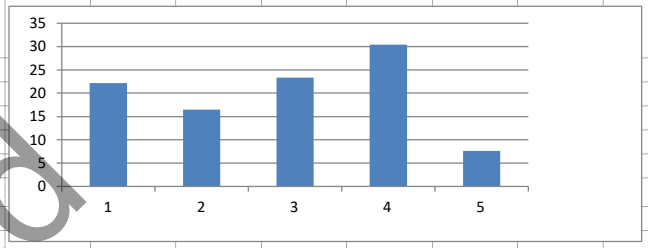
Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 10/31/2023

Line Item	Uncertainty Component		Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control		0.803	%	Normal	A	1.41	703	0.568	22
2	Matrix - Duplicates		0.597	%	Normal	A	1.41	2243	0.422	16
3	Aqueous QC Bias		0.846	%	Normal	A	1.41	224	0.598	23
4	Pipettor/Diluter		0.780	%	Normal	B	1.00		0.780	30
5	CRM - Calibrators		0.390	%	Normal	B	2.00		0.195	8
	Combined Standard Unc	u_c							1.23	100
	Expanded Unc	U (k=2)		95.45%					2.45	
	Expanded Unc	U (k=3)		99.73%					3.68	
	Reported Uncertainty:		**5.0**	**99.99%**	*4.0756*	*k*				



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070122-063023) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot # 092421JM and 041323RB.
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 2244 samples analyzed from 070122 through 063023 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - concentration with the largest percent difference from the target; 0.040 g/100mL Lipomed Aqueous Control; Lot #s 14082019-B. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery from serial #s ML600HF11786S1, ML600AJ16402, ML600BB17066 (k=1, Calibrate Inc. 10/13/22)
5	CRM Calibrators uncertainty - based on certificates of analysis for the lot #s used in this time period with the largest relative expanded uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070122-063023

 # Entries

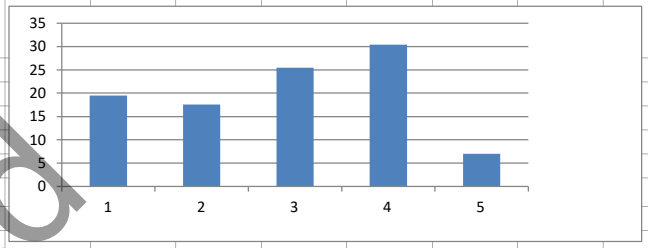
9

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
JSH	8/10/2022	WBC	092421JM	0.1529	0.199	-23.17%	Jack	Rosner's Outlier Test
GMS	9/12/2022	WBC	092421JM	0.1818	0.199	-8.64%	Jack	Rosner's Outlier Test
RB	10/18/2022	WBC	092421JM	0.1563	0.199	-21.46%	Jill	Rosner's Outlier Test
JSH	11/4/2022	WBC	092421JM	0.1555	0.199	-21.86%	Jack	Rosner's Outlier Test
NI	2/8/2023	WBC	092421JM	0.1845	0.199	-7.29%	Jack	Rosner's Outlier Test
GMS	2/28/2023	WBC	092421JM	0.1251	0.199	-37.14%	Jack	Rosner's Outlier Test
GMS	2/28/2023	WBC	092421JM	0.1010	0.199	-49.25%	Jack	Rosner's Outlier Test
DJS	5/12/2023	WBC	092421JM	0.0926	0.199	-53.47%	Jack	Rosner's Outlier Test
RB	5/19/2023	WBC	092421JM	0.1869	0.199	-6.08%	Jill	Rosner's Outlier Test

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 10/20/2022 (updated 1/30/23 to include coverage probability calculation)

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.770	%	Normal	A	1.41	703	0.545	20
2	Matrix - Duplicates	0.693	%	Normal	A	1.41	2528	0.490	18
3	Aqueous QC Bias	1.008	%	Normal	A	1.41	247	0.713	26
4	Pipettor/Diluter	0.850	%	Normal	B	1.00		0.850	30
5	CRM - Calibrators	0.390	%	Normal	B	2.00		0.195	7
	Combined Standard Unc	u_c						1.34	100
	Expanded Unc	U (k=2)	95.45%					2.69	
	Expanded Unc	U (k=3)	99.73%					4.03	
	Reported Uncertainty:	**5.0**	**99.97%**	*3.7214*	*k*				



