



Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after changing the vent valve, pressurization valve, and sample probe.
Analyte	Ethanol, Methanol, Acetone, Isopropanol
Units of Measure	g/100 mL
Analyst Performing Verification Study	Jesal Patel
Responsible Supervisor	Dayong Lee, Ph.D.
Start Date	May 28, 2020
Completion Date	May 28, 2020
Primary Matrix	Blood
Secondary Matrices	Serum, Plasma, Alcoholic Beverages, Other Liquid Specimens
Low Calibrator Concentration	0.010
Highest Calibrator Concentration	0.500 (Ethanol), 0.400 (Methanol, Acetone, Isopropanol)
Equipment/Instrument	Headspace 3 This instrument is fit for use on casework for Alcohol and Other Volatiles Analysis.
Instrument Serial Number	Headspace CN16140002 Gas Chromatograph US16163003
Method	VOLATILES

Verification Approval

Analyst: _____ Date

Responsible Supervisor: _____ Date

Verification Study**BIAS AND PRECISION**

Analyte: *Ethanol*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID1*

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1484</i>	<i>0.0754</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.1466	0.0741	0.0798	0.0191
	2	0.1480	0.0744	0.0803	0.0191
	3	0.1468	0.0747	0.0799	0.0191
	Mean	0.1471	0.0744	0.0800	0.0191
	SD	0.000757	0.000300	0.000265	0.000000
	%CV	0.515%	0.403%	0.331%	0.000%
	% Bias	-0.85%	-1.33%	0.00%	-0.52%

Comments: MQC2 (Lot: 1806057); BQC1 (Lot: 1907006); EQC (Lot: 03102016-A); LMQC (Lot: 200204-LMQC)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study**BIAS AND PRECISION**

Analyte: *Ethanol*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID2*

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1484</i>	<i>0.0754</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.1464	0.0744	0.0797	0.0191
	2	0.1474	0.0747	0.0802	0.0192
	3	0.1466	0.0751	0.0797	0.0191
	Mean	0.1468	0.0747	0.0799	0.0191
	SD	0.000529	0.000351	0.000289	0.000058
	%CV	0.360%	0.470%	0.361%	0.302%
	% Bias	-1.08%	-0.88%	-0.17%	-0.35%

Comments: MQC2 (Lot: 1806057); BQC1 (Lot: 1907006); EQC (Lot: 03102016-A); LMQC (Lot: 200204-LMQC)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study

Analyte: *Methanol*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID1*

BIAS AND PRECISION

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0917</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.0896	0.0189
	2	0.0915	0.0191
	3	0.0905	0.0190
	Mean	0.0905	0.0190
	SD	0.000950	0.000100
	%CV	1.050%	0.526%
	% Bias	-1.27%	-1.04%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study

Analyte: *Methanol*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID2*

BIAS AND PRECISION

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0917</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.0891	0.0190
	2	0.0909	0.0192
	3	0.0899	0.0191
	Mean	0.0900	0.0191
	SD	0.000902	0.000100
	%CV	1.002%	0.524%
	% Bias	-1.89%	-0.52%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study

Analyte: *Isopropanol*
Units: *g/100 mL*
Instrument: *Headspace 3 FID1*

BIAS AND PRECISION

Analyst: *Jesal Patel*
Study Dates: *5/28/20 to 5/28/20*
Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0977</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 <i>Within Run</i>	1	0.0972	0.0191
	2	0.0971	0.0190
	3	0.0968	0.0189
	Mean	0.0970	0.0190
	SD	0.000208	0.000100
	%CV	0.215%	0.526%
	% Bias	-0.68%	-1.04%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study

Analyte: *Isopropanol*
Units: *g/100 mL*
Instrument: *Headspace 3 FID2*

BIAS AND PRECISION

Analyst: *Jesal Patel*
Study Dates: *5/28/20 to 5/28/20*
Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0977</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 <i>Within Run</i>	1	0.0972	0.0191
	2	0.0968	0.0191
	3	0.0967	0.0189
	Mean	0.0969	0.0190
	SD	0.000265	0.000115
	%CV	0.273%	0.607%
	% Bias	-0.82%	-0.87%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study**BIAS AND PRECISION**

Analyte: *Acetone*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID1*

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1391</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.1361	0.0191
	2	0.1359	0.0190
	3	0.1345	0.0186
	Mean	0.1355	0.0189
	SD	0.000872	0.000265
	%CV	0.643%	1.400%
	% Bias	-2.59%	-1.56%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.

Verification Study**BIAS AND PRECISION**

Analyte: *Acetone*
 Units: *g/100 mL*
 Instrument: *Headspace 3 FID2*

Analyst: *Jesal Patel*
 Study Dates: *5/28/20 to 5/28/20*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1391</i>	<i>0.0192</i>
Run 1 28-May-20 ALC_20200528_JP_HS3 Within Run	1	0.1361	0.0191
	2	0.1355	0.0190
	3	0.1344	0.0186
	Mean	0.1353	0.0189
	SD	0.000862	0.000265
	%CV	0.637%	1.400%
	% Bias	-2.71%	-1.56%

Comments: LMQC (Lot: 200204-LMQC); MQC2 (Lot: 1806057)

Acceptance Criteria: Refer to the Analysis of Alcohol and Other Volatiles by Headspace GC-FID section of the Toxicology Section Analytical Manual Standard Operating Procedures Version 3.4.