

11/30/2023

Worklist: 6585

REVIEWED By Britany Wylie at 8:39 pm, Dec 02, 2023

LAB CASE	ITEM	ITEM TYPE	DESCRIPTION		,,,,,,,,
C2023-2309	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2470	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by I	C-QQQ	
C2023-2473	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by I	C-QQQ	
C2023-2475	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2488	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2489	1	ВСК	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2498	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2514	1	ВСК	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2538	1	ВСК	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2580	2	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by I	C-QQQ	
C2023-2582	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2586	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2605	1	UCK	AM 25/AM 26 Urine MultiDrug/THC Screen by I	C-QQQ	
C2023-2609	2	ВСК	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2628	1	BLOOD	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	
C2023-2655	1	BCK	AM 25/AM 26 Blood MultiDrug/THC Screen by	.C-QQQ	



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

Extraction Date: <u>11/28/23</u> Plate lot#: 230712 Analyst: <u>Anne Nord</u> Plate retest date: 1/12/2024

Mobile phase A:10mM Ammonium FormateMobile phase B:0.1% Formic Acid in MeOH0.5M Ammonium HydroxideEthyl AcetateLC 20% MethanolBlank Blood Lot:23J52629Blank Urine lot:8423Column: Agilent Phenyl Hexyl (4.6x50mm, 2.7um)LCMS-QQQ ID:69679

Pre-Analytic:

- \boxtimes 1. Check levels of mobile phases and needle wash refill as needed. Ensure waste is not full.
- \boxtimes 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.
- Z. 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: P31168J
- 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.
- S. Transfer **300 μL of blood or urine+base** mixture to corresponding wells of SLE+ plate.
- 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
- \boxtimes 7. Wait 5 minutes.
- \boxtimes 8. Add 900 µL ethyl acetate.
- \boxtimes 9. Wait 5 minutes.
- ☑ 10. Apply positive pressure for approx. 10-15 seconds. (12-15 PSI- Selector to the left).
- \boxtimes 11. Add **900 \muL ethyl acetate.**
- \boxtimes 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
- I5. Reconstitute in 100 μL 20% LC MeOH in LC Water and heat seal plate with foil. Place in autosampler and run worklist.

Post-Analytic

- \boxtimes 1. Open quantitation software and create a new quantitation batch.
- \boxtimes 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.
- \boxtimes 4. Did all QCs pass for each analyte? (If no is it described in comments?)
- S. Central File Packet to include: LIMS Worklist, Method Checklist, Calibration and Control Reports

COMMENTS: Mikel Buffaloe- hands of the analyst.

	1	2	3	4	5	6	7	8	9	10	11	12
A				2488-1	2628-1					2580-2		
В	cal 1			2489-1	2655-1					2605-1	2470-1	
С	internal urine control			2498-1	negative blood						2473-1	
D				2514-1	negative urine							
E					2538-1							internal urine control
F				2582-1	2309-1 SLE and injection plate							internal urine control
G			2309-1 mixing plate	2586-1								cal 1
н			2475-1	2609-2								cal 1

C2023-___-

plate position 2



Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\mds.batch.binCalibration Last Update11/29/2023 1:02:44 PM

Instrument	69679
Туре	Cal
Acq. Method	mds713.m
Sample Position	P2-B1
Injection Volume	2.5
Acq. Date-Time	11/28/2023 12:25:22 PM
Sample Info.	

