

## **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 report will be in reference to the Draeger Alcotest 9510 Evidential Breath Test Instrument. The instrument may be referred to throughout this document as any of the following: The Draeger Alcotest 9510, the 9510, the Draeger.

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

**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 and Quantification Testing"

**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/Quantification Testing"
- Repeat the listed above steps for each of the following solutions: 0.010 g/210L, 0.015 g/210L, 0.020 g/210L, and 0.030 g/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:**

The level of detection (LOD) and level of quantification (LOQ) was completed by four individuals on four separate 9510 instruments. The tests were limited to series of five samples each due to the low ethanol vapors utilized and possibility of solution depletion on more than five samples. Samples are considered to be accurate at bias levels of +/- 5% or if the measured concentration mean is less than or equal to +/- 0.005 g/210L as compared to the reference sample being tested. The coefficient of variation (CV) testing are considered to be reliable if the CV is less than 3% or 0.0042 standard deviation.

LOD/ LOQ testing was conducted utilizing the following simulator solution batch numbers and reference values:

BATCH NUMBER	REFERENCE VALUE
N/A WATER	0.0000
T00011	0.0102
T00012	0.0150
T00001	0.0203
T00005	0.0302

**DEIONIZED WATER TESTING:**

The water was placed into a simulator and heated to 34°C +/- .2°C. The water was then connected to the instrument and 5 samples of the water vapor were introduced to the instrument via the simulator connection ports. In 3 of 4 tests samplings the instrument read 0.000 on all five samples on both the infrared as well as fuel cell detection features. On the 4<sup>th</sup> instrument result values as high as 0.001 g/210L on the infrared detection and 0.002 g/210L on the fuel cell features were obtained. These minor trace values could be attributed to electronic noise within the instrument or small residual amounts of ethanol that were previously in the simulator.

**TESTING FOR 0.010:**

The reference value as identified by the Washington State Toxicology Laboratory was 0.102 g/210L. The information is provided for each of the 4 instruments tested in the chart below:

BATCH NUMBER: <u>T00011</u> REFERENCE VALUE: <u>0.0102 g/210L</u>							NUMBER OF SAMPLES <b>5</b>			
DRAEGER SERIAL NUMBER	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
ARAF-0021	0.0104	0.0104	0.0005	0.0005	1.96%	1.96%	4.81%	4.81%	0.0002	0.0002
ARAH-0099	0.0100	0.0100	0.0000	0.0000	-1.96%	-1.96%	0.00%	0.00%	-0.0002	-0.0002
ARAH-0089	0.0100	0.0100	0.0000	0.0000	-1.96%	-1.96%	0.00%	0.00%	-0.0002	-0.0002
ARZB-0001	0.0100	0.0100	0.0000	0.0000	-1.96%	-1.96%	0.00%	0.00%	-0.0002	-0.0002

The values produced by the 0.010 solution were well within the acceptable bias and coefficient of variation criteria.

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**TESTING FOR THE 0.015:**

The reference value identified by the Washington State Toxicology Laboratory was 0.0150 g/210L. The information is provided for each of the four instruments tested in the chart below:

BATCH NUMBER: <u>T00012</u> REFERENCE VALUE: <u>0.0150 g/210L</u>							NUMBER OF SAMPLES <b>5</b>			
DRAEGER SERIAL NUMBER	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
ARAF-0021	0.0140	0.0148	0.0000	0.0004	6.67%	1.33%	0.00%	2.70%	-0.0010	-0.0002
ARAH-0099	0.0142	0.0150	0.0004	0.0000	-5.33%	0.00%	2.82%	0.00%	-0.0008	0.0000
ARAH-0089	0.0150	0.0150	0.0000	0.0000	0.00%	0.00%	0.00%	0.00%	0.0000	0.0000
ARZB-0001	0.0146	0.0148	0.0005	0.0004	-2.67%	-1.33%	3.42%	2.70%	-0.0004	-0.0002

The values produced by the 0.015 solution were well within the acceptable bias and coefficient of variation criteria.

**TESTING FOR THE 0.020:**

The reference value identified by the Washington State Toxicology Laboratory was 0.0203 g/210L. The information is provided for each of the four instruments tested in the chart below:

BATCH NUMBER: <u>T00001</u> REFERENCE VALUE: <u>0.0203 g/210L</u>							NUMBER OF SAMPLES <b>5</b>			
DRAEGER SERIAL NUMBER	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
ARAF-0021	0.0200	0.0200	0.0000	0.0000	-1.48%	-1.48%	0.00%	0.00%	-0.0003	-0.0003
ARAH-0099	0.0196	0.0196	0.0005	0.0005	-3.45%	-3.45%	2.55%	2.55%	-0.0007	-0.0007
ARAH-0089	0.0198	0.0208	0.0004	0.0004	-2.46%	2.46%	2.02%	1.92%	-0.0005	0.0005
ARZB-0001	0.0206	0.0202	0.0005	0.0004	1.48%	-0.49%	2.43%	1.98%	0.0003	-0.0001

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The values produced by the 0.020 solution were well within the acceptable bias and coefficient of variation criteria.

**TESTING FOR THE 0.030:**

The reference value identified by the Washington State Toxicology Laboratory was 0.0302 g/210L. The information is provided for each of the four instruments tested in the chart below:

BATCH NUMBER: <u>T00005</u> REFERENCE VALUE: <u>0.0302 g/210L</u>							NUMBER OF SAMPLES <b>5</b>			
DRAEGER SERIAL NUMBER	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
ARAF-0021	0.0300	0.0298	0.0000	0.0004	-0.66%	-1.32%	0.00%	1.34%	-0.0002	-0.0004
ARAH-0099	0.0290	0.0290	0.0000	0.0000	-3.97%	-3.97%	0.00%	0.00%	-0.0012	-0.0012
ARAH-0089	0.0300	0.0300	0.0000	0.0000	-0.66%	-0.66%	0.00%	0.00%	-0.0002	-0.0002
ARZB-0001	0.0288	0.0286	0.0004	0.0005	-4.64%	-5.30%	1.39%	1.75%	-0.0014	-0.0016

The values produced by the 0.030 solution were well within the acceptable bias and coefficient of variation criteria.

**CONCLUSION**

Four solution values were tested on the four separate instruments. All of the instruments met the bias criteria of +/- 5% for accuracy or a true difference between the reference material value and the mean of the samples provided being less than or equal to 0.005 g/210L. In fact there was no value from any of the tests that exceeded higher than 0.0016 g/210L.

The coefficient of variation (precision) testing all met the criteria of less than 3% or less than or equal to 0.0042 standard deviation.

Based on the successful completion of these tests it is reasonable to consider the level of detection for the Draeger Alcotest 9510 to be 0.010 g/210L.

Based on the accuracy levels defined for this testing it is reasonable to consider the level of quantification of ethanol at a level of 0.010 g/210L.

## **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% or a standard deviation of  $\leq 0.0042$ .

### **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.

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- Perform a series of five supervisor tests on the solution.
- Print the ticket from the instrument utilizing the internal printer on the instrument.
- 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.

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**ACCURACY AND PRECISION TESTING SUMMARY**

ACCURACY TESTS								NUMBER OF SAMPLES			
DATE OF TESTS: <u>4/23/2013</u>								5			
DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>											
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0208	0.0212	0.0004	0.0004	2.46	4.43	1.92	1.89	0.0005	0.0009
T00006	0.0406	0.0412	0.0424	0.0004	0.0005	1.48	4.43	0.97	1.18	0.0006	0.0018
T00009	0.0599	0.0598	0.0618	0.0004	0.0004	-0.17	3.17	0.67	0.65	-0.0001	0.0019
T00003	0.0820	0.0814	0.0834	0.0013	0.0019	-0.73	1.71	1.60	2.28	-0.0006	0.0014
T00007	0.1007	0.1026	0.1052	0.0009	0.0013	1.89	4.47	0.88	1.24	0.0019	0.0045
12050*	0.1534	0.1548	0.1576	0.0008	0.0005	0.91	2.74	0.52	0.32	0.0014	0.0042
T00014	0.2038	0.2050	0.2080	0.0000	0.0000	0.59	2.06	0.00	0.00	0.0012	0.0042
T00013	0.2550	0.2542	0.2586	0.0025	0.0022	-0.31	1.41	0.98	0.85	-0.0008	0.0036
T00015	0.3023	0.3060	0.3090	0.0007	0.0007	1.22	2.22	0.23	0.23	0.0037	0.0067
T00016	0.3558	0.3530	0.3562	0.0007	0.0008	-0.79	0.11	0.20	0.22	-0.0028	0.0004
T00002	0.4122	0.3996	0.4018	0.0124	0.0132	-3.06	-2.52	3.10	3.29	-0.0126	-0.0104
T00017	0.5054	0.4974	0.5058	0.0009	0.0013	-1.58	0.08	0.18	0.26	-0.0008	0.0004
T00018	0.6107	0.5970	0.6118	0.0012	0.0013	-2.24	0.18	0.20	0.21	-0.0137	0.0011

\*Solution Batch 12050 was QAP Solution utilized in testing.

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ACCURACY TESTS								NUMBER OF SAMPLES			
DATE OF TESTS: <u>4/24/2013</u>								5			
DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>											
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0202	0.0210	0.0004	0.0000	-0.49	3.45	1.98	0.00	-0.0001	0.0007
T00006	0.0406	0.0410	0.0410	0.0000	0.0000	0.99	0.99	0.00	0.00	0.0004	0.0004
T00009	0.0599	0.0604	0.0600	0.0005	0.0000	0.83	0.17	0.83	0.00	0.0005	0.0001
T00003	0.0820	0.0820	0.0820	0.0000	0.0000	0.00	0.00	0.00	0.00	0.0000	0.0000
T00007	0.1007	0.1016	0.1010	0.0005	0.0000	0.89	0.30	0.49	0.00	0.0009	0.0003
12050*	0.1534	0.1540	0.1538	0.0000	0.0008	0.39	0.26	0.00	0.52	0.0006	0.0004
T00014	0.2038	0.2040	0.2048	0.0012	0.0013	0.10	0.49	0.59	0.63	0.0002	0.0010
T00013	0.2550	0.2544	0.2574	0.0005	0.0005	-0.24	0.94	0.20	0.19	-0.0006	0.0024
T00015	0.3023	0.3048	0.3076	0.0004	0.0009	0.83	1.75	0.13	0.29	0.0025	0.0053
T00016	0.3558	0.3536	0.3568	0.0005	0.0004	-0.62	0.28	0.14	0.11	-0.0022	0.0010
T00002	0.4122	0.4070	0.4138	0.0017	0.0028	-1.26	0.39	0.42	0.68	-0.0052	0.0016
T00017	0.5054	0.5016	0.5090	0.0011	0.0010	-0.75	0.71	0.22	0.20	-0.0038	0.0036
T00018	0.6107	0.5954	0.6130	0.0024	0.0012	-2.51	0.38	0.40	0.20	-0.0153	0.0023

\*Solution Batch 12050 was QAP Solution utilized in testing.

