



Internal Memorandum

TO: Ed Luce, Quality Systems Specialist

FROM: Mary Celotti, Laboratory Director

DATE: February 24, 2010

RE: Request for Investigation – Quality Aspects of the Alcohol Program

Based on our discussions, listed below are the areas that should be addressed in your investigation:

- 1.) Review of Record-keeping practices in the DataMaster Breath Testing equipment maintenance/repair area. This should also include a review of the process for documenting, reviewing and filing of the paperwork. Suggestions for improving the record-keeping processes should be noted if applicable.
- 2.) Review of Standard Operating Procedures (SOPs) for calibrating, maintaining and repairing the DataMaster instruments: Specifically, do the SOPs exist and include reference to:
  - a. Repeatedly running the simulator solution until the instrument passes
  - b. Keep replacing parts until the instrument work again
  - c. Adding Acetone to the interference solution to pass the instrument
  - d. Raising the temperature of a simulator when it's not out of range in order to pass the instrument
  - e. Neglecting to perform suck-back tests on instruments with broken one-way valves in order to pass the instrument
- 3.) Review of Instrument Technical Support Inquiries to determine if the above have occurred and number of instances:
  - a. Repeatedly running the simulator solution until the instrument passes
  - b. Keep replacing parts until the instrument work again
  - c. Adding Acetone to the interference solution
  - d. Raising the temperature of a simulator when it's not out of range
  - e. Neglecting to perform suck-back tests on instruments with broken one-way valves
- 4.) Review of Instrument Warranty and Part Ordering Process to Determine if Additional Parts for Older Instruments Are Being Ordered Under Newer Instrument Serial Numbers (for no charge).

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5.) Determine with NPAS, whether NPAS Demo model can be used for parts

6.) Washington County Instruments: 1.) Determine if installation of "insulation" on simulator (Montpelier DMT) is an ethical issue 2.) Determine if DMT instruments with simulator vapor readings biased low, need to be pulled and recalibrated. Determine if instruments with identical issues in other counties, were pulled and recalibrated (consistency of practice).

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# Memo

**To:** Mary-Stella Celotti, Laboratory Director  
**From:** Edmond P. Luce, Laboratory Ethics & Compliance Officer (EL)  
**CC:** Robert Drawbaugh, Toxicology Program Chief  
**Date:** July 29, 2010  
**Re:** Investigation of DataMaster Processes in Franklin County vs. Washington County

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This investigation is to determine the consistency of practices across the DataMasters installed in Franklin County and Washington County and to review these practices and related processes against allegations of unethical conduct.

The observations of this investigation are as follows:

1. For the Franklin County DataMasters, only the Franklin County Sheriffs Office Instrument and the Grand Isle Sheriffs Office Instrument showed TSIs initiated for issues related to low Simulator Solution Concentrations. Each DataMaster had two TSIs initiated for this issue.
  - a. The Franklin County Sheriffs Office TSIs were both resolved as follows; one with an on-site visit and after review of Simulator Solution Change protocol with the instrument supervisor and the other was resolved in-house after the adjustment of instrument parameters (lamp & cooler) back into specifications.
  - b. The Grand Isle Sheriffs Office TSIs were both resolved on-site; one was resolved after the correct Simulator Solution information was used by the instrument supervisor and the other was resolved after the repair of leaks in the Simulator Jar.
2. All other TSIs for the Franklin County DataMasters were for instrument related issues: including, Pump Errors, Blank Screens, Detector Voltage Issues, Instrument Room Renovations and failure of the Suck-Back Test at Installation.
3. For the Washington County DataMasters, four of the six instruments had TSIs initiated for issues related to low Simulator Solution Concentrations.
  - a. The Barre Police Department single TSI was resolved on-site after adjustment of Simulator Temperature closer to specifications.
  - b. The Berlin Police Department single TSI was resolved on-site after instrument parameters were confirmed to be within specifications.
  - c. The Middlesex VT State Police single TSI was resolved on-site after instrument parameters were confirmed to be within specifications.
  - d. The Montpelier Police Department two TSIs were both resolved on-site. The first one was resolved by closing a HVAC vent blowing on the Simulator Jar and the second

was resolved by insulating the Simulator Jar with foam packing material. This insulation was removed approximately two months later.

