BLALC Volatiles QA_QC Data Spreadsheet-v5.xls

Quantitative Analysis for Ethanol & Qualitative Analysis for Other Volatiles

g/100cc g/100cc g/100cc g/100cc g/100cc g/100cc **Overall Results** acceptable 0.99972 L600HC11378 0.07990.2118 0.2154 0.07644/15/22 5784 Column2 Acceptable Range 0.0688-0.0840 0.1953-0.2387 FN07101701 Calibration Date: 4/15/22 Device: Hamilton MICROLAB Liquid Processor/Dilutor Serial Number: Run Date(s): Worklist #: 0.99953 Lot # **Target Value** 0.2170 0.0764 Analytical Method(s): 1.0 Column 1 Jul-22 1907006 1907007 Lot # **Volatiles Quality Assurance Controls** Exp: Expiration **Curve Fit:** Multi-Component mixture: Jul-23 Jul-23 **Control level** Level 2 Level 1

	Mean	0.0529	0.1005	0.1979	0.2951	#DIV/0!	0.5032					7
	Column 1 Column 2 Precision	0.0009	0	0.0008	0.0011	0	0.0008					
	Column 2	0.0525	0.1005	0.1983	0.2957		0.5028	(+) 20%	248994.8			
	Column 1	0.0534	0.1005	0.1975	0.2946		0.5036				Overall Results	g/100cc
	ange	5	0	0	0	0	0				Overal	0.079
	Acceptable Range	0.045 - 0.055	0.090 - 0.110	0.180 - 0.220	0.270 - 0.330	0.360 - 0.440	0.450 - 0.550	(-) 20%	165996.6		Acceptable Range	0.076 - 0.084
	A										Accept	0.07
Ethanol Calibration Reference Material	Target Value	0.050	0.100	0.200	0.300	0.400	0.500	Average	207495.7	Aqueous Controls	Target Value	0.080
Ethanol C	Calibrator level	50	100	200	300	400	500	Internal Standard	N-Propanol:		Control level	80

Revision: 4 Issue Date: 01/24/2022 Issuing Authority: Quality Manager

APPROVED By John Garner at 2:41 pm, Apr 18, 2022

REVIEWED By Galina Giso at 7:48 am, Apr 19, 2022

BLALC Volatiles QA_QC Data Spreadsheet-v5.xls

	Internal Standal	Internal Standard Monitoring Worksneet	
Worklist #:	5784	Run Date(s):	4/15/22
			「「「「「「「」」」」「「」」」」」」「「「」」」」」」」」」」」」」」

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77		Average	183152	182416.5	186915	190767.5	232036	208876	206573.5	210535	232292	241393.5	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Exp Date: 8/2/22		Column 2 Value	177861	177146	181580	185327	225024	202728	200384	204214	225059	233899				
Prep Date: 2/2/22		Column 1 Value	188443	187687	192250	196208	239048	215024	212763	216856	239525	248888				
Internal Standard Solution:		Sample Name	0.080A	0.080B	QC1-1A	QC1-1B	QC1-2A	QC1-2B	QC2-1A	QC2-1B	QC2-2A	QC2-2B	,			

Combined Average	(-)20%	(+)20%
207495.7	165996.6	248994.8

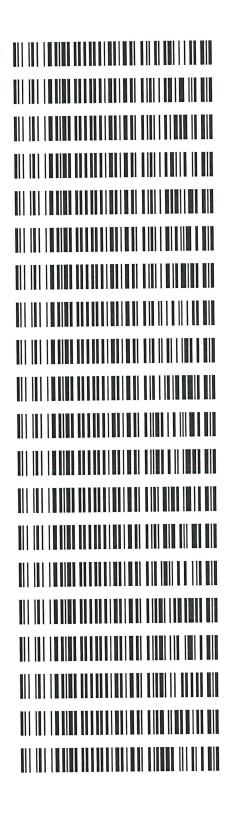
Revision: 4 Issue Date: 01/24/2022 Issuing Authority: Quality Manager R

