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Benzodiazepine Urgent Medical Device Recall

FREQUENTLY ASKED QUESTIONS

What products are affected by this recall?

Multi-drug tests, containing a BZO test strip, which have been manufactured in cup, dip card and cassette formats. See attached list for affected parts and lots.

Why is the product being recalled?

The BZO test strip present in affected product lots does not consistently detect up to 3 (of the 19) BZO compounds at the concentrations listed in the Specificity section of the package insert. Affected product lots continue to perform as expected for the remaining 16 BZO compounds, including Oxazepam. As described in the Intended Use section of the product insert, Oxazepam is the BZO compound to which the test has been calibrated. Affected lots also continue to perform as expected for all of the non-BZO drugs to which the assay is calibrated.

How does reduced reactivity to Lorazepam affect test results when screening urine samples?

There is potential for negative BZO results when evaluating urine containing the BZO compound Lorazepam, since it has no subsequent metabolite with which the test is known to react. This is the reason for recall.

How does reduced reactivity to Clonazepam affect test results when screening urine samples?

The majority (>98%) of Clonazepam is converted in urine to 7-aminoclonazepam, a metabolite to which affected product has been demonstrated to be reactive. Therefore, reduced reactivity to Clonazepam is not expected to impact BZO test results.

How does reduced reactivity to Nordiazepam affect test results when screening urine samples?

Nordiazepam is metabolized to Oxazepam, the Benzodiazepine compound to which the assay is calibrated. Each lot of product is tested for its ability to detect Oxazepam. Therefore, reduced reactivity to Nordiazepam is not expected to impact BZO test results.

What is the cause of this product issue?

Initial investigation has identified the cause of the failure as a raw material issue. Specifically, the antibody responsible for detection of the BZO compounds has been shown to have variable performance between lots.

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What alerted EDI to this issue?

Express Diagnostics Int'l (EDI) was contacted by several customers who had failed to detect BZO in a sample tested as part of their CAP (College of American Pathologists) survey. Investigation into these complaints identified the reduced reactivity issue.

Are any additional quality control procedures required?

EDI has increased its testing of BZO compounds in order to identify potential issues prior to release of the product. EDI is not recommending any additional QC measures for laboratories/customers.

Is this action being mandated by FDA?

No. This is a voluntary field action being undertaken by EDI, who has reported it to FDA.

What is being done to correct the problem?

EDI is implementing several additional process controls and QC procedures to prevent a recurrence of this issue in the future.

If I distributed the product to other facilities or customers, am I required to notify them?

Yes. You must follow directions provided in the Urgent Medical Device Recall notification and forward to all customers to whom you have distributed affected product. You are required to account for all product you've received. For all distributed product you are expected to provide the following:

a Initial customer notification method, date, and customers notified (customer # is acceptable).
b For non-responding customers: method and date of 2nd and 3rd notification attempts.
c Number of completed Customer Verification Forms received from contacted customers.
d Quantity, part number, and lot number of kits returned by customers.

How do I receive replacements for the product?

Complete the Customer Verification Form included in your Urgent Medical Device Recall Notice, indicating the number of replacements required, and fax it to 1-507-526-2253 or scan and email to quality@drugcheck.com. Your distributor will contact you with instruction on how to return product.

What about Product I have used? Will you provide replacement or credit for consumed product?

No. Simply fill out the Customer Verification Form in the Urgent Medical Device Recall Notification. We will replace the amount you are returning for replacement free of charge. However, in cases where the amount of product replaced exceeds the amount of product returned, you may be billed for the difference