



to be date of distribution

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

Our records indicate that you are a current BacT/ALERT[®] system user or have received one or more of the following products.

Description: BacT/ALERT [®] Blood Collection Adapter Cap	Catalog Number: 279012
Description: BacT/ALERT [®] Blood Collection Adapter Cap	Catalog Number: 210361
Description: BacT/ALERT [®] Blood Collection Kit – Standard	Catalog Number: 410796

Description of issue:

bioMérieux has recently become aware of an issue that affects the BacT/ALERT[®] Blood Collection Adapter Cap. The BacT/ALERT[®] adapter cap is used in combination with third-party blood collection set to facilitate the filling of blood into BacT/ALERT[®] blood culture bottles. An internal investigation has determined that in some circumstances the blood collection set luer thread is disengaging from the BacT/ALERT[®] adapter cap. We have confirmed no changes have been made to the bioMérieux adaptor cap that could contribute to this behavior. It has been determined that the BacT/ALERT[®] adapter cap is not compatible with the BD Vacutainer[®] Safety-Lok Blood Collection Set reference # 367286 and # 367281. Further investigations are being conducted to confirm compatibility with other blood collection systems, however no other compatibility issues have been detected at this time.

Impact to customer:

When blood collection sets are used that have incompatible threads, the blood collection luer needle could back out of the adapter cap during normal use. Although the user may screw the blood collection needle all the way down, the threads do not firmly connect to the adapter cap. This may result in an exposure to biohazard due to a needle stick during the collection of blood. In response, we have modified our instructions for use to provide additional guidance on securing the blood collection set during sample collection. Pending introduction of the new labeling, we would like to make you aware of this change. Please review the enclosed correction to the Instructions For Use when using the BacT/ALERT[®] Blood Collection Adapter Cap.

Required actions:

We request you take the following actions at this time:

1. Ensure this letter and guidance on how to maintain control of the luer connector by securing it between the thumb and forefinger are distributed to all appropriate personnel within your organization.
2. Fill out and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

[\[Enter Local Contact\]](#)

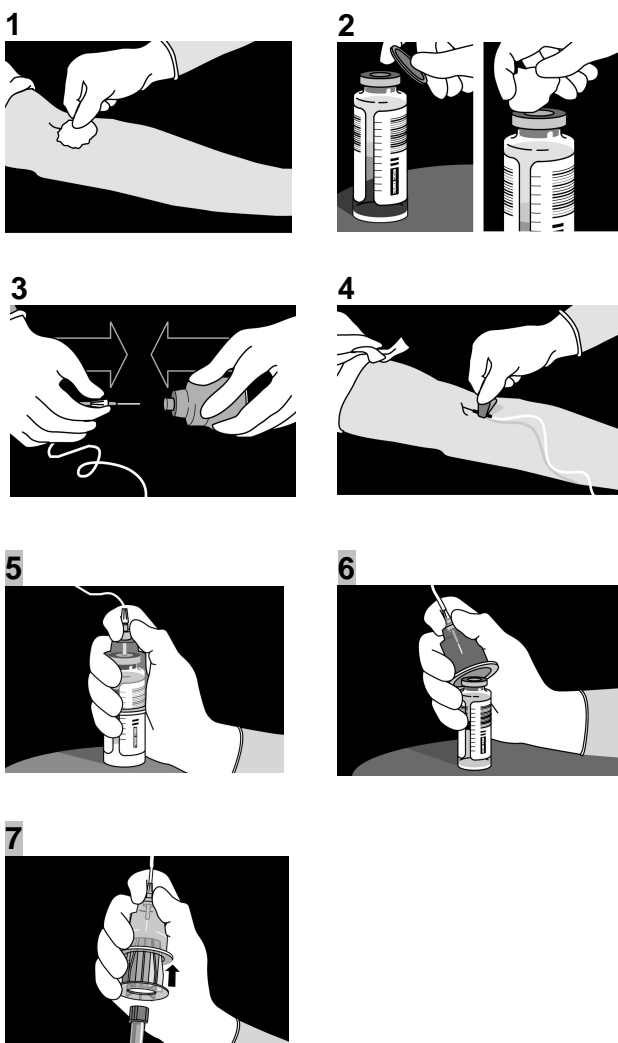


Attachment B: Instructions For Use

Instructions for Use: BacT/ALERT® Blood Collection Adapter (P/N 279012 & 210361)

Note: Refer to the complete package insert provided with the product for additional product information and intended use.

DENOTES REVISED SECTION



TEST PROCEDURE

1. Clean the selected venipuncture site as recommended by your facility's approved procedure. Allow to air dry. (Fig. 1)
2. Remove flip caps from the required number of appropriately labeled BacT/ALERT culture bottles and disinfect the exposed septa with an alcohol pad (or equivalent). Allow to air dry. Bottle(s) should be maintained in an upright position during the collection procedure. (Fig. 2)
3. Tightly connect the Adapter Cap to the luer connector of the butterfly blood collection set. (Fig. 3)
4. Perform venipuncture. When the needle is in the vein, secure it with tape or hold it in place. (Fig. 4)
5. Maintain control of the luer connector by securing it between the thumb and forefinger. Place the Adapter Cap on the aerobic BacT/ALERT culture bottle septum and press down to penetrate and obtain blood flow. Verify that blood flows into the bottle. Hold the Adapter Cap down on the bottle during collection. Line demarcations on the bottle label indicate sufficient blood volume fill. (Fig. 5)
6. After obtaining the specified amount of blood, move the Adapter Cap from the aerobic bottle to the anaerobic bottle (if required) and continue the collection. Do not remove the needle from the patient's vein during this process. (Fig. 6)

Note: If additional blood is required for other tests, place the Adapter Insert into the Adapter Cap and lock into place. This makes the cap compatible with vacuum collection tubes. (Fig. 7)

7. After blood collection is complete, remove the Adapter Cap from the culture bottle and then remove the needle from the patient's vein.