4. The other two TSIs for the Washington County DataMasters were for instrument issues; one for Touch-Screen issues and the other for the temperature monitoring not being turned on at installation.

After reviewing and comparing the DataMaster processes for these two installation batches, there appears to be no faults in the actions taken to maintain these instruments.

5. This investigator does not believe the installation of insulation on the Simulator jar on the Montpelier Police Department DataMaster presents an ethical issue. Two TSIs documented this process and both included documentation of what was done and the rationale behind it. The first TSI showed resolution after the HVAC vent was closed and this led to the logical next step of insulating the Simulator jar to resolve the second TSI. There was no malicious intent indicated and these processes are a part of troubleshooting DataMaster issues.
6. Investigation of the failure to perform suck-back tests is not possible as there is no instrument produced documentation when this test is done; however, the DataMaster would not proceed with Diagnostic Testing if this portion of the test was not performed.
7. Review of Standard Operating Procedures (SOP) related to these processes indicates that there are SOPs available for the Calibration & Certification of these DataMasters; including installation. There are no SOPs for the Maintenance & Repair portion of these processes. The review of TSIs leads to the conclusion that the processes used to resolve DataMaster TSIs are an evolving process and the allegation of unethical practices is inappropriate and unwarranted.
8. The DataMaster Warranty and the ordering procedures of parts for these DataMasters were reviewed and no faults or unethical practices were found in these processes as confirmed by a letter from the instrument manufacturer, National Patent Analytical Systems Inc., dated March 15<sup>th</sup>, 2010.
9. The review of the record keeping practices throughout this investigation indicates that the Program is doing its best to maintain complete and accurate records. The records that were available were well organized and accessible. There were a few minor deficiencies noted and these will be shared with the Program at a later date and suggestions for improvements will be discussed at that time.

This investigator concludes that there have not been any unethical practices demonstrated during this lengthy and thorough investigation. (Reference Memo from the Laboratory Director to the Quality Systems Specialist dated February 24<sup>th</sup>, 2010.)

*Acknowledged,  
RJ Sawbump  
7/30/10*

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RJ [Signature]  
7/30/10*

Title: <b>Laboratory Calibration of DataMaster DMT</b>		<b>Page 1 of 8</b>
Doc. No. P-Alc-117 <b>Draft</b> Revision No.0	Approved By: _____ Owner: Toxicology Program Chief	Date Effective: _____

*First*

## 1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the calibration of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2 The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

## 2.0 Responsibility

- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed periodically by toxicology staff. Revisions of the procedure will be made when a need is identified.

## 3.0 Precautions

- 3.1 Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

## 4.0 Procedure Steps

### 4.1 Materials and Supplies are all located in Room 124.

- 4.1.1 DataMaster DMT Instrument.
- 4.1.2 NIST Traceable Thermometer.
- 4.1.3 Two Guth 34C-NP Simulators.

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- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

## 4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
  - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
  - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
    - 4.2.5.2.1 If the solution has been open for no more than one week.
    - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
  - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

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4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7.2 If new bottle of external standard solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

### 4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 When instructed to "Connect Water," attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.3.2.3 When instructed to "Connect Ethanol," attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol." Disconnect the simulator from the simulator tower. Press OK when ready.

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- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within  $\pm 3\%$  of the certified value of the solution with a standard deviation  $\leq 0.002$ . The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.
- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's testing binder; discard the extra copy.
- 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is

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- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.
- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's testing binder; discard the extra copy.
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deployed, then they will be put with the instrument's on-site maintenance records.

- 4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster serial number, calibration solution lot number, certified concentration, and solution temperature. Also document the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed.

## **5.0 Emergency or High Priority Situations**

- 5.1 The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT calibration to be a high priority and request calibration as soon as possible.

