



Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after shutdown to disconnect instrument power supply from generator.
Analyte	Ethanol, Methanol, Acetone, Isopropanol
Units of Measure	g/100 mL
Analyst Performing Verification Study	Jesal Patel
Responsible Supervisor	Corissa Rodgers
Start Date	May 13, 2022
Completion Date	May 18, 2022
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	ALC.M

Verification Approval

Analyst:	Jesal Patel <small>Digitally signed by Jesal Patel DN: cn=Jesal Patel, o=Houston Forensic Science Center, ou=Toxicology, email=jpatel@houstonforensicscience.org, c=US Date: 2022.05.20 11:55:27 -05'00'</small>	5/20/22	Date
Responsible Supervisor:	Corissa L. Rodgers, M.S. <small>Digitally signed by Corissa L. Rodgers, M.S. Date: 2022.05.20 12:02:50 -05'00'</small>	5/20/22	Date

Verification Study**BIAS AND PRECISION**

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

Analyst: *Jesal Patel*
 Study Dates: *5/13/2022 to 5/18/2022*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC	
<i>Target Concentration (g/100 mL):</i>		<i>0.1440</i>	<i>0.0761</i>	<i>0.0800</i>	<i>0.0192</i>	
Run 1	1	0.1452	0.0742	0.0803	0.0194	
	2	0.1439	0.0750	0.0808	0.0195	
	3	0.1442	0.0752	0.0810	0.0194	
ALC_20220518_JP	Within Run	Mean	0.1444	0.0748	0.0807	0.0194
		SD	0.000681	0.000529	0.000361	0.000058
		%CV	0.471%	0.707%	0.447%	0.297%
		% Bias	0.30%	-1.71%	0.87%	1.22%

Comments: MQC2 (Lot: 1907009); BQC1 (Lot: 1907006); EQC (Lot: 20012020-B); LMQC (Lot: 210623-LMQC)

Bias:

$\leq \pm 5\%$ if target concentration is >0.05 g/100 mL
 $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mL
 Within Run Precision: $\%CV \leq \pm 10\%$

Acceptance Criteria:**Verification Study****BIAS AND PRECISION**

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

Analyst: *Jesal Patel*
 Study Dates: *5/13/2022 to 5/18/2022*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC	
<i>Target Concentration (g/100 mL):</i>		<i>0.1440</i>	<i>0.0761</i>	<i>0.0800</i>	<i>0.0192</i>	
Run 1	1	0.1449	0.0743	0.0801	0.0194	
	2	0.1437	0.0751	0.0808	0.0194	
	3	0.1440	0.0751	0.0809	0.0194	
ALC_20220518_JP	Within Run	Mean	0.1442	0.0748	0.0806	0.0194
		SD	0.000624	0.000462	0.000436	0.000000
		%CV	0.433%	0.617%	0.541%	0.000%
		% Bias	0.14%	-1.66%	0.75%	1.04%

Comments: MQC2 (Lot: 1907009); BQC1 (Lot: 1907006); EQC (Lot: 20012020-B); LMQC (Lot: 210623-LMQC)

Bias:

$\leq \pm 5\%$ if target concentration is >0.05 g/100 mL
 $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mL
 Within Run Precision: $\%CV \leq \pm 10\%$

Acceptance Criteria:

Verification StudyAnalyte: *Methanol*Units: *g/100 mL*Instrument: *Headspace 3 FID1***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0904</i>	<i>0.0192</i>
Run 1 ALC_20220518_JP	1	0.0916	0.0194
	2	0.0899	0.0195
	3	0.0903	0.0195
<i>Within Run</i>		0.0906	0.0195
		0.000889	0.000058
		0.981%	0.297%
		0.22%	1.39%

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$ **Verification Study**Analyte: *Methanol*Units: *g/100 mL*Instrument: *Headspace 3 FID2***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0904</i>	<i>0.0192</i>
Run 1 ALC_20220518_JP	1	0.0910	0.0193
	2	0.0893	0.0194
	3	0.0894	0.0193
<i>Within Run</i>		0.0899	0.0193
		0.000954	0.000058
		1.061%	0.299%
		-0.55%	0.69%

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$

Verification StudyAnalyte: *Isopropanol*Units: *g/100 mL*Instrument: *Headspace 3 FID1***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0929</i>	<i>0.0192</i>
Run 1 ALC_20220518_JP	1	0.0929	0.0193
	2	0.0933	0.0193
	3	0.0930	0.0193
<i>Within Run</i>		Mean	0.0931
		SD	0.000208
		%CV	0.224%
		% Bias	0.18%

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$ **Verification Study**Analyte: *Isopropanol*Units: *g/100 mL*Instrument: *Headspace 3 FID2***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0929</i>	<i>0.0192</i>
Run 1 ALC_20220518_JP	1	0.0931	0.0194
	2	0.0935	0.0194
	3	0.0933	0.0193
<i>Within Run</i>		Mean	0.0933
		SD	0.000200
		%CV	0.214%
		% Bias	0.43%

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$

Verification StudyAnalyte: *Acetone*Units: *g/100 mL*Instrument: *Headspace 3 FID1***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1403</i>	<i>0.0192</i>
Run 1	1	0.1415	0.0191
	2	0.1419	0.0190
	3	0.1415	0.0190
ALC_20220518_JP	<i>Within Run</i>	Mean	0.1416
		SD	0.000231
		%CV	0.163%
		% Bias	0.95%
			0.0190

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$ **Verification Study**Analyte: *Acetone*Units: *g/100 mL*Instrument: *Headspace 3 FID2***BIAS AND PRECISION**Analyst: *Jesal Patel*Study Dates: *5/13/2022 to 5/18/2022*Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1403</i>	<i>0.0192</i>
Run 1	1	0.1413	0.0191
	2	0.1417	0.0190
	3	0.1412	0.0190
ALC_20220518_JP	<i>Within Run</i>	Mean	0.1414
		SD	0.000265
		%CV	0.187%
		% Bias	0.78%
			0.0190

Comments: MQC2 (Lot: 1907009); LMQC (Lot: 210623-LMQC)

Acceptance Criteria:

Bias:

 $\leq \pm 5\%$ if target concentration is >0.05 g/100 mL $\leq \pm 10\%$ if target concentration is ≤ 0.05 g/100 mLWithin Run Precision: $\%CV \leq \pm 10\%$

SUMMARY OF VERIFICATION PERFORMANCE

Units: *g/100 mL*

Instrument: *Headspace 3*

Analyst: Jesal Patel

Study Dates: *5/13/2022 to 5/18/2022*

Matrix: *Blood*

Failed Runs (include dates/reasons):

ALC_20220513_KMY: samples were aliquoted on 5/13/2022, stored in the refrigerator, and analyzed on Headspace 3 on 5/16/2022. The autosampler stability for acetone is up to 48 hours after preparation and for methanol is up to 24 hours after preparation. Although the samples were refrigerated, the storage stability has not been validated, therefore acetone and methanol could not be verified from that run.

Deviations from SOP:

N/A

Other Notes:

N/A

Conclusion:

Headspace 3 is fit for use on casework analysis of ethanol, methanol, isopropanol, and acetone.