NORTH CAROLINA IN THE GENERAL COURT OF JUSTICE

SUPERIOR COURT DIVISON

COUNTY OF XXXXX FILE NO: 19CRS XXXX

STATE OF NORTH CAROLINA )

) MOTION IN LIMINE TO EXCLUDE

vs. ) STATE’S EXPERT TESTIMONY

)

DEFENDANT, )

DEFENDANT. )

)

NOW COMES the Accused, through counsel, pursuant to the Fifth, Sixth, and Fourteenth Amendments to the United States Constitution, Article I, Sections 19, 23, and 24 of the Constitution of North Carolina, and N.C. Gen. Stat. §8C-1, Rules 401, 403 and 702, and *State v. McGrady*, 368 N.C. 880 (2016), and moves this Honorable Court to exclude the opinion testimony of ANALYST regarding results of the blood-alcohol analysis she performed due to the issuance of a nationwide recall of a vital piece of equipment used in blood-alcohol testing. In support of this Motion, the Accused shows unto this Honorable Court as follows:

FACTS

1. The defendant has been accused of driving while impaired by alcohol based upon a stop conducted by OFFICER on DATE (dates between the dates of 8/31/2018 and present are applicable).
2. The defendant consented to have her blood drawn with the knowledge that it would be subject to a blood-alcohol test.
3. The test was conducted using a “vacutainer” created and sold by Becton, Dickinson and Company (BD). The vacutainer held the blood between the time it was drawn and when it was analyzed.
4. A notice first distributed on May 30th, 2019, and then updated on June 12, 2019, informed customers of a recall notice for the “BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations” that were produced in Lot# 8187663. The recall notice specified that several hundred vacutainers in the lot were manufactured without an essential additive necessary to preserve the blood and avoid coagulation. *See* Becton Dickinson, *Amended Urgent Medical Device Recall: BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations* at 1 (June 12, 2019), *available at* https://forensicresources.org/wp-content/uploads/2019/07/Customer-Letter-BD-Vacutainer-Flouride-Tubes-for-BAC-Determinations-7-1.pdf (hereinafter known as BD Recall Letter). Without the additive, analysis might yield “falsely high” results. *See id.* Over 100 of these defective tubes that were distributed for use were not returned following the recall.
5. Without the additive, according to BD’s recall notice, “the sample may clot and should be recollected as per good clinical practice.” BD notes that “once blood is collected in the tubes, the clinician will be unable to determine if the tube contains additive or not.” *See* *id.*
6. There is no indication on the record that the vacutainer used in the State’s blood alcohol analysis was not from the affected lot. There is no indication in the record that the additive, required to ensure preservation and anticoagulation, was present at the time the blood was drawn into the vacutainer. The label is currently obstructed by the sealing process, rendering it impossible to determine if the vacutainer in question, and the blood alcohol analysis which relied upon it, are affected by the lack of the additive.
7. The State has the burden to prove beyond a reasonable doubt that the defendant was driving under the influence of alcohol, as alleged, on the night of her arrest. It is the burden of the State to demonstrate that the test being conducted accurately demonstrates the alcohol content of the defendant’s blood on the night of her arrest.
8. The State has not demonstrated the additive was present in the vacutainer and that the blood-alcohol analysis was capable of producing accurate results.

BACKGROUND ON THE PRODUCT RECALL

With worldwide distribution and nearly $16 billion of revenue in 2018, Becton Dickinson is one of the largest suppliers of medical equipment in the country. *BD Announces Results For 2018 Fourth Quarter And Full Year; Provides Fiscal 2019 Guidance*, Cision PR Network (Nov. 6, 2018), *available at* <https://www.prnewswire.com/news-releases/bd-announces-results-for-2018-fourth-fiscal-quarter-and-full-year-provides-fiscal-2019-guidance-300744342.html>. One product, the “BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations,” is vitally important to law enforcement agencies around the county. This vacutainer is used as a container to hold blood between the time it is drawn and when it is tested at a crime laboratory. *See* BD Recall Letter at 1. If the blood is improperly stored, blood alcohol analysis may not accurately demonstrate the actual amount of alcohol present in the blood of the defendant. *See id.*

