



HEALTH & ENVIRONMENTAL TESTING LABORATORY
Forensic Chemistry Section

Blood Alcohol Procedure

PE Blood Alcohol Analysis Procedures: Doc # = 016
Effective Date: 08/06/2019

Approved by: Quality Manager
Revision Date: 07/23/2026

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Forensic Chemistry Section

About this Document

The Forensic Lab Director / Quality Manager reviews this document at least annually. If changes are made, analysts acknowledge the updated procedures. Obsolete procedures are archived and retained in the laboratory for at least two years.

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Introduction & Scope

Forensic alcohol analysis is defined as the practical application of specialized devices, instruments, and methods by trained laboratory personnel to measure the concentration of ethyl alcohol in samples of blood from persons involved in a potential criminal matter.

The method selected for the determination of alcohol content of blood samples utilizes headspace sampling and Gas Chromatograph-Flame Ionization Detector to perform a test that is both qualitative and quantitative. The procedure calls for the addition of a small aliquot of sample mixed with an internal standard solution. A portion from the headspace of this mixture is injected onto gas chromatographic columns that are capable of separating ethyl alcohol from acetone and the common aliphatic alcohols (i.e., methanol, isopropanol, etc.). Quantitation is accomplished through comparison to calibration curves.

Blood alcohol concentrations > 0.08 g/100 ml blood are prima facie evidence in operating under the influence violations.

Other volatile substances can be detected by this procedure. The most common volatiles in body fluids are ethanol, methanol, isopropanol, and acetone. All of these substances can be separated from ethanol on the gas chromatograph. HETL does not quantitate or report volatiles other than ethanol.

Evidence Handling and Preservation

All laboratory personnel will handle submitted materials in a manner that assures the integrity of the evidence. Prior to starting and during the processing of evidence, the analyst will employ the following practices:

- The work area will be clean and free of any excess debris.
- Countertops will have adequate space for working with samples
- All glassware and tools to be used will be clean
- Crimp top vials, etc are used only once, then discarded
- To prevent cross contamination of samples, only one case will be opened by the analyst at a time
- Reagents and solvents will be kept in closed containers when not being used in the analysis

Prior to and following testing, the evidence will be properly secured, and during analysis the evidence will be in the custody of the analyst, as described by the Quality Manual.

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Evidence to be analyzed will be removed from evidence refrigerator/freezer and the reverse side of the pink Receipt/Request for Examination Contract will be filled out (i.e., internal chain of custody)

The analyst will ensure a proper seal is in place prior to opening the evidence. If the item is found to not be properly sealed, or lacking initials across the seal, a note will be made on the worksheet and communicated to the customer on the case report.

If blood evidence is opened and found to contain a broken or leaking blood collection tube and the volume in the broken tube or leaked volume is enough to perform the requested testing. The sample from the broken/leaking tube shall be decanted into a clean glass screw topped extraction tube, labeled, sealed, and stored with the emptied blood tube for the case. This is to protect the testing analysts from broken glass when aliquoting the sample for testing. Documentation shall be recorded on the blood kit inventory that this process occurred.

If blood evidence is received in a gel separator tube and needs to be transferred to a secondary tube to allow for aliquoting and testing. The sample from the gel separator tube shall be decanted into a clean tube/vial, labeled, sealed, and stored with the emptied blood tube for the case.

If blood evidence is opened and found to contain a mixture of two or more leaking tubes the leaked sample(s) will not be retained or tested.

The analyst opening the kit will initial stickers bearing the Lab Identification Number. All paperwork contained in the kit will be labeled with the laboratory identification number and initialed by the analyst that opened the kit.

If the subject's name is not available at the time of log-in, the analyst will write the subject's name on the label at the time of analysis (if known).

The analyst will verify all identification numbers and names agree with the Receipt/Request for Examination Contract. If the kit, upon opening, is found to contain non HETL approved collection materials this shall be noted on the inventory form and STARLIMS metadata shall be updated appropriately.

If a non-HETL approved collection kit or materials were submitted, the WO# field in STARLIMS folder metadata shall be filled in with N/A.

The collection kit and all specimens will be labeled with the lab identification number, name of the subject (if known) and the initials of the analyst that opened the kit.

The analyst will verify the case information provided with the kit matches the HETL folder, sample information from the Laboratory Blood Analysis Request form submitted with the sample and all Starlims labels. Any discrepancy shall be documented by the analyst within the case notes, batch sheet(s), and/or with a photograph/photocopy of the evidence.

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Minor discrepancies shall be communicated with the customer on the case report. Major discrepancies shall require customer communication and correction prior to testing.

Receipt/Contract for Examination	Laboratory Blood Analysis Request	Action
None	BAC, TOX, or BAC/TOX	Perform testing requested on single form
BAC, TOX, or BAC/TOX	None	Perform testing requested on single form
BAC/TOX	BAC	Perform BAC & TOX testing
BAC/TOX	TOX	Perform BAC & TOX testing
BAC or TOX	BAC and TOX	Perform BAC & TOX testing
BAC	TOX	Prior to any testing reach out to submitting agency to confirm testing requested
TOX	BAC	Prior to any testing reach out to submitting agency to confirm testing requested

	Action needed:	Blood/Urine Kit Inventory Form Items Received Table:	Starlims Metadata:	Starlims Items Received Table:
Blood Tubes/Urine Container & Paperwork Contain matching collection date & times	None	Record collection date & time		
Blood Tubes/Urine Container & Paperwork collection date &/or times do not match (Major Discrepancy) <i>Example: collection date/time prior to incident date/time.</i>	Communicate discrepancy with submitted and obtain correct information prior to finalizing COA.	Record collection date & time from tubes/container (even if it is not correct)	Record correct/verified collection date and time obtained from submitting agency. If submitting agency does not provide information Record collection date & time from tubes/container (even if it is not correct) or leave blank	

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Blood Tubes/Urine Container & Paperwork collection date &/or times do not match (Minor Discrepancy) <i>Examples: collection times within ~10mins, typos (2023 vs 2024, duplication of birth date/year, 24hr clock vs 12 hr clock)</i>	None	Record collection date & time from tubes/container	Record collection date & time from tubes/container (In cases with multiple tubes/collection times any time may be used)	Record collection date & time from tubes/container
Blood Tubes/Urine Container are unlabeled or missing collection information. Paperwork contains collection date & time.	None	Collection Date: NA Collection Time: NA	Record collection date & time from paperwork	
Blood Tubes/Urine Container contains collection date & time. Paperwork missing collection information	None	Record collection date & time from tubes/container		
Blood Tubes/Urine Container are unlabeled or missing collection information. Paperwork missing collection information	None (reach out or leave blank)	Collection Date: NA Collection Time: NA	Leave blank	

The analyst will fill out the Blood Kit Inventory Worksheet and perform a kit inventory, making any necessary notations. For non-approved HETL collection materials, refer to the manufacture's information or the below reference table.

Manufacturers cap/label	Additive(s)	Blood type
Light Blue	Sodium Citrate	Whole Blood

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		(If centrifuged-Plasma)
Gold, Red/Black Mix	Clot activator & separation gel	Serum (*if centrifuged)
Red	None (glass) Clot activator (plastic)	Clotted whole blood (If centrifuged-Serum)
Green	Sodium Heparin Lithium Heparin	Whole Blood (If centrifuged-Plasma)
Light Green, Green/Gray Mix	Lithium Heparin & separation gel	Plasma (*if centrifuged)
Lavender/Pink	K2EDTA	Whole Blood
Gray	Potassium Oxalate & Sodium Fluoride	Whole Blood
*If centrifuged separation gel will travel from the bottom of the tube to the middle of the tube (to between the red blood cells and the serum/plasma).		

For continuity the volumes entered into the blood inventory worksheet and subsequent StarLIMS items received table shall adhere to the following format:

	Volume (mL)
Visibly empty blood tube, no label	0 (put collection date & time as NA)
Visibly empty blood tube, with label	0
Visible droplets of blood in tube (unusable testing volume)	<0.5
Low volume of blood in tube (unusable testing volume)	<0.5
Usable testing volume of blood in tube	Approximate volume

If any packaging items/paperwork submitted are contaminated with biological fluids, the item is difficult to describe, or a more detailed description is necessary, the analyst shall document the items within the case notes, batch sheet(s), and/or with a photograph/photocopy, using a state-controlled camera (not a personal camera or cell phone). If a picture is taken, the following instructions should be followed.