## **6.0 Quality Criteria and Corrective Action**

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2 The calibration factor for b2 must be  $0.002 \leq b2 \leq 0.012$ . If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within  $\pm 3\%$  of the certified value of the simulator solution, or the standard deviation is  $>0.002$ , the instrument shall be recalibrated.
- 6.4 The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.
- 6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.
  - 6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.
  - 6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

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6.5.3 This procedure will be performed again when the problem is resolved.

## **7.0 Preventative Maintenance and Backup Procedures**

- 7.1 If a problem is encountered that cannot be resolved by toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
- 7.2 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.3 No back-up procedure available.

## **8.0 References**

- 8.1 VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report with ranges.
- 8.8 Appendix B: Acceptable Calibration Check Report



Appendix A  
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306  
Calibration Date: 08/21/2009  
Calibrated by: STEVEN E HARNOIS  
Lot: 10-02-100



Ca	=	0.101000		
CAL	=	1.022435	0.800 <=	CAL < 1.200
b1	=	0.000010	0.000 <=	b1 < 0.004
b2	=	0.004077	0.001 <=	b2 < 0.012
b3	=	0.000000	0.000 <=	b3 < 0.004
Xq	=	0.088161	0.050 <=	Xq < 0.200
a21	=	1.193076	1.050 <=	a21 < 1.300
a31	=	0.459486	0.300 <=	a31 < 0.800

Acceptable range for b2 is  
 $0.002 \leq b2 \leq 0.012$

Performed by SEH

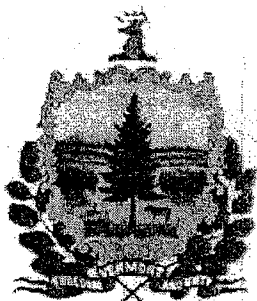
Date 08/21/2009

DMT Serial Number #122306

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# Appendix B Acceptable Calibration Check Report



