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False Positives with Non-FDA Approved Blood Testing

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ABSTRACT

Blood Phosphatidylethanol (PEth) is a metabolite of alcohol that has an extended window of detection with a half-life of 2 - 14 days. A PEth test is a *non*-FDA-approved "Laboratory Developed Test" (LDT), used to determine if those monitored in an alcohol, or court ordered, prevention program have consumed alcohol over a 2 - 4-week period prior to the test. Despite experts testifying that it is impossible to receive a false positive, a growing number of individuals have claimed sobriety despite positive results. People have lost their careers, the custody of their children, and even their lives due to a positive PEth test result despite purported abstinence. The intent of this study was to assess the validity of the PEth test by determining if a positive test was possible even with an individual who abstained from alcohol consumption over a 30-day period. Ten out of 20 DBS blood tests, from the *same* blood for comparison, indicated excessive alcohol consumption despite abstinence, whereas ten DBS and 1 whole blood identified no consumption. The results of this research were conclusive that *a* false positive test can result without alcohol consumption, invalidating the validity of the PEth test. Additional research could identify the reasons false positives occur, including the many variables throughout the process from collection to storage and shipping, and lack of standard operating procedures at the lab, but also due to the variability in human genetics and physiology. However, the only purpose of *this* study was to determine if the test was valid by identifying if a false positive was possible without alcohol consumption. The resulting recommendation from this research includes a heightened awareness that false-positive blood PEth test results do occur, and caution should be observed in overreliance on this test as proof of alcohol consumption.

1. INTRODUCTION

Phosphatidylethanol (PEth) is a lipid metabolite of ethanol (EtOH) formed from phosphatidylcholine

and ethanol by a reaction catalyzed by phospholipase D (PLD). PEth measurement has been established as an alcohol biomarker within both clinical and forensic applications, although the question of whether a positive blood PEth test is proof of drinking, or a negative result identifies abstinence, remains a concern. However, the PEth test has been increasingly utilized to assist detection of alcohol consumption in forensic administrative settings, even though research has indicated PEth formation *after* a sample has been collected [1]. Why a positive blood PEth test without alcoholic beverage consumption may occur is the subject of concern, as the opposite may be enabling alcohol consumption, where prohibited, such as an airline pilot, placing lives in jeopardy. Therefore, the question as to the validity of the PEth test must be answered.

Currently, blood samples testing for PEth are collected either via venipuncture with a whole blood sample, in a vacutainer tube, or via a finger prick where blood is dropped onto a card, filling five circles, identified as a Dry Blood Spot (DBS) PEth test. Due to the ease of collection, DBS testing has been purported to be "a game changer in alcohol biomarkers" [2].

Studies have shown that significant exposure to ethanol (approximately 100 grams) is required over a period of weeks for a blood sample to test positive for PEth at a 20 ng/ml, the widely used cutoff for abstinence [3, 4]. There is no scientific rationale for the 20 ng/ml cutoff other than it was simply a random number that is utilized to identify the impact of incidental exposure.

To date, the favored assumption is that PEth detection can only occur with alcohol consumption, and that incidental exposure to environmental alcohol is unlikely to produce enough exposure for a positive PEth test. Yet studies are emerging that identify otherwise. Notwithstanding the high use of hand sanitizer at the onset of Covid, the question of whether ethanal-based hand sanitizer could have an impact on PEth testing has also become a topic of discussion.

Problems arise when a developer of a product, such as the PEth test, also owns the *only* laboratory that utilizes the test, and their profit is directly tied to an assertion that the test is 100% reliable and false positives are not possible. Yet there appears to be no checks and balances tracking for accuracy. Bantel *et al*., (2024) sought to increase understanding by testing a variety of processes to determine reliability, yet identified limited standardization and comparability between varying methods, resulting with only 90% obtaining a singular sample to be within acceptable limits, and only 73% of tests overall were within limits [5]. There is also no FDA approval. To test the validity of the PEth test, without requiring individuals to drink excessive amounts of alcohol, was only possible by testing for a false positive. This was not to test the frequency of false positives, but simply to determine if a false positive was *possible*. Even one false positive can destroy a life or take down an airplane.