On May, 30, 2019, BD issued a recall notice for a lot of around 240,000 “BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations.” *See id.* BD has requested that any entity that purchases the vacutainers “[i]mmediately review your inventory for the specific catalog and lot number listed above. Destroy all product subject to the recall in accordance with your institution’s process for destruction.” *See id.* Furthermore, groups which receive the recall notice are asked to “Share this Urgent Medical Device Recall notification with all users of the product in your facility to ensure that they are also aware of this recall.” *See id.*

According to BD, “A small portion of this lot has been confirmed to have no additive within the tube.” *See id.* This additive is vital to ensure that testing yields accurate results. *See id.* BD further explains that “in cases where the sample is processed without the preservative (additive) in the tube, testing has yielded reliable results if the samples were stored at room temperature for no longer than two days.” *See id.* Any sample stored for greater than two days may give false readings that compromise the integrity of the analysis resulting in erroneous findings of alcohol in the defendant’s blood. *See id.*

ARGUMENT

In order for expert opinion testimony to be admissible it must satisfy each prong of Rule 702. In *State v. McGrady*, 368 N.C. 880, 889 (2016), North Carolina adopted the more stringent *Daubert* standard governing the admission of expert testimony. Testimony offered by the State’s expert witness do not meet these requirements as established by the legislature and case law and should therefore be excluded.

Rule 702 demands that the trier of fact would benefit from “scientific, technical, or other specialized knowledge” in attempting to determine a contested fact. N.C.G.S. § 8C-1, Rule 702(a). Because the State has offered no evidence that the vacutainer used in the blood test contained the preservative powder, the State’s expert will be unable to establish the validity of the blood alcohol test and therefore, cannot provide specialized knowledge that would assist the trier of fact.

Since BD’s issuance of the nationwide recall, it is vital to validate that vacutainers used in any blood-alcohol analysis were properly manufactured with the necessary preservative. As noted by the Texas Forensic Science Commission when addressing this recall’s impact on law enforcement, “Only the individual(s) who performed the blood draw or witnessed the draw would have firsthand knowledge of whether the additive powders were present in the tube(s) at the time of blood collection.” Texas Forensic Science Commission, *Becton Dickinson (BD) Tube Recall*, at 1 (July, 8 2019), *available at* <https://www.txcourts.gov/media/1444363/bd-memorandum-070819-5.pdf> (hereafter TFSC Memo). This Commission goes on to declare that “[i]t is not feasible to determine whether the additive powders (preservative, anticoagulant, or both) were present after blood was introduced into the tube. While a possible impact of the missing anticoagulant is that the blood would appear visually different to a forensic analyst due to clotting, it is possible for clotting to occur in grey top tubes containing additive powders. It is also possible for a tube without additive to lack any visual indication of blood clotting.” *See id.* at 2. Here, it is not possible for the State’s expert to make any scientifically valid claim regarding the accuracy of the test because there is no method for determining if the vacutainer was manufactured with the additive needed for reliable results. If the expert cannot rationally make statements as to the validity of the test, there is no question of fact which her “knowledge, skill, experience, training, or education” will assist in any way.

Federal and North Carolina case law have also articulated additional factors which might be used when determining if expert testimony should be admissible. Among other considerations, the court can take into account “Whether the expert has adequately accounted for obvious alternative explanations.” *McGrady*, 368 N.C. 880 at 891. Without any evidence demonstrating the presence of the anticoagulant, the witness cannot testify as to validity of the results in any way. Even if she correctly performed the analysis, there is simply no way to determine if the vacutainer was capable of producing reliable results. Any statements made regarding the validity of the testing are strictly guesses outside the realm of her scientific expertise. Furthermore, BD itself has given “obvious alternative explanations” for the results of the blood test by stating that results from affected vacutainers might be “falsely high”. Any testimony as to the amount of alcohol in the blood of the accused is ignoring the officially stated, “obvious alternative explanations” identified by BD, the Texas Forensic Science Commission, and various other agencies. *See* BD Recall Letter at 1; *see* TFSC Memo at 2; *see generally* Houston Forensic Science Center, *Blood tube vendor recalls vials, drunk driving tests at risk* (June 21, 2019), *available at* https://forensicresources.org/wp-content/uploads/2019/07/Houston-Forensic-Science-Center.pdf (“BD’s recall statement says the manufacturer failed to include a crucial preservative in some vials. The preservative, which is a powder, prevents the blood from clotting and the blood alcohol concentration from changing”).

