



URGENT: FIELD SAFETY NOTICE

Product: Quidel Triage TOX Drug Screen Control 1

Catalog Number: 94413

Quidel Triage TOX Drug Screen Control 1 Lot Number C3470AN

April 9, 2019

Dear Valued Customer,

Quidel Corporation is initiating a voluntary product recall for **Quidel Triage TOX Drug Screen Control 1, Part Number 94413, Lot Number C3470AN**. Due to an error in the programming of the Control CODE CHIP module for this lot, a failing result is inappropriately displayed for AMP and mAMP. The Quidel Triage Meter displays a POS result for AMP and mAMP when the correct result is NEG. In addition, the message "QC Sample out of Range" will also appear/print. This issue does not impact the Quidel Triage TOX Drug Screen test or any previously reported patient results. The Quidel Triage TOX Drug Screen Controls are to be used with the Quidel Triage TOX Drug Screen tests and Quidel Triage Meters to assist the end user in monitoring patient performance. Because of this issue, alternate Quidel Triage TOX Drug Screen Control 1 lots must be used.

Quidel will provide replacement product or credit your account.

Quidel requests that you take the following action:

1. Check the Quidel Triage TOX Drug Screen Control 1 you have on hand to determine if you have any of the affected lot number (C3470AN).
2. If you locate the above-noted lot number, please properly destroy them to ensure they are not used.
3. If you have forwarded this lot to another facility, please forward this communication to that facility.
4. Complete the enclosed Inventory Assessment / Certificate of Destruction form (Attachment 1) and return to CustomerNotifications@quidel.com.
5. If you have any questions or require assistance, please contact Quidel Technical Support:
 - For US and Canada, please call 800-874-1517, option 2
 - For Europe and Middle East, please call +353 (91) 412 474

All relevant National Competent Authorities have been advised of this FSCA. In Germany, please contact our European Representative:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany
Tel.: +4951162628630
Fax: +4951162628633

Quidel is taking this action because we are dedicated to providing quality products, and we are committed to supporting our valued customers. Quidel sincerely regrets any inconvenience this may cause and encourages you to contact us if you need assistance or further information.

Sincerely,

Tom Clement
Vice President