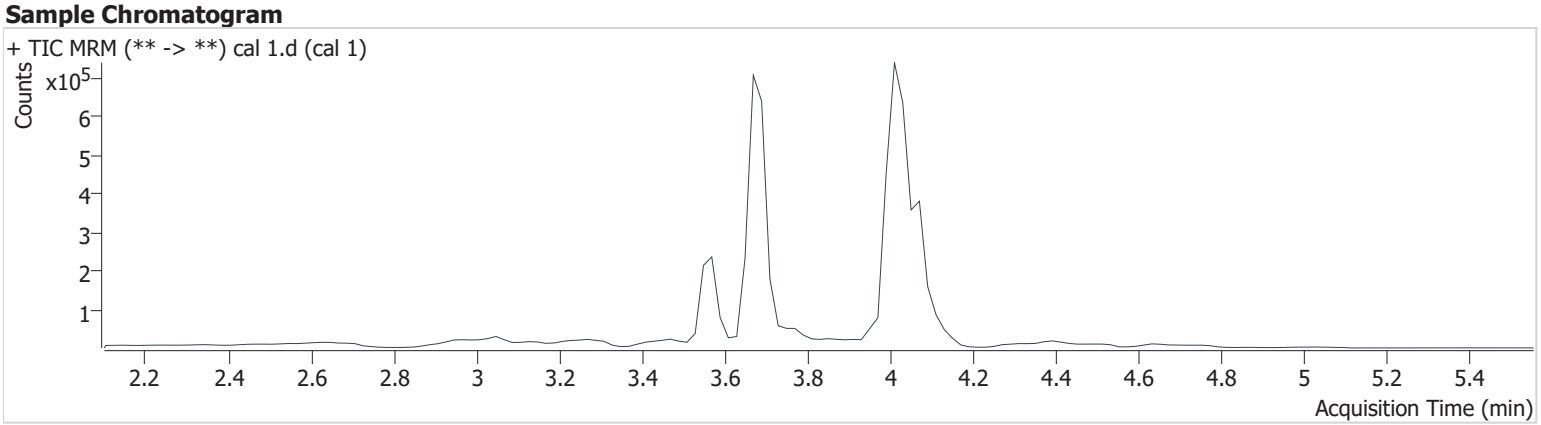
dropped cal 1 due to poor response and chromatography.

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	cal 1.d
Type	Cal	**Sample**	cal 1
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-A1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 3:20:57 PM		
Sample Info.			

Sample Chromatogram



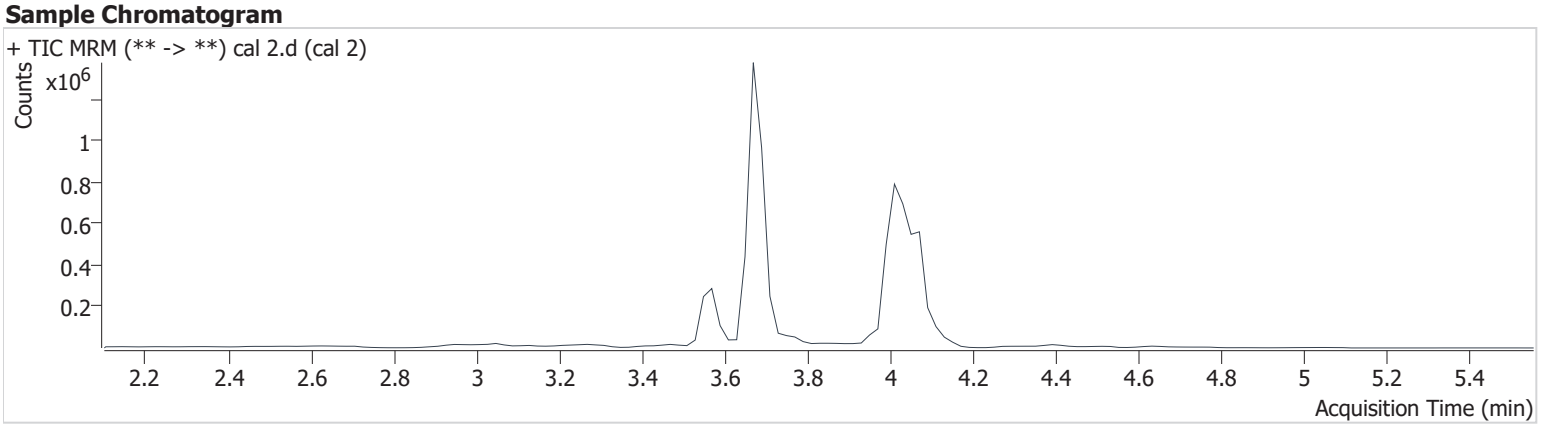
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	5896	637893	1.174 ng/ml **Low**
THC-COOH	3.569	46364	599408	4.848 ng/ml **Low**

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 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	5/24/2022 3:27:35 PM		
Sample Info.			

