

Alaska Scientific Crime Detection Laboratory

Breath Alcohol Procedure Manual

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Version: 8.0

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Introduction

Overview of the Breath Alcohol Program

The Scientific Crime Detection Laboratory (crime lab) is part of the Department of Public Safety. Per 13 AAC 63.010, the Commissioner will designate an employee of the crime lab as the Scientific Director of the blood and breath alcohol testing program. Records of these designations are located in the laboratory SharePoint document library:

[Tech Lead Appointments - Toxicology](#)

The Scientific Director is responsible for all aspects of the breath alcohol program including calibration of breath test instruments; training and certification of breath test operators and breath test supervisors; and maintaining the scientific integrity of the breath test program.

The breath alcohol program staff falls under the supervision of the Scientific Director and, as his/her designee(s), carry out the tasks associated with running the statewide breath testing program.

Evidential Breath Test Instrument

Per 13 AAC 63.020 and 13 AAC 63.030, the Scientific Director must approve a breath test instrument for use in the State of Alaska as well as maintain a list of all approved breath test instruments and associated equipment.

The current breath test instrument approved for use in the State of Alaska is the "DataMaster DMT" originally manufactured by National Patent Analytical Systems and now manufactured by Intoximeters, Inc under the product name "Intox DMT". The approved associated equipment list is maintained in Appendix I of this manual.

Breath Alcohol in JusticeTrax

Overview

The breath alcohol laboratory in JusticeTrax requires a separate login from the laboratory database. The analyst username for the breath alcohol database is the analyst's last name.

The electronic case mask for breath alcohol cases in JusticeTrax begins with the letter B (example: B-100XXX with 100XXX being the instrument serial number).

Each electronic case in JusticeTrax has the instrument assigned to it as evidence. The evidence is titled using the instrument serial number and a unique evidence barcode is affixed to the side panel of each instrument.

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Nanuk Cases

The laboratory uses hard-sided cases for the safe transport of DataMaster DMT instruments. These cases are tracked as evidence using the B-NANUK electronic case and each case is individually barcoded for tracking purposes.

DataMaster and Nanuk Case Chain of Custody

Instruments and Nanuk cases are tracked using the evidence barcodes in the same manner as other evidence. JusticeTrax maintains an electronic record of the dates, times, and involved parties for each transfer.

The "Breath Test Section" is a laboratory staff member (person) and is the location of all instruments and Nanuk cases when stored at the lab. Intoximeters as well as individual law enforcement agencies are classified as storage locations. DataMasters are electronically transferred from the Breath Test Section to each location when sent into the field.

Breath Alcohol Requests in JusticeTrax

DataMaster-specific laboratory functions are documented in JusticeTrax with various request types (excluding Change in Instrument Status Forms). Refer to [Technical Procedures](#) for more information about the technical aspects of each request.

Requests may be created by the analyst or technician when the technical procedure is being performed or has been completed. The request is assigned to the person performing the procedure.

NOTE: For a Calibration performed by a technician who cannot issue the calibration certificate, the Calibration request in JusticeTrax must be assigned to an analyst prior to data entry.

Each request type has an associated controlled form. The completed controlled form is stored as an attachment within that request type before the request is finalized. Request-related controlled forms are technically and administratively reviewed as a part of that specific request.

Some request types have associated Custom Forms in JusticeTrax for data entry in addition to the controlled form (e.g., Evaluation, Calibration).

All requests require some findings to be entered to trigger the next milestone in JusticeTrax. For request types that do not require data entry, a space or the analyst's/technician's initials may be entered.

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Breath Alcohol Program Terminology

The Breath Alcohol Program previously used the following terms and definitions:

Calibration: When the instrument reading is adjusted to match a known reference.

Certification: The final testing process before an evidential breath test instrument is approved for use in the field. This process included linearity testing.

The Breath Alcohol Program now uses the following Metrology terms:

Adjustment: When the instrument reading is adjusted to match a known reference.

Calibration: The final testing process before an evidential breath test instrument is approved for use in the field. This process includes As Left linearity testing.

As Found: A demonstration of the as-is performance of the instrument when received by the laboratory.

As Left: A demonstration of the instrument performance when approved for evidential use; a component of the calibration process.

Abbreviations

AAC	Alaska Administrative Code
ANAB	ANSI-ASQ National Accreditation Board
APSC	Alaska Police Standards Council
BAPM	Breath Alcohol Procedure Manual
C	Celsius, a unit of temperature
C of A	Certificate of Analysis
CTS	Collaborative Testing Services, a forensic proficiency test supplier
DMV	Alaska Department of Motor Vehicles
DPS	Alaska Department of Public Safety
FAO	Forensic Alcohol Opinion, a type of laboratory interpretation report
g/210 L	Grams of ethanol per 210 liters of breath, a unit of concentration
Intox	Abbreviation for Intoximeters, Inc., the current DataMaster DMT and Intox DMT product owner
k	The coverage factor, a multiplier used to expand the standard uncertainty
LIMS	Laboratory Information Management System, a computer system
M	The Mean; an average
mL	Milliliter, a unit of volume
NIST	The National Institute for Standards and Technology

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NPAS	National Patent Analytical Systems, the initial DataMaster DMT product manufacturer
PPM/ppm	Parts per million, a unit of concentration
PT:	Proficiency Test
RFI	Radio frequency interference, a status message caused by radio waves
SOR	Standard out of range, a status message
U	The expanded combined uncertainty calculated for ethanol dry gas standard measurements
µL	Microliter, a unit of volume
V	Volts, a unit of electrical potential
VOC	Verification of Calibration, a check of the DataMaster DMT accuracy and repeatability

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Administrative Procedures

Verification of Calibration (VOC) Reports

Per 13 AAC 63.100, the accuracy of the calibration of the breath test instruments must be verified at least every 60 days. The documentation of this accuracy check is the verification of calibration report. The accuracy check performed for the VOC report consists of a diagnostic check and five tests of the external dry gas ethanol standard. The VOC procedure is incorporated into the instrument software under the direction of the Scientific Director. A VOC is initiated by the instrument software in intervals of less than 60 days AND whenever the external dry gas ethanol standard is changed. Breath test operators and breath test supervisors may also initiate a VOC.

The instrument software is scheduled to initiate a VOC on the following dates at 12:00 PM:

January 3rd
February 21st
April 11th
May 30th
July 18th
September 5th
October 24th
December 12th

Upon the completion of a successful VOC, the instrument stores a copy of the report to memory. If a VOC does not complete successfully, the instrument will not permit subject tests until a valid VOC has been completed.

The instrument memory is periodically uploaded to a crime lab computer via a modem line to the DMHost software. The completed VOC is printed from the uploaded file, technically reviewed by a member of the breath alcohol discipline, then signed by the Scientific Director and notarized. All VOCs are scanned and stored on the laboratory network drive. Copies of all VOCs are uploaded to the crime lab website.

The dates listed above are not the only acceptable dates for VOCs. The only requirement is that a VOC be performed every 60 days when an instrument is in service.

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Technical Review of VOC Reports

A technical review of each VOC is performed by a qualified member of the breath alcohol discipline prior to the report being reviewed and signed by the Scientific Director. Technical review of VOCs includes the following:

- External dry gas ethanol standard cylinder lot number and expiration date are correct and are included on the crime lab's list of approved cylinder lots.
- The five external standard results fall within +/- 0.005 of the target value adjusted for barometric pressure.
- The standard deviation of the five external standard results is ≤ 0.0030 .
- Each component of the diagnostic check reads "PASSED".
- No status messages are present.
- Verify the software version is the current approved version.

The technical reviewer will initial and date the VOC indicating the technical review was performed.

The Scientific Director completes an additional technical review and then signs the VOC indicating the instrument was approved for continued evidentiary use as of the date the VOC was performed. A VOC is not an approved report until signed by the Scientific Director and notarized.

DMHost

The DMHost software is provided by Intoximeters and communicates, through modem lines, with breath test instruments to upload data written to memory. The DMHost software enables breath analysts to remotely access instruments in the field for troubleshooting purposes. Breath analysts can view the Technician screen remotely; however, voltages and settings can only be adjusted when an instrument is at the crime lab.

Uploading Data from Breath Test Instruments

The DataMaster DMT writes subject tests, diagnostic tests, VOCs, supervisor tests, status messages, adjustment records, tank change records and software update records to the instrument memory. The DMHost software enables the breath test program to retrieve data collected by the breath test instruments in the field. The data is then stored in the DMHost database which is housed on a secure server.

All data retrieved by DMHost from the breath test instruments are considered an official record and are not altered by breath alcohol program staff. Data collected may be searched as well as have reports generated and printed. Breath test instruments in the field are uploaded periodically.

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Subpoenas, Discovery, and Court Testimony

Breath alcohol program staff to work with the legal community to provide testimony and information about the breath alcohol program, evidentiary breath testing instruments, and alcohol impairment.