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

The basis for the data above:

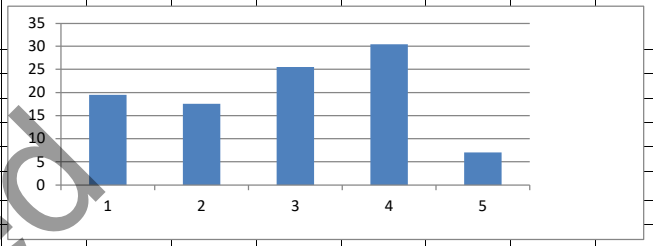
1	Measurement Process Reproducibility (data from 070121-063022) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot # 052920JM and 092421JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 2529 samples analyzed from 070121 through 063022 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - concentration with the largest percent difference from the target; 0.040 g/100mL Lipomed Aqueous Control; Lot #s 14082019-B. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery from serial #s MD96HH2479, ML600HF11786S1, MD96HB2375, ML600AJ16402, ML600BB17066 (k=1, Calibrate Inc. 10/13/21)
5	CRM Calibrators uncertainty - based on certificates of analysis for the lot #s used in this time period with the largest relative expanded uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 10/20/2022

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.770	%	Normal	A	1.41	703	0.545	20
2	Matrix - Duplicates	0.693	%	Normal	A	1.41	2528	0.490	18
3	Aqueous QC Bias	1.008	%	Normal	A	1.41	247	0.713	26
4	Pipettor/Diluter	0.850	%	Normal	B	1.00		0.850	30
5	CRM - Calibrators	0.390	%	Normal	B	2.00		0.195	7
	Combined Standard Unc	u_c						1.34	100
	Expanded Unc	U (k=2)						2.69	
	Expanded Unc	U (k=3)						4.03	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070121-063022) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #052920JM and 092421JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 2529 samples analyzed from 0701201 through 063022 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - concentration with the largest percent difference from the target;0.040 g/100mL Lipomed Aqueous Control; Lot #s 14082019-B. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery from serial #s MD96HH2479, ML600HF11786S1, MD96HB2375, ML600AJ16402, ML600BB17066 (k=1, Calibrate Inc. 10/13/21)
5	CRM Calibrators uncertainty - based on certificates of analysis for the lot #s used in this time period with the largest relative expanded uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070121-063022

 # Entries

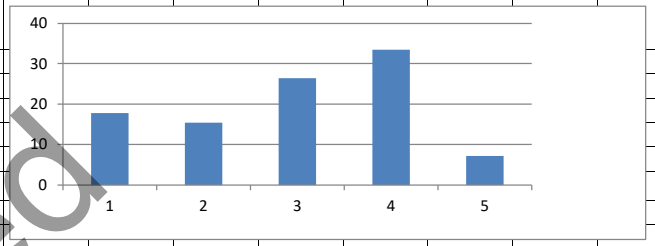
2

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
JSH	9/14/2021	Whole Blood	052920JM	0.0399	0.198	-79.85%	Jill	AqC 0.04 and WBC switched when loading instrument
JSH	9/14/2021	Aqueous Control	14082019-B	0.1932	0.040	383.00%	Jill	AqC 0.04 and WBC switched when loading instrument

