CRIMINAL MOTION ORDER

IN THE MUNICIPAL COURT OF THE CITY OF SEATTLE

IN RE EXPIRED BLOOD VIALS

Order on Criminal Motion

Case # 4240001602

The judges have conferred and are issuing the following two opinions, pursuant to SMCLR 8.2.4. Judges McDowall and Gregory have signed one opinion (Attachment A), Judge Shadid has issued a separate opinion (Attachment B). Pursuant to SMCLR 8.2.4, other judges of the court can adopt either opinion in cases appearing before them.

The Clerk is directed to set the consolidated cases for pretrial hearings as follows, based upon the prior hearings held in each case:

Court 1101:

663118	JAMES, MOHAMMED
663330	LYONS, JASMINE
674579	JAINESE, BOBBY LEE
674463	MORALES MORALES, JUAN
4240000653	BLANCO, ROMAN
4240001892	RAJESH, DAVEN KENNETH
677852	YIDEGO, DERES

Court 1001

675787	DARDEN, BRITTANY
676623	CLEMENTS, ZHANNA
674724	VARGAS CRUZ, JUAN
671312	DAILY, SHELBY

CRIMINAL MOTION ORDER

676186	ORTIZ, ISMAEL
4240000491	ROGERS, MARK
677920	BERRY, SUZANNE
4240001251	ROBERTSON, JEFFREY
4240000660	PITTMAN, ASTRO

Court 903

4240000443	BOWMAN, RICARDO
4240001895	ALDRICH, HALLIE
4240000896	PAE, JULIA
670378	SHIRAZY, SULEIMAN
677940	GUZMAN, ALEJANDRO
674429	WATKINS, DOMINIQUE

Court 1103

677915	VALLEJO PEREZ, JONATHAN
676472	GREENE, SIMON RHYS
677976	PEDROSO, FREDERICK
677954	TOBIN, PETER
4240002614	MARSHALL, KOBIE

The commencement date for each of these cases will be October 7, 2024. Expiration date for all cases is January 6, 2025.

Dated: October 3, 2024

JUDGE CATHERINE McDOWALL

JUDGE DAMON SHADID

JUDGE WILLIE GREGORY

CRIMINAL MOTION ORDER

CRIMINAL MOTION ORDER

ATTACHMENT "A"

McDOWALL/GREGORY OPINION

SEATTLE MUNICIPAL COURT

In Re EXPIRED BLOOD VIALS	Case No.: 4240001602 MCDOWALL/GREGORY OPINION

The Court, having determined this motion is a matter of citywide significance pursuant to SMCLR 8.2.4, heard the matter *en banc* on September 9-10, 2024, before Judge Catherine McDowall, Judge Damon Shadid, and Judge Willie Gregory.

The defendants in these consolidated cases have all been charged with Driving Under the Influence or Physical Control, and each defendant has moved to suppress the results of the blood test because the analysis performed by the Washington State Toxicology Laboratory occurred after the expiration date listed on the tube used to store the defendant's blood. This ruling will apply only to blood results where the sample was taken before the tubes expired, but the testing occurred after the expiration date.[1]

---

[1] Four of the 27 cases consolidated in this hearing involve blood results that do not contain ethanol as a positive result, they only reveal presence of drugs. The parties only briefed and argued the effect of the post-expiration testing on ethanol samples. Therefore this ruling will only apply to blood results related to ethanol levels obtained in tests performed after the vials expired.

ISSUES PRESENTED

1. Can the City of Seattle make a prima facie showing that the test results in cases where the analysis occurred after the expiration date on the vials comply with Washington Administrative Code (WAC) 448-14-020?
2. Should ER 702 bar the admission of results from the expired vials?

ANALYSIS

1. Prima Facie Evidence

Blood alcohol tests are subject to the requirements of RCW 46.61.506, which provides states that analysis of the person's blood "shall have been performed according to methods approved by the state toxicologist." RCW 46.61.506 (emphasis added). WAC 448-14 contains the methods approved by the toxicologist related to analysis of a defendant's blood. In these consolidated cases, the defense challenges only the City's compliance with WAC 448-14-020(3)(b), which requires that

> [b]lood samples for alcohol analysis must be preserved with an anticoagulant and enzyme poison sufficient in amount to prevent clotting and stabilize the alcohol concentration. Suitable preservatives and anticoagulants include the combination of sodium fluoride and potassium oxalate.

A blood sample is admissible to show intoxication if the proponent can establish with prima facie evidence that the requirements of the WAC are met. State v. Brown, 145 Wn. App. 62, 69-70 (2008) (citing State v. Hultenschmidt, 125 Wn. App. 259, 265 (2004). "Prima facie evidence" is defined as "evidence of sufficient circumstances that would support a logical and reasonable inference of the facts sought to be proved." RCW 46.61.506(4)(b). The applicable

statutes require judges, when determining whether foundational requirements are met, to assume the truth of the prosecution's evidence and all reasonable inferences from it in a light most favorable to the prosecution. Brown, 145 Wn. App at 69-70.

The crux of the issue in this case is therefore a preliminary finding of admissibility of the blood results. If the results are admissible, then the defense may challenge the reliability or accuracy of the tests. State law makes clear that once a prima facie case has been made, challenges to the accuracy or reliability of the test "shall not preclude the admissibility of the test," but should be considered by the trier of fact to determine what weight to give the test result. See RCW 46.61.506(4)(b) and (c) (relating specifically to breath analysis). See also, Brown, 145 Wn. App. At 70 (applying RCW 46.61.506(4)(c) to blood test analysis).

In these cases, the City provided the certification of the blood vials at issue in this case, which demonstrate that the vials used to collect the samples contained an anticoagulant and enzyme poison that complies with the WAC. The defense does not dispute that at the time of collection of the blood sample, the certification is sufficient to establish this foundational requirement. Once prima facie evidence is submitted, the toxicology report must be admitted, any challenges to the accuracy then go to the weight, not the admissibility. King County Dist. Ct. West Div., 175 Wn. App. 630 (2013).

The defense argues, however, that the delay in testing of the vials until after the expiration date means that the manufacturer's certification is no longer valid, because they cannot warrant the condition of the vials past the expiration date. The defense provided evidence from Ms. Janine Arvizu that suggests a theoretical hypothesis as to how the amount of fluoride in

the tubes could possibly degrade over time, therefore not providing a sufficient enzyme poison to stabilize the ethanol levels in the tubes.

In response, the City provided testimony from the State Toxicologist, Amanda Black, that acknowledged the theoretical possibility that this hypothesis could occur, but provided substantial evidence to demonstrate that the interaction described by Ms. Arvizu is extremely unlikely. First, the hypothesis only described the interaction as it relates to water, but does not account for the presence of the other materials contained in blood. Second, she reviewed relevant scientific literature and available research to conclude that testing the vials after expiration would not substantially alter the result of the test. Third, accrediting agencies who analyzed procedures and policies of the Toxicology Lab did not seek to revoke accreditation even though they were fully aware that the lab was testing vials after the expiration date on the tubes. As such, the method "approved" by the toxicologist allows for testing of the tubes after the expiration date, provided that the sample was collected before the tube expired.

Drawing all inferences in favor of the City, as we are required to do, the City Attorney has presented prima facie evidence of the foundational requirements required by the RCW and the WAC, and any challenge to the accuracy of the test due to the testing of the vial after expiration goes to the weight and not the admissibility.