Subpoenas

The breath alcohol program receives subpoenas for breath-only cases addressed to all analysts in the discipline. The forensic alcohol supervisor assigns an analyst for testimony based on workload.

Discovery

The breath alcohol program provides public access to most records associated with the breath program on the crime lab website: [DataMaster DMT Information](#).

The laboratory [Quality Assurance Manual](#) provides descriptions of the Discovery Levels and how they relate to the breath alcohol program.

Additional breath alcohol discovery requests (beyond publicly available records) are handled by the Scientific Director or his/her designee. Depending on the feasibility and resources needed to fulfill a request, the crime lab may require a court order.

Discovery requests are created, stored, and identified as described in the [JusticeTrax LIMS-Plus 3.8 Manual](#).

Testimony

Testimony regarding the breath alcohol program follows the guidelines in the laboratory's testimony policy ([Quality Assurance Manual](#)). Testimony may be provided in state, municipal, and federal courts upon request and with approval from the discipline supervisor.

Breath alcohol analysts provide testimony regarding the breath alcohol program, evidentiary breath testing instruments, and alcohol impairment. The [Interpretation of Alcohol Results Manual](#) discusses common forensic alcohol testimony topics.

Department of Motor Vehicles (DMV)

The Department of Motor Vehicles (DMV) holds administrative proceedings regarding impaired driving cases and may request information regarding these cases. DMV case information requests are treated as laboratory discovery requests. Occasionally, expert testimony may be provided for hearings upon request and with approval by the discipline supervisor.

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Other Breath Alcohol Program Records

The [DataMaster DMT Information](#) page contains breath alcohol program records kept in the normal course of business. These records are not related to a specific case. Copies of some records (e.g., DataMaster instrument records) are also stored on a secure network drive and/or SharePoint document library.

Breath Test Records

The DMT Breath Test Records > Breath Test Records.pdf is a report pulled from the DMHost database and posted on the website approximately monthly. This report lists all breath tests that the crime lab has a record of organized by instrument serial number and date. If the lab has not yet received an electronic record for a test, that test will not appear in the report. The list may include breath tests performed for training or demonstration purposes under the Test Type: TEST.

If a subject has blown into a DataMaster, a positive ethanol reading was recorded, and then a status message occurs, this test is considered incomplete by the breath alcohol program even though a Subject Alcohol value may be present in the Breath Test Records.pdf document. In this case, a Status Code will appear next to the Subject Alcohol value which may be interpreted by referring to the [Appendix II: DataMaster DMT Status Codes Key](#).

NOTE: Previous versions of the Breath Test Records.pdf document are not retained by the crime lab.

Breath Test Operator List

The Current Breath Test Operators List tab contains 2 PDFs, each containing lists of currently certified Breath Test Operators in Alaska. The list marked "Pre-ACADIS" also lists currently certified DataMaster Supervisors.

These PDFs are updated approximately monthly. Previous versions of these reports are not retained by the crime lab.

Forensic Alcohol Opinion (FAO) Reports

Forensic Alcohol Opinion (FAO) reports are case-specific written opinions generated by breath alcohol analysts regarding topics such as breath test validity, proper DataMaster DMT calibration at the time of a test, and alcohol interpretation. FAOs may be written upon request, depending on the facts of the case.

The format for FAOs is an electronic report generated in the JusticeTrax LIMS system. An FAO is created under a specific laboratory case number which may be created specifically for this request and may house other case-specific information

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such as communications, search warrants, hospital testing reports, or other materials used as the basis for the opinion. Cases are created in JusticeTrax as described in [Documentation of Communications](#).

All FAO reports are reviewed by another competent breath program member before release.

Evidential Breath Test Instrument Software

Current and archived versions of software used by the DataMaster DMT are saved on the laboratory network drive:

<I:\Locked\Chemistry\Breath\DMT Software>

Software versions are verified or validated by a discipline analyst prior to use. The degree of verification or validation will depend on the complexity of the proposed changes. Complex software updates may require a validation proposal in line with laboratory validation guidelines listed in the Quality Assurance Manual.

The Scientific Director approves all software for use with the DataMaster DMT prior to its use for evidential testing.

Breath Alcohol Documentation Requirements

DataMaster-specific forms and their respective documentation are scanned as PDFs after completion. Completed forms are stored in a secure network drive and are uploaded to JusticeTrax while awaiting technical review. Once technical review is complete, the JusticeTrax request is rolled to the released status (where applicable) and the document is posted on the crime lab website.

The following are examples of DataMaster-specific forms:

- Change in Instrument Status
- Acceptance
- Check In
- Evaluation
- Repair
- Adjustment
- Calibration
- Closeout

Document Review and Discovery

Datamaster-specific forms are technically and administratively reviewed by another breath program analyst. After review is completed, the finalized document is discovered via the Crime Lab website.

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For services that require manual data entry into JusticeTrax (e.g., Evaluation, Calibration), this data entry will be reviewed in addition to the scanned paper forms, preferably via a Crystal Report.

Evaluation Technical Review

Manual data entry by the analyst includes (where applicable):

- Most recent date instrument was received by the laboratory
- Instrument condition
- As Found barometer/hygrometer/thermometer traceability
- Environmental conditions during the As Found testing
- Traceability information for As Found dry gas standards
- As Found dry gas standard target values
- As Found dry gas standard measurements and averages
- As Found comments

Calibration Technical Review

Manual data entry by the analyst includes:

- As Found Evaluation identifier from JusticeTrax
- As Left barometer/hygrometer/thermometer traceability
- Environmental conditions during the As Left testing
- Traceability information for As Left dry gas standards
- As Left dry gas standard target values
- As Left dry gas standard measurements and averages
- As Left comments

Calibration Technical Review and Discovery Sequence

1. Analyst or Technician completes the Calibration tasks, assembles the combined document including the data printouts, and uploads the document to JusticeTrax and the laboratory network drive.
2. Analyst or Technician (if able to authorize calibration certificates) enters the required data into JusticeTrax and rolls the Calibration request to Draft Complete.
3. Technical reviewer completes review of the uploaded document and draft calibration Crystal Report generated by JusticeTrax.
4. Once review is complete, the technical reviewer rolls the Calibration request to released status which finalizes the Crystal Report.
 - a. Technical review is complete at this step.
5. To discover the Calibration document, combine the finalized Crystal Report with the completed calibration form. This document must meet the [Document Naming and Identification](#) requirements listed below before being posted to the website. This step may be completed by the original analyst or the technical reviewer.

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Document Naming and Identification

Instrument-specific records being posted on the Crime Lab website will be uniquely identified using the document name, a corresponding stamp on each page of the document, and page numbering in the format "page m of n". The naming convention for these documents is as follows:

100XXX YYYY.MM.DD Name of Document

The name of the document will refer to the type of form and may include additional information such as (Amended), if necessary.

In addition to DataMaster-specific records, the In Field Instrument Review records must follow the file naming and identification requirements. Requirements for In Field Instrument Review are described in the [Verification of Calibration and In Field Instrument Review Work Instructions](#).

Documentation of Communications

There are three categories of communications documented in the breath program:

- Instrument-related communications,
- Law enforcement agency-specific communications, and
- Case-specific communications.

Instrument-Related Communications

Routine communications related to a breath instrument are documented using Change in Instrument Status Forms. Examples include:

- Instrument is being placed into or out of service
- Documentation of status messages
- Troubleshooting performed and resolution

Law Enforcement Agency-Specific Communications

Communications specific to a law enforcement agency but NOT directly related to an instrument or breath test result(s) will be documented in the case activities of the agency case in the LIMS. Attachments may be stored in the case info folder of the attachments tab; however, a case activity should be entered indicating that the information is stored there. Each agency has a case created in the "Breath" lab of JusticeTrax with the format B-Agency name. A list of the agency case assignments is available [Appendix III: B-Agency Cases in JusticeTrax](#). Examples of agency-specific communications are:

- Verbal or electronic communications regarding:
 - o Modem line functioning

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- Data file transfers
- Breath Test Operator training
- Breath alcohol program policy compliance

Case-Specific Communications

Case-specific communications, both verbal and written, including consultations, opinions, or interpretations will be documented in the LIMS under a laboratory case number. Refer to [LIMS Cases for Breath Case-Specific Information](#) regarding creating a case for breath program-related content.

For all types of communications, the level of detail will be sufficient such that, in the absence of the original breath program analyst, another breath program analyst could evaluate its content. Any documents provided to the analyst during these communications will be added to the case file.

NOTE: This requirement does not apply to the content of court testimony because that is documented through court transcripts.

LIMS Cases for Breath Case-Specific Information

A new case will be created in the laboratory testing LIMS ("ASCDL") using the agency case number listed on the DataMaster subject test report. At a minimum, the subject's first and last name will also be entered into the case file. All subject test reports related to the case will be added to the LIMS attachments tab.