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 11/29/2021

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.704	%	Normal	A	1.41	722	0.498	18
2	Matrix - Duplicates	0.610	%	Normal	A	1.41	2443	0.432	15
3	Aqueous QC Bias	1.049	%	Normal	A	1.41	261	0.742	26
4	Pipettor/Diluter	0.939	%	Normal	B	1.00		0.939	33
5	CRM - Calibrators	0.400	%	Normal	B	2.00		0.200	7
	Combined Standard Unc	u_c						1.38	100
	Expanded Unc	U (k=2)						2.76	
	Expanded Unc	U (k=3)						4.14	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070120-063021) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #021419JM and 052920JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 2444 samples analyzed from 070120 through 063021 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - concentration with the largest percent difference from the target;0.040 g/100mL Lipomed Aqueous Control; Lot #s 14082019-B. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery from serial #s MD96HH2479, ML600HF11786, MD96HB2375, ML600AJ16402, ML600BB17066 (k=1, Calibrate Inc. 10/30/20 and 5/4/21)
5	CRM Calibrators uncertainty - based on certificates of analysis for the lot #s used in this time period with the largest relative expanded uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.
Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070120-063021

 # Entries

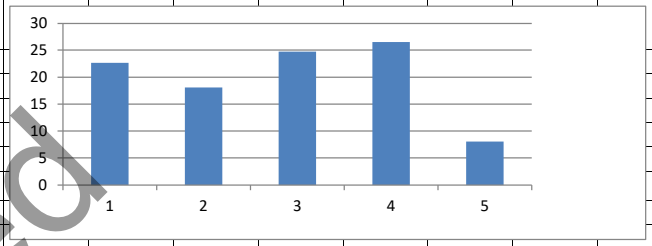
1

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
NI	12/2/2020	Whole Blood	052920JM	0.1029	0.198	-48.03%	Jack	Outlier Tests (Grubbs'/Rosner's)

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 12/4/2020

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.798	%	Normal	A	1.41	725	0.564	23
2	Matrix - Duplicates	0.639	%	Normal	A	1.41	2586	0.452	18
3	Aqueous QC Bias	0.873	%	Normal	A	1.41	262	0.617	25
4	Pipettor/Diluter	0.662	%	Normal	B	1.00		0.662	27
5	CRM - Calibrators	0.400	%	Normal	B	2.00		0.200	8
	Combined Standard Unc	u_c						1.18	100
	Expanded Unc	U (k=2)						2.35	
	Expanded Unc	U (k=3)						3.53	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070119-063020) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #021419JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 2587 samples analyzed from 070119 through 063020 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - concentration with the largest percent difference from the target;0.040 g/100mL Lipomed Aqueous Control weighted by # of replicates per control lot and reported as RSD; Lot #s 09022015-A and 14082019-B. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery from serial #s MD96HH2479, ML600HF11786, MD96HB2375 (k=1, Calibrate Inc. 10/24/19)
5	CRM Calibrators uncertainty - based on certificates of analysis for the lot #s used in this time period with the largest relative expanded uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070119-063020

 # Entries

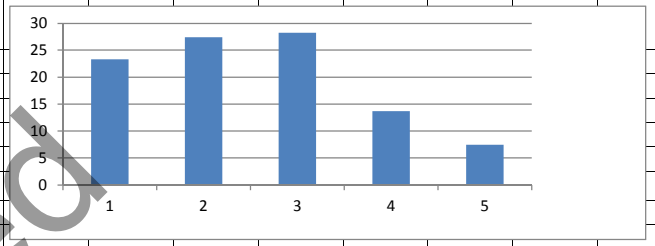
12

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
JSH	5/1/2020	Whole Blood	021419JM	0.0000	0.201	-100.00%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1430	0.201	-28.86%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1436	0.201	-28.56%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1431	0.201	-28.81%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1429	0.201	-28.91%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1432	0.201	-28.76%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
DJS	4/16/2020	Whole Blood	021419JM	0.1425	0.201	-29.10%	Jill	WBC container cap not crimped adequately resulting in evaporation/ethanol loss
NI	1/7/2020	Whole Blood	021419JM	0.1374	0.201	-31.64%	Jill	Outlier Tests (Grubbs'/Rosner's)
JSH	11/20/2019	Whole Blood	021419JM	0.1416	0.201	-29.55%	Jill	Outlier Tests (Grubbs'/Rosner's)
JSH	8/28/2019	Whole Blood	021419JM	0.1446	0.201	-28.06%	Jill	Outlier Tests (Grubbs'/Rosner's)
NI	12/9/2019	Whole Blood	021419JM	0.1861	0.201	-7.41%	Jack	Outlier Tests (Grubbs'/Rosner's)
GMS	4/28/2020	Whole Blood	021419JM	0.1867	0.201	-7.11%	Jack	Outlier Tests (Grubbs'/Rosner's)

