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1.0 Purpose and Scope

1.1 This manual describes the analysis of samples for ethyl alcohol (ethanol) using headspace gas chromatography.

1.2 Samples to be analyzed may include calibration standards, quality control standards, whole blood controls, and evidence samples which are thought to contain ethanol.

1.3 The scope of this manual includes preparation of reagents, retrieving and opening of evidentiary samples, preparation of vials for analysis, instrument setup, data review and release, documentation, and quality control criteria.

2.0 Responsibility

2.1 All analysts authorized to perform analysis of blood or other samples for ethanol content are responsible for following these procedures as written.

2.2 These procedures are reviewed periodically by the Toxicology Section staff. Revisions are made at that time or when there is an identified need to change this written manual to be compatible with changing needs in the analytical process. In the event that there are changes to be made to this manual, the analyst must report those changes in detail to the Toxicology Section Supervisor in a timely manner.

2.3 All analysts performing these procedures and reporting analytical results for forensic purposes must be fully trained and demonstrate initial competency in the use of these procedures in accordance with the Alcohol Training Manual (TOX_P300). All analysts must show ongoing competency by successfully analyzing at least one proficiency test annually.

2.3.1 Proficiency samples will be prepared as casework. Results will be unknown to the analyst prior to testing. Proficiency test results must fall within ± 3 standard deviations of the grand mean reported by the test provider.

2.4 Analysts will ensure that an adequate amount of sample processing supplies are on hand at all times. Orders should be placed when supplies are low to ensure that new stock arrives and can be quality control checked before supplies are completely empty.

3.0 Emergency or High Priority Situations

3.1 The Commissioner of Public Safety, Laboratory Director or Toxicology Section Supervisor can designate samples as high priority.

3.2 High priority samples are analyzed as soon as possible after successful calibration.

3.3 Priority sample results are reviewed and released as soon as they are available, once they pass the quality assurance criteria.

4.0 Quality Assurance

4.1 It is expected that the analyst will report any unacceptable or anomalous behavior of any analytical system immediately to the Toxicology Section Supervisor. It is further expected that appropriate actions will follow as soon as possible and be properly documented.

4.2 Equipment

4.2.1 Balance

4.2.1.1 The analytical balance will be checked monthly with NIST traceable weights. This check will be recorded in the corresponding VFL Balances Equipment QA/QC binder.

4.2.1.2 The analytical balance will have its calibration evaluated and certified by an approved vendor. The resulting documentation will be maintained.

4.2.1.3 Any balance maintained to the same standard may be used as a back-up if the primary balance is unavailable.

4.2.2 Pipettes

4.2.2.1 Measurements made by the Toxicology Section using pipettes are critical.

4.2.2.2 Pipettes used by the Toxicology Section, including fixed and variable volume pipettes have their calibration evaluated and certified by an approved vendor. The resulting documentation will be maintained.

4.2.2.3 If a pipette is sent out for service, an inspection of the package/pipette will be performed to check for any shipping and handling concerns prior to being returned for use. The calibration certificate will be reviewed in accordance with QA_P100_6.4 Equipment QC.

4.2.2.4 If a question arises regarding the proper functioning of a pipette, a performance check or calibration service by an approved vendor may be initiated.

4.2.2.4.1 Performance checks will be performed in accordance with QA_P100_6.4_Equipment QC.

4.2.2.4.2 Performance checks will be reviewed and filed in the VFL Pipettes Equipment QA/QC binder.

4.3 GC-FID Instrumentation

4.3.1 All maintenance performed, including routine and preventative maintenance as well as troubleshooting activities, should be recorded in the Instrument Maintenance Log.

4.3.2 Day of use

4.3.2.1 Ensure that the helium carrier gas is turned on with an appropriate delivery pressure (approximately 80 psi). Replace the cylinder if the remaining pressure in the tank is insufficient for analysis.

4.3.2.2 Ensure that the air compressor and zero air generator are turned on with an appropriate delivery pressure (approximately 45 psi).

4.3.2.3 Ensure that the hydrogen generator is turned on and that the deionized water reservoir is sufficiently full. If not, add deionized water to the reservoir.

