

**URGENT MEDICAL DEVICE RECALL**

December 13, 2007

Re: Triage® Micro *C. Difficile* Panel, Biosite Catalog Number 96000

Dear Valued Customer,

The purpose of this letter is to inform you that Biosite Incorporated is initiating a voluntary recall of all Triage Micro *C. difficile* Panel kits. Please discontinue use and discard appropriately ALL kits of Triage Micro *C. difficile* Panel.

Our records indicate that you have received Triage Micro *C. difficile* kits from Biosite Incorporated with current expiration dating:

Product Name	Cat. Number	Lot Number	Expiration Date
Triage Micro <i>C. difficile</i> Kit	96000	180263	2007/12/26
		187303	2007/12/26
		181472*	2008/01/02
		183607*	2008/01/02
		181471	2008/01/19
		188135	2008/01/19
		185593*	2008/03/10
		186624*	2008/03/10
		187398	2008/01/10
		190790*	2008/03/10
		189158	2008/05/02

\* Confirmed lots with decreased Toxin A color strength

Internal investigations have revealed that Toxin A results in the Triage Micro *C. difficile* Panel have shown falsely lower visual signals in certain lots compared to results observed with previous lots. We have discovered a decrease in color strength over time within the Toxin A test zone where analyte measurement could read up to 30% less than expected. This decrease in Toxin A color strength may increase the potential for false negative Toxin A interpretations. Customers who received the affected lots were previously sent correspondence regarding this situation.

Replacement kits were produced and passed all quality and performance specifications. Upon subsequent internal testing, as part of our routine quality procedures, we discovered that newly manufactured kits may also experience the problem of decreased color strength within the Toxin A test zone. The degradation of visually interpreted color strength over time may occur in certain lots after two months and in other lots, the issue does not occur through the kit expiration date.

While Biosite believes the likelihood of users experiencing a false negative Toxin A interpretation is low, we have taken a conservative approach and are conducting the voluntary recall in the best interests of our customers. We have also made the decision to suspend shipment of all Triage Micro *C. difficile* Panel kits pending resolution of the signal degradation phenomenon. Investigations are focusing on common components used in the production of Toxin A reagents.

With regard to results previously reported using the Triage Micro *C. difficile* Panel, results are valid, as per the product package insert, if no color bar appears in the NEG CTRL Zone AND color bars do appear in both of the POS CTRL Zones. As long as the test device control zones generated valid results, previous patient results should not be a concern. The Triage Micro *C. difficile* Panel does not provide a definitive diagnosis of *C. difficile* associated disease. The test only demonstrates the presence of the organism and/or Toxin A in stool. As with all *in vitro* diagnostic tests, the test results should be interpreted by the physician in conjunction with other laboratory test results and patient clinical findings.

### **REQUIRED ACTION**

#### **Distributors and Subsidiaries Outside the United States**

- Discontinue use and discard appropriately all kits of Triage Micro *C. difficile* Panel.
- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice and to indicate the number of kits discarded.
- Contact your local Biosite representative or Biosite distributor representative regarding kit replacement needs.

### **REPLACEMENT PRODUCTS**

#### **TECHLAB Toxin A/B Quik Chek™, 25 test kit**

- Inverness Medical Catalog Number 30394
- ThermoFisher Catalog Number 22293515

#### **TECHLAB C. Diff Quik Chek™ (Common Antigen/GDH), 25 test kit**

- Inverness Medical Catalog Number 30390
- ThermoFisher Catalog Number 23046935

For each kit of Triage<sup>®</sup> Micro *C. difficile* Panel (20 test kit) that was discarded as per the quantity indicated on the Verification Form, you will receive one kit each of TECHLAB Toxin A/B Quik Chek™ and TECHLAB C. Diff Quik Chek™, each kit containing 25 tests. Procedure documents and MSDS information will be included. There are no other single cartridge test devices available that match the test menu of the Triage Micro *C. difficile* Panel.

**CONTACT INFORMATION**

**Outside the United States:**

**For additional product needs**, please contact your local Biosite representative or Biosite distributor representative.

**For technical information**, please direct any questions or concerns to Biosite Technical Support via email to [techservice@biosite.com](mailto:techservice@biosite.com).

We sincerely regret any inconveniences this product performance issue may have caused. Biosite is fully committed to the safety of your patients and to providing high quality products and services. We are working diligently to ensure that future Triage<sup>®</sup> Micro *C. difficile* Panel kits meet all performance specifications through kit expiration and we will provide additional updates as information becomes available.

Thank you for your cooperation and support.

Sincerely,



Senior Manager, Regulatory Compliance



Director, Quality Assurance

Please complete this form even if you do not have any involved product and **Fax Back** to Biosite Technical Support at Fax Number 858-695-9964.

**Verification Form – Urgent Medical Device Recall  
Triage Micro *C. difficile* Panel, 96000**

1. We acknowledge receipt of the Biosite Product Recall notice dated December 13, 2007 for the Triage Micro *C. difficile* Panel.
2. We confirm that all areas where the product could be located have been checked.
3. **SELECT ONE OF THESE STATEMENTS\*, SIGN THIS FORM and FAX to Biosite Technical Support at Fax Number: (858) 695-9964.**

- We do not have any affected product.
- Product was redistributed to another facility – Name and address of facility:  
\_\_\_\_\_
- We are destroying/discarding the following product(s) – Please confirm the product, lot number(s), the quantity destroyed and date destroyed.

Product Name	Part Number	Lot Number(s) (please list below)	Kit Quantity Discarded/ To Be Replaced
Triage Micro <i>C. difficile</i> Panel	96000		

DATE\*: \_\_\_\_\_

Authorized SIGNATURE\*: \_\_\_\_\_

PRINT NAME\*: \_\_\_\_\_

TITLE\*: \_\_\_\_\_ Department: \_\_\_\_\_

INSTITUTION\*: \_\_\_\_\_

ADDRESS\*: \_\_\_\_\_

CITY\*: \_\_\_\_\_ STATE\*: \_\_\_\_\_ COUNTRY\*: \_\_\_\_\_

PHONE\*: \_\_\_\_\_

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Biosite Technical Support at Fax Number (858) 695-9964.

\* Mandatory field