COMMONWEALTH OF MASSACHUSETTS

ESSEX, SS.

CONCORD DISTRICT COURT
NO. 1248CR1075 and others

COMMONWEALTH

v.

EVANDO ANANIAS and OTHERS

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE BREATH ALCOHOL CONTENT PERCENTAGE RESULTS USING THE ALCOTEST 9510 AND ANY OPINION TESTIMONY

The Consolidated Defendants have moved to exclude from any trial any and all evidence derived from the results of the Alcotest 9510, including any and all opinion evidence, as unreliable and inadmissible. In the alternative, the Consolidated Defendants move for a hearing wherein the proponent of the evidence, the testing results produced by the Alcotest 9510 and any and all opinion testimony, must demonstrate that the evidence is reliable and admissible. As stated in their motion to exclude, the failure to exclude such evidence, or alternatively, to require the proponent to demonstrate its reliability would violate the Consolidated Defendants' rights to due process, a fair trial, the confrontation of witnesses, to present a defense, to not have unreliable evidence presented, under the 5th, 6th and 14th Amendments to the Federal Constitution, art. 12 of the Massachusetts Declaration of Rights, the common law's prohibition to the introduction of unreliable evidence. See Commonwealth v. Camblin, 471 Mass. 639 (2015); Commonwealth v. Lanigan, 419 Mass. 15 (1994); Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993); Kumho Tire Co. v. Carmichael, 562 U.S. 1 (1999); Massachusetts Guide to Evidence, Section 702; see also Strengthening Forensic Science in the United States: A Path Forward, National Research Council, National Academies Press (2009).

This memorandum does not purport to lay out all the complexities of the issues being challenged. In accordance with the parties' understanding, this memorandum outlines the various issues and incorporates by reference the various expert reports submitted to the court on December 5, 2016.[1] Accordingly, this memorandum is a summary of the issues being challenged and that must be addressed by the Commonwealth to the satisfaction of the court acting as gatekeeper before any such evidence can be determined to be reliable and admissible.

A.

SUMMARY OF RELEVANT LAW

As relevant case law makes clear, "[i]f the process or theory underlying a scientific expert's opinion lacks reliability, that opinion should not reach the trier of fact." Commonwealth v. Lanigan, 419 Mass. 15, 26 (1994). The trial court has an critical role: "As a gatekeeper, the judge must make a preliminary assessment whether the theory or methodology underlying the proposed testimony is sufficiently reliable to reach the trier of fact." Commonwealth v. Shanley, 455 Mass. 752, 761 (2010).

> For these purposes, expert testimony is sufficiently reliable if the underlying theory or methodology is either (1) generally accepted in the relevant scientific community, see Frye v. United States, 296 F. 1013 (D.C. Cir. 1923); or (2) satisfies the alternative requirements adopted in Lanigan, supra, at 25-26.

Shanley, supra, 455 Mass. at 761. "[R]eliability, not cross-examination, is the 'due process touchstone.'" Commonwealth v. Given, 441 Mass. 741, 747 n.9 (2004), quoting Commonwealth v. Durling, 407 Mass. 108, 115 (1990) .

Defining what is the relevant scientific community is a critical aspect of the inquiry. "A

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[1]The Consolidated Defendants are mindful of the Protective Order and the limitations placed on publishing what may be considered confidential information.

relevant scientific community must be defined broadly enough to include a sufficiently broad sample of scientists so that the possibility of disagreement exists." Canavan's Case, 432 Mass. 304, 314 n.6 (2000). It is important to note that given that many of the challenges are grounded in the unreliability of the source code that is used in the Alcotest 9510, it is the software industry, which is the relevant community for "general acceptance" of the source code. This simple proposition makes it clear that it is not any community of breathalyzer manufacturers or certifying agencies that make up this relevant and distinct community.

A prior finding that a methodology and accompanying opinion testimony is sufficiently reliable does not eliminate the need to revisit the issue. "[The Court] ha[s] not 'grandfathered' any particular theories or methods for all time, especially in areas where knowledge is evolving, and new understandings may be expected as more studies and tests are conducted." Commonwealth v. Shanley, supra, 455 Mass. at 763 n.15. "Judges, however, need not admit (and juries need not wrestle with) every application of a testing method -- no matter how dubious -- merely because another application of the method has been deemed reliable." Commonwealth v. Patterson, 445 Mass. 626, 648 (2005). It is understood that "[f]uture challenges should focus on the soundness . . . of the particular testing process . . . and, if raised, on the proper implementation of that process in the given case." Id., quoting Commonwealth v. Curnin, 409 Mass. 218, 222 n.7 (1991).

