

## TESTING SUMMARY

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  $\pm 5\%$  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:

- $\pm 5\%$  of reference value  
OR
- $\leq 0.005$  of when the reference value is subtracted from the mean of the 10 samples for reference values 0.15 and lower and  $\leq 0.008$  for reference values of 0.151 and higher.

When choosing an acceptable precision standard, the WSP BTP has long used the standard of  $\leq 3\%$  repeatability. 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  $\pm 5\%$  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  $\pm 5\%$  criteria. The exceptions are the four instruments below. Each of these instruments failed to meet either of criteria ( $\pm 5\%$  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 above 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

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

ARAF-0029

BATCH # AND REF VALUE	BIAS WITHIN +/- 5% ON I/R SENSOR	BIAS WITHIN +/- 5% ON E/C SENSOR	MEAN - REF VALUE $\leq$ 0.005 I/R SENSOR OR $\leq$ 0.008 FOR BATCH D00007 D00008 D00009	MEAN - REF VALUE $\leq$ 0.005 E/C SENSOR OR $\leq$ 0.008 FOR BATCH D00007 D00008 D00009	CV $\leq$ 3% I/R SENSOR	CV $\leq$ 3% E/C SENSOR	STANDARD DEVIATION $\leq$ 0.0042 I/R SENSOR	STANDARD DEVIATION $\leq$ 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



ARAF-0029

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

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

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	21.11	0.0019	15.56	0.0014
D00002 0.0147	-4.76	-0.0007	-4.76	-0.0007
D00003 0.0204	-6.86	-0.0014	-6.86	-0.0014
D00004 0.0408	2.94	0.0012	-3.92	-0.0016
D00005 0.0804	3.11	0.0025	-3.61	-0.0029
D00006 0.1522	3.29	0.0050	0.59	0.0009
D00007 0.2024	3.46	0.0070	2.87	0.0058
D00008 0.3044	3.88	0.0118	1.61	0.0049
D00009 0.4026	3.50	0.0141	-3.83	-0.0154

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

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



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

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

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



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



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

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

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



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

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

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



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



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

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

ARAH-0107

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



ARAH-0107

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)

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