Uncertainty of Measurement for Quantitative Methods

Analyte(s)	**Ethanol**
Units of Measure	**g/100mL**
Lowest Calibrator Concentration	**0.010**
Highest Calibrator Concentration	**0.500**
Sample Volume	**100 µL**
Analyst Preparing Uncertainty Estimation	**K. Baylor and M. Henry**
Laboratory Director	**Derek Sanders**
Matrix	**Blood**
Measurement Process	**Regression Analysis**
Traceability of Calibrators	**Certificates of Analysis**
Reporting Confidence Interval	**99.73% (k=3)**
Instrument	**BAC-1 and BAC-2**
Standard Operating Procedure	**TOX-03-00 Validation of Quantitative Methods and LOG-41-05 Uncertainty of Measurement**
Method Name	**BAC.M**

Uncertainty of Measurement Approval

Analyst: Kayla M. Baylor 11/17/2023
Date

Analyst: Melina Henry 11/17/2023
Date

Laboratory Director: Derek Sanders 20 Nov 2023
Date

Quality Manager: Lisa Wentz 20 Nov. 2023
Date

Note: No data in the UM has been changed. UM is being printed and re-signed to capture addition of header and footer.

Uncertainty of Measurement Budget

Category	Uncertainty Component	Method of Evaluation	Comments
Staff	Multiple Analysts	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
	Training	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
	Experience	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
Calibrators	Purity of Certified Reference Material (CRM)	Type B: CRM certificate of analysis	Maximum uncertainty from certificates of analysis reported at k=2.
Internal Standard	Purity of Reagent	No Influence	Same IS lot used throughout batch.
	Preparation of Internal Standard	No Influence	Same IS lot used throughout batch.
Case Sampling	Pipetting of case sample	Type A: External calibration certificates	Maximum %RSD from data on calibration certificates; certifcate data provided at end of packet.
	Homogenization	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
	Temperature	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
	Mixing and homogeneity in vial	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
	Duplicate analysis	Type B: Duplicate Agreement	SOP allowance of 5% at specification limit of 0.08g/100mL stated in the Texas Penal Code
Instrumental Analysis	Instrument parameter settings (e.g., oven temperatures, injection volume, injection types, incubation time and temperature, column condition, autosampler syringe, autosampler reproducibility, etc).	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.
Analyte Stability	Sample stability during analysis	Type A: Measurement Reproducibility	Pooled %RSD from historical control data.

Uncertainty of Measurement Estimation Form

Analyte: Ethanol
Analytical Range: 0.01 - 0.50 g/100 mL

Line Item	*Uncertainty Component*	*Details*	*Value*	*Units*	*Distribution*	*Type*	*Divisor*	*Degrees Freedom (n-k)*	*Standard Uncertainty*	*Component Contribution %*
1	Measurement Reproducibility	-	2.816	%	Normal	A	1.00	175	2.816	29
2	CRM Uncertainty	-	0.500	%	Normal	B	2.00	infinite	0.250	3
3	100 µL with Pipette	Addition of CRM to vial using 10-100 or 20-200 µL pipette.	1.582	%	Normal	A	1.00	9	1.582	17
4	1000 µL with Pipette	Addition of internal standard using repeater pipette.	2.040	%	Normal	A	1.00	9	2.040	21
5	Duplicates		5.000	%	Rectangular	B	1.73	inifite	2.890	30
										100
	Combined Standard Uncertainty		u_c						4.797	%
	Expanded Uncertainty (99.73% CI)		*UM (k=3)*						14.391	%
	Rounded Expanded Uncertainty (99.73% CI) for Casework		*UM* (*k*=3)						**14.39**	%

NOTE: Regardless of the number of digits that are showing in a cell, Excel carries the maximum number of significant figures in the background and will use the entire number for further calculations.