As the gatekeeper, a court must exercise its discretion in determining whether a hearing to determine the reliability of a methodology is to be conducted and the scope of any hearing. The record must be clear, otherwise an appellate court is "unable to ascertain how the judge would have ruled on the admissibility of the [] evidence" had he exercised his discretion.

Commonwealth v. Barrett, 418 Mass. 788, 795-796 (1994). The Supreme Judicial Court, in reviewing a challenge to an earlier breathalyzer machine, stated that "[w]ere [the Court] to leave to the jury the highly technical issue of the reliability of [the breathalyzer machine, Smith & Wesson Breathalyzer Model 900A,], the end result, in all likelihood, would be confusion instead of enlightenment.'" Commonwealth v. Neal, 392 Mass. 1, 19 (1984), quoting Commonwealth v. Fatalo, 346 Mass. 266, 269 (1963). And the Neal court was concerned with a "battle of the experts" and instructed on the "desirability of judicial determination" in order to avoid "the danger that on the introduction of such evidence a trial could descend into a battle of the experts on the probative value of the . . . . test rather than a determination of the guilt or innocence of a defendant." Id.

The defendant acknowledges that not every challenge to the reliability of a scientific test or methodology necessitates a Daubert-Lanigan hearing as a matter of right. See e.g., Commonwealth v. Sliech-Brodeur, 457 Mass. 300, 327-328 (2010). Abuse of discretion is the standard to be applied or "whether [the court's ruling] was otherwise tainted with error of law." See Commonwealth v. Devlin, 365 Mass. 149, 152 (1974). "Where the record shows that the judge has failed to exercise discretion, there exists an error of law requiring reversal." Commonwealth v. Adjutant, 443 Mass. 649, 666 (2005).

In the context of the Consolidated Defendants' rights to challenge the Alcotest 9510 and to require its proponent to demonstrate its reliability to the gatekeeper, it is a well-accepted axiom that "[f]undamental fairness entitles [these consolidated defendants] defendants to 'an adequate opportunity to present their claims fairly within an adversary system" as required by their rights to a fair trial and due process of law as guaranteed by Article 12 of the Massachusetts

Declaration of Rights and the Fourteenth Amendment to the United States Constitution..]'" Ake v. Oklahoma, 470 U.S. 68, 77 (1985), quoting Ross v. Moffitt, 417 U.S. 600, 612 (1974).

The Alcotest 9510 is a different machine than the models examined in prior proceedings. See e.g., State v. Chun, 194 N.J. 54 (2008), and Commonwealth v. Camblin, 471 Mass. 639 (2015)(both dealing with the Alcotest 7110). The reliability of the breathalyzer machine in Camblin has yet to be determined by a Massachusetts appellate court. At this juncture, the Alcotest 9510, its methodology, the source code utilized and some of the underlying principles relied upon in its functioning must be carefully scrutinized as "novel." When novel scientific tests purport to apply generally accepted scientific principles, for example, like evolving DNA testing methodologies, latent print examination and firearms and toolmarks, and breathalyzers, the general acceptance at issue is whether the new technique accurately and reliably implements the generally accepted scientific principles.

> Future challenges should focus on the soundness and general acceptance of the particular testing process for forensic use, and, if raised, on the proper implementation of that process in the given case. Until such questions are resolved by a judge, a jury should not be given the evidence and allowed to determine the validity and soundness of the process because evidence of this character has too great a potential for affecting a jury's judgement.

Commonwealth v. Curnin, supra, 409 Mass. 218, 222 n.7 (emphasis added).

The Consolidated Defendants recognized that when determining the reliability of a methodology, that this court may look to opinion of courts in other jurisdictions. Commonwealth v. Kater, 388 Mass. 519, 527 (1983); but compare Commonwealth v. Camblin, supra. However, great caution must be exercised where the methodology at issue is different, novel or evolving, and especially where the issues raised are not identical and the challenges are more specific then

previous challenges. As noted, the Alcotest 9510's reliability has not been determined, What's more, the Consolidated Defendants have caused dynamic testing to be conducted, an analysis that neither the manufacture nor the Commonwealth has done on the Alcotest 9510. Accordingly, the Commonwealth should be precluded at this juncture from challenging the relevant findings and should be required to demonstrate reliability of the Alcotest 9510 using a combination of static code review and dynamic testing.

B.

