



Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after replacing the back column.
Analyte	Ethanol, Methanol, Acetone, Isopropanol
Units of Measure	g/100 mL
Analyst Performing Verification Study	Brooke A. Mendenhall
Responsible Supervisor	Corissa L. Rodgers
Start Date	August 28, 2023
Completion Date	August 30, 2023
Primary Matrix	Blood
Secondary Matrices	Serum, Plasma, Alcoholic Beverages, Other Liquid Specimens
Lowest 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: _____ 09/06/2023
Date

Responsible Supervisor: _____ 09/06/2023
Date

Verification Study**BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC	
<i>Target Concentration (g/100 mL):</i>		<i>0.1599</i>	<i>0.0804</i>	<i>0.0800</i>	<i>0.0192</i>	
Run 1	1	0.1577	0.0793	0.0804	0.0194	
	2	0.1589	0.0797	0.0809	0.0195	
	3	0.1574	0.0794	0.0805	0.0194	
ALC_20230830_BAM	<i>Within Run</i>	Mean	0.1580	0.0795	0.0806	0.0194
		SD	0.000794	0.000208	0.000265	0.000058
		%CV	0.502%	0.262%	0.328%	0.297%
		% Bias	-1.19%	-1.16%	0.75%	1.22%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2101199); EQC (Lot: 20012020-B); LMQC (Lot: 230222-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 mL
Within Run Precision: %CV $\leq \pm 10\%$

Verification Study**BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC	
<i>Target Concentration (g/100 mL):</i>		<i>0.1599</i>	<i>0.0804</i>	<i>0.0800</i>	<i>0.0192</i>	
Run 1	1	0.1576	0.0794	0.0802	0.0194	
	2	0.1589	0.0799	0.0807	0.0195	
	3	0.1575	0.0796	0.0804	0.0195	
ALC_20230830_BAM	<i>Within Run</i>	Mean	0.1580	0.0796	0.0804	0.0195
		SD	0.000781	0.000252	0.000252	0.000058
		%CV	0.494%	0.316%	0.313%	0.297%
		% Bias	-1.19%	-0.95%	0.54%	1.39%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2101199); EQC (Lot: 20012020-B); LMQC (Lot: 230222-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 mL
Within Run Precision: %CV $\leq \pm 10\%$

Verification Study

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

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1001</i>	<i>0.0192</i>
Run 1 ALC_20230830_BAM Within Run	1	0.0970	0.0194
	2	0.0990	0.0195
	3	0.0970	0.0195
	Mean	0.0977	0.0195
	SD	0.001155	0.000058
	%CV	1.182%	0.297%
	% Bias	-2.43%	1.39%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-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 mL
 Within Run Precision: $\%CV \leq \pm 10\%$

Verification Study

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

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1001</i>	<i>0.0192</i>
Run 1 ALC_20230830_BAM Within Run	1	0.0967	0.0194
	2	0.0984	0.0194
	3	0.0967	0.0194
	Mean	0.0973	0.0194
	SD	0.000981	0.000000
	%CV	1.009%	0.000%
	% Bias	-2.83%	1.04%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-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 mL
 Within Run Precision: $\%CV \leq \pm 10\%$

Verification Study**BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1012</i>	<i>0.0192</i>
Run 1	1	0.1017	0.0194
	2	0.1015	0.0194
	3	0.1012	0.0193
ALC_20230830_BAM	<i>Within Run</i>	Mean	0.1015
		SD	0.000252
		%CV	0.248%
		% Bias	0.26%
			0.0194
		0.00058	0.298%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-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 mL
Within Run Precision: %CV $\leq \pm 10\%$

Verification Study**BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*
 Study Dates: *8/28/2023 to 8/30/2023*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1012</i>	<i>0.0192</i>
Run 1	1	0.1018	0.0194
	2	0.1016	0.0194
	3	0.1013	0.0195
ALC_20230830_BAM	<i>Within Run</i>	Mean	0.1016
		SD	0.000252
		%CV	0.248%
		% Bias	0.36%
			0.0194
		0.00058	0.297%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-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 mL
Within Run Precision: %CV $\leq \pm 10\%$

Verification StudyAnalyte: **Acetone**Units: **g/100 mL**Instrument: **Headspace 3 FID1****BIAS AND PRECISION**Analyst: **Brooke A. Mendenhall**Study Dates: **8/28/2023 to 8/30/2023**Matrix: **Blood**

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		0.1456	0.0192
Run 1 ALC_20230830_BAM	1	0.1477	0.0196
	2	0.1484	0.0194
	3	0.1447	0.0193
<i>Within Run</i>		Mean	0.1469
		SD	0.001966
		%CV	1.338%
		% Bias	0.92%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-LMQC)

Acceptance Criteria:

Bias:

≤ ± 5% if target concentration is >0.05 g/100 mL

≤ ± 10% if target concentration is ≤0.05 g/100 mL

Within Run Precision: %CV ≤ ± 10%

Verification StudyAnalyte: **Acetone**Units: **g/100 mL**Instrument: **Headspace 3 FID2****BIAS AND PRECISION**Analyst: **Brooke A. Mendenhall**Study Dates: **8/28/2023 to 8/30/2023**Matrix: **Blood**

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		0.1456	0.0192
Run 1 ALC_20230830_BAM	1	0.1476	0.0196
	2	0.1484	0.0194
	3	0.1447	0.0194
<i>Within Run</i>		Mean	0.1469
		SD	0.001947
		%CV	1.325%
		% Bias	0.89%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 230222-LMQC)

Acceptance Criteria:

Bias:

≤ ± 5% if target concentration is >0.05 g/100 mL

≤ ± 10% if target concentration is ≤0.05 g/100 mL

Within Run Precision: %CV ≤ ± 10%

SUMMARY OF VERIFICATION PERFORMANCE

Units: *g/100 mL*

Instrument: *Headspace 3*

Analyst: *Brooke A. Mendenhall*

Study Dates: *8/28/2023 to 8/30/2023*

Matrix: *Blood*

Failed Runs (include dates/reasons):

ALC_20230828_BAM: The methanol concentration in two aliquots of MQC2 fell outside acceptable range. Note that the MQC2 sub-lot, 2206153-D, was nearing the 45-day expiration date of 9/3/2023. A new MQC2 sub-lot, 2206153-E, was used in ALC_20230830_BAM and met acceptance criteria.

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.