



TEXAS FORENSIC
SCIENCE COMMISSION

Justice Through Science

*1700 North Congress Ave., Suite 445
Austin, Texas 78701*

MEMORANDUM

TO: Texas Criminal Justice Stakeholders

FROM: Texas Forensic Science Commission

DATE: July 8, 2019

RE: Becton Dickinson (BD) Tube Recall

On May 30, 2019, Becton Dickinson (BD) issued a recall notification for BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations (grey top tubes) catalog number 367001 and lot number 8187663. On June 12, 2019, BD issued an amended notice.¹ BD began distributing this lot to customers nationwide in August 2018.

According to BD public statements, certain tubes within the lot were identified as having been shipped without additive powders (sodium fluoride and potassium oxalate), which function as a preservative and anticoagulant (to prevent clotting). According to BD, the issue “only impacts 300 tubes within the lot and BD has recovered 199 of those tubes.” BD identified a “manufacturing issue” as the root cause for the missing additive. BD further represents that the company has remedied the manufacturing issue.

POTENTIAL TEXAS IMPACT:

Laboratories accredited in blood alcohol under Texas law are aware of the recall and taking steps to notify stakeholders. Numerous Texas-accredited laboratories have received grey top tubes from the affected lot. Wherever possible, laboratories are working with submitting agencies to retrieve any unused tubes from the affected lot and replace them with new tubes. However, for tubes that were already used for blood draws before BD issued its recall notice, laboratories are unable to ascertain based on a review of the case documentation whether the tube(s) used in any particular case were among the 101 tubes identified by BD as missing additive powders.

For forensic samples collected in grey top tubes from the affected lot:

Only BD can respond to issues or questions about the manufacture, percentages of tubes affected, root causes for the error, likelihood or not of continued production defects or other related items. Subpoenas, discovery requests and documentation requests in the state of Texas should be sent to BD’s registered Texas agent:

¹ The recall notice is available at <https://www.bd.com/en-us/support/recall-notifications/recall-notification---bd-vacutainer-fluoride-tubes-for-blood-alcohol-determinations>.

C T Corporation System
1999 Bryan Street
Suite 900
Dallas, TX, 75201
214-932-3601

QUESTION:

- 1. How can I determine whether additives were present in the tube at the time of blood collection in a particular blood alcohol case?**

ANSWER:

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. Similarly, only the individual(s) who performed the blood draw or witnessed the draw have firsthand knowledge of the conditions of the blood draw, including whether it was a “clean” draw with no deviation from standard procedure.

It 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.

QUESTION:

- 2. What is the impact of the missing additive on the blood alcohol results?**

ANSWER:

This answer is conditioned upon three assumptions: (1) the information and statements by BD about the manufacturing defect are complete and accurate; (2) the blood draw in any given case was appropriately clean and without variance; and (3) the blood tube was stored in a refrigerated environment.

The scientific literature indicates in study conditions that alcohol concentrations are not significantly affected by the lack of sodium fluoride preservative. At higher than refrigerated temperatures, alcohol concentrations tend to decrease without the preservative present. Some studies indicate that under very specific conditions, alcohol can increase when the blood is inoculated with *C. albicans* (a common yeast that lives on humans) and where no preservative is present.

See attached bibliography for scientific references.

Questions regarding this statement should be directed to the Commission's General Counsel, Lynn Garcia, at 512-936-0770 or lynn.garcia@fsc.texas.gov.

Bibliography/References

Effect of storage conditions on ethanol concentrations

Laurens JB, Sewell FJJ, Kock MM. Pre-analytical factors related to the stability of ethanol concentration during storage of ante-mortem blood alcohol specimens. *J Forensic Leg Med.* England: 2018 Elsevier Ltd and Faculty of Forensic and Legal Medicine; 2018;155-63.

Penetar DM, McNeil JF, Ryan ET, Lukas SE. Comparison among plasma, serum, and whole blood ethanol concentrations: impact of storage conditions and collection tubes. *J Anal Toxicol.* 2008 Sep;32(7):505-10.