The Consolidated Defendants set forth below the issues that render the Alcotest 9510 unreliable and any related opinion evidence inadmissible. The Consolidated Defendants have filed six expert reports on December 5, 2016, supporting each one of these issues and expects that at any hearing, the issues will be further explained in greater detail.[2] The expert reports are incorporated herein by reference. This memorandum will rely upon and not repeat herein the experts' descriptions of the software, firmware and physical characteristics of the Alcotest 9510 contained in detailed fashion in their reports. In addition, this memorandum does not repeat the experts' qualifications as they are likewise detailed in their reports or contained in *curriculum vitae* attached where submitted.[3]

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[2] The Consolidated Defendants were only required to submit expert reports on December 5, 2016, specifically concerning the static and dynamic testing conducted. The Consolidated Defendants nonetheless submitted additional reports to help frame all of the issues and to provide notice to the Commonwealth. In contrast, the Commonwealth did not file any expert reports on or after December 5, 2016.

[3] An expert's report is cited by using the expert's initials followed by the relevant page numbers of the specific report. The six experts are as follows: Evan Kovanis ("EK"); Jacob Harel ("JH"); Dr. Andreas Stolz ("AS"); Dr. Michael Hlastala ("MH"); Dr. Joseph Anderson ("JoA"); and Janine Arvizu ("JaA").

Two of the six reports of experts who conducted static and dynamic testing of the Alcotest 9510 and their conclusions are set forth below. Many of the issues raised by these two experts and additional experts are set forth in Section C., below.

In summary, Evan Kovanis, concluded that based on his static and dynamic analysis of the Alcotest 9510 source code and system, that "that the firmware source code running on the embedded Renesas M16 processor contains numerous conditions that call into question the accuracy and reliability of the firmware during normal operation[,]" including "(i) unchecked return values that can ignore errors in the analysis, (ii) hardware configuration errors that indicate the EC sensor is not present, (iii) uninitialized variables that introduce uncertainty into the analysis, (iv) data management and integrity inconsistencies and problems, (v) clipped sensor measurements that obscure sensor measurements, (vi) hardware error checking that may not accurately report device failures, (vii) absence of a revision control system, and (viii) lack of adherence to programming best practices." EK at 38. In addition, Evan Kovanis concluded that "the Windows CE software running on the Cirrus Logic processor in the Draeger Alcotest 9510 contains numerous conditions that could cause the software to output inaccurate results during normal operation[,]" and that "the 9510 Windows CE software exposed issues in the source code that include (I) a security access key that could be copied to enable access to 9510 system settings, (ii) an easily guessed and unencrypted security string phrase, and (iii) an unencrypted security access key that could allow unauthorized modification of the 9510 system[,]" and that "[t]hese software issues indicate the breath alcohol test results produced by the Alcotest 9510 should not be considered reliable." EK at 38.

Additionally, Jacob Harel, conducted extensive testing of the Alcotest 9510 and

concluded as follows: System accuracy testing rendered correct results for wet simulator testing but calibration verification tests showed drifts in measurement of the infrared sensor as high as 5% using dry gas concentrations of 0.2%, concluding that the "accuracy of the system with higher concentration is lower." JH at 17. The application and use of the USB Access Key demonstrates a potential security vulnerability permitting an unauthorized person to counterfeit the USB key and later system configuration and parameters that in turn affect the BAC testing results. JH at 18. The electrochemical sensor reports an error message at times of fatigue but nonetheless permits other tests to proceed and this is critical since the Alcotest 9510 relies on agreement between relevant values derived from the infrared and electrochemical sensors and unreliable results from the latter would directly impact the reliability of the Alcotest 9510 results. System calibration of the Alcotest 9510 is complicated requiring significant operator involvement including calculating correction factors based on system results and retesting that can result in inaccurate measurement of BAC %. JH at 18 - 19. Interfering chemicals are not accurately detected by the Alcotest 9510. JH at 19. There is a lack of traceability of test results that directly impact the reliability and accuracy of any reported results. JH at 19.

SPECIFIC ISSUES AND EXPERT CONCLUSIONS

1. The source code utilized in the Alcotest 9510 fails to meet accepted industry standards and best practices as it concerns revision control systems, programming best practices and security practices and the use of a USB access key, in the relevant field that results in unreliable Breath Alcohol Content Percentage ("BAC %") results.

Evan Kovanis detailed in his report that the failure of the manufacturer to use adequate revision control systems prevents adequate source code modification and monitoring of changes being made to the source code, and that this "indicates that industry best practices may not have

been followed" and "goes against accepted standards in the computer science community." EK at 34 - 35. In addition, he explained that the failure to use industry best practices indicate the lack of quality of the 9510 source code wherein he found mistakes, empty code statements, and programming code that fails to execute as expected such as with conditional values. EK at 35 - 36. He also determined there were a variety of serious security problems with the use of a removable USB Access Key that is not encrypted, can be copied by anyone, uses a phrase that can be easily guessed and therefore permits "an unauthorized person the ability to modify significant aspects of the 9510 software that runs on the Alcotest 9510 hardware." EK at 36 - 38.