Rule 702(a)(1) requires that “The [witness’s] testimony is based upon sufficient facts or data.” Here, because there is no evidence that a vital component of an accurate blood alcohol test was present, the testimony offered by the State’s witness does not have the support of sufficient facts or data as required by law.

As Becton Dickinson stated in its letter to consumers, “…once blood is collected in the tubes, the clinician will be unable to determine if the tube contains additive or not.” *See* BD Recall Letter at 1. The State has failed to demonstrate that the equipment it has relied upon was properly manufactured. It is standard laboratory procedure to frequently calibrate and conduct baseline testing to ensure that equipment used to collect forensic evidence is properly functioning and producing accurate results. *See* North Carolina State Crime Lab, § 5.4 *Technical Procedure for Headspace Gas Chromatography to Quantitate and Version 12 Identify Volatiles in Liquids* at 9-11 (2015) (identifying a “daily system check,” and a minimum of 10% control samples in each sample sequence to verify accurate results during blood alcohol analysis); *see* North Carolina State Crime Lab, §§ 5.2, 5.3.4 *Technical Procedure for Ultraviolet Spectroscopy* at 4 (2014) (proper use of an Ultraviolet spectrophotometer requires a routine monthly maintenance and “a successful blank” with generated data). There is currently no way to determine if the vacutainer was working properly when the blood analysis was completed, meaning there is no objective way to determine if the test results are accurate. Unlike other laboratory equipment which can be recalibrated to retest a substance if there is evidence of malfunction, a faulty vacutainer will render the sample unreliable because the blood alcohol levels might change prior to the analysis. No amount of retesting will change an unreliable sample. Because there is no way to identify if the preservative was present, and there is no way to determine the analysis’s accuracy, the State simply does not have “sufficient facts or data” upon which to build the expert’s testimony.

Rule 702(a)(2) requires that expert testimony “is the product of reliable principles and methods.” Here, the lack of an adequate recording system or any verification regarding the presence of a vital preservative demonstrates a lack of reliable methodology which can guarantee accurate results.

This issue could have been resolved if CRIME LAB or the hospital/agency collecting the blood sample kept adequate records of the products used for forensic analysis. In its letter to customers notifying them of the recall, BD offered several indications that can identify whether the tube might be missing the additive. These indications are clearly visible before the vacutainer is sealed and include the lot number, the expiration date, and the product number. *See generally* BD Recall Letter. Neither HOSPITAL nor CRIME LAB recorded any of this information despite its vital importance in ensuring the accused can adequately defend herself by determining if faulty equipment was used against her. It is regularly required that chain of custody, underlying data, and testing results are meticulously documented to ensure the integrity of evidence. The State’s failure to record the lot number, product number, or expiration date of the vacutainer makes it impossible to establish the reliability of the analysis without additional testing.

Additionally, the State has offered no evidence that the preservative powder was present at the time the blood was drawn, making the determinations reached by the analysis inconclusive at best. As noted by BD, any vacutainer missing the preservative can result in a “falsely high” result for a blood alcohol exam. While North Carolina State Crime Laboratory analysts are supposed to record “[a]ny unusual observations regarding the condition of the specimen or specimen container (e.g., leaking, non-red color for blood, damage, clotting, small volume),” BD and the Texas Forensic Science Commission have stated that the lack of the additive would not be detectible based on any observations after the blood is drawn. *See* BD Recall Letter at 1; *See* TFSC Memo at 2.Without any procedure to recording or testing for the presence of the additive, the methodology is unreliable since the distribution of the defective vacutainers. Without any indication that the vacutainer contained the preservative, the State’s methodology fails to establish the reliability of its testing and cannot overcome the protections afforded by Rule 702(a)(2).