Photography procedure

- Using all appropriate PPE, place the item to be photographed on a distraction-free background. Remove gloves to ensure the camera remains clean.
- Ensure proper lighting is being used.
- Take a photograph with a scale and a label containing the HETL case number, item number, and photographer's initials.
- Print the photograph(s) with the date and time stamp on it, in color and include it in the casefile for retention.

Retention and Storage of Photographs

- All photographs should be retained as a part of case documentation.

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- Original photographs should not be destroyed. All photographs, including poor quality or unintended photographs should remain a part of case documentation. Save the photographs in the appropriate folder on the K drive.
- Photographs may be introduced as evidence and therefore need to be maintained to prevent loss and degradation.

Paperwork or packaging that has biological contamination, the contaminated packaging/paperwork may be destroyed after proper documentation of the item, updating the chain of custody as necessary.

The blood kit box/container will be labeled with the date and analyst's initials who completed the kit inventory. The blood kit box/container (everything other than blood tubes) will be stored in an appropriately labeled box which is given a unique identification number. The storage box identification number will be recorded on the Chain of Custody form. This box will be retained until filled in the laboratory. All filled boxes will be placed in long term evidence storage, for a period of at least six months, until being returned to the submitter or destroyed.

The analyst that opened the kits shall ensure the correct test codes are applied to the sample in StarLIMS.

After analysis the remaining blood tubes will be sealed in a plastic tube container/bag, the seal initialed by the analyst, and stored in a tube storage rack in the locked evidence refrigerator. The tube rack and position and evidence refrigerator will be recorded on the chain of custody. All blood tubes will be held in locked storage for a period of at least six months upon completion of analysis, until being returned to the submitter or destroyed. Beverage samples will be destroyed upon completion of testing. Sample disposal shall be performed in accordance with HETL hazardous waste disposal policies. The casefile shall be updated to indicate the sample has been destroyed.

By request, longer term storage/preservation of samples will be granted. A copy of the request will be attached to the chain of custody, and the original will be in the appropriate case file. The tubes are to be moved to a tube rack in a refrigerator designated for long-term storage, the kit box or other sample packaging will be moved to the box labeled designated for long-term storage, and the chain of custody will be updated accordingly and moved to a section designated for long-term storage chain of custody forms.

Definitions

Calibrators: Laboratory fortified samples that are prepared from a certified reference material of known concentration, used to create a calibration curve for an assay.

Calibration Range/Limit of Quantitation: The quantitative range between the Reporting Limit and the Upper Limit of Quantitation (ULOQ) used in the calibration curve.

Positive Quality Controls: Samples prepared from a certified reference material of known concentration that are used to check the accuracy of a calibration curve and to ensure compounds are detected by the method.

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Negative Quality Controls: Samples containing internal standard used to confirm no compound of interest or carry over.

Internal Standard(s): All calibrators, QC, and case samples are fortified with internal standard at a consistent concentration. Internal standard is used to calculate quantitative values by measuring the area response each compound of interest as a ratio compared to the area of the compound of interest's associated internal standard.

Reporting Limit (RL): The lowest concentration at which an analyte has been validated to be reported by the laboratory.

Upper Limit of Quantitation (ULOQ): The highest concentration calibration point included in the calibration curve

Quality Assurance

Specimen Requirements

Whole blood

Serum

Plasma

Liquids and/or beverages (not on the HETL ANAB Scope of Analysis)

Laboratory Consumables

Vendor supplied storage directions and expiration dates shall be followed. No supplies past suggested expiration shall be used for testing subject specimens for all Blood Alcohol Testing Program laboratory consumables. Items without expiration date shall be assigned an expiration date of no later than one year from the date of receipt. For supplies stored and used in the laboratory for specimen testing the following information shall be recorded on the container or packaging:

- Date Received
- Date Opened with Initials of Analyst
- Laboratory Expiration Date-unless documented on vendor's COA.

Blood Collection Kits Quality Assurance

To evaluate collection kits, one random kit from each lot number received is selected for quality control testing. The chemist performing the quality control testing will complete the appropriate collection kit QC form/reagent sheet listing all the lot numbers and expiration dates, if applicable, associated with the kit. Upon completion of testing the generated data and form is reviewed and approved. If the quality control testing shows no evidence of contamination, staff are notified the kits have been approved and can be stamped "Approved by Maine HETL".

Processing and testing procedure:

1. Record the kit lot, blood tube lot, and PI pad lot numbers on the worksheet.

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2. Add 1 mL of DI water and the liquid contents of the PI pad to one tube and vortex.
3. Label one 20mL headspace vials with identification number.
4. Using the auto dispenser - pipette 2500 uL of internal standard solution into each vial, and 250ul of water/sodium fluoride/potassium oxalate/iodine mixture into the vial.
5. Seal the vial by crimping the vial cap.
6. Vortex the vial.
7. Inject on a GC-FID using the dual column ethanol data acquisition method.
8. Complete the Blood Kit QC Form and submit to the Quality Manager for review and approval.

Acceptable results exhibiting no interferences caused by manufacturing contaminants or interfering compounds are required prior to the lot number being distributed. Records containing the results, pass/fail status, and lot number of the collection kits shall be maintained.

Safety Precautions:

The solvents used are considered toxic. Repeated or prolonged exposure can produce targeted organ damage. Proper PPE shall be used when handling solvents. Chemists should be familiar with Safety Data Sheets for all chemicals and drug standards used in the blood alcohol testing methods.

Blood from unknown case samples shall be handled following Universal Precaution guidelines. Face/benchtop splash shields in addition to PPE shall be utilized while pipetting blood.

Waste Management:

The most current approved version of the laboratory's hazardous waste plan shall be followed for the generating, labeling, and disposal of all hazardous waste generated by these methods. Maine Department of Environmental Protection rules Chapter 850: Identification of Hazardous Waste, Chapter: 851 Standards for Generators of Hazardous Waste, and Chapter 858: Universal Waste Rules shall be adhered to. Waste disposal for blood testing methods should follow the most recent waste stream evaluation forms on file in the section.

Bleach shall be added to the beaker containing the water that was used to rinse the diluter during analysis. The solution will then require reduction, following the HETL policy, and the solution can be poured down the drain.

GC Vials containing water and aqueous alcohol/volatiles are disposed of in a glass waste box. GC vials containing blood and alcohol/volatiles are disposed of in the mixed dual waste box.

The concentration of any alcohol/volatiles present in the vials is low enough to no longer be considered hazardous.

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Equipment Maintenance and Calibration

Perkin Elmer Headspace GC-FID:

Daily (when in use), before running calibration or sample sequence:

- Instrument check sequence consisting of one negative control and two controls (aqueous or whole blood) or calibrators

As Needed:

- Back-up data to external hard drive
- Clean Needle

Annually:

- PM by vendor

As Needed:

- Change Column
- Trim Column
- Bake Out Column

Hamilton Diluter – Microlab 600 Series

Annually:

- calibration

Parker Balston Hydrogen Generator:

As Needed:

- Fill with Deionized Water

As Needed:

- Service A (Refer to Manufacturers Manual)

Every 12 Months:

- Service B (Refer to Manufacturers Manual)

Reagents, Standards, and Quality Control Materials

Refer to Quality Manual and Relevant Reagent Sheets.

Ethanol Calibrators and Quality Controls:

- Purchased from an approved vendor (such as Cerilliant / Lipomed, etc)

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- Whole Blood Controls from an approved vendor (such as CliniQA Laboratories, etc), only run when a whole blood sample is present in batch
- Serum Controls from an approved vendor (such as UTAK), only run when a serum sample is present in the batch

Calibrators are aliquoted directly from a freshly opened ampule. Aqueous quality controls are aliquoted from a freshly opened ampule or, with supervisor approval, an approved working stock. Whole blood quality controls are aliquoted directly from the reagent container. All are diluted in the same manner as case samples using the diluter. See appropriate reagent sheet for serum control preparation procedures.

Volatiles other than Ethanol: Volatile calibrators shall be purchased from an approved vendor (such as Cerilliant, Lipomed, etc). Controls containing volatiles are part of the whole blood controls from CliniQA Laboratories. Volatile calibrations will be updated twice a year.