Sample Chromatogram



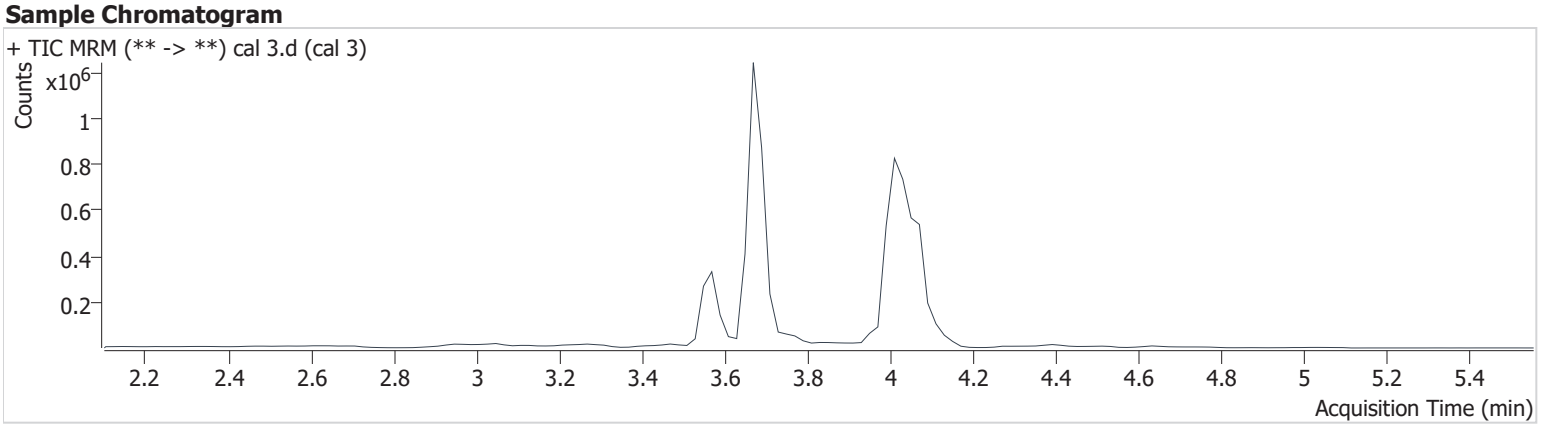
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	21416	957841	2.836 ng/ml **Low**
THC-COOH	3.569	123669	685543	10.663 ng/ml
THC-OH	3.679	17024	3682765	3.175 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	cal 3.d
Type	Cal	**Sample**	cal 3
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-C1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 3:34:11 PM		
Sample Info.			

Sample Chromatogram



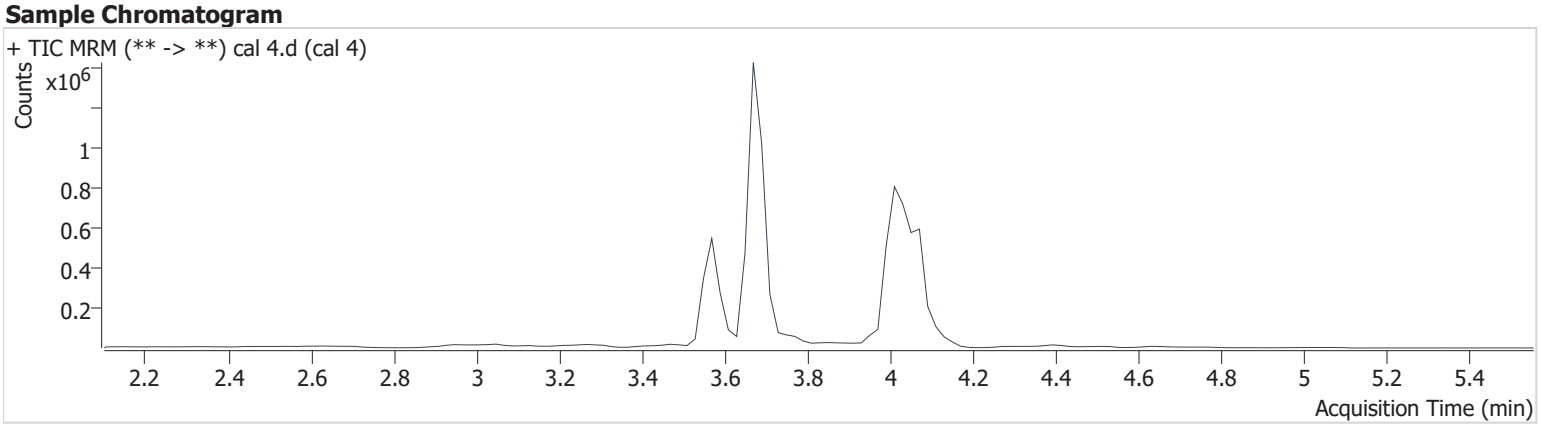
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	33050	889607	4.711 ng/ml
THC-COOH	3.569	229333	663240	19.996 ng/ml
THC-OH	3.679	24599	3288981	4.964 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	cal 4.d
Type	Cal	**Sample**	cal 4
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-D1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 3:40:47 PM		
Sample Info.			