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 13, Effective Date 2/6/2019)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 11/15/2019

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.772	%	Normal	A	1.41	872	0.546	23
2	Matrix - Duplicates	0.908	%	Normal	A	1.41	3046	0.642	27
3	Aqueous QC Bias	0.936	%	Normal	A	1.41	314	0.662	28
4	Pipettor/Diluter	0.321	%	Normal	B	1.00		0.321	14
5	CRM - Calibrators	0.350	%	Normal	B	2.00		0.175	7
	Combined Standard Unc	u_c						1.13	100
	Expanded Unc	U (k=2)						2.26	
	Expanded Unc	U (k=3)						3.40	
	Reported Uncertainty:	**5.0**							



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 calculation

The basis for the data above:

1	Measurement Process Reproducibility (data from 070118-063019) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #s120117JM and 021419JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 3047 samples analyzed from 070118 through 063019 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - the concentration with the largest percent difference from the target; 0.040 g/100mL Lipomed Aqueous Control Lot # 09022015-A. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample or internal standard delivery serial #MD96KE1165 (k=1, Calibrate Inc. 10/11/18)
5	CRM Calibrators uncertainty - all of the certificates of analysis for the lot #s used in this time period have the same uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070118-063019

 # Entries

3

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
GMS	3/6/2019	Whole Blood	120117JM	0.1396	0.200	-30.20%	Jill	Grubbs' Test/Rosner's
DJS	8/29/2018	Whole Blood	120117JM	0.1746	0.200	-12.70%	Jack	Grubbs' Test/Rosner's
JM	2/27/2019	Whole Blood	120117JM	0.1881	0.200	-5.95%	Jill	Grubbs' Test/Rosner's

Measurement Uncertainty Estimation Form

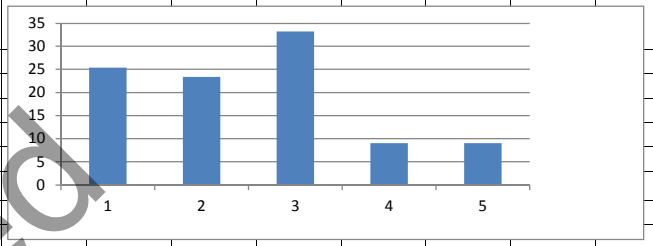
Measurement: Concentration of Ethanol in whole blood/plasma/serum

Range of measurement values: 0.025 to 0.400 g/100mL

Procedure name and revision: Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 12, Effective Date 4/10/2018)

Estimation prepared by: *Toxicology Section* **Date Prepared:** 10/25/2018

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.695	%	Normal	A	1.41	853	0.492	25
2	Matrix - Duplicates	0.641	%	Normal	A	1.41	3005	0.453	23
3	Aqueous QC Bias	0.910	%	Normal	A	1.41	309	0.643	33
4	Pipettor/Diluter	0.174	%	Normal	B	1.00		0.174	9
5	CRM - Calibrators	0.350	%	Normal	B	2.00		0.175	9
	Combined Standard Unc	u_c						0.96	100
	Expanded Unc	U (k=2)						1.92	
	Expanded Unc	U (k=3)						2.88	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1. Measurement Process Reproducibility (data from 070117-063018) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #s120116JM and 120117JM
2. Matrix Duplicates - this is the standard deviation from duplicate analysis from 3006 samples analyzed from 070117 through 063018 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3. Aqueous QC Bias - the concentration with the largest percent difference from the target;0.300 g/100mL Lipomed Aqueous Control Lot # 18052015-A/1. Assumes a normal distribution.
4. Pipettor/Diluter - this is the largest uncertainty for sampleor internal standard delivery serial #MD96HH2479 (k=1, Calibrate Inc. 10/23/17)
5. CRM Calibrators uncertainty - all of the certificates of analysis for the lot #s used in this time period have the same uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision: This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.