Data File Sample Operator Comment am 25 cal a1.d am 25 cal b1 Anne Nord

Sample Chromatogram



Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
10-OH-Carbamazepine	3.882	406962	1795.0	44.1	474943	10.000
6-MAM	2.878	22991	20871.7	10592.3	888485	10.000
7-aminoclonazepam	3.602	142919	3345.5	1872.1	1108759	10.000
7-aminoflunitrazepam	3.833	451298	725.2	42611.0	1108759	10.000
9-Hydroxyrisperidone	3.948	2233655	2000609.3	44353.3	1108759	10.000
Acetyl Fentanyl	3.814	148446	28.0	19631.1	3469402	10.000
Acetyl Norfentanyl	2.902	101199	614.5	189.9	9243740	10.000
a-hydroxyalprazolam	4.705	50367	559186.6	13902.1	474943	10.000
alpha-hydroxymidazolam	4.658	526281	772.3	486.1	2673483	10.000
alpha-PHP	3.868	1389009	771.9	770.0	3416564	10.000
alpha-PVP	3.561	1611440	3662.5	5029.8	3416564	10.000
Alprazolam	4.784	740737	528.7	698.8	2673483	10.000
Amitriptyline	4.620	1012049	394.3	1385.9	3593533	10.000
Amphetamine	2.953	1062943	988.0	7914.1	3416564	10.000
Benzoylecgonine	3.478	20483	667.4	∞	76563	10.000
Bromazolam	4.871	251632	2053.6	6278.9	2673483	10.000
Brompheniramine	4.215	62432	12538.6	4036.9	4997079	10.000
Buprenorphine	4.132	2464	749.2	4603.1	1002149	10.000
Bupropion	3.837	1672888	1578.5	592.7	6986846	10.000
Carbamazepine	4.376	2808989	336.3	310.6	2433510	10.000
Carisoprodol	4.313	417932	291.4	118.5	2314681	10.000
Chlordiazepoxide	4.786	219756	2196.5	211.9	2673483	10.000
Chlorpheniramine	4.095	2845525	54119.0	28.6	4997079	10.000
Chlorpromazine	4.844	927391	3158.6	441508.2	3774723	10.000
Citalopram	4.260	1386720	205.0	894.0	30065096	10.000
Clomimpramine	4.859	1062871	810.7	3758.4	1986851	10.000
Clonazepam	4.645	110161	576.2	17721.1	24144	10.000
Clonazolam	4.534	145467	35974.6	23158.8	474943	10.000
clozapine	4.382	1598445	944972.3	434741.8	7289208	10.000
Cocaethylene	3.876	1621586	534447.0	190783.6	10604391	10.000
Cocaine	3.662	2083143	2869.2	1565.9	10604391	10.000
Codeine	2.729	138086	1505.5	4034.0	2433510	10.000
Cyclobenzaprine	4.542	1668261	2558.7	67.8	3593533	10.000
Desipramine	4.589	2516622	18823.6	1871.5	3593533	10.000

Generated at 1:03 PM on 11/29/2023

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Dextromethorphan	4.220	969043	173815.0	215978.7	4997079	10.000
Dextrorphan	3.450	1236995	768169.1	437.7	3416564	10.000
Diazepam	5.062	437767	295579.5	245003.4	2673483	10.000
Dihydrocodeine	2.697	428424	671.8	5098.4	2433510	10.000
Dimethyltriptamine	3.026	877571	∞	550.9	3416564	10.000
Diphenhydramine	4.175	5032482	1362.1	554.8	30065096	10.000
Doxepin	4.326	931866	251.4	35.8	7289208	10.000
Doxylamine	3.665	3383211	361.0	226.7	3416564	10.000
Duloxetine	4.540	54290	17821.3	166187.6	1986851	10.000
EDDP	4.218	126685	363.0	201.9	569225	10.000
Estazolam	4.710	1094183	681.2	726.8	2673483	10.000
Etizolam	4.765	54870	606.9	245438.1	2673483	10.000
Fentany	4.074	127244	99227.8	623.0	7916014	10.000
Flualprazolam	4.613	266055	43770.7	70862.1	2673483	10.000
Flunitrazepam	4.753	489079	220169.6	1335.5	474943	10.000
Fluorofentanyl	4.104	125943	73535.9	4668.2	7916014	10.000
Fluoxetine	4.523	1472754	561.3	111.0	1986851	10.000
Flurazenam	4 241	1285603	766.8	133137 3	1002149	10,000
Hydrocodone	2 973	397459	6672 5	232.6	2433510	10.000
Hydromorphone	2 367	420152	6315.1	571 7	86522	10.000
hydroxyzine	4 656	20132	631166 1	826255 5	7280208	10.000
Iminramine	4 587	22210/3	2244 7	674.3	3503533	10,000
Ketamine	3 406	1021603	3370.4	177.2	3680731	10.000
Lamotrigine	3 605	00522	172 5	262.8	3416564	10.000
Levamicole	2 019	708011	534105 5	202.0	10604301	10.000
Levallisole	2.910	175752	270.5	212.2	1108750	10.000
Levellacelan	Z.010	12207	2/9.0 EQ 0	JJ1.9	1100/33	10.000
Maprotilino	4 610	011/70	276702 0	22 <u>.</u> 0 200 2	2502522	10.000
Mon	2 007	0114/9	2/0/02.0	200.2	10167624	10.000
	2.00/	1011574	535.0 636.7	0.60C	10107034	10.000
	2 1/0	19113/4	1256220 2	/0/4.1	10107034	10.000
Monoridino	2.148	1040400	1200000	490.4	1010/034	10.000
Mependine	2.00/	910142	2200.J	113./	2214601	10.000
Methodono	2"\2T	1010/0	55970.4	120074.2	2314001	10.000
Methamphotomine	4.004	3042302	2000.C	1209/4.2	10167624	10.000
Methoasthamal	3.043	1297500	4990.6	400 1	1010/034	10.000
Methocarbamol	3.698	854/4	1060.0	480.1	2314681	10.000
Metnyiphenidate	3.606	3377595	3169.6	/5/./	59590/9	10.000
Mide la va	3.511	384017	/111.1	50154.2	3410504	10.000
Midazolam	4.4/5	24/160	/6545.9	81457.7	1108/59	10.000
Mirtazapine	3./2/	1021/50	2382.4	1803.0	1002149	10.000
Mitragynine	4.256	185934	253.1	268000.4	/916014	10.000
Morphine	2.186	92466	59.2	1488.6	86522	10.000
Norbuprenorphine	3.918	34031	14954.2	8184.0	1002149	10.000
Nordiazepam	4.911	133532	128.0	337.6	26/3483	10.000
Norfentanyl	3.391	19/1052	/69.8	355.0	9243740	10.000
Norhydrocodone	2.9/4	59376	337.4	394.4	2433510	10.000
norketamine	3.392	134/83	11/.4	405593.9	3680/31	10.000
Normeperidine	3.699	115382/	990.0	10/5.3	86522	10.000
Noroxycodone	2.942	3/8284	8	3/8.0	2433510	10.000
Nortriptyline	4.637	914913	796326.6	227.9	1986851	10.000
O-desmethyl-tramadol	2.931	2590547	4006.8	495.7	3469402	10.000
O-Desmethylvenlafaxine	3.327	782253	271.1	10377.8	3469402	10.000
Olanzapine	3.200	638385	122856.2	90816.1	1986851	10.000
Oxazepam	4.726	69283	92.9	23.9	474943	10.000
Oxycodone	2.925	783027	421.4	58424.3	3680731	10.000
Oxymorphone	2.273	503561	568.3	236.4	86522	10.000
Paroxetine	4.551	220117	1011.7	44537.2	1986851	10.000
Phenazepam	4.841	196641	∞	34548.5	2673483	10.000
Phencyclidine	4.022	2281021	740.5	418.2	3469402	10.000
Phentermine	3.227	480352	∞	130.2	5959079	10.000