False Positives

Proponents of PEth testing assert that there are no substantiated false positives [6]. Contrary to those assertions, research has confirmed the presence of alcohol vapors during the DBS drying phase has led to false positive results [7]. Additional research confirmed that tests have identified that PEth formation in wet blood post-sampling will occur; however, if the DBS filter-paper test cards were stored at room temperature for 48 hours, they were not subject to the same post-sampling formation of PEth [1]. Beck also recommended the use of a PLD inhibitor to avoid results of a positive test result that could otherwise be challenged, yet this has suggestion has yet to become standard practice [1].

Numerous anecdotal reports corroborate the growing number of individuals who have asserted they had not consumed alcohol and yet received a positive DBS PEth test. Not only is the PEth test not FDA approved, but at the time of this writing, the researcher was unable to find any validation studies regarding DBS PEth testing that could identify pre-or post-collection variables to include but not limited to hand sanitizer or sample collection processes. The methodology in which the DBS sample is obtained, dried, stored and shipped could be associated with fermentation and resulting formation of PEth.

According to the FDA, inaccurate tests have far-reaching effects when they reveal false-positive results and are equally detrimental when the LDT results in a false negative [8]. Despite the FDA concerns with inaccurate test results, laboratories are *not* required to report adverse events into a central database; therefore, they do not provide comprehensive data to quantify the inaccuracy of LDTs [9]. Such events could be identified as results of false positives, identification of false negatives, or the mixing of individuals' samples.

Yet without cooperation of the test developer/owner with the only lab producing and testing PEth, research is limited and, in some cases, blocked.

PEth Testing and Pilots

HIMS (Human Intervention Motivational Study) is a substance abuse treatment program that evolved from a 1975 study focused on airline pilots with alcohol use disorder (AUD). Present day, each airline establishes a HIMS program of their own, based upon FAA criteria and the associated union contract. Choice Labs is a middleman connecting ARCpoint labs, the collection sight of DBS PEth, to USDTL, the singular laboratory that analyzes pilots' blood on behalf of the airline.

Three in-house unofficial studies at Choice labs occurred to better understand DBS PEth test results with hand sanitizer, and documented alcohol consumption prior to testing. In the first test, hand sanitizer was applied throughout the day to replicate a typical nurse's exposer. Capillary blood was then collected via the DBS PEth test procedure. Test results indicated negative for PEth. Next, hand sanitizer was dripped onto the finger with the first drop of blood and another capillary blood sample was drawn via DBS. The blood tainted with hand sanitizer was placed on the first of five circles, all of which were sequentially filled. Circle one detected a PEth level of 22 ng/ml, circle two delectated less than 20 ng/ml and there was no PEth detected on circles three, four, and five. This result indicated a negative test result based upon the three negatives of the five circles. The third test conducted by Choice labs was on ten lawyers. These attorneys were curious as to the quantitative numbers between the amount of alcohol and the associated PEth levels associated with custody orders. Each of these attorneys consumed alcohol daily and documented their consumption. All ten attorneys were then tested for PEth via the DBS capillary collection method. Results identified that three of the ten DBS test results were negative for alcohol consumption, despite those individuals having consumed alcohol. The recommendation from Choice Labs to the attorneys was to place their clients requiring abstinence on a mobile breathalyzer, in lieu of PEth. Choice labs also conducted multiple DBS tests on the owner of the lab, *after* having consumed alcohol, and reported that those tests produced negative results, despite alcohol consumption [10]. The validity of the PEth test with these varying results leave doubt to the validity of the test for both false positives and false negatives.

Hand Sanitizer

Research is limited regarding the effect of hand sanitizer on DBS PEth testing. United States Drug Testing Laboratories (USDTL), the only laboratory that utilizes DBS PEth testing, conducted a study with only 4 *volunteers*, therefore, they were unable to rule out either way the effects of hand sanitizer [11]. Yet some assert that for hand sanitizer to effect DBS PEth results, the individual would have to either bathe in a vat of it, or drink enough to become intoxicated [2]. However, research has also indicated that the use of ethanolic hand cleaner prior to DBS PEth testing has produced elevated levels of PEth [12].