In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070117-063018

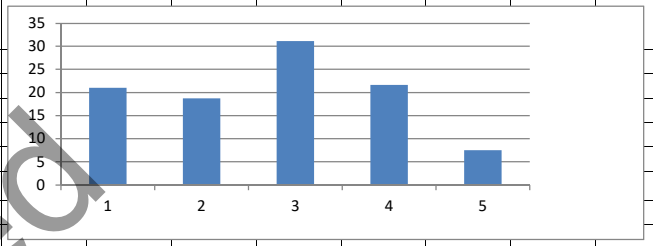
# Entries	
0	*NO DATA EXCLUDED FROM UNCERTAINTY CALCULATION 070117-063018*

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100mL
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 11, Effective Date 10/19/2017)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 10/30/2017

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.690	%	Normal	A	1.41	914	0.488	21
2	Matrix - Duplicates	0.616	%	Normal	A	1.41	3168	0.436	19
3	Aqueous QC Bias	1.023	%	Normal	A	1.41	338	0.723	31
4	Pipettor/Diluter	1.007	%	Normal	B	2.00		0.504	22
5	CRM - Calibrators	0.350	%	Normal	B	2.00		0.175	8
	Combined Standard Unc	u_c						1.11	100
	Expanded Unc	U (k=2)						2.22	
	Expanded Unc	U (k=3)						3.33	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070116-063017) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #s122915JM and 120116JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 3169 samples analyzed from 070116 through 063017 with alcohol concentrations ranging from 0.025-0.400 g/100mL. Assumes a normal distribution.
3	Aqueous QC Bias - the concentration, weighted by # of replicates per control lot, with the largest uncertainty;0.040 g/100mL Lipomed Aqueous Control Lot #s 30112011-B and 09022015-A. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sampleand internal standard delivery serial# MD96HB2375 (k=2, Calibrate Inc. 11/21/16)
5	CRM Calibrators uncertainty - all of the certificates of analysis for the lot #s used in this time period have the same uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

Data Excluded from Uncertainty Calculation for Date Range 070116-063017

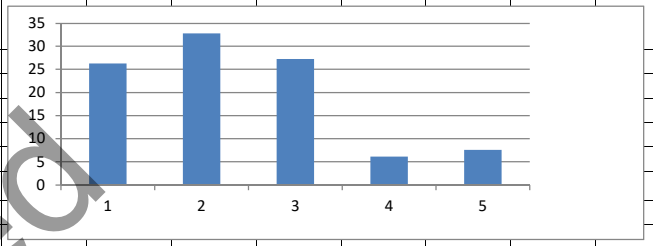
 # Entries
5

Analyst Initials	Date	Type	Lot	Result(s)	Target	% Difference	Instrument	Comment
KK	8/26/2016	whole blood	122915JM	0.0398	0.1970	-79.80%	Hobbes II	GC Busy error at vial 48, causing a vial number/data path mismatch, aqueous 0.040 QC mislabeled as WBC
JSH	10/4/2016	*201600001835826 matrix*	n/a	0.1543 and 0.2965	n/a	-63.09%	Jill	analyst notes state "insufficient amount pipetted"
DJS	11/10/2016	whole blood	122915JM	0.1484	0.199	-25.43%	Hobbes II	Grubb's Test/Rosner's Test
JSH	11/22/2016	whole blood	122915JM	0.1500	0.199	-24.62%	Jill	Grubb's Test/Rosner's Test
DJS	12/28/2016	whole blood	122915JM	0.1430	0.199	-28.14%	Jill	Grubb's Test/Rosner's Test

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100ml
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 9, Effective Date 5/24/2016)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 11/16/2016