am 25 cal b1

Generated at 1:03 PM on 11/29/2023

Name	RT	Resp.	S/N	S/N	ISTD Resp.	Calc. Conc.
Phenytoin	4.268	61905	12809.8	17.2	24144	10.000
primidone	3.531	55873	17386.7	183.3	24144	10.000
Promethazine	4.495	2771132	1698.4	576.0	3593533	10.000
Pseudoephedrine	2.738	34279782	2128.6	12264.0	5959079	10.000
Quetiapine	4.425	2217465	3367.0	4938.8	4997079	10.000
Risperidone	4.117	2450856	1805.6	63630.3	4997079	10.000
Sertraline	4.816	404692	3868.4	849.5	1986851	10.000
Sufentanil	4.348	99711	13147.0	360.7	7916014	10.000
Tapentadol	3.531	1926891	3856.4	458.3	3680731	10.000
Temazepam	4.877	626971	401.4	52.3	2673483	10.000
Topiramate	3.936	5148	906.0	1275.8	29612	10.000
Tramadol	3.496	5599392	∞	144.0	888485	10.000
Trazodone	4.211	1576828	656238.8	287677.0	7208171	10.000
Venlafaxine	3.926	2757946	1098081.0	893.1	3469402	10.000
Xylazine	3.408	126807	79 <u>.</u> 2	1409.1	3469402	10.000
Zaleplon	4.509	474079	215569.1	184312.2	474943	10.000
Zolpidem	3.816	2397641	650315.6	706.3	11377795	10.000
Zopiclone	3.919	214776	1452.0	8	1102207	10.000



Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\mds.batch.binCalibration Last Update11/29/2023 1:02:44 PM

Instrument	69679
Туре	Sample
Acq. Method	mds713.m
Sample Position	P2-C1
Injection Volume	2.5
Acq. Date-Time	11/28/2023 12:32:14 PM
Sample Info.	