Sample Chromatogram



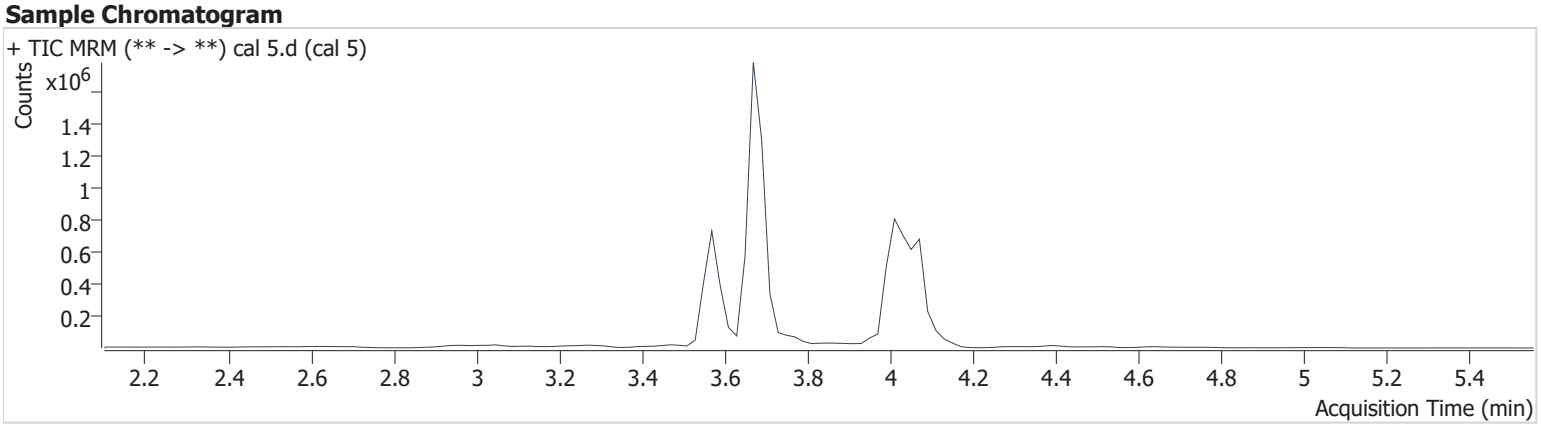
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	72051	970406	9.412 ng/ml
THC-COOH	3.569	581090	675782	49.006 ng/ml
THC-OH	3.679	51635	3543603	9.406 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	cal 5.d
Type	Cal	**Sample**	cal 5
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-E1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 3:47:23 PM		
Sample Info.			