4.3.3 Routine Maintenance

4.3.3.1 Clean the headspace needle approximately every 500 injections.

4.3.3.2 Check needle seal assembly and replace headspace o-ring seals approximately every 1500 injections

4.3.3.3 Replace headspace needle seal assembly approximately every 2500 injections

4.3.3.4 Run reproducibility tests, replace o-rings, magazine, and trap according to manufacturer's recommendations.

4.3.4 Annual

4.3.4.1 Schedule on-site preventative maintenance with service engineer.

4.3.4.2 Refer to operator manuals and Instrument Maintenance Log for additional maintenance and troubleshooting procedures.

4.4 Reference Materials

4.4.1 Calibration Standards

4.4.1.1 NIST traceable aqueous ethanol standards are used for calibration. Calibration standards with concentrations of 0.010, 0.020, 0.050, 0.080, 0.200, and 0.400 g/100 mL are purchased from an ISO/IEC 17025 and/or ISO 17034accredited supplier.

4.4.1.2 Prior to using a new lot of calibration standard, one vial from the lot should be run as a sample (in duplicate) to verify the lot falls within ± 5% of the manufacturer's certified concentration. A new shipment of the same lot does not require verification.

4.4.1.3 After a new lot of calibration standard is verified, the data package from the verification run will undergo a Technical Review and be kept on file with the Toxicology Section. Completed verification packages should include the manufacturer's Certificate of Analysis (COA), calculation summary sheet, and all documents generated during the analysis. .

4.4.1.4 Calibration standards are stored in the refrigerator.

4.4.2 Whole Blood Ethanol Control

4.4.2.1 A whole blood ethanol control is used as a within-run quality control for all batches containing whole blood samples. A whole blood control with a concentration of approximately 0.080 g/100 mL is purchased from an approved supplier.

4.4.2.2 Prior to using a new lot of whole blood ethanol control, 10 replicates of the control will be analyzed by two analysts and a Target Value (TV) based on the calculated average will be determined. The acceptance range will be ± 10% from the TV.

4.4.2.3 The TV must be within ± 20% of the manufacturer's reported value. If this criterion is not met, the lot may be rejected.

4.4.2.4 For a new shipment of the same lot, one vial from the lot should be run as a sample (in duplicate) to verify the lot falls within ± 5% of the Target Value determined previously. If the new shipment falls within this range, the original TV for the lot will be used. If the new shipment does not fall with this range, a new TV may be determined or a new lot may be purchased.

4.4.2.5 After the parameters for a new lot have been determined or a new shipment has been verified, the data package from the analysis will undergo a Technical Review and be kept on file with the Toxicology Section. Completed verification packages should include the manufacturer control sheet, calculation summary sheet, and all documents generated during the analysis.

4.4.2.6 Once opened, a vial of whole blood control may be used for 30 days. The date the vial is opened will be documented on the QC summary sheet and on the container.

4.4.2.7 Whole blood ethanol controls are stored in the refrigerator.

4.4.3 Aqueous Ethanol Control

4.4.3.1 A NIST traceable aqueous ethanol standard is used as a within-run control in all analytical batches. An aqueous ethanol standard with a concentration of 0.080 g/100 mL (of a different lot than the calibration standard) is purchased from an ISO/IEC 17025 and/or ISO 17034 accredited supplier.

4.4.3.2 Prior to using a new lot of aqueous ethanol control, one vial from the lot should be run as a sample (in duplicate) to verify the lot falls within ± 5% of the manufacturer's certified concentration. A new shipment of the same lot does not require verification.

4.4.3.3 After a new lot of aqueous ethanol control is verified, the data package from the verification run will undergo a Technical Review and be kept on file with the Toxicology Section. Completed verification packages should include the manufacturer's COA, calculation summary sheet, and all documents generated during the analysis.

4.4.3.4 Aqueous ethanol standards are stored in the refrigerator.

4.4.4 Verifications of reference materials will be documented in the Reagent Preparation Log.

4.4.5 Results from each analysis of calibration check samples, whole blood ethanol controls and aqueous ethanol controls will be documented in the GC-FID Control Chart.

4.5 In-House Preparations

4.5.1 Solutions prepared in-house for use in casework will be performance checked prior to use in casework. Specifications for these checks are defined in Section 5.0.