BLALC Volatiles QA_QC Data Spreadsheet-v5.xls

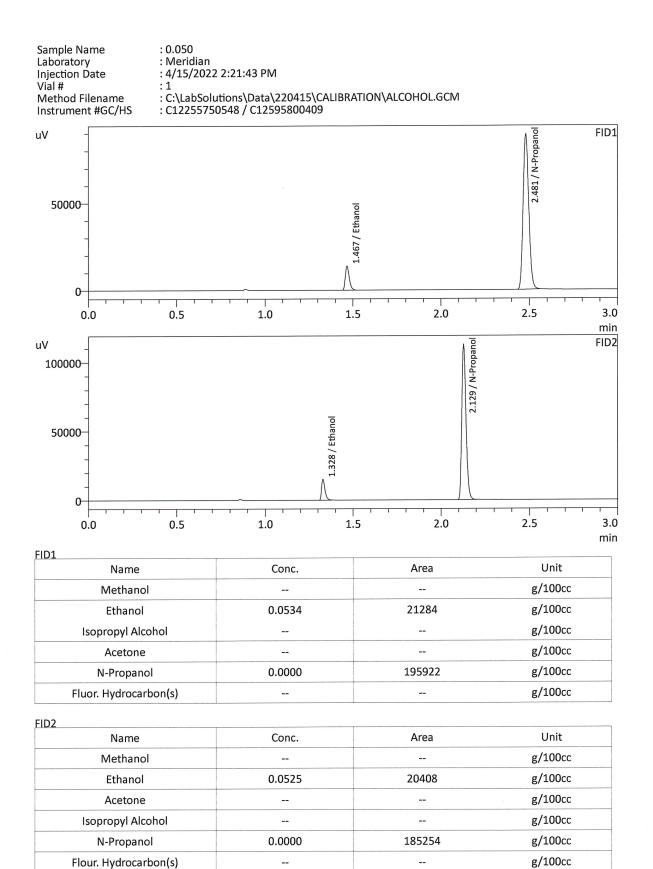
Page: 2 of 2

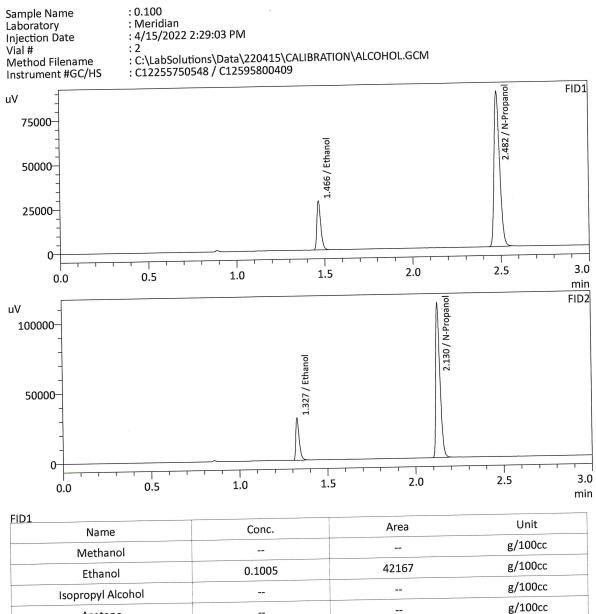
Worklist: 5784

LAB CASE	ITEM	ITEM TYPE	DESCRIPTION
M2022-1373	1	ВСК	Alcohol Analysis
M2022-1417	2	ВСК	Alcohol Analysis
M2022-1418	1	ВСК	Alcohol Analysis
M2022-1419	1	BCK	Alcohol Analysis
M2022-1420	. 1	BCK	Alcohol Analysis
M2022-1421	1	ВСК	Alcohol Analysis
M2022-1422	1	BCK	Alcohol Analysis
M2022-1436	1	BCK	Alcohol Analysis
M2022-1437	1	BCK	Alcohol Analysis
M2022-1447	2	BCK	Alcohol Analysis
M2022-1484	1	BCK	Alcohol Analysis
M2022-1485	1	BCK	Alcohol Analysis
M2022-1534	1	BCK	Alcohol Analysis
M2022-1535	1	BCK	Alcohol Analysis
M2022-1542	1	BCK	Alcohol Analysis
M2022-1547	1	BCK	Alcohol Analysis
M2022-1548	1	BCK	Alcohol Analysis
M2022-1549	1	BCK	Alcohol Analysis
M2022-1561	1	BCK	Alcohol Analysis
M2022-1578	8 1	BCK	Alcohol Analysis



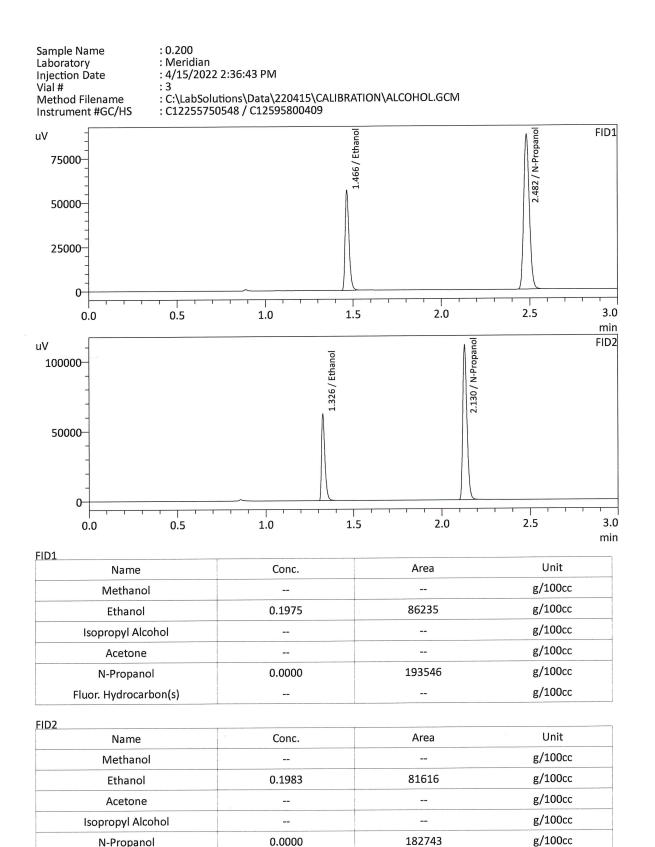
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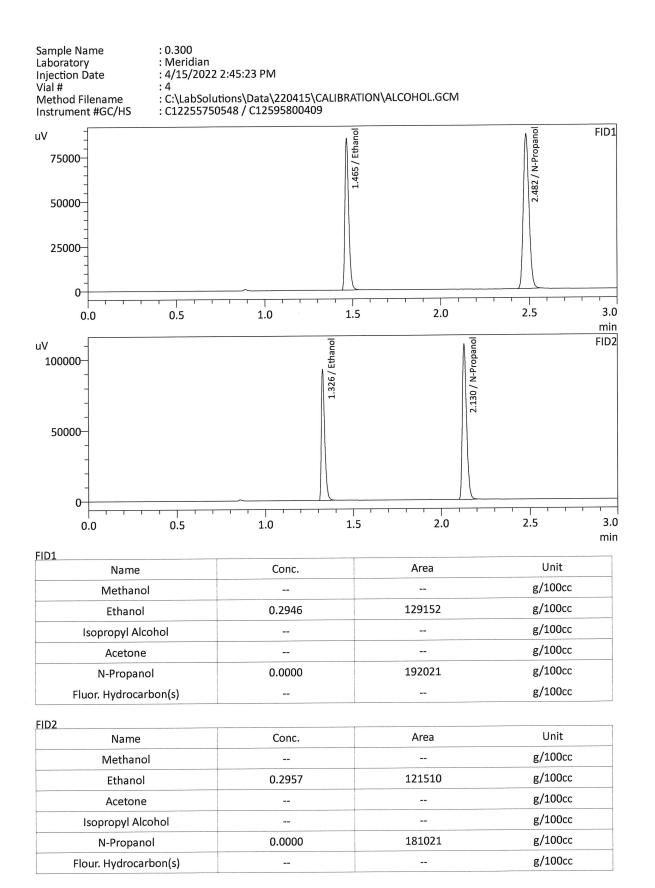
FID2	0	Area	Unit
Fladi. Hydrocarbon(dy			
Fluor. Hydrocarbon(s)			g/100cc
N-Propanol	0.0000	192874	g/100cc
Acetone			-
			g/100cc