## ACCURACY AND PRECISION TEST

STATE OF VERMONT

DataMaster DMT: 101708

Date: 03/16/2010

Time: 07:08:56

SUPERVISOR NAME: ALB CAL CHECK

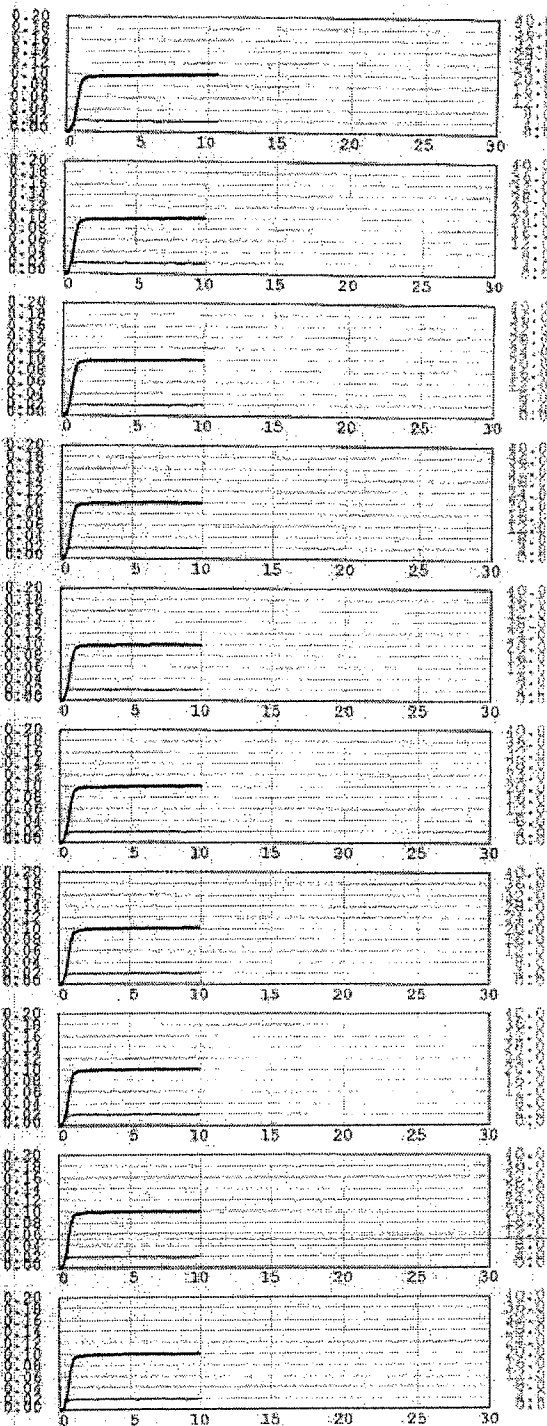
SOLUTION LOT #: 10-23-100

SOLUTION CONCENTRATION: 0.100

BLANK TEST	0.000	07:09
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (34.3°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.3°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.3°C)	0.099	07:14
SIMULATOR VAPOR (34.3°C)	0.100	07:15
SIMULATOR VAPOR (34.2°C)	0.101	07:16
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:18
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20

Average = 0.099

Std Dev = 0.0006



DMT Serial Number #101708

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4.1.6. Guth 34C and/or 2100 wet bath simulators.

**Figure 1: Certification Solutions**

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

## 4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, room temperature. Also, the solution lot number, concentration, date opened, expiration date and simulator temperature of each concentration.

## 4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
  - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
  - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
  - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
  - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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4.1.6. Guth 34C and/or 2100 wet bath simulators.

**Figure 1: Certification Solutions**

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

## 4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, room temperature. Also, the solution lot number, concentration, date opened, expiration date and simulator temperature of each concentration.

## 4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
  - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
  - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
  - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
  - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R<sup>2</sup>" to perform an R<sup>2</sup> statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RFI test press the "RFI" button. When the detector voltage box pops up, key a handheld radio within two feet of the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) **Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
- B) **Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
- C) **Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported. **NOTE:** The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the one-way valve may be damaged requiring the replacement of the breath tube.
- D) **Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.

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4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.4. Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a passing Certification Report.

## **5.0 Emergency or High Priority Situations**

5.1. The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification be completed as soon as possible.

## **6.0 Quality Criteria and Corrective Action**

6.1. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

6.2. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.

6.3. Each new instrument being tested will have its own testing and maintenance binder. This binder contains a notebook for documenting instrument performance issues and errors.

6.4. Once an instrument has completed its initial testing and is prepared for deployment, all performance issues and errors are documented on a Technical Service Inquiry (Alc 626). TSI's are filed in each instrument's file located in the locked filing cabinet in Room 124.

## **7.0 Preventative Maintenance and Backup Procedures**

7.1. If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.

7.1.1. Contact NPAS at 1-800-800-8143 or [service@npas.com](mailto:service@npas.com).

7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

## **8.0 References**

8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).

8.2. DataMaster DMT Service Manual.

8.3. VDHL DataMaster DMT Power-Up Procedure (P-Alc-116).

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8.4. VDHL Laboratory Calibration of DataMaster DMT (P-Alc-117).

8.5. Technical Support Inquiry (Alc 626).

8.6. Logbook: DataMaster Certification Solution Information

8.7. Appendix A: Acceptable Certification Report.

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## Appendix A Acceptable Certification Report

### CERTIFICATION REPORT

DataMaster DMT: 101708  
 Calibration Date: 12/16/2008  
 Certification Date: 12/16/2008  
 Certified by: STEVEN E HARNOIS



#### Diagnostic Results

##### VERSIONS

DMT 1.00  
 PIC 2.05  
 Modem 1.04  
 Questions 1.00  
 Reports 1.00

##### TEMPERATURES

Sample Chamber = 48.80°C  
 Breath Tube = 46.63°C

##### SETTINGS

Lamp Voltage = 2.20 V  
 Cooler Voltage = 2.05 V  
 Bias Voltage = 120.1 V  
 Chopper Freq = 537.5 Hz

##### PUMP INFO

Flow Rate = 4.625 L/M

##### DETECTOR INFO

PUMP ON OFF  
 MAX(V) -0.0236 -0.0197  
 MIN(V) -0.0264 -0.0224

##### FILTER INFO

Filter 1 -0.023 Zero = true  
 Filter 2 0.420 Zero = true  
 Filter 3 0.648 Zero = true