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ACCURACY TESTS								NUMBER OF SAMPLES			
DATE OF TESTS: <u>4/25/2013</u>								5			
DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>											
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0206	0.0210	0.0005	0.0000	1.48	3.45	2.43	0.00	0.0003	0.0007
T00006	0.0406	0.0420	0.0420	0.0000	0.0000	3.45	3.45	0.00	0.00	0.0014	0.0014
T00009	0.0599	0.0608	0.0608	0.0004	0.0004	1.50	1.50	0.66	0.66	0.0009	0.0009
T00003	0.0820	0.0828	0.0828	0.0004	0.0004	0.98	0.98	0.48	0.48	0.0008	0.0008
T00007	0.1007	0.1012	0.1016	0.0004	0.0005	0.50	0.89	0.40	0.49	0.0005	0.0009
12050*	0.1534	0.1546	0.1556	0.0005	0.0011	0.78	1.43	0.32	0.71	0.0012	0.0022
T00014	0.2038	0.2048	0.2078	0.0004	0.0004	0.49	1.96	0.20	0.19	0.0010	0.0040
T00013	0.2550	0.2556	0.2588	0.0005	0.0013	0.24	1.49	0.20	0.50	0.0006	0.0038
T00015	0.3023	0.3036	0.3086	0.0009	0.0011	0.43	2.08	0.30	0.36	0.0013	0.0063
T00016	0.3558	0.3526	0.3558	0.0015	0.0011	-0.90	0.00	0.43	0.31	-0.0032	0.0000
T00002	0.4122	0.4032	0.4086	0.0028	0.0023	-2.18	-0.87	0.69	0.56	-0.0090	-0.0036
T00017	0.5054	0.4924	0.4976	0.0009	0.0005	-2.57	-1.54	0.18	0.10	-0.0130	-0.0078
T00018	0.6107	0.5990	0.6116	0.0019	0.0019	-1.92	0.15	0.32	0.31	-0.0117	0.0009

\*Solution Batch 12050 was QAP Solution utilized in testing.

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ACCURACY TESTS								NUMBER OF SAMPLES			
DATE OF TESTS: <u>4/23/2013</u>								5			
DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>											
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0198	0.0212	0.0004	0.0004	-2.46	4.43	2.02	1.89	-0.0005	0.0009
T00006	0.0406	0.0400	0.0416	0.0000	0.0005	-1.48	2.46	0.00	1.20	-0.0006	0.0010
T00009	0.0599	0.0602	0.0616	0.0004	0.0005	0.50	2.84	0.66	0.81	0.0003	0.0017
T00003	0.0820	0.0822	0.0832	0.0008	0.0008	0.24	1.46	0.97	0.96	0.0002	0.0012
T00007	0.1007	0.1016	0.1022	0.0009	0.0008	0.89	1.49	0.89	0.78	0.0009	0.0015
12050*	0.1534	0.1542	0.1536	0.0008	0.0009	0.52	0.13	0.52	0.59	0.0008	0.0002
T00014	0.2038	0.2070	0.2070	0.0017	0.0012	1.57	1.57	0.82	0.58	0.0032	0.0032
T00013	0.2550	0.2574	0.2566	0.0005	0.0005	0.94	0.63	0.19	0.19	0.0024	0.0016
T00015	0.3023	0.3064	0.3046	0.0025	0.0023	1.36	0.76	0.82	0.76	0.0041	0.0023
T00016	0.3558	0.3552	0.3528	0.0024	0.0022	-0.17	-0.84	0.68	0.62	-0.0006	-0.0030
T00002	0.4122	0.4100	0.4118	0.0034	0.0053	-0.53	-0.10	0.83	1.29	-0.0022	-0.0004
T00017	0.5054	0.5000	0.4992	0.0066	0.0061	-1.07	-1.23	1.32	1.22	-0.0054	-0.0062
T00018	0.6107	0.6030	0.6088	0.0072	0.0065	-1.26	-0.31	1.19	1.07	-0.0077	-0.0019

\*Solution Batch 12050 was QAP Solution utilized in testing.

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ACCURACY TESTS DATE OF TESTS: <u>4/24/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0202	0.0204	0.0004	0.0005	-0.49	0.49	1.98	2.45	-0.0001	0.0001
T00006	0.0406	0.0410	0.0408	0.0000	0.0004	0.99	0.49	0.00	0.98	0.0004	0.0002
T00009	0.0599	0.0608	0.0606	0.0004	0.0005	1.50	1.17	0.66	0.83	0.0009	0.0007
T00003	0.0820	0.0836	0.0822	0.0005	0.0008	1.95	0.24	0.60	0.97	0.0016	0.0002
T00007	0.1007	0.1020	0.1006	0.0007	0.0005	1.29	-0.10	0.69	0.50	0.0013	-0.0001
12050*	0.1534	0.1556	0.1540	0.0005	0.0007	1.43	0.39	0.32	0.45	0.0022	0.0006
T00014	0.2038	0.2076	0.2064	0.0005	0.0015	1.86	1.28	0.24	0.73	0.0038	0.0026
T00013	0.2550	0.2594	0.2602	0.0005	0.0008	1.73	2.04	0.19	0.31	0.0044	0.0052
T00015	0.3023	0.3076	0.3074	0.0018	0.0011	1.75	1.69	0.59	0.36	0.0053	0.0051
T00016	0.3558	0.3616	0.3600	0.0011	0.0000	1.63	1.18	0.30	0.00	0.0058	0.0042
T00002	0.4122	0.4156	0.4142	0.0005	0.0013	0.82	0.49	0.12	0.31	0.0034	0.0020
T00017	0.5054	0.5066	0.5092	0.0021	0.0018	0.24	0.75	0.41	0.35	0.0012	0.0038
T00018	0.6107	0.6104	0.6160	0.0011	0.0012	-0.05	0.87	0.18	0.19	-0.0003	0.0053

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

ACCURACY TESTS DATE OF TESTS: <u>4/25/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0206	0.0208	0.0005	0.0004	1.48	2.46	2.43	1.92	0.0003	0.0005
T00006	0.0406	0.0410	0.0412	0.0007	0.0008	0.99	1.48	1.71	1.94	0.0004	0.0006
T00009	0.0599	0.0616	0.0610	0.0005	0.0000	2.84	1.84	0.81	0.00	0.0017	0.0011
T00003	0.0820	0.0830	0.0822	0.0000	0.0004	1.22	0.24	0.00	0.49	0.0010	0.0002
T00007	0.1007	0.1032	0.1026	0.0008	0.0005	2.48	1.89	0.78	0.49	0.0025	0.0019
12050*	0.1534	0.1558	0.1560	0.0013	0.0016	1.56	1.69	0.83	1.03	0.0024	0.0026
T00014	0.2038	0.2086	0.2090	0.0009	0.0012	2.36	2.55	0.43	0.57	0.0048	0.0052
T00013	0.2550	0.2572	0.2560	0.0013	0.0012	0.86	0.39	0.51	0.47	0.0022	0.0010
T00015	0.3023	0.3082	0.3080	0.0008	0.0000	1.95	1.89	0.26	0.00	0.0059	0.0057
T00016	0.3558	0.3596	0.3570	0.0005	0.0010	1.07	0.34	0.14	0.28	0.0038	0.0012
T00002	0.4122	0.4108	0.4070	0.0016	0.0010	-0.34	-1.26	0.39	0.25	-0.0014	-0.0052
T00017	0.5054	0.5062	0.5028	0.0036	0.0029	0.16	-0.51	0.71	0.58	0.0008	-0.0026
T00018	0.6107	0.6088	0.6080	0.0004	0.0007	-0.31	-0.44	0.07	0.12	-0.0019	-0.0027

**SUMMARY:**

When the data from the Accuracy & Precision is examined there was one instance of an outlier for instrument ARAH-0098 on 4/23/2013. The precision data on solution T00002 was above expected ranges of 3% (3.10% IR & 3.29% EC) and above the standard deviation requirement of 0.0042 (0.0124 IR & 0.0132 EC). This appears to be from not allowing the simulator to completely equilibrate and the values slowly rising from start to finish. This is the only outlier from the data collected over three days.

### **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. This will be demonstrated by analyzing at least six different concentrations and determining that they meet the accuracy and precision standards. The results of the previous section will be used to establish our measurement range.