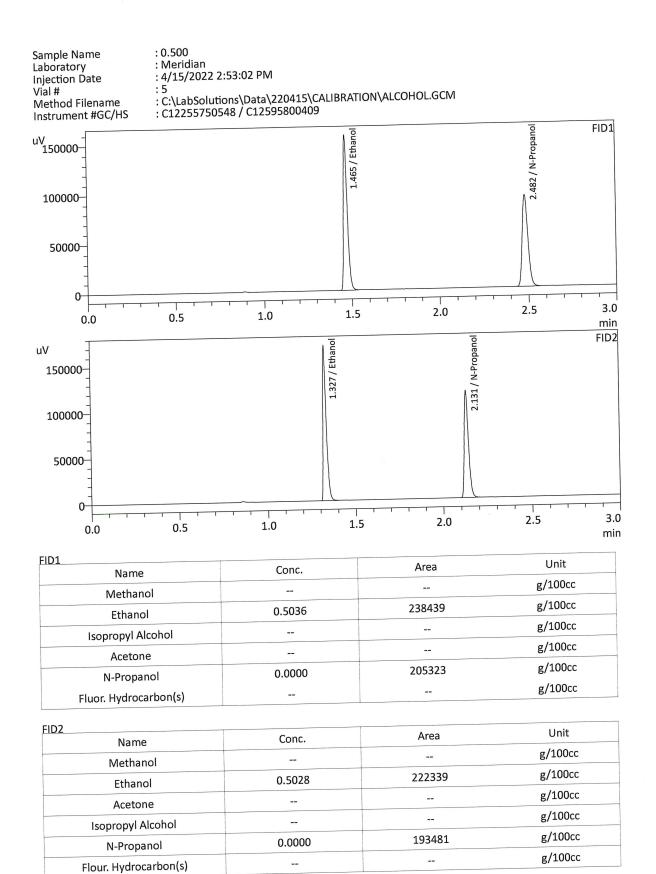
FID2 Name	Conc.	Area	Unit	
Methanol			g/100cc	
Ethanol	0.1005	40280	g/100cc g/100cc	
Acetone				
			g/100cc	
Isopropyl Alcohol	0.0000	182309	g/100cc	
N-Propanol			g/100cc	
Flour. Hydrocarbon(s)			0,	

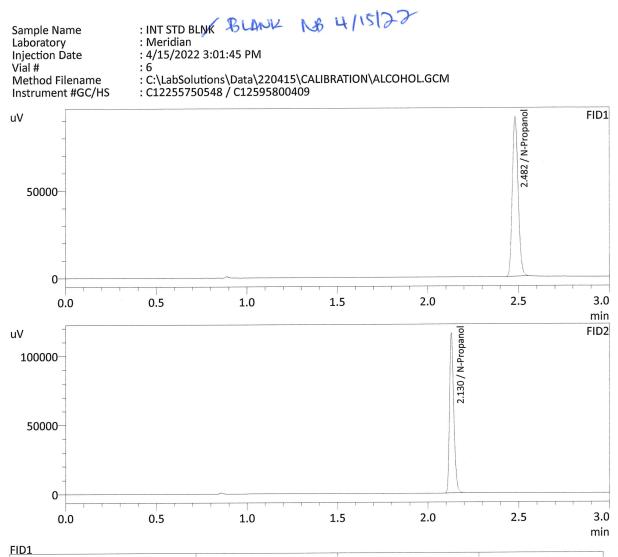


Flour. Hydrocarbon(s)

g/100cc







Name	Conc.	Area	Unit	
Methanol			g/100cc g/100cc g/100cc	
Ethanol				
Isopropyl Alcohol				
Acetone			g/100cc	
N-Propanol	0.0000	201265	g/100cc	
Fluor. Hydrocarbon(s)			g/100cc	

FI	D2	

FID2				
Name	Conc.	Area	Unit	
Methanol			g/100cc	
Ethanol			g/100cc	
Acetone			g/100cc	
Isopropyl Alcohol			g/100cc	
N-Propanol	0.0000	190269	g/100cc	
Flour. Hydrocarbon(s)			g/100cc	

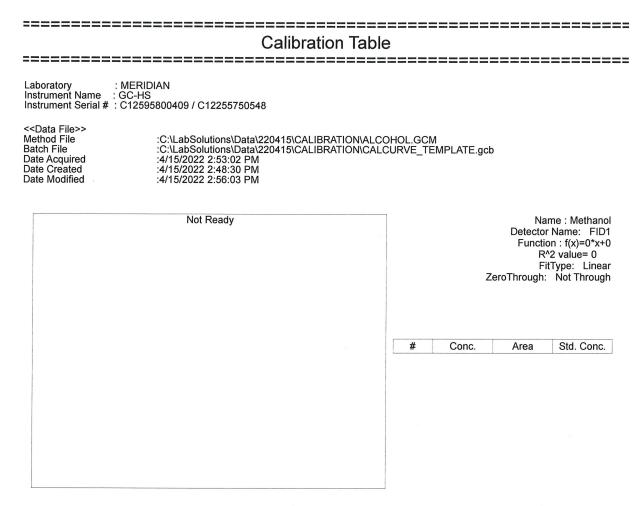
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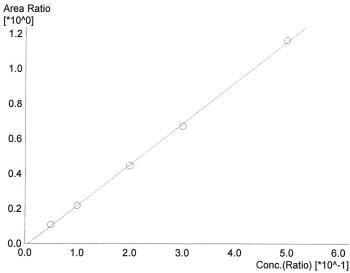
Meridian Blood Alcohol Analysis Batch Table

Shimadzu GC-2030 Serial #C12255750548 Shimadzu HS-20 Serial #C12595800409 Lab Solutions Software Ver. 5.99 Copyright (C) 2008-2020 Shimadzu Corporation

Vial#	Sample Name	Sample Type	Level#	Method File
1	0.050	1:Standard:(I)	1	ALCOHOL.GCM
2	0.100	1:Standard	2	ALCOHOL.GCM
3	0.200	1:Standard	3	ALCOHOL.GCM
4	0.300	1:Standard	4	ALCOHOL.GCM
5	0.500	1:Standard	5	ALCOHOL.GCM
6	INT STD BLNK	0:Unknown	0	ALCOHOL.GCM

Blank

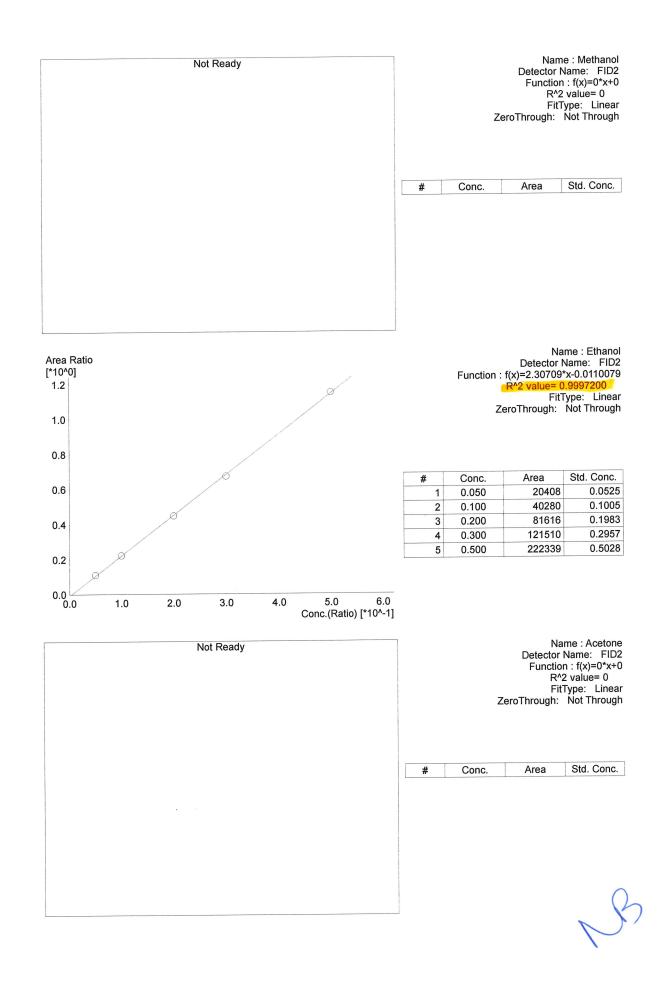




Name : Ethanol Detector Name: FID1 Function : f(x)=2.33818*x-0.0164445 R^2 value= 0.9995301 FitType: Linear ZeroThrough: Not Through