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Technical Procedures

DataMaster-specific records of technical procedures are saved to a secure network drive and LIMS after completion along with their supporting documents. All technical records are technically and administratively reviewed prior to being posted to the crime lab website and having the JusticeTrax request rolled to the released status (where applicable).

DataMaster Acceptance, Check In, and Change in Instrument Status

When a new instrument is initially received by the laboratory from the manufacturer, a [DataMaster Acceptance](#) form is completed by the receiving breath analyst or technician.

When instruments arrive at the laboratory from the field or are returned to the laboratory from a factory repair, the breath test instrument will follow a check in procedure. The check in procedure may be performed by an analyst or technician. The check in procedure includes updating the instrument's chain of custody in LIMS and uploading the instrument to retrieve test records stored in memory (only applies if coming from the field). The check in process is documented on the [DataMaster Check In](#) form. If the instrument is returning from a factory repair or Adjustment, the documentation provided by the factory will be attached to the check in form.

Breath Test Supervisors communicate with the breath alcohol discipline about the stat of their agency's instrument using a [Change In Instrument Status](#) form. This form includes information on the instrument location, a reason for the status change and/or documentation of status messages produced, and the date and time when the status of the instrument changed (e.g., it was taken out of service).

Change In Instrument Status forms are scanned into the Attachments tab of the appropriate instrument case file and do not have a separate LIMS request type.

Instrument Evaluation

Evaluation is performed by a qualified breath analyst or technician and is documented using the [DataMaster Evaluation](#) form.

The date received recorded in the Evaluation should be the date the instrument was transferred to the laboratory from the JusticeTrax chain of custody.

The Evaluation process includes a visual inspection, As Found Linearity testing (if possible), a VOC, a Non-drinking Subject Test, and a determination of the next step for the instrument after Evaluation (Repair, Adjustment, or Calibration).

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This determination may be made by a technician, but this decision and the Evaluation form are reviewed by a qualified breath analyst. The selected next step may change during technical review depending on the outcome of the Evaluation testing.

If an instrument is found to need repair and is unable to complete As Found Linearity and/or a VOC and/or a Non-drinking Subject Test due to being non-functional (e.g., the display does not respond, faulty 5-way valve, etc.), this testing is not required.

As Found Linearity Requirements

Each external ethanol standard is analyzed five times at the following levels: 0.020, 0.080, and 0.300 g/210L. The allowable range for the external dry gas ethanol standard is +/- 0.005 or 5%, whichever is greater, of the target value adjusted for barometric pressure. The standard deviation of the five values must not be greater than 0.0030.

The linearity test report in the DataMaster displays a Slope and R-squared value; however, there is no acceptance requirement for these values during As Found testing.

If the As Found testing does not meet the accuracy requirements:

- If the instrument generated a status message such as "Gas Flow Error" or "Blank Error", attempt to resolve the issue before testing that concentration again.
- If the instrument generated a "Standard Out of Range", test the tank a second time or switch to another dry gas tank of the same level. If a second "Standard Out of Range" message is produced, initiate a [Quality Assurance Review](#).

Evaluation VOC Requirements

A VOC will be completed during Evaluation, where possible. The passing requirements are the same as a routine VOC ([Technical Review of VOC Reports](#)) with the addition of a required internal standard value of $\leq 3.00\%$. The person performing the Evaluation will verify the instrument is using the current software version and note this on the Evaluation form.

Evaluation Non-drinking Subject Test Requirements

The Non-drinking Subject Test should complete without generating status messages. The test may be repeated if a status message is generated to determine if the issue is persistent.

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Determine Next Step

At the end of the Evaluation, the next step for the instrument is determined. In general, a suspected functional problem may be marked as Condition of item: Needs Repair while an accuracy or linearity issue may be marked as Condition of item: Good and Ready for Adjustment. If all testing completes normally, the instrument may proceed to Calibration. The person performing the Evaluation will record the end date of lab work on the Evaluation form.

Instrument Repair

If a repair is required and can be performed at the laboratory, a qualified breath analyst will complete the repair process. The analyst completing the repair will perform appropriate testing to verify the repair fixed the issue. Any repairs performed in-house will be documented on the [DataMaster Repair](#) form.

If the repair cannot be performed in-house and factory repair is needed, the instrument will be sent to the manufacturer for this repair. Documentation about repairs completed by the manufacturer is returned to the crime lab with the instrument and is attached to the [DataMaster Check In](#) form when the instrument is received.

When a repair has been completed, either by the manufacturer or the crime lab, the instrument must complete Calibration prior to being placed in service at an agency. NOTE: Exchanging external accessories such as printers and keyboards do not require Calibration because they do not alter the analytical components of the instrument (how the sample is measured).

Repair documentation is technically and administratively reviewed by a qualified breath analyst.

Instrument Adjustment

Refer to the [Breath Alcohol Program Terminology](#) for the definition of Adjustment and comparison to legacy terms.

Adjustment may be performed by a qualified breath analyst or technician at the crime lab. Adjustment may also be performed by the factory. After an Adjustment, an instrument is not approved for evidential use until [Instrument Calibration](#) has been completed.

DataMaster DMT adjustment is performed using a single quantitative ethanol solution in a wet bath simulator whose thermometer has been verified against a calibrated external thermometer. The crime lab uses a vapor concentration of 0.100 g/210L. A factory adjustment may use a different ethanol concentration. Once an adjustment

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has been performed, the instrument is not re-adjusted unless it is determined that the adjustment is needed, for example, during Evaluation.

Laboratory Adjustment Procedure

The breath program performs adjustment of the DataMaster DMT using a wet bath ethanol simulator solution and a blank simulator solution. The blank simulator solution is 500 mL of deionized water. Wet bath ethanol simulator solutions used by the crime lab are commercially-prepared and purchased from an ISO/IEC 17025 and ISO/IEC 17034-accredited supplier. Solutions have a liquid concentration that yields an ethanol vapor concentration of 0.100 g/210L at 34°C when measured by a breath alcohol instrument.

When it is determined that an instrument requires adjustment, a Laboratory Adjustment request will be created in the LIMS.

Fill and Verify Wet Bath Simulators

Fill one simulator with 500 mL of deionized water. Fill a second simulator with a new bottle of 0.100 ethanol simulator solution. A new bottle of simulator solution will be used each day instruments are adjusted. Record the following information on the label of each simulator:

- Simulator solution identifier (e.g., 0.100 or Blank)
- Simulator solution manufacturer (where applicable)
- Simulator solution expiration date (where applicable)
- Initials and date of person filling the simulator

Turn on both simulators and allow them to warm up for one hour before Adjustment.

Simulators used for Adjustment must have their thermometer readings verified prior to use. Refer to [Simulator Thermometer Verification](#) for the verification procedure, acceptance requirements, and documentation.

Initiate DataMaster DMT Adjustment

The DataMaster DMT software allows the breath analyst or technician to select the number of replicate measurements of the simulator that the instrument requires for adjustment. This option is found under the DMT Icon > Setup menu. The number of replicates for adjustment will be set to run three (3) for both the blank and 0.100 g/210L simulator solutions.

Before initiating an adjustment, connect a piece of tubing with a female simulator fitting to the DataMaster "CAL" port. To initiate an adjustment, select "Calibrate" from DMT icon menu. The DataMaster DMT instrument software prompts the user to attach the corresponding simulator to the "CAL" port at the correct time during the adjustment sequence. When the adjustment process has been completed, the new "Cal Factors" will be printed.

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Adjustment Documentation

DataMaster adjustment is documented on the [DataMaster Adjustment](#) form. The reason for adjustment (e.g., internal standard >4.00%, failed linearity, etc.) appears on this form.

Additional required traceability information includes:

- 0.100 ethanol simulator solution manufacturer, lot number, and expiration date
- Wet bath simulator serial numbers and verification confirmation
- External calibrated thermometer serial number and expiration date

Attach the printed "Cal Factors" to the Adjustment form.

Each laboratory adjustment record is technically and administratively reviewed by a qualified breath analyst.

Instrument Calibration

Calibration is the final demonstration of instrument performance including accuracy, precision, linearity, and ability to trigger intended status messages. Successful calibration certifies the instrument for evidential testing in the State of Alaska. All DataMaster DMT calibrations are performed at the crime lab.

An instrument is required to undergo Calibration after being received from the manufacturer, after a repair that has an effect on the analytical components of the instrument, after adjustment, and after preventative maintenance.

The DataMaster DMT calibration process includes:

- Diagnostic and voltage checks
- Review of the Diagnostic internal standard value
- Technician screen settings:
 - o Setting the sensitivity to radio frequency interference (RFI)
 - o Adjusting the internal barometer reading
 - o Checking and verifying the volume measurement
- Demonstrating the minimum accepted sample volume
- Documenting the As Left testing environmental conditions
- As Left linearity testing using dry gas external standards
- Functional tests
- A verification of calibration (VOC)
- A non-drinking subject test
- Administrative functions to close out the Calibration process

DataMaster DMT calibration is documented on the [DataMaster Calibration](#) form.