#### **DEFINITIONS**

Measurement range is the tested concentration range where the linearity, precision and accuracy can be established.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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MEASUREMENT RANGE TEST SUMMARY

MEASUREMENT RANGE DATE OF TESTS: <u>4/23/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0208	0.0212	0.0004	0.0004	2.46	4.43	1.92	1.89	0.0005	0.0009
T00006	0.0406	0.0412	0.0424	0.0004	0.0005	1.48	4.43	0.97	1.18	0.0006	0.0018
T00009	0.0599	0.0598	0.0618	0.0004	0.0004	-0.17	3.17	0.67	0.65	-0.0001	0.0019
T00003	0.0820	0.0814	0.0834	0.0013	0.0019	-0.73	1.71	1.60	2.28	-0.0006	0.0014
T00007	0.1007	0.1026	0.1052	0.0009	0.0013	1.89	4.47	0.88	1.24	0.0019	0.0045
12050*	0.1534	0.1548	0.1576	0.0008	0.0005	0.91	2.74	0.52	0.32	0.0014	0.0042
T00014	0.2038	0.2050	0.2080	0.0000	0.0000	0.59	2.06	0.00	0.00	0.0012	0.0042
T00013	0.2550	0.2542	0.2586	0.0025	0.0022	-0.31	1.41	0.98	0.85	-0.0008	0.0036
T00015	0.3023	0.3060	0.3090	0.0007	0.0007	1.22	2.22	0.23	0.23	0.0037	0.0067
T00016	0.3558	0.3530	0.3562	0.0007	0.0008	-0.79	0.11	0.20	0.22	-0.0028	0.0004
T00002	0.4122	0.3996	0.4018	0.0124	0.0132	-3.06	-2.52	3.10	3.29	-0.0126	-0.0104
T00017	0.5054	0.4974	0.5058	0.0009	0.0013	-1.58	0.08	0.18	0.26	-0.0008	0.0004
T00018	0.6107	0.5970	0.6118	0.0012	0.0013	-2.24	0.18	0.20	0.21	-0.0137	0.0011

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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MEASUREMENT RANGE DATE OF TESTS: <u>4/24/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0202	0.0210	0.0004	0.0000	-0.49	3.45	1.98	0.00	-0.0001	0.0007
T00006	0.0406	0.0410	0.0410	0.0000	0.0000	0.99	0.99	0.00	0.00	0.0004	0.0004
T00009	0.0599	0.0604	0.0600	0.0005	0.0000	0.83	0.17	0.83	0.00	0.0005	0.0001
T00003	0.0820	0.0820	0.0820	0.0000	0.0000	0.00	0.00	0.00	0.00	0.0000	0.0000
T00007	0.1007	0.1016	0.1010	0.0005	0.0000	0.89	0.30	0.49	0.00	0.0009	0.0003
12050*	0.1534	0.1540	0.1538	0.0000	0.0008	0.39	0.26	0.00	0.52	-0.0006	0.0004
T00014	0.2038	0.2040	0.2048	0.0012	0.0013	0.10	0.49	0.59	0.63	0.0002	0.0010
T00013	0.2550	0.2544	0.2574	0.0005	0.0005	-0.24	0.94	0.20	0.19	-0.0006	0.0024
T00015	0.3023	0.3048	0.3076	0.0004	0.0009	0.83	1.75	0.13	0.29	0.0025	0.0053
T00016	0.3558	0.3536	0.3568	0.0005	0.0004	-0.62	0.28	0.14	0.11	-0.0022	0.0010
T00002	0.4122	0.4070	0.4138	0.0017	0.0028	-1.26	0.39	0.42	0.68	-0.0052	0.0016
T00017	0.5054	0.5016	0.5090	0.0011	0.0010	-0.75	0.71	0.22	0.20	-0.0038	0.0036
T00018	0.6107	0.5954	0.6130	0.0024	0.0012	-2.51	0.38	0.40	0.20	-0.0153	0.0023

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

MEASUREMENT RANGE DATE OF TESTS: 4/25/2013 DRAEGER SERIAL NUMBER: <u>ARAH-0098</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0206	0.0210	0.0005	0.0000	1.48	3.45	2.43	0.00	0.0003	0.0007
T00006	0.0406	0.0420	0.0420	0.0000	0.0000	3.45	3.45	0.00	0.00	0.0014	0.0014
T00009	0.0599	0.0608	0.0608	0.0004	0.0004	1.50	1.50	0.66	0.66	0.0009	0.0009
T00003	0.0820	0.0828	0.0828	0.0004	0.0004	0.98	0.98	0.48	0.48	0.0008	0.0008
T00007	0.1007	0.1012	0.1016	0.0004	0.0005	0.50	0.89	0.40	0.49	0.0005	0.0009
12050*	0.1534	0.1546	0.1556	0.0005	0.0011	0.78	1.43	0.32	0.71	0.0012	0.0022
T00014	0.2038	0.2048	0.2078	0.0004	0.0004	0.49	1.96	0.20	0.19	0.0010	0.0040
T00013	0.2550	0.2556	0.2588	0.0005	0.0013	0.24	1.49	0.20	0.50	0.0006	0.0038
T00015	0.3023	0.3036	0.3086	0.0009	0.0011	0.43	2.08	0.30	0.36	0.0013	0.0063
T00016	0.3558	0.3526	0.3558	0.0015	0.0011	-0.90	0.00	0.43	0.31	-0.0032	0.0000
T00002	0.4122	0.4032	0.4086	0.0028	0.0023	-2.18	-0.87	0.69	0.56	-0.0090	-0.0036
T00017	0.5054	0.4924	0.4976	0.0009	0.0005	-2.57	-1.54	0.18	0.10	-0.0130	-0.0078
T00018	0.6107	0.5990	0.6116	0.0019	0.0019	-1.92	0.15	0.32	0.31	-0.0117	0.0009

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

MEASUREMENT RANGE DATE OF TESTS: <u>4/23/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0198	0.0212	0.0004	0.0004	-2.46	4.43	2.02	1.89	-0.0005	0.0009
T00006	0.0406	0.0400	0.0416	0.0000	0.0005	-1.48	2.46	0.00	1.20	-0.0006	0.0001
T00009	0.0599	0.0602	0.0616	0.0004	0.0005	0.50	2.84	0.66	0.81	0.0003	0.0017
T00003	0.0820	0.0822	0.0832	0.0008	0.0008	0.24	1.46	0.97	0.96	0.0002	0.0012
T00007	0.1007	0.1016	0.1022	0.0009	0.0008	0.89	1.49	0.89	0.78	0.0009	0.0015
12050*	0.1534	0.1542	0.1536	0.0008	0.0009	0.52	0.13	0.52	0.59	0.0008	0.0002
T00014	0.2038	0.2070	0.2070	0.0017	0.0012	1.57	1.57	0.82	0.58	0.0032	0.0032
T00013	0.2550	0.2574	0.2566	0.0005	0.0005	0.94	0.63	0.19	0.19	0.0024	0.0016
T00015	0.3023	0.3064	0.3046	0.0025	0.0023	1.36	0.76	0.82	0.76	0.0041	0.0023
T00016	0.3558	0.3552	0.3528	0.0024	0.0022	-0.17	-0.84	0.68	0.62	-0.0006	-0.0030
T00002	0.4122	0.4100	0.4118	0.0034	0.0053	-0.53	-0.10	0.83	1.29	-0.0022	-0.0004
T00017	0.5054	0.5000	0.4992	0.0066	0.0061	-1.07	-1.23	1.32	1.22	-0.0054	-0.0062
T00018	0.6107	0.6030	0.6088	0.0072	0.0065	-1.26	-0.31	1.19	1.07	-0.0077	-0.0019

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

MEASUREMENT RANGE DATE OF TESTS: <u>4/24/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0202	0.0204	0.0004	0.0005	-0.49	0.49	1.98	2.45	-0.0001	0.0001
T00006	0.0406	0.0410	0.0408	0.0000	0.0004	0.99	0.49	0.00	0.98	0.0004	0.0002
T00009	0.0599	0.0608	0.0606	0.0004	0.0005	1.50	1.17	0.66	0.83	0.0009	0.0007
T00003	0.0820	0.0836	0.0822	0.0005	0.0008	1.95	0.24	0.60	0.97	0.0016	0.0002
T00007	0.1007	0.1020	0.1006	0.0007	0.0005	1.29	-0.10	0.69	0.50	0.0013	-0.0001
12050*	0.1534	0.1556	0.1540	0.0005	0.0007	1.43	0.39	0.32	0.45	0.0022	0.0006
T00014	0.2038	0.2076	0.2064	0.0005	0.0015	1.86	1.28	0.24	0.73	0.0038	0.0026
T00013	0.2550	0.2594	0.2602	0.0005	0.0008	1.73	2.04	0.19	0.31	0.0044	0.0052
T00015	0.3023	0.3076	0.3074	0.0018	0.0011	1.75	1.69	0.59	0.36	0.0053	0.0051
T00016	0.3558	0.3616	0.3600	0.0011	0.0000	1.63	1.18	0.30	0.00	0.0058	0.0042
T00002	0.4122	0.4156	0.4142	0.0005	0.0013	0.82	0.49	0.12	0.31	0.0034	0.0020
T00017	0.5054	0.5066	0.5092	0.0021	0.0018	0.24	0.75	0.41	0.35	0.0012	0.0038
T00018	0.6107	0.6104	0.6160	0.0011	0.0012	-0.05	0.87	0.18	0.19	-0.0003	0.0053

\*Solution Batch 12050 was QAP Solution utilized in testing.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

MEASUREMENT RANGE DATE OF TESTS: <u>4/25/2013</u> DRAEGER SERIAL NUMBER: <u>ARAH-0091</u>								NUMBER OF SAMPLES <b>5</b>			
SOLUTION INFORMATION		MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		MEAN DIFFERENCE FROM REFERENCE VALUE IN g/210L	
BATCH#	REF	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C
VALUE											
T00001	0.0203	0.0206	0.0208	0.0005	0.0004	1.48	2.46	2.43	1.92	0.0003	0.0005
T00006	0.0406	0.0410	0.0412	0.0007	0.0008	0.99	1.48	1.71	1.94	0.0004	0.0006
T00009	0.0599	0.0616	0.0610	0.0005	0.0000	2.84	1.84	0.81	0.00	0.0017	0.0011
T00003	0.0820	0.0830	0.0822	0.0000	0.0004	1.22	0.24	0.00	0.49	0.0010	0.0002
T00007	0.1007	0.1032	0.1026	0.0008	0.0005	2.48	1.89	0.78	0.49	0.0025	0.0019
12050*	0.1534	0.1558	0.1560	0.0013	0.0016	1.56	1.69	0.83	1.03	0.0024	0.0026
T00014	0.2038	0.2086	0.2090	0.0009	0.0012	2.36	2.55	0.43	0.57	0.0048	0.0052
T00013	0.2550	0.2572	0.2560	0.0013	0.0012	0.86	0.39	0.51	0.47	0.0022	0.0010
T00015	0.3023	0.3082	0.3080	0.0008	0.0000	1.95	1.89	0.26	0.00	0.0059	0.0057
T00016	0.3558	0.3596	0.3570	0.0005	0.0010	1.07	0.34	0.14	0.28	0.0038	0.0012
T00002	0.4122	0.4108	0.4070	0.0016	0.0010	-0.34	-1.26	0.39	0.25	-0.0014	-0.0052
T00017	0.5054	0.5062	0.5028	0.0036	0.0029	0.16	-0.51	0.71	0.58	0.0008	-0.0026
T00018	0.6107	0.6088	0.6080	0.0004	0.0007	-0.31	-0.44	0.07	0.12	-0.0019	-0.0027

**SUMMARY:**

The measurement range utilized the same test results as the accuracy & precision tests. The results, like the accuracy & precision, had the one outlier, instrument ARAH-0098 on 4/23/2013. The precision data on solution T00002 was above expected ranges of 3% (3.10% IR & 3.29% EC) and above the standard deviation requirement of 0.0042 (0.0124 IR & 0.0132 EC). This appears to be from not allowing the simulator to completely equilibrate and the values slowly rising from start to finish. This is the only outlier from the data collected over three days. All other results yielded appropriate accuracy and precision ranges for each of the levels tested.