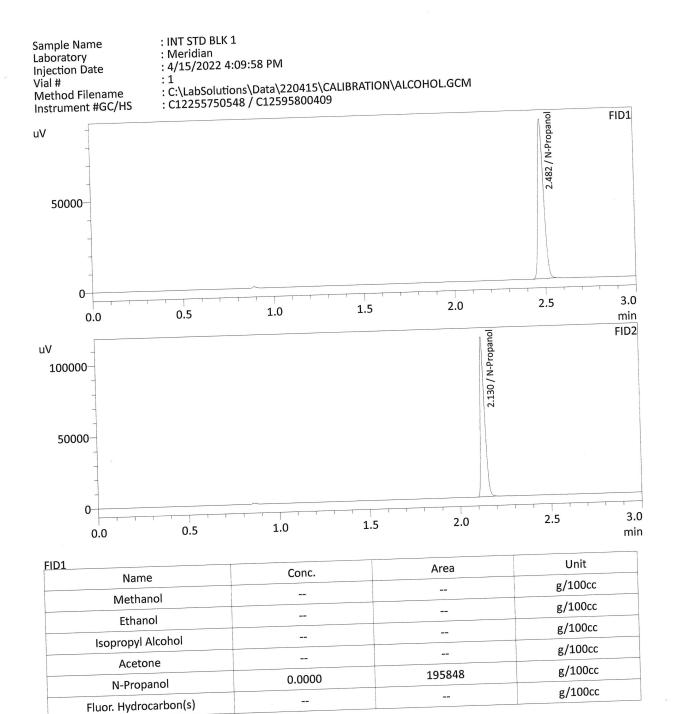
#	Conc.	Area	Std. Conc.
1	0.050	21284	0.0534
2	0.100	42167	0.1005
3	0.200	86235	0.1975
4	0.300	129152	0.2946
5	0.500	238439	0.5036

Not Ready	Name : Isopronul Alcohol
	Name : Isopropyl Alcohol Detector Name: FID1 Function : f(x)=0*x+0
	R ² value= 0
	FitType: Linear ZeroThrough: Not Through
	# Conc. Area Std. Conc.
Not Ready	Name : Acetone
	Detector Name: FID1 Function : f(x)=0*x+0
	R ² value= 0
	FitType: Linear ZeroThrough: Not Through
	# Conc. Area Std. Conc.
	_
Not Ready	Name : Fluor. Hydrocarbon(s) Detector Name: FID1
	Function : f(x)=0*x+0
	R^2 value= 0
	FitType: Linear ZeroThrough: Not Through
	# Conc. Area Std. Conc.
	Ω
	a K



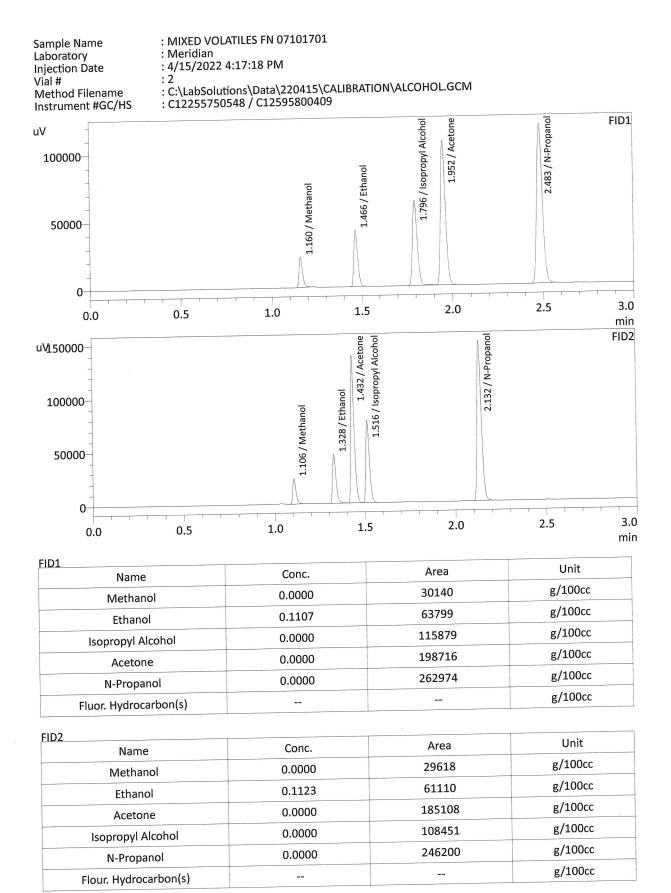
Not Ready	Name : Isopropyl Alcohol Detector Name: FID2 Function : f(x)=0*x+0 R^2 value= 0 FitType: Linear ZeroThrough: Not Through
	# Conc. Area Std. Conc.
Not Ready	Name : Flour. Hydrocarbon(s) Detector Name: FID2 Function : f(x)=0*x+0 R^2 value= 0 FitType: Linear ZeroThrough: Not Through
Not Ready	Function : f(x)=0*x+0 B^2 value= 0

S,



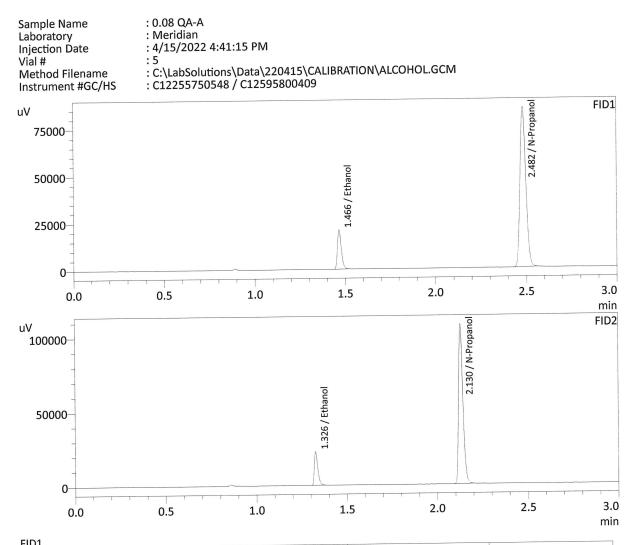
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FID2	Conc.	Area	Unit
Name	Conc.		g/100cc
Methanol			g/100cc
Ethanol			g/100cc
Acetone			g/100cc
Isopropyl Alcohol		185300	g/100cc
N-Propanol	0.0000		g/100cc
Flour. Hydrocarbon(s)			0,