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Who May Perform Calibration

Per 13 AAC 63.100, the Scientific Director has designated that the DataMaster DMT may be calibrated by a qualified breath analyst or technician at the crime laboratory.

When a calibration is completed, a calibration certificate is issued for that specific DataMaster DMT. Only qualified breath analysts or technicians who meet the minimum qualifications may issue calibration certificates. If the calibration lab work has been performed by a technician who does not meet the minimum qualifications, a qualified breath analyst must issue and authorize the certificate for that calibration. Breath analysts and technicians who are capable of issuing calibration certificates are authorized to do so in writing.

Diagnostic Check

A Diagnostic check is performed to check for basic instrument functions, voltages, and temperatures. The internal standard value must be $\leq 3.00\%$ to proceed with calibration.

Technician Screen

All of the following checks and settings are performed using the Technician screen found under the DMT icon. The Technician screen is printed after the checks have been completed to document the values.

Voltage Checks

The DataMaster DMT has digital potentiometers whose current values may be viewed and adjusted in the Technician screen. During calibration, these voltages are checked to ensure they are within normal operating ranges published by the instrument manufacturer.

The voltage ranges are:

- Lamp: Maximum 2.60 volts (V)
- Cooler: Maximum 2.00 V
- Detector: Between -0.100 V and 0.100 V

Radio Frequency Sensitivity

The instrument's sensitivity to radio frequency is set during calibration. Prior to adjusting the sensitivity, the person performing the calibration will ensure that all radios are turned Off in the vicinity of the instrument. The sensitivity is set by pressing the Set button which should trigger a series of beeps as the instrument sets a baseline level from which it measures radio frequency. The radio frequency sensitivity is verified with Functional tests later in Calibration.

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Internal Barometer

The DataMaster DMT uses an internal barometer to adjust the target value of ethanol dry gas standards according to the current barometric pressure. The pressure reading is displayed in the Technician screen. During calibration, the analyst or technician uses a NIST-traceable external calibrated barometer to verify the internal barometer reading. If the internal barometer reading is different, the reading is adjusted to match the external barometer.

Volume Setting

The DataMaster DMT uses a mass airflow sensor to determine the flow rate of breath or dry gas through the instrument. During a subject test and calibration testing, the flow rate and time are used to calculate the breath/air volume.

The analyst or technician will use a graduated syringe to provide 1.5 liters (L) of air to the instrument through the breath hose to ensure the volume reading is 1.50 L +/- 0.10 L. If the volume reading is outside of this, the flow controller set screw inside the instrument will be adjusted and the test will be repeated until it meets the requirement.

Print "Cal Factors"

Print the current "Cal Factors" from the Reports stored in the instrument memory and include with the Calibration documentation.

Minimum Volume Test

The minimum volume test ensures that the instrument is requiring the appropriate minimum breath volume of 1.5 liters (L).

This test is performed similarly to the [Volume Setting](#) above; however, this test is performed during a subject test sequence instead of within the Technician screen. Using a graduated syringe, provide air samples beginning at 1.3 L through the breath hose during one test sequence. Samples are provided in increments of 0.1 L until the instrument registers sufficient volume to accept the sample.

The minimum volume be ≥ 1.3 L and ≤ 1.7 L. If the volume is not in this range, repeat the [Volume Setting](#) task and reprint the Technician screen before repeating the minimum volume test.

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Document As Left Environmental Conditions

Record the current barometric pressure, temperature, and relative humidity using a calibrated external measuring device.

As Left Linearity Testing

As Left linearity testing demonstrates the DataMaster DMT's ability to accurately read ethanol at a range of concentrations. The Linearity Test function is selected from the DMT icon main menu. Testing consists of 6 levels of ethanol dry gas standards at the following concentrations (when measured at standard pressure):

- 52 ppm 0.020 g/210L
- 103.5 ppm 0.040 g/210L
- 208 ppm 0.080 g/210L
- 260.5 ppm 0.100 g/210L
- 390 ppm 0.150 g/210L
- 780 ppm 0.300 g/210L

Each ethanol dry gas standard is analyzed five times. The allowable range is +/- 0.005 or 5%, whichever is greater, of the target value adjusted for barometric pressure. The standard deviation of the five values must be ≤ 0.0030 . The linearity test report from the DataMaster displays a Slope and R-squared value. The Slope requirement is 1.000000 +/- 0.030000. The R-squared requirement is at least 0.999000.

Functional Tests

The DataMaster DMT generates status messages to inform the operator when certain conditions are met that may impact instrument operation. During calibration, some status messages are triggered to ensure the instrument is functioning properly. It is not possible to trigger every DataMaster DMT status message because some require there to be a functional problem with the instrument. The following is a list of status messages that are triggered during the calibration process and how they are triggered:

Incomplete

An Incomplete status message is generated when the subject does not provide a breath sample that meets the minimum requirements of the instrument within the two minutes allotted for a subject sample. To trigger this status message, a subject test is initiated, but one or more sample requirements are deliberately not met.

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Maximum Attempts Exceeded

Maximum Attempts Exceeded occurs when the DataMaster DMT detects more than 10 incomplete attempts within the two minutes allotted for the subject sample. This status message is triggered by starting a subject test sequence and providing 10 attempts, each below minimum requirements, during the two minutes allotted. An attempt is defined as three 0.25 (quarter) second readings above the minimum flow rate.

Interference Detected (Subject Sample)

An Interference Detected status message is generated when the DataMaster detects the presence of a substance other than ethanol in the sample provided. This determination is made based on the ratio of the readings from the three filter system.

Locate pre-made [Solutions Used for Interference Testing](#) or prepare fresh, if needed. Allow the solutions to warm to temperature for at least 30 minutes before using. During a subject test sequence, introduce the interference solutions through the breath hose by pushing air through the simulator with a graduated syringe.

Record the 0.100 simulator solution manufacturer(s), lot number(s), expiration date(s), and wet bath simulator serial numbers from the labels on the wet bath simulators into the correct locations on the [DataMaster Calibration](#) form.

Perform the [Simulator Thermometer Verification](#). After completion, mark the verification confirmation for each simulator on the [DataMaster Calibration](#) form. Record the calibrated external thermometer serial number and calibration due date as well.

Interference tests will be printed with View Details to display the filter readings. All filter 2 readings (4 total) from the external standards will be averaged, rounded to four digits, and the averaged value must be within +/- 0.0040. This will be repeated for all filter 3 readings. The results of the calculations will be recorded on the printouts to be included in the calibration record. If an averaged values does not meet the specified requirement, the instrument will return to [Instrument Adjustment](#).

NOTE: The unspiked 0.100 ethanol solution is not held to the 5% accuracy requirement for the purposes of interference testing.

Invalid

An Invalid status message is generated when the DataMaster DMT detects a negative slope in the subject's breath alcohol profile. This may indicate "mouth alcohol" or a high concentration of ethanol in the subject's mouth. This status message can be triggered by swishing ethanol-containing mouthwash in the mouth prior to providing a breath sample to the instrument.

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Radio Frequency Interference (RFI) Detected

A radio frequency interference detected status message (RFI) is generated when the DataMaster DMT detects the presence of radio frequency in the vicinity of the instrument. This status message is generated by starting a subject test sequence and keying a radio in the room with the DataMaster. The check is successful if the instrument generates an RFI status message.

Administrative Tasks

The following administrative tasks are also performed during calibration:

- Verify the touch screen inputs are accurate using a stylus or pen tip
- Using the DMT icon > Functions menu, Reset Options to return the tests to default settings such as whether a signature is requested after a subject test
- Using the DMT icon > Functions menu, Clear Memory to remove the laboratory testing from the upload memory

VOC and Non-Drinking Subject Test

DataMaster DMT calibration requires a verification of calibration (VOC) and a non-drinking subject test. The analyst will ensure a 208 ppm ethanol (0.080 g/210L at standard pressure) external dry gas ethanol standard is installed and initiate a VOC and subject test using default software options. The subject test printout will be attached to the calibration paperwork.

NOTE: The VOC report is not part of the calibration paperwork, but will be technically reviewed and signed by the Scientific Director.

Calibration Wrap Up

Upload

The person completing the calibration will connect the DataMaster to the DMHost computer and poll the instrument using the modem line. This will transfer the calibration VOC and non-drinking subject test into the database and demonstrate the instruments ability to upload.

Remove Tank Prior to Shutdown

While the instrument is still on, remove the ethanol dry gas tank. This will cause the tank pressure to register zero in the software. After the tank is removed, shut down and store the instrument.