5.0 Solution Preparation

5.1 Reagents

5.1.1 Ethanol (200 proof ACS/USP grade)

5.1.2 Acetaldehyde (ACS reagent grade)

5.1.3 Acetone (ACS reagent grade)

5.1.4 Isopropanol (ACS reagent grade)

5.1.5 Methanol (ACS reagent grade)

5.1.6 N-propanol (ACS reagent grade)

5.1.7 T-butanol (ACS reagent grade)

5.1.8 diH_2O

5.2 Apparatus

5.2.1 Volumetric flasks

5.2.2 Pipettes

5.2.3 Screw cap glass bottles

5.2.4 Glass vials with septa and screw caps

5.2.5 Analytical balance

5.3 Internal Standard Preparation

5.3.1 Add approximately 500 mL of diH_2O to a 1 L volumetric flask.

5.3.2 Add 0.5 g n-propanol.

5.3.3 Add 0.15 g t-butanol.

5.3.4 Bring to volume with diH_2O and shake well to dissolve solids.

5.3.5 Transfer to a labeled 1 L bottle.

5.3.6 Document the solution in the Reagent Preparation Log.

5.3.6.1 The lot number is IS-MMDDYYYY, where MMDDYYYY is the date of preparation.

5.3.6.2 Solution expires one year from date of preparation.

5.3.6.3 Solution is stored in the refrigerator.

5.3.7 One vial of a newly prepared internal standard solution is analyzed using 500 µl internal standard + 250 µl previously verified blank and deemed acceptable for use in casework when only two peaks are present. These two peaks must be present with retention times consistent with n-propanol and t-butanol.

5.3.8 The chromatograms from the analysis will undergo a Technical Review and documentation of passing QC is recorded in the Reagent Preparation Log. Analytical results, including the run list and internal standard chromatogram, will be dated and initialed by the analyst and kept on file with the Toxicology Section.

5.4 Timing Mix Preparation

5.4.1 Add a small amount of diH_2O to a 100 mL volumetric flask.

5.4.2 Add ~0.06 g acetaldehyde.

5.4.3 Add ~0.12 g methanol.

5.4.4 Add ~0.06 g acetone.

5.4.5 Add ~0.08 g isopropanol.

5.4.6 Add ~0.08 g ethanol.

5.4.7 Bring to volume with diH_2O.

5.4.8 Transfer to a glass vial with a septum and screw cap. Label the vial.

5.4.9 Document the solution in the Reagent Preparation Log.

5.4.9.1 The lot number is TMX-MMDDYYYY, where MMDDYYYY is the date of preparation.

5.4.9.2 Solution expires one year from date of preparation.

5.4.9.3 Solution is stored in the refrigerator.

5.4.10 One vial of a newly prepared timing mix solution is analyzed with the addition of internal standard and deemed acceptable for use in casework when each chemical

in the mixture is detected with baseline separation and the retention times are consistent with the components of the mixture.

5.4.11 The chromatograms from the analysis will undergo a Technical Review and documentation of passing QC is recorded in the Reagent Preparation Log. Analytical results, including the run list and timing mix chromatogram, will be dated and initialed by the analyst and kept on file with the Toxicology Section.

5.4.12 Once approved, a calibration factor for each compound will be calculated for each column by dividing the peak area ratio for that compound (peak area/IS area) by the mass of compound added. This calibration factor will be entered into the instrumental calibration method for all calibration runs using the new timing mix lot. See Instrument Maintenance Log for additional information.

5.5 Aqueous Blank Preparation

5.5.1 Deionized water will be used as an aqueous blank.

5.5.2 Document the preparation in the Reagent Preparation Log.

5.5.2.1 The preparation date is the date the deionized water is bottled.

5.5.2.2 The lot number is BL-MMDDYYYY, where MMDDYYYY is the date of preparation.

5.5.2.3 The aqueous blank is stored in the refrigerator.

5.5.2.4 Prepared aqueous blank is approved for use until consumed or contamination is suspected.

5.5.3 One vial of a newly prepared aqueous blank is analyzed and deemed acceptable for use in casework when no peaks above threshold are observed when analyzed without the addition of internal standard solution.

5.5.4 The chromatograms from the analysis will undergo Technical Review and documentation of passing QC is recorded in the Reagent Preparation Log. Analytical results, including the run list and blank chromatogram, will be dated and initialed by the analyst and kept on file with the Toxicology Section.

6.0 Evidence Handling

6.1 Evidence Storage and Retention

6.1.1 Samples submitted for alcohol analysis are stored in an evidence intake refrigerator (Room 155A) until brought to the toxicology lab for analysis. Samples in personal custody, but not currently being analyzed, are stored in a refrigerator.

6.1.2 Subsequent to analysis, ensure all blood tubes are sealed using evidence tape and returned to the evidence refrigerator for storage.