Laboratory N	o.: 0.080 QA		Item #		Analysis Date(s):	4/15/2022
	Column 1 FID A	Column 2 FI B	D Column Precision	Mean Value	Sample A-B Difference	Over-all Mean
Sample Results	0.0788	0.0785	0.0003	0.0786	0.0025	0.0799
(g/100cc)	0.0813	0.0810	0.0003	0.0811	0.0023	0.0775
Analysis Met	hod					
Refer to Blood	Alcohol Metho	d #1				
Instrument II	nformation			Instrument i	information is stor	ed centrally.
Refer to Instrume	ent Method: Alcol	hol.m/.gcm, Vola	atiles.m/.gcm			
Reporting of	Results		Uncertain	ty of Measure	ment (UM%):	5.00%
Ove	erall Mean (g/10)0cc)	Low	High	5% of	f Mean
0.079		0.075	0.083	0.0	004	
]	Reported Res	ult	_	
	c.		0.079			

Calibration and control data are stored centrally.

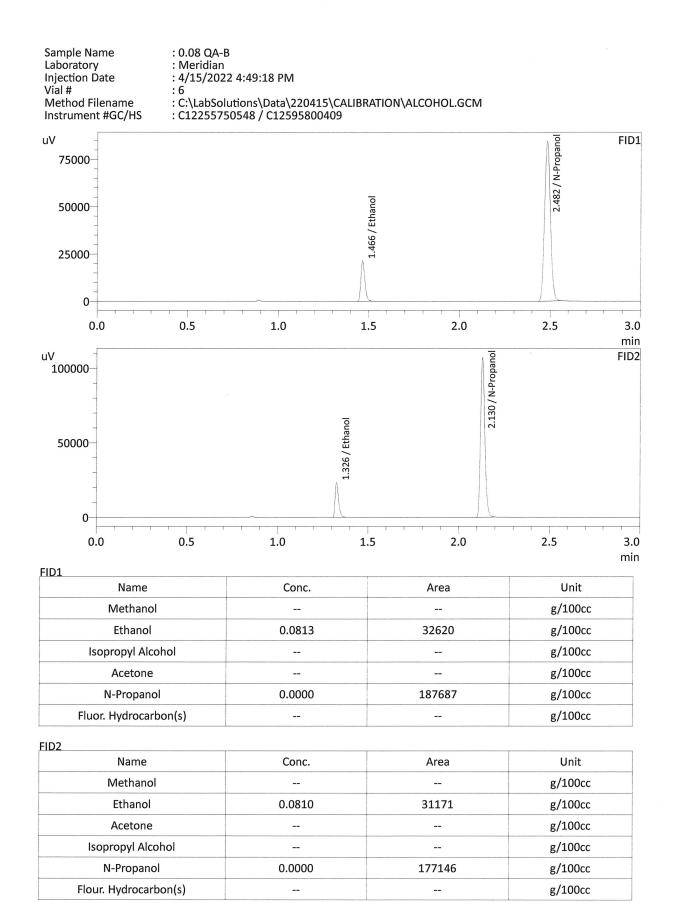


FID1			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0788	31634	g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	188443	g/100cc
Fluor. Hydrocarbon(s)			g/100cc
FILOI. HYDrocarbon(s)			0.

FI	D2
_	

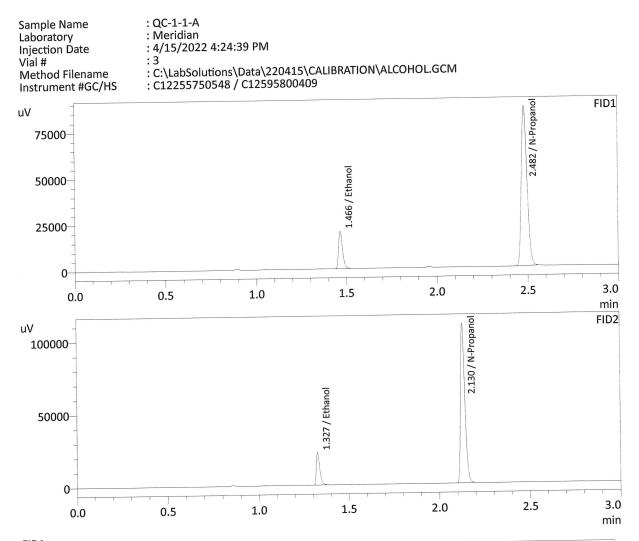
-ID2			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0785	30271	g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	177861	g/100cc
Flour. Hydrocarbon(s)			g/100cc

B



Laboratory No.: QC1-1		Item #		Analysis Date(s):	4/15/2022	
	Column 1 FID A	Column 2 FID B	Column Precision	Mean Value	Sample A-B Difference	Over-all Mean
Sample Results	0.0764	0.0761	0.0003	0.0762	0.0004	0.0764
(g/100cc)	0.0768	0.0764	0.0004	0.0766	0.0004	0.0701
Analysis Met	hod					
Refer to Blood	Alcohol Metho	d #1				
					×	
Instrument II	nformation			Instrument	information is stor	ed centrally.
Refer to Instrume	ent Method: Alco	hol.m/.gcm, Volat	iles.m/.gcm			
Reporting of	Results	and a second	Uncertain	ty of Measure	ement (UM%):	5.00%
Ove	erall Mean (g/10)0cc)	Low	High	5% of	f Mean
0.076		0.072	0.080	0.0	004	
		R	eported Res	ult		
			0.076			

Calibration and control data are stored centrally.