##### CALIBRATION CHECK

Xq = 0.1275 0.14%

#### Options

Printer: yes  
 Number of Copies: 3  
 Number of Supervisor Tests: 10  
 Tolerance Check: yes  
 Data Collection: yes  
 Units: g/210L  
 Simulator Check: yes  
 Uses Wet Bath Simulator: yes  
 Simulator Nominal: 0.101  
 Digital Simulator: none  
 Simulator Before: yes  
 Simulator Between: yes  
 Simulator After: no  
 Number of Subject Tests: 2  
 Ask Questions: yes  
 Query Refusal: yes  
 Alcohol Display: yes  
 Show Two Digits: no  
 Volume Display: yes  
 Number of Calibration Tests: 1  
 Calibrate with Wet Bath: yes  
 Calibration Nominal: 0.100



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**Linearity Check Results**

True Value	Reported Average	Std Dev
0.020 g/210L	0.018 g/210L	0.001
Lot # 09-06-020		
0.080 g/210L	0.078 g/210L	0.001
Lot # 09-01-080		
0.162 g/210L	0.161 g/210L	0.000
Lot # 09-03-160		
0.397 g/210L	0.404 g/210L	0.001
Lot # 09-12-400		

 $R^2 = 0.9999$ **Acetone Interference Test**

Lot # 09-01-08A

Interference Detected

**Mouth Alcohol Test**

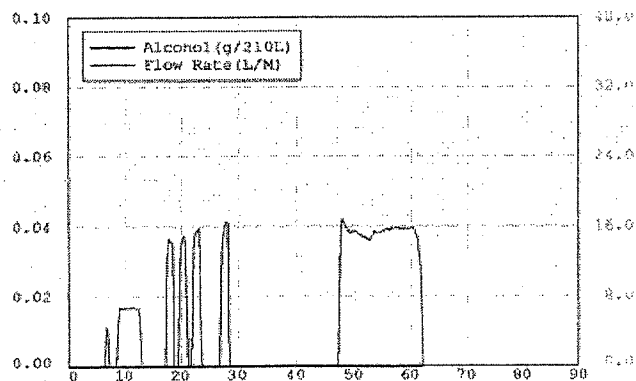
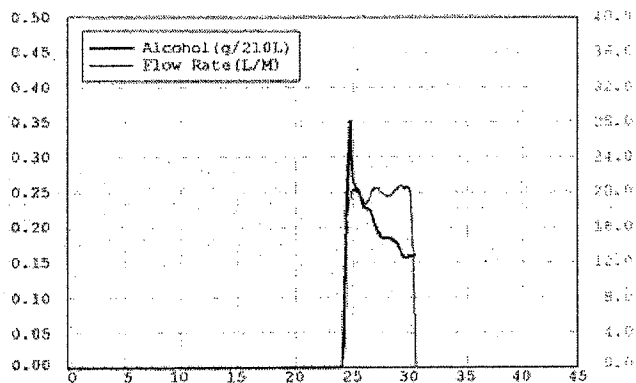
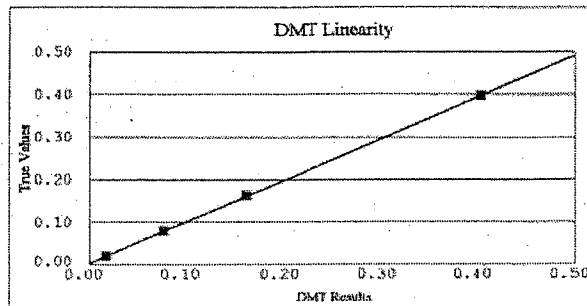
Mouth Alcohol Detected

**RF Interference Test**

RFI detected

**Sample Acceptance Test**

Passed

**CERTIFICATION PASSED**

Performed by \_\_\_\_\_

Date 12/16/2008

Reviewed by \_\_\_\_\_

Date 12/16/08

DMT Serial Number #101708

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12/16/2008 09:34

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## 1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory (VDHL) staff for the installation of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes site inspection, installation and testing of evidentiary breath testing instruments at police agencies.

## 2.0 Responsibility

- 2.1. All instruments shall only be installed by trained laboratory staff.
- 2.2. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.3. This procedure will be reviewed periodically by toxicology staff. Revisions of the procedure will be made when a need is identified.