6.1.3 Evidentiary blood tubes are kept for at least 90 days subsequent to analysis. They may be disposed of after that time in accordance with the Evidence Handling Manual (EH_P100).

6.2 Opening Evidentiary Blood Kits and Blood Tube Labeling

6.2.1 Kits must be opened and the corresponding blood tubes labeled one at a time at the lab bench.

6.2.2 Compare the evidence with the information in FA.

6.2.3 Compare any identifying information written on seals, blood tubes, the kit, and submission form(s). If there are any noteworthy discrepancies, make a comment on the worksheet. If there is a question regarding the identification of a sample, contact the Toxicology Section Supervisor or designee.

6.2.4 It is permissible to use an expired kit; the expiration date refers to the vacuum of the blood tubes. If the tubes filled, regardless of the expiration date, the sample is deemed acceptable.

6.2.5 Note in FA the number of tubes submitted in the kit (typically three) and whether or not each tube was sealed. Label each blood tube with the corresponding identification number (e.g. A1-1, A1-2, A1-3).

6.2.5.1 Any unsealed tubes will be sealed with evidence tape, dated and initialed.

6.2.5.2 One tube from each kit should be kept unopened for independent testing at the subject's discretion.

6.2.5.3 Evidentiary samples submitted for analysis should be collected in grey-topped tubes. Each tube should contain at least 2 mL of blood and be fluid enough to aliquot.

6.2.6 Any anomalies in the evidence submitted will be documented in the case record.

7.0 Headspace Vial Preparation

7.1 Standards, Controls, and Samples

7.1.1 Internal standard

7.1.2 Aqueous blank

7.1.3 Timing mix

7.1.4 Calibration standards

7.1.5 Whole blood ethanol control

7.1.6 Aqueous ethanol control

7.1.7 Calibration check samples (CCS)

7.1.8 Evidentiary samples

7.2 Apparatus

7.2.1 Vortex

7.2.2 250 µL and 500 µL fixed volume and 100-1000 µL adjustable pipettes

7.2.3 Pipette tips

7.2.4 20 mL round bottom headspace autosampler vials

7.2.5 Septum caps

7.2.6 Crimping tool

7.2.7 Vial racks and tube racks

7.2.8 Biological Safety Cabinet (BSC)

7.3 Procedure

7.3.1 Remove the aqueous blank, timing mix, calibration standards, whole blood control, aqueous control, internal standard, and evidentiary samples to be analyzed from the refrigerator and allow them to come to room temperature prior to preparation.

7.3.2 Ensure that all standards are unexpired and have been verified prior to use.

7.3.3 Check the "opened" date on the current vial of whole blood ethanol control (Level 1 0.08 ethanol from Cliniqa or equivalent). If the vial has been open for more than 30 days, dispose of it in the biohazard waste and retrieve a new vial.

7.3.4 Select one blood tube from each evidentiary submission for analysis and place it in a tube rack.

7.3.5 Label 20 mL round bottom headspace autosampler vials for each of the following:

7.3.5.1 Opening aqueous blank.

7.3.5.2 Each of the six calibration standards (A-F).

7.3.5.3 Timing mix.

7.3.5.4 Whole blood control in duplicate.

7.3.5.5 Aqueous control in duplicate.

7.3.5.6 Each of the evidentiary samples to be analyzed in duplicate. Label the vials with the respective item number.

7.3.5.7 A sufficient number of Calibration Check Samples (CCS).

7.3.5.7.1 CCS will consist of 0.050 g/100 mL (low) and 0.200 g/100 mL (high) calibration standards.

7.3.5.7.2 CCS will be analyzed in duplicate after QC and at the end of each analytical batch, with no more than 10 sample vials bracketed between CCS vials. Low and high concentration CCS will alternate throughout the batch.

7.3.5.8 Closing aqueous blank.

7.3.6 Transfer 500 µL of internal standard to each headspace vial.

7.3.7 Add 250 µL of each solution to its corresponding headspace vial.

7.3.7.1 Prior to aliquotting blood, vortex each tube to homogenize it.

7.3.8 Using a cap crimping tool, seal the vials with a septum cap.

7.3.9 Prepared samples can be held at room temperature before analysis for a maximum of 24 hours.

8.0 Instrumental Analysis

8.1 Principle of Measurement

8.1.1 Ethanol and related volatile organic compounds are determined in samples by Headspace Gas Chromatography (GC) with Flame Ionization Detection (FID). A mixture of an internal standard solution, a surrogate, and the sample to be analyzed, is heated in a vial sealed with a septum. This is allowed to equilibrate so that proportional amounts of the volatile compound are present in the liquid and headspace. A portion of the vapor above the heated sample is transferred and injected onto the columns of the gas chromatograph. A dual-column GC uses two columns with different stationary phase composition through which the sample vapor is transported. Each column has a unique retention time for each compound, allowing for the confirmatory identification of compounds of interest.

