



October 05, 2010

URGENT: FIELD SAFETY NOTICE

Potential Safety Issue Affecting All Access/Access 2 Systems

The information in this letter applies to stand-alone Access and Access 2 Systems, as well as the SYNCHRON LXi 725 and UniCel DxC 600i Integrated Systems, which use an external liquid waste bottle.

Item	Part Number
Liquid Waste Bottle	6769C

Dear Beckman Coulter Access System Customer:

BACKGROUND

Your Access or Access 2 Immunoassay System, or Access 2 Integrated System, utilizes an external liquid waste bottle to collect liquid waste generated by the system. It is important for operators to be aware of signs of deterioration of the plastic bottle in order to safely handle the system waste.

ISSUE

Beckman Coulter has recently received two reports of Access waste bottles that ruptured and expelled liquid waste, exposing the operator to the system liquid waste. Over time, waste bottles can degrade, become brittle and potentially crack.

IMPACT

All liquid wastes, including assayed patient samples, are collected by the system in the liquid waste bottle. **Failure of the waste bottle can result in the operator being exposed to biohazardous materials.**

ACTION

Inspect each Access/Access 2 waste bottle for signs of aging or deterioration. New bottles are opaque white in color.

Signs of deterioration include:

- Any color change to the bottle (yellow, orange or pink)
- Cracking
- Crazeing (spider web cracking)

Any defect that is not removed by routine cleaning is a sign of deterioration. It is important to routinely inspect the area nearest the handle and along all seams of the bottle.

If upon inspection you detect any issues with your waste bottles, contact your local Beckman Coulter representative to obtain a replacement. Request part number 6769C.

Keep this information should you require a replacement bottle in the future.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. Please complete and return the enclosed response form within 10 days so we can be certain you received this important notification.

RESOLUTION

Beckman Coulter recommends routine inspection of the waste bottles for signs of deterioration. Rinsing the bottles multiple times with water between uses, storing the bottles out of direct sunlight when not in use as well as more frequent emptying of the bottles may also prolong their service life.

Beckman Coulter offers a service kit which may be used to replace the waste bottle and direct liquid waste to a floor drain. As site conditions vary, Beckman Coulter requires a consultation with your technical support representative to determine if your system can be fitted with a floor drain kit.

If you need assistance or have any questions regarding this notification, please contact your local Beckman Coulter Technical Support Representative.

Thank you for your continued support of Beckman Coulter products.

Sincerely,



Group Manager, Corporate Quality and Regulatory Affairs

Enclosure:
Response form

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