Data File Sample Operator Comment am 25 internal control urine d1.d am 25 internal control urine c1 Anne Nord





D:\MassHunter\Data\2023\am 25-26\112823\QuantResults\mds.batch.bin **Batch results** Calibration Last Update 11/29/2023 1:02:44 PM data file name was not updated in the worklist the sample name is correct.

69679 Instrument Sample Туре Acq. Method mds713.m Sample Position P2-C5 **Injection Volume** 2.5 Acq. Date-Time 11/28/2023 12:38:57 PM Sample Info.

Data File Sample Operator Comment am 25 negative blood e1.d am 25 negative blood c5 Anne Nord



Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\mds.batch.binCalibration Last Update11/29/2023 1:02:44 PM

Instrument	69679
Туре	Sample
Acq. Method	mds713.m
Sample Position	P2-D5
Injection Volume	2.5
Acq. Date-Time	11/28/2023 2:06:10 PM
Sample Info.	

Data File Sample Operator Comment am 25 negative urine d3.d am 25 negative urine d3 Anne Nord

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

Extraction Date: <u>11/28/23</u> Analyst: <u>Anne Nord</u>

Plate lot#: 230627 Plate retest date: 12/27/2023

Mobile phase A:10mM Ammonium FormateMobile phase B:0.1% Formic acid in MeOH0.1% Formic Acid in WaterMTBEHexaneBlank Blood Lot:23J52629Urine Blank:8423Column:Agilent Phenyl Hexyl (4.6x50mm: 2.7 um)LCMS-QQQ ID:69679

Pre-Analytic:

- \boxtimes 1. Check levels of mobile phases and needle wash refill as needed. Ensure waste is not full.
- \boxtimes 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.
- In the second second

Pipette 1000 μL blood (calibrated pipette) in wells of analytical (standards) plate. Pipette ID: I41142J Pipette 1000 ul urine to analytical (standards) plate.

- \boxtimes 3. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
- A. Pipette 500 μL 0.1% formic acid in blood wells 500 ul saturated phosphate buffer in urine wells of analytical plate.
- \boxtimes 5. Place on shaking incubator at ambient temp., 900 rpm for 15 minutes.
- 8 6. Transfer 800 μL of blood acid or urine acid mixture to corresponding wells of SLE+ plate.
- 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
- \boxtimes 8. Wait 5 minutes.
- \boxtimes 9. Add 2.25 mL MTBE (add in 3 increments of 750 µL).
- \boxtimes 10. Wait 5 minutes.
- ☑ 11. Apply positive pressure for approx. 10-15 seconds. (12-15 PSI- Selector to the left).
- \boxtimes 12. Add **2.25 mL hexane** (add in 3 increments of 750 µL).
- \boxtimes 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
- 2 16. Reconstitute in 100 μL 100% LCMS MeOH and heat seal plate with foil. Place in autosampler and run worklist.

Post-Analytic

- \boxtimes 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.
- \boxtimes 3. Retention time within +/- 2% or +/-0.100 min whichever is greater of the average retention time of the calibrators.
- \boxtimes 4. Did all QCs pass for each analyte? Yes
- S. Central File Packet to include: LIMS Worklist, Method Checklist, Calibration and Control Reports

COMMENTS: Mikel Buffaloe hands of the analyst

	1	2	3	4	5	6
а	cal 1	Internal control urine	2538-1	2473-1		
b	cal 2	negative blood	2582-1	2580-2		
с	cal 3	2309-1	2586-1	2605-1		
d	cal 4	2475-1	2609-2			
e	cal 5	2488-1	2628-1			
f	cal 6	2489-1	2655-1			
g	cal 7	2498-1	negative urine			
h	Internal control (blood)	2514-1	2470-1			

Plate position 3

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Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	QC
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-H1
Injection Volume	5
Acq. Date-Time	11/28/2023 4:12:23 PM
Sample Info.	

Data File Sample Operator Comment qc 5-15 ng blood.d qc 5-15 ng blood Anne Nord

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Sample
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-A2
Injection Volume	5
Acq. Date-Time	11/28/2023 4:18:51 PM
Sample Info.	

Data File Sample Operator Comment QC 5-10 urine d QC 5-10 urine Anne Nord

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Sample
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-B2
Injection Volume	5
Acq. Date-Time	11/28/2023 4:25:19 PM
Sample Info.	

Data File Sample Operator Comment negative blood.d negative blood Anne Nord

Batch results D:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.bin Calibration Last Update 11/29/2023 8:58:54 AM data file name was not updated in the worklist the sample name is correct.