Conflicting Research

Despite those who say a false positive is "impossible" PEth has been detected post sample collection following DBS and whole blood collections [1]. Whereas Reisfield *et al.* [6] (2020) assert that it's unknown if interindividual distinction could make a difference with incidental alcohol exposure to produce PEth, others have asserted that factors within individuals could affect Phospholipase D activity, the enzyme that creates PEth, and therefore may affect levels of PEth [13, 14]. Research also identifies PEth sensitivity relating to biological factors such as hemoglobin, liver fibrosis, BMI, HIV status, race and ethnicity [15]. Clearly indicating there is a human component to the results. Yet limitations have been noted as to the inability to assess sensitivities to the biomarkers [6]. Yet Beck *et al.* [1] identified a high sensitivity to biomarkers supporting Peterson's [16] assertion that none of the available biomarkers are ideal.

Some studies identify that there is no difference with the formation of PEth with respect to gender, due to women typically having higher fat content, with a lower hydration level, as comparable to the same weight man, due to alcohol being insoluble in fat [12, 17, 18]. However, this assumption does not take into account a pound per pound athletic woman versus an overweight male.

While PEth testing utilizes either whole blood or Dried Blood Spot (DBS) capillary collection methodologies, it appears that incidental exposure to hand sanitizers has increased the risk of the DBS collection method [7].

2. SIGNIFICANCE

In that PEth testing is being utilized to monitor parents in custodial agreements and individuals in alcohol avoidance programs, (physicians, lawyers, airline pilots, those in safety sensitive occupations, and individuals on an organ recipient lists), validity is essential. A false positive test result could have a far-reaching and devastating impact on the individual's life. Currently, when an individual tests positive for PEth, that test is considered *absolute proof* of alcohol consumption, and the individual is in violation of monitoring or custodial agreements. Significant sanctions are then applied including loss of the pilot's medical license, or legal licenses with associated career loss, denial of liver transplants resulting in loss of life, or forcing a parent to unjustly give up custody of his/her child(ren). On the contrary, if a false negative is possible, an invalid test could be placing passengers, patients, and children, lives in harms way. Research to ascertain the validity of the PEth test is essential to avoid unnecessary harm to those of sustained abstinence, or those who depend upon sobriety.

Experts have asserted that 400 - 500 PEth tests over seven or eight years have been conducted yet, there was never any assessment to the accuracy of those tests, despite numerous claims of false positive test results [19]. A high number of tests conducted does not make a test valid. One test with a false positive would leave the test suspect.

In that PEth is being utilized in legal cases to the downfall of those individuals who assert sobriety, taking children from parents, and denying transplants, or releasing individuals to perform high-risk professions sober, it becomes essential to learn if the DBS PEth test is reliable.

3. OBJECTIVE

The objective of this study was to identify the validity of the DBS PEth test, by determinizing if a false positive was possible. The methodology of testing for false positives, verses false negatives, was chosen to remove potential harm and risk to participants, both physical and psychological, by not forcing anyone to consume enormous quantities of alcohol. The focus of the research was to determine if a false positive was possible. Even *one* false positive would identify the lack of validity and reliability of a test that asserts a false positive cannot occur. This study was not to identify *why* false positives occurred through varying methods, or even to determine the probability of occurrence, or the likelihood of false positives across different testing conditions, or to determine the generalizability among a broader population. The *only purpose* of this study was to determine if a false positive from a DBS PEth test *could* occur, despite the individual not having consumed alcohol. Present time, proponents of DBS PEth testing believe that false positives are not possible. The goal of this research was to identify the validity and reliability of the DBS testing method, through identification of a false positive.

4. METHODOLOGY

USDTL LABORATORY TESTING

Eliminate Variables at the USDTL Lab

USDTL is the only commercial laboratory that conducts DBS PEth testing. To validate the process at the lab, Substance Abuse and Mental Health Services Administration (SAMHSA) inspector assessed the USDTL lab as a result of a legal case.