Case Documentation

Case File

Each Sample case file/folder shall contain: *(Each piece of paper within a casefile shall contain the Laboratory Identification Number (Sample #) and analyst initials.)*

- Laboratory Blood Analysis Request Form, if received by submitting agency
- Receipt/Contract for Examination Form/Chain of Custody
- Blood Kit Inventory Worksheet
- Raw data from the instrument
- Case Review Form
- Any paperwork/cards included in the blood collection kit as well as any communications regarding the sample

Batch File

Each batch file shall contain: *(Each piece of paper within a batch shall contain the analyst initials.)*

- Instrument sequence
- Batch summary report
- Raw QC data from the instrument
- Batch Review Form & Bench sheet
- Photocopy of Calibration Review Form & Bench Sheet: must be included in the batch file unless the Calibration file and the Batch file are going through the technical and administrative review process together.
- If applicable, initial instrument check

Calibration File

Each Calibration file shall contain: *(Each piece of paper within a batch shall contain the analyst initials.)*

- Instrument sequence
- Calibration summary report

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- Calibration Detailed Report
- Calibration Curve by Compound
- Raw calibration/QC data from the instrument
- Calibration Review Form & Bench sheet
- If applicable, initial instrument check

Estimation of the Uncertainty of Measurement

An estimation of the uncertainty of measurement shall be determined using an uncertainty budget for all quantitative analytical procedures and reported on the Certificate of Analysis. Documentation, when applicable, shall be retained by the Quality Manager.

Traceability is established by using NIST/Guide 34 or ISO 17034 traceable standards, obtained by an approved vendor, and utilized equipment calibrated to ISO17025 standards.

The uncertainty budget shall include Type A (random) uncertainties and Type B (systematic) uncertainties. As illustrated below these uncertainties include:

Uncertainty Component	Method of Evaluation
Staff	
Multiple Analysts	Covered in Type A Evaluation of Process reproductivity data-blood matrix QC sample.
Training	
Experience	
Bias	
% Bias of method	Taken from Type A Evaluation of Process reproductivity data-blood matrix QC sample.
Calibrators	
CRM-uncertainty in the stated reference value	Type B Evaluation
Matrix of calibrators and measurand	Initially evaluated during method validation. Quantified in Type A Evaluation of process reproducibility data-blood matrix QC sample.
Quality Control Samples	

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CRM-second source; uncertainty in the stated reference value	Type B Evaluation
Matrix control-stability	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample.
Sampling of Measurand	
Homogenization	Initially evaluated during method validation. Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample.
Temperature-all calibrators, quality control samples, and the measurand are brought to room temperature. Variation in the time allowed to reach room temperature. Variation in room temperature at different times of year.	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample.
Internal Standard Preparation	
Components	No influence. The measurement result will only be impacted by the volume of the internal standard added to each sample.
Concentration of Internal Standard	No influence. Procedural requirement to use the same lot of internal standard for all samples in an analytical batch.
Preparation of aliquots of Calibrators, Quality Control Samples and Measurand	
Pipets. Volume of sample, volume of internal standard and calibration uncertainty or criteria for calibration and proper function check.	Type B Evaluation.
Variation in use by multiple staff	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample
Autosampler vials	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample
Time between replicate sampling of measurand	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample.

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Calibration of measuring system	
Uncertainty in the calibrator values	Duplicate listing of Component-see calibrator section above
Matrix of calibrators and measurand	Duplicate listing of Component-see calibrator section above
Instrument precision	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample
Analysis	
Instrument parameter settings	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample
Interference from the matrix	Duplicate listing of components-see Sampling of Measurand section above
Interference from reagents	This component is not an uncertainty component but is a quality control concern. The laboratory analyzes a Negative Control that contains no analyte (compounds of interest) but does evaluate all reagents used in the analytical method. The laboratory procedure specifies acceptable criteria for this quality control sample.
Interference from other compounds	This component is not an uncertainty component but is a quality control concern. The laboratory, as part of the validation process to ensure proper functioning of the measuring system analyzed a mixture of compounds to ensure no interference.
Stability of sample(s) from preparation through analysis	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample and through the procedure administrative requirement for agreement of replicates
Data Processing	
Calibration model	Covered in Type A Evaluation of process reproducibility data-blood matrix QC sample and through CRMs used as QC

Adapted from: ASCLD/LAB Executive Director, ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty- ANNEX D the Uncertainty Component and Method of Evaluation table. ASCLD/LAB Document Control Number AL-PD-3065 Ver 1.0 2013.

Type A uncertainties shall be evaluated using historical control charts to establish standard deviations. For new methods that lack historical control data a minimum of 30 controls that meet all detection, identification, and concentration

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accuracy (as set forth in the Data Analysis Acceptance Criteria: Quality Controls section of this document) shall be analyzed to determine the pooled relative standard deviation of the mean. The pooled relative standard deviation equation is as follows:

$$RSD_{pooled} = \sqrt{\frac{[(n1-1) * (RSD1)^2] + [(n2-1) * (RSD2)^2] + [(n3-1) * (RSD3)^2]}{(n1+n2+n3)-3}}$$

Instrument and Equipment used for analysis:

PerkinElmer Headspace Autosampler Gas Chromatograph Flame Ionization Detector- dual-column

Headspace Autosampler- TurboMatrix 110

Gas Chromatograph Flame Ionization Detector (GC-FID)- Clarus 590

Hamilton Diluter – 600 Series

Microlab 600

The following components are recognized as potentially contributing to UofM:

- Whole Blood control (Reproducibility)
- Aqueous Controls (evaluation of bias)
- Temperature (liquids and ambient)
- Variation of time and room temperature
- Uncertainty stated on COA's
- Matrix differences
- Diluter: samples, controls, calibrators, and internal standard
- Stability of controls and calibrators
- Staff variability
- Headspace variability
- Concentration
- Internal Standard (n-propanol) stability and concentration
- Stability
- Instrument parameters
- Instrument precision
- Calibration model
- Integration parameters / processing of data

The following components are considered of significance:

- Whole Blood Matrix Control - Type A: (reproducibility of assay)
- Matrix - Type B: (5% administrative rule)
- Calibrators- Type B from COA
- Diluter for Calibrators - Type B from calibration certificate
- Diluter for Samples - Type B from calibration certificate

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Aqueous Controls - Type B from COA (evaluation of bias)

It is noted that if a K value is provided by the vendor, then we shall use that value. If no K value is provided, then the uncertainty of measurement shall be determined based off the tolerance provided by the calibration vendor.

The use of internal standards, for all quantitative analysis, minimizes other sources of uncertainty.

Data from controls are tracked in a Microsoft Excel Spreadsheet. Calibration certificates of the pipets and volumetric flasks used as well as the Certificates of Analysis of respective calibrators and QC standards are retained by the Quality Manager. From these tracking documents it can be determined that the data is or is not of a normal distribution, skewed and the mean and standard deviation calculated. Additional graphs can also be created as warranted. All values of uncertainty from individual components deemed significant (as listed above) are converted to percent uncertainty (See ASCLD/LAB Annex D AL-PD-3065 Ver 1.0.)

All impacting uncertainties are combined using the Root Sum Squares technique:

$$U_{combined} = \sqrt{(U_1^2 + U_2^2 + U_3^2 \dots)}$$

The expanded uncertainty for a confidence interval of 95.45% (more commonly referred to as 95%) is determined using the equation:

$$U_{expanded} = U_{combined} * k$$

For methods lacking sufficient historical data, a corrected coverage factor (K_{corr}) shall be used based on the Student's t Table to compensate for the unreliable estimates derived from random uncertainties in the instances where few measurements are made. A K_{corr} shall be selected to meet a 95.45% confidence interval using the correct degrees of freedom, also known as n-1 selected to express this. Methods containing sufficient historical data shall utilize an appropriate k value based on the Student's t Table.

The schedule to review the measurement of uncertainty shall be conducted annually or upon the addition or replacement of laboratory equipment or other factors considered of significance once enough data has been obtained to be evaluated. The Quality Manager will retain calculations, verifications of spreadsheets, graphs, and other relevant data.

Specific Analytical Procedure:

Instrument Sequence

Case samples are run in duplicate. At minimum a batch should contain a Negative Control (2500uL of 0.2% n-propanol in DI water), aqueous Quality Controls covering at least the minimum reporting level, a mid-range, and a high-range, and

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matrix matched control(s) when appropriate. If a batch contains whole blood sample then both a low concentration whole blood control and a high concentration whole blood control containing volatiles shall be included. If a batch contains serum samples, then a serum control shall be included. If a batch only contains aqueous beverage samples, then only aqueous controls are required. The following is an example of how casework samples and QC checks/standards may appear on the batch sheet as appropriate.