\*Solution Batch 12050 was QAP Solution utilized in testing.

## **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.

#### **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.

**4C: INSTRUCTIONS – HIGH 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 High Temp Spreadsheet”. Ensure first test has ambient room temperature between 74 degrees Fahrenheit and 90 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.

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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**TEMPERATURE TEST SUMMARY**

TEMPERATURE CONDITION TESTING  
DATE OF TESTS: 4/24/2013  
DRAEGER SERIAL NUMBER: ARAF-0030  
REFERENCE THERMOMETER NUMBER: 90940026

**NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
T00006	0.0408	72.5	0.0420	0.0420	0.0000	0.0000	2.94	2.94	0.00	0.00	72.7
T00003	0.0820	73.4	0.0850	0.0842	0.0000	0.0004	3.66	2.68	0.00	0.48	72.9
T00004	0.1537	72.7	0.1584	0.1582	0.0009	0.0015	3.06	2.93	0.57	0.95	72.5
765817 (DRY GAS)	0.080	72.5	0.0820	0.0820	0.0000	0.0000	2.50	2.50	0.00	0.00	70.0

**BELOW NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
12038	0.0407	58.3	0.0358	0.0360	0.0013	0.0010	-12.04	-11.55	3.63	2.78	59
T00003	0.0820	58.8	0.0738	0.0730	0.0033	0.0034	-10.00	-10.98	4.47	4.66	59.2
T00004	0.1537	61.9	0.1400	0.1372	0.0007	0.0008	-8.91	-10.74	0.50	0.58	58.3
765817 (DRY GAS)	0.080	58.3	0.0824	0.0822	0.0005	0.0004	3.00	2.75	0.61	0.49	58.3

**ABOVE NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
12038	0.0407	77.0	0.0464	0.0484	0.0005	0.0005	14.00	18.92	1.08	1.03	78.8
T00003	0.0820	80.6	0.0788	0.0816	0.0038	0.0036	-3.90	-0.49	4.82	4.41	81.9
T00004	0.1537	82.6	0.1488	0.1518	0.0081	0.0082	-3.19	-1.24	5.44	5.40	81.9
765817 (DRY GAS)	0.080	81.5	0.0810	0.0824	0.0000	0.0005	1.25	3.00	0.00	0.61	81.1

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**TEMPERATURE CONDITION TESTING**  
**DATE OF TESTS: 4/24/2013**  
**DRAEGER SERIAL NUMBER: ARAH-0100**  
**REFERENCE THERMOMETER NUMBER: 90940026**

**NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
T00006	0.0408	72.5	0.0400	0.0400	0.0000	0.0000	-1.96	-1.96	0.00	0.00	72.3
T00003	0.0820	72.9	0.0800	0.0810	0.0000	0.0000	-2.44	-1.22	0.00	0.00	72.9
T00004	0.1537	72.5	0.1528	0.1550	0.0004	0.0010	-0.59	0.85	0.26	0.65	72.5
765817 (DRY GAS)	0.080	70.2	0.0780	0.0804	0.0000	0.0005	-2.50	0.50	0.00	0.62	70.5

**BELOW NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
T00006	0.0408	58.5	0.0356	0.0362	0.0005	0.0004	-12.75	-11.27	1.40	1.10	57.9
T00003	0.0820	59.7	0.0736	0.0746	0.0009	0.0009	-10.24	-9.02	1.22	1.21	57.9
T00004	0.1537	61.8	0.1380	0.1372	0.0007	0.0022	-10.21	-10.74	0.51	1.60	58.9
765817 (DRY GAS)	0.080	58.3	0.0780	0.0820	0.0000	0.0000	-2.50	2.50	0.00	0.00	58.8

**ABOVE NORMAL TEMPERATURE RANGE**

SOLUTION INFORMATION		TEMP. BEFORE	MEAN VALUE		STANDARD DEVIATION		BIAS%		CV OR PRECISION%		TEMP AFTER
BATCH #	REF VALUE		I/R	E/C	I/R	E/C	I/R	E/C	I/R	E/C	
T00006	0.0408	76.5	0.0422	0.0446	0.0004	0.0005	3.43	9.31	0.95	1.12	78.1
T00003	0.0820	79.9	0.0768	0.0806	0.0036	0.0035	-6.34	-1.71	4.69	4.34	81.1
T00004	0.1537	82.6	0.1492	0.1552	0.0031	0.0037	-2.93	0.98	2.08	2.38	82.0
765817 (DRY GAS)	0.080	81.9	0.0770	0.0816	0.0000	0.0005	-3.75	2.00	0.00	0.61	81.5

**TEMPERATURE SUMMARY:**

Each of the temperature tests were completed on two instruments.

Normal temperature tests resulted in all accuracy tests that were less than or equal to 5% and precision values less than 3%. The temperatures ranged from 70.0 degrees Fahrenheit to 72.9 degrees Fahrenheit.

Below normal temperatures were completed in a cooled room that ranged in temperature from 57.9 degrees Fahrenheit to 59.2 degrees Fahrenheit. As expected the accuracy criteria was unable to be obtained on any of the solutions with the exception of the dry gas tests. Each of the dry gas tests conducted resulted in accuracy levels that were within current standards of +/-5% and precision values of less than or equal to 3%.

Above normal temperatures were completed in a room that had been warmed to a range of 78.1- 82.0 degrees Fahrenheit. Similarly to the below temperature testing, it was difficult to obtain results on some of the solutions that were within current criteria. Again, the exception was the dry gas tests which were well within current standards of +/-5% and precision values of less than or equal to 3%.

#### **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.

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**4D: BAROMETRIC PRESSURE CONDITIONS TEST SUMMARY**

**BAROMETRIC PRESSURE TESTING**

DRAEGER 9510 SERIAL NUMBER: ARAF-0030 BAROMETER SERIAL NUMBER: 74003877

DATE TESTED: 4/25/2013

DRY GAS LOT# 765817

EXPIRATION: 5/6/2013

TEST 1A

LOCATION: FLSB HEADQUARTERS OFFICE, SEATTLE, WA (Less than 100 ft above sea level)

TEST 2A

LOCATION: HYAK DEPARTMENT OF TRANSPORTATION FACILITY, SNOQUALMIE PASS, WA  
(Over 3000 ft above sea level)

1A DRAEGER PRESSURE: <u>1018 mbar</u>		2A DRAEGER PRESSURE: <u>927 mbar</u>		DIFFERENCE IN RESULTS (1A-2A) IN g/210L	
1A REFERENCE BAROMETER PRESSURE: <u>1017.0 mbar</u>		2A REFERENCE BAROMETER PRESSURE: <u>929.0 mbar</u>			
1A I/R RESULTS	1A E/C RESULTS	2A I/R RESULTS	2A E/C RESULTS	DIFFERENCE I/R	DIFFERENCE E/C
0.083	0.082	0.083	0.080	0.000	0.002
0.083	0.081	0.083	0.080	0.000	0.001
0.082	0.080	0.083	0.080	-0.001	0.002
0.083	0.080	0.083	0.080	0.000	0.000
0.083	0.080	0.083	0.081	0.000	-0.001

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**BAROMETRIC PRESSURE TESTING**

DRAEGER 9510 SERIAL NUMBER: ARAH-0099 BAROMETER SERIAL NUMBER: 74003877

DATE TESTED: 4/25/2013

DRY GAS LOT# 1161031

EXPIRATION: 5/19/2014

**TEST 1A**

LOCATION: FLSB HEADQUARTERS OFFICE, SEATTLE, WA (Less than 100 ft above sea level)

**TEST 2A**

LOCATION: HYAK DEPARTMENT OF TRANSPORTATION FACILITY, SNOQUALMIE PASS, WA  
(More than 300 ft above sea level)

1A DRAEGER PRESSURE: <u>1018 mbar</u>		2A DRAEGER PRESSURE: <u>929 mbar</u>		DIFFERENCE IN RESULTS (1A-2A) IN g/210L	
1A REFERENCE BAROMETER PRESSURE: <u>1018.0 mbar</u>		2A REFERENCE BAROMETER PRESSURE: <u>927.8 mbar</u>			
1A I/R RESULTS	1A E/C RESULTS	2A I/R RESULTS	2A E/C RESULTS	DIFFERENCE I/R	DIFFERENCE E/C
0.079	0.081	0.080	0.082	-0.001	-0.001
0.080	0.081	0.080	0.081	0.000	0.000
0.080	0.081	0.079	0.081	0.001	0.000
0.080	0.081	0.080	0.081	0.000	0.000
0.080	0.081	0.080	0.081	0.000	0.000

**SUMMARY:**

Barometric pressure testing was completed on two instruments. The tests conducted were done using dry gas. The gas was measured at or near sea level and the pressure was measured at 1018 mbar by the Draeger instruments and compared to 1017 & 1018 mbar on the reference barometer. The criteria recommended by the manufacturer is to have the pressure checks of the instrument be within 10 mbar of the reference. The dry gas was tested yielding the expected results. The instruments were then driven to the Department of Transportation facility near the Snoqualmie Pass summit. The Pressure was measured 927 & 929 mbar by the two instruments and 929 & 927.8 mbar by the reference barometer. The gas was then tested at this pressure level and the instruments produced values very similar to those found at or near sea level.