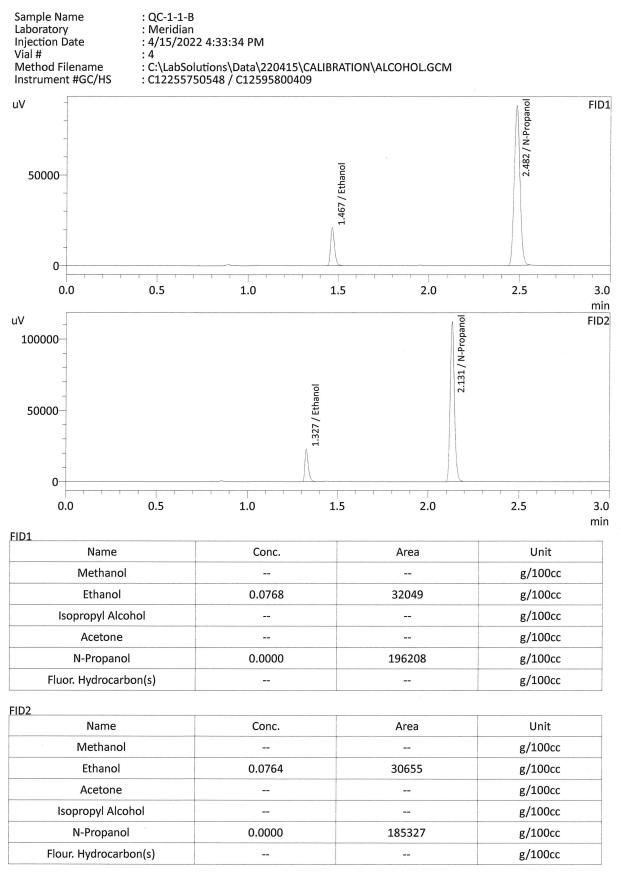


FID1 Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0764	31219	g/100cc
Isopropyl Alcohol			g/100cc
			g/100cc
Acetone	0.0000	192250	g/100cc
N-Propanol	0.0000		g/100cc
Fluor. Hydrocarbon(s)			6/10000

FID2

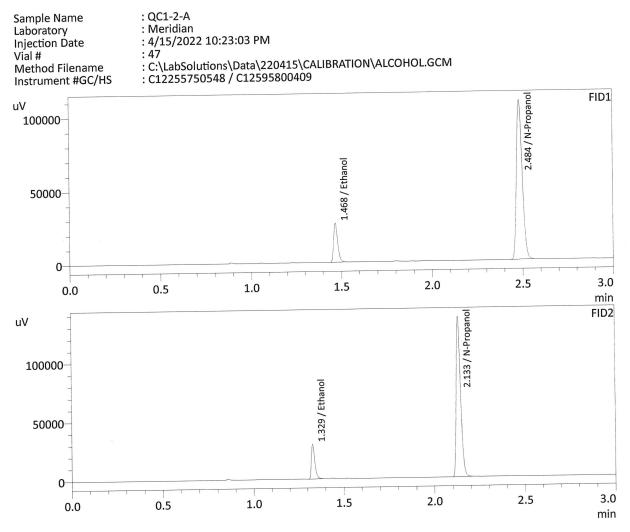
FID2 Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0761	29898	g/100cc
Acetone			g/100cc
			g/100cc
Isopropyl Alcohol		181580	g/100cc
N-Propanol	0.0000	101300	g/100cc
Flour. Hydrocarbon(s)			g/100cc

2



Laboratory N	Laboratory No.: QC1-2 Item #		Analysis Date(s):	4/15/2022		
	Column 1 FID A	Column 2 FID B	Column Precision	Mean Value	Sample A-B Difference	Over-all Mean
Sample Results	0.0803	0.0804	0.0001	0.0803	0.0007	0.0799
(g/100cc)	0.0795	0.0797	0.0002	0.0796	0.0007	
Analysis Met	hod					
Refer to Blood	Alcohol Metho	od #1				
Instrument I	nformation			Instrument i	information is stor	ed centrally.
Refer to Instrum	ent Method: Alco	hol.m/.gcm, Volat	iles.m/.gcm			
Reporting of	Results		Uncertain	ty of Measure	ment (UM%):	5.00%
Ove	erall Mean (g/1	00cc)	Low	High	5% 0	f Mean
0.079 0.075 0.083			0.	004		
	and a second	R	Reported Res	ult		
			0.079			

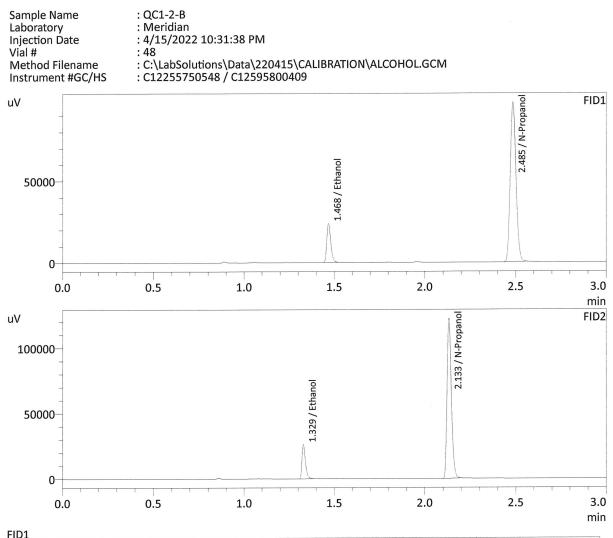
Calibration and control data are stored centrally.



Conc.	Area	Unit
		g/100cc
0.0803	40961	g/100cc
		g/100cc
		g/100cc
0.0000	239048	g/100cc
		g/100cc
	 0.0803 	0.0803 40961 0.0000 239048

-	00
ъ	1117
	102

Conc.	Area	Unit
		g/100cc
0.0804	39277	g/100cc
		g/100cc
		g/100cc
0.0000	225024	g/100cc
		g/100cc
	 0.0804 0.0000	0.0804 39277 0.0000 225024



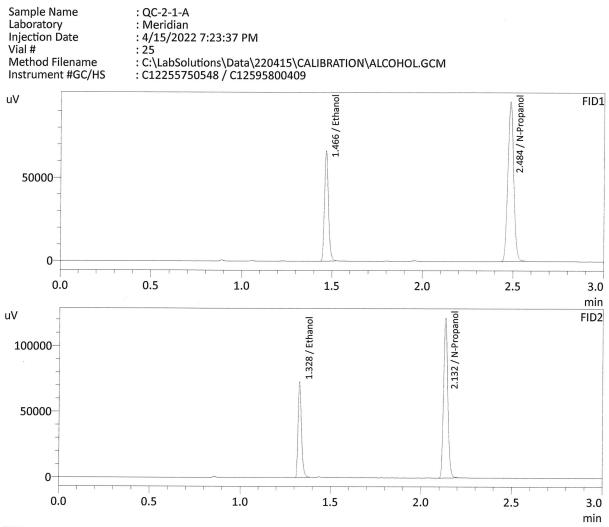
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0795	36440	g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	215024	g/100cc
Fluor. Hydrocarbon(s)			g/100cc

FID2			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.0797	35075	g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	202728	g/100cc
Flour. Hydrocarbon(s)			g/100cc