Decision to Accept Calibration

If an instrument fails any portion of the calibration process, the instrument will return to [Instrument Repair](#) or [Instrument Adjustment](#) depending on the nature of the issue. All instruments must have a passing calibration prior to being placed in service in the field.

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Calibration Documentation

Once an instrument has completed the calibration process, the person performing the Calibration will record the end date of lab work on the Calibration controlled form. Then the qualified breath analyst or technician will assign the calibration request in LIMS. The calibration paperwork will be scanned and attached to the request. A Custom Form allows entry of As Left linearity data into JusticeTrax to generate the draft calibration certificate.

The instrument calibration must be technically and administratively reviewed by a qualified breath analyst prior to the instrument being sent out for evidential use. Technical review is documented in the LIMS.

The breath alcohol discipline does not apply calibration labels/stickers to the Datamaster DMT instruments.

Calibration Technical Records

Overview

The Toxicology-Calibration technical record is comprised of the calibration certificate produced in JusticeTrax as well as the supporting documentation including the Calibration controlled form and instrument printouts. Specific requirements for the calibration certificate and other components of the technical record are detailed in this section.

Calibration Certificate Requirements

Each successful DataMaster DMT calibration will generate a unique calibration certificate in JusticeTrax. The calibration certificate is the report for the Breath Alcohol Calibration laboratory service. Calibration certificates have the following elements:

- Title: Breath Alcohol Calibration Report
- Name and address of the laboratory
- Page numbering indicating that each page is part of the report and an indication of the end
- Description of the calibration item: DataMaster DMT
- Calibration item serial number
- Date received (derived from the chain of custody for that instrument)
- Condition of the item: Good or Needs Repair
- Method Used: DataMaster DMT Calibration/Current Breath Alcohol Procedure Manual
- Calibration Range: 0.020 g/210L - 0.300 g/210L
- Report Date: Date calibration certificate was issued after review is completed
- As Found linearity testing (pulled in automatically from As Found Evaluation preceding the Calibration):
 - o As Found Start Date (start of Evaluation lab work)
 - o As Found End Date (date Evaluation initially marked Draft Complete)
 - o As Found Analyst or Technician name

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- As Found environmental conditions
- As Found linearity testing results (if applicable)
 - Ethanol dry gas standard nominal values
 - Target values adjusted for barometric pressure
 - Lot numbers
 - Measured results in g/210L
- As Left linearity testing:
 - As Left Start Date (start of Calibration lab work)
 - As Left End Date (date Calibration initially marked Draft Complete)
 - As Left environmental conditions
 - As Left linearity testing results
 - Ethanol dry gas standard nominal values
 - Target values adjusted for barometric pressure
 - Lot numbers
 - Measured results in g/210L
 - The mean of each concentration (M)
 - The estimated uncertainty at each concentration (U) determined from the most recent breath alcohol calibration uncertainty report
- A statement about the measurement uncertainty only applying to the measurements of ethanol dry gas standards
- A statement referencing the expanded combined uncertainty (U) including the coverage factor ($k=2$) and the coverage probability (95%)
- A statement about ethanol dry gas standards quality and traceability
- A statement that the report applies only to the item being calibrated
- A statement about external barometer traceability
- The name and signature of the person that authorized the calibration
- The date on which the calibration certificate was technically reviewed
- The name of the person that performed the technical review

Additional Technical Record Requirements

In addition to the calibration certificate, the technical record will include the completed Calibration controlled form as well as the supporting instrument printouts demonstrating completion of linearity as well as each functional test. The technical record will include the dates of each lab activity (refer to [Appendix V: Lab Activity Dates](#)).

Amendments to Technical Records

For Calibration request attachments in JusticeTrax (such as controlled forms and instrument printouts), amendments to these attachments after the request was turned in for technical review must be made in such a way that the original data is retained, the altered aspects are clear, and the person responsible for the change is identified.

Examples of this include a digital correction to a controlled form PDF or a hand correction to an instrument printout that is then scanned in as an attachment.

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Calibration Certificates on the Crime Lab Webpage

After a calibration certificate has been reviewed and is ready for release, it will be printed as a PDF and combined with the supporting documentation (including any amendments) before posting on the crime lab website.

Amended Calibration Certificates

An amendment to a calibration certificate may be necessary if an error is found after the certificate has been posted on the crime lab website.

In this instance, a copy of the original certificate will be downloaded and placed in the Case Attachments as described in the [JusticeTrax LIMS-Plus 3.8 Manual](#). Afterward, the milestone for the calibration request from which the calibration certificate was generated will be rolled back to Findings Entered so that the correction can be completed. Add the Case Complexity "Amended Report" to the calibration request. Add a statement to the findings indicating "This amended calibration certificate serves to replace the calibration certificate issued on date" similar to the process described in the [Quality Assurance Manual](#).

Once the changes have been reviewed, the calibration request will be marked releasable again. Add the amended calibration certificate to the PDF with the original certificate that had been posted on the crime lab website. Upload the new PDF to the website with _AMENDED added to the file name.

Rejected Calibrations

A Calibration may be rejected if one or more performance issues are detected during the calibration process. When a Calibration is rejected, data entry into JusticeTrax is not required; therefore, no calibration certificate is generated. After attaching the Calibration documents, the Calibration request will be canceled.

Rejected calibrations (controlled form and instrument printouts) are still retained in JusticeTrax with the Calibration request. The reason for the rejection as well as date and the person responsible will be clearly marked on the rejected Calibration documents. A watermark may be used to clearly indicate the Calibration as having been rejected.

Rejected Calibrations are discovered to the Crime Lab website the same as other instrument records. The file name will include the word "Rejected".

Preventative Maintenance

To ensure that instruments in the field remain in good working order, the crime lab has instituted a preventative maintenance schedule. This ensures that every

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instrument is returned to the crime lab for a visual inspection and calibration at least every four years. If an instrument is returned to the laboratory for repair before four years has elapsed, the preventative maintenance will be performed at that time and the four-year period will be restarted.

Preventative maintenance consists of a Check In, [Instrument Evaluation](#), [Instrument Repair](#) (if needed), and [Instrument Calibration](#). When an instrument has been brought in for preventative maintenance, the Check In form will be used to document that preventative maintenance was the reason for the return.

Breath Alcohol Program Quality Assurance

Quality Assurance of In-House Instruments

New lots of ethanol dry gas and ethanol simulator solutions are verified prior to use as described in this manual. At least 3 calibrated DataMaster DMTs are maintained at the crime lab for this function.

Prior to being used for verification of purchased standards, in-house instrument must complete the procedure detailed in this section. Once completed, this testing is valid for 5 calendar days:

- [Diagnostic Check](#)
- [Voltage Checks](#)
- [Internal Barometer](#) – Set to match NIST-Traceable Barometer
- Print Technician Screen
- Abbreviated Linearity using Ethanol Dry Gas Standards:
 - o 52 ppm 0.020 g/210L
 - o 208 ppm 0.080 g/210L
 - o 780 ppm 0.300 g/210L

Each external ethanol standard is analyzed five times. The allowable range is +/- 0.005 or 5%, whichever is greater, of the target value adjusted for barometric pressure. The standard deviation of the five values must be ≤ 0.0030 . The Slope requirement is 1.000000 +/- 0.030000. The R-squared requirement is at least 0.999000.

Quality assurance documentation for in-house instruments includes the results of all testing and is maintained with the documentation for the lot of ethanol dry gas or ethanol simulator solution being verified.

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External Ethanol Dry Gas Standards Quality Assurance and Traceability

Ethanol dry gas cylinders are used as external standards with the DataMaster DMT in the field, as well as for As Found/As Left linearity testing during the calibration process at the crime lab.

External dry gas ethanol standards are purchased from an ISO/IEC 17025 and ISO/IEC 17034-accredited manufacturer, are NIST-traceable, and come with a certificate of analysis (C of A). When new cylinders arrive at the lab, they will be marked with Received By initials and date. The 0.080 g/210L cylinders are also logged into LIMS and barcoded for tracking purposes.

A verification will be performed on each new ethanol dry gas lot by analyzing at least three cylinders five times each on three calibrated DataMasters. In situations where only one or two cylinders from a lot are purchased, each cylinder is tested. If cylinders from a lot already verified by the laboratory are received, no further verification is needed for this lot. The acceptance requirements for verification testing are:

- Every measured value is within +/- 0.005 or 5% of the target value adjusted for barometric pressure.
- The standard deviation is ≤ 0.0030 on each DataMaster DMT.
- The rounded 3-digit average from all 3 DataMasters for each tank is within +/- 0.004 or 4% of the C of A value adjusted for barometric pressure.

To calculate the rounded 3-digit average, record the reported four digit average from each calibrated DataMaster, average those three values, and round to three digits.

This process will be repeated for all tanks being tested. The rounded 3-digit average for each tank will be documented on the print outs.

