Draeger Alcotest 9510 Verification Executive Summary

Introduction:

The Draeger Alcotest 9510 instrument is designed to obtain evidential breath alcohol test results with a high level of evidential reliability. The 9510 employs two different and independent analytical technologies for the analysis and quantitation of the subject's breath alcohol concentration. The use of both infrared spectroscopy and electro-chemical fuel cell technology offers a high level of forensic analytical integrity for the samples.

The IR system operates at the 9.5 micron wavelength and is not susceptible to the vast majority of potentially interfering substances on human expired breath from a subject. It also eliminates the need for mechanical moving parts that are often associated with the use of multiple different filters. The fuel cell technology is known for its high degree of accuracy, reliability, specificity and fast recovery between samples. The use of two different analytical systems also offers the system the ability to provide a true ambient air check prior to the introduction of a sample into the sample chamber. The fuel cell allows for the IR system to set a true zero point for analysis.

By utilizing certified dry gas standards for the performance verifications, the Draeger 9510 will be able to ensure a high degree of accuracy and reliability for the quantitative results. The dry gas system, which has dual cylinder capabilities, can also employ two different concentrations for use as an external standard. Through advances in technology, the periodic performance verifications can also be done automatically. This will ensure that the monthly verifications of the 0.200 concentration will be performed and the occasional lapse can be avoided.

The modern design and technology allows for the integration of communication and data storage/backup capabilities. The test results can be quickly 'pushed' to a database server for retention as well as discoverability of the redacted results from a secure server host. This will maintain the instrumental and procedural redundancies for the critical documentation of evidential breath testing results.

Ethyl Alcohol Analysis:

The 9510 was tested with both wet bath standards as well as with certified dry gas standards. The 9510 responded well within specifications and showed no aberrations within its results. The capabilities of the instrument also allow for the 'matching' of the two technologies within the calibration routine. Since the fuel cell is a chemical process, the differences observed between the wet bath standard results (with 100% humidity saturation of the sample) and the dry gas standards (with no water/humidity) can be easily remedied through a simple adjustment to the dry gas offset of the fuel cell. Since the components of the fuel cell are hygroscopic (water loving) the alcohol within a humid sample will be 'pulled into' the fuel cell faster than that of a dry gas ethanol standard. This happens at a constant rate and can be adjusted by an ISP certified analyst to match within the menu options. For raw data results, see the attached data.

RFI and interferrents:

The RFI immunity of the instrument was demonstrated and documentation of its analysis and testing was reviewed at the Draeger facility in Irving, TX during the factory training received by ISPFS personnel. The RFI testing showed that the instrument was sufficiently shielded to provide RFI immunity throughout the frequency ranges commonly encountered. For full analysis of the RFI data and study results, please contact Draeger Safety Diagnostics, Inc., at 1-866-385-5900.

In addition to the RFI testing that was conducted by Draeger, the 9510 unit was tested in Idaho and showed no detectable reaction when present during the acquisition of the breath test. The RFI would theoretically affect the results if present during the acquisition of the breath samples, so 2 instruments were evaluated using standard police officer shoulder radio equipment (Motorola XTS 2500 both old and new model versions). The instrument was provided with alcohol negative breath samples and it showed no reaction when RFI was presented throughout the breath sampling. The raw data results are attached.

Commonly encountered interferrents on human expired breath include but at not limited to acetone, isopropyl alcohol and methanol. All three substances were tested at varying levels. Although the levels might not be physiologically possible, they were tested to prove the instruments capabilities and lack of response to these substances. Sufficient indications for each substance would be considered to 'pass' if the interferrent was flagged as an interfering substance, or produced no viable result upon introduction to the instrument. The three substances were tested at both the 0.100 v/v level as well as the 0.400 v/v level. For all three substances, the 0.400 level represents a physiologically unachievable level in human expired breath.

Acetone tested at the 0.100 level resulted in IR/EC values of 0.005/0.002, 0.005/0.001, 0.004/0.002, and 0.004/0.001 for the lower level testing. At the higher level (0.400), the IR/EC results (0.019/0.003) were flagged as INTERFERENT DETECTED and the testing sequence was aborted. Acetone shows no reaction within the fuel cell and shows little to no IR absorption in the 9.5 micron region. This shows that the instrument performs as expected for physiologically relevant and non-relevant levels. See attached data.

Isopropyl alcohol tested at the 0.100 level resulted in IR/EC values of 0.025/0.062 and was flagged as INTERFERENT DETECTED and the testing sequence was aborted. At the higher level (0.400), the IR/EC results (0.094/0.230) were flagged as INTERFERENT

DETECTED and the testing sequence was aborted. Isopropyl alcohol shows a reduced reaction within the fuel cell and shows reduced IR absorption in the 9.5 micron region. This shows that the instrument performs as expected for physiologically relevant and non-relevant levels. See attached data.