Washington case law strongly supports this interpretation. For example, in City of Seattle v. Allison, the Washington Supreme Court rejected a challenge to the admissibility of breath tests where the defendants presented evidence that based on variances in thermometers used in the breath testing machines, it was "possible" to have a reading outside the range specified as a requirement in the WAC. 148 Wn.2d 75, 78-79 (2002). In that case, the

defendants argued that the State should be required to prove the actual temperature reading of the machine at the time of the test, despite the fact that the WAC required only that the temperature be within a certain range. Id. The Supreme Court rejected this interpretation, holding that the breath test documents provided sufficient prima facie evidence of the foundation requirements for admissibility of the tests, and that any "arguments as to reliability of the particular test results are questions for the jury." Allison, 148 Wn.2d at 86.

In Brown, the court upheld the admission of blood test results where the toxicologist's testimony established a prima facie case of compliance with the WAC. There, the toxicologist testified that he read the labels on the tubes used for collection of the blood sample, which stated that the vials contained sodium fluoride and potassium oxalate. The toxicologist also observed that the blood in the tube was not clotted, and alcohol was detected in the sample. The appellate court held that these inferences were sufficient to establish that the anticoagulant and enzyme poison were present in sufficient quantities to comply with the WAC. Brown, 145 Wn. App. At 71.

In the cases at issue in this en banc proceeding, the parties do not dispute that the anticoagulant and enzyme poison were present in sufficient amounts at the time of the collection of the sample (relying on the manufacturer certification). The defense argues that it is possible that the amount of enzyme poison could have decreased after the expiration date on the vial, due to the chemical interaction posited by Ms. Arvizu. But Ms. Black testified that the likelihood of that happening is very small (if it exists at all) and further testified that based on review of scientific literature and other information, she reasoned that the enzyme poison would still be present in sufficient amounts to meet the requirements of the WAC even past the expiration date

on the tube. Notably, the WAC does not require a specific quantitative measurement of the enzyme poison. It only requires that it be present "sufficient in amount" to stabilize the ethanol in the sample. Ms. Black's testimony provides sufficient basis for which the court to infer that the amount present in the vial is sufficient even when the testing occurs after the expiration date of the vial.

Cases cited by the defense are inapposite. For example, in State v. Garrett, the court upheld the suppression of a blood result where it was undisputed that the vials did not contain the anticoagulant required by the WAC. 80 Wn. App. 651 (1996). In that case, the toxicologist homogenized the sample with a tissue grinder to restore the blood to an unclotted state. But the WAC specifically requires the blood sample to be preserved with an anticoagulant. WAC 448-14-020(3)(b). Because the tube did not contain the anticoagulant at the time of collection, it did not comply with the WAC and therefore was properly suppressed.

In Singh v. State Department of Licensing, the court ruled that the government had not met its prima facie burden where the evidence was insufficient demonstrate the presence of the anticoagulant and enzyme poison as required by the WACs. In that case, the hearing examiner did not admit the manufacturer's certification describing the presence of the materials in the tubes because it was notarized rather than signed under penalty of perjury. Because the certificate was excluded, there was no evidence in the record that established the presence of those materials. Singh, 5 Wn. App. 2d 1, 9-10.

In these cases, it is undisputed that the vial contained the enzyme poison "sufficient in amount" to stabilize the alcohol concentration at the time of collection. Ms. Black's testimony regarding her review of available scientific literature, consultation with nationwide experts, and

review by accrediting bodies provide ample support for the conclusion that testing the vials past the expiration date is still scientifically sound, and meets the requirements of the WAC. Any challenges to this conclusion go to the weight of the evidence, not the admissibility.

The Shadid Opinion in this case spends more than ten pages of analysis contesting the validity of the studies relied upon by Ms. Black to support her conclusion that testing the vials after the expiration date of the vials would not lead to inaccurate testing. The opinion rejects the City's invitation "to *infer* that there was sufficient fluoride in the expired tubes." Shadid Opinion at 22. However, the court in a pretrial hearing to determine whether foundational requirements for the admissibility of test results is required to draw inferences in favor of the City attorney. Brown, 145 Wn. App. At 69-70.

2. ER 702 Challenge

The defense alternatively challenges the admissibility of the blood analysis that is performed on tubes that expire after the sample is collected, on the basis that admission of the scientific evidence violates ER 702. This rule provides that scientific evidence is admissible if it "will assist the trier of fact to understand the evidence or to determine a fact in issue." ER 702. The defense argues that the toxicology analysis in cases with expired vials would not be helpful to the jury because it would be unreliable.

We reject this claim. Any challenge to the reliability or accuracy of the blood analysis in these cases goes to the weight, and not the admissibility. The City has met its burden to prove prima facie evidence that the WAC was followed, and therefore, the blood results are per se admissible.

Cases cited by the defense actually support the City's position. In State v. Johnson, 161 Wn App. 1013 (2011)(unpublished), the appellate court found that the record contained substantial evidence to support the trial court's finding that use of the expired tubes did not compromise the validity of the blood test results. Defense points to the testimony of the toxicologist that "the expiration date on the tubes refers to the shelf-life of the chemical additives in the tube." Def. Brief at 15. The defense ignores the fact that the same witness also testified that the additives in the tube "are stable components." This conclusion was supported by the fact that the sample was still liquid when she tested it (suggesting presence of the anticoagulant), and by the reasonable inference that the enzyme poison also mixed with the blood. Johnson at *3. The prima facie case was satisfied, and the appellate court upheld the trial court's decision to deny the suppression motion.

The defense also relies on State v. Cauthron, 120 Wn.2d 879 (1993), for the proposition that ER 702 may bar admission of scientific testimony when a "precise problem" is identified that would render the test unreliable. Def. Brief at 14. But Ms. Arvizu's testimony does not demonstrate any "precise problem" that would render the blood tests inadmissible once the prima facie evidence was presented. Her testimony is the hypothetical theory of one scientist, describing a process that might cause the result to be unreliable, if certain extraordinary conditions were met. But Ms. Arvizu could not point to a single example of this hypothesis occurring in any laboratory setting or in any scientific literature. There is no precise problem that would automatically render these tests unreliable – there is only a hypothetical process that has never been demonstrated to have actually occurred.

The evidence of blood analysis that was performed after expiration of the tubes is admissible under ER 702.

CONCLUSION

The defense motion to suppress toxicology results obtained from vials that expired before the testing occurred is denied. The City has established with prima facie evidence that the post-expiration testing meets the requirements of the WAC. Any further challenge to the accuracy or reliability of the tests goes to the weight of the evidence and should be considered by the trier of fact.

The defense motion to suppress pursuant to ER 702 is denied. An expert may testify as to the results obtained from the expired vials, and any further challenge to their conclusion goes to weight of the evidence.

Dated: October 3, 2024.

Judge Catherine McDowall
Seattle Municipal Court

Judge Willie Gregory
Seattle Municipal Court

CRIMINAL MOTION ORDER

ATTACHMENT "B"

SHADID OPINION

IN THE MUNICIPAL COURT OF THE STATE OF WASHINGTON
IN AND FOR THE CITY OF SEATTLE

In Re Expired Blood Vials	No. 4240001602 RULING ON EXPIRED BLOOD VIALS JUDGE DAMON SHADID

QUESTION PRESENTED

Whether blood test results obtained from the Washington State Patrol's Forensic Toxicology Lab ("Toxicology Lab" or "Washington Toxicology Lab") testing for blood ethanol stored in expired blood vials should be suppressed, or if the court should impose some other remedy.

