ECRI

Alerts Workflow

View

Applicable – Open

Accession Number: H0971 01
Channel: Devices
ECRI Priority: High
FDA: Not Specified
Published: 02/13/2025
Last Updated: 02/13/2025

BD—Vacutainer Citrate Blood Collection Tubes (1 Lot): May Overfill [ECRI Exclusive Hazard Report] [Update]

Product Identifier:
Manufacturer(s):
BD , 1 Becton Dr, Franklin Lakes, NJ 07417-1880, United States
Summary:
Update Reason: Additional lot number affected. This Alert provides new information based on a member report regarding an additional lot number (4198275) exhibiting the problem covered in Hazard Report H0971.

Problem:

1. Multiple tubes from lot 4157065 and 4198275 of BD Vacutainer buffered sodium citrate blood collection tubes (product number 363083) have been reported as overfilling.
2. If blood from an overfilled tube is used:
    1. The ratio of sodium citrate to blood may be incorrect and could cause erroneous results, which may lead to incorrect anticoagulant therapy.
    2. Patients may require repeat venipuncture.

ECRI Recommendations:

Note: ECRI's recommendations are based upon ECRI's experience and our scientific team's opinions specific to this Alert, at the time that the recommendations are issued. These recommendations may differ from the manufacturer's recommendations, and your organization should consult with internal experts before implementing ECRI's recommendations.

Materials Management, Clinical Laboratory:

1. Consider the removal of BD Vacutainer Citrate blood collection tubes (product number 363083, lot number 4157065 and 4198275) from inventory in your facility.
2. Have additional buffered sodium citrate blood collection tubes available.
3. Report problems to BD by e-mail at ProductComplaints@BD.com, and to ECRI and FDA.

Background:

1. An ECRI member reports multiple BD Vacutainer tubes from one lot overfilled, resulting in repeat patient venipunctures.
2. The lot was removed from service.

Manufacturer Perspectives

BD states:

1. This alert is not part of an active BD field action/recall related to Vacutainer Citrate blood collection tubes.
2. BD does not agree with ECRI's recommendation to remove BD buffered sodium citrate vacutainer product number 363083, lot 4157065, expiration date 2/28/2025 from use use or return for reimbursement/replacement.
3. Before ECRI's notification, BD had not received the reported complaint from the customer for lot 4157065. BD's Quality Team is investigating the reported complaint based on the current information received. BD maintains complaint files, and has established processes for receiving, reviewing, and investigating complaints. All complaints are processed and evaluated in a uniform manner, and when applicable, reported to FDA or other applicable regulatory agencies as required.
4. As a reminder, it is important that any complaints should be reported to BD at ProductComplaints@BD.com for investigation and, when possible, that products are returned to BD to support the investigation.

UMDNS Term(s):
Tubes, Blood Collection [14183]
Geographic Region(s):
(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution:
Clinical Laboratory/Pathology, Nursing, OR/Surgery, Risk Management/Continuous Quality Improvement, Phlebotomy, Materials Management
Comment:

- This alert is a living document and may be updated when ECRI receives additional information.