Rule 702(a)(3) requires that “[t]he witness has applied the principles and methods reliably to the facts of the case.” Because there is no evidence that the vacutainer produced by the State was capable of producing a reliable result, there is simply no way to demonstrate that the witness properly applied the principles and methods to the facts of the case. The methodology the State’s witness will testify about inherently relies upon the proper functioning of equipment. Given the recall from BD, and without any indication that the vacutainer in question is capable of accuracy, there is no reliable way to determine if the witness’s analysis used a properly preserved sample or not. Without proof of the additive, the expert cannot show her testimony is based on reliable principles and methods at the present case.

Rule 403 states that “Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or … waste of time.” N.C.G.S. § 8C-1, Rule 403. Here, since there is no indication that the vacutainer in question contained the necessary preservative, testimony by the State’s witness fails to clear the legal hurdle created by this rule.

The first point worth consideration is that by BD’s own admission, a “clinician will be unable to determine if the tube contains additive or not” after blood has been drawn into the vacutainer.*See* BD Recall Letter at 1. Without any evidence of the preservative, and with knowledge that there are defective vacutainers in circulation, it is inappropriate to allow an analyst to testify to the results of her blood analysis. It would be highly prejudicial to allow her testimony when the State has offered nothing conclusively showing that the equipment used as evidence against the accused was properly functioning despite a massive, nation-wide recall.

Testimony by the State’s witness will likely confuse the issue of fact she is trying to help the fact finder understand. The ultimate question is whether the blood she analyzed contained a level of alcohol above the legal limit on the night the accused was stopped and arrested. While analysis and the subsequent testimony would normally be a strong indication of the blood-alcohol content on the date it was drawn, given the circumstances in this present case, the analyst only has knowledge regarding the alcohol content of the blood on the day it was tested. In its “AMENDED URGENT MEDICAL DEVICE RECALL,” BD noted that in a defective vacutainer, the sample could only be reliable if properly stored for no more two days at room temperature. *See* BD Recall Letter at 1. Because the analysis took place long after two days of storage, because blood in a faulty vacutainer is only reliable for two days, because there is no evidence offered by the State indicating the preservative was present, because the lack of a preservative might lead to a “falsely high” result, and because BD and forensic science communities have identified that there are vacutainers missing the vital preservative currently in circulation, the analyst can only attest to the alcohol present in the blood on the day of the analysis. The issue at hand is whether the defendant was driving with an illegal amount of alcohol in her blood, not the blood alcohol content of the sample on the day it was analyzed. Any testimony offered by the State’s expert can only serve to help determine the latter, not the former. It is difficult to distinguish these issues, making the analyst’s testimony a waste of time far more likely to prejudice and confuse than to help with any findings of fact.

CONCLUSION

1. Rule 702 states that expert testimony can only be admitted if: “(1) The testimony is based upon sufficient facts or data; (2) The testimony is the product of reliable principles and methods; (3) The witness has applied the principles and methods reliably to the facts of the case.” In this case, the State fails to meet this burden.
2. Rule 403 allows evidence to be excluded if it is prejudicial, will likely confuse or mislead a jury or wastes time. Here, with no method of verification that the vacutainer was properly functioning, any testimony offered by the State’s expert will be a waste of time with a high probability of misleading the trier of fact and confusing the actual issue at hand.
3. It is the command of both the State and Federal constitution that the accused receive a fair trial and the due process of law. To allow the analyst’s testimony regarding the results of the blood-alcohol test would unduly prejudice the Accused and would violate his rights under the5th, 6th, and 14th Amendments of the United States Constitution and Section I, Articles 19, 23, and 24 of the North Carolina Constitution.

RELIEF SOUGHT

WHEREFORE, the Accused moves this Honorable Court to summarily grant this Motion and to enter an Order excluding the analyst’s testimony related to the results of the blood-alcohol test at trial in this case. In the alternative, the Accused requests a pre-trial evidentiary hearing on the admissibility of this evidence.

Respectfully submitted this the \_\_\_\_\_ day of July, 2019.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attorney

**CERTIFICATE OF SERVICE**

THIS IS TO CERTIFY that the undersigned attorney served a copy of the foregoing Motion In Limine To Exclude State’s Expert Testimony on the State of North Carolina by hand delivery to the District Attorney’s Office:

Assistant District Attorney XXX

Address

This the \_\_\_\_\_\_ day of May, 2019.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attorney