LEGAL ISSUES

1. Preliminary Question: Does the Washington Administrative Code Section 448-14, specifically the presence of the enzyme poison, apply to all stages of the blood vial or only at the collection phase?

   Answer: The Washington Administrative Code 448-14 applies to all stages of the blood vial, including collection, storage and testing.

2. Has the government met its prima facia burden in proving that the Toxicology Lab's testing of the expired blood vials complied with RCW 46.61.506 and WAC 448-14-010 in that the testing of the expired blood vials was precise and accurate?

Answer: No.

3. Has the government met its prima facia burden in proving that the Toxicology Lab's testing of the expired blood vials complied with RCW 46.61.506 and WAC 448-14-020 by producing evidence that blood samples for alcohol analysis were preserved with "an enzyme poison sufficient in amount to . . . stabilize the alcohol concentration" namely sodium fluoride and its active by product in an aqueous solution, fluoride?

   Answer: No.

4. If the government has met its prima facia burden under the Revised Code of Washington ("RCW") and The Washington Administrative Code ("WAC"), should the blood alcohol results stemming from the Toxicology Lab's testing of the expired vials be suppressed pursuant to Evidence Rule 702?

   Answer: Yes (ruling in the alternative to above).

BACKGROUND

The City has charged all defendants in the consolidated motion with either Driving Under the Influence or Actual Physical Control.[1] The parties agree that all the cases contain certain consistent facts. Law enforcement collected defendants' blood in unexpired Becton Dickinson (hereafter "BD") vacutainer blood vials. The vials had an "expiration date" of approximately two years listed on the vial, the vials' packaging, and the vials' Certificate of Compliance.[2] The Toxicology Lab stored the vials, without testing them, until after the vials' two-year expiration date. Subsequent to the expiration date, the Washington State Toxicology Lab tested the vials. The results of this testing are at issue in this motion.

[1] RCW 46.61.502 and 46.61.504 respectively.

[2] See City's Response Brief at 2.

Seattle Municipal Court Presiding Judge Faye Chess designated this litigation as an "Issue of Citywide Significance" pursuant to Seattle Municipal Court Local Rule (SMCLR) 8.2.4 on May 20th, 2024.[3] Judges Catherine McDowall, Willie Gregory, and Damon Shadid were assigned to the panel. Both sides submitted briefing. Evidence and arguments were heard on September 9-11th, 2024.

Defense presented the testimony of Janine Arvizu, a chemist and Quality Auditor of forensic laboratories. City presented the testimony of the Washington State Toxicologist Amanda Black. Oral arguments followed testimony.

AUTHORITY

Blood alcohol tests for DUI related cases are subject to the requirements of RCW 46.61.506[4] requiring all blood alcohol tests be "performed according to methods approved by the state toxicologist."[5] Methods approved by the state toxicologist are enshrined in the Washington Administrative Code (WAC). WAC 448-14-010 codifies that testing must be accurate and precise and sets forth the criteria for approved methodology for blood analysis. One element of blood alcohol testing is sample collection and preservation, which requires in part:

> Blood samples for alcohol analysis must be preserved with an … enzyme poison sufficient in amount to … stabilize the alcohol concentration. Suitable preservatives … include … sodium fluoride.[6]

"These requirements ensure that the blood sample is properly preserved for testing."[7] "The WAC regulations do not detail the approved testing methods, but rather outline the criteria any approved method must meet.[8] The regulations require that any testing method must meet

---

[3] See Order on Criminal Motion in court file.
[4] *See Singh v. State, Dept. of Licensing*, 5 Wn.App.2d 1, 7 (2018).
[5] RCW 46.61.506(3)
[6] WAC 448-14-020(3)(b)
[7] *State v. Clark*, 62 Wash. App. 263, 270(1991).
[8] Citations omitted.

"strict standards for precision, accuracy, and specificity." [9][10] "To introduce the results of a blood alcohol test, the State has the burden of proving that the analysis was performed in compliance with the regulations contained in chapter 448–14 WAC.[11] If the testing method meets the requirements of the WAC regulations, "there is sufficient assurance of accuracy and reliability of test results to allow for general admissibility of test results."[12][13]

The government has the initial burden of establishing a prima facie case that blood preservation and testing were correctly performed and, therefore, free of adulteration that could produce error.[14] To meet this prima facie burden, the City must provide "clear evidence of compliance with the analytical testing procedures" and must establish that "a valid blood test [was] performed according to methods approved by the state toxicologist."[15] Washington law defines prima facia evidence as:

> [E]vidence of sufficient circumstances that would support a logical and reasonable inference of the facts sought to be proved. In assessing whether there is sufficient evidence of the foundational facts, the court or administrative tribunal is to assume the truth of the prosecution's or department's evidence and all reasonable inferences from it in a light most favorable to the prosecution or department.[16]

"The language of WAC 448-14-020(3)(b) is mandatory, *notwithstanding the government establishing a prima facie case that the sample was unadulterated.*"[17] Washington courts have "consistently required clear evidence of proper blood sample preservation *in addition to*

---

[9] State v. Mee Hui Kim, 134 Wash.App. 27, 38.
[10] Citations omitted.
[11] Citations omitted.
[12] Id at 39.
[13] Citations omitted.
[14] *State v. Brown*, 145 Wash. App. 62, 69–70, 184 P.3d 1284 (2008). *State v. Wilbur-Bobb*, 134 Wn.App. 627, 630 (2006). S *State v. Brown*, 145 Wn.App. 62, 69-70 (2008).
[15] *Wilbur-Bobb*, 134 Wn.App. at 630 (citing RCW 46.61.506(3)).
[16] RCW 46.61.506(4)(b).
[17] *State v. Garrett*, 80 Wn.App. 651, 910 P.2d 552 (1996), *Brown*, 145 Wn.App. at 71-72 (emphasis added).

compliance with the analytical testing procedures and have overturned criminal convictions when the evidence failed to show compliance with WAC 448-14-020(3)."[18]

In *Singh v. State Department of Licensing*, the court suppressed defendant's blood test result because the government could not demonstrate the use of an enzyme poison.[19] "Without evidence that the collection tubes met the WAC requirements, the Department did not establish a prima facie case that the preservation of Singh's blood complied with the statutory requirements."[20] The court noted that the testing toxicologist's "certification establishe[d] a prima facie case for only her compliance in administering the analytical tests of Singh's blood, *not the specifics of sample preservation.* Thus, even drawing all inferences in favor of the [government, the toxicologist's] report does not establish compliance with WAC 448–14–020(3)."[21]

City's Expert State Toxicologist Amanda Black testified that accuracy of the blood sample depends on how close the measurement of the blood sample would be to a blood sample that was tested at the time of collection. The WACs do not differentiate accuracy depending on whether the blood alcohol content goes up or down. The concern is that the tested sample produces an accurate result (See, for example, *State v. Bosio*, 107 Wash.App. 462, 466-467 (2001): "The purpose of requiring the use of anticoagulants and enzyme poison in the blood sample is to prevent clotting or ***loss of alcohol concentration*** in the sample" (emphasis added)).