8.1.2 Each column is attached to a FID, in which the vaporized ethanol or other volatile compound mixed with hydrogen enters a jet where it is burned in an air atmosphere. The jet itself serves as one electrode and a second electrode is placed above the flame. A potential is applied across these electrodes. When molecules enter the flame, ionization occurs yielding a current flow which, after proper amplification, may be displayed on the computer terminal. The FID is a mass-sensitive detector and its response is proportional to the total number of ions entering the detector per unit time. For each sample, the responses from FID channels A and B from all replicates are averaged for quantitation of compounds of interest. The quantitative range for this method is 0.010 – 0.400 g/100 mL.

8.2 Equipment & Materials

8.2.1 All equipment and materials are located in room 265 unless otherwise stated.

8.2.2 Perkin Elmer Clarus 580 gas chromatograph with flame ionization detector and Elite BAC-1 and BAC-2 Advantage columns, or equivalent.

8.2.3 Perkin Elmer TurboMatrix 110 headspace autosampler.

8.2.4 Desktop PC and printer with TotalChrom Workstation Software.

8.2.5 Parker Dominick Hunter hydrogen generator, or equivalent hydrogen supply.

8.2.6 Compressed UHP grade helium.

8.2.7 Jun Air compressor and Parker Balston Zero Air generator, or equivalent air supply.

8.3 Data System Setup

8.3.1 Set up the TotalChrom Workstation data system as described in the Instrument Maintenance Log.

8.3.2 Save current calibration methods and sequences to the appropriate folder on the hard drive using a date-stamped file name.

8.4 Autosampler and Chromatograph Setup

8.4.1 Refer to Section 4.3 and the Instrument Maintenance Log for set up.

9.0 Quality Control and Corrective Action

9.1 Analytical sequences must contain:

9.1.1 An aqueous blank at the beginning and end. Any integrated peaks present other than the surrogate and internal standard require the approval of the Toxicology Section Supervisor or their designee.

9.1.2 Six certified ethanol calibration standards of the following concentrations:

STD A	0.010 g/100 mL
STD B	0.020 g/100 mL
STD C	0.050 g/100 mL
STD D	0.080 g/100 mL
STD E	0.200 g/100 mL
STD F	0.400 g/100 mL

9.1.2.1 Calibration standards must be within 10% of their certified values after truncation to three decimal places.

9.1.2.2 The correlation coefficient of the calibration line for each channel must be 0.99 or greater. If not, the calibration must be repeated.

9.1.3 A timing mix sample exhibiting baseline separation between all components with no co-elution.

9.1.4 Duplicate samples of a whole blood ethanol control.

9.1.4.1 The whole blood control must not have been opened more than 30 days prior to analysis.

9.1.4.2 The mean of all channel results must be within 10% of the accepted target value after truncation to three decimal places.

9.1.5 Duplicate samples of an aqueous ethanol control.

9.1.5.1 The mean of the channel results must be within 10% of the certified concentration after truncation to three decimal places.

9.1.6 Calibration check samples using 0.050 and 0.200 g/100 mL standards, alternatingly analyzed in duplicate after QC, every 10^{th} vial throughout the analytical batch, and at the end of every run.

9.1.6.1 The mean of the channel results must be within 10% of the certified concentration after truncation to three decimal places.

9.1.6.2 CCS outside the acceptance criteria must be reanalyzed along with all evidentiary samples that are not bracketed between passing CCS.

9.1.7 All evidentiary samples run in duplicate.

9.1.7.1 If the sample replicates do not meet these criteria, the analysis must be repeated (two new preparations from the sample) and all replicates meeting the acceptance criteria will be included in the final sample average result calculation.

9.1.7.2 Mean sample results are truncated to three decimal places.

9.2 All sample analysis results must be within 5% of the mean result for that sample when rounded to four decimal places.

9.3 All sample analysis results must yield a coefficient of variation below 5%.

9.4 Samples not meeting quality control criteria may be reanalyzed provided that they are accompanied by WB Control, bracketing aqueous blanks and CCS, the same internal standard lot number is used, and the samples are run within 24 hours of the original calibration.