2. The source code utilized in the Alcotest 9510 operates using unchecked return values resulting in unreliable BAC % results.

Evan Kovanis describes in detail how the 9510 "consistently fails to check function return values" that are intended to "indicate whether the tasks of a function were executed without error." EK at 14 - 15. He specifically describes how certain critical functions are called but not checked, a programming code practice not "generally accepted" in the computer science community. EK at 15. He further explained how certain functions share memory that results in his observing that 94 of 294 calls ignored the relevant return value, having a direct impact on the 9510's ability to properly calculate the BAC. EK at 16 - 17.

3. The source code utilized in the Alcotest 9510 utilizes an electrochemical sensor bit location in hardware configuration that results in unreliable BAC % results.

Evan Kovanis explains how the manufacturer's firmware makes mistakes as it seeks to control the function of the critical component, the electrochemical sensor. "It appears that the 9510 source code makes a mistake in the decimal value assigned" that "impacts a number of

conditional statements and execution paths" by reporting in essence that the electrochemical sensor is "off" when in fact it is "on". EK at 17 - 18. "This situation may impact system accuracy since the ... variable is used throughout the 9510 system to ensure accurate operation." EK at 18. As further explained, this directly impacts the accuracy of the electrochemical sensor and its related functioning to the infrared sensor and would permit "errors" going "undetected." EK at 19 - 20. "Since this error value, which is used to flag a breath test as faulty, remains undetected, the results of the test cannot be deemed reliable." EK at 20.

4. The source code utilized in the Alcotest 9510 operates using uninitialized variables that results in unreliable BAC % results.

Evan Kovanis explains using various examples of the effect the Alcotest 9510's source code programming use of uninitialized variable. EK at 21 - 25. What he demonstrates is that the values stored before the variable is accurately and properly initialized results in inaccurately reflecting the output value of one of the key components of the machine, the infrared sensor. EK at 22. This in turn directly affects the certainty and reliability of the sensor's measurement, having a "direct impact on the reliability of the final Blood Alcohol Content Percentage[.]" EK at 23. "In other words, the reliability of the test results produced by the 9510 firmware cannot be confirmed due to the uninitialized variables in its source code." EK at 23. And the observed uninitialized variables directly affect other key components and the measurements derived and relied on the machine purporting to be accurate, that is, the cuvette and the breath hose and its heating element. EK at 24. These programming errors are not generally accepted. EK at 24 - 25.

5. The source code utilized in the Alcotest 9510's has flawed data integrity and management programming that results in unreliable BAC % results.

Evan Kovanis specifically describes how the infrared sensor values are used to calculate the final breath test result. EK at 25 - 27. This enables him to explain thereafter the significance of the lack of data integrity and management in the Alcotest 9510 firmware. For instance, he explains how critical baseline measurements used to establish that the cuvette only contains ambient air are inaccurate due to flawed data integrity and management. In essence, the machine's firmware "does not check the ambient air for alcohol because the call of" a critical programming function does not occur because another critical piece of information has been demonstrated not to be properly "set." EK at 27 - 28. According to Evan Kovanis, this "calls the reliability of the [infrared sensor] zero value into question because the air inside the cuvette is not checked by the functions purporting to check it. EK at 28. He thereafter points out the misuse of global error variable intended to keep track of errors occurring throughout the firmware, concluding that this misuse "can cause the use of unreliable data and loss of error state information, raising questions about the validity of the breath test result." EK at 28 - 29.

6. The source code utilized in the Alcotest 9510 operates using clipping of sensor measurements that results in unreliable BAC % results.

Evan Kovanis discusses "several locations" where the "clipping of sensor measurements" impact the reliability of the machine's reported results. In short, the Alcotest 9510 does not account for the infrared sensor output value that is below zero, clipping any such value to "zero." EK at 29 - 30. This in turn "directly influences the calculation of the slope of the breath sample data[.]" EK at 30. This is a critical calculation since the manufacturer's theory is that the "slope of the breath sample data" is used to determine when a purported measured level of alcohol has

stabilized – a necessary occurrence for the machine to accept the breath sample. Based on clipping as demonstrated, the infrared sample data is unreliable because the "determination of the slope is not necessarily based on the actual" infrared sensor output value. EK at 30. In other words, it is evident that the Alcotest 9510's use of clipping directly impacts a critical calculation used to generate a BAC %. Evan Kovanis goes on to give other examples where clipping not only effects the infrared sensor but the electrochemical sensor. EK at 30 - 32. One direct result is that the machine "ignores malfunctions or errors that cause the [electrochemical] sensor to report a negative voltage which would be an indication that the sensor is not operating normally. EK at 32. Clipping as is occurring in the execution of the code "skew[s] test results" and "would result in the BAC % test result being unreliably reported without detection by the 9510 or the operator." EK at 32.