---

[18] *Singh*, 5 Wn.App.2d at 8. See, e.g. State v. Hultenschmidt, 125 Wash. App. 259, 266 (2004) (blood analysis was not valid without evidence that enzyme poison was in the sample tube despite prima facie evidence that the sample was free from adulteration); State v. Bosio, 107 Wash. App. 462, 468 (2001) (police officer and nurse testified about the presence of anticoagulant in the bottom of the sample vial but no evidence established use of enzyme poison); Garrett, 80 Wash. App. at 653 (blood analysis was not valid where sample vial did not contain anticoagulant despite evidence that the sample was free from adulteration). The uniformity of these procedures "ensure[s] that the test results will be accurate and reliable" prior to admission at trial. *Bosio*, 107 Wn.App. at 467 (emphasis added).

[19] Id. at 8-9

[20] Id. at 10.

[21] Id. (emphasis added).

The Washington Administrative Code is also silent regarding when the enzyme poison must be present in the vial. CAO asserted that the enzyme poison must only be confirmed in the vial at the time of collection. They assert that no amount of time past expiration of the vial is relevant to the question of whether the enzyme poison satisfied the WAC, as the WAC was satisfied at the time of collection. Defense asserts, on the other hand, that the enzyme poison must be confirmed throughout the lifecycle of the vial to satisfy the WAC. They stipulate that BD's assertions regarding the presence of the enzyme poison is sufficient to satisfy the WAC *until the date of expiration*. However, they argue that after expiration, the Toxicology Lab and prosecuting authority must show that the enzyme poison was present *at the time of testing.*

The WAC reads: "Blood samples for alcohol analysis must be preserved with an … enzyme poison sufficient in amount to … stabilize the alcohol concentration."[22] To admit the blood test results, the State must present "prima facie proof that the test chemicals and the blood sample are free from adulteration that could conceivably introduce error to the test results."[23] The issue of testing expired blood vials appears to be one of first impression for the appellate courts. However, the language used in appellate decisions is illustrative of why the court should interpret the WAC as requiring proof of the enzyme poison at the time of testing, not at the time of collection.

<u>WAC 448-14-020(3)(b) Applies to all stages of the vials' use, including collection, preservation and testing</u>

The *Singh* court held that the government "has the initial burden of establishing a prima facie case that blood *preservation* and testing were correctly performed."[24] The court goes on to

---

[22] WAC 448-14-020(3)(b).
[23] *Wilbur-Bobb*, 134 Wash. App. at 630, 141 P.3d 665.
[24] *Singh* at 8 (emphasis added).

emphasize that "Washington courts have consistently required clear evidence of proper blood sample *preservation* in addition to compliance with the analytical testing procedures."[25] The *Singh* court held that the governments burden is two-fold. They must both "show that the *preservation* and *testing* of [defendant's] blood samples complied with all WAC requirements."[26] While the government in *Singh* was able to show "compliance in administering the analytical tests", they were unable to show that they complied with "the specifics of sample preservation."[27]

The court's emphasis on sample preservation in the WAC strongly suggests that the government must show the presence of enzyme poison at the time of testing. In unexpired vials, this is a simple task, as the government would have the Certificate of Compliance from BD as well as testimony from both the person collecting the sample, and the toxicologist testing the sample. However, after the vial expires, the government can no longer rely on the manufacturers' statements, certificates of compliance, or assumptions to prove that there remained sufficient enzyme poison to stabilize the alcohol concentration of the blood. Post expiration, the only way for the government to prove their prima facie case would be to present testimony or evidence that the solution in the expired vial was tested *for the enzyme poison at the time of testing*. Without such a test on the expired vial at the time of testing, it is impossible to know whether the solution contained any enzyme poison at all, or whether the amount left in the tube was *still* sufficient to stabilize the alcohol concentration. In fact, because the blood is being tested for the first time after the vial has expired, it is impossible to know whether the blood concentration remained stable at all during preservation.

---

[25] Id. (emphasis added).
[26] Id. at 10 (emphasis added).
[27] Id. (emphasis added).

This preliminary ruling, standing on its own, is dispositive in the case. All parties agree that the Toxicology Lab did not perform any independent testing for enzyme poison after the vial's expiration date. Instead, the Toxicology Lab relied on studies to justify their position that the court can infer the presence of sufficient enzyme poison after the vial's expiration date. As discussed below, the studies presented by the government and the Toxicology Lab are insufficient for the court to make such an inference.

Judge McDowall's competing opinion (supported by Judge Gregory) states that the court must *infer* the presence of the enzyme poison, regardless of how long after the date of expiration the blood is tested. Her ruling cites "substantial evidence" by the State Toxicologist Amanda Black. While it is true that the court must draw inference in favor of the government, the court is not a rubber stamp when it comes to the admission of blood test results.[28]

Past cases have held that the Certificate of Compliance is sufficient to prove the existence of the enzyme poison. In the present cases, the government cannot rely on the Certificate of Compliance as that document was expired at the time of testing. Amanda Black admitted on the stand she had made an erroneous assumption about the expiration date. She then retroactively sought to apply studies to justify her position. Even drawing inferences in favor of the government, the court must look critically at the evidence presented by Ms. Black to justify their position. Upon even a cursory analysis, it is quite clear that there is not "substantial evidence" to prove the existence of the enzyme poison after the vial's expiration, and indeed, there is not enough evidence to even draw an inference of such based upon the testimony and exhibits of the government.

[28] This opinion is not suggesting that Judge McDowall's well-reasoned opinion is a "rubber stamp." The opinions disagree as to the level of scrutiny that should be applied to the government's prima facia evidence.

The competing opinion also ignores the evidence presented by the manufacturer of the vial itself, stating that there was absolutely no guarantee after expiration of the existence of the enzyme poison. The manufacturer does not support any use of their vial after expiration.

The competing opinion also ignores the rigorous methodology laid out by the Food and Drug Administration required to extend an expiration date. The Toxicology Lab did not follow any of the FDA's methodology to justify their actions.

The competing opinion lacks a detailed analysis of the actual articles presented by the Toxicology Lab to justify their position. As shown below, only one study with a small sample size could possibly be used to infer the existence of the enzyme poison after the vial's expiration. This study does not specifically address enzyme poison, nor does it study the effects of contamination of the blood vial by bacteria. Even drawing every possible favorable inference from this study, as discussed at length below, a single study should *never* be used to draw firm scientific conclusions.

Finally, the competing opinion seems to dismiss the possibility of bacterial contamination of the vials. Not a single article presented by the government tested for bacterial contamination, and therefore *no inferences* can be drawn regarding the possibility of bacterial contamination on the vial.

DISCUSSION

Blood Vial Expiration Dates

The Washington State Toxicology Lab uses BD Vacutainer® Tubes (term used interchangeably with "vials" "blood vials" "tubes" etc.) for the collection, storage and testing of

blood samples taken from defendants pursuant to a warrant for collection of blood.[29] All BD vials come with an expiration date marked on the packaging the vial is delivered in, each individual vial, and on the Certificate of Compliance for each batch of vials.

BD determines the expiration date for the vials pursuant to guidance from the Federal Food and Drug Administration ("FDA"). The testing must be rigorous and exhaustive to comply with FDA guidelines. The testing is not limited to the vacuum or the seal of the vial. Instead, the testing must cover all aspects and uses of the vial, including storage of collected samples.[30] The FDA also provides for exhaustive testing procedures for extending the shelf life or expiration of devices.[3132] Although the required parameters of the testing to determine the expiration date of the vials is clear, the resulting testing BD uses to establish the expiration date is considered proprietary information and the specifics of the study are not available to the public (including this court, the Washington State Toxicology Lab, or the parties involved in this litigation). Any specifics of the BD study are unknown, and it is therefore impossible for the parties to determine the exact reasons why and how BD determined the expiration date of the vials.