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Laboratory N	o.: QC2-1		Item #		Analysis Date(s):	4/15/2022
na da anna ga ann an Anna Anna Anna Anna	Column 1 FID A	Column 2 FID B	Column Precision	Mean Value	Sample A-B Difference	Over-all Mean
Sample Results	0.2105	0.2119	0.0014	0.2112	0.0012	0.2118
(g/100cc)	0.2118	0.2131	0.0013	0.2124	0.0012	0.2110
Analysis Met	hod					
Refer to Blood	Alcohol Metho	d #1				
Instrument II	nformation			Instrument i	nformation is stor	ed centrally.
Refer to Instrume	ent Method: Alco	hol.m/.gcm, Volat	iles.m/.gcm			
Reporting of	Results	an han an tha a than an that an a share	Uncertaint	ty of Measure	ment (UM%):	5.00%
Ove	erall Mean (g/10)0cc)	Low	High	5% of	? Mean
0.211 0.200 0.222 0.011)11		
		R	eported Res	ult		
			0.211			

Calibration and control data are stored centrally.

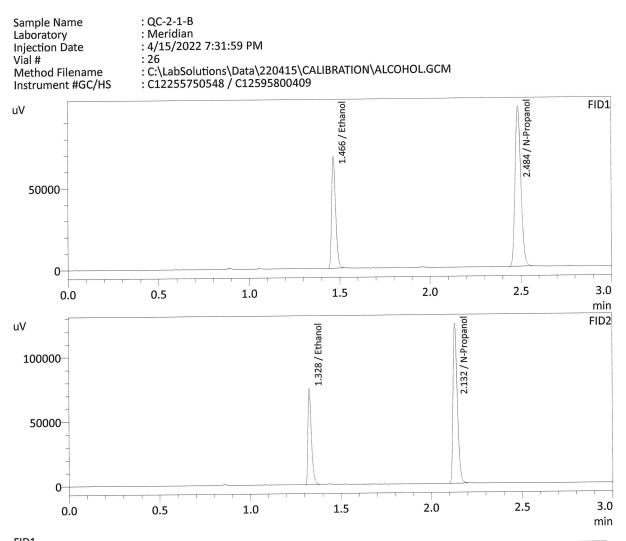


FID1

Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.2105	101237	g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	212763	g/100cc
Fluor. Hydrocarbon(s)			g/100cc

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Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.2119	95785	g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	200384	g/100cc
Flour. Hydrocarbon(s)			g/100cc

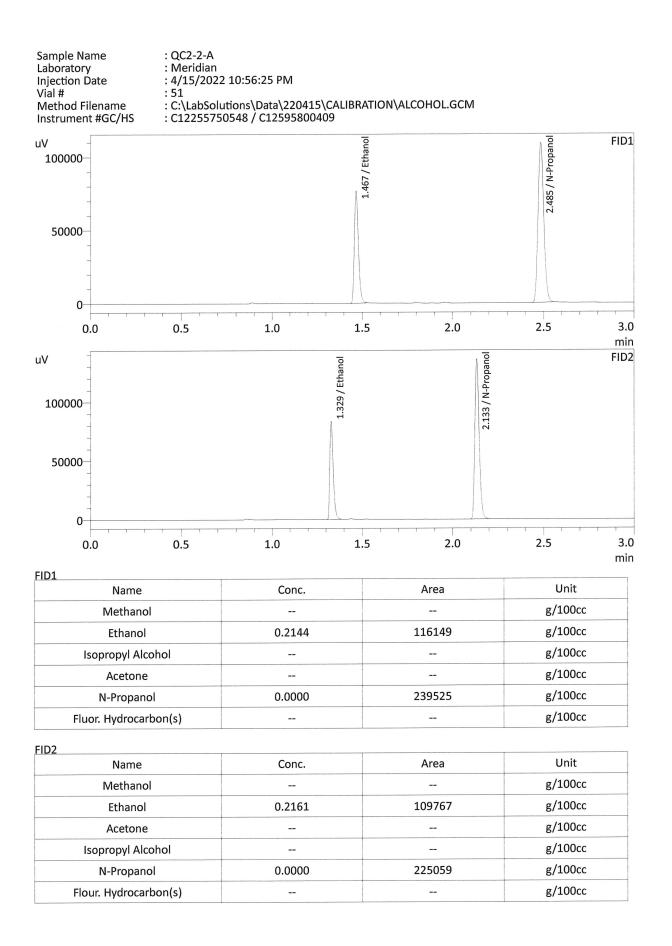


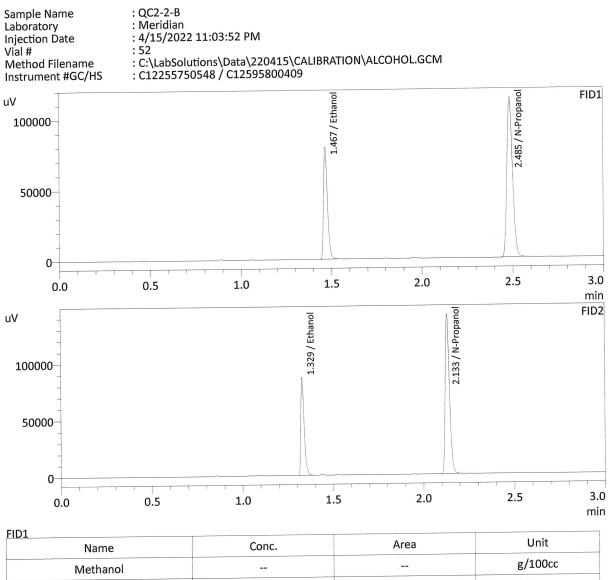
FID1			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.2118	103856	g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	216856	g/100cc
Fluor. Hydrocarbon(s)			g/100cc

ID2			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.2131	98185	g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	204214	g/100cc
Flour. Hydrocarbon(s)			g/100cc

Laboratory No.: QC2-2		Item #		Analysis Date(s):	4/15/2022	
	Column 1 FID A	Column 2 FII B	Column Precision	Mean Value	Sample A-B Difference	Over-all Mean
Sample Results	0.2144	0.2161	0.0017	0.2152	0.0004	0.2154
(g/100cc)	0.2147	0.2165	0.0018	0.2156	0.0004	0.2154
Analysis Metl	ıod					
Refer to Blood	Alcohol Metho	d #1				
Instrument Information Instrument information is stored centrally.						
Refer to Instrument Method: Alcohol.m/.gcm, Volatiles.m/.gcm						
Reporting of Results Uncertainty of Measurement (UM%): 5.00%						
Overall Mean (g/100cc)			Low	High	5% of	[°] Mean
0.215			0.204	0.226	0.0)11
	Reported Result		ult			
		0.215				

Calibration and control data are stored centrally.



