

DRAEGER 9510 VALIDATION TESTING

This report has been prepared by the Washington State Patrol Impaired Driving Section/Breath Test Program. The report includes detailed instructions for the testing and validation of the Draeger Alcotest 9510 Evidential Breath Test Instrument and summary conclusions.

The use of the word instrument in this manual will be in reference to the Draeger Alcotest 9510 Evidential Breath Test Instrument.

The summary conclusions included in the report reflect the fitness for purpose of the instrument. All testing was performed by the Washington State Patrol Breath Test Program personnel. The instruments utilized were owned by the Washington State Patrol and the testing was performed on calibrated instruments.

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STANDARD EQUIPMENT USED

- Calibrated Draeger Alcotest 9510 Instrument
- Guth model 34C or 2100 Simulators with thermometers that have been certified per policies.
- Calibration Method used shall be the current The Quality Assurance Procedure-Calibration/ Quality Assurance Plan for Instrument Validation approved on 4/22/2013 by the Impaired Driving Section Commander.

SECTION 1
LIMIT OF DETECTION AND QUANTITATION

CRITERIA

For the limit of detection (LOD) testing, the Draeger Alcotest 9510 should be capable of detecting alcohol at or below 0.02g/210L. For the limit of quantitation (LOQ) testing, the instrument should be capable of accurately measuring alcohol concentration of at least 0.02g/210L.

DEFINITIONS

Limit of detection: The LOD is an estimate of the lowest concentration of alcohol that can be reliably detected or identified but not necessarily quantified by the analytical method.

Limit of quantitation: LOQ is the lowest concentration at which the analytical system is capable of providing a quantitative result that can be characterized according to its accuracy and precision. The LOQ can be estimated using the concentration of lowest non-zero calibrator, by estimating LOQ using concentration of decision point, and/or by estimating LOQ using reference materials. This analysis shall be done using concentration of decision point.

For both LOD and LOQ the instrument will be evaluated in the range of 0.010 – 0.030g/210L.

SUPPLIES

- Laboratory grade deionized water provide by Washington State Toxicology Laboratory
- Simulator solutions at multiple concentrations, provided and tested by the Washington State Toxicology Laboratory
 - 0.010g/210L
 - 0.015g/210L
 - 0.020g/210L
 - 0.030g/210L
- Simulator Solution Test Reports provided by Washington State Toxicology Laboratory.

- Excel spreadsheet titled "Limit of Detection"

INSTRUCTIONS

- Pour approximately 500mL of deionized water into the simulator and turn the simulator on. Allow the solution to heat to 34° centigrade +/- 0.2° centigrade.
- Attach the simulator to the instrument.
- Perform a series of five supervisory tests on the solution.
- Print the ticket from the instrument utilizing the internal printer.
- On the provided Excel Spreadsheet titled "Limit of Detection," type in all applicable data.
- Record the test results on the provided Excel Spreadsheet titled "Limit of Detection/Quantitation"
- Repeat the listed above steps for each of the following solutions: 0.010g/210L, 0.015g/210L, and 0.020g/210L.
- Type in the name of the technician in the appropriate space provided as well as the technician that reviewed the results in the space provided.
- Once the document has been reviewed for correct data entry, print the Excel Spreadsheet and attach the internal printout in the appropriate location.

LOD/LOQ TEST SUMMARY:



SECTION 2 **ACCURACY & PRECISION**

CRITERIA

The instrument should be capable of measuring a known tested standard (simulator solution) within an accuracy range of +/- 5% or 0.005 g/210L, whichever is greater. Precision must be within 3%.

DEFINITIONS

Accuracy: The closeness of agreement between a measured quantity value and a nominal or known true value of a measurand. It is usually reported as a percent difference. The term bias may also be used to describe accuracy.

Precision: (expressed numerically as imprecision) The measure of the closeness of agreement between a series of measurements obtained from multiple samplings of the same homogenous sample. The term coefficient of variation may also be used to describe precision.

SUPPLIES

- Simulator Solution Test Reports provided by Washington State Toxicology Laboratory
- Simulator solution provided and tested by the Washington State Toxicology Laboratory
 - Levels to be tested: 0.020, 0.040, 0.060, 0.080, 0.100, 0.150, 0.200, 0.250, 0.300, 0.350, 0.400, 0.500, 0.600.
- Excel spreadsheet titled "Accuracy & Precision Testing"

INSTRUCTIONS

- Pour contents of the solution into the simulator and turn the simulator on. Allow the solution to heat to 34° centigrade +/- 0.2° centigrade.
- Attach the simulator to the instrument.
- Perform a series of five supervisor tests on the solution.
- Print the ticket from the instrument utilizing the internal printer on the instrument.