BD, however, is unequivocal regarding their expiration date, stating the "expiration date applies to the tube and its components as a whole."[33] BD determines exact expiration dates

---

[29] Ex. 7 Defense Attachment E "Declaration By BD Representative in Response to Subpoena to Appear at Trial (July 15, 2024). "BD Vacutainer® Tubes, Needles and Holders are used together as a system for the collection of venous blood. BD Vacutainer® Tubes are used to transport and process blood for testing serum, plasma, or whole blood in a clinical Lab setting. The use of BD Vacutainer® Tubes extends beyond the date of the original blood collection. That use includes, but may not be limited to, storage of the blood within the Tube, in addition to the processing (or extraction) of the blood from the Tube for testing. BD does not make any representation or claim regarding any use of any BD Vacutainer® Tubes for any purpose post-date of any Tubes' expiration date." Emphasis added. Interrogatory 6.

[30] See Defense Brief Attachment C "Shelf Life of Medical Devices" April 1991 Food and Drug Administration

[31] Id.

[32] The terms "Shelf Life" and "Expiration Date" may be used interchangeably. "Shelf life is the term or period during which a commodity remains suitable for the intended use. An expiration date is the termination of shelf life, after which a percentage of the commodity, e.g., medical devices, may no longer function as intended." Defense Brief Attachment C "Shelf Life of Medical Devices."

[33] Ex. 7 Defense Attachment E "Declaration By BD Representative in Response to Subpoena to Appear at Trial (July 15, 2024).

"based on ethanol studies conducted to support the tubes' performance throughout its shelf life."[34] BD specifically advises against use of the tubes, for any reason, after the expiration date[35] ("BD does not support use of a tube beyond its labeled expiration date." BD states that the vials "are manufactured to accurately determine blood alcohol content up to their date of expiration" and that they cannot guarantee any use, for any reason, of the vials after expiration).[36] As part of the testing to determine expiration date, BD confirms that the vial's expiration "is determined according to a specific additive: blood ratio." They emphasize that "[s]pecific lab testing and/or expert analysis would be necessary to determine the efficacy of any BD Vacutainer® Tubes post-expiration date, as the Tubes' expiration date, alone, likely cannot be the only factor to their efficacy."[37] BD does not specify what testing, specifically, would be necessary to extend the expiration date of the vials, in whole or in part. However, the FDA has given guidelines to companies that wish to extend the expiration date of their devices.[38] While the FDA guidance may not be dispositive to the question of whether the Toxicology Lab complied with the WACs, they are at least illustrative of the rigor necessary to ensure expired vials yield accurate results.

Breakdown of Sodium Floride in an Aqueous Solution

All the BD vials at issue in this case comply with the Washington State Administrative Code (WAC) 448-14-020(3)(b) on delivery. Specifically, when the tubes are delivered to the various agencies that administer blood draws, the vials contain 100.0 mg (+-10mg) of Sodium Floride ("NaF") which acts as "an enzyme poison sufficient in amount t to . . . stabilize the alcohol concentration" in the vial compliant with WAC 448-14-020(3)(b). All parties agree that

---

[34] Id.
[35] Id.
[36] Id.
[37] Id.
[38] See Defense Brief Attachment C "Shelf Life of Medical Devices" April 1991 Food and Drug Administration

the enzyme poison NaF is present in the vials at the time of delivery. All parties agree that the 100 mg of NaF is sufficient until the expiration date on the vial to stabilize the alcohol concentration.[39] Both experts testified that the fluoride ("F") component of NaF is the active ingredient of the enzyme poison. The amount of fluoride present in the delivered tube is 45 mg (with the other 55 mg being sodium). At issue in this case is whether the vials comply with the WAC after the expiration date of the vial. The defense's assertion is that the City has not made a prima facie case that the enzyme poison (F) is still present in sufficient quantities to stabilize the alcohol concentration after the vial's expiration date.

Both defense and city experts agreed on the basic chemistry at play when blood is stored in glass BD vials.[40] The basic chemical process is as follows[41]:

- Blood composition is approximately 50% water.
- When NaF is mixed with water, the sodium and fluoride break apart, creating free floating positively charged sodium ions (Na+) and negatively charged fluoride ions (F-).
- When F- molecules interact with water molecules (H20) the chemicals go through hydrolysis. Hydrolysis is the process in which the fluoride and the water interact to create hydrofluoric acid (HF). HF is extremely corrosive.[42]
- Hydrofluoric acid interacts with glass.[43] HF does not interact with plastic. All vials used for DUI investigations in Washington State are made from glass (silicone dioxide SiO2).
- The chemical reaction between HF and SiO2 bonds fluoride to the glass.

---

[39] Defense expert agreed that 100 mg NaF met the "meet consensus standards" for stabilizing blood alcohol up until the expiration date.
[40] All vials used in Washington for DUI investigations are made of glass.
[41] Obviously simplified for the court's usage today.
[42] "Hydrofluoric acid (HF) is a liquid or gas which is the most corrosive acid known when in concentrated form." Hydrofluoric acid - OHS Information Sheet - Health Safety & Wellbeing (monash.edu).
[43] Id.

- When fluoride is bonded to glass, the fluoride is no longer available in the solution to act as an enzyme poison.

Based upon the above chemical reaction, *the longer a blood sample is stored, the less fluoride is present in the vial to act as an enzyme poison.*

Dr. Arvizu also described the process in which fluoride prevents fermentation in the blood sample. She states that fermentation could only happen if the blood sample at the time of collection was contaminated by bacteria or other microorganisms. She emphasized that while there is sufficient fluoride present until expiration date to prevent fermentation, after expiration date it is at least possible for a contaminated sample to *increase* in alcohol concentration. Therefore, the basic science of preservation with fluoride is to both stabilize the alcohol concentration from increasing or decreasing.[44]

To reiterate: the enzyme poison serves two purposes to ensure the accuracy of the blood test result. It prevents the alcohol level from *reducing*, thus lowering the tested alcohol concentration, and it prevents the alcohol concentration from *increasing* by preventing fermentation that may take place if the blood draw results in bacterial contamination being introduced to the blood sample. Defense expert testified that bacterial contamination happens in approximately 10-15%

---

[44] The defense expert provided extensive testimony regarding the process in which blood could begin the process of fermentation if the amount of fluoride in the blood solution drops too low. This testimony is useful in explaining how blood concentration may go up over time. However, accuracy is determined by the test result increasing OR decreasing in amount over time. Both an increase or a decrease in the test result would be inaccurate and therefore barred under the WAC. The consensus in Washington is to use BD vials that contain 100 mg NaF to stabilize alcohol concentrations. It is obvious, therefore, that the drafters of the WACs understood the chemical process that could result in fermentation, and therefore guarded against such process by insisting that an enzyme poison be present in the storage vials. It is also clear that, according to the FDA regulations regarding expiration date studies, that BD tested to ensure that the amount of F in the stored blood sample would remain high enough to stabilize alcohol concentrations until the expiration date listed on the vial.

of blood samples taken. Since DUI blood draws cannot employ alcohol swabs, the percentage of contamination may be even higher for DUI blood draws.[45]

The competing opinion states that hydrolysis in blood is only a hypothesis. However, the testimony of both doctors agreed that hydrolysis is a distinct possibility. The hypothetical issue pertained to fermentation *after* hydrolysis, not to hydrolysis itself. Amanda Black did testify that she did not know how much hydrolysis would take place in blood, and that there were no studies confirming or denying the rate of hydrolysis in these vials. But the existence of hydrolysis is a fact.