Sequence Information - Channel A						
c:\c\data\methods\het\bac						
Row	Name	Number	Inst Method	Proc Method	Calib Method	Row
1	Negative Control	01	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
2	WBC1 E/P 4/21/25	02	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
3	WBC2 E/P 4/21/25	03	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
4	SERUM CONTROL E/P 04/30/25	04	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
5	LIPOMED 0.010 C1455105 4/2025 4/1	05	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
6	CASE1-01	06	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
7	CASE1-02	07	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
8	CASE2-01	08	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
9	CASE2-02	09	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
10	CASE3-01	10	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
11	CASE3-02	11	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
12	LIPOMED 0.100 25052023A 5/2025 4/1	12	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
13	CASE4-01	13	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
14	CASE4-02	14	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
15	CASE5-01	15	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
16	CASE5-02	16	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
17	CASE6-01	17	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
18	CASE6-02	18	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
19	LIPOMED 0.400 12052023B 5/2025 4/1	19	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
20	Negative Control	20	c:\c\data\methods\het\bac	c:\c\data\methods\het\proca_031425_b	c:\c\data\methods\het\proca_031425_b	C:\C\DATA\Results\2025
21						
General / Sample Description / Methods / Data files / LIMS / Sample Values / Calibration / User Data /						

Sequence Information - Channel B						
Row	Name	Number	Inst Method	Proc Method	Calib Method	Row
1	Negative Control	01	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
2	WBC1 E/P 4/21/25	02	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
3	WBC2 E/P 4/21/25	03	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
4	SERUM CONTROL E/P 04/30/25	04	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
5	LIPOMED 0.010 C1455105 4/2025 4/1	05	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
6	CASE1-01	06	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
7	CASE1-02	07	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
8	CASE2-01	08	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
9	CASE2-02	09	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
10	CASE3-01	10	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
11	CASE3-02	11	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
12	LIPOMED 0.100 25052023A 5/2025 4/1	12	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
13	CASE4-01	13	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
14	CASE4-02	14	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
15	CASE5-01	15	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
16	CASE5-02	16	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
17	CASE6-01	17	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
18	CASE6-02	18	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
19	LIPOMED 0.400 12052023B 5/2025 4/1	19	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025
20	Negative Control	20	c:\c\data\methods\het\bac	c:\c\data\methods\het\procb_031425_b	c:\c\data\methods\het\procb_031425_b	C:\C\DATA\Results\2025

Whole blood and serum controls must be run at the beginning of the sequence.

Prior to a sequence being run it shall be checked by a secondary individual. At minimum all of the following shall be performed

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1. Read off sample vial position of each aqueous QC as a “spot check”
2. Read off sample vial position of starting and ending samples of batch
3. When going between circles/rings of the autosampler read off the sample vial position end of the outer ring and the first vial position of the inner ring.

It is noted that reading off every single vial position with sample name is also acceptable.

Quality Control Requirements & Acceptance Criteria

Pre-Run

Daily (initial) instrument checks will be performed when the instrument is in use, prior to a calibration or sample sequence or after any instrument repair/instrument failure. These checks will be reviewed by the analyst for acceptability, initialed for approval and stored in the corresponding batch folder. The check shall consist of sequence containing:

- one Negative Control
- two standards (aqueous or whole blood)

Acceptability criteria for this initial instrument check consist of the Negative Control results below 0.010 g/dL to be considered passing and the Positive Controls containing the compound of interest at the expected retention time. The concentration may be evaluated by the analyst for acceptability to move forward, but, as different internal standard lot numbers may be utilized, it is not included in this acceptability criteria.

Within-Run

Quality Controls shall be analyzed during the analytical testing process. These Quality Controls are used to:

- Determine the performance of the analytical or testing system.
- Quantitate the variability of results from the analysis or test in terms of precision and accuracy.

The frequency of Quality Controls will be determined by:

1. The number of samples being run in a particular sequence.
 - a. After every three case sample sets an aqueous Quality Control shall be run.
 - b. Whole Blood Control 1 and Whole Blood Control 2 shall be run at least once per batch when whole blood samples are included in the batch.
 - c. One serum control shall be run when serum samples are included in the batch.

Acceptance criteria for both QC checks, calibrations and sample sequences can be found in the Calculations table. Wherever possible, control charts will be set up and used to record results from selected function and control checks. Determination will be made whether the testing or analytical process is out of control and corrective actions taken will be recorded.

Calibrators and Quality Controls shall be from different sources. Lot numbers and expiration dates will be recorded on associated bench sheets. Calibrators and Quality Controls will be traceable to ISO 17034 compliant suppliers whenever possible. The Quality Manager will maintain appropriate records of approved vendors, and how vendors are approved.

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NOTE: Make notation in any impacted calibration/batch/casefile of any instrument repair or any issue that prevents the run from going to completion. A Pre-Run initial instrument check shall be performed after any instrument failure, before processing further casework samples. Recalibration may be necessary depending upon the scope of the repair.

Frequency of Updating the Calibration Curve

A calibration will be updated at least once every 28 Days (preparation day=Day 0), when samples are analyzed. This data will be stored with the ethanol control documents. Calibrators used to create the calibration curve will be of the following concentrations (g/100ml): 0.010, 0.050, 0.100, 0.200, 0.300, 0.400, 0.500. As soon as a calibration curve has been run that is now the active calibration curve and older previously run calibration curves cannot be used. Three second source aqueous Quality Controls will be run with the curve to check accuracy of calibration curve. These aqueous Quality Controls shall consist of a minimum reporting level, a mid-range, and a high range. The below table illustrates the aqueous quality controls and the range they fall within the 0.010 – 0.500 g/dL calibration curve:

Low Range Aqueous Controls	Mid- Range Aqueous Controls	High Range Aqueous Controls
0.01 g/dL (reporting level) 0.08 g/dL	0.100 g/dL 0.150 g/dL 0.200 g/dL	0.300 g/dL 0.400 g/dL

Criteria for acceptance will be:

- An r^2 value of .998 or greater for both Channels
- All calibrators and second source standards must pass using acceptance criteria defined in Calculations and Reporting of Results

Sample Preparation

1. Mix the sample thoroughly, allow samples to mix on rocker for at least 10 minutes. Homogenize the sample and break up any clots, where possible. If homogenized, the sample must be placed on a rocker a second time for a minimum of ten minutes.
2. Label two 20mL headspace vials with identification number and suffix (1 or 2).
3. Prime diluter at least 3 times with DI water before initial use
4. Prepare all sample 1 vials at the same time, then repeat for sample 2 vials. Using the auto dispenser re-pipetter - pipette 2500 uL of internal standard solution into each vial, and 250ul of sample into each vial.
5. Between all case samples, Negative Controls, and Quality Controls rinse the diluter with DI water.
6. Seal the vial by crimping the vial cap.
7. Vortex the vial.

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Calibrators, Quality Controls, and whole blood samples can be prepared and stored in the refrigerator for 6 days (D0,1,2,3,4,5,6) before being run on the instrument. If samples are prepared, but not able to be run within 6 days, they must be discarded and prepared again, and a note must be added to the casefile that an aliquot of the sample was taken but not analyzed. Serum samples and beverage must be tested on the same day of preparation. Sample preparation date and control preparation date will be recorded on the Batch Review Form & Bench Sheet.

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Calculations and Reporting of Results

Calculations:

All samples (sample, positive quality control, or calibrator) must be within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater, when comparing between Channel A and B.

Additionally, positive quality controls run with the calibration and the positive quality controls run within the sample batches must be within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater, of the expected manufacturer's value.

RPD is calculated using the following formula: $| (x_2 - x_1) | / ((x_2 + x_1) / 2)$. (Samples less than 0.010 g/dL will be reported as '< 0.010 g/dL' even if difference in duplicates is greater than .005 g/dL)

To better define and clarify exactly what is acceptable and what is not:

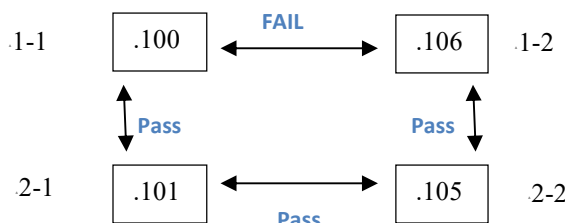
There are 4 results from each case (duplicate samples examined by dual column FID). Samples will be compared as such:

Vial 1: Result 1 to Result 2:

Vial 2: Result 1 to Result 2:

Vial 1: Result 1 to Vial 2: Result 1:

Vial 2: Result 2 to Vial 2: Result 2:

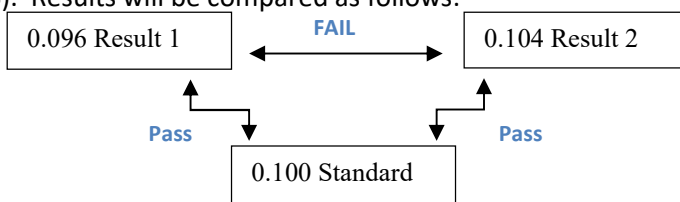


CLARIFICATION FOR STANDARDS: There are 2 results from each QC Check-Standard, one from each channel. (Result 1 – Channel A and Result 2-Channel B). Results will be compared as follows:

Result 1 to Result 2

Result 1 to nominal value of Standard

Result 2 to nominal value of Standard



For both Casework and Standards: Acceptable results are less than or equal to 5.0% RPD, or 0.005, whichever is greater. Meaning, 5.01% = Fail. 0.005 = PASS

If any sample from casework fails, new vial(s) will be prepared and tested along with at least 1 Negative Control, 2 aqueous controls, and 1 matrix matched control, depending on the sample matrix.