The USDTL process was observed, and standard operating procedures (SOP) were viewed to ensure they were scientifically valid and that the technicians were following SOP. The validation data were viewed specifically due to the dried blood spot tests. After spending a day at the laboratory, the inspector was assured that the testing process was accurate and a very sound forensic process [19].

For the purposes of this research, the USDTL facility in Des Moines, Iowa, was not considered a contributing factor to the outcome of the test results. However, this research did not claim that there could not be human error or lack of standardization regarding the laboratory's policies and procedures.

Eliminate Donor Variables

To control all the variables of the subjects donating blood, based upon diet, age, weight, fat content, gender, body chemistry, and to ensure there could be no contributing factors due to the difference in body chemistry, all 5 samples were taken from the same participant. In that one human was used removes the possibility of any confounding variables as aforementioned beyond the collection methodology. Regardless, the goal was to determine if a false positive PEth result was possible.

Operational Definitions

- A description document was a typed set of directions as to how each blood sample was to be collected.
- PEth was defined by an ng/ml level.
- Whole Blood Sample was defined as the sample taken intravenously from an arm.
- DBS Blood Sample was defined as a capillary blood sample taken by a finger prick with five drops on testing paper.
- Standard DBS testing was defined as the required protocol of blood collection, drying, and packaging methodology per USTDL standard operating procedures.
- Non-standard DBS testing was defined as a variation of the standard method of blood acquisition to include:
  1) Testing paper folded closed, no airflow prior to packaging in the drying box,
  2) Pressing the finger to the paper during the collection process,
  3) Lab technician utilizing hand sanitizer prior to collection of samples, and
  4) Lab technician milking the finger to produce blood drops on the sample paper.

Materials and Methods

The participant had abstained from all alcohol since June 18, 2023, to the time of collection on July 20, 2023. Five blood samples were collected from the participant. Four of those samples were dropped onto five spots, on four cards, for a total of twenty different DBS tests. The fifth blood draw was a whole blood via venipuncture. All five blood samples were drawn by a technician from ARCpoint labs in Seattle Washington and shipped to USDTL labs for processing.

USDTL utilizes a five-circle DBS filter-paper test card, taking five samples for each card, the researcher provided a total of 21 samples for testing—one vial of whole blood and 20 circles. However, for the purpose of this study, each card will be discussed as "a sample test card" of which contains five tests per card.

The researcher provided five blood samples of her own blood to control for variables: One whole blood draw, one capillary blood draw for a DBS PEth test drawn per USDTL standard operating procedures, and three capillary blood draws for DBS PEth tests that were manipulated contrary to the required process. The description document for each of the five samples was as follows:

1) Intravenous whole blood, following standard testing protocol,
2) Fingerpick to obtain a capillary blood draw for a DBS PEth test following standard testing protocol,
3) Fingerpick to obtain capillary blood for a DBS PEth test following standard testing protocol except for:
a) Folded the card prior to placing into the drying box.
4) Fingerpick to obtain capillary blood for a DBS PEth test not following standard protocol by:
a) Using hand sanitizer,
b) Not wiping the first drop of blood,
c) Pressing the finger onto the test strip, and
d) Folded the card prior to placing into the drying box.
5) Fingerpick to obtain capillary blood for DBS PEth test not following standard protocol by:
a) Using hand sanitizer,
b) Not wiping the first drop of blood
c) Milking the finger,
d) Pressing the finger onto the test strip, and
e) Folded the card prior to placing into the drying box.

All samples were placed individually into a cardboard box, and then the box was placed into a cabinet. The office was airconditioned and cool enough to need a sweater for comfort. The researcher was told that

the samples would be shipped by ARC Point labs to the USDTL labs for PEth analysis that evening.

The description documents with the methodology process, numbered 1 - 5, were each presented to the technician as a typed document that described in detail the step for each test. The technician followed the guidelines per USDTL standard procedures on tests one and two as outlined on the description documents. The technician then followed the methodology outlined on the description documents for tests 3 - 5. Both the researcher and technician signed and dated each document asserting that the collection process was accomplished as described per the description documents, and that the blood for all twenty-one samples was collected from the researcher, albeit different names were added to the forms for anonymity at the lab to eliminate any bias.