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.857	%	Normal	A	1.41	935	0.606	26
2	Matrix - Duplicates	1.069	%	Normal	A	1.41	3313	0.756	33
3	Aqueous QC Bias	0.888	%	Normal	A	1.41	247	0.628	27
4	Pipettor/Diluter	0.282	%	Normal	B	2.00		0.141	6
5	CRM - Calibrators	0.350	%	Normal	B	2.00		0.175	8
	Combined Standard Unc	u_c						1.18	100
	Expanded Unc	U (k=2)						2.35	
	Expanded Unc	U (k=3)						3.53	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070115-063016) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD; Lot #s011615JM and 122915JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 3314 samples analyzed from 070115 through 063016. Assumes a normal distribution.
3	Aqueous QC Bias - the concentration, weighted by # of replicates per control lot, with the largest uncertainty;0.040 g/100mL Lipomed Aqueous Control Lot #s 30112011-B and 09022015-A. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample and internal standard delivery serial# MD96KE1165 (k=2, Calibrate Inc. 10/21/15)
5	CRM Calibrators uncertainty - all of the certificates of analysis for the lot #s used in this time period have the same uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

QC Data Excluded from Uncertainty Calculation for Date Range 070115-063016

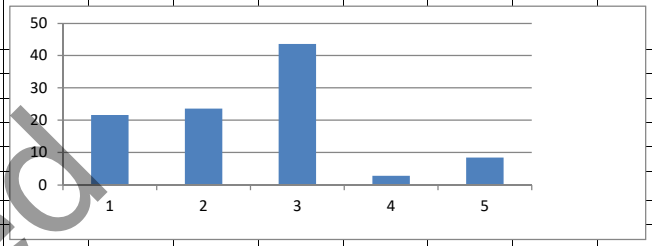
 # Entries
1

Analyst Initials	Date	Control Type	Lot	Result	Target	% Difference	Instrument	Comment
JSH	12/18/2015	whole blood	011615JM	0.1485	0.1970	-24.62%	Hobbes II	Grubbs Outlier Test

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol in whole blood/plasma/serum
Range of measurement values:	0.025 to 0.400 g/100ml
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17, Revision 8, Effective Date 11/5/2015)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 12/2/2015

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.632	%	Normal	A	1.41	1119	0.447	22
2	Matrix - Duplicates	0.687	%	Normal	A	1.41	4244	0.486	24
3	Aqueous QC Bias	1.272	%	Normal	A	1.41	399	0.900	44
4	Pipettor/Diluter	0.115	%	Normal	B	2.00		0.058	3
5	CRM - Calibrators	0.350	%	Normal	B	2.00		0.175	8
	Combined Standard Unc	u_c						1.13	100
	Expanded Unc	U (k=2)						2.26	
	Expanded Unc	U (k=3)						3.39	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070114-063015) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD, Lot #s 030714JM and 011615JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 4245 samples analyzed from 070114 through 063015. Assumes a normal distribution.
3	Aqueous QC Bias - the concentration with the largest uncertainty, 0.080 g/100mL Lipomed Aqueous Control Lot #14112011-A. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample and internal standard delivery serial# MD96KE1165 (k=2, Calibrate Inc. 10/8/14)
5	CRM Calibrators uncertainty - all of the certificates of analysis for the lot #s used in this time period have the same uncertainty. Certificates indicate a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