If any QC Check-Standard fails, then all casework samples that bracket the failure will be re-aliquoted and tested, with at least 1 Negative Control, 2 aqueous standards, and 1 matrix matched control, depending on the sample



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matrix.

Whole Blood & Serum Controls: Whole blood controls (low and high) and the serum control each have 2 results, one from each Channel (Channel A and Channel B) and are compared to each other and to the range provided by the manufacturer. Acceptable results consist of the values falling within the manufacturer's range or our calculated range and the results between Channel A and Channel B being within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater.

For whole blood controls, when compared to the range provided by the manufacturer, both results (Channel A and B) must be within the published range. If the two values are greater than 0.005 or 5% RPD, and/or either result from Channel A or B is outside the published range, then all whole blood samples within the batch will be rejected and re-tested.

For serum controls, both results (Channel A and B) must be within 5% of the expected concentration or the range established for that lot following the QC procedure outlined in the reagent log, whichever is determined as the passing criteria for that lot during the QC check. If the two values are greater than 0.005 or 5% RPD, and/or either result from Channel A or B is outside 5% of the expected concentration or accepted range for that lot, then all serum samples within the batch will be rejected and re-tested. The mean values of the controls are being continuously tracked by the Quality Manager.

Negative Control: Results must be below 0.010 g/dL to be considered passing. If a Negative Control fails, all samples in the batch will be rejected and re-tested.

Reporting of Confirmatory Blood Alcohol Testing:

All Case Files, Batch Files, and Calibration files are Technically Reviewed, followed by Administrative Review.

All test results are recorded to at least three decimal places.

Individual results from each case are averaged and always rounded down to three decimal places (example: 0.10375 is rounded down to 0.103).

An uncertainty of measurement for each result is calculated based upon the most current expanded uncertainty value. The resulting value is always rounded up to three decimal places, regardless of what the 4th significant figure is (example: 0.01424 is rounded up to 0.015). Any results less than 0.100 g/dL will be reported out with an uncertainty of 0.009 g/dL.

Results are reported in grams of alcohol per 100 mL of blood (g/100 mL of blood), this is also referred to as grams per deciliter (g/dL).

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An inventory table will be included on the report to indicate the number and types of tubes received, the collection information, the approximate volume of each tube, and an indication as to which tubes were tested.

Serum/Plasma results will be reported as a serum result with the applied current uncertainty of measurement estimate. The resulting range will be converted to whole blood on a secondary expert opinion letter, using a conversion factor of 1.22:1*. A comment stating "See expert opinion letter for conversion" will be listed on the report. The range of values will be truncated on the low end and rounded up on the high end.

* Measuring Blood Alcohol Concentration for Clinical and Forensic Purposes, AW Jones and Derrick Pounder, Handbook of Drug Abuse, S Karch, MD, 1998

Aqueous beverage sample results will be reported as the raw result with the current uncertainty of measurement estimate. The resulting range will be reported on a secondary expert witness letter, dividing the results by the density of ethanol (0.789) to yield a volume per volume alcohol percentage. The range of values will be truncated on the low end and rounded up on the high end.

Expert opinion letters will list all references used and contain, at minimum, the HETL case number and Subject's name, when applicable.

Any method deviations will be communicated to the customer on the report in the form of a comment. Comments shall also be made on the report for any samples where a full analysis could not be completed, with the reason why noted.

If a blood sample is inconclusive, the test code should remain the same and the inconclusive result and reason for the determination shall be included on the COA in the form of a comment. Below is an example comment listed could be on the COA, "Sample result has been deemed inconclusive due to [enter reason]"

Concentrations of ethanol below 0.010 g/100mL will be reported as "<0.010 g/100mL"

Any sample determined to be greater than the largest calibrator will be reported as '> 0.xxx' (Where xxx denotes the concentration of the largest / highest calibrator).

After the administrative review is completed, the analyst will complete the notarization of the report, and it will be sent to the customer. A copy of the consent cards, if received, from inside the kit box will also be sent to the customer with the report. The consent card will be labeled with the laboratory identification number, the initials of the analyst that inventoried the kit, and the initials of any analyst that analyzed the sample.

Samples submitted by the Office of the Chief Medical Examiner (OCME) will be tested for alcohol and drugs, when possible. The OCME has requested to have all reports sent unsigned via email, one signed copy will be retained in the casefile.

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Carryover:

Carryover may occur due to extremely high drug concentrations in biological samples and extreme caution is warranted when carryover is detected. When this occurs, the supervisor must be notified to provide guidance and review of the analytical results. All analytical test methods have been validated to establish that at extremely high concentrations of the compounds of interest exhibit no carryover into the following samples.

Dilutions:

Dilutions have not been validated and are not authorized to be performed for blood alcohol sample testing.

References:

ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Annex D. (ASCLD/LAB document: AL-PD-3065 Ver 1.0 22 May 2013)

Moffat, A. C., Osselton, M. D., Widdop, B., & Watts, J. (2011). Clarke's analysis of drugs and poisons: In pharmaceuticals, body fluids and postmortem material. London: Pharmaceutical Press.

ASB Standard for the Minimum Content Requirements of Forensic Toxicology Procedures, ANSI/ASB Standard 152, First Edition 2021

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Appendix

Perkin Elmer Instrument Setup: Suggested guidance in the following tasks

1. Launch TC Navigator Software on computer and log in.
2. Check water level on hydrogen generator.
3. Check carrier pressure is about 30 psi on headspace screen.
4. Check helium tank is on and replace if necessary.
5. Check flames are lit by looking at the mV for each detector flame.
 - a. If flames are not lit, follow below procedure.
 - i. Turn Flow On and Light Flames:
 1. On TC Navigator Software → Run → Release Control (If not already released)
 2. On GC home screen (blue bar at top of screen should say Method 5) → Tools → Configuration → A-FIDW → Select Setpoint boxes → Set Air to 450 mL/min; Set H2 to 45 mL/min
 3. On GC home screen → Select A-FIDW → Select Ignite box to light flame (wait for the click of the flame lighting and ensure voltage (mV) increases and stabilizes)
 4. Repeat for B-FIDW
6. On TC Navigator Software → Run → Take Control
7. (Optional) Turn off H2 and Air when changing tanks and to save gas when instrument is not running:
 - a. Turn Flow Off:
 - i. On TC Navigator Software → Run → Release Control
 - ii. On GC screen (blue bar at top of screen should say Method 5) → Tools → Configuration → A-FIDW → Select Setpoint boxes for H2 and Air to 0.
 - iii. Repeat for B-FIDW
8. Create data file path:
 - a. Open file explorer on computer
 - b. Navigate to C:/TC DATA/Results
 - c. Open most recent casework folder by navigating to the current year folder
 - d. Make a new folder with date and initials (mmddyyXX), subsequent runs on the same date appended with letter after date (mmddyya, mmddyyb, etc...)
9. Build Sequence:
 - a. In TC Navigator Software select Build → Sequence
 - b. Edit sequence log table:
 - i. Under Type field
 1. fill down with 'Sample'
 - ii. Under Name field
 1. enter all sample names and QC and standard lot numbers and exp dates
 - iii. Under Number field
 1. right click on number column
 2. select smart fill