9.5 In the event that a CCS does not meet the acceptance criteria, all evidentiary samples not bracketed between acceptable CCS should be reanalyzed.

9.6 Ethanol concentrations will be calculated as the rounded average of all results from channels A and B from all replicates of that sample. If the fifth digit to the right of the decimal place is five or greater, the value will be rounded up to four decimal places. Otherwise, it will be rounded down to four decimal places.

9.7 All coefficients of variation (%CV) will be calculated as

$$\%CV = \frac{s}{mean\ response}$$

where *s* is the standard deviation of all channel response results for each sample, and the mean response is the average of the channel results, rounded to four decimal places.

9.8 Surrogate compound concentrations for each replicate must be between 0.900 and 1.100.

9.9 Internal standard peaks for quantitative samples must fall within ± 20% of the average internal standard peak area from the current calibrators.

9.10 Exceptions may be made on a case by case basis with the approval of the Toxicology Section Supervisor (or their designee). Documentation of all analyses performed must be retained in the casework packet.

10.0 Estimation of Uncertainty of Measurement

10.1 All validated instruments are included in the estimation of measurement uncertainty.

10.2 The estimation of measurement uncertainty for the instrument and method is performed using the GUM Approach as defined in the ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Annex A (Refer to the Measurement Uncertainty - Ethanol Concentration in Whole Blood binder).

10.2.1 A 99.73% level of confidence will be used to determine the expanded uncertainty.

10.2.2 The expanded uncertainty will be rounded up to two significant figures.

10.3 Calculate the confidence interval (CI) for each result by multiplying the truncated measured result by the expanded uncertainty. This value will be reported along with the measured result.

10.3.1 The reported estimated measurement uncertainty will be rounded up to three decimal places.

10.4 To assist with the application of blood ethanol results, the interval will be reported in the following format:

0.XXX ± 0.YYY g/100 mL ethanol

10.5 The estimated uncertainty of measurement will be reviewed at least annually or if any significant change in the expanded uncertainty is suspected.

10.6 The reported result is the result at the time of analysis, and does not account for changes in sample composition which may occur subsequent to or before examination.

11.0 Data Review

11.1 Procedure

11.1.1 Generate a data output file from the TotalChrom workstation attached to the GC-FID for the analytical batch, and enter this raw data into the Data Processing Worksheet (TOX_F100_1) to generate the QC summary and case insert sheets.

11.1.2 Upon successful completion of analysis, the analyst must perform a primary data review of their packages.

11.1.3 The completed Case File includes:

11.1.3.1 Toxicology Case Specific Review Checklist (QA_F100_7.7_17).

11.1.3.2 VFL lab report and FA worksheet.

11.1.3.3 Case insert from data processing worksheet (TOX_F100_1).

11.1.3.4 Case specific chromatograms.

11.1.3.5 A request for analysis form (EH_F100_2).

11.1.4 The completed Batch File includes:

11.1.4.1 Blood Alcohol Batch File Review Checklist (QA_F100_7.7_18).

11.1.4.2 QC summary and raw data sheets from data processing worksheet (TOX_F100_1).

11.1.4.3 Sequence list(s), calibration graphs, and all non-case specific chromatograms generated during the analytical process.

11.1.5 Analyst Review

11.1.5.1 Ensure the criteria defined in Section 9.0 are met.

11.1.5.2 Ensure that transcription is correct and proper rounding rules have been followed.

11.1.5.2.1 Sample results will be truncated to three decimal places before measurement uncertainly is calculated as outlined in Section 10.2.

11.1.5.3 All samples with an average concentration of < 0.010 g/100 mL will be reported as below the laboratory's reporting threshold for ethanol.

11.1.5.4 All samples with an average concentration > 0.400 g/100 mL will be reported as greater than the upper limit of quantitation for ethanol.

11.1.5.5 Any samples which fail to meet quality control criteria for analysis may be reported as not meeting quality control criteria; quantitative results are not reported.

11.1.6 Technical Review:

11.1.6.1 A qualified analyst must perform a technical review of the complete Batch and Case Specific data packages.

11.1.6.2 Ensure that the data packages are complete and all forms are complete and accurate.

11.1.6.3 Confirm all calculations that are not part of a validated worksheet.

11.1.6.4 If data quality issues have been identified during review, the reviewer must attempt resolution through discussion with the analyst and/or Toxicology Section Supervisor. If issues cannot be resolved, it may be necessary to prepare and analyze new aliquots of the submitted sample.

