



Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after the installation of the new computer and completion of annual preventative maintenance.
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	May 21, 2024
Completion Date	May 21, 2024
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 2 This instrument is fit for use on casework for Alcohol and Other Volatiles Analysis.
Instrument Serial Number	Headspace CN15070059 Gas Chromatograph CN15123149
Method	ALC.M

Verification Approval

Analyst: _____ Date

Responsible Supervisor: _____ Date

Verification Study**BIAS AND PRECISION**

Analyte: *Ethanol*
 Units: *g/100 mL*
 Instrument: *HeadSpace 2 FID1*

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1590</i>	<i>0.0814</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1578	0.0801	0.0803	0.0196
	2	0.1591	0.0802	0.0804	0.0196
	3	0.1593	0.0807	0.0805	0.0198
Within Run	Mean	0.1587	0.0803	0.0804	0.0197
	SD	0.000814	0.000321	0.000100	0.000115
	%CV	0.513%	0.400%	0.124%	0.587%
	% Bias	-0.17%	-1.31%	0.50%	2.43%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2302119); EQC (Lot: 20012020-B); LMQC (Lot: 240109-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 2 FID2*

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1590</i>	<i>0.0814</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1559	0.0811	0.0802	0.0194
	2	0.1571	0.0813	0.0804	0.0196
	3	0.1570	0.0815	0.0801	0.0197
Within Run	Mean	0.1567	0.0813	0.0802	0.0196
	SD	0.000666	0.000200	0.000153	0.000153
	%CV	0.425%	0.246%	0.190%	0.781%
	% Bias	-1.47%	-0.12%	0.29%	1.91%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2302119); EQC (Lot: 20012020-B); LMQC (Lot: 240109-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 2 FID1*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0979</i>	<i>0.0192</i>
Run 1 <i>ALC_20240521_BAM</i>	1	0.0971	0.0196
	2	0.0988	0.0197
	3	0.0992	0.0199
Within Run	Mean	0.0984	0.0197
	SD	0.001115	0.000153
	%CV	1.134%	0.774%
	% Bias	0.48%	2.78%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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 2 FID2*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0979</i>	<i>0.0192</i>
Run 1 <i>ALC_20240521_BAM</i>	1	0.0957	0.0195
	2	0.0972	0.0197
	3	0.0977	0.0199
Within Run	Mean	0.0969	0.0197
	SD	0.001041	0.000200
	%CV	1.075%	1.015%
	% Bias	-1.06%	2.60%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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: *Isopropanol*
 Units: *g/100 mL*
 Instrument: *Headpace 2 FID1*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1020</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1025	0.0195
	2	0.1023	0.0195
	3	0.1020	0.0195
<i>Within Run</i>	Mean	0.1023	0.0195
	SD	0.000252	0.000000
	%CV	0.246%	0.000%
	% Bias	0.26%	1.56%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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: *Isopropanol*
 Units: *g/100 mL*
 Instrument: *Headpace 2 FID2*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1020</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1013	0.0193
	2	0.1010	0.0195
	3	0.1006	0.0195
<i>Within Run</i>	Mean	0.1010	0.0194
	SD	0.000351	0.000115
	%CV	0.348%	0.594%
	% Bias	-1.01%	1.22%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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: *Acetone*
 Units: *g/100 mL*
 Instrument: *Headspace 2 FID1*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1487</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1521	0.0188
	2	0.1514	0.0186
	3	0.1489	0.0187
Within Run	Mean	0.1508	0.0187
	SD	0.001682	0.000100
	%CV	1.116%	0.535%
	% Bias	1.41%	-2.60%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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: *Acetone*
 Units: *g/100 mL*
 Instrument: *Headspace 2 FID2*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *5/21/2024 to 5/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1487</i>	<i>0.0192</i>
Run 1 ALC_20240521_BAM	1	0.1505	0.0187
	2	0.1497	0.0186
	3	0.1470	0.0187
Within Run	Mean	0.1491	0.0187
	SD	0.001834	0.000058
	%CV	1.230%	0.309%
	% Bias	0.25%	-2.78%

Comments: MQC2 (Lot: 2206153); LMQC (Lot: 240109-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 $\leq \pm 10\%$

SUMMARY OF VERIFICATION PERFORMANCE

Units: *g/100 mL*

Instrument: *Headspace 2*

Analyst: *Brooke A. Mendenhall*

Study Dates: *5/21/2024 to 5/21/2024*

Matrix: *Blood*

Failed Runs (include dates/reasons):

N/A

Deviations from SOP:

N/A

Other Notes:

N/A

Conclusion:

Headspace 2 is fit for use on casework analysis of ethanol, methanol, isopropanol and acetone.