## **SECTION 5** **INTERFERENCE**

### **CRITERIA**

The Draeger Alcotest 9510 should be capable of detecting interferences that have the potential to bias an evidentiary breath test.

### **DEFINITION**

Interferent: A substance from a common source that, during an analysis, displays the same characteristics as ethanol, resulting in an error in the quantification of the ethanol sample being analyzed.

### **SUPPLIES**

- Laboratory grade deionized water provided by Washington State Toxicology Laboratory
- Excel spreadsheet titled "Interference (Acetone, Isopropyl Alcohol, or Methanol)"
- Acetone
  - Manufacturer specification sheet
- Isopropyl Alcohol
  - Manufacturer specification sheet
- Methanol
  - Manufacturer specification sheet
- Ten alcohol free subjects

### **INSTRUCTIONS FOR EVALUATING MATRIX INTERFERENCES**

- Complete each of the interfering substance criteria listed hereafter, in addition to the below instructions.
- Using a certified PBT, test the subject to ensure they are alcohol free.
- Have the subject provide a complete evidentiary breath test on the instrument.
- Retain the breath test document as part of the validation documentation.
- Have the same subject do a complete breath test on at least two other instruments used in the interference validation.
- Repeat the four previous steps with nine other alcohol free subjects.

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**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: INTERFERENCE/ACETONE DETECTION TEST SUMMARY**

<b>DRAEGER SERIAL NUMBER: <u>ARAF-0002</u></b> <b>SIM SERIAL NUMBER: <u>DR4971</u></b> <b>THERMOMETER SERIAL NUMBER: <u>DR4971</u></b> <b>REAGENT LOT NUMBER: <u>113751</u></b>								
ACETONE ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	12:44	0.000	0.000	12:47	N	
0.150	0.000	0.000	14:54	0.000	0.000	14:57	N	
0.300	0.002	0.000	15:15	0.001	0.000	15:18	N	
0.450	0.003	0.000	08:29	0.003	0.000	08:32	N	
0.600	0.004	0.000	08:48	0.003	0.000	08:51	N	
0.750	0.005	0.000	09:08	0.004	0.000	09:11	N	
0.900	0.005	0.000	09:19	0.005	0.000	09:22	N	
1.050	0.006	0.000	09:33	0.006	0.000	09:36	N	
1.200	0.006	0.000	09:46	0.006	0.000	09:49	N	
1.350	0.007	0.000	09:57	0.006	0.000	10:00	N	
1.500	0.007	0.000	10:16	0.007	0.000	10:19	N	
1.650	0.008	0.000	10:26	0.007	0.000	10:29	N	
1.800	0.009	0.001	10:39	0.008	0.001	10:42	N	
1.950	0.009	0.001	10:48	0.009	0.002	10:51	N	
2.100	0.011	0.002	10:59				Y	

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**DRAEGER SERIAL NUMBER: ARAH-0081**  
**SIM SERIAL NUMBER: DR4971**  
**THERMOMETER SERIAL NUMBER: DR4971**  
**REAGENT LOT NUMBER: 113751**

ACETONE ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	12:36	0.000	0.000	12:39	N	
0.150	0.000	0.000	14:07	0.000	0.000	14:10	N	
0.300	0.001	0.000	15:28	0.001	0.000	15:31	N	
0.450	0.003	0.000	08:26	0.002	0.000	08:29	N	
0.600	0.004	0.000	08:47	0.003	0.000	08:50	N	
0.750	0.005	0.000	09:03	0.004	0.000	09:05	N	
0.900	0.006	0.000	09:19	0.005	0.000	09:22	N	
1.050	0.006	0.000	09:34	0.006	0.000	09:37	N	
1.200	0.006	0.000	09:46	0.006	0.000	09:49	N	
1.350	0.006	0.000	10:06	0.006	0.000	10:09	N	
1.500	0.007	0.000	10:15	0.007	0.001	10:18	N	
1.650	0.009	0.000	10:25	0.008	0.000	10:28	N	
1.800	0.009	0.000	10:39	0.008	0.000	10:42	N	
1.950	0.010	0.000	10:49	0.009	0.000	10:52	N	
2.100	0.010	0.000	11:12	0.009	0.001	11:15	N	

**DRAEGER SERIAL NUMBER: ARAF-0023**  
**SIM SERIAL NUMBER: DR4971**  
**THERMOMETER SERIAL NUMBER: DR4971**  
**REAGENT LOT NUMBER: 113751**

ACETONE ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	12:24	0.000	0.000	12:27	N	
0.150	0.000	0.000	13:51	0.000	0.000	13:54	N	
0.300	0.001	0.000	15:43	0.001	0.000	15:46	N	
0.450	0.002	0.000	08:36	0.002	0.000	08:39	N	
0.600	0.003	0.000	08:52	0.002	0.000	08:55	N	
0.750	0.004	0.000	09:09	0.004	0.000	09:12	N	
0.900	0.005	0.000	09:22	0.004	0.000	09:25	N	
1.050	0.006	0.000	09:37	0.006	0.000	09:39	N	
1.200	0.006	0.000	09:49	0.006	0.000	09:52	N	
1.350	0.007	0.000	09:57	0.006	0.000	10:00	N	
1.500	0.007	0.000	10:16	0.007	0.000	10:19	N	
1.650	0.008	0.000	10:26	0.007	0.000	10:29	N	
1.800	0.009	0.000	10:38	0.008	0.000	10:41	N	
1.950	0.009	0.000	10:48	0.009	0.000	10:51	N	
2.100	0.010	0.000	10:59				Y	

**SUMMARY:**

The acetone testing produced results that were not expected. This was as a result of testing with water only and no ethanol mixed with the solutions. The instrument detection features required an ethanol level and this was not known at the time of these tests. There will be follow up testing once the instrument software is changed to allow for the acetone detection at lower ethanol level.

UPDATE: The following Interference/Acetone tests were conducted on instrument serial number ARAH-0084 on June 4, 2013. The tests were conducted using a base ethanol concentration of 0.01 g/210L (Batch #T00011). These tests were follow up test conducted based on initial feedback from the manufacturer and the software algorithm for interfering substances. The interference detection features performed as expected once the algorithm was updated and a base ethanol level of 0.01 g/210L was utilized for the testing. A letter was also produced by the manufacturer and has also been provided to explain the algorithm and update to the software.

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**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: INTERFERENCE/ISOPROPYL DETECTION TEST SUMMARY**

DRAEGER SERIAL NUMBER: <u>ARAF-0002</u> SIM SERIAL NUMBER: <u>DR4483</u> THERMOMETER SERIAL NUMBER: <u>DR4483</u> REAGENT LOT NUMBER: <u>DC073</u>								
ISOPROPYL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	12:58	0.000	0.000	13:01	N	
0.150	0.006	0.013	15:33	0.006	0.013	15:37	N	OUTSIDE 10%
0.300	0.010	0.021	15:51				Y	
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

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<b>DRAEGER SERIAL NUMBER: ARAH-0081</b> <b>SIM SERIAL NUMBER: DR4483</b> <b>THERMOMETER SERIAL NUMBER: DR4483</b> <b>REAGENT LOT #: DC073</b>								
ISOPROPYL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	13:19	0.000	0.000	13:22	N	
0.150			13:52					INVALID SAMPLE 2 TIMES
0.300	0.009	0.017	15:17	0.009	0.017	15:20	N	SAMPLES OUTSIDE OF 10%
0.300	0.010	0.019	15:57				Y	
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

<b>DRAEGER SERIAL NUMBER: ARAF-0023</b> <b>SIM SERIAL NUMBER: DR4483</b> <b>THERMOMETER SERIAL NUMBER: DR4483</b> <b>REAGENT LOT #: DC073</b>								
ISOPROPYL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	13:06	0.000	0.000	13:08	N	
0.150	0.003	0.009	14:03	0.004	0.009	14:06	N	
0.300	0.008	0.016	14:34	0.008	0.017	14:37	N	
0.300	0.009	0.017	14:47	0.008	0.017	14:50	N	
0.300	0.008	0.017	14:57	0.008	0.017	15:00	N	
0.300	0.010	0.019	16:01				Y	
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

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**SUMMARY:**

Results produced were not expected as a result of the software programming identified in the acetone testing. The same follow up testing will be completed once the software is updated.

UPDATE: The following Interference/Isopropyl tests were conducted on instrument serial number ARAH-0084 on June 4, 2013. The tests were conducted using a base ethanol concentration of 0.01 g/210L (Batch #T00011). These tests were follow up test conducted based on initial feedback from the manufacturer and the software algorithm for interfering substances.

DRAEGER SERIAL NUMBER: <u>ARAH-0084</u> SIM SERIAL NUMBER: <u>DR2775</u> THERMOMETER SERIAL NUMBER: <u>DR2775</u> REAGENT LOT #: <u>DG648</u>								
ISOPROPYL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.009	0.009	16:08	0.009	0.009	16:11	N	
0.150	0.018	0.030	16:25				Y	
0.300								
0.300								
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

**SUMMARY:**

After the software update was performed and a base ethanol level was utilized, the expected interference detection results were obtained.