Ethanol Dry Gas Verification Documentation

The C of A, results of the verification, and documentation from the [Quality Assurance of In-House Instruments](#) are scanned and placed in the SharePoint document library and the crime lab webpage.

[Breath Alcohol Quantitative Reference Material Records](#)

If any lot of ethanol dry gas standards does not meet the verification requirements, it will be rejected, and the Scientific Director will contact the manufacturer.

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Ethanol Dry Gas Safety

When not in use, dry gas cylinders will be stored in a manner that prevents being knocked over or dropped. Acceptable storage areas include the lower cabinets of the breath alcohol laboratory or inside the cylinder shipping boxes.

Dry gas cylinders must be fully drained and rendered incapable of holding pressure before being discarded.

Ethanol Wet Bath Simulator Solutions

Quality Assurance and Traceability

Commercially-prepared ethanol wet bath simulator solutions are used for [Instrument Adjustment](#) and Interference Detected [Functional Tests](#). Ethanol simulator solutions are purchased from an ISO/IEC 17025 and ISO/IEC 17034-accredited manufacturer, are NIST-traceable, and come with a C of A. When new solution bottles arrive at the lab, they are marked with the Received By initials and date.

When a new shipment of 0.100 ethanol simulator solution arrives, one bottle from the lot will be tested 5 times on three certified DataMasters. If bottles from a lot already verified by the laboratory are received, no further verification is needed for this lot. The requirements for this testing are as follow:

- Each measured value is within +/- 5% of the expected value from the C of A.
- The standard deviation must be ≤ 0.0030 on each DataMaster DMT.
- The rounded 3-digit average from all 3 DataMasters is within +/- 3% of the expected value from the C of A.

To calculate the rounded 3-digit average, record the reported four digit average from each calibrated DataMaster, average those three values, and round to three digits.

This rounded 3-digit average will be documented on the instrument print out.

Ethanol Simulator Solution Verification Documentation

The C of A, results of the verification, and documentation from the [Quality Assurance of In-House Instruments](#) are scanned and placed in the SharePoint document library and crime lab webpage.

[Breath Alcohol Quantitative Reference Material Records](#)

If a lot of ethanol simulator solution does not meet the verification requirements, it will be researched to determine the reason. The lot will not be used for testing until

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a resolution has been reached. If necessary, the lot will be and the Scientific Director will contact the manufacturer.

Wet Bath Simulators

The crime lab uses simulators manufactured by Guth Laboratories that are NIST-traceable and come with a calibration certificate. Simulators are returned to Guth Laboratories annually for calibration and maintenance.

The specifications for calibration of wet bath simulators are:

- Calibrated at 34 degrees Celsius
- Passing specification is +/- 0.1 degree Celsius
- As Found/As Left testing results must be listed on the calibration certificate
- An indication if an adjustment was made must appear on the calibration certificate

Certificates of calibration for the simulators are scanned and placed in the SharePoint document library and on the crime lab webpage.

[Breath Alcohol Wet Bath Simulator Calibration Certificates](#)

Simulators calibrated by Guth Laboratories are verified against an external calibrated thermometer calibrated by an ISO 17025-accredited calibration laboratory prior to use.

Simulator Thermometer Verification

Prior to being used for [Instrument Adjustment](#) or [Interference Detected \(Subject Sample\)](#), wet bath simulators must have their thermometer reading verified against a calibrated external thermometer.

To verify a simulator thermometer, fill a wet bath simulator with the intended simulator solution. Allow the simulator to warm to temperature for at least 30 minutes before verification.

Locate a calibrated external thermometer. Insert the thermometer probe through the port in the top of the simulator so that the probe tip is submerged in the simulator solution. Allow the thermometer probe to equilibrate completely before recording the reading. Record the following information in the Simulator Thermometer Verifications spreadsheet:

- Simulator serial number
- Simulator thermometer verification date
- External thermometer serial number
- External thermometer calibration due date
- Simulator thermometer reading (degrees Celsius, 1 decimal place)
- External thermometer reading (degrees Celsius, 2 decimal places)

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A verification is successful if the external calibrated thermometer and internal thermometer differ by not more than 0.2°C.

The Simulator Thermometer Verifications spreadsheet will calculate the difference in the thermometer readings (rounded to 1 decimal place) and display PASS or FAIL according to the passing criteria:

[Breath Alcohol Simulator Thermometer Verifications](#)

If the verification fails, select another simulator, transfer the simulator solution to that simulator, and allow it to warm to temperature. Each wet bath simulator used must be verified prior to being used for testing. Simulators not capable of passing verification should be marked as out of service until returned to the manufacturer for maintenance and internal thermometer calibration.

External Calibrated Barometer

An external calibrated barometer is used for verification and adjustment of the internal DataMaster DMT barometer and also for recording environmental (ambient) conditions at the time of testing. The external barometer is purchased from an ISO 17025-accredited manufacturer, is NIST-traceable, and comes with a calibration certificate. Barometer calibration certificates are scanned and placed in the SharePoint document library and on the crime lab webpage.

[Breath Alcohol Barometer Calibration Certificates](#)

External barometers are replaced when their manufacturer calibration expires and are not recalibrated. External calibrated barometers must meet the following specifications:

- Capable of measuring with the following specifications:
 - o Barometric pressure
 - inHg (inches of mercury)
 - Nominal 29.00 to 31.00 inHg (982 to 1049 mbar)
 - +/- 0.15 inHg (+/- 5 mbar)
 - o Ambient temperature
 - Degrees Celsius
 - Nominal 20 to 26 degrees Celsius
 - +/- 2 degrees Celsius
 - o Relative humidity
 - %RH
 - Nominal value 30 to 70% RH
 - +/- 5 %RH

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External Calibrated Thermometer

An external calibrated thermometer is used to verify the temperature readings of the wet bath simulators. External thermometers are purchased from an ISO 17025-accredited manufacturer, are NIST-traceable, and come with a calibration certificate. Calibration certificates are scanned and placed in the SharePoint document library and on the crime lab webpage.

[Breath Alcohol Thermometer Calibration Certificates](#)

External thermometers are replaced when their manufacturer calibration expires and are not recalibrated. External calibrated barometers must meet the following specifications:

- Capable of measuring solution temperature (submerged in liquid) with the following specifications:
 - o Degrees Celsius
 - o Minimally within the range of 32 to 34 degrees Celsius
 - o +/- 0.05 degrees Celsius

Solutions Used for Interference Testing

Interference Solution Preparation

Solutions used for the Interference Detected checks in [Functional Tests](#) are prepared at the crime lab. Each of three calibrated wet bath simulators has a new bottle of 0.100 ethanol simulator solution added to it. One simulator is spiked with 200 µL of acetone. A second simulator is spiked with 200 µL of isopropanol. The third simulator is not spiked.

NOTE: Spiking of ethanol solutions is not considered changing a reference material because there are no quantitative acceptance requirements for interference testing.

Documentation of Preparation

Each spiked simulator is documented as a reagent using the [Reagent Preparation Form](#). A lot number is assigned in the following format: YYYYMMDDXXX where XXX is the initials of the analyst preparing the solution. Reagent Preparation Forms are stored in a binder in the breath lab space until the form is completely filled or replaced. Forms that are no longer in use will be scanned and archived in the laboratory SharePoint document library.

For the spiked simulators, label each wet bath simulator with the corresponding reagent lot number, preparation date, initials of the person preparing the reagent, and the expiration date. Spiked simulator solutions expire 3 months from the date of preparation or when the wet bath simulator calibration expires, whichever is earlier.

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For the unspiked 0.100 simulator solution, label the wet bath simulator with the manufacturer name and concentration, the date the solution was put into the simulator, the initials and date of the person that filled the simulator, the expiration date, and that the simulator contains a negative control for interference testing. A 0.100 simulator solution used for interference testing expires 3 months from the date when it was placed into the wet bath simulator or when the wet bath simulator calibration expires, whichever is earlier.

Use of Interference Solutions

Solutions used for interference testing are allowed to warm to temperature for at least 30 minutes before use. These solutions are not verified prior to use.

In Field Instrument Review

After the dates on which software-initiated VOCs occur (refer to [Verification of Calibration \(VOC\) Reports](#)), a breath alcohol analyst will perform a review of the instruments in the field using the [Verification of Calibration and In Field Instrument Review Working Instructions](#) and [In Field Instrument Review Worksheet](#).

The In Field Instrument Review process involves downloading test data for the relevant date range from the DMHost database using the "In Field Instrument Review" and "In Field Instrument Review VOC" reports from DMHost Report Writer.

Downloaded data is entered in the [In Field Instrument Review worksheet](#). A qualified breath alcohol analyst reviews the worksheet and follow up on higher-than-expected occurrences of status messages. Once completed, the worksheet and a summary of findings are scanned and placed in the SharePoint document library and on the crime lab webpage.

