



## Verification of Quantitative Methods

Purpose	To show the instrument is fit for use after replacing the front column and maintenance performed.
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	September 30, 2024
Completion Date	September 30, 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: \_\_\_\_\_ 10/4/2024  
Date

Responsible Supervisor: \_\_\_\_\_  
Date

**Verification Study****BIAS AND PRECISION**

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

Analyst: *Brooke A. Mendenhall*  
 Study Dates: *9/30/2024 to 9/30/2024*  
 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>
<b>Run 1</b> ALC_20240930_BAM	1	0.1581	0.0786	0.0797	0.0197
	2	0.1563	0.0784	0.0797	0.0197
	3	0.1567	0.0789	0.0798	0.0197
<b>Within Run</b>	<b>Mean</b>	<b>0.1570</b>	<b>0.0786</b>	<b>0.0797</b>	<b>0.0197</b>
	<b>SD</b>	<b>0.000945</b>	<b>0.000252</b>	<b>0.000058</b>	<b>0.000000</b>
	<b>%CV</b>	<b>0.602%</b>	<b>0.320%</b>	<b>0.072%</b>	<b>0.000%</b>
	<b>% Bias</b>	<b>-1.24%</b>	<b>-1.95%</b>	<b>-0.33%</b>	<b>2.60%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*  
 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>
<b>Run 1</b> ALC_20240930_BAM	1	0.1568	0.0796	0.0796	0.0197
	2	0.1560	0.0795	0.0796	0.0197
	3	0.1564	0.0799	0.0795	0.0197
<b>Within Run</b>	<b>Mean</b>	<b>0.1564</b>	<b>0.0797</b>	<b>0.0796</b>	<b>0.0197</b>
	<b>SD</b>	<b>0.000400</b>	<b>0.000208</b>	<b>0.000058</b>	<b>0.000000</b>
	<b>%CV</b>	<b>0.256%</b>	<b>0.261%</b>	<b>0.073%</b>	<b>0.000%</b>
	<b>% Bias</b>	<b>-1.64%</b>	<b>-0.67%</b>	<b>-0.54%</b>	<b>2.60%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*  
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0979</i>	<i>0.0192</i>
<b>Run 1</b> <i>ALC_20240930_BAM</i>	1	0.0973	0.0197
	2	0.0954	0.0197
	3	0.0963	0.0198
<b>Within Run</b>	<b>Mean</b>	<b>0.0963</b>	<b>0.0197</b>
	<b>SD</b>	<b>0.000950</b>	<b>0.000058</b>
	<b>%CV</b>	<b>0.987%</b>	<b>0.293%</b>
	<b>% Bias</b>	<b>-1.60%</b>	<b>2.78%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*  
 Matrix: *Blood*

Run Date	Run Order	MQC2	LMQC
<i>Target Concentration (g/100 mL):</i>		<i>0.0979</i>	<i>0.0192</i>
<b>Run 1</b> <i>ALC_20240930_BAM</i>	1	0.0962	0.0198
	2	0.0949	0.0198
	3	0.0960	0.0199
<b>Within Run</b>	<b>Mean</b>	<b>0.0957</b>	<b>0.0198</b>
	<b>SD</b>	<b>0.000700</b>	<b>0.000058</b>
	<b>%CV</b>	<b>0.731%</b>	<b>0.291%</b>
	<b>% Bias</b>	<b>-2.25%</b>	<b>3.30%</b>

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  $\leq 0.05$  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: *Brooke A. Mendenhall*  
 Study Dates: *9/30/2024 to 9/30/2024*  
 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_20240930_BAM	1	0.1019	0.0196
	2	0.1017	0.0195
	3	0.1011	0.0195
<i>Within Run</i>	<b>Mean</b>	<b>0.1016</b>	<b>0.0195</b>
	<b>SD</b>	<b>0.000416</b>	<b>0.000058</b>
	<b>%CV</b>	<b>0.410%</b>	<b>0.296%</b>
	<b>% Bias</b>	<b>-0.42%</b>	<b>1.74%</b>

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  $\leq 0.05$  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: *Brooke A. Mendenhall*  
 Study Dates: *9/30/2024 to 9/30/2024*  
 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_20240930_BAM	1	0.1011	0.0196
	2	0.1016	0.0195
	3	0.1010	0.0195
<i>Within Run</i>	<b>Mean</b>	<b>0.1012</b>	<b>0.0195</b>
	<b>SD</b>	<b>0.000321</b>	<b>0.000058</b>
	<b>%CV</b>	<b>0.318%</b>	<b>0.296%</b>
	<b>% Bias</b>	<b>-0.75%</b>	<b>1.74%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*  
 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_20240930_BAM	1	0.1476	0.0187
	2	0.1452	0.0186
	3	0.1434	0.0186
<i>Within Run</i>	<b>Mean</b>	<b>0.1454</b>	<b>0.0186</b>
	<b>SD</b>	<b>0.002107</b>	<b>0.000058</b>
	<b>%CV</b>	<b>1.449%</b>	<b>0.310%</b>
	<b>% Bias</b>	<b>-2.22%</b>	<b>-2.95%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*  
 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_20240930_BAM	1	0.1466	0.0187
	2	0.1452	0.0186
	3	0.1434	0.0187
<i>Within Run</i>	<b>Mean</b>	<b>0.1451</b>	<b>0.0187</b>
	<b>SD</b>	<b>0.001604</b>	<b>0.000058</b>
	<b>%CV</b>	<b>1.106%</b>	<b>0.309%</b>
	<b>% Bias</b>	<b>-2.44%</b>	<b>-2.78%</b>

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  $\leq 0.05$  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: *9/30/2024 to 9/30/2024*

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.