7. The source code utilized in the Alcotest 9510 operates using a flawed programming for hardware error checking and results in unreliable BAC % results.

As Evan Kovanis earlier pointed out in the context of other issues, the source code that checks for hardware errors uses uninitialized variables to record the number of errors that have occurred. One critical operating measurement is the heater control and heater values. These critical measurements rely on the code functions and interrupts that must occur as a result of code programming during a "window of time" when the relevant error checking variable is non-zero. EK at 32 - 33. But the source code "does not ensure that the . . . interrupt will occur during the window of time" and if that is the case, "hardware errors may be missed or reported incorrectly depending on the initial value of the error counting variables." EK at 33. Using other examples, he concluded that the source codes hardware checking "introduces uncertainty" and "is not a

programming standard that is accepted in the computer science community." EK at 33 - 34.

8. The electrochemical sensor used in the Alcotest 9510 experiences fatigue and affects the reliability of results especially with regard to long-term performance of the Alcotest 9510.

Jacob Harel concluded that based on his testing, the long-term performance of the electrochemical sensor and its effectiveness is compromised when it receives a great deal of concentrated use or high concentrations of alcohol. JH at 50. But it is not only long-term use that raises reliability concerns but also "concentrated bursts of use" where the sensor reported a fatigue error but still does not block certain testing, demonstrating the inherent unreliability of any testing results. JH at 50. This fatigue factor raises further concerns in the ability of the sensor to detect interfering substances (discussed more fully below). JH at 50. The manufacturer claims to address long-term deterioration of the sensor using an algorithm that generates calibration parameters, but this manufacturer's unwillingness to produce the algorithm (embedded in the source code for "Quadr software" or "Quadratic Correction Program" that was not produced) prevented assessment of the effect of the algorithm on the sensor. JH at 35, 50 - 51.

9. The Alcotest 9510 calibration protocols are flawed and do not result in accurate calibration rendering unreliable results.

Jacob Harel tested the machine and its calibration protocols and methodology. Setting aside the issue of measurement uncertainty and traceability, quality control and other factors impacted calibration discussed more fully below in the context of additional expert reports, Jacob Harel determined the calibration methodology to be complex, not adequately explained to the operator, and resulting in the "drift" of test results reported by the infrared sensor exceeding 5%. See JH at 28 - 34. The process requires the operator to conduct a "number of verification tests

following the initial calibration" and then to "calculate a number of correction factors and enter them into the system." JH at 30. Jacob Harel reports that during the first step of calibration using the applicable Office of Alcohol and Testing manual, that the "tight" tolerances the system uses are different from the tolerances noted in the manual. JH at 33. This can obviously "confuse the operator and distort the calibration process." JH at 33. He goes on to describe the second step in calibration, utilizing dry gas simulator. Here, he observed that after following the protocols, the calibration verification test was outside the OAT accepted tolerances. JH at 34. He then tried two more adjustments before passing the verification test. See JH at 34 - 35 and enclosed charts detailing the calibration data. Jacob Harel thereafter reports that based on the above, that

> This shows that multiple iterations of system adjustments can compensate for significant error in the IR and EC measurement--errors that can point to a potential problem in the system. This adjustment may mask a problem with the IR or EC sensors. Another concern I have regarding this phase of the calibration is the fact that the OAT manual calls for one iteration of calibration verification. My experience shows that there could be significant variation between the calibration verification tests when multiple iterations are run during the same test. This is especially apparent for the 0.4% concentration as can be seen in tests 984, 985, and 986.

JH at 34, with test data reported in chart at 34 - 35. As he concluded, later in his report, this raises reliability issues with the Alcotest 9510 calibration protocol (without even considering the other related issues of uncertainty and traceability).

10. The Alcotest 9510 fails to detect and accurately report interfering substances and results in unreliable BAC % results.