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3. sample number pattern = ##
4. uncheck the Synchronize with vial numbers box
5. enter start & end row numbers
- iv. Under Inst Method field
 1. right click and click folder icon to navigate to correct method
 2. select instrument method "hetlbac" (file path: c:/tc data/methods/hetlbac)
- v. Under Proc Method for Channel A field
 1. right click and select Change Values
 2. click the folder icon to navigate to most recent method/date "hetlproca_mmddyy"
 3. repeat for Channel B and select most recent method/date "hetlprocb_mmddyy"
- vi. Under Calib Method for Channel A field
 1. right click and select Change Values
 2. click the folder icon to navigate to most recent method/date "hetlproca_mmddyy"
 3. repeat for Channel B and select most recent method/date "hetlprocb_mmddyy"
 - a. Note – Proc method and Cal method should be the same date
- vii. Rpt FMT leave empty
- viii. Under Raw Data File
 1. right click for Channel A
 2. select Path
 3. check the "Apply to other channel" box
 4. select the folder icon next to "New Path"
 5. browse to the correct results (C:\TCDATA\Results\Year Casework\Month\Date)
- ix. If data file number is not autopopulated – right click for each channel – smart fill
- x. Save As and name the same as result folder
- xi. Print the sequence.
- xii. Load vials on headspace autosampler.
- xiii. Sequence Verification Step – As samples and controls after the vials are loaded into the sample tray read off vial labels to a second person while the second person verifies the order listed on the printed sequence. Once the correct order has been verified the second person will signoff on the sequence.
- xiv. Enter the vial range on Headspace touch screen
- xv. Click Start on Headspace touch screen (method: bac)
- xvi. Click Actions in menu bar in TC Navigator software
- xvii. Click set up
- xviii. Set up instrument window opens
 1. Check Sequence Name
 2. Check vial numbers
 3. For calibration sequences, check mark the box "suppress reports/plots" in the Setup Parameters tab and under Processing
 4. Click OK

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10. Updating Method Calibration

- a. Run a calibration sequence according to the above section "CREATING A SEQUENCE"
- b. Name the sequence and results folder as mmddyyCAL
- c. Update old calibration with new data.
- d. Select Build Method
- e. Open the last calibration method date for A
 - i. In menu bar, select Components, click Calibrate
 - ii. Click the folder button and navigate to the results folder of the new calibration
 - iii. Select the seven calibration data files for channel A.
 - iv. Assign the appropriate concentration levels – make sure replace box is checked
 1. Error message will pop up because only the Ethanol calibrators are being updated.
 - v. In menu bar, select Other, click Fit Analysis, save method as hetlproca_mmddyy
 1. A graph will pop up in the window of the methanol calibration.
 - vi. In menu bar, select Data, click Next Component
 1. Ethanol graph should now be on the screen.
 - vii. Print the graph
 - viii. Close the window
- f. Open the last calibration method date for B
 - i. Select the seven calibration data files for channel B.
 - ii. Process the new calibration against the old calibration.
- g. Select Build Sequence, select Load sequence stored on disk
- h. Navigate to Sequences folder
- i. Under file type, select .idx with date of sequence
- j. Open the .idx file of the newest calibration sequence
- k. Save Sequence
- l. Under Inst Method for Channel A
 - i. right click
 - ii. select Change Values
 - iii. click the folder icon and navigate to the new calibration date that reads hetlproca
 - iv. Repeat for Channel B
- m. Under Proc Method for Channel A
 - i. right click
 - ii. select Change Values
 - iii. click the folder icon and navigate to the new calibration date that reads hetlproca
 - iv. Repeat for Channel B
- n. In menu bar
 - i. select Actions
 - ii. click Batch
 - iii. change the results folder file path under Change File Path to the new calibration date results folder

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11. Updating One Compound in Calibration

- a. Select the Build tab, and choose Graphic Edit
- b. Select the raw file to be updated
- c. Select the File tab, choose Open, and apply the correct method
- d. Select the Calibration tab, and choose Edit Components
- e. Select the compound/peak of interest to be updated
- f. Mark the box labeled Update Calibration
- g. Select the appropriate concentration Level from the drop-down menu
- h. Select Replace under the Calibration Type
- i. Click Next
- j. Select the return arrow (top left corner of the window)
- k. Select the File tab, and choose New Data File and repeat steps 2-9 for all Channel A files
- l. Save and rename the processing method for Channel A
- m. Repeat steps 1-11 for Channel B

12. Updating Noise/Area Threshold for Data Analysis Method:

- a. Build → Graphic Edit → Select appropriate result file
- b. File → Open → Open appropriate method to update
- c. Process → Noise/Area Threshold... → Outline a section/draw a box on a flat area of baseline
- d. A window will pop up with the suggested and current noise threshold (NT) and area threshold (AT).
- e. Enter the below threshold levels:
 - i. Current NT: 10
 - ii. Current AT: 25

13. Adding New User in TotalChrome Software

- a. Open TC Navigator
- b. Click Admin in the file menu – click show admin tool bar
- c. Click system configuration
- d. Click users in menu bar – click Add
- e. Enter all information (don't check box)
- f. Click ok
- g. Don't change anything in next window – click ok
- h. Click instrument access – check all instrumnets – click ok
- i. Click password – enter new password – click never expires
- j. Close Software and reopen – type in user name for first time to add to drop down

Enter password

14. Print reports manually from TotalChrom Software as they do not print at time of analysis

- a. Click Display → TC Publisher reporting
- b. Click "Report Options" in the Preview/Create Reports tab

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i. In the Data box, choose the correct sequence (.idx file)

ii. In the Report box, choose the correct report

C:\TC Data\Methods\HETLBACREPORT.tpm

Click Okay

15. Adding a new printer to TotalChrom Software

a. Click Admin → System Configuration

b. In the Printers tab

i. Delete the old printer

ii. Add the new printer

c. In the Users tab

i. Choose the new printer from the dropdown menu for all users

16. Summary Reports: **Calibration or Batch**



a) Open Summary

b) File/ Open Format- Choose HETL Calibration Summary

c) Results/From Sequence:

Select the IDX sequence, the folder, check both A and B channels (Mix)

d) Report format file:

Select **HETL Batch Summary-All** OR **HETL Calibration Summary** Report

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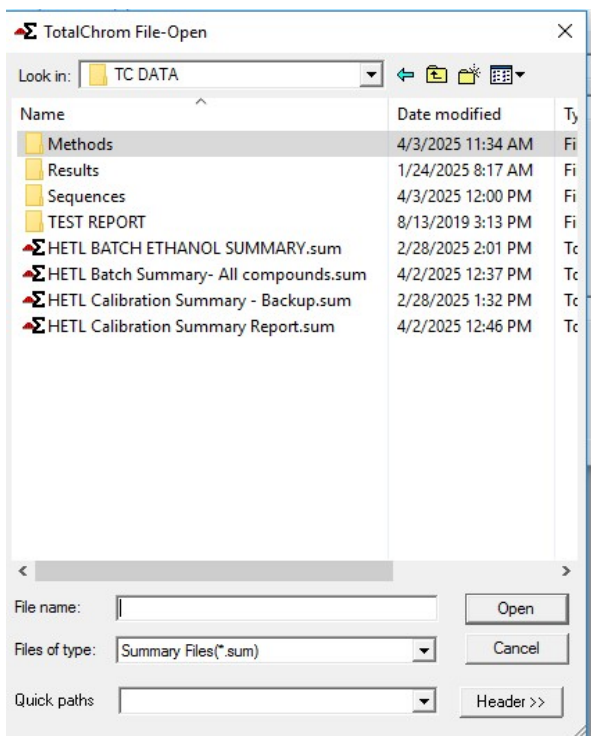
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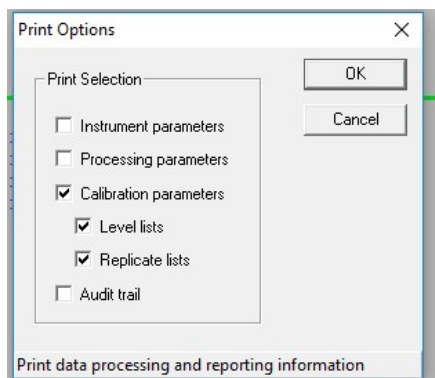
Forensic Chemistry Section



e) Print Preview or Print

17. Print Calibration Detailed Report:

- Open the data analysis method (Process A or Process B)
- File/print
- Deselect Instrument Parameters and Processing parameters:



-
-
-
- d) Ok/ Print

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Instrument & Method Information:

Instrument

PerkinElmer HeadSpace TurboMatrix 110 Sampler

PerkinElmer Clarus 590 gas chromatograph (GC)

Instrument Name: HS110

TotalChrom 6.3.3.0691 software

Detector –Flame Ionization (FID)