[Breath Alcohol In Field Instrument Reviews](#)

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Training Provided

Breath Test Supervisor Training

One of the duties of the breath alcohol discipline is to train and certify Breath Test Supervisors. Per 13 AAC 63.070, a Breath Test Supervisor must complete a course approved by the Scientific Director. The course content is written and taught by the breath alcohol discipline and approved by the Scientific Director.

To be certified as a Breath Test Supervisor, the applicant must obtain a score of 75 percent or higher on a written examination covering the content of the course. The examination is written by the breath alcohol discipline and approved by the Scientific Director. Upon successful completion of the Breath Test Supervisor course, a list is provided to the Alaska Police Standard Council (APSC) and a certificate is issued indicating the Breath Test Supervisor is authorized to instruct Breath Test Operator courses.

The Breath Test Supervisor certification expires at 11:59 pm on December 31 of the third year after issued. Per 13 AAC 63.080, to recertify as a Breath Test Supervisor the applicant must complete a recertification course approved by the Scientific Director. The recertification course content is written and taught by the breath alcohol discipline and approved by the Scientific Director.

Breath Test Supervisors are approved to perform evidential breath tests as their training exceeds that of Breath Test Operators. Therefore, a currently certified Breath Test Supervisor does not need current Breath Test Operator training to perform evidential breath tests.

Breath Test Operator Training

Breath Test Operators are trained by Breath Test Supervisors in accordance with 13 AAC 63.050 and 13 AAC 63.060. The breath alcohol discipline provides the approved training program to the Breath Test Supervisors. Breath Test Operator examinations are conducted through the ACADIS online platform. Breath alcohol analysts may also provide Breath Test Operator training using the approved training materials.

To certify a Breath Test Operator, the instructor will submit a [Breath Test Operator Certification Recertification Form](#) to the crime lab listing the people the Supervisor intends to train at least 2 business days prior to the occurrence of the course. The breath alcohol discipline will then assign the student to the appropriate electronic course in the Alaska Police Standards Council (APSC) portal. The Breath Test Operator exam will be completed online, and the certificate will be available in the student's profile after completion.

Per 13 AAC 63.050, a Breath Test Operator certificate expires at 11:59 pm on December 31 of the third year after issued.

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Proficiency Testing

All proficiency tests for breath alcohol will be conducted on an instrument with calibration completed by the analyst taking the proficiency within the last seven days.

Simulator Solutions

Simulator solution proficiency tests allow the analyst to administer the test through either the calibration port, breath port, or both depending on the type of instrument. The DataMaster DMT typically measures simulator solutions through the simulator port which would be the equivalent of calibration port administration.

A simulator solution can also be administered through the breath hose with the use of a graduated syringe with a mouthpiece attached. Since both breath port and calibration port administration are possible on the DataMaster DMT, the analyst will complete both administration techniques. However, since the DataMaster DMT is designed to evaluate breath alcohol simulator solutions through the simulator port, the final rating will be evaluated only on the calibration port results.

After completion of analysis, the simulator solutions will be returned to the original bottles, resealed, and returned to the evidence vault prior to administrative review. The chemistry supervisor will destroy the samples after the results have been received from the proficiency test provider.

Ethanol Dry Gas Cylinders

Ethanol dry gas cylinder proficiency tests may only be tested by attaching the tank to the internal regulator of the DataMaster DMT.

After completion of analysis, the ethanol dry gas cylinders will be resealed and returned to the evidence vault. External dry gas proficiency tests may be retaken as internal proficiencies by other analysts. After all testing is completed and external proficiency results have been received, the chemistry supervisor will drain and dispose of the cylinders.

Proficiency Test Passing Requirements

Passing Requirements Overview

In general, the guideline for satisfactory completion is based on the manufacturer's expected results and the grand mean of respondents. This means ± 2 standard deviations of the Grand Mean. Where a mean and standard deviation are provided for ANAB respondents only, this is the mean that will be used for comparison.

For internal proficiencies, the chemistry supervisor will determine the appropriate acceptance criteria. Preferably these are equal to or derived from the external

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proficiency manufacturer specifications (e.g., calculating the manufacturer's standard deviation from the Z-score or En score).

Consideration of Uncertainty of Measurement

The current [Appendix IV: Uncertainty of Measurement for Ethanol Dry Gas Standards](#) may be considered when evaluating proficiency test results.

Simulator Solution Proficiency Specifics

For simulator solution proficiency tests that are analyzed via the calibration port and breath hose, the calibration port results will be used to determine if the proficiency test results pass.

Ethanol Dry Gas Cylinder Proficiency Specifics

Measurements of ethanol dry gas cylinders are impacted by the barometric pressure at the time of the test. Manufacturers generally require the test taker to account for this impact using a mathematical correction to standard pressure.

CTS Dry Gas Proficiency Test Instructions

1. Go to the DMT icon, Setup, enter the lab password, select External Standard and turn the Tolerance Check Off.
2. Ensure Supervisor is set to 5 for the number of tests.
3. Save to return to the home screen.
4. **Before removing the existing tank**, open the Supervisor Test window. This will prevent an immediate VOC requirement.
5. Remove the existing tank and install the first dry gas proficiency test tank.
6. Enter the name and certificate number to start the Supervisor test.
7. When the popup for the standard type and level come up, enter Dry and 0.080, then select OK. NOTE: If cancel is selected, the prior 0.08 tank information will be printed on the test strip and this will have to be corrected by the proficiency test taker.
8. After the first tank completes and the test strip prints, again select Supervisor test, remove the first tank, install the second tank and repeat the steps from #6. Repeat this process until printed results are obtained for all tanks.
9. When all tanks are complete, select Supervisor Test one more time to reinstall the 0.08 tank that was in the instrument before. From the Functions menu, Reset Options and Clear Memory.
10. Use the [Breath Calibration Dry Gas PT Pressure Correction Worksheet](#) to adjust the measured average (of 5 replicates) for each tank to standard pressure (29.92 inHg). Enter the corresponding information such as Test Date and Instrument Serial Number as well. When complete, print this document to a PDF.
11. Attach the instrument printouts for each tank as well as the PDF pressure correction worksheet to the proficiency test request in JusticeTrax.

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12. For EXTERNAL PTs: Open the CTS data entry form from the CTS forensics portal. Use the test number to locate the correct test. **Read the entire data entry form paying special attention to the requested number of significant figures.**
 - a. Review the PDF pressure correction worksheet to ensure the number of significant figures matches what is requested. If so, enter the requested testing information into the CTS form. When selecting an uncertainty value to report for each tank (See Appendix IV: [Uncertainty of Measurement for Ethanol Dry Gas Standards](#)), choose the uncertainty value that is associated with the Nominal Ethanol Concentration that is less than or equal to the measured value from the proficiency test sample (example: measured 0.160 > 0.150 nominal; therefore, choose the uncertainty value for 0.300).
 - b. When entry is complete, submit the review to the Alcohol group. Notify the breath alcohol staff that the proficiency test (and any associated Calibrations) are ready for review.
13. For INTERNAL PTs: Notify the breath alcohol staff that the proficiency test (and any associated Calibrations) are ready for review.

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Appendix I: Approved Equipment

External Ethanol Dry Gas Standards

Agencies obtain external ethanol dry gas standards from the breath alcohol discipline. Dry gas standards used by the discipline are purchased from an ISO 17025 accredited manufacturer, are NIST-traceable, and come with a certificate of analysis (C of A). Each lot received by the crime lab is approved for use by the breath alcohol discipline after a verification has been performed ([Quality Assurance and Traceability](#)). For this reason, only dry gas standards provided by the breath alcohol discipline may be used with evidential breath testing instruments.

Mouthpieces

Mouthpieces are obtained from the breath alcohol discipline or the Department of Public Safety (DPS) Supply. The current mouthpieces used are Guth ULTRAP Mouthpieces.

DataMaster Parts and Accessories

External accessories used with the DataMaster DMT include the breath hose and USB keyboard. Breath hoses contain the instrument radio frequency (RF) antenna which is calibrated with the instrument. Breath hoses may not be replaced in the field. Any compatible USB keyboard may be used with the DataMaster DMT.

External Printers

The first external printer is provided by the breath alcohol discipline. It is an HP LaserJet Professional model number P1606dn or similar model. Replacement printers, paper, and toner are the responsibility of the individual agency. Any compatible toner cartridges may be used with the printer. Any compatible external printer may be used with the DataMaster DMT.

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DataMaster DMT Serial Number List

The following are the serial numbers of the DataMaster DMT instruments approved for use in the state of Alaska.