The Washington State Forensic Toxicology Lab's ("Toxicology Lab's") Process and Justification for Extending the Expiration Date of the Expired Vilas

According to their website, the Toxicology Lab receives over ten thousand (10,000) blood vials per year to analyze in DUI cases.[46] City expert Washington State Toxicologist Amanda Black testified that the Toxicology Lab had always *assumed* that the expiration date on the BD vials only applied to the vacuum seal of the BD vials which enable the original blood draw (collection phase of the vial's life). She testified that this was her understanding of information given to them by BD in the past. However, the court notes that Ms. Black did not cite any specific documentation that would support this assertion, nor did the City provide any documentation or exhibits that would verify that BD has changed their position in the past. Ms. Black also testified that she only became aware that there may be an issue with expiration dates when litigation regarding the testing of the expired tubes began. Once Ms. Black became aware

---

[45] Since the blood draws are meant (in part) to measure alcohol concentration of blood at the time of the draw, the technician cannot use an alcohol swab to sterilize the skin. Alcohol is the fastest and most effective way to sterilize skin prior to a blood draw. The technician therefore must use slower acting and less effective chemicals to sterilize the skin prior to the blood draw, making the possibility of bacterial contamination of the blood sample even higher.

[46] Crime & Forensic Lab Services - Washington State Patrol

that BD's expiration date applied to all aspects of the vial, from collection, to storage, to testing, she sought out studies that would validate the Toxicology Lab's practice of testing expired tubes.

Ms. Black confirmed on the stand that the Toxicology Lab did not do any additional testing on the vials beyond analyzing the blood for drugs and alcohol. She confirmed that there are tests that could be performed to ascertain the levels of fluoride left in the bottle after the vial's expiration, but that the Toxicology Lab did not do this testing. She confirmed that the studies and articles provided by the City as exhibits were the same articles she and her colleagues relied upon to extend the expiration date of the vials. The Toxicology Lab did not utilize any of the processes laid out by the FDA for extending the expiration date of the expired vials.[47] The Toxicology Lab's only action to justify the testing of the vials was to retroactively apply studies of vials to their current practice. Based upon this application, Ms. Black testified that she believed testing expired vials was valid under the Washington Administrative Code.

Below is an analysis of the studies used by the Toxicology Lab to justify their practice of testing expired vials. However, it should be noted at the outset that none of the studies proffered by the Toxicology Lab and the City measured the subtraction of fluoride in glass tubes over time. None of the studies determined whether, due to the amount of fluoride in the vial reducing over time, if there remained sufficient fluoride in the vial to stabilize alcohol concentration under the WAC. None of the studies offered specifically identified the minimum amount of fluoride needed to continue to stabilize alcohol concentration. None of the studies addressed the addition of bacterial contamination into the tubes that could arise at the time of collection. None of the studies determined how much fluoride remaining in the vial would be necessary to counteract a bacterial contamination. Most of the studies' findings did not apply to expired vials, or used

[47] Defense Brief Attachment C "Shelf Life of Medical Devices" April 1991 Food and Drug Administration.

plastic vials that are not relevant to the case at hand. Most of the studies showed a marked decrease in ethanol levels over time which would be exacerbated when there were lower levels of fluoride in the vial. However, the studies showing a decrease in ethanol did not test for bacterial contamination, and therefore could not address whether there was sufficient fluoride remaining in the vial to prevent fermentation. Most of the studies did show, quite conclusively, that the longer the vial is stored, the lower the accuracy of the test result.

In short, none of the studies, evidence or testimony proffered by the Toxicology Lab or the City show that an expired vial retains a sufficient amount of fluoride to stabilize alcohol concentration comporting with WAC 448-14-020(3)(b), nor that testing the vials after expiration would produce an accurate result under WAC 448-14-010. In fact, most of the studies show that the accuracy of results decreases over time, and the inaccuracy can be exacerbated in the absence of sodium fluoride.

On the other hand, almost every exhibit admitted into evidence contradicts Ms. Black's testimony on the testing of expired vials, including, but not limited to: 1) BD's assertions regarding expiration date in their interrogatories, 2) FDA guidelines regarding determination of expiration date dating back to the 1980s, 3) the Certificate of Compliance filed with the vials listing the expiration date, and 4) the Product Insert that came with the vials specifically stating that the vials should not be used after the expiration date. The City goes through great lengths to justify the assumption that the expiration date applies only to the time of collection. However, the City's own witness acknowledged that her assumption was wrong and sought to correct that erroneous assumption by retroactively applying articles and studies to their practice of testing expired tubes.

In addition to the fact that none of the studies proffered by the government to support the testing of expired blood vials is directly on point or show a compliance with the WAC, even

assuming for arguments sake that the first study[48] (see below) was relevant to the question at hand, it must be emphasized that this is only one study:

> Scientists have known about biases in single observations for centuries. A wealth of empirical evidence amassed across many disciplines tells us that single studies can be biased, are often seriously methodologically flawed and highly time and context dependent, and have findings that are likely to be misinterpreted and misrepresented (sometimes by the authors themselves). Increasingly it is accepted that decisions should not be based on the findings from single primary studies but rather informed by actionable messages derived from synthesised evidence based on systematic reviews.[49]

"Most primary research needs to be set in context, verified, and built on, moving the field forward incrementally before it can then have wider application."[50] In criminal cases, where Constitutional rights and freedom are at stake, the Court must hold the Toxicology Lab to basic standards of science and scientific research. The City, and by extension the Toxicology Lab, has asked this court to make an inference from three articles of questionable relevance and reliability that the measured alcohol concentration in an expired vial will always and only ever decrease relative to the subject's original blood alcohol after the expiration of the vial. The combined results of these studies hint at a hypothesis that bears further study. It does not help the court reach a conclusion, either scientifically or legally. While the court will use established science to form reasonable conclusions, the court will not invent its own scientific results as a basis to accept evidence that lacks a reliable measure of accuracy and precision as demanded by the WAC.

Good science does not rely on one study nor does it begin with a conclusion and then search for justification for that conclusion. Instead, as scientists, if the Toxicology Lab wanted to

---

[48] City's Exhibit 2 (Brief and Hearing): Long-Term Blood Alcohol Stability in Forensic Antemortem Whole Blood Samples.

[49] Why Promote the Finding of Single Research Studies? BMJ 2008 Mr 29; 336(7646): 722 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276286/#:~:text=A%20wealth%20of%20empirical%20evidence,sometimes%20by%20the%20authors%20themselves).

[50] Id.

extend the expiration date on their vials, they should have done exhaustive testing on the expired vials to ensure that the complied with the Washington Administrative Code. If there were multiple studies directly on point, they could theoretically have relied on those studies as well to justify their position that expired vials produce scientifically accurate results and comply with the WAC regarding enzyme poison. The Toxicology Lab has failed in this fundamental application of basic scientific research. If the Toxicology Lab wanted to move forward with testing the expired vials in the absence of further research, they could have tested the fluoride content of each expired vial contemporaneously with the blood alcohol. They also chose not to perform this additional test which may have brought them into compliance with the WAC. Finally, the Toxicology Lab could have triaged the vials by their expiration date, ensuring that all the vials were tested prior to the vial expiring. Ms. Black testified that the Toxicology Lab never adopted this practice, even when it became obvious that many of the vials would expire in storage awaiting Toxicology Lab testing.

