



Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after the installation of a new computer.
Analyte	Ethanol, Methanol, Acetone, Isopropanol
Units of Measure	g/100 mL
Analyst Performing Verification Study	Jihau Yu
Responsible Supervisor	Corissa L. Rodgers
Start Date	June 21, 2024
Completion Date	June 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: _____ 07/01/2024
Date

Responsible Supervisor: _____ 07/01/2024
Date

Verification Study**BIAS AND PRECISION**

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

Analyst: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1575	0.0803	0.0808	0.0200
	2	0.1565	0.0802	0.0807	0.0198
	3	0.1577	0.0805	0.0812	0.0199
Within Run	Mean	0.1572	0.0803	0.0809	0.0199
	SD	0.000643	0.000153	0.000265	0.000100
	%CV	0.409%	0.190%	0.327%	0.503%
	% Bias	-1.11%	-1.31%	1.12%	3.65%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2302119); 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: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1574	0.0815	0.0806	0.0201
	2	0.1565	0.0814	0.0806	0.0198
	3	0.1577	0.0816	0.0810	0.0199
Within Run	Mean	0.1572	0.0815	0.0807	0.0199
	SD	0.000624	0.000100	0.000231	0.000153
	%CV	0.397%	0.123%	0.286%	0.766%
	% Bias	-1.13%	0.12%	0.92%	3.82%

Comments: MQC2 (Lot: 2206153); BQC1 (Lot: 2302119); 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: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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 ALC_20240621_JY	1	0.0963	0.0203
	2	0.0957	0.0199
	3	0.0967	0.0200
Within Run	Mean	0.0962	0.0201
	SD	0.000503	0.000208
	%CV	0.523%	1.037%
	% Bias	-1.70%	4.51%

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: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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 ALC_20240621_JY	1	0.0959	0.0203
	2	0.0954	0.0199
	3	0.0965	0.0201
Within Run	Mean	0.0959	0.0201
	SD	0.000551	0.000200
	%CV	0.574%	0.995%
	% Bias	-2.01%	4.69%

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: *Headspace 3 FID1*

BIAS AND PRECISION

Analyst: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1018	0.0197
	2	0.1015	0.0197
	3	0.1019	0.0196
<i>Within Run</i>	Mean	0.1017	0.0197
	SD	0.000208	0.000058
	%CV	0.205%	0.294%
	% Bias	-0.26%	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: *Headspace 3 FID2*

BIAS AND PRECISION

Analyst: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1017	0.0197
	2	0.1014	0.0197
	3	0.1018	0.0197
<i>Within Run</i>	Mean	0.1016	0.0197
	SD	0.000208	0.000000
	%CV	0.205%	0.000%
	% Bias	-0.36%	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 FID1*

BIAS AND PRECISION

Analyst: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1457	0.0192
	2	0.1461	0.0194
	3	0.1468	0.0194
Within Run	Mean	0.1462	0.0193
	SD	0.000557	0.000115
	%CV	0.381%	0.597%
	% Bias	-1.68%	0.69%

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: *Jihau Yu*
 Study Dates: *6/21/2024 to 6/21/2024*
 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_20240621_JY	1	0.1457	0.0192
	2	0.1461	0.0194
	3	0.1468	0.0194
Within Run	Mean	0.1462	0.0193
	SD	0.000557	0.000115
	%CV	0.381%	0.597%
	% Bias	-1.68%	0.69%

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: *Jihau Yu*

Study Dates: *6/21/2024 to 6/21/2024*

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.