Class 2 Device Recall VACUETTE LH Lithium Heparin Separator Tubes

See Related Information[22]

Date Initiated by Firm	July 29, 2026
Date Posted	October 21, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0200-2027
Recall Event ID	99518[23]
510(K)Number	K960857[24]
Product Classification	Tubes, vials, systems, serum separators, blood collection[25] - **Product Code** JKA[26]
Product	Brand Name: VACUETTE Product Name: LH Lithium Heparin Separator Model/Catalog Number: 454008P Product Description: Greiner VACUETTE Blood Collection Tube with Lithium Heparin and Gel Separator (13 x 75 mm, 3.5ml)
Code Information	Lot Code: Item Number: 454008P Lot Number: B26043FM UDI: Rack: 29120017579032, Case: 39120017579039 Expiration Date: 2027-07-12
FEI Number	3001451379
Recalling Firm/ Manufacturer	Greiner Bio-One North America, Inc. 4238 Capital Dr Monroe NC 28110-7681
For Additional Information Contact	Angela Drysdale 001-704-7768646
Manufacturer Reason for Recall	Lot B26043FM may include EDTA contamination which introduces potassium while chelating calcium in patient samples, leading to falsely elevated potassium (K+) and falsely decreased calcium (Ca++) results which have the potential to cause hyperkalemia.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On 07/29/2026, an "URGENT MEDICAL DEVICE RECALL NOTICE" was emailed to customers informing them that, Greiner Bio-One North America identified a potential ethylenediaminetetraacetic acid (EDTA) contamination issue in a specific lot of VACUETTE Lithium Heparin serum separator tubes. Use of affected tubes may lead to: " Falsely elevated potassium (K+) results " Falsely decreased calcium (Ca++) results Customers are instructed to: " Immediately identify and quarantine all remaining units of item 454008P, lot B26043FM. " Stop using the affected lot for blood collection.

" Notify relevant staff (phlebotomy, lab, clinical teams) of this advisory.
" Review any recent patient results obtained using this lot. Consider repeat testing with a
different lot if results appear inconsistent with clinical presentation.
" Follow proper order of draw, and recollection procedures when re-testing.

For unused product disposal (if destroyed by customer/distributor)
" The unused blood collection tubes contain chemical additives (LH and serum separator). Recommend following OSHA process, and/or your facility's environmental
health and safety (EHS) policies and procedures for disposal.

For questions or documentation (Acknowledgement and Receipt Form) to Recalls.US@gbo.com or please call 800-515-8112.

Quantity in Commerce	860450
Distribution	U.S. Nationwide distribution in the states of CO, FL, IL, MO, NE, NY, OH, PA, and VA.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = JKA[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99518
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K960857
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JKA
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JKA

27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JKA
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JKA&knumber=&applicant=Greiner%20America%2C%20Inc%2E

Page Last Updated: 10/26/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99518
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K960857
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JKA
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JKA
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JKA
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JKA&knumber=&applicant=Greiner%20America%2C%20Inc%2E