June 25, 2019

The Texas Department of Public Safety (DPS) Crime Laboratory has recently been made aware that Becton Dickinson (BD) — a medical technology company — has issued a recall on a number of blood tubes manufactured by the company, which may have been utilized in DPS blood kits. The BD Vacutainer Fluoride Tubes for Blood Alcohol Determination have been recalled (Lot number 8187663, Expiration date 2020/7/31). The recall was initiated after it was discovered that a small portion of the lot of blood tubes did not include the additive that prevents clotting. The recalled lot consists of 240,000 tubes; of those tubes, BD admits that only 300 of the tubes did not receive the additive. BD has recovered approximately 200 of the 300 non-additive tubes.

The DPS Crime Laboratory contacted our blood kit vendor to inquire if the recalled tubes may have been included in DPS blood kits. The vendor indicated that the recalled BD Vacutainers are most likely associated with some DPS kits assembled in early 2019; these kits have an expiration date of July 31, 2020. The recalled tubes inside the kit will have lot number 8187663 and an expiration of 2020/7/31.

The DPS Crime Laboratory is in the process of locating all affected DPS blood kits in order to isolate them and prevent their use. The department requests that all law enforcement agencies inspect any and all kits in their possession. If you have DPS blood kits with the July 31, 2020, expiration date, please note that it may be affected by this recall. The department is asking anyone with an affected kit to contact their local DPS laboratory for more information on exchanging the kits.

The DPS Crime Laboratory is committed to quality and wants to ensure that all affected kits are properly analyzed. Please submit your current specimens expeditiously to your local laboratory for analysis, especially if your kits are associated with the recall.

DPS recognizes the potential impact that this recall may have on impaired driving cases throughout the state. We are notifying our customers to minimize the impact of this recall. Our Forensic Scientists are subject matter experts who are prepared to answer questions regarding the analysis of cases impacted by this recall.

If you have questions or need assistance, please contact your Regional DPS Crime Laboratory.
DPS Blood Alcohol Kit Recall

The recalled tubes are associated with DPS blood kits that have an expiration date of July 31, 2020 as shown above.

If you have any kits with this expiration date, please do not use them. Contact your local DPS Crime lab to exchange them for new kits.
URGENT MEDICAL DEVICE RECALL

BD Vacutainer® Sodium Fluoride/Potassium Oxalate 100mg/20mg Tubes

May 30, 2019

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog Number</th>
<th>Lot Number</th>
<th>UDI (GTIN, DI + PI)</th>
<th>Exp. Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Vacutainer® Sodium Fluoride/Potassium Oxalate 100mg/20mg Tubes</td>
<td>367001</td>
<td>0187663</td>
<td>0130318260036760018(17)288731 (10)8187663(30)0100</td>
<td>2020/7/31</td>
</tr>
</tbody>
</table>

For the Attention of: Distributor

Description of the problem and health hazard(s):

BD is conducting a voluntary medical device recall for the catalog and lot number shown above for the BD Vacutainer® Sodium Fluoride/Potassium Oxalate 100mg/20mg Tubes. This lot has been confirmed to have reduced or no additive within the tube.

As per good clinical practice, visual inspection of the BD Vacutainer® Sodium Fluoride/Potassium Oxalate 100mg/20mg Tubes prior to blood collection may detect reduced or no additive within the tube. However, once blood is collected in the tubes, the clinician will be unable to determine if the tube contains additive or not. If reduced additive or no additive is present in the tube the sample may clot and glycolysis will not be sufficiently inhibited which will result in the reduction of glucose values over a period of time. This may potentially produce erroneous results which could lead to incorrect treatment of patients, the recollection of samples or, retesting of patients, resulting in delayed reporting of test results and patient treatment.

The root cause was related to a manufacturing error and has been corrected.

Distribution of the affected lots began on August 31, 2018 and our records indicate you may have received the affected product.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalog and lot number listed below. Return all product subject to recall according to the Packing Instructions enclosed.

2. Identify all your customers that purchased any affected product, as defined in this recall notification. E-mail an excel file listing of all customers to BDRC2@bd.com, within 72 hours of receipt of this letter so that BD may notify your customers directly.

3. Complete the attached Distributor Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your credit accordingly.

Actions to be Taken by BD:

1. BD will provide a credit for all returned inventory.
2. BD will mail additional communications to customers if the requested customer list is provided by the distributor.
3. Corrective actions have been initiated to prevent recurrence of the identified root cause.

Please use the contacts provided below for complaints, adverse event reports, or questions regarding this recall.

<table>
<thead>
<tr>
<th>BD Contact</th>
<th>US Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer/Technical Support</td>
<td>888-237-2762 OPT 3, OPT 2; Monday – Friday 8:00am - 5:00pm (CT)</td>
</tr>
</tbody>
</table>
AMENDED URGENT MEDICAL DEVICE RECALL
BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations

June 12, 2019

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog Number</th>
<th>Lot Number</th>
<th>UDI (GTIN, DI + PI)</th>
<th>Exp. Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations</td>
<td>367001</td>
<td>8187663</td>
<td>(01)30382903670018(17)200731(10)8187663(30)0100</td>
<td>2020/7/31</td>
</tr>
</tbody>
</table>

For the Attention of: Lab Director/Recall Coordinator

Description of the problem and health hazard(s):

You may have received a recall communication from BD on, May 30, 2019, that incorrectly identified the name of the product subject to the recall. Although the catalog and lot number for the one affected lot of product was correct, the product name was incorrect. This notice replaces the initially distributed notice dated May 30, 2019.

BD is conducting a voluntary medical device recall for the catalog and lot number shown above for the BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations. A small portion of this lot has been confirmed to have no additive within the tube.

As per good clinical practice, in 95% of the cases, missing additive would be detected when a visual inspection of the BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations prior to blood collection. However, once blood is collected in the tubes, the clinician will be unable to determine if the tube contains additive or not. If no additive is present in the tube the sample may clot and should be rejected and recollected as per good clinical practice.

Based on publicly available scientific literature, 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. If the sample was stored for more than 2 days, the result for blood alcohol determination might not be accurate (either falsely low or falsely high).

The root cause was related to a manufacturing error and has been corrected.

Distribution of the affected lot began on August 31, 2018 and our records indicate you may have received the affected product.

Please Take the Following Actions:

1. Immediately 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.

2. 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.

3. Complete the attached Customer Response/Certificate of Destruction Form and return to the BD contact noted on the form regardless of whether you have any affected material or not so that BD may acknowledge your receipt of this notification and process your product replacement, if applicable.

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Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA’s MedWatch Adverse Event Reporting program.

Web: MedWatch website at www.fda.gov/medwatch   Phone: 1-800-FDA-1088 (1-800-332-1088)
Mail: MedWatch, HF-2, FDA, 5600 Fisher’s Lane, Rockville, MD 20852-978

Actions Taken by BD:
1. Corrective actions have been initiated to prevent recurrence of the identified root cause.

Contact Information:
Please use the contact information provided below for complaints, adverse event reports, or questions regarding this recall.

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BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Aparna Jha Ahuja, MD  
PG cert Hosp Management, DCH&FW, IF CAP  
WW Vice President Medical Affairs, PAS

Gail Griffiths  
Sr. Director, Corporate Regulatory Compliance  
BD US Region