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- Record the test results on the provided Excel spreadsheet titled "Accuracy & Precision Testing".
- Enter names of the technician and the reviewer in the designated appropriate spaces.
- Once the document has been reviewed for correct data entry, print the Excel Spreadsheet and attach the internal printout in the appropriate location.
- Repeat this testing sequence on each of the solution levels provided to you.
 - Levels to be tested: 0.020, 0.040, 0.060, 0.080, 0.100, 0.150, 0.200, 0.250, 0.300, 0.350, 0.400, 0.500, 0.600.
- The next available day, repeat the entire testing sequence using a fresh solution from the same batch number. This process will be repeated until three days of testing has been completed.

ACCURACY AND PRECISION TESTING SUMMARY

SECTION 3 **MEASUREMENT RANGE**

CRITERIA

The instrument should be capable of measuring a known tested standard (simulator solution) at levels where linearity, precision and accuracy can be established. This testing is similar to accuracy testing but will define linearity from levels of 0.250-0.600 as identified below.

DEFINITIONS

For the purpose of this validation process, the measurement range is the tested concentration range where the linearity, precision and accuracy can be established. This will be demonstrated by analyzing at least six different concentrations and determining that the accuracy and precision meet the standards. Accuracy levels will be defined as +/-5% Accuracy compared to solution reference value. Precision levels will be less than or equal to 3% . The results of the previous section will be used to establish our measurement range.

MEASUREMENT RANGE TEST SUMMARY

SECTION 4 **ROBUSTNESS & RUGGEDNESS**

CRITERIA

The instrument should be capable of testing in varying ambient conditions such as temperature and pressure changes.

DEFINITIONS

Robustness/Ruggedness: The measure of an analytical method's resistance to result changes when minor deviations are made from the experimental conditions described in the method. It provides an indication of the method's reliability given the small changes that are expected to occur or could possibly occur during routine use.

SUPPLIES

- Simulator solutions provided by the Washington State Toxicology Laboratory
 - Solution values of 0.040, 0.080, and 0.150.
- Simulator Solution Test Reports provided by the Washington State Toxicology Laboratory
- Excel spreadsheets titled "Robustness Normal Temp Spreadsheet, Robustness Low Temp Spreadsheet, and Robustness High Temp Spreadsheet
- Barometer
- Thermometer for ambient air temperature measurement
- 0.080 Ethanol Breath Standard (Ethanol Nitrogen mixture)

4A: INSTRUCTIONS - NORMAL LABORATORY TEMPERATURE CONDITIONS

SUPPLIES

- Simulator solutions with values of 0.040g/210L, 0.080g/210L, and 0.150g/210L.
- Thermometer to measure ambient air temperature
- 0.08 Ethanol Breath Standard (Ethanol/ Nitrogen mixture)

INSTRUCTIONS

- Record ambient air temperature on provided Excel spreadsheet titled "Robustness Normal Temp Spreadsheet". Ensure first test has ambient room temperature between 68 degrees Fahrenheit and 74 degrees Fahrenheit.
- Complete five supervisory tests on the instrument for each solution value and the ethanol dry gas standard. Record each value on the spreadsheet. Attach the internal printouts together and attach them to the spreadsheet for verification purposes.

4A: ROBUSTNESS NORMAL TEMPERATURE TEST SUMMARY

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4B: INSTRUCTIONS – LOW TEMPERATURE CONDITIONS

SUPPLIES

- Simulator solutions with values of 0.040g/210L, 0.080g/210L, and 0.150g/210L.
- Thermometer to measure ambient air temperature
- 0.08 Ethanol Breath Standard (Ethanol/ Nitrogen mixture)

INSTRUCTIONS

- Record ambient air temperature on provided the Excel spreadsheet titled “Robustness Low Temp Spreadsheet”. Ensure tests have ambient room temperature between 45 degrees Fahrenheit and 68 degrees Fahrenheit.
- Complete five supervisory tests on each solution value and the ethanol dry gas standard. Record each value on the spreadsheet. Attach the internal printouts together and attach them to the spreadsheet for verification purposes.

4B: ROBUSTNESS LOW TEMPERATURE CONDUTIONS TEST SUMMARY

4D: INSTRUCTIONS – BAROMETRIC PRESSURE CONDITIONS

SUPPLIES

- Barometer
- 0.08 Ethanol Breath Standard (Ethanol/ Nitrogen mixture)

INSTRUCTIONS

- Place the instrument in an environment that is less than 200 feet above sea level. Record ambient air pressure reading from the barometer and compare reading to ambient pressure reading on the instrument. If necessary, adjust pressure reading on the instrument to the reading on the barometer. After adjustment, run a series of five supervisory tests using the dry gas 0.08. Print the internal document from the instrument and record the values on the provided Excel Spreadsheet.
- Using the same instrument, proceed to a location that is at least 2500 feet above sea level (e.g. Stevens pass ski resort base is 4062 feet above sea level).
- Record the barometer make and serial number on the spreadsheet.
- Record the ambient air pressure reading from the barometer and compare reading to the ambient air pressure reading on the instrument. Record any deviation in readings but do not make any adjustments as done at original testing site below 200 feet. Run a series of five supervisory tests using the same dry gas value used at or near sea level and record the values on the provided Excel Spreadsheet that contain the values from the at or near sea level recording.

