0817 - GSS INFO – BacT/ALERT® – Culture Reagent *Instructions for Use* Update

Add Date of Distribution

Dear bioMérieux Customer,

In accordance with bioMérieux change management procedures, you have received this letter as a notification of a change to the *Instructions for Use* for the following product(s) used by your institution.

BacT/ALERT SA®	**Part Number (P/N): 259789**	**Current IFU: 43-03003**
BacT/ALERT SN®	**Part Number (P/N): 259790**	**Current IFU: 43-03014**
BacT/ALERT FA®	**Part Number (P/N): 259791**	**Current IFU: 43-03033**
BacT/ALERT FN®	**Part Number (P/N): 259793**	**Current IFU: 43-03043**
BacT/ALERT PF®	**Part Number (P/N): 259794**	**Current IFU: 43-03054**
BacT/ALERT MB®	**Part Number (P/N): 251011**	**Current IFU: 43-02494**

bioMérieux regularly reviews the *Instructions for Use* to ensure the content remains relevant to current product usage.

We would like to notify you in advance of changes relating to the following sections of the *Instructions for Use*,

- Specimen Collection and Preparation

This section has been modified to include added guidance for the phlebotomist when using the direct draw inoculation procedure using a butterfly blood collection set and the BacT/ALERT Blood Collection Adapter Cap. The phlebotomist must monitor the direct draw process closely at all times during collection to assure proper flow is obtained and to avoid backflow of the BacT/ALERT culture bottle contents into a patient. Due to the presence of chemical additives in the BacT/ALERT culture bottle, it is important to prevent possible backflow and subsequent adverse reactions by following the guidance provided.

To provide you the opportunity to incorporate these changes immediately, the modified text is included as an attachment to this letter. This information supersedes that received with your product until the next revisions to the *Instructions for Use* are issued. Please take appropriate action.

bioMérieux is committed to providing our customers with the highest quality service possible. 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.

Sincerely,

Enc.

Attachment 1: Section: Specimen Collection and Preparation

Attachment 1: Example (BacT/ALERT® FA, Part Number (P/N): 259791)

SPECIMEN COLLECTION AND PREPARATION

NOTE: BacT/ALERT® FA culture bottles should be utilized by trained healthcare personnel. Correct specimen collection is extremely important when obtaining blood culture specimens. Refer to Cumitech 1C[5] for the proper specimen collection procedure.

NOTE: Take care to prevent contamination during both bottle preparation and inoculation of the patient sample. Proper skin disinfection is an essential requirement to reduce the incidence of contamination.

NOTE: Although not recommended by bioMérieux, blood may be drawn directly into collection tubes containing SPS. Tubes containing other anticoagulants should never be used for blood culture.[4]

NOTE: bioMérieux recommends that inoculated culture bottles be placed into the BacT/ALERT Microbial Detection System as soon as possible after collection. Inoculated culture bottles delayed in entry should be maintained at room temperature until they can be loaded into the instrument.

Bottle preparation

1. Label the culture bottle with patient information. The icons on the bottle label can be defined by the user.
2. Remove plastic flip-top from culture bottle. Prior to inoculation, disinfect the culture bottle top with an alcohol swab or equivalent. Allow to air dry.
3. Clean the selected venipuncture site as recommended by your institution's approved procedure.

Direct draw inoculation procedure

NOTE: If inoculating more than one type of BacT/ALERT blood culture bottle using a butterfly blood collection set and direct draw adapter cap, inoculate first the aerobic culture bottle and then the anaerobic culture bottle so that any oxygen trapped in the tubing will not be transferred to the anaerobic bottle.

NOTE: Monitor the direct draw process closely at all times during collection to assure proper flow is obtained and to avoid flow of the bottle contents into the adapter tubing. Due to the presence of chemical additives in the culture bottle, it is important to prevent possible backflow and subsequent adverse reactions by following all steps below.

a. Hold the culture bottle at a position below the patient's arm with the bottle in an upright position (stopper uppermost).
b. Collect the blood using a butterfly blood collection set and the BacT/ALERT Blood Collection Adapter Cap as recommended by your institution's approved procedure and inoculate directly into the culture bottle at the patient's bedside. Although lower sample volumes can be used, recovery may be improved using a sample volume closer to the recommended 10 ml. To prevent over inoculation, monitor the blood volume intake into the culture bottle, using the 5 ml incremental markings on the bottle label.
c. Release the tourniquet as soon as the blood starts to flow into the culture bottle, or within 2 minutes of application.
d. Do not allow the culture bottle contents to touch the stopper or the end of the needle during the collection procedure. A contaminated culture bottle could contain positive pressure, and if used for direct draw, may cause reflux into the patient's vein. Culture bottle contamination may not be readily apparent. Monitor the direct draw process closely to avoid reflux. Do not use a bottle that contains media exhibiting turbidity, a yellow sensor, or excess gas pressure; these are signs of possible contamination.

Syringe draw inoculation procedure

NOTE: If inoculating more than one type of BacT/ALERT blood culture bottle using syringe draw, inoculate first the anaerobic culture bottle and then the aerobic culture bottle so that any oxygen trapped in the syringe will not be transferred to the anaerobic bottle. Line demarcations on the bottle label should be used to assist in estimating the sample volume.

a. Perform venipuncture and blood transfer to the BacT/ALERT culture bottle according to your institution's established procedures.

4. Transfer the inoculated culture bottle promptly to the testing laboratory.