Methyl alcohol poses a unique challenge for the 9510 because is exhibits distinct absorption in the 9.5 micron region as well as reaction within the fuel cell technology. Methanol, however, being a different chemical than ethyl alcohol, will react at a different rate on the fuel cell. This analysis allows the instrumental technology to differentiate methanol from ethanol within the diagnostic system. Methanol tested at the 0.100 level resulted in IR/EC values of 0.090/0.121 and was flagged as INTERFERENT DETECTED and the testing sequence was aborted. At the higher level (0.400), the IR/EC results (0.352/0.438) were flagged as INTERFERENT DETECTED and the testing sequence was aborted. Methyl alcohol shows an increased reaction within the fuel cell and shows reduced IR absorption in the 9.5 micron region. This shows that the instrument performs as expected for physiologically relevant and non-relevant levels. See attached data.

Fluorinated hydrocarbons are present in many over the counter products (computer dusters, air in a can, etc.) and pose a potential interferrent as an inhalant if abused. These substances are highly volatile and will show up on human expired breath if ingested/inhaled. The instrument was tested utilizing Difluoroethane (DFE) that was introduced directly into the mouthpiece as well as into water within a simulator. The concentration used was not possible to quantitate due to the high volatility of the substance and the inability to obtain certifiable concentration reference standards. The substance, when introduced into the analytical system, showed a marked absorption profile and since it is so highly volatile, it presented itself as a majority in the initial breath through the instrument. In the testing where the substance was introduced directly into the mouth piece, it was flagged as mouth alcohol and also exceeded the measurement range of the instrument (0.630). Upon introduction into the water simulator, the sample showed a mouth alcohol breath alcohol profile on both testing opportunities. This shows that the instrument performs as anticipated with difluoroethane within the instrument. See the attached data for the raw testing results for the interfering substances testing.

Software:

The current version of software that was validated for this instrument:

Measurement System - 8325419, Ver. 1.2, Checksum 0x8AB4

Windows CE System - 8325418, Ver. 1.2, Checksum 0xDEBE

Configuration - 8325417, Ver. 1.3, AP/NAP CRC 0x283A / 0x69C6

Initial Uncertainty of Measurement:

The individual units have statistical capabilities to analyze and record their individual statistical data associated with the analysis of the performance verification check standard results and calculate the standard deviations and relative standard deviations. During the validation process, the initial uncertainty of measurement (UM) was assessed and the combined relative standard deviations were calculated. The results were as follows.

Individual standard deviations:

	Instrument	ARFK-0002	ARFK-0003	ARFK-0004
0.040:	std dev:	0.000801	0.000394	0.000605
	Rel std dev:	2.003%	0.985%	1.512%
0.080:	std dev:	0.000598	0.000503	0.000788
	Rel std dev:	0.748%	0.628%	0.985%
0.200:	std dev:	0.001129	0.002007	0.003626
	Rel std dev:	0.564%	1.004%	1.813%

The instrument performed within specifications and taking the worst case scenario for the UM, the relative standard deviations (normalized by percent of target) show that the instrument performs within ~+/-2% of target at each level, with the majority of analyses being half of that value. It would be a safe assessment to assert that the instrument reports the values to +/- 2%. This value will represent the initial UM until each instrument is able to generate enough data to compile its own UM data in the form of the standard deviations and relative standard deviations.

Method Validation:

During the validation process for the instrument, the method that was created (BrAC method 7.0) for the initial certification and re-certification of the units was tested fully. Instruments were taken out of calibration and then utilizing the method, were brought back into conforming specifications. All tested units passed their method certification process and are all performing within specification for laboratory certification.

The participating individuals in the method validation will utilize that participation as their competency testing for the use of the method for purposes of certification and re-certification of the Alcotest 9510 instruments. Rachel Cutler and Jeremy Johnston participated fully in the method validation. Individuals that did not participate fully will need to complete a competency test prior to being signed off to utilize the BrAC method 7.0.

Conclusion:

The instrument meets or exceeds the standards for testing set out in the instrumental validation plan. The software has been validated and the final version number will be established prior to final approval of the instrument and the use of the units within the field. All data associated with the validation study is kept centrally with the Volatiles Analysis Discipline Leader in hard copy and/or electronic format.

Jeremy Johnston

Volatiles Analysis Discipline Leader

Idaho State Police Forensics