QC Data Excluded from Uncertainty Calculation for Date Range 070114-063015

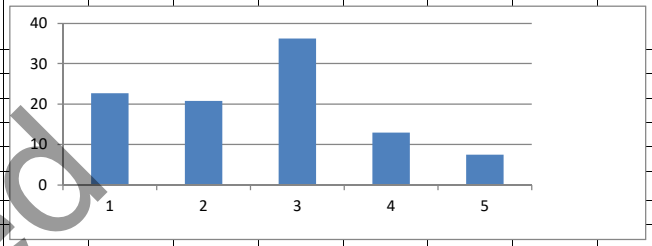
 # Entries
6

Analyst Initials	Date	Control Type	Lot	Result	Target	% Difference	Instrument	Comment
DJS	7/30/2014	Whole Blood	030714JM	0.1729	0.1980	-12.68	Hobbes II	Grubbs Test
JSH	11/20/2014	Whole Blood	030714JM	0.0396	0.1980	-80.00	Hobbes II	Control vials switched (0.040 Aqueous QC analyzed)
JSH	11/20/2014	Aqueous	30112011-B	0.1983	0.0400	395.75	Hobbes II	Control vials switched (0.198 Whole Blood QC analyzed)
DJS	1/21/2015	Whole Blood	030714JM	0.2995	0.1980	51.26	Hobbes II	Control vials switched (0.300 Aqueous QC analyzed)
DJS	1/21/2015	Aqueous	05012012-B	0.1989	0.3000	-33.70	Hobbes II	Control vials switched (0.198 Whole Blood QC analyzed)
FLS	2/11/2015	Whole Blood	030714JM	0.1436	0.1980	-27.47	Hobbes II	Grubbs Test

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol
Range of measurement values:	0.025 to 0.400 g/100ml
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17 Revision 6 Effective Date 12/1/2014)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 12/2/2014

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole Blood Control	0.75063727	%	Normal	A	1.41	1297	0.530780702	23
2	Matrix - Duplicates	0.68807262	%	Normal	A	1.41	5335	0.486540817	21
3	Aqueous QC Bias	1.19846726	%	Normal	A	1.41	839	0.847444328	36
4	Pipettor/Diluter	0.60413355	%	Normal	B	2.00		0.302066773	13
5	CRM - Calibrators	0.35000000	%	Normal	B	2.00		0.175	7
	Combined Standard Unc	u_c						1.165539079	100
	Expanded Unc	U (k=2)						2.331078158	
	Expanded Unc	U (k=3)						3.496617236	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1	Measurement Process Reproducibility (data from 070113-063014) - Whole Blood Controls made in-house by the Phoenix Crime Laboratory weighted by # of replicates per control lot and reported as RSD, Lot #s 042413JM and 030714JM
2	Matrix Duplicates - this is the standard deviation from duplicate analysis from 5336 samples analyzed from 070113 through 063014. Assumes a normal distribution.
3	Aqueous QC Bias - the concentration with the largest uncertainty weighted by # of replicates per control lot and reported as RSD, 0.080 g/100mL Lipomed Aqueous Control Lot #s 21022011-A and 14112011-A. Assumes a normal distribution.
4	Pipettor/Diluter - this is the largest uncertainty for sample and internal standard delivery serial # MD96HB2375 (k=2, Calibrate Inc. 10/2/13)
5	CRM Calibrators uncertainty - this is the largest uncertainty for any of the CRMs used in the calibration curve. Certificate indicates a normal distribution, k=2 approx. 95% confidence interval.

Revision:	This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
	In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

QC Data Excluded from Uncertainty Calculation for Date Range 070113-063014

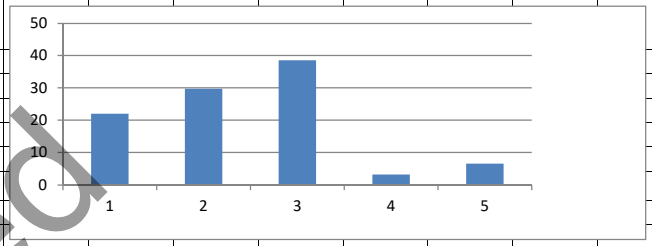
 # Entries
4

Analyst Initials	Date	Control Type	Lot	Result	Target	% Difference	Instrument	Comment
NC	8/20/2013	Whole Blood	042413JM	0.1849	0.1980	-6.62	Calvin	insufficient amount pipetted
JSH	2/19/2014	Whole Blood	042413JM	0.1634	0.1980	-17.47	Hobbes II	Grubbs outlier test
ABG	5/13/2014	Whole Blood	030714JM	0.2056	0.1980	3.84	Hobbes II	maintenance performed on pip/dil
ABG	5/13/2014	Aqueous	30112011-B	0.0408	0.0400	2.00	Hobbes II	maintenance performed on pip/dil