Dr. Andreas Stolz explains in his report how the Alcotest 9510 is advertised as producing a reading "specific for ethanol (drinking alcohol)" using a infrared absorption spectrometry and

fuel cell technology and explains the underlying principles of the relevant technology. AS at 1 - 3. It does not. Dr. Stolz demonstrates in attached Tables (AS at 5 - 6) and explains that the Alcotest 9510 in specific instances renders a BAC % reading where "no ethanol was added to the simulator." AS at 3. The Alcotest 9510 therefore failed to detect certain interfering substances – a failure that directly impacts any notion of reliability of the machine. Dr. Stolz used a variety of interfering substances at varying concentrations. Dr. Stolz concludes that

> the results of the interference test demonstrate that the Drager Alcotest 9510 instrument cannot reliably identify interfering substances. Wet bath simulators with mixtures containing only de-ionized water and interfering substances were reported with breath alcohol concentration values as high as 0.02%. Such results are high enough that they could have legal consequences for certain persons. The addition of interfering substances to an ethanol solution can raise the reported value from below 0.08% to above the legal threshold of 0.08% without an interference detected.

AS at 4.

Dr. Joseph Anderson filed a report that further explains the Alcotest 9510's inability to reliably detect interfering substances notwithstanding the manufacturer's claims. JoA at 1. Dr. Anderson explains the applicable physiology and how many interferrent chemicals can enter the human body through ingestion, inhalation or transdermal diffusion and subsequently be mistakenly detected and interfere with the ethanol measurement by the Alcotest 9510. JoA at 1 - 2. He goes on to explain how these interferrent chemicals are found in a variety of common products, used in a variety of settings including household use, hobbyists and in the workplace and are readily available to influence results in the flawed Alcotest 9510 system. JoA at 2. Dr. Anderson discusses in part reliance on Henry's Law in the application specific to the Alcotest 9510 methodology and the need to have certain assumptions met before application of Henry's

Law can be valid. JA at 2. In short, Dr. Anderson's report establishes that the Alcotest 9510 results cannot be deemed presently reliable.

Jacob Harel worked with Dr. Stolz on the interfering substances testing. His conclusions echo those of Dr. Stolz and he specifically reports that

> There are interfering chemicals that the system could not detect as an interference and instead reported high blood alcohol levels without any ethyl alcohol used in the test. Some of the tests showed that with ethyl alcohol within the legal limit, the system reported results that are above the legal limit in Massachusetts. This is a serious flaw in the breathalyzer that can lead to positive results when, in fact, there is actually no alcohol in the test subject's system.

JH at 51. See also discussion and testing data reported at JH at 43 - 46.

11. The Alcotest 9510 methodology implemented in the development and use of the machine does not meet relevant industry standards of traceability, an uncertainly budget or measurement of uncertainty necessary to determine the accuracy of and error rate associated with any reported BAC %, resulting in unreliable BAC % results.

Dr. Andreas Stolz also reported on the absence of measurement uncertainty and measurement traceability that renders the Alcotest 9510's measurements "scientifically unreliable." AS at 7. Dr. Stolz explains why these two requirements are required by international standards (e.g., ISO 17025) and as embodied in the National Academy of Sciences 2009 report, Strengthening Forensic Sciences in the United States, and the National Institute of Standards and Technology. AS at 7. One example of how these two factors and their absence impact the interpretation and reliability of the Alcotest 9510 results concerns the use of a dry gas calibration and wet bath simulators in conjunction with measurement of a subject's breath sample. As Dr. Stolz explains, it is critical to have a traceable measurement regarding these measurements to account to varying factors, for example, the atmospheric pressure at the time of calibration and

verification using dry gas the temperature of wet bath simulators to "establish the traceability for breath alcohol measurement." AS at 7 - 8. In addition, a third critical missing measurement concerns the fact that there is "[n]o applicable measurement uncertainty for the measurement of human breath samples has been provided. An uncertainty value evaluated with wet bath simulators or dry gas control samples is not applicable to human breath samples, as it would not contain all sources of variability." AS at 8. The absence of generally accepted practices in utilizing principles of measurement uncertainty and traceability render the Alcotest 9510 measurement scientifically unreliable.

Jane Arvizu filed a report that describes additional issues arising with operation and requirements of the Office of Alcohol Testing ("OAT") regarding the Alcotest 9510, related to uncertainty and traceability and how it impacts quality control, certification standards, calibration, the establishment of training standards. Importantly, Jane Arvizu points out that while the Massachusetts State Police Crime Laboratory is accredited to ISA 17025 by ASCLD/LAB, the OAT is excluded from the scope of the accreditation. JaA at 1 - 2. In describing and discussing various aspects relevant to generally accepted practices, Jane Arvizus discusses OAT "quality system elements" and practices that include maintaining technical records, testing and calibration methods, equipment maintenance, measurement traceability, sampling of bulk preparations and internally prepared reference materials. After detailing the importance and relevance of these practices, she concludes for each topic area that "[t]he OAT breath alcohol program lacks efficacious quality system elements that are necessary for scientifically reliable calibrations. The breath test instrument calibrations performed under the auspices of the OAT program do not meet the requirements of international consensus standards,

and should not be assumed to be reliable." JaA at 6.