Measurement Reproducibility

Ethanol

Pooled %RSD:	2.816				
k	5				
Control	Extra Low QC	Low QC	Blood QC A	Blood QC B	High QC
Lot	R-23-5000	15122021-A	2101199	2110181	30012020-A
Avg Control Result	0.0189	0.0799	0.0776	0.1977	0.4047
Control SD	0.0009	0.0017	0.0017	0.0059	0.0061
%RSD	4.53	2.19	2.15	2.99	1.51
(N-1)x%RSD^2	656.36	172.43	161.05	313.92	84.00
C_{Target}	0.0180	0.0800	0.0778	0.1976	0.4000
Control Acceptability (±)	10%	5%	5%	5%	5%
Acceptance Range Low	0.0162	0.0760	0.0739	0.1877	0.3800
Acceptance Range High	0.0198	0.0840	0.0817	0.2075	0.4200
N	33	37	36	36	38
	0.0188	0.0784	0.0782	0.1978	0.4038
	0.0198	0.0792	0.0767	0.1960	0.4013
	0.0189	0.0802	0.0778	0.1988	0.4066
	0.0186	0.0792	0.0772	0.1938	0.3995
	0.0188	0.0790	0.0770	0.2009	0.4020
	0.0187	0.0781	0.0785	0.1965	0.3989
	0.0200	0.0802	0.0796	0.2084	0.4073
	0.0205	0.0811	0.0795	0.2002	0.4094
	0.0226	0.0785	0.0789	0.2002	0.4072
	0.0183	0.0786	0.0765	0.1966	0.3984
	0.0189	0.0812	0.0793	0.2000	0.4029
	0.0190	0.0791	0.0785	0.1986	0.4131
	0.0188	0.0803	0.0750	0.1915	0.3999
	0.0187	0.0794	0.0769	0.1958	0.4088
	0.0189	0.0799	0.0801	0.1922	0.4055
	0.0191	0.0868	0.0780	0.1946	0.4008
	0.0193	0.0849	0.0793	0.2046	0.4246
	0.0192	0.0794	0.0793	0.2064	0.4083
	0.0183	0.0796	0.0799	0.1985	0.3988
	0.0184	0.0817	0.0806	0.2094	0.4105
	0.0184	0.0801	0.0783	0.2093	0.4110
	0.0187	0.0795	0.0787	0.1925	0.4124
	0.0184	0.0797	0.0765	0.2118	0.3993
	0.0185	0.0792	0.0766	0.1898	0.4047
	0.0187	0.0789	0.0747	0.1950	0.3964
	0.0195	0.0783	0.0795	0.1948	0.3998
	0.0191	0.0794	0.0778	0.1985	0.4073
	0.0181	0.0807	0.0763	0.1927	0.4075
	0.0182	0.0785	0.0764	0.1944	0.4076
	0.0182	0.0794	0.0769	0.1934	0.4018
	0.0179	0.0808	0.0762	0.1992	0.4111
	0.0187	0.0782	0.0758	0.1933	0.4075
	0.0187	0.0796	0.0766	0.1877	0.3946
		0.0783	0.0782	0.1877	0.4001
		0.0808	0.0740	0.1972	0.4003
		0.0782	0.0750	0.1991	0.4051
		0.0809			0.3946
					0.4128

Data from Certified Reference Material Certificates of Analysis

Max % Uncertainty	0.500

Analyte	CRM Source	Lot Number	CRM Concentration (g/100 mL)	CRM Expanded Uncertainty (g/100 mL)	CRM Uncertainty (%)	k
Ethanol	Cerilliant	FN12272201	0.010	0.00005	0.500	2.00
Ethanol	Cerilliant	FN03122112	0.025	0.00010	0.400	2.00
Ethanol	Cerilliant	FN06171903	0.050	0.00019	0.380	2.00
Ethanol	Cerilliant	FN11172002	0.100	0.00040	0.400	2.00
Ethanol	Cerilliant	FN02052101	0.200	0.00080	0.400	2.00
Ethanol	Cerilliant	FN03052102	0.400	0.00200	0.500	2.00
Ethanol	Cerilliant	FN06262004	0.500	0.00200	0.400	2.00

Data from External Calibration Certificates (10-100 µL Pipettes)

MAX %RSD
1.582

		% Actual Imprecision (Stdev /Mean)	
Date of Calibration	Target Volume (µL)	**41815**	
7/3/2023	10	0.718	
	50	0.060	
	100	0.070	
7/10/2023	100	0.300	
10/12/2023	10	1.582	
	50	0.830	
	100	0.207	

Data from External Calibration Certificates (20-200 µL Pipettes)

MAX %RSD
0.995

		% Actual Imprecision (Stdev /Mean)	
Date of Calibration	Target Volume (µL)	**23A35053**	
7/3/2023	20	0.495	
	100	0.202	
	200	0.050	
7/10/2023	20	0.289	
	100	0.501	
	200	0.250	
10/12/2023	20	0.995	
	100	0.360	
	200	0.161	

Data from External Calibration Certificates (Repeater Pipette)

MAX %RSD
2.040

		% Actual Imprecision (Stdev /Mean)	
Date of Calibration	Target Volume (µL)	**H44205L**	**H44206L**
7/3/2023	1000	0.140	0.200
	5000	0.022	0.026
	10000	0.026	0.016
7/10/2023	100	1.388	0.091
	1000	1.348	1.695
	5000	0.401	2.040
	10000	1.275	1.580
10/12/2023	1000	0.342	1.285
	5000	0.030	0.252
	10000	0.385	0.244

Date	Section	Previous	Changed to	Reason	By whom
11/2/2023	N/A	N/A	Added header information.	Altered to include header information.	KB/MH
11/9/2023	N/A	N/A	Added header information to remaining tabs except cover page. Added footer to all tabs.	Altered to add header and footer information.	KB