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**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: INTERFERENCE/METHANOL DETECTION TEST SUMMARY**

DRAEGER SERIAL NUMBER: <u>ARAF-0002</u> SIM SERIAL NUMBER: <u>DR4484</u> THERMOMETER SERIAL NUMBER: <u>DR4484</u> REAGENT LOT #: <u>DH791</u>								
METHANOL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	13:09	0.000	0.000	13:12	N	
0.150			13:51					INVALID SAMPLE
0.150			14:00					INVALID SAMPLE
0.150	0.024	0.027	14:44				Y	
0.300								
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

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<b>DRAEGER SERIAL NUMBER: <u>ARAH-0081</u></b> <b>SIM SERIAL NUMBER: <u>DR4484</u></b> <b>THERMOMETER SERIAL NUMBER: <u>DR4484</u></b> <b>REAGENT LOT #: <u>DH791</u></b>								
METHANOL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	13:04	0.000	0.000	13:07	N	
0.150	0.023	0.028	14:36				Y	
0.300								
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

<b>DRAEGER SERIAL NUMBER: <u>ARAF-0023</u></b> <b>SIM SERIAL NUMBER: <u>DR4484</u></b> <b>THERMOMETER SERIAL NUMBER: <u>DR4484</u></b> <b>REAGENT LOT #: <u>DH791</u></b>								
METHANOL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.000	0.000	12:54	0.000	0.000	12:57	N	
0.150	0.022	0.027	15:33				Y	
0.300								
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

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**SUMMARY:**

Results produced were not expected as a result of the software programming identified in the acetone testing and isopropyl testing. The same follow up testing will be completed once the software is updated.

UPDATE: The following Interference/Methanol tests were conducted on instrument serial number ARAH-0084 on June 4, 2013. The tests were conducted using a base ethanol concentration of 0.01 g/210L (Batch #T00011). These tests were follow up test conducted based on initial feedback from the manufacturer and the software algorithm for interfering substances.

<b>DRAGER SERIAL NUMBER: <u>ARAH-0084</u></b> <b>SIM SERIAL NUMBER: <u>DR2775</u></b> <b>THERMOMETER SERIAL NUMBER: <u>DR2775</u></b> <b>REAGENT LOT #: <u>DH791</u></b>								
METHANOL ADDED IN ml	I/R VALUE SAMPLE 1	E/C VALUE SAMPLE 1	TIME OF TEST	I/R VALUE SAMPLE 2	E/C VALUE SAMPLE 2	TIME OF TEST	INTERFERENCE DETECTED Y/N	COMMENTS
0.000	0.009	0.009	16:49	0.009	0.009	16:53	N	
0.150	0.027	0.027	17:16				Y	
0.300								
0.450								
0.600								
0.750								
0.900								
1.050								
1.200								
1.350								
1.500								
1.650								
1.800								
1.950								
2.100								

**SUMMARY:**

After the software update was performed and a base ethanol level was utilized, the expected interference detection results were obtained.

## **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

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- 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.

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**CARRYOVER SUMMARY:**

Test Sample for instrument ARAF-0021 at 0.30 g/210L:

DRAEGER SERIAL NUMBER: ARAF-0021			DATE: 4/24/2013	
SOLUTION BATCH NUMBER	SOLUTION REFERENCE VALUE	I/R RESULT	E/C RESULT	TIME
T00015	0.3023	0.289	0.286	12:09
H2O	0.0000	0.000	0.001	12:11
T00015	0.3023	0.302	0.298	12:13
H2O	0.0000	0.000	0.000	12:16
T00015	0.3023	0.304	0.302	12:19
H2O	0.0000	0.000	0.000	12:21

Test Sample for instrument ARAF-0021 at 0.50 g/210L:

DRAEGER SERIAL NUMBER: ARAF-0021			DATE: 4/24/2013	
SOLUTION BATCH NUMBER	SOLUTION REFERENCE VALUE	I/R RESULT	E/C RESULT	TIME
T00017	0.5054	0.480	0.482	12:55
H2O	0.0000	0.000	0.000	12:57
T00017	0.5054	0.495	0.498	13:00
H2O	0.0000	0.000	0.000	13:03
T00017	0.5054	0.498	0.502	13:06
H2O	0.0000	0.000	0.000	13:08

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Test Sample for instrument ARAH-0103 at 0.30 g/210L:

DRAEGER SERIAL NUMBER: ARAH0103			DATE: 4/24/2013	
SOLUTION BATCH NUMBER	SOLUTION REFERENCE VALUE	I/R RESULT	E/C RESULT	TIME
T00015	0.3023	0.304	0.305	13:31
H2O	0.0000	0.000	0.000	13:34
T00015	0.3023	0.305	0.306	13:35
H2O	0.0000	0000	0.000	13:38
T00015	0.3023	0.307	0.308	13:40
H2O	0.0000	0.000	0.000	13:42

Test Sample for instrument ARAH-0103 at 0.50 g/210L:

DRAEGER SERIAL NUMBER: ARAH-0103			DATE: 4/24/2013	
SOLUTION BATCH NUMBER	SOLUTION REFERENCE VALUE	I/R RESULT	E/C RESULT	TIME
T00017	0.5054	0.491	0.498	14:07
H2O	0.0000	0.000	0.000	14:09
T00017	0.5054	0.493	0.503	14:11
H2O	0.0000	0.000	0.000	14:14
T00017	0.5054	0.496	0.506	14:16
H2O	0.0000	0.000	0.000	14:19

**SUMMARY:**

The carryover testing completed produced valuable data that assured no carryover from sample to sample when different samples are utilized.

**SECTION 7**

**VALIDATION TESTING FALL 2013**

Additional testing was completed to ensure accuracy and reliability of the instruments prior to deployment in the field. This testing consisted of 10 Draeger Alcotest 9510 instruments. The testing of the instruments utilized multiple solution values (identified below). The testing was conducted on the 10 Draeger instruments on five separate days and the data compiled. All data was run utilizing the same protocol and raw data supplied may be used for Accuracy & Precision, Measurement Range, Level of Detection, and Level of Quantification.

**SOLUTION VALUES TO BE TESTED**

Approximate values in g/210L See individual batch numbers for precise value as identified by G/C
0.010
0.015
0.020
0.040
0.080
0.150
0.200
0.300
0.400

**SUPPLIES**

- Draeger Alcotest 9510 instrument/s
- Guth Model 34C or Model 2100 simulators
- Laboratory grade deionized water provide by Washington State Toxicology Laboratory
- Simulator solutions at multiple concentrations identified above that were provided and tested by the Washington State Toxicology Laboratory
- Simulator Solution Test Reports provided by Washington State Toxicology Laboratory.

## **INSTRUCTIONS**

- Only use Draeger instrument/s that have been calibrated using the current draft of the calibration procedure. The printed Calibration Adjustment Record that is generated by the instrument at the conclusion of the procedure will serve as the document to be technically and administratively reviewed and issued for purposes of this testing. Documenting the technical and administrative review and certificate issuance shall be completed by the approved reviewer signing and dating at the bottom of the document after all data entry such as solution reference values, systematic error, standard deviation, coefficient of variation computations have been verified. Use of the current Excel QAPCalc record may be used for these computation verification checks.
- Set up Draeger instrument to perform 10 supervisory tests.
- Add solution to simulator and heat to appropriate temperature of  $34^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ . Allow at least 15 minutes for headspace and tubing of simulator to equilibrate.
- Attach simulator to Draeger and start the 10 supervisory tests.
- At completion of tests, print the results on the internal printer from the Draeger instrument and enter results into provided spreadsheet. Attach the internal printer document to the same spreadsheet by pasting in the location indicated on the spreadsheet.
- Provide the internal printout/s along with the spreadsheet with completed data to an approved technical reviewer to ensure data was entered correctly.
- Each document (spreadsheet and form with attached printouts) will be signed and dated by the technician performing the testing as well as the technician performing the technical review.
- Repeat testing on each instrument on five separate days. The days do not have to be back to back.
- At the end of the five days of testing, all documents will be provided to BTP supervisors without staples, and in an individual folder labeled with the instrument serial number and date range of the tests. Example: ARAH-5555 October 1-8, 2013.

TESTING SUMMARY FALL 2013

The following is a summary of testing conducted on 10 Draeger Alcotest 9510 breath testing instruments. The testing was completed in September & October of 2013 by the Washington State Patrol (WSP) Breath Test Program (BTP).

The testing was completed using instruments which were calibrated according to instructions within this document. Those calibration procedures consisted of the drafted proposal for the future Technical Manual Procedures, however, no calibration certificate was issued. The "DRAEGER ALCOTEST 9510 CALIBRATION/ADJUSTMENT RECORD" which is generated by the instrument was utilized to document the appropriate calibration status.

Each instrument was tested over a series of five days. Each of those five days included a sampling of nine external standard solutions which were created, tested, and provided by the Washington State Toxicology Laboratory. Each of these solution concentrations were examined by the instruments for bias percentage, coefficient of variation, and difference value between the mean of the 10 samples and the reference value as provided by the laboratory. The equations listed below were used for each of the testing procedures:

For each equation below

- $x$  = mean of the 10 samples analyzed by the instrument
- $y$  = reference value of solution provided by Toxicology Laboratory
- SD = standard deviation calculated from 10 samples analyzed

$$\text{Bias \%} = \frac{x-y}{y} \cdot (100)$$

$$\text{Coefficient of Variation \%} = \frac{SD}{x} \cdot (100)$$

$$\text{Difference Value} = x-y$$

When developing acceptable bias criteria, the WSP BTP looked to the National Highway Traffic Safety Administration (NHTSA) Model Specifications for Evidential Breath Test Instruments. NHTSA Model Specifications only recommend testing at the following test standards: (QUOTED DIRECTLY FROM FEDERAL REGISTER Vol. 58, No. 179)

4.1 Test 1. Precision and Accuracy. Test at each of the specified BAC [ $SE \leq 0.005$  BAC;  $SD \leq 0.0042$ ].

Test 1.1: 0.020 BAC [ $SE \leq 0.005$  BAC;  $SD \leq 0.0042$ ]

Test 1.2: 0.040 BAC [ $SE \leq 0.005$  BAC;  $SD \leq 0.0042$ ]

Test 1.3: 0.080 BAC [ $SE \leq 0.005$  BAC;  $SD \leq 0.0042$ ]

Test 1.4: 0.160 BAC [ $SE \leq 0.008$  BAC;  $SD \leq 0.0042$ ]

The following test is information only for the potential users. There is no performance requirement.