Jacob Harel also reported on the lack of traceability and commented on his opinion that the lack of traceability adversely affected test results since calibration is compromised. See discussion and testing data at JH at 46 - 49.

12. The Alcotest 9510's application and methodology relies on flawed scientific theories and principles as applied, including aspects of Henry's Law, and results in unreliable BAC % results.

Dr. Michael Hlastala filed a report that explains the assumptions made in the application of Henry's Law and other physiological aspects to the methodology used in the Alcotest 9510. Such assumptions are directly applicable to the use of the constant correlation factor of 2100 that is used to determine blood alcohol concentration. In summary here, Dr. Hlastala specifically states that according to applicable Massachusetts regulations (501 CMR 2.05), that

> "The breath test device must have the following capabilities: 1) analyzing samples of alveolar or deep lung air,". However, the Alcotest 9510 is unable to obtain air that has an alcohol concentration equal to that of alveolar air. The end-exhaled air alcohol concentration is always lower than alveolar air alcohol concentration because of the deposition of alcohol (with its extremely solubility in both water and blood) onto the airway tissue during exhalation 1 . In effect, the assumption by the designers of the Alcotest 9510 that end-exhaled breath is always alveolar in concentration, there is an inherent over correction by the Alcotest 9510. Subject who exhale a lesser volume are more likely to have a lower breath alcohol concentration. Subjects who exhale a greater volume of air are more likely to have a higher breath alcohol concentration. The Alcotest 9510 does not analyze samples of alveolar air alcohol concentration.

MH at 1. Dr. Hlastala goes on to explain why the Alcotest 9510 fails to reliably do what it purports to do and is required to do pursuant to Massachusetts law. As he states, "[o]verall, there is considerable variation in the amount of air exhaled by any given subject. This results in a bias against subject who exhale longer into the Alcotest 9510. The longer you blow, the higher you

go." MH at 1. Additionally, a higher body temperature imports additional bias, an elevated BAC % level into the reported Alcotest 9510 results. Since the machine does not correct for temperature bias, the results are not reliable. Finally, breathing patterns (hyper- and hypoventilation) influence the reported results. MH at 2. Accordingly, the Alcotest 9510's inability to correct for these differences result in inaccurate and differing results in BAC %.

In addition, it is either asserted throughout the various reports, or due to no production of any document attesting to the additional factors bearing upon admissibility, the Consolidated Defendants assert that the Alcotest 9510's methodology and application of the methodology is unreliable and inadmissible as a result of the following:

13. The lack of general acceptance in the relevant community as it concerns the source code programming, best practices, calibration methodology, and reliance on scientific principles not applicable to the Alcotest 9510.

14. That the Alcotest 9510's source code and its operation has not and cannot be adequately subjected to adequate testing, peer review and publication as a direct result of the conduct of its manufacturer.

15. That there is no reported error rate or attempt to demonstrate unreported and undetected errors that can and do occur in the operation of the Alcotest 9510 using the current source code.

16. That the Alcotest 9510 methodology, underlying theory or process, is not governed by recognized standards.

D.

THE SPECIFIC ISSUES RAISED HEREIN HAVE NOT BEEN PREVIOUSLY EXAMINED

The Consolidated Defendants have made a sufficient showing to require exclusion of the evidence or to have a full hearing addressing all of the issues raised. The issues raised herein on behalf of the Consolidated Defendants have either (1) not been raised or determined by prior

decisional law, (2) explored only in the same general topic area (e.g., uninitialized variables, global variables and error checking), (3) were not examined using any dynamic testing analysis or static analysis in conjunction with dynamic testing analysis, and finally, (4) dealt with a different machine, the Alcotest 7110.

In Commonwealth v. Camblin, 471 Mass. 639 (2015), the Supreme Judicial Court commented in returning the case to the trial court, that

> In the circumstances here, however, where the applicable statutes and regulations do not provide specific standards relating to the source code of breathalysers, and existing case law offers no guidance about the reliability of the Alcotest [7110]'s methodology for measuring and analyzing the quantity of alcohol in a person's breath, the judge should have held a hearing to determine whether the source code and other challenged features of the Alcotest functioned in a manner that reliably produced accurate breath test results. See Shanley, 455 Mass. at 763 n.15 (although Daubert-Lanigan hearing "may not always be required where qualified expert testimony of the same type and offered for the same purpose has been accepted as reliable in the past in Massachusetts appellate cases," this court has "not 'grandfathered'any particular theories or methods for all time").