1	100342		31	100373		61	100406		91	100685*
2	100343		32	100374		62	100410		92	100686
3	100344		33	100375		63	100411		93	100687
4	100345		34	100376		64	100412		94	100688
5	100346		35	100377		65	100413		95	100689
6	100347		36	100378		66	100414		96	100690
7	100348		37	100379		67	100415		97	100691
8	100349		38	100380		68	100416		98	100692
9	100350*		39	100381		69	100417		99	100693
10	100351		40	100382		70	100418		100	100694
11	100352		41	100383		71	100665		101	100695
12	100353		42	100384		72	100666		102	100696
13	100354		43	100385		73	100667		103	100697
14	100355		44	100386		74	100668		104	100698
15	100356		45	100387		75	100669		105	100699
16	100357		46	100388		76	100670		106	100700
17	100358		47	100389		77	100671			
18	100359		48	100390		78	100672			
19	100360		49	100391		79	100673			
20	100361		50	100392		80	100674			
21	100362		51	100395		81	100675			
22	100363		52	100396		82	100676			
23	100364		53	100397		83	100677*			
24	100365		54	100398		84	100678			
25	100366		55	100399		85	100679		Military	100225
26	100367		56	100400		86	100680		Military	100420
27	100368		57	100402		87	100681		Military	100421
28	100369		58	100403		88	100682		Military	100422
29	100370		59	100404		89	100683		Military	100423
30	100371		60	100405		90	100684		Military	100424

*Instrument was closed out and is no longer approved for use.

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Appendix II: DataMaster DMT Status Codes Key

Status Code	Status Message
0	Communication Error
1	Communication Error
2	Communication Error
3	Communication Error
4	Communication Error
5	User Abort
6	Pump Error
7	Filter 1 Won't Zero
8	Filter 2 Won't Zero
9	Filter 3 Won't Zero
10	Ambient Fail
11	Standard Out of Range
12	Simulator Time Out
13	Simulator Temp High
14	Simulator Temp Low
15	Simulator Temp Unknown
16	Blank Error
17	Internal Standard Error
18	Invalid Sample
19	Interference Detected (External Standard)
20	Detector Overflow
I	Incomplete
X	Interference Detected

Status Code	Status Message
21	Sample Chamber Temp High
22	Sample Chamber Temp Low
23	RFI
24	Barometer Error
25	Breath Tube Temp High
26	Breath Tube Temp Low
27	Incomplete Sample
28	Filter wheel Error
29	Sample Agreement Error
30	Suck Back Error
31	Calibration Error
32	Undefined Error
33	Diagnostic Failed
34	Fuel Cell Disagreement
35	Fuel Cell Error
36	Tank Pressure Too Low
37	Gas Flow Error
40	Static Analysis Error
100	Standard Deviation Error
101	Maximum Attempts Exceeded
102	Interference Detected (Subject Sample)
V	Invalid
R	Subject Refused

Please note this is a list provided by the manufacturer. Not all codes may be applicable to Alaska instruments.

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Appendix III: B-Agency Cases in JusticeTrax

B-ANC AIR. PD	B-FT.WAINWRIGHT
B-ANCHORAGE PD	B-GIRDWOOD PD
B-AST/ANGOON	B-GLACIER BAY
B-AST/ANIAK	B-HAINES PD
B-AST/BETHEL	B-HOMER PD
B-AST/CANTWELL	B-HOONAH PD
B-AST/DELTA	B-HOOPER BAY PD
B-AST/EMMONAK	B-JBER
B-AST/FAIRBANKS	B-JUNEAU PD
B-AST/GALENA	B-KAKE PD
B-AST/GLNALLEN	B-KETCHIKAN PD
B-AST/HEALY	B-KING COVE PD
B-AST/KETCHIKAN	B-KODIAK PD
B-AST/KODIAK	B-KOTZEBUE PD
B-AST/MCGRATH	B-METLAKATLA PD
B-AST/MSW	B-NOME PD
B-AST/NENANA	B-NORTH POLE PD
B-AST/SELDOVIA	B-NSBPD
B-AST/SOLDOTNA	B-PALMER PD
B-AST/ST. MARYS	B-PETERSBURG PD
B-AST/TALKEETNA	B-SAND POINT PD
B-AST/TOK	B-SEWARD PD
B-AST/WILLOW	B-SITKA PD
B-BETHEL PD	B-SKAGWAY
B-BRISTOL BB PD	B-SOLDOTNA PD
B-CLEAR AFB	B-ST. PAUL PD
B-CORDOVA	B-UAA PD
B-CRAIG PD	B-UAF PD
B-DENALI NP	B-UNALAKLEET PD
B-DILLINGHAM PD	B-UNALASKA PD
B-EIELSON AFB	B-VALDEZ PD
B-FAI AIRPT PD	B-WASILLA PD
B-FAIRBANKS PD	B-WHITTIER PD
B-FT. GREELY	B-WRANGELL PD
B-FT. YUKON PD	B-YAKUTAT PD

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Appendix IV: Uncertainty of Measurement for Ethanol Dry Gas Standards

The initial estimation of the uncertainty of measurement for ethanol dry gas standards has been performed and is documented in a report titled "2022.09.21 Breath Alcohol Uncertainty of Measurement Report".

The initial report addressed the following elements:

- A statement defining the measurand (ethanol vapor concentration)
- A statement regarding how traceability is established
- Descriptions of the equipment used
- All uncertainty components considered
- All uncertainty components of significance and how they were evaluated
- Data used to estimate repeatability
- All calculations performed
- The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty

All uncertainty components considered are detailed in the report; however, the two quantitative values included in the estimation are the repeatability of measurements of ethanol dry gas standards performed at the laboratory (Type A uncertainty) and the uncertainty in the certified reference values of the ethanol dry gas standards used (Type B uncertainty).

A coverage factor of $k=2$ was selected for expansion of the uncertainty corresponding to a coverage probability of 95%. The rounding of the expanded uncertainty is addressed in the uncertainty report.

The estimation of the uncertainty for this program will be reevaluated in approximately June, 2024. Each estimation of uncertainty will include the following elements:

- statement defining the measurand (ethanol vapor concentration)
- statement of how traceability is established for the measurement
- the equipment (e.g., measuring device[s] or instrument[s]) used
- all uncertainty components considered
- all uncertainty components of significance and how they were evaluated
- data used to estimate repeatability, intermediate precision, and/or reproducibility
- all calculations performed (examples: visible in Excel or demonstration calculations included in uncertainty written report)
- the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty

Breath alcohol calibration uncertainty is expressed on the calibration certificate as flat values measured in g/210L in the format $M \pm U$ where M is the mean of the

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measured results for each ethanol dry gas concentration measured during the As Left linearity testing and U is the estimated uncertainty for that same nominal concentration.

The current expanded combined uncertainties for the measurement of ethanol dry gas standards are follows:

Nominal Ethanol Concentration (g/210L)	Reporting Range (g/210L)	Uncertainty (g/210L)
0.020	0.000 – 0.020	0.002
0.040	0.021 – 0.040	0.003
0.080	0.041 – 0.080	0.004
0.100	0.081 – 0.100	0.004
0.150	0.101 – 0.150	0.005
0.300	0.151 – 0.600	0.011

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Appendix V: Lab Activity Dates

The following lab activities are conducted during Breath Alcohol Calibration. The Technician and/or authorizer of the calibration certificate record(s) the dates of each lab activity in the technical record. This table lists the location where the lab activity dates are recorded and is intended to be used as a guide for the analyst and technical reviewer.

Activity Name	Location of Date
Calibration process	Automatically printed on the attached instrument printouts
Review of Calibration data (Technician)	Added to the combined PDF of the instrument printouts
Review of Calibration data (authorizer)	Added to the combined PDF of the instrument printouts
Interference calculation	Written or typed adjacent to the calculation on the combined PDF of the instrument printouts

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Revision History

Location	Revision made
Throughout	Corrected grammar and spelling. Reworded for clarity, where appropriate. Added crosslinks and hyperlinks. Fixed broken links to reference SharePoint where appropriate.
Abbreviations	Added definitions for CTS and PT
Determine Next Step	Clarify selection of condition of item. Added requirement to record end date of lab work on controlled form.
Calibration Documentation	Added requirement to record end date of lab work on controlled form.
Calibration Certificate Requirements	Clarified the meaning of the dates that appear on the calibration certificate.
Amendments to Technical Records	New section
Rejected Calibrations	New section
Calibration Certificate Requirements	Revised the requirement for the name and signature on the calibration certificate to be the person that authorized the certificate.
Ethanol Dry Gas Cylinders	Complete rewrite
Ethanol Dry Gas Cylinder Proficiency Specifics	New section
Wet Bath Simulators	Added specifications on calibration
External Calibrated Barometer	Complete rewrite. Clarified these are not recalibrated. Added specifications for calibrated devices.
External Calibrated Thermometer	Complete rewrite. Clarified these are not recalibrated. Added specifications for calibrated devices.
Appendix IV: Uncertainty of Measurement for Ethanol Dry Gas Standards	Clarified reporting range of ethanol dry gas uncertainty values; added requirements for each uncertainty estimation