Petkovic S, Savic S, Zgonjanin D, Samojlik I. Ethanol concentrations in antemortem blood samples under controlled conditions. *Alcohol Alcohol.* England; 2008;658-60.

Stojiljkovic G, Maletin M, Stojic D, Brkic S, Abenavoli L. Ethanol concentration changes in blood samples during medium-term refrigerated storage. *Eur Rev Med Pharmacol Sci.* 2016 Dec;20(23):4831-6.

Winek CL, Paul LJ. Effect of short-term storage conditions on alcohol concentrations in blood from living human subjects. *Clin Chem.* 1983 Nov;29(11):1959-60.

Winek T, Winek CL, Wahba WW. The effect of storage at various temperatures on blood alcohol concentration. *Forensic Sci Int.* Ireland; 1996;179-85.

Extreme conditions of ethanol production

Chang J, Kollman SE. The effect of temperature on the formation of ethanol by *Candida albicans* in blood. *J Forensic Sci.* 1989 Jan;34(1):105-9.

Petkovic SM, Simic MA, Vujic DN. Postmortem production of ethanol in different tissues under controlled experimental conditions. *J Forensic Sci.* 2005 Jan;50(1):204-8.

Yajima D, Motani H, Kamei K, Sato Y, Hayakawa M, Iwase H. Ethanol production by *Candida albicans* in postmortem human blood samples: effects of blood glucose level and dilution. *Forensic Sci Int.* Ireland; 2006;116-21.

Analysis of clotted samples

Senkowski CM, Thompson KA. The accuracy of blood alcohol analysis using headspace gas chromatography when performed on clotted samples. *J Forensic Sci.* 1990 Jan;35(1):176-80.

Chang J, Kollman SE. The effect of temperature on the formation of ethanol by *Candida albicans* in blood. *J Forensic Sci.* 1989 Jan;34(1):105-9.

Laurens JB, Sewell FJJ, Kock MM. Pre-analytical factors related to the stability of ethanol concentration during storage of ante-mortem blood alcohol specimens. *J Forensic Leg Med.* England: 2018 Elsevier Ltd and Faculty of Forensic and Legal Medicine; 2018;155-63.

Penetar DM, McNeil JF, Ryan ET, Lukas SE. Comparison among plasma, serum, and whole blood ethanol concentrations: impact of storage conditions and collection tubes. *J Anal Toxicol.* 2008 Sep;32(7):505-10.

Petkovic SM, Simic MA, Vujic DN. Postmortem production of ethanol in different tissues under controlled experimental conditions. *J Forensic Sci.* 2005 Jan;50(1):204-8.

Petkovic S, Savic S, Zgonjanin D, Samojlik I. Ethanol concentrations in antemortem blood samples under controlled conditions. *Alcohol Alcohol.* England; 2008;658-60.

Senkowski CM, Thompson KA. The accuracy of blood alcohol analysis using headspace gas chromatography when performed on clotted samples. *J Forensic Sci.* 1990 Jan;35(1):176-80.

Stojiljkovic G, Maletin M, Stojic D, Brkic S, Abenavoli L. Ethanol concentration changes in blood samples during medium-term refrigerated storage. *Eur Rev Med Pharmacol Sci.* 2016 Dec;20(23):4831-6.

Winek CL, Paul LJ. Effect of short-term storage conditions on alcohol concentrations in blood from living human subjects. *Clin Chem.* 1983 Nov;29(11):1959-60.

Winek T, Winek CL, Wahba WW. The effect of storage at various temperatures on blood alcohol concentration. *Forensic Sci Int.* Ireland; 1996;179-85.

Yajima D, Motani H, Kamei K, Sato Y, Hayakawa M, Iwase H. Ethanol production by *Candida albicans* in postmortem human blood samples: effects of blood glucose level and dilution. *Forensic Sci Int.* Ireland; 2006;116-21.