4D: BAROMETRIC PRESSURE CONDITIONS TEST SUMMARY

- Repeat the four previous steps with nine other alcohol free subjects.

5A: INSTRUCTIONS FOR ACETONE DETECTION EVALUATION

- Pour approximately 500 mL of deionized water into the simulator and turn the simulator on. Allow solution to heat to 34° centigrade +/- 0.2° centigrade.
- Set the instrument up to perform an evidentiary breath test. When prompted to blow, attach the front simulator port to the instrument via the breath tube and blow through the top port of the simulator to provide a sample.
- Record the results on the attached spreadsheet.
- Add 0.15mL of acetone to the simulator and conduct another evidentiary breath test.
- Record the results on the attached spreadsheet titled "Interference Acetone".
- Continue the above sequence until the instrument detects the interference.

5A: ACETONE DETECTION TEST SUMMARY

5B: INSTRUCTIONS FOR ISOPROPYL ALCOHOL DETECTION EVALUATION

- Pour approximately 500 mL of deionized water into the simulator and turn the simulator on. Allow solution to heat to 34° centigrade +/- 0.2° centigrade.
- Set the instrument up to perform an evidentiary breath test. When prompted to blow, attach the front simulator port to instrument via the breath tube and blow through the top port of the simulator to provide a sample.
- Record the results on the attached spreadsheet.
- Add 0.15mL of isopropyl alcohol to the simulator and conduct another evidentiary breath test.
- Record the results on the attached spreadsheet.
- Continue the above sequence until the instrument detects the interference.

5B: ISOPROPYL DETECTION TEST SUMMARY

5C: INSTRUCTIONS FOR METHANOL DETECTION EVALUATION

- Pour approximately 500 mL of deionized water into the simulator and turn the simulator on. Allow solution to heat to 34° centigrade +/- 0.2° centigrade.
- Set the instrument up to perform an evidentiary breath test. When prompted to blow, attach the front simulator port to instrument via the breath tube and blow through the top port of the simulator to provide a sample.
- Record the results on the attached spreadsheet.
- Add 0.15mL of methanol to the simulator and conduct another evidentiary breath test.
- Record the results on the attached spreadsheet.
- Continue the above sequence until the instrument detects the interference.
- Attach the reagent specification sheet to the results sheet and provide all documents to a Breath Test Program supervisor for review.

5C: METHANOL DETECTION TEST SUMMARY

SECTION 6 **CARRYOVER**

CRITERIA

The instrument should be capable of analyzing samples without risk of contamination from a prior sample.

DEFINITION

Carryover: The appearance of unintended analyte signal in a sample after the analysis of a positive sample.

SUPPLIES

- Simulator solutions provided by the Washington State Toxicology Laboratory with vapor concentrations of approximately 0.300 and 0.500 g/210L.
- Simulator solution test reports provided by the Toxicology Laboratory. Excel Spreadsheet titled "CARRYOVER TESTING"

INSTRUCTION

- Utilize 0.300 and 0.500 solutions approved and obtained from Washington State Toxicology Laboratory.
- Have two simulators available that are QAP certified.
- Place 0.300 solution into one of the simulators.
- Place approximately 500 mL of Laboratory grade deionized water into the second approved simulator.
- Ensure the solutions are heated to 34 degrees centigrade +/- 0.2 degrees centigrade.
- Connect the simulator with the 0.300 solution to the instrument.
- Insert the key
- Select the menu option
- Select the maintenance option
- Double tap the supervisory test option
 - For Test-Gas select Wet
 - Leave concentration as entered

- For units select g/210L
- For resolution select 3
- For Gas-Input select cuvette inlet
- Run one sample on the instrument. After the screen displays analyzing disconnect the simulator with the 0.300 solution and connect the simulator with the deionized water.
- Repeat the steps above starting with select menu.
- Remove the print tape and record the results and time of the external standard EC reading from both supervisory tests on the Excel spreadsheet provided.
- Print the spreadsheet and indicate the name of technician on the document.
- Paste the results on the printed sheet in the appropriate space.
- Name of the technician verifying the values shall be recorded on the form in the appropriate spot.
- Repeat this process two more times, for a total of three pairs of supervisory tests.
- This series of three tests should be repeated with the 0.500 simulator solution.
- No more than three minutes should elapse between the analysis of the alcohol solution and the analysis of the deionized water. There is no time limit between pairs of supervisory tests.

CARRYOVER TEST SUMMARY