Analysis of the Studies Used by the Toxicology Lab to Extend the Expiration Date

City's Exhibit 2 (Brief and Hearing): Long-Term Blood Alcohol Stability in Forensic Antemortem Whole Blood Samples

In this study 117 vials were tested before expiration, then stored for long periods of time (approximately 5-10 years). The blood was then retested to determine if ethanol values had changed significantly. This study was peer reviewed and, though it facially appears to support the City's position, is not reliable to show that the Toxicology Lab complied with WAC 448-14-020 for at least 3 reasons: 1) The experimental population of the vials tested in this study exclude contamination, making it irrelevant to the question of fermentation which may increase alcohol concentration. Under the actual conditions of blood sample collections in DUI investigations, 10-15% (possibly more) may be contaminated by bacteria. 2) The rate of decline of alcohol

concentrations in expired vials is variable after expiration. The study does not speak to how much fluoride was left in the vial or how much would be needed to stabilize the alcohol concentration. 3) The experimental population is small (117 vials), and the results are limited to one study making it impossible to conclude that the results can and would be duplicated without more evidence.[51]

No bacterial contamination or any other kinds of contamination was introduced to any of the 117 samples. No contamination was known to be in any of the vials during either testing phase. The study concluded samples that were negative prior to vial expiration remained negative after expiration and samples that were positive prior to expiration showed a decrease in ethanol over time.

The study does make clear that blood testing becomes less accurate (in this case lower) the longer the vial is stored. However, without specific testing for the amount of fluoride in the bottle during the first test and then testing the amount of fluoride in the bottle after expiration, and without the introduction of a bacterial contaminate to at least a portion of the vials, the study cannot infer the amount of F in the bottle would be in a sufficient amount to stabilize alcohol concentration and therefore comply with WAC 448-14-020 either at the time of testing or retesting.

The fact that testing becomes less accurate over time tends to support the defense position that testing after expiration provides less accurate results and therefore cannot be deemed to be accurate under the WACs.

City's Exhibit one (Brief and hearing): Comparison of Blood Ethanol Concentrations in Samples Simultaneously Collected into Expired and Unexpired Venipuncture Tubes

[51] As noted above, the Washington Toxicology Lab analyzes over 10,000 blood vials per year.

Although this article was published in a peer-reviewed journal, it was not a research study. The sample size was small: 48 subjects. The study collected blood from subjects with unexpired vials and expired vials. Both types of vials started with 100 mg of Sodium Floride. No bacteria or other contaminate was introduced into the vials at the time of collection or any time thereafter. Both expired and unexpired vials were tested one week after collection of blood.

The study did not measure the amount of fluoride in the bottles at the time of testing. The study did not ascertain the reduction in fluoride levels in a glass tube over time. The study did not show if there was a sufficient amount of enzyme left in the vials to stabilize alcohol concentrations.

The findings in the article only show that *after one week of storage*, blood collected in expired tubes and blood collected in unexpired tubes had similar alcohol readings (not statistically significantly different).

The only conclusion that can be drawn from this article is irrelevant to the question at hand. The article speaks to the stability of the NaF prior to blood collection, not the breakdown of F post collection when introduced into an aqueous solution. The article has nothing to do with the *storage* of the blood in expired tubes and the effect that storage has on the amount of F removed from the solution due to storage. The article does not address the interaction of hydrofluoric acid with glass.

The court can therefore find no evidence in this study that the Toxicology Lab's practice of testing expired tubes comply with WAC 448-14-020 showing that there was sufficient F in the solution at the time of testing the unexpired vials to stabilize blood concentration.

City's Exhibit 3 (Brief and Motion): The effects of storage on the accuracy of Blood alcohol Readings

This study was conducted in New South Wales. The study used plastic vials, making the findings irrelevant to the glass vials used in Washington.[52] The sample size is tiny, 14 total subjects, which cannot and should not be considered statistically significant. Only half the bottles in the study contained sodium fluoride. None of the vials were expired. The vials were only stored for a total of 42 days, not for over 2 years as in the current case. The amount of fluoride in the bottles was never tested. No bacterial contamination was introduced to any of the vials.

The results of the study were to show ethanol levels went down over time, supporting the defense's argument that testing vials becomes less accurate over time.

City's Exhibit 4 (Brief and Motion)

This study had a sample size of 288, with only 144 of the vials containing sodium fluoride. The study was limited in scope to show the effects of storage temperature on blood ethanol levels. The vials were not expired and only stored for a total of 35 days. The study did not measure the amount of fluoride in the bottle at the time of the second test.

The study concluded that higher storage temperatures, even for short periods of time, make blood ethanol level testing far less accurate, with BAC dropping 10-19% over 35 days of storage. The study also showed the benefit of sodium fluoride as a preservative, noting that ethanol levels in vials containing sodium fluoride remained stable for as long as five and a half months, far longer than vials that did not contain sodium fluoride. However, the study did note: "Whether the loss of BAC was due to the absence of [fluoride] or not is not known"[53] but did note a different study which concluded that the important factors that affect BAC are temperature, fluoride

---

[52] As noted above, plastic vials to not react with hydrofluoric acid, glass vials do, causing the amount of fluoride in a glass vial to decrease over time.
[53] At 184

concentration and time of storage." "A whole blood sample analyzed after exposure to elevated temperature may produce lower BAC than it originally contained at the time of collection."[54]

Once again, the court fails to find how this study supports the notion that testing expired vials comply with WAC 448-14-010 (accuracy) or 020 (level of enzyme poison).

City's Exhibit 5 (Brief and Motion): Inferences and Legal considerations following a Blood collection Tube Recall

This article is not a scientific study and is written with a strong law enforcement bias. However, despite these limitations the article still notes that "Certain impairing drugs (e.g., cocaine and 6-acetylmorphine) are unstable in blood an tend to degrade without an enzyme inhibitor, such as sodium fluoride, present."[55] The article also notes that in "reviewing available literature related to current practices and the stability of ethanol in stored blood samples, there does not appear to be a clear consensus regarding the amount of sodium fluoride preservative necessary, if any at all, which blood is taken from living subjects under sterile conditions for … forensic ethanol analysis."

The article notes that sodium fluoride may or may not stabilize alcohol concentration for 2 weeks, with other studies showing shorter and longer periods depending on storage conditions. The article cites studies that contaminated the sample with yeast. One study found that added yeast and glucose did in fact increase ethanol in the absence of sodium fluoride, while another showed that without glucose ethanol was not produced. Both studies cited were for short periods of time: up to 29 weeks.

Once again, the court fails to find how this study supports the notion that testing expired vials comply with WAC 448-14-010 (accuracy) or 020 (level of enzyme poison).

---

[54] Id.
[55] At 3

City's Exhibit 6 (Brief and Hearing) LabNotes "The Evolution of Evacuated Blood Collection Tubes"

This handout describes blood vials in general, not the specific vials used for DUI blood analysis in Washington. The handout notes that "Most dry additives tend not to be a limiting factor in determining the shelf life of evacuated tube."[56] This finding alone would point the reader away from the assumption that expiration dates would only apply at the stage of collection.

CONCLUSIONS OF LAW

1. Preliminary Ruling: WAC 448-14-020(3)(b) Applies to all stages of the vials' use, including collection, preservation and testing

See above for discussion and analysis.