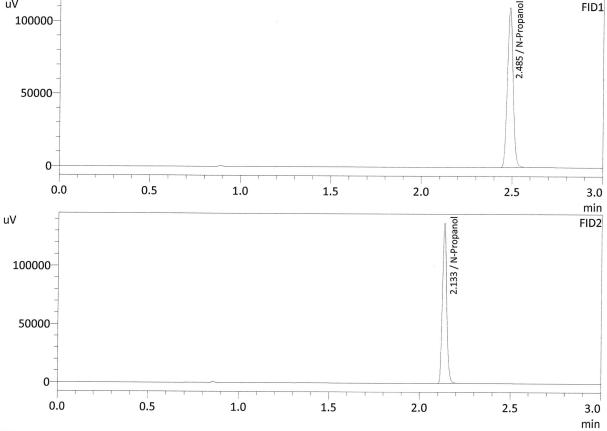


Name	COIIC.	Aicu	•••••
Methanol			g/100cc
Ethanol	0.2147	120865	g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	248888	g/100cc
Fluor. Hydrocarbon(s)			g/100cc
FILOI. HYDROCALDON(S)			-

FID2			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol	0.2165	114278	g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	233899	g/100cc
Flour. Hydrocarbon(s)			g/100cc

PNK

Sample Name Laboratory Injection Date Vial # : INT STD BLNK : Meridian : 4/15/2022 11:11:39 PM : 53 : C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM : C12255750548 / C12595800409 Method Filename Instrument #GC/HS uV 100000-



FID1

FID1			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol			g/100cc
Isopropyl Alcohol			g/100cc
Acetone			g/100cc
N-Propanol	0.0000	241586	g/100cc
Fluor. Hydrocarbon(s)			g/100cc

FID2

1102			
Name	Conc.	Area	Unit
Methanol			g/100cc
Ethanol			g/100cc
Acetone			g/100cc
Isopropyl Alcohol			g/100cc
N-Propanol	0.0000	227676	g/100cc
Flour. Hydrocarbon(s)			g/100cc

Meridian Blood Alcohol Analysis Batch Table

Shimadzu GC-2030 Serial #C12255750548 Shimadzu HS-20 Serial #C12595800409 Lab Solutions Software Ver. 5.99 Copyright (C) 2008-2020 Shimadzu Corporation

Vial#	Sample Name	Method File
1	INT STD BLK 1	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
2	ED VOLATILES FN 071	0 ^C ·\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
3	OC-1-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
4	ОС-1-1-В	C·\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
5	0.08 QA-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
6	0.08 QA-B	C·\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
7	M2022-1373-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
8	M2022-1373-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
9	M2022-1417-2-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
10	M2022-1417-2-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
11	M2022-1418-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
12	M2022-1418-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
13	M2022-1419-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
14	M2022-1419-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
15	M2022-1420-1-A	C:LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
16	M2022-1420-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
17	M2022-1421-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
<u>18</u> 19	M2022-1421-1-B M2022-1422-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
20	M2022-1422-1-A M2022-1422-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
20	M2022-1422-1-B M2022-1436-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
$\frac{21}{22}$	M2022-1430-1-A M2022-1436-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
22	M2022-1430-1-B M2022-1437-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
24	M2022-1437-1-A M2022-1437-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
25	OC-2-1-A	C·\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
26	0C-2-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
27	M2022-1447-2-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
28	M2022-1447-2-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
29	M2022-1484-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
30	M2022-1484-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
31	M2022-1485-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
32	M2022-1485-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
33	M2022-1534-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
34	M2022-1534-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
35	M2022-1535-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
36	M2022-1535-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
37	M2022-1542-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
38	M2022-1542-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
39	M2022-1547-1-A M2022-1547-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
40	M2022-1547-1-B M2022-1548-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
41	M2022-1548-1-A M2022-1548-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
42	M2022-1548-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
43	M2022-1549-1-A M2022-1549-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
45	M2022-1561-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
46	M2022-1561-1-R M2022-1561-1-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
40	QC1-2-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
48	OC1-2-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
49	M2022-1578-1-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
50	M2022-1578-1-B	C·\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
51	QC2-2-A	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
52	QC2-2-B	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM
53	INT STD BLNK	C:\LabSolutions\Data\220415\CALIBRATION\ALCOHOL.GCM

Request for Departure from an Analytical Method or Quality Standard

Deviation Number (assigned by QM): BLA-22-01

Date of Request: 1/21/2022

Requestor/Discipline: Melissa (Nikka) Bradley/Blood Alcohol

Analytical Method/Quality Standard, Revision #: AM#1 Analysis for Volatiles by Headspace GC/ 4.3.9

Temporary or Permanent Deviation: Permanent

<u>Scope of Deviation</u> There is a noticeable increased drift of internal standard (n-propanol signals) from the calibrators, beginning of the run and towards the end of the sample run that is consistent in multiple batches of blood alcohol runs. Because all the samples that are analyzed are being compared to calibrators that are performed at the beginning of the run, the n-propanol signal of end samples tend to be outside or close to being outside of the +/- 20% of the mean value from the calibration curve used Despite this drift the values of known control samples are within acceptable limits.

Deviation Request

4.3.9.1.1 The average values for the internal standard will be established by averaging the IS counts throughout the calibration curve samples.

Requesting that the internal standard monitoring average be changed to average the aqueous and matrix controls within the run.

4.3.9.1.1 The average values for the internal standard will be established by averaging the IS counts from the aqueous control and all matrix blood control samples.

Technical Justification for Analytical Method Deviations:

The designed purpose of the internal standard monitoring is to evaluate the quality of injection of each sample. There is a gradual increase of internal standard response from the beginning of the batch (calibrators and early samples) to the end that is inherent to the current instrument set up as shown in trends from previous batches in multiple laboratories. Attempts to pre-condition/warm up the instrument using by running a pre-batch sequence utilizing old calibrator/blank samples prior to running a new calibration curve did not appear to minimize this occurrence. Furthermore, it can be seen that the drifting trend is not due to the extraction procedure because some of the later batch samples were extracted prior to the samples that are injected during the run. It is worth noting that despite this



trend, the values of the known control samples are still within the specified acceptable range. By utilizing known control n-propanol signals throughout the batch, any potential drift will be taken into account while still being able to monitor a possible mis-injection or partial injection throughout the batch/sequence.

This deviation will have an expiration date of July 1st, 2022.

Technical Review

Departure approved

Comments: Forms will be updated to reflect the new process concurrent with the deviation.

Departure Not Approved Comments:

Approver: Title: Discipline Lead Date: 1/21/22

Quality Review

Quality Approver: Jason Crowe Title: Quality Manager Date: 01/24/2022

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