If any PEth indication was present the USDTL labs would retain the samples to re-run the tests in order to confirm any positive test results. The negative test results would arrive first and positive test results later if they existed. This was the case as test results numbers 4 and 5 arrived two days after test results 1 - 3.

Methodology Discussion

The utilization of one individual to donate blood for all 5 blood draws for 21 different tests, created an added level of control over the variability of the human regarding weight, height, gender, diet, metabolism or anything unknown that may naturally create PEth. The choice to compare multiple samples of blood drawn from the same person, who proclaimed not to have consumed alcohol for thirty days, ensured no alcohol consumption compliance. Otherwise, all 21 tests would have created PEth.

The various methods of sampling this blood were exampled by previous collection methods, as described by individuals during their standard PEth test. The variability could be due to human error, lack of training, or simply lack of due diligence without a full understanding of the ramifications.

The rationale to vary collection methods was to manipulate the standard process based upon comparable collection methods that have varied with actual tests. This was not to determine what causes a false positive but may provide insight to future research, down that path. Utilizing a whole blood PEth test, and 5 DBS PEth tests following the established collection method, was hypothesized to show accuracy, to establish that the donator did not consume alcohol.

Regardless of the collection process, blood samples from one human, the same human, tested with 21 different tests should all be exact. The results indicate otherwise.

5. RESULTS

- Samples taken by methodologies of one, two, and three were received on July 24, 2023, and all three indicated: **Negative.**
- Samples taken by methodologies four and five were received on July 26, 2023, and both indicated: **Positive.**
- Sample taken by methodology four identified:
  - **21 ng/ml.**
- Sample taken by methodology five identified:
  - **83 ng/ml.**

Each DBS PEth sample 6989-6992 included five tests per sample. The results of samples four and five, with a total of ten tests, are consistent with heavy drinking weeks prior and up to the test (see Table 1).

Table 1. PEth test results.

Sample	Test	Type	Blood	Results
6988	1	WB	PEth	Negative
6989	2	DBS	PEth	Negative
6990	3	DBS	PEth	Negative
6991	4	DBS	PEth	Positive 21 ng/ml
6992	5	DBS	PEth	Positive 83 ng/ml

6. DISCUSSION

The steps utilized in test numbers four and five in this collection process were designed to replicate previous DBS PEth testing processes that have been collected for individuals in a similar manner, of whom subsequently received positive test results but argued total abstinence [20]. Two of the four test cards resulted in 10 different tests. These 10 tests identifying PEth were then subject to repeated testing, per standard USTDL protocol. Fifty percent of the DBS tests identified PEth. While experts have contended that false positives are not possible, this research contradicts that assertion, indicating otherwise, and invalidating the reliability of the DBS PEth test. In that only three of the five tests per card must identify negative results to be negative, it is inconclusive if there were an addition four false positives. Therefore, it will only be asserted that 10 out of 20 DBS tests were false positive results.

All 21 blood samples were collected from the same participant on the same day. Twenty of those samples were DBS PEth tests. The researcher had abstained from alcohol for one month. The first 10 of the 20 DBS samples support alcohol abstinence, yet 10 of the samples from the very same blood, tested twice, tested positive, indicating that false positives do exist. This may be a direct result of the collection method, in that all samples were placed in a similar drying box, in the same cabinet, and sent to the same lab for analysis. The variability between results appears to be the result of non-standard collection methods, but this inconclusive and not relevant to this study, only providing information for future research. The research is conclusive that a false positive in possible.

The folding of the card flat did not create PEth in test number 3, in any of the five samples, despite the requirement to maintain airflow. The technician is directed to fold the card in a manner that air will flow through it for drying in the cardboard box. However, this card folded could have lifted in the drying box unknowingly providing airflow, therefore the type of folding is inconclusive on its own. The tests that were positive, could have also remained closed, and could have been a contributing factor to the positive test results. This too in inconclusive.

