

Verification of Quantitative Methods

| Purpose | To show that the instrument is fit for use after completion of annual preventative maintenance. | | |
|---------------------------------------|---|--|--|
| Analyte | Ethanol | | |
| Unit of Measure | g/100 mL | | |
| Lowest Calibrator Concentration | 0.010 g/100mL | | |
| Highest Calibrator Concentration | 0.500 g/100 mL | | |
| Primary Matrix | Blood | | |
| Secondary Matrices | Alcoholic Beverages and Other Liquid Specimens | | |
| Analyst Performing Verification Study | Melissa Henry | | |
| Reviewer | Kayla Baylor | | |
| Start Date | January 30, 2024 | | |
| Completion Date | January 30, 2024 | | |
| Instrument | BAC-1 | | |
| Method | BAC.M | | |

Validation Approval

Analyst:

Date

Reviewer:

Date

BIAS AND PRECISION

Analyst: Melissa Henry C+ d. Do 1/30/2024

| Study | Dates: | 1/30/202 |
|-------|---------|----------|
| | Matrix: | Blood |

| Batch Name | Run Order | Low QC | Blood QC A | Blood QC B | High QC |
|-----------------|--------------------------|--------|------------|------------|---------|
| Target | Concentration (g/100mL): | 0.080 | 0.0778 | 0.1976 | 0.400 |
| BAC_20240130_MH | 1 | 0.0764 | 0.0763 | 0.1926 | 0.4033 |
| | 2 | 0.0768 | 0.0763 | 0.1942 | 0.4085 |
| | 3 | 0.0774 | 0.0765 | 0.1966 | 0.4159 |
| Within Run | Mean | 0.0769 | 0.0764 | 0.1945 | 0.4092 |
| | SD | 0.0005 | 0.0001 | 0.0020 | 0.0063 |
| | %CV | 0.65% | 0.15% | 1.04% | 1.55% |
| | % Bias | -3.92% | -1.84% | -1.59% | 2.31% |

Acceptance Criteria:

Verification Study

Analyte: Ethanol

%Bias: ≤5% if target concentraton is > 0.05 g/100mL ≤10% if target concentraton is ≤ 0.05 g/100mL Within-Run %CV ≤10%

| rification St | udy | | | | | | BIAS AND PRECIS |
|--------------------|-----------------|--------------------------|---------|---|--|---------|------------------------|
| Analyte: Ethanol | | | | | Analyst: Melissa Henry Study Dates: 1/30/2024 | | |
| Units: g/100 mL | | | | | | | |
| Instrument: | BAC-1 F | ID2 | | | | | Blood |
| Γ | Batch Name | Run Order | Low QC | Blood QC A | Blood QC B | High QC | |
| ľ | Target C | Concentration (g/100mL): | 0.080 | 0.0778 | 0.1976 | 0.400 | |
| F | BAC_20240130_MH | 1 | 0.0757 | 0.0759 | 0.1925 | 0.4058 | 1 |
| | | 2 | 0.0764 | 0.0759 | 0.1944 | 0.4112 | |
| | | 3 | 0.0775 | 0.0762 | 0.1971 | 0.4190 | |
| | Within Run | Mean | 0.0765 | 0.0760 | 0.1947 | 0.4120 | |
| | | SD | 0.0009 | 0.0002 | 0.0023 | 0.0066 | |
| | | %CV | 1.19% | 0.23% | 1.19% | 1.61% | |
| | | % Bias | -4.33% | -2.31% | -1.48% | 3.00% | |
| Comments: | | % Blas | -4.33% | -2.31% | -1.48% | 3.00% | 1 |
| ceptance Criteria: | | | ≤10% if | arget concentraton i target concentraton Within-Run %CV ≤10 | is ≤ 0.05 g/100mL | | |

| | | SUMMARY OF VALIDATION PERFORMANCE | |
|-----------------|------------------------------|--|--|
| | Ethanol g/100 mL BAC-1 | Analyst: Study Dates: Matrix: | |
| Failed Runs (in | clude dates/reasons): | | |
| | Date | Reason | |
| | N/A | N/A | |
| | | | |
| Deviat | ions from SOP: | Ν/Α | |
| | | | |
| Notes: | | Ν/Α | |
| c | onclusion: | BAC-1 is fit for analysis of ethanol casework. | |
| | | | |