11.1.7 Administrative and Director Review

11.1.7.1 Upon completion of the technical review, an administrative and director review of the Batch and Case Specific data packages will be completed.

11.1.8 All review criteria must be met before the final report can be released.

12.0 Backup Procedures

12.1 Any secure storage refrigerator in rooms 155A, 266, or 265B may be used to store samples.

13.0 References

13.1 Alcohol Training Manual (TOX_P300)

13.2 Equipment QC (QA_P100_6.4)

13.3 VFL Balances Equipment QA/QC binder

13.4 VFL Pipettes Equipment QA/QC binder

13.5 Instrument Maintenance Log

13.6 Clarus 500 GC Hardware Guide

13.7 Clarus 500/580 GC User's Guide

13.8 TotalChrom Workstation User's Guide – Volume I

13.9 TotalChrom Workstation User's Guide – Volume II

13.10 TurboMatrix Headspace Sampler and HS40/110 Trap User's Guide

13.11 GC-FID Control Chart

13.12 Reagent Preparation Log

13.13 Evidence Handling Manual (EH_P100)

13.14 ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Annex A; Details on the NIST 8-Step Process. ASCLD/LAB – International.

13.15 Measurement Uncertainty - Ethanol Concentration in Whole Blood binder

13.16 Blood Alcohol Batch File Review Checklist (QA_F100_7.7_18)

13.17 Toxicology Case Specific Review Checklist (QA_F100_7.7_17)

13.18 Data Processing Worksheet (TOX_F100_1)

13.19 Request for Analysis for Alcohol/Drugs in Blood (EH_F100_2)

DOCUMENT HISTORY			
DATE	**VERSION**	**APPROVED BY**	**ACTIVITY OR REVISION**
11/25/2013	3	MS	Updated to new format; minor changes made throughout document
12/20/2013	4	MS	Acceptance parameters in Section 3.6.1.2 redefined
12/16/2014	5	TT	Addition of MU & table of contents; use of purchased calibrators; misc. minor changes made throughout document (NOTE: this version replaces ALC_P101, ALC_P102, ALC_P103 and ALC_P104)
12/31/2014	6	TT	Sections 10.5 and 12.1.3.4 added.
1/20/2015	7	TT	Correction of calibration interval for pipettes; addition of storage conditions for purchased reagents and IS; removal of salt from IS preparation
2/27/2015	8	Lab Director	Section 10.0 updated to comply with ASCLD/LAB Policy on Measurement Uncertainty; updated name of Blood Alcohol Data Review Checklist
3/07/2016	9	Lab Director	Sections 4.0, 7.0, 8.0, 9.0, and 11.0 updated to reflect new instrumentation and procedure; new sample preparation and data processing/review procedures added; ALC_F100_1 added; section 10.0 updated for new MU reference material; Appendix I removed; minor updates throughout
9/28/2016	10	Lab Director	Section 11 updated to include new form (ALC_F100_2); minor updates throughout; updated ALC_F100_1 to correct MU rounding and handling of below threshold results
7/18/2018	11	Lab Director	Updated verification requirements and added expiration date criteria to WB QC; updated form numbers; changed Alcohol section to Toxicology section (ALC to TOX); minor changes throughout; TOX_F100_1 & TOX_F100_2 updated (previously ALC_F100_1 & ALC_F100_2; lot number section removed from TOX_F100_2)
8/15/2019	12	Lab Director	Removed critical requirement for balance; added whole blood control acceptance criteria; removed diluting of samples; added wording for quantitative range of method; retired TOX_F100_2; removed abbreviations section; minor changes throughout; updated TOX_F100_1
9/28/2020	13	Lab Director	Updated evidence handling to address storage issues; added exception language (Section 9.8)
6/16/2021	14	Lab Director	Updated sections 4.3 and 8.4 for consistency with other manuals; added 10.1 Instrumentation included in MU; minor formatting changes throughout; updated TOX_F100_1
8/10/2022	15	Lab Director	Changed pipette calibration interval; removed12.2; changed MU from 99.7 to 99.73; removed historical

			calibrations; modified TV determination process for WB; added WB QC to rerun batches; minor formatting changes throughout; TOX_F100_1 updated to remove blanks from IS average and correct MU from 99.7% to 99.73%