What is unknown is if pressing the finger to the paper, milking the finger, or the quantity of hand sanitizer was the primary contributing factor of the test results of 83 ng/ml. One concern with a finger prick blood sample versus whole blood, taken from the arm, is that capillary blood is "polluted by fluids from tissues and cells" suggesting that the latter measurements are less accurate [21].

The cutoff for assumed alcohol consumption is 20 ng/ml. This number accounts for incidental exposure but in fact is an arbitrary number. Anything over 20 ng/ml is considered to have consumed alcohol, anything under is considered negative. There is no definitive answer as to what the numbers of 21 ng/ml and 83 ng/ml equate to with the amount of alcohol consumption. Each body metabolizes alcohol a bit differently. However, a 2012 study that included 1339 participants identified that a PEth result of 73 indicated the individual drank up to 4 drinks daily [22].

Contrary to Lewis [10] assertion that this is a "game changer in alcohol biomarkers" due to the ease in collection, the researcher found the DBS PEth testing to be extremely time consuming in relation to the whole blood PEth test. A couple minutes to draw a vial of blood, but 10 - 20 minutes to get the normal sample from a finger prick for each of the five tests per card. The standard procedure for a DBS PEth test requires the first drop of blood to be wiped away and the puncture sight to fill five circles, approximately the size of a nickel, with blood on a card without touching it. This was problematic due to clotting and the cooler temperature of the room. The first test, the collector pricked the finger a half dozen times bruising it to enable the filling of five circles with enough blood for a sample taking approximately 20 minutes to accomplish.

The second sample the collector utilized a hot water bottle (a rubber glove filled with hot water) to warm the hand, but the process was equally as difficult by wiping the first drop and multiple pricks and took approximately the same amount of time. The third DBS sample was also heated but due to the ability to touch the finger to the paper and not wiping the first drop, as directed per the description document, the process was a bit quicker, approximately 15 minutes. Finally, the fourth DBS collection, also warmed, with milking the finger, multiple pricks, and touching the card to the paper, as directed per the description,

document, enabled a far quicker process than the "normal" DBS collection method approximately 10 minutes. Milking the finger was a time saver.

The questions for further research is whether these individuals collecting the blood are lacking patience to follow the standard process and simply rushing by kneading the finger and/or pressing to the paper, the lack of training, or whether the collection process contributed to the false positive. Regardless to the reason *why* the false positive results, this research identified PEth resulted in ten of the DBS blood tests with a subject who abstained from alcohol consumption.

The results obtained in this research provide evidence that the DBS PEth test is invalid in that false positives have appeared even in a small sample size of 10 tests out of 20. There is no question that the participant abstained from alcohol to have received three negative PEth tests, with the same blood as those that were positive. If the participant had not abstained, this would indicate the results of three false negatives. The same blood gathered with different steps produced different results.

This pilot study did not determine the reasons as to *why* there were 10 false positive test results, only that false positive test results do exist by the methodology of capillary blood collection indicating that hand sanitizer, pressing the finger to the paper, and/or or milking the finger, or another unknown, somehow created a false positive test results. There was no research conducted as to which of the variables induced, or a combination thereof, or the quantifying the amount of hand sanitizer utilized was the reason for the false positive. This research only attempted to determine if it *was* possible to obtain a false positive, in analysis of the validity of the DBS PEth test.

This research, albeit limited by a small sample of 21 blood tests, should open the door for additional studies to fully understand the validity of the DBS PEth test. Research could identify what causes false positive test results, to include testing in different geographical locations, perhaps with higher humidity than Seattle Washington, collection in a non-airconditioned room, with a variety of people, to determine a variance in a person's metabolism and chemistry, and to introduce a variety of foods into the diet in effort to find the causal link of false positives. The sample itself is also required to dry for one hour prior to bagging. If a drying box is placed directly into a plastic bag for shipping, due to the test being taken at the end of the day, this could also impact results according to the USTDL named procedures advising drying procedures.

Interviews with those who have received what they claim to be false positive test results have identified that their tests were "bagged up" and sealed immediately, or they simply did not stay to watch the ensuing process. Furthermore, prior to placing a blood specimen into a plastic bag, desiccant packs should be added to absorb moisture, and whether that happens is unknown.