Commonwealth v. Camblin, 471 Mass. at 650. Furthermore, the Supreme Judicial Court commented on national standards certification as not addressing the source code-related issues. Id., at 650, n.24 ("The National Highway Traffic Safety Administration (NHTSA), on whose list of conforming products the Alcotest was required to appear for use in Massachusetts, see 501 Code Mass. Regs. § 2.38 (2006), does not analyze a breathalyzer's source code when determining whether it conforms to NHTSA's standards.")

What's more, the Supreme Judicial Court made clear that the Camblin trial court's reliance on New Jersey v. Chun, 194 N.J. 54 (2008) was misplaced.

> The judge's second reason for declining to hold a hearing was that the New Jersey Supreme Court, in Chun, 194 N.J. 54, already had considered and rejected a challenge to the reliability of the Alcotest. Although the court in Chun did address

> the reliability of the Alcotest and of its source code in particular, see id. at 75, 121-131, it did not address all of the challenges the defendant in this case raises to the Alcotest's reliability. For example, the court in Chun did not consider whether the Alcotest tests exclusively for ethanol or whether the Alcotest's calibration system fails to adequately measure the reliability of the device.

Commonwealth v. Camblin, 471 Mass. at 651, n. 25. That is the case here: (1) The Chun case involved varying and different issues as well as dealt with the Alcotest 7110; (2) there is no existing case law, (3) there are no applicable statutes and regulations that address the multiple and complex issues regarding the Alcotest 9510's source code and other issues, and (4) certifications by agencies of the Alcotest 9510 do not address the source code issues, and (5) neither the Commonwealth nor the manufacturer have seen fit to conduct or submit any analytical reports regarding dynamic testing of the Alcotest 9510. And as of this date, the reliability hearing conducted in the remanded Camblin proceedings and the court's decision have not been reviewed by our appellate courts making it clear that any findings of the lower court do not have any precedential value, even if they were directly on point which they are not for all the reasons stated above. Finally, it is not clear at all what exactly was addressed in the Camblin trial court's decision as the memorandum is general in its treatment of the issues raised and only dealt with static code analysis.

Aside from the readily distinguishable aspect of the Chun decision, there is an important lesson that flows from the Chun decision: That the New Jersey court's findings at most find the Alcotest 7110 only "generally reliable" and specially noted nine specific issues requiring "modification" that had to be dealt with in New Jersey's use of the Alcotest 7110 that included (1) modifications to the firmware and requiring it to be "locked" to address security issues; (2) modifying the minimum breath sample criteria; (3) modification to firmware to set acceptable

tolerance ranges for breath sample readings; (4) modifications to the firmware to correct buffer overflow programming errors; (5) modifications to the firmware to correct error detection; (6) modification to firmware to report infrared and electrochemical sensor readings related to fuel cell drift; (6) modification to the firmware to address calibration, certification and linearity; (7) modifications to the firmware to report why there has been no reportable results; (8) modification to the firmware to print out related data including solution change reports, calibration documents and a listing of the temperature probe serial numbers and values, and (9) modification to the firmware to report out which firmware version was used to generate a breath alcohol content percentage report. See New Jersey v. Chun, 194 N.J. at 65, 151 - 153. It appears that, notwithstanding the "general reliable" determination, absent any dynamic testing analysis and data as is present in this case, many issues requiring modification to the Alcotest 7110 were determined by the court.

It is anticipated, based on the expert report submissions and lack of any substantive reports being filed by the Commonwealth or manufacture thus far, that a hearing conducted on the Consolidated Defendants' motion to exclude is expected to generate significant errors and problems with the Alcotest 9510.[4] Accordingly, the many issues raised by the Consolidated Defendants are distinct and different from any raised and litigated in other courts and require a full hearing if the evidence is not deemed inadmissible at the outset.

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[4] The Commonwealth and the manufacturer have submitted only one report from Security Innovations that involved static review and no dynamic analysis of the relevant source code. Importantly, while Security Innovations determined that the source code passed its "static" analysis, their report raised issues with the Alcotest 9510 source code and commented that additional testing would need to be conducted to address the questions raised in its analysis.

CONCLUSION

For the reasons set forth above, the Consolidated Defendants' motion to exclude any and all evidence derived from the results of the Alcotest 9510, including any and all opinion evidence, as unreliable and inadmissible should be allowed. Alternatively, the Consolidated Defendants move for a hearing wherein the proponent of the evidence, that is, the testing results produced by the Alcotest 9510 and any and all opinion testimony, must demonstrate that the evidence is reliable and admissible.

RESPECTFULLY SUBMITTED,
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