Test 1.5: 0.300 BAC

Because the WSP BTP tested at numerous ethanol levels, (see Figure 1 below) acceptable criteria for acceptability needed to be established. The WSP BTP has long used bias criteria of +/- 5% of the reference value for its Quality Assurance standards. The NHTSA standard recommends systematic error criteria of  $\leq 0.005$  for standards tested between 0.020 and 0.080 or  $\leq 0.008$  for a standard of 0.160. For purposes of this testing, the bias criteria below was used:

- +/- 5% of reference value  
OR
- $\leq 0.005$  when the reference value is subtracted from the mean of the 10 samples for reference values 0.16 and lower and  $\leq 0.008$  for reference values above 0.16.

When choosing an acceptable precision standard, the WSP BTP has long used the standard of  $\leq 3\%$  precision. The NHTSA standard recommends a standard deviation of  $\leq 0.0042$ . However, NHTSA only recommends testing at the levels listed above: 0.02, 0.04, 0.08, and 0.160. They provide no precision acceptability standards for solutions outside of these ranges. For purposes of this testing, the precision criteria below was used:

- $\leq 3\%$  coefficient of variation  
OR
- $\leq 0.0042$  standard deviation

The following pages of this summary include accuracy and/or precision comparison charts for each instrument. The charts only include the highest single day value for each solution that was tested over five days. For accuracy/bias, this number can be either positive or negative. The number chosen from the data was the largest found from the five days of testing on each solution.

The typical data trends found were that a bias percentage of +/- 5% and precision percentage of  $\leq 3\%$  were more difficult to obtain at lower concentrations (0.04 and lower). However, when comparing the mean to the reference values, these were never outside of the  $\leq 0.005$  criteria. Similarly, some of the higher concentrations were found to be outside of the  $\leq 0.005$  or  $\leq 0.008$  criteria, but almost always met the +/- 5% criteria. The exceptions are the four instruments below. Each of these instruments failed to meet either of criteria (+/-5% bias and a difference greater than 0.005 g/210L). Those details are documented below.

### ACCURACY

- **ARAH-0084** did not meet either bias or systematic error criteria as described below:
  - Batch D00006, the EC was outside of both criteria on day 1 only
    - -7.29% bias (difference of -0.0111) day 1
  - Batch D00007, the EC was outside of both criteria on days 4 & 5
    - -5.48% bias (difference of -0.0111) day 4
    - -5.19% bias (difference of -0.0105) day 5
  - Batch D00008, the EC was outside of both criteria on days 4 & 5
    - -7.06% bias (difference of -0.0215) day 4
    - -6.14% bias (difference of -0.0187) day 5
  - Batch D00009, the EC was outside of both criteria on days 2, 4, & 5
    - -5.32% bias (difference of -0.0214) day 2
    - -6.81% bias (difference of -0.0274) day 4
    - -7.25% bias (difference of -0.0292) day 5
- **ARAH-0094** did not meet either bias or systematic error criteria as described below:
  - Batch D00007, the EC was outside of both criteria on days 2, 4, & 5
    - -5.73% bias (difference of -0.0116) day 2
    - -6.27% bias (difference of -0.0127) day 4
    - -5.68% bias (difference of -0.0115) day 5
  - Batch D00009, the EC was outside of both criteria on day 5 only
    - -5.12% bias (difference of -0.0206) day 5

- **ARAH-0103** did not meet either bias or systematic error criteria as described below:
  - Batch D00008, the EC was outside of criteria on day 5 only
    - -5.95% bias (difference of -0.0181) day 5
  - Batch D00009, the EC was outside of criteria on days 3 & 5
    - -5.59% bias (difference of -0.0225) day 3
    - -5.12% bias (difference of -0.0206) day 4
  
- **ARAH-0107** did not meet either bias or systematic error criteria as described below:
  - Batch D00005, the EC was outside of both criteria on days 2, 3, 4, & 5
    - -7.21% bias (difference of -0.0058) day 2
    - -7.09% bias (difference of -0.0057) day 3
    - -6.59% bias (difference of -0.0053) day 4
    - -7.71% bias (difference of -0.0063) day 5
  - Batch D00006, the EC was outside of both criteria on days 2, 3, 4, & 5
    - -6.64% bias (difference of -0.0101) day 2
    - -6.11% bias (difference of -0.0093) day 3
    - -6.31% bias (difference of -0.0096) day 4
    - -7.16% bias (difference of -0.0109) day 5
  - Batch D00007, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -5.24% bias (difference of -0.0106) day 1
    - -5.09% bias (difference of -0.0103) day 2
    - -6.08% bias (difference of -0.0123) day 3
    - -5.63% bias (difference of -0.0114) day 4
    - -8.40% bias (difference of -0.0170) day 5
  - Batch D00008, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -6.31% bias (difference of -0.0192) day 1
    - -6.24% bias (difference of -0.0190) day 2
    - -7.95% bias (difference of -0.0242) day 3
    - -7.82% bias (difference of -0.0238) day 4
    - -10.22% bias (difference of -0.0311) day 5
  - Batch D00009, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -6.98% bias (difference of -0.0281) day 1
    - -6.46% bias (difference of -0.0260) day 2
    - -8.07% bias (difference of -0.0325) day 3
    - -8.94% bias (difference of -0.0360) day 4
    - -9.44% bias (difference of -0.0380) day 5

Note that all of the four above instruments that were unable to obtain accuracy either by a bias percentage or a difference in values only had these on the electrochemical (EC or fuel cell sensor). In the scenarios above, none of the instruments produced bias percentages and/or difference values that were outside of tolerance on both the infrared and electrochemical sensors. In discussions with the manufacturer, some fuel cells will fatigue faster than others. The higher the alcohol volumes that these fuel cells are subjected to on a repeated basis (back to back as done in this testing) it becomes more likely to see fuel cell fatigue and values as demonstrated in the four instruments above. This is quite often remedied with replacement of a fuel cell and recalibration of the instrument.

In addition, when examining each of the above instruments that had these accuracy readings outside of tolerances it is easily seen from the data that when a fuel cell is experiencing fatigue, it begins to read ethanol lower than expected, not higher. When relating to a subject breath sample, the error is always in favor of the subject, not penalizing by causing higher than expected readings. Also, the instrument has built in safeguards to prevent a valid test from occurring when the IR value is more than a 0.008 g/210L difference from the EC value or a difference of greater than 10% in the IR vs. EC values (whichever is higher). This is the mechanism to screen for interfering substances. These interferences will not be detected when the instrument is in the Supervisory Test mode as was utilized in this testing. However, if a breath sample is being analyzed and the criteria for interfering substances is not met, the test would be aborted and an error logged in the instrument memory.

## **PRECISION**

Precision results occurred much like the accuracy results. The  $\leq 3\%$  for precision was difficult to obtain at low concentration levels (0.02 and below). However, a standard deviation of  $\leq 0.0042$  was easily obtained at these levels. Similarly, the  $\leq 3\%$  precision value was easily obtainable at higher concentration levels. However, a standard deviation of  $\leq 0.0042$  was sometimes difficult to produce at higher concentration levels (0.30 and above).

There was one outlier data set produced which yielded results that were outside of each of the precision tolerances, that data is listed below:

- **ARAH-0084** did not meet precision criteria as stated below:
  - Batch D00006, both the IR and EC values were outside of the precision criteria on day 1 only.
    - IR 4.95% CV (SD 0.0072) day 1
    - EC 5.46% CV (SD 0.0077) day 1

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Each of the other four days of testing on this instrument met the precision standards well within permissible levels and the day 1 testing appears to be an isolated incident, likely caused by a leak in the simulator or connection of simulator to the instrument. The serial numbers of the instruments that were examined are as follows:

ARAF-0029  
ARAH-0076  
ARAH-0077  
ARAH-0081  
ARAH-0084  
ARAH-0089  
ARAH-0093  
ARAH-0094  
ARAH-0103  
ARAH-0107

Each of the above instruments are the property of the Washington State Patrol and contained software developed for the Washington State Patrol by Draeger Safety Diagnostics, Incorporated.

The target values, batch numbers and reference values are listed below:

<b>SOLUTION TARGET CONCENTRATION</b>	<b>BATCH NUMBER</b>	<b>REFERENCE VALUE</b>
0.010	D00001	0.0090
0.015	D00002	0.0147
0.020	D00003	0.0204
0.040	D00004	0.0408
0.080	D00005	0.0804
0.150	D00006	0.1522
0.200	D00007	0.2024
0.300	D00008	0.3044
0.400	D00009	0.4026

Figure 1

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BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	Y	N	Y	Y	N	N	Y	Y
D00003 0.0204	Y	N	Y	Y	N	N	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	N	Y	Y	Y	Y
D00008 0.3044	Y	Y	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	Y	N	N	Y	Y	Y	Y

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COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	24.44	0.0022	25.56	0.0023
D00002 0.0147	-4.76	-0.0007	-7.48	-0.0011
D00003 0.0204	-2.45	-0.0005	-7.35	-0.0015
D00004 0.0408	-2.45	-0.0010	-7.60	-0.0031
D00005 0.0804	0.75	0.0006	-3.98	-0.0032
D00006 0.1522	2.23	0.0034	-2.43	-0.0037
D00007 0.2024	2.32	0.0047	-4.69	-0.0095
D00008 0.3044	1.91	0.0058	-3.32	-0.0101
D00009 0.4026	3.06	0.0123	-4.32	-0.0174

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0076

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	Y	Y	Y	Y	N	Y	Y	Y
D00003 0.0204	N	N	Y	Y	Y	Y	Y	Y
D00004 0.0408	Y	Y	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	Y	Y	Y	Y	Y
D00008 0.3044	Y	Y	N	Y	Y	Y	Y	Y
D00009 0.4026	Y	Y	N	N	Y	Y	N	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0076

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	<b>21.11</b>	<b>0.0019</b>	<b>15.56</b>	<b>0.0014</b>
D00002 0.0147	<b>-4.76</b>	<b>-0.0007</b>	<b>-4.76</b>	<b>-0.0007</b>
D00003 0.0204	<b>-6.86</b>	<b>-0.0014</b>	<b>-6.86</b>	<b>-0.0014</b>
D00004 0.0408	<b>2.94</b>	<b>0.0012</b>	<b>-3.92</b>	<b>-0.0016</b>
D00005 0.0804	<b>3.11</b>	<b>0.0025</b>	<b>-3.61</b>	<b>-0.0029</b>
D00006 0.1522	<b>3.29</b>	<b>0.0050</b>	<b>0.59</b>	<b>0.0009</b>
D00007 0.2024	<b>3.46</b>	<b>0.0070</b>	<b>2.87</b>	<b>0.0058</b>
D00008 0.3044	<b>3.88</b>	<b>0.0118</b>	<b>1.61</b>	<b>0.0049</b>
D00009 0.4026	<b>3.50</b>	<b>0.0141</b>	<b>-3.83</b>	<b>-0.0154</b>