## 3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All instruments shall undergo a power-up procedure, calibration and certification before installation may occur. See P-Alc-116, P-Alc-117 and P-Alc-118.
- 3.3. All reports generated during this procedure must be retained, this includes those displaying error messages or failures. One copy of the report will be retained by the agency in which the instrument is installed. One copy of the report will be returned to VDHL, reviewed by another trained technician and filed in the appropriate instrument's file in the DataMaster filing cabinet in room 124.

## 4.0 Procedure Steps

### 4.1. Materials and Supplies

- 4.1.1. DataMaster DMT Instrument with keyboard and simulator lock.
- 4.1.2. HP 5650 or equivalent (HP PLC3e, PLC4 or PLC5) printer and USB cable.
- 4.1.3. Uninterruptible Power Supply (UPS) or Line Power Conditioner.
- 4.1.4. Guth 34C-NP Wet Bath Simulator.
- 4.1.5. DataMaster Simulator Solution ~0.100 EtOH.
- 4.1.6. DataMaster Mouthpieces.
- 4.1.7. Radio Frequency Transmitter.

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4.1.8. Field Service Tool Kit.

#### **4.2. Transport**

- 4.2.1. Contact the agency representative at the site of the pending installation to schedule date and time for instrument installation.
- 4.2.2. Use a protective cover when transporting instruments through precipitation and prevent simulator solution from freezing during cold weather.
- 4.2.3. The simulator should be transported 'dry' –i.e. simulator solution should be removed before transport.

#### **4.3. Site Inspection and DataMaster Placement for New Sites**

- 4.3.1. All agencies shall agree to a DataMaster Site Maintenance Agreement as part of a DataMaster Site Evaluation Checklist (Alc 904) prior to an instrument being deployed to an agency.
- 4.3.2. With an agency representative present, complete a DataMaster Site Evaluation Checklist (Alc 904).
- 4.3.3. The area of instrument placement must meet specifications outlined in the site inspection standards as listed in P-Alc-210.
- 4.3.4. Review the area for limited access, instrument security, cleanliness, adequate ventilation, stable temperature, and lack of potentially interfering volatile substances. Ensure availability of appropriate power and telephone outlets. If any deficiencies are noted, document them on the Site Evaluation Checklist; submit this to the Toxicology Program Chief for disposition.

#### **4.4. Setting up the DataMaster DMT**

- 4.4.1. Plug the UPS or line conditioner into a power outlet. Plug the DataMaster DMT and printer into the UPS or line conditioner.
- 4.4.2. Turn the DMT on. Depending on instrument temperature, a minimum of ten minutes is necessary for the instrument to come to temperature and be ready to perform an installation. When the instrument reaches adequate temperature, the screen will display "Ready, Push Run".
- 4.4.3. Plug in the printer, turn it on and connect it to the DMT using a USB cable. Fill the printer with ink and paper (as necessary).
- 4.4.4. Connect the keyboard to a USB slot in the back of the DMT.
- 4.4.5. Add solution to the simulator. Replace the simulator head snugly. Affix one copy of the simulator solution label to the top of the simulator head.

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4.3.1. All agencies shall agree to a DataMaster Site Maintenance Agreement as part of a DataMaster Site Evaluation Checklist (AIC 904) prior to an instrument being deployed to an agency.

4.3.2. With an agency representative present, complete a DataMaster Site Evaluation Checklist (AIC 904).

4.3.3. The area of instrument placement must meet specifications outlined in the site inspection standards as listed in P-AIC-210.

4.3.4. Review the area for limited access, instrument security, cleanliness, adequate ventilation, stable temperature, and lack of potentially interfering volatile substances. Ensure availability of appropriate power and telephone outlets. If any deficiencies are noted, document them on the Site Evaluation Checklist; submit this to the Toxicology Program Chief for disposition.

## **4.4. Setting up the DataMaster DMT**

4.4.1. Plug the UPS or line conditioner into a power outlet. Plug the DataMaster DMT and printer into the UPS or line conditioner.