Sample Chromatogram



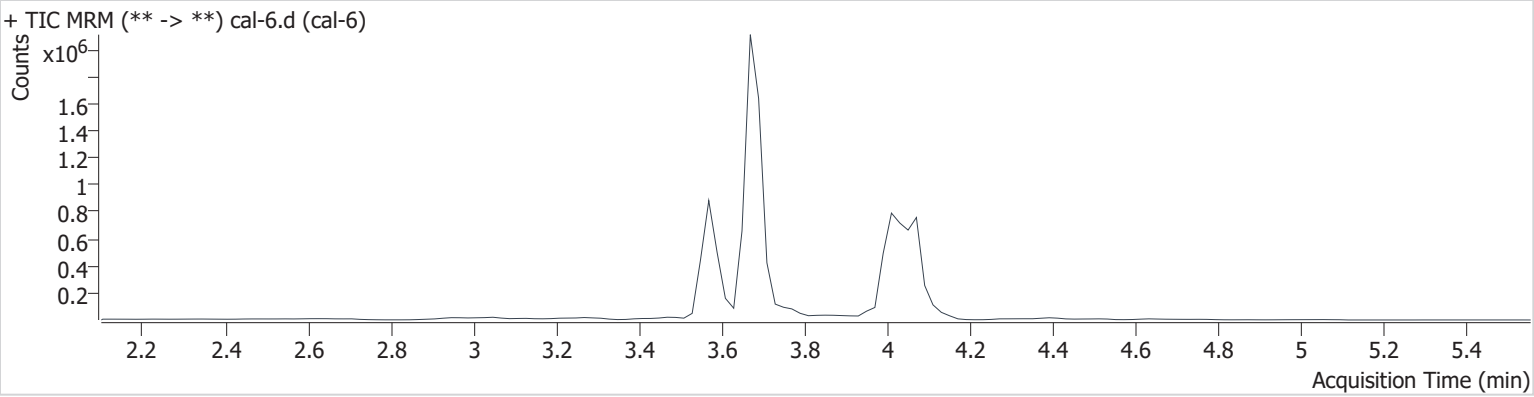
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	196148	1005031	24.735 ng/ml
THC-COOH	3.569	898898	681046	74.964 ng/ml
THC-OH	3.679	146382	3711035	24.983 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 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	5/24/2022 3:53:59 PM		
Sample Info.			

Sample Chromatogram



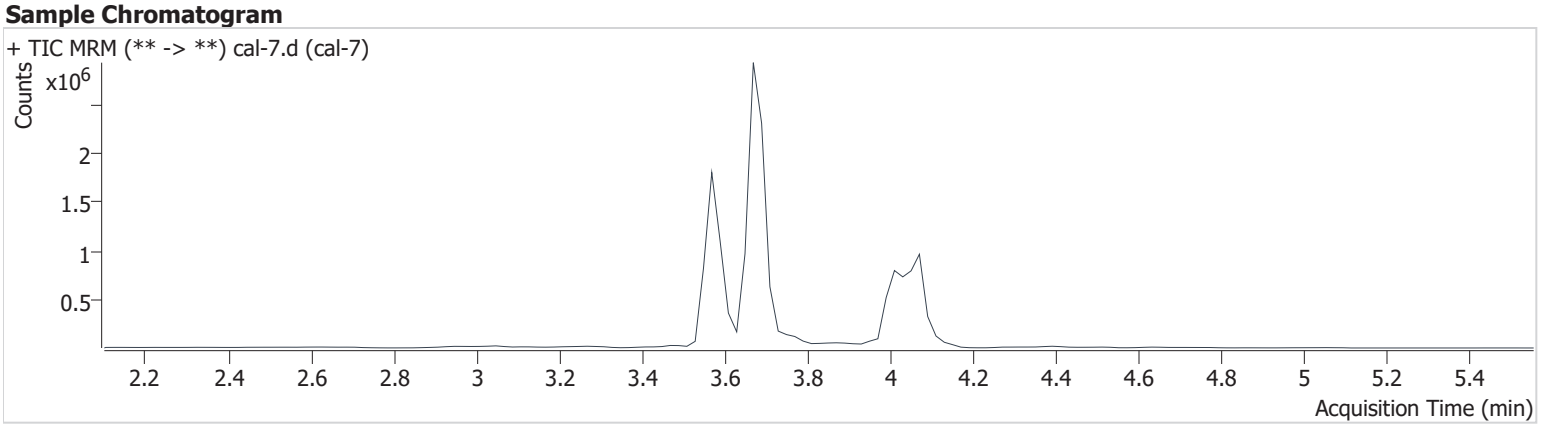
Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	375065	957375	49.649 ng/ml
THC-COOH	3.569	1160382	668257	98.470 ng/ml
THC-OH	3.679	284795	3557485	50.416 ng/ml

AM #26 Cannabinoids Screen Results

Batch results D:\MassHunter\Data\2022\am 25-26\052422\QuantResults\cann.batch.bin
Calibration Last Update 5/25/2022 7:52:13 AM

Instrument	69679	**Data File**	cal-7.d
Type	Cal	**Sample**	cal-7
Acq. Method	am 26 cann scr 5-5-20.m	**Operator**	Anne Nord
Sample Position	P3-G1	**Comment**	
Injection Volume	5		
Acq. Date-Time	5/24/2022 4:00:35 PM		
Sample Info.			

Sample Chromatogram



Name	RT	Resp.	ISTD Resp.	Final Conc.
THC	4.084	778219	971804	101.483 ng/ml
THC-COOH	3.569	2858617	646593	249.963 ng/ml
THC-OH	3.679	559762	3513478	100.056 ng/ml