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0077

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN – REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN – REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	Y	N	Y	Y	Y	Y	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	Y	Y	Y	Y	Y
D00008 0.3044	Y	Y	N	Y	Y	Y	Y	Y
D00009 0.4026	Y	Y	Y	N	Y	Y	N	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0077

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	18.89	0.0017	16.67	0.0015
D00002 0.0147	12.24	0.0018	-5.44	-0.0008
D00003 0.0204	-4.41	-0.0009	-6.86	-0.0014
D00004 0.0408	-2.45	-0.0010	-5.64	-0.0023
D00005 0.0804	-0.75	-0.0006	-3.86	-0.0031
D00006 0.1522	1.25	0.0019	-2.56	-0.0039
D00007 0.2024	1.24	0.0025	-1.73	-0.0035
D00008 0.3044	3.52	0.0107	-1.97	-0.0060
D00009 0.4026	1.04	0.0042	-2.71	-0.0109

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0081

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN – REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN – REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	Y	N	Y	Y	N	Y	Y	Y
D00004 0.0408	Y	Y	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	N	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	Y	Y	Y	Y	Y
D00008 0.3044	Y	Y	N	Y	Y	Y	N	N
D00009 0.4026	Y	Y	N	N	Y	Y	N	N

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0081

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	14.44	0.0013	12.22	0.0011
D00002 0.0147	-6.80	-0.0010	-5.44	-0.0008
D00003 0.0204	2.45	0.0005	-6.86	-0.0014
D00004 0.0408	1.23	0.0005	-3.19	-0.0013
D00005 0.0804	2.61	0.0021	-2.86	-0.0023
D00006 0.1522	3.61	0.0055	2.23	0.0034
D00007 0.2024	3.36	0.0068	2.92	0.0059
D00008 0.3044	3.88	0.0118	-2.20	-0.0067
D00009 0.4026	2.86	0.0115	-2.14	-0.0086

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0084

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	N	N	Y	Y	Y	Y	Y	Y
D00004 0.0408	N	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	N	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	N	N	N	N	N	N	N
D00007 0.2024	Y	N	Y	N	Y	Y	Y	Y
D00008 0.3044	Y	N	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	N	Y	N	Y	Y	Y	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0084

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	24.44	0.0022	21.11	0.0019
D00002 0.0147	10.88	0.0016	-11.56	-0.0017
D00003 0.0204	-6.86	-0.0014	-12.25	-0.0025
D00004 0.0408	-5.39	-0.0022	-10.54	-0.0043
D00005 0.0804	-2.24	-0.0018	-6.09	-0.0049
D00006 0.1522	-4.47	-0.0068	-7.29	-0.0111
D00007 0.2024	-1.98	-0.0040	-5.48	-0.0111
D00008 0.3044	-2.17	-0.0066	-7.06	-0.0215
D00009 0.4026	-1.22	-0.0049	-7.25	-0.0292

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0089

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	N	N	Y	Y	N	N	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	Y	Y	Y	Y	N
D00008 0.3044	Y	Y	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	Y	Y	N	Y	Y	Y	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0089

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	12.22	0.0011	23.33	0.0021
D00002 0.0147	-5.44	-0.0008	-6.80	-0.0010
D00003 0.0204	-5.88	-0.0012	-6.37	-0.0013
D00004 0.0408	-3.92	-0.0016	-5.15	-0.0021
D00005 0.0804	-1.12	-0.0009	-3.98	-0.0032
D00006 0.1522	3.15	0.0048	-2.89	-0.0044
D00007 0.2024	-0.99	-0.0020	-3.26	-0.0066
D00008 0.3044	-1.18	-0.0036	-4.73	-0.0144
D00009 0.4026	1.14	0.0046	-4.37	-0.0176

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0093

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	Y	N	Y	Y
D00003 0.0204	N	N	Y	Y	N	N	Y	Y
D00004 0.0408	Y	Y	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	Y	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	Y	Y	Y	Y	Y
D00008 0.3044	Y	Y	Y	Y	Y	Y	Y	Y
D00009 0.4026	Y	Y	N	N	Y	Y	Y	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0093

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	28.89	0.0026	25.56	0.0023
D00002 0.0147	-5.44	-0.0008	-8.84	-0.0013
D00003 0.0204	-14.22	-0.0029	-18.14	-0.0037
D00004 0.0408	-2.21	-0.0009	-4.66	-0.0019
D00005 0.0804	-3.23	-0.0026	-4.98	-0.0040
D00006 0.1522	2.43	0.0037	-2.43	-0.0037
D00007 0.2024	2.96	0.0060	3.11	0.0063
D00008 0.3044	1.81	0.0055	1.51	0.0046
D00009 0.4026	2.31	0.0093	2.26	0.0091

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0094

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	N	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	Y	Y	Y
D00003 0.0204	Y	N	Y	Y	N	N	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	N	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	N	Y	Y	Y	Y
D00007 0.2024	Y	N	Y	N	Y	Y	Y	Y
D00008 0.3044	Y	Y	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	N	Y	N	Y	Y	Y	Y

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0094

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	24.44	0.0022	17.78	0.0016
D00002 0.0147	-6.12	-0.0009	-12.24	-0.0018
D00003 0.0204	-4.90	-0.0010	-11.76	-0.0024
D00004 0.0408	-2.94	-0.0012	-8.33	-0.0034
D00005 0.0804	-1.37	-0.0011	-5.47	-0.0044
D00006 0.1522	1.18	0.0018	-4.86	-0.0074
D00007 0.2024	-2.03	-0.0041	-6.27	-0.0127
D00008 0.3044	-0.66	-0.0020	-4.73	-0.0144
D00009 0.4026	-0.47	-0.0019	-5.12	-0.0206

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
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ARAH-0103

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	Y	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	Y	N	Y	Y	Y	Y	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	Y	Y	Y	Y	Y	Y	Y
D00006 0.1522	Y	Y	Y	N	Y	Y	Y	Y
D00007 0.2024	Y	Y	Y	N	Y	Y	Y	Y
D00008 0.3044	Y	N	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	N	Y	N	Y	Y	N	N

WASHINGTON STATE PATROL-IMPAIRED DRIVING SECTION-BREATH TEST PROGRAM  
DRAEGER 9510 VALIDATION

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ARAH-0103

COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	-4.44	-0.0004	-8.89	-0.0008
D00002 0.0147	-10.20	-0.0015	-14.97	-0.0022
D00003 0.0204	-3.92	-0.0008	-8.33	-0.0017
D00004 0.0408	-4.41	-0.0018	-7.60	-0.0031
D00005 0.0804	-1.12	-0.0009	-4.98	-0.0040
D00006 0.1522	-1.51	-0.0023	-3.88	-0.0059
D00007 0.2024	-1.58	-0.0032	-4.30	-0.0087
D00008 0.3044	-1.94	-0.0059	-5.95	-0.0181
D00009 0.4026	-1.49	-0.0060	-5.59	-0.0225

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

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BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE ≤ 0.005 I/R SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE ≤ 0.005 E/C SENSOR OR ≤0.008 FOR BATCH D00007 D00008 D00009	CV ≤ 3% I/R SENSOR	CV ≤ 3% E/C SENSOR	STANDARD DEVIATION ≤ 0.0042 I/R SENSOR	STANDARD DEVIATION ≤ 0.0042 E/C SENSOR
D00001 0.0090	Y	N	Y	Y	N	N	Y	Y
D00002 0.0147	N	N	Y	Y	N	N	Y	Y
D00003 0.0204	N	N	Y	Y	N	Y	Y	Y
D00004 0.0408	Y	N	Y	Y	Y	Y	Y	Y
D00005 0.0804	Y	N	Y	N	Y	Y	Y	Y
D00006 0.1522	Y	N	Y	N	Y	Y	Y	Y
D00007 0.2024	Y	N	Y	N	Y	Y	Y	Y
D00008 0.3044	Y	N	Y	N	Y	Y	Y	Y
D00009 0.4026	Y	N	Y	N	Y	Y	Y	Y

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COLUMNS	A	B	C	D
BATCH # AND REF VALUE	GREATEST BIAS PERCENTAGE I/R	DIFFERENCE MEAN-REF I/R VALUE FROM COMPARING VALUE FROM COLUMN A	GREATEST BIAS PERCENTAGE E/C	DIFFERENCE MEAN-REF E/C VALUE FROM COMPARING VALUE FROM COLUMN C
D00001 0.009	1.11	0.0001	-11.11	-0.0010
D00002 0.0147	-10.20	-0.0015	-13.61	-0.0020
D00003 0.0204	-6.86	-0.0014	-12.25	-0.0025
D00004 0.0408	-4.66	-0.0019	-11.76	-0.0048
D00005 0.0804	-1.74	-0.0014	-7.71	-0.0062
D00006 0.1522	-1.71	-0.0026	-7.16	-0.0109
D00007 0.2024	-0.94	-0.0019	-8.40	-0.0170
D00008 0.3044	-1.54	-0.0047	-10.22	-0.0311
D00009 0.4026	-1.09	-0.0044	-9.44	-0.0380

COLUMN A: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT I/R DETECTOR (POSITIVE OR NEGATIVE)

COLUMN B: USING SAME VALUES THAT DETERMINED COLUMN A, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE

COLUMN C: GREATEST OR LARGEST BIAS PERCENTAGE FOUND DURING 5 DAYS OF TESTS AT E/C DETECTOR (POSITIVE OR NEGATIVE)

COLUMN D: USING SAME VALUES THAT DETERMINED COLUMN C, THE DIFFERENCE BETWEEN THE MEAN OF THE SAMPLES FROM THE REFERENCE VALUE