4.4.2. Turn the DMT on. Depending on instrument temperature, a minimum of ten minutes is necessary for the instrument to come to temperature and be ready to perform an installation. When the instrument reaches adequate temperature, the screen will display "Ready, Push Run".

4.4.3. Plug in the printer, turn it on and connect it to the DMT using a USB cable. Fill the printer with ink and paper (as necessary).

4.4.4. Connect the keyboard to a USB slot in the back of the DMT.

4.4.5. Add solution to the simulator. Replace the simulator head snugly. Affix one copy of the simulator solution label to the top of the simulator head.

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4.4.6. Plug the simulator in to the UPS or line conditioner. Ensure the simulator powered on correctly and the paddle is rotating.

4.4.7. Attach the BNC connector to the head of the simulator. Ensure the DMT registers a temperature for the simulator. Connect the simulator to the simulator tower on the DMT. Lock the arms around the simulator head using a small padlock.

4.4.8. On the "Ready, Push Run" screen, press the NPAS logo to open the drop down menu. Select TECH MODE. Enter password.

4.4.8.1. On the Technician screen, press the "Set RFI" button to set the Radio Frequency sensitivity. The instrument will adjust the RF sensitivity to the ambient level. Press "Save" to save the RF setting.

4.4.8.2. Exit when complete.

4.4.9. Ensure the date and time are correct. Adjust as necessary.

#### **4.5. Installation Protocol**

4.5.1. Open the drop down menu. Select: Protocols → Installation. Fill in all fields on the data entry screen as required.

4.5.2. The instrument will now perform a mandatory thirty minute wait period which gives the simulator solution time to warm up and equilibrate.

4.5.3. Once the wait period is complete, the instrument will automatically begin the Installation Protocol. Follow all instructions on the screen. The instrument will only continue on to the next step once each check passes.

4.5.3.1. The first step is a Diagnostic Check. The instrument will run a self check to ensure all temperatures, settings and components are functioning properly.

4.5.3.2. The second step is an Accuracy and Precision Check. The instrument will run five replicates of the simulator solution and calculate and average and standard deviation. The average must be within  $\pm 5\%$  of the certified simulator solution concentration and the standard deviation must be  $< 0.002$ .

4.5.3.3. The third step is the Radio Frequency Interference check.

4.5.3.3.1. When prompted to perform the RFI check, if the agency has a console radio located in their building, have dispatch key all commonly used frequencies. The instrument should not react to dispatch frequencies. If a dispatch frequency causes an RFI error, post a sign warning operators to be aware of the potential RF interferences.

4.5.3.3.2. Key a handheld radio within two feet of the instrument. An RFI should be reported. If the instrument's radio frequency sensitivity is incorrect, reset the sensitivity and begin the test again.

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4.5.3.4. The final step is a sample acceptance check.

4.5.3.4.1. Press "OK" when you are ready to start the test. The DMT will run through a series of quality control checks.

4.5.3.4.2. When prompted "Please Blow" and an intermittent tone is heard, insert a new mouthpiece into the breath tube.

4.5.3.4.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.

**A: Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.

**B: Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.

**C: Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported.

**D: Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was  $\geq 0.002$  g/210L or if the breath sample was not accepted and at least 1.7L of air had been delivered.

4.5.3.4.4. Once the Sample Acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.5.3.5. Once the protocol is complete, the instrument will prompt for technician signature. Sign in the box and press "finished". Two copies of the report will now print.

#### 4.6. Record Keeping

4.6.1. When the Installation reports print, file one copy with the onsite maintenance records. One copy of the report will be returned to the laboratory and reviewed by another technician, then filed in the DataMaster filing cabinet in room 124.

4.6.2. In the DataMaster Maintenance Logbook (AIC 803) affix one copy of the simulator solution label, document your name, date of installation and note any corrective actions that may have been performed.

4.6.3. In the DataMaster Operators Logbook (AIC 603) document your name, under the "subject" column write "test/Install" and enter the result of the simulator vapor average.

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## **5.0 Emergency or High Priority Situations**

- 5.1. The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT Installation to be a high priority and request service as soon as possible.