69679
Sample
am 26 cann scr 5-5-20
P3-G3
5
11/28/2023 5:49:27 P

D.m M

Data File Sample Operator Comment negative urine b4.d negative urine g3 Anne Nord

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Type	Sample
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-H1
Injection Volume	5
Acq. Date-Time	11/29/2023 8:44:41 AM
Acq. Date-Time Sample Info.	11/29/2023 8:44:41 AM

Data File Sample Operator Comment end of run blood control.d blood control Anne Nord

7

cal-7

100.6

100.0

100.6

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-A1
Injection Volume	5
Acq. Date-Time	11/28/2023 3:26:56 PM
Sample Info.	

Data File Sample r 5-5-20.m Operator Comment cal 1.d cal 1 Anne Nord

cal 2.d

Anne Nord

cal 2

AM #26 Cannabinoids Screen Results

Data File

Operator

Comment

Sample

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-B1
Injection Volume	5
Acq. Date-Time	11/28/2023 3:33:34 PM
Sample Info.	

cal 3.d

Anne Nord

cal 3

AM #26 Cannabinoids Screen Results

Data File

Operator

Comment

Sample

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-C1
Injection Volume	5
Acq. Date-Time	11/28/2023 3:40:02 PM
Sample Info.	

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

69679
Cal
am 26 cann scr 5-5-20.m
P3-D1
5
11/28/2023 3:46:30 PM

Data File Sample Operator Comment cal 4.d cal 4 Anne Nord

cal 5.d

Anne Nord

cal 5

AM #26 Cannabinoids Screen Results

Data File

Operator

Comment

Sample

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-E1
Injection Volume	5
Acq. Date-Time	11/28/2023 3:52:58 PM
Sample Info.	

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-F1
Injection Volume	5
Acq. Date-Time	11/28/2023 3:59:27 PM
Sample Info.	

Data File Sample Operator Comment cal-6.d cal-6 Anne Nord

cal-7.d

Anne Nord

cal-7

AM #26 Cannabinoids Screen Results

Data File

Operator

Comment

Sample

Batch resultsD:\MassHunter\Data\2023\am 25-26\112823\QuantResults\cann.batch.binCalibration Last Update11/29/2023 8:58:54 AM

Instrument	69679
Туре	Cal
Acq. Method	am 26 cann scr 5-5-20.m
Sample Position	P3-G1
Injection Volume	5
Acq. Date-Time	11/28/2023 4:05:55 PM
Sample Info.	

Request for Departure from an Analytical Method or Quality Standard

Deviation Number (assigned by QM): ISP Dev QUAL-23-02

Date of Request: 8/8/23

Requestor/Discipline: Anne Nord / Quality manual

<u>Analytical Method/Quality Standard, Revision #:</u> Quality manual Revision 9 16.2.5c.2.6 Training in the use and understanding of analytical methods shall include the analysis of training samples. The trainee may, under the direct observation of a competent analyst, handle case samples, but the trainer will make all conclusions and must be present and observe all aspects of the work (the trainee works as the hands of the trainer). All evidence in the "hands of the trainer" process will be checked out by the trainer and the chain of custody shall be maintained in the name of the trainer/trained analyst. Probative samples may be independently handled by the trainee if the evidence can be analyzed without changing it (e.g. comparison of latent prints or bullets). Examination reports shall be based solely on examinations performed by or directly observed by approved analysts. The report will be issued by the trainer/trained analyst. The analytical notes will clearly indicate the samples handled by the trainee. In the case of controlled substances, if an additional training sample is taken it will be stored in a secure locked location (either a drug locker or the controlled substance cabinet)

<u>Temporary or Permanent Deviation:</u> Permanent until the next version of the quality manual is released and analytical notes can be defined.

<u>Scope of Deviation</u> (record specific information, e.g. affected programs, evidence types, expected end date; etc): Documentation for hands of the trainer, in case records.

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

The quality manual currently requires that documentation that the trainee handled samples will be in the "analytical notes" the manual does not further define what is meant by analytical notes. I am requesting to document this in the case notes that are attached in ILIMS or if there is batch data associated with the analysis it may be documented in the central batch data.

<u>Technical Justification for Analytical Method Deviations</u>: The batch data and the notes packet are both part of the case record. They both provide a path to clear documentation of what the trainee handled or did.

Departure approved Comments:

Departure Not Approved Comments:

Approver: Title: Date:

Quality Review

Quality Approver: Corinna Owsley Title: Acting Quality Manager Date: 8-8-23