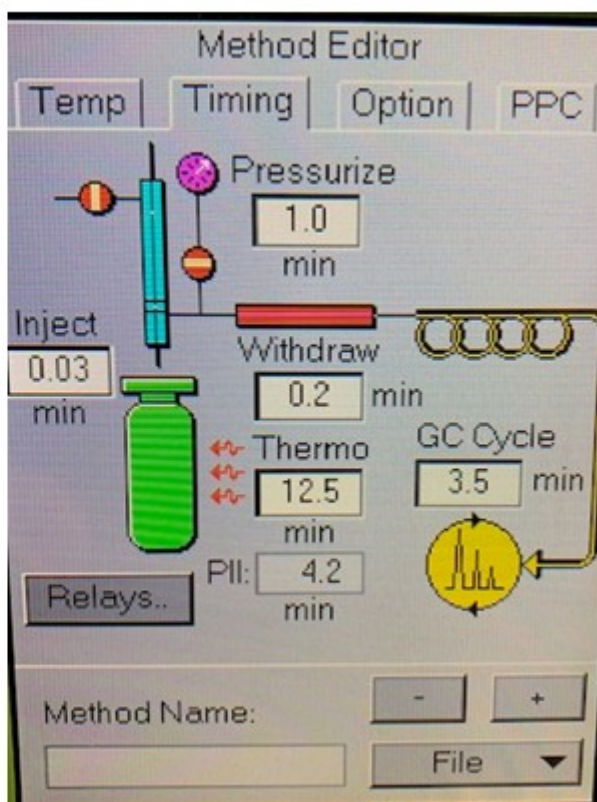
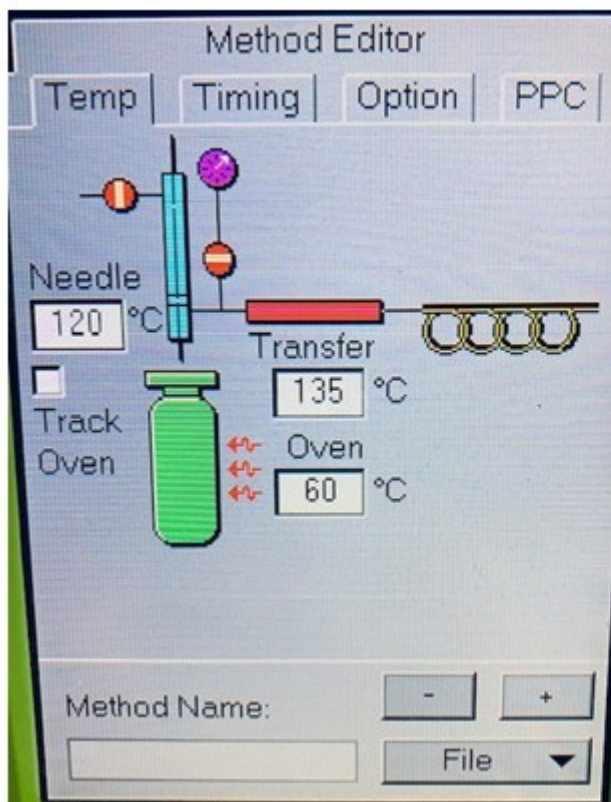
Columns – Elite BAC-1 Advantage 30 meter, 0.32 mmID, 1.8um df; Elite-BAC-2-Advantage 30meter, 0.32mmID, 0.6um df

Carrier Gas – Helium UHP

Detector Gas – Hydrogen

Data Acquisition Method

Headspace Autosampler Parameters – See screen shots below



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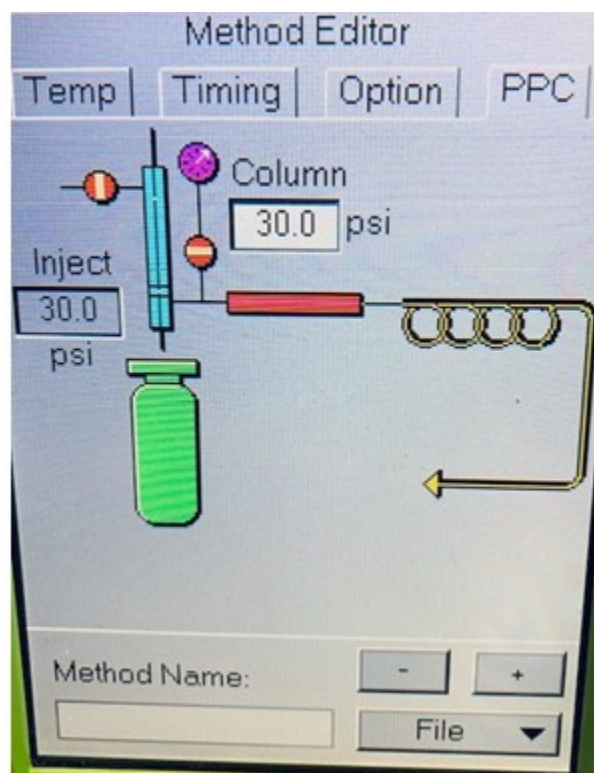
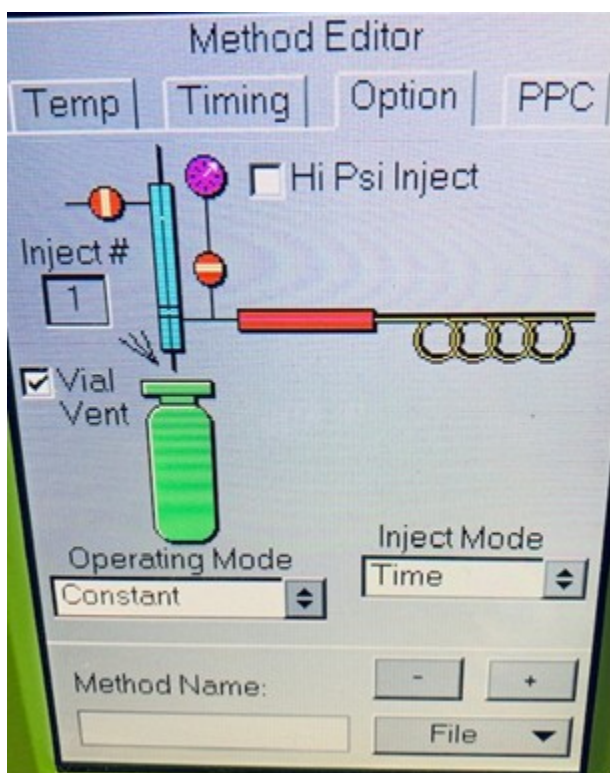
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Gas Chromatograph Parameters:

Split Flow: 20.0 mL/min

Initial Setpoint: 25.0 PSIG

Detector A & B Gas Flows:

Air: 450.0 mL/min

H2: 30.0 mL/min

Heated Zones-Detector A & B: 220°C

Oven Program

Initial Temp: 40°C

Initial Hold: 2.50 min

Total Run Time: 2.50 min

Data Analysis Parameters:

Processing parameters:

Bunch Factor: 1 points

Noise Threshold: 1uV

Area Threshold: 100.000 uV

Peak Separation Criteria:

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Width Ratio: 0.200

Valley to Peak Ratio: 0.010

Exponential Skim Criteria:

Peak Height Ratio: 5.000

Adjusted Height Ratio: 4.000

Valley Height Ratio: 3.000

Component Information (Compounds of Interest):

Component Type: Single Peak Component

Retention Times (minutes):

	Methanol	Ethanol	Isopropanol	Acetone
Column A	0.900	1.127	1.375	1.488
Column B	0.867	1.027	1.167	1.119

Search Window: 0.00 s, 3.00%

Internal Standard: n-Propanol

Find peak closest to expected RT in window

Calibrating Area ratio versus Amount ratio using 1st Order Fit

Curve will ignore the origin

Amounts will not be scaled prior to the regression

Weighting factor for the regression: 1

Component Standard Purity Percentage: 100.0000%

Component Information (Internal Standard):

Component Type: Single Peak Component

Retention Times (minutes):

	n-Propanol
Column A	1.882
Column B	1.624

Search Window: 5.00 s, 3.00%

Internal Standard: n-Propanol

Find peak closest to expected RT in window

This component is an internal standard

Calibrating Area ratio versus Amount ratio using 1st Order Fit

Curve will include the origin

Amounts will not be scaled prior to the regression

Weighting factor for the regression: 1

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Forensic Chemistry Section

Revision Table:

REVISED BY	REV#	DATE	Revisions
LN	1*	6/8/21	Evidence Handling and Preservation: Updated documentation of discrepancies to include the option of a photograph of evidence. Added procedure for handling packaging/paperwork which is contaminated with biological fluids. Revisoins: Added Revision table to document.
LN	2	07/29/21	Section III F was updated to remove the transfer of the liquid to the second tube in the kit. The second tube will be reserved for blood drug testing.
LN	3	01/06/22	Section V Updating Method Calibration: added "save sequence" following letter d Section VI: Serum control passing range updated to include a laboratory determined range based on QC data. Rerun section updated to include serum matrix.
LN	4	04/12/22	Section I F added guidance to see reagent records for preparation instructions. Section II added guidance to evidence control while testing and ensuring a proper seal is in place prior to testing. Clarified the analyst opening the kit should be the one initialing the stickers. Included a section on dealing with minor discrepancies. Added that photographs shall be taken using a state controlled device. Added steps for the analyst opening the kits to add the case number to the blood kit box excel sheet and ensure all test codes are assigned in LIMS. Section V added instructions for updating one compound in calibration curve Section VI added devaiitons shall be communicated to customer in the form of a comment on the report, and consent cards will be sent along with the report to the customers. Section IX added second diluter
EAf, LN, & MS	5	6/30/22	Added postmortem sample reporting to VI. Reporting Criteria. V. Gas Chromatogram Instrument Setup section rewritten and added Added Whole Blood Controls to section I Preparations of Solutions. Updating Noise/Area Threshold for Data Analysis Method. Added small grammatical and formatting changes throughout document.

