



Verification of Quantitative Methods

Purpose	Test run on 10/16/2024 showed a shift in retention times and that the column was not sufficiently conditioned after installation. After further conditioning, test run ALC_20241021_TEST and ALC_20241021_TEST2 showed no further shifting in retention times. Verification completed to establish retention times.
Analyte	Ethanol, Methanol, Acetone, Isopropanol
Units of Measure	g/100 mL
Analyst Performing Verification Study	Brooke A. Mendenhall
Responsible Supervisor	Jessica L. Ayala
Start Date	October 21, 2024
Completion Date	October 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 3
Instrument Serial Number	Headspace CN16140002 Gas Chromatograph US16163003
Method	ALC.M

Verification Approval

Analyst: _____ 10/24/2024
Date

Responsible Supervisor: _____ 10/24/2024
Date

Verification Study**BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1590</i>	<i>0.0802</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 ALC_20241021_BAM	1	0.1564	0.0784	0.0797	0.0196
	2	0.1577	0.0792	0.0806	0.0198
	3	0.1580	0.0790	0.0801	0.0198
Within Run	Mean	0.1574	0.0789	0.0801	0.0197
	SD	0.000850	0.000416	0.000451	0.000115
	%CV	0.540%	0.528%	0.563%	0.585%
	% Bias	-1.03%	-1.66%	0.17%	2.78%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2401241); EQC (Lot: 517757); 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 3 FID2*

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 Matrix: *Blood*

Run Date	Run Order	MQC2	BQC1	EQC	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.1590</i>	<i>0.0802</i>	<i>0.0800</i>	<i>0.0192</i>
Run 1 ALC_20241021_BAM	1	0.1561	0.0790	0.0793	0.0197
	2	0.1573	0.0799	0.0802	0.0198
	3	0.1562	0.0799	0.0796	0.0198
Within Run	Mean	0.1565	0.0796	0.0797	0.0198
	SD	0.000666	0.000520	0.000458	0.000058
	%CV	0.425%	0.653%	0.575%	0.292%
	% Bias	-1.55%	-0.75%	-0.38%	2.95%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2401241); EQC (Lot: 517757); 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 3 FID1*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 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_20241021_BAM</i>	1	0.0958	0.0194
	2	0.0974	0.0197
	3	0.0976	0.0197
Within Run	Mean	0.0969	0.0196
	SD	0.000987	0.000173
	%CV	1.018%	0.884%
	% Bias	-0.99%	2.08%

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 3 FID2*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 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_20241021_BAM</i>	1	0.0956	0.0196
	2	0.0970	0.0199
	3	0.0963	0.0199
Within Run	Mean	0.0963	0.0198
	SD	0.000700	0.000173
	%CV	0.727%	0.875%
	% Bias	-1.63%	3.13%

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 3 FID1*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 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_20241021_BAM	1	0.1022	0.0197
	2	0.1020	0.0197
	3	0.1022	0.0196
<i>Within Run</i>	Mean	0.1021	0.0197
	SD	0.000115	0.000058
	%CV	0.113%	0.294%
	% Bias	0.13%	2.43%

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 3 FID2*

BIAS AND PRECISION

Analyst: *Brooke A. Mendenhall*
 Study Dates: *10/21/2024 to 10/21/2024*
 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_20241021_BAM	1	0.1024	0.0199
	2	0.1023	0.0199
	3	0.1014	0.0199
<i>Within Run</i>	Mean	0.1020	0.0199
	SD	0.000551	0.000000
	%CV	0.540%	0.000%
	% Bias	0.03%	3.65%

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 3 FID1**

BIAS AND PRECISION

Analyst: **Brooke A. Mendenhall**
 Study Dates: **10/21/2024 to 10/21/2024**
 Matrix: **Blood**

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		0.1487	0.0192
Run 1 ALC_20241021_BAM	1	0.1526	0.0198
	2	0.1515	0.0196
	3	0.1504	0.0197
<i>Within Run</i>	Mean	0.1515	0.0197
	SD	0.001100	0.000100
	%CV	0.726%	0.508%
	% Bias	1.88%	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 3 FID2**

BIAS AND PRECISION

Analyst: **Brooke A. Mendenhall**
 Study Dates: **10/21/2024 to 10/21/2024**
 Matrix: **Blood**

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		0.1487	0.0192
Run 1 ALC_20241021_BAM	1	0.1528	0.0199
	2	0.1517	0.0196
	3	0.1491	0.0198
<i>Within Run</i>	Mean	0.1512	0.0198
	SD	0.001900	0.000153
	%CV	1.257%	0.773%
	% Bias	1.68%	2.95%

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 3*

Analyst: *Brooke A. Mendenhall*

Study Dates: *10/21/2024 to 10/21/2024*

Matrix: *Blood*

Failed Runs (include dates/reasons):

N/A

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.