Measurement Uncertainty Estimation Form

Measurement:	Concentration of Ethanol
Range of measurement values:	0.025 to 0.400 g/100ml
Procedure name and revision:	Protocol for the Analysis of Ethanol (TOX-SOP-17 Revision 5 Effective Date 12/11/2013)
Estimation prepared by: *Toxicology Section*	**Date Prepared:** 12/11/2013

Line Item	Uncertainty Component	Value	Units	Distribution	Type	Divisor	Degrees Freedom (n-1)	Standard Uncertainty	Component Contribution %
1	Reproducibility Whole blood control	0.83520487	%	Normal	A	1.41	2208	0.590579031	22
2	Matrix - Duplicates	0.79820765	%	Normal	A	1.00	8663	0.798207648	30
3	Aqueous QC Bias	1.46165414	%	Normal	A	1.41	132	1.033545551	39
4	Pipettor/Diluter	0.17015933	%	Normal	B	2.00		0.085079666	3
5	CRM- Calibrators	0.35000000	%	Normal	B	2.00		0.175	7
	Combined Standard Unc	u_c						1.446374432	100
	Expanded Unc	U (k=2)						2.892748863	
	Expanded Unc	U (k=3)						4.339123295	
	Reported Uncertainty:	**5.0**							



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

The basis for the data above:

1. Measurement Process Reproducibility (data from 010112-063013) - Whole Blood Controls made in house by the Phoenix Crime Laboratory weighted by # of replicated per control lot and reported as RSD, Lot #s 091611JM, 071012JM, and 042413JM
2. Matrix Duplicates - This is the standard deviation from duplicate analysis from 8664 cases reported from 010112 through 063013. Assumes a normal distribution.
3. Aqueous QC Bias - the largest uncertainty used in the evaluation of bias based on 133 replicated of the 0.025 g/100mL Cerilliant CRM Lot # FN032210-01. Assumes a normal distribution.
4. Pipettor/Diluter - this is the largest uncertainty for sample and internal standard delivery serial # MD96HB2375 (k=2, Calibrate Inc. 10/4/12)
5. CRM Calibrators uncertainty - this is the largest uncertainty for any of the CRMs used in the calibration curve. Certificate indicates a normal distribution, k=2 approx. 95% confidence interval.

Revision: This budget uses as a reference ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - ANNEX D / Toxicology Testing Discipline Example - Concentration of Ethanol in an Ante-Mortem Blood Specimen.
In place of the tolerances used in the example it incorporates actual values obtained from the Phoenix Crime Laboratory.

UNCONTROLLED DOCUMENT

Whole Blood QC Data Excluded from Uncertainty Calculation for Date Range 010112-063013

 # Entries
8

Analyst Initials	Date	Control Type	Lot	Result	Target	% Difference	Instrument	Comment
NI	2/7/2012	Whole Blood	091611JM	0.1770	0.1990	-11.06	Calvin	Grubbs Outlier Test
NI	5/2/2012	Whole Blood	091611JM	0.1954	0.1990	-1.81	Susie	Power failure, Repipetted and rerun on 5/3/12
NI	5/2/2012	Whole Blood	091611JM	0.1961	0.1990	-1.46	"	"
GMS	7/17/2012	Whole Blood	091611JM	0.2769	0.1990	39.15	Hobbes II	Not enough internal standard pipetted
GMS	10/23/2012	Whole Blood	071012JM	0.0782	0.1960	-60.10	Hobbes II	Control vials switched (0.080 Aqueous QC analyzed)
NI	11/7/2012	Whole Blood	071012JM	0.0000	0.1960	-100.00	Calvin	Chromatography not acceptable and no result obtained
KK	3/27/2013	Whole Blood	071012JM	0.1400	0.1960	-28.57	Hobbes II	Grubbs Outlier Test
GMS	6/27/2013	Whole Blood	042413JM	0.0783	0.1980	-60.45	Calvin	Control vials switched (0.080 Aqueous QC analyzed)