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LN	6	08/17/22	Updated section I, III, and VI to only require matrix matched controls when those specific matrices are included in the batch. Batches with only aqueous samples do not require a whole blood control or serum control.
LN	7	11/08/22	Updated Section II to note that beverage samples are destroyed upon completion of testing. Updated Section IV to clarify that only blood samples may be prepared and stored for up to six days before analysis. Updated section VI and VII to note that any tubes received for analysis other than HETL approved gray top tubes will be noted on the report.
LN	8	11/17/22	Updated following addendum verification to adjust the AT and NT in the method. Fixed typo for instrument model. Added the software model used to section I.
LN	9	06/30/23	Appendix added: instrument processing method Section II: added procedure for documenting evidence with a camera. Section IV 1.: added "Homogenize the sample and break up any clots, where possible. If homogenized, sample must be placed on a rocker a second time for a minimum of ten minutes" Section IV: Waste section added
LN	10	10/26/23	Section II – updated the box location to the COC instead of worksheet. Removed reference to excel sheet for tracking boxes. Section IV changed vial naming scheme from vial A and vial B to vial 1 and vial 2 Waste – updated to include bleach reduction prior to disposal. Section V – added step 9 xviii 3, 14, and 15 Section VI – changed vial naming scheme from vial A and vial B to vial 1 and vial 2 to prevent confusion with blood kit inventory sheet. Added section discussing blood kit inventory table that will be included in reports. Updated process for reporting of serum and beverage samples. Removed comment requirements for items included on report. Updated spelling throughout. Added requirements for expert letter.

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EAF	11	01/18/24	Added to Evidence Handling and Preservation section "For continuity the volumes entered into the blood inventory worksheet and subsequent StarLIMS items received table shall adhere to the following format: (table containing guidance with different volumes)" Added non-HETL approved collection material reference table. Added to evidence handling: If a non-HETL approved collection kit or materials were submitted, the WO# field in STARLIMS folder metadata shall be filled in with N/A. If the kit, upon opening, is found to contain non HETL approved collection materials this shall be noted on the inventory form and STARLIMS metadata shall be updated appropriately.
LN/AH	12	03/28/24	Updated inconclusive requirements and waste section. Removed requirement to add note on report if non-HETL kit was used and collection site of PM samples, this is now recorded in report table. Workflow table added. Corrected vial A and B to 1 and 2 in section IV. Table VI corrected vial A and B to 1 and 2. Grammar and spelling updated.
EAF	13	4/9/24	If blood evidence is opened and found to contain a broken or leaking blood collection tube and meets the following criteria: • The volume in the broken tube or leaked volume is enough to perform the requested testing • Any leaked sample is from one tube, for example leaked sample that is a mixture of two leaking tubes will not be retained or tested. The sample from the broken/leaking tube shall be decanted into a clean glass screw topped extraction tube, labeled, sealed, and stored with the emptied blood tube for the case. This is to protect the testing analysts from broken glass when aliquoting the sample for testing. Documentation shall be recorded on the blood kit inventory that this process occurred. Added clarification about where to store photographs.
EAF	14	8/27/24	Added: Aqueous standard are aliquoted from a freshly opened ampule or, with supervisor approval, an approved working stock.

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EAf	15	12/20/24	Reformatted Introduction and Scope, and condensed contents of Notes into this section. Added: Waste management, laboratory consumables and safety precautions, definition, Carryover, and Dilution sections to the document. Included more details in UoM section Updated: calibration curve stability from 7 days to 4 weeks. And QC check of Blood Kits from 2mL of DI water to 1mL of DI water. Consolidated all instrument setup, parameters, and methods together into appendix Clarified existing language: Calculations and Reporting of Results, Calculations: "All samples (sample, control, calibrator, or standards) must be within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater, when comparing between Channel A and B. " & "Additionally, standards run with the calibration and the standards run within the sample batches must be within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater, of the expected manufacturer's value. " Whole blood & Serum Controls: " Acceptable results consist of the values falling within the manufacturer's range or our calculated range and the results between Channel A and Channel B being within ± 0.005 g/dL or $\pm 5\%$ relative percent difference (RPD), whichever is greater. " Updated maintenance (monthly & annually) to match maintenance log.
EAf	16	1/3/25	Fully changed QC check of Blood Kits from 2mL of DI water to 1mL of DI water (was not properly captured in previous revision).
EAf	17	2/28/2025	Added to QC and sample run scheme: Prior to a sequence being run it shall be checked by a secondary individual. At minimum all of the following shall be performed 1. Read off sample vial position of each aqueous QC as a "spot check" 2. Read of sample vial position of starting and ending samples of batch 3. When going between circles/rings of the autosampler read off the sample vial position end of the outer ring and the first vial position of the inner ring. It is noted that reading off every single vial position with sample name is also acceptable.

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EAf	18		Updated to capture new instrument reports and other below changes: Added Definition for Negative Control, Change all "Blanks" to Negative Control. Added Batch Summary Report, Calibration Summary Report, and Calibration Detailed Report to required documents. Added Calibration Review Form & Bench sheet and Batch Review Form and Bench Sheet to required documents. Expanded Case Documentation Section for required documents Added acceptability criteria for initial/daily instrument check Changed language from PE Alcohol Analysis Worksheet to Batch Review Form & Bench Sheet as needed. Replaced method information with Data Acquisition Method Parameters and Data Analysis Method Parameters.
EAf	19	4/25/25	Full Document review with staff and all sections received clarification. Major revision includes the use of new instrument reports (calibration summary, batch summary, and detailed calibration reports) to replace handwritten worksheet.
EAf	20	8/29/25	Removed diluter names "woody" and "buzz" from equipment list.
EAf	21	9/22/25	Within frequency of updating calibration curve section added the following clarifying language with associated table "The below table illustrates the aqueous quality controls and the range they fall within the 0.010 – 0.500 g/dL calibration curve:" See associated Improvement Report.

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EAf	22	5/28/26	• Safety Precautions: updated HETLs waste disposal plan title. • Opening & Storage of Submitted Blood Evidence: Added to action table if Receipt/Contract for Examination has BAC or TOX and Analysis Request has BAC & TOX. And added: Sample disposal shall be performed in accordance with HETL hazardous waste disposal policies. The casefile shall be updated to indicate the sample has been destroyed. Added If blood evidence is received in a gel separator tube and needs to be transferred to a secondary tube to allow for aliquoting and testing. The sample from the gel separator tube shall be decanted into a clean tube/vial, labeled, sealed, and stored with the emptied blood tube for the case. • Added Blood Collection Kits Quality Assurance section • Reporting Criteria: changed "Expert witness letter" to "Expert Opinion Letter". added Samples submitted by the Office of the Chief Medical Examiner (OCME) will be tested for alcohol and drugs, when possible. The OCME has requested to have all reports sent unsigned via email, one signed copy will be retained in the casefile. • Equipment Maintenance and Calibration: Added dilutor to section and updated hydrogen generator information. • Instrument Sequence: updated to meet 7.2.1.1.2 "Whole blood and serum controls must be run at the beginning of the sequence. • Instrument sequence information: removed requirement to have control preparation date, lot #s, and expiration date put into instrument sequence (only needs to be recorded on benchsheet). Preparation dates also changed to being recorded on the Batch Review Form & Benchsheet.
EAf	23	07/23/26	Updated blood inventory volume table with Visibly empty blood tube, no label-volume (mL) 0 (put collection date & time as NA). Combined duplicate sections Blood Collection Kits Quality Assurance and QC Check of Blood Kits

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