Research should also look into the probability of both a false positive and false negative. However, even one in the wrong circumstances could be detrimental.

Sample Size Concern

The question as to sample size is readily addressed due to the research question as to the reliability and validity of the DBS PEth test.

USTDL utilized a sample size of 4 to test hand sanitizer, yet this research utilized a process of testing 20 blood samples, with varying results [10]. Had the study produced negative results without any false positives, those results would be inconclusive due to the small sample size, such as USTDL's hand sanitizer test with 4 individuals was inconclusive due to the small sample size and no results. However, when not just one test, but ten identified PEth without alcohol consumption, the sample size is no longer relevant as the results are conclusive.

A larger sample size would benefit future research to determine the *probability* of a false positive or to understand *why* these false positives occurred, beyond alcohol consumption. However, this was not the goal of this research.

The limited sample size of 20 different DBS blood samples, was due to the research question—is a false positive possible, to assess the validity of the PEth test. The indication of PEth at the onset, ends the study. Ten false positives out of 20 samples from the same blood identified definitive results—false positives are possible and therefore questions the validity of the DBS PEth test.

7. LIMITATIONS

The primary limitation of this research was the inability to test those who have previously received a false positive who are subject to monitoring, such as airline pilots or physicians. A false positive would destroy their careers. More so, unless the participants are in an intake facility, with full monitoring, for thirty days, there is no definitive proof that they did not consume alcohol. The very reason for comparing the same blood with different collection methods.

There is limited research regarding PEth testing. Anyone profiting from this test appears to be unwilling to participate in research that will prove their product produces false positives at the expense of those mandated to take the test. No incentive remains to address the issue at this time. The greatest limitation is due to those selling and profiting from the test are unwilling to invalidate their product.

While some researchers would assert the small sample size of one human donating five samples of blood to be test 21 different times as a limitation of this study, it is not. In that the *only* goal of this research was to determine if a "singular" false positive was possible, and *not* the frequency of that event or the reasons attributing to the results, with the variability of testing methods, then one human, 21 blood samples, 20 DBS samples, 10 of which were positive and 10 negative proved false positives are in fact possible.

8. CONCLUSION

If the participant involved in this study had been mandated to take a DBS PEth test and subsequently received either of these two false positive tests she would have lost her pilot's license, her career, the custody of her children, and/or her life, depending upon the reason she was being monitored, despite not having consumed any alcohol.

There is no greater crime than to "try and convict" an innocent person with such far reaching and devastating impact on their life. With respect to aviation safety, in that the owner of Choice labs conducted research that identified three out of ten individuals who drank for a month still tested negative for PEth, the unreliability of a monitoring system designed to keep alcohol out of the flight deck has failed. Suggestion of a mobile breathalyzer should be heeded.

This study showed that 10 false positive tests resulted despite alcohol abstinence. Ten blood spots out of 20 detected PEth. Therefore, false positive test results do exist with the DBS PEth test.

9. DECLARATION STATEMENT

Ethics approval and informed consent were not sought for this case study because the researcher was the blood donor, and the blood draw and testing protocol outlined in this research were conducted in a licensed ARCpoint laboratory in Seattle, Washington per ARCpoint laboratory standard operating procedures. "ARCpoint Labs is nationally recognized and maintains the highest standards of training and technical expertise in laboratory screening, workplace safety, and patient well-being" [21]. While the procedures in this study are considered to constitute research on human subjects, the only procedure was on the researcher voluntarily allowing five blood draws in a licensed ARCpoint laboratory [23]. The blood samples were then shipped to USDTL labs for evaluation, per standard laboratory operating procedures. I give my consent for the publication of identifiable details, which include my personal blood screening results, to be published in the above Journal and Article. The data set in this article was previously published with Mendeley Data 16 April 2024|Version 1|DOI:10.17632/fg3r3gf7rj.1.

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CONFLICTS OF INTEREST

The author declares no conflicts of interest regarding the publication of this paper.

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