## **6.0 Quality Criteria and Corrective Action**

- 6.1. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event. Write the problem and corrective actions taken on the failing installation reports and in the instrument's maintenance log.
- 6.2. After three failed installation attempts, the installation is considered failed and the instrument shall be returned to VDHL for further evaluation.
- 6.3. If the problem is not correctable in the field or a repair or technical evaluation is needed, a DataMaster Technical Support Inquiry worksheet (AIC 626) must be started. The instrument shall be returned to the laboratory for further evaluation. Once the repair is complete, the TSI is finished and placed in the instrument's file. This procedure may be begun again when the problem is resolved.

## **7.0 Preventative Maintenance and Backup Procedures**

- 7.1. If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. (NPAS) will be contacted for technical support.
- 7.1.1. Contact NPAS at 1-800-800-8143 or [service@npas.com](mailto:service@npas.com).
- 7.2. If an agency's instrument requires repair and cannot be returned to service within two weeks, a replacement instrument may be installed at that site.

## **8.0 References**

- 8.1. DataMaster DMT In-house Service Manual.
- 8.2. VDHL DataMaster DMT Power-Up Procedure (P-AIC-116).
- 8.3. VDHL Laboratory Calibration of DataMaster DMT (P-AIC-117).
- 8.4. VDHL Laboratory Certification of DataMaster DMT (P-AIC-118).
- 8.5. VDHL BAC DataMaster Field Installation (P-AIC-210).
- 8.6. DataMaster Site Evaluation Checklist (AIC 904).
- 8.7. DataMaster Maintenance Logbook (AIC 803).
- 8.8. DataMaster Operators Logbook (AIC 603).
- 8.9. DataMaster Technical Support Inquiry worksheet (AIC 626).

Appendix A  
Acceptable Installation Report

## INSTALLATION REPORT

DataMaster DMT: 122206  
Location: WILLISTON VSP  
Calibration Date: 06/10/2009  
Certification Date: 06/11/2009  
Installation Date: 06/11/2009  
Installed By: STEVEN E HARNOIS



Site meets specification in doc P-ALC-210

## Diagnostic Results

VERSIONS  
DMT 1.00  
PIC 2.05  
Modem 1.04  
Questions 1.00  
Reports 1.00

## TEMPERATURES

Sample Chamber = 48.78°C  
Breath Tube = 48.10°C  
Digital Skin = 33.9°C

## SETTINGS

Lamp Voltage = 1.51 V  
Cooler Voltage = 1.53 V  
Bias Voltage = 20.1 V  
Chopper Freq = 543.3 Hz

## PUMP INFO

Flow Rate = 4.536 L/M

## DETECTOR INFO

PUMP ON OFF  
MAX(V) 0.0139 0.0191  
MIN(V) 0.0128 0.0175

## FILTER INFO

Filter 1 0.017 Zero = true  
Filter 2 0.712 Zero = true  
Filter 3 1.485 Zero = true

## CALIBRATION CHECK

Xq = 0.0798 0.76%

INSTALLATION PASSED

## Accuracy and Precision Check

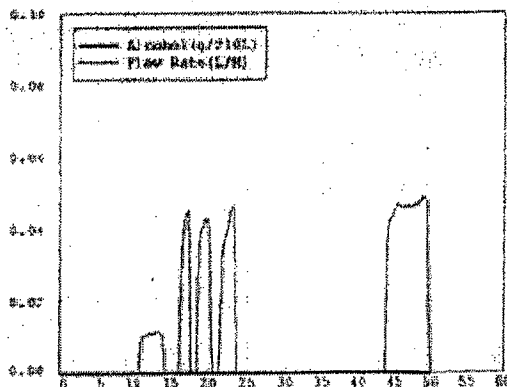
Concentration = 0.100 g/210L  
Lot # = 09-40-100  
Average = 0.102 g/210L  
Std Dev = 0.000

## RFI Interference Test

RFI detected

## Sample Acceptance Test

Passed



Performed by \_\_\_\_\_

Date 06/11/2009

Reviewed by \_\_\_\_\_

Date 6/15/09

DMT Serial Number #122206

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