2. The City has not met its prima facia burden showing that test results of alcohol concentration after the vials have expired are accurate under WAC 448-14-010.

All experts testified that the accuracy of the results decrease the more time from collection the sample is taken. Many of the City's studies showed a marked *decrease* in alcohol concentrations over time, deviations outside the margin of error necessary for an accurate test. Although, based on FDA guidelines, it can be inferred that BD tested the vial's accuracy prior to the expiration date, the testing did not lead them to extend the expiration date of the vials. The City is unable to provide a prima facia evidence of the accuracy of the test results after expiration. The City has therefore not met its prima facia burden for admitting blood results from expired vials. These test results are therefore suppressed.

3. The City has not met its prima facia case to show that there was sufficient enzyme poison in the expired vial at the time of testing to satisfy WAC 448-14-020(3)(b)

[56] At 3.

The City encourages the court to *infer* that there was sufficient fluoride in the expired tubes because at least one of their studies showed that alcohol concentrations remained consistent from the time of testing until well after the expiration of the vials. Only one of the City's studies could conceivably stand for this proposition: City's Exhibit 2 *Long-Term Blood Alcohol Stability in Forensic Antemortem Whole Blood Samples*. An analysis of the study is above, but to re-iterate: the study's sample size was extraordinarily small. The study did not investigate vials that were stored for long periods of time with bacterial contamination. At most, this study stands for the proposition that a vial that does not contain any contaminants (i.e. remains sterile) is capable of storing blood after the vial's expiration date. However, we cannot infer from this study that the fluoride in the tube is there at all post expiration and if the preservation of the sample after expiration was due to the fluoride or some other cause. We cannot infer that there remained enough fluoride in the tube to prevent a bacterial contamination from causing fermentation in the tube.

Therefore, similar to *Singh*, the most this study can show us is that the blood was unadulterated at the time of testing. Similar to *Singh*, there is no direct evidence that the enzyme poison remained in the vial at the time of testing after expiration.

Another flaw in the Toxicology Lab's methodology is time of testing. We can look at the blood sample in 3 different stages. Stage one collection. During collection, the blood alcohol result will be as close to accurate as possible, representing the true amount of alcohol in a defendant's system at the time of the blood draw. Stage 2 is storage pre-expiration. Blood stored at this stage is assumed, based upon the WACs, to provide an accurate test result within the margin of error. Stage 3 is testing after expiration. All the included studies sample differences between stages 2 and 3. None of them ascertain the level of alcohol in the vial at the time of

collection. Such information would be enormously helpful to the finder of fact in determining what chemical processes may have occurred in the vial during storage resulting in an increase, decrease, or no change to the sample. In addition, to comply with the WAC, there would need to be independent testing to determine what amount of fluoride needs to remain in the tube to stabilize the alcohol concentration from either increasing or decreasing. None of the studies cited give fluoride levels after the sodium fluoride was introduced into the aqueous solution. *It is therefore impossible for the trier of fact to determine if there remained any fluoride in the solution after expiration.*

4. In the Alternative, the Court Rules that the use of Testing Expired Blood Vials Violates ER 702

In the alternative, the Court finds that admitting testing on expired blood vials would violate ER 702. ER 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.[57]

Evidence admitted under ER 702 must "satisfy the predicate two-part inquiry. . . whether the witness qualifies as an expert, and whether the testimony would be helpful to the trier of fact."[58] For example, the Washington State Supreme Court held in *Baity* that to admit evidence from a Drug Recognition Expert ("DRE") under ER 702, "[a] proper foundation for DRE testimony would include a description of the DRE's training, education, and experience in administering the test, *together with a showing that the test was properly administered.*[59] Under

---

[57] Washington Rules of Evidence ER 702.
[58] *State v. Baity*, 140 Wash.2d 1, 18 (2000).
[59] Id. Emphasis added.

ER 702, if a "precise problem" is identified with testing that would "render the test unreliable," testimony concerning that testing is inadmissible under ER 702.[60]

City's witness Amanda Black qualifies as an expert for the purposes of testing blood vials for drugs. This court assumes for purposes of this ruling that the testing toxicologist in every case would also qualify as an expert in the subject matter. Therefore, the court moves to the second step of the ER 702 analysis.

Amanda Black freely admitted on the stand that the Washington State Forensic Toxicology Lab tested the expired blood vials based on the mistaken assumption that the expiration date of the blood vials only applied to the vacuum seal of the vial at the time of blood collection, not the storage or testing stages of the vial. Amanda Black also testified that she now understands, based upon BD's clear information, that testing expired vials was improper and did not comply with BD's instructions. In Short, Amanda Black acknowledged that testing expired vials violated the clear instructions given to the Toxicology Lab from BD.

Ms. Black defends her assumption by stating that she felt BD had given different information to her in the past that supported her erroneous assumption. She did not specifically state what this information was. The City made no attempt to submit any evidence that BD's position on expired vials has ever changed. Every document produced from BD makes clear that the expiration date of the vials applies to all stages of the vials: collection, storage, and testing. BD's stance is reiterated in their interrogatories submitted to the court, in their internal emails, in their product insert, and on their Certificate of Compliance. Furthermore, FDA protocols demand that BD test all parts of the vial for expiration date. Although the Toxicology Lab would not have had access to the internal BD study that determined the expiration date of their vials, any expert

---

[60] *See State v. Cauthron*, 120 Wn.2d 879, 890 (1993), *overruled in part on other grounds by State v. Buckner*, 133 Wn.2d 63 (1997).

in the area of blood analysis should have known the FDA requirements for determining vial expiration.

Therefore, the Toxicology Lab either did not know of the FDA requirement that make clear the expiration date testing would apply to all stages of the vial, or they knew of the FDA requirements but chose to ignore those requirements and test the expired vials anyway. In both instances, it is clear that the Toxicology Lab performed the test incorrectly.

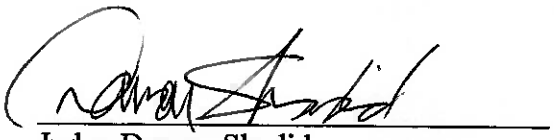
To ameliorate this faulty testing, the Toxicology Lab has provided off topic studies to retroactively justify their position that the testing of the expired vials complied with the WAC. As stated above, only one study relied on by the Toxicology Lab could conceivably support their conclusion. But even if this study did support their position (which this court does not believe) the reliance on one study violates basic fundamentals of scientific research.

The incorrect testing of the vials is problematic in multiple ways described above. The accuracy of the test could have been affected by the long storage time in the tube, making the alcohol concentration higher or lower than at the time of collection. The unknown amount of fluoride in the vial post expiration could have affected whether the alcohol concentration had remained stable. The relevant studies and both expert witnesses agree that, in a vial free of contamination, blood concentration tend to go down over time. The longer a vial is stored, the less accurate the test result will be at the time of testing.

BD did exhaustive testing on their vials regarding collection, storage, and testing. They emphasize that using the vials after the expiration is off label, and that they cannot guarantee the accuracy of blood testing results post expiration. One off topic peer reviewed study with a small sample size and multiple opinion articles is not enough to counteract the clear instructions and guidance BD has given the Toxicology Lab regarding the proper use of their vials.

Therefore, the government cannot show that the testing of the blood in the above cases was done correctly. The court bars the evidence under ER 702.

So ordered the 3rd day of October 2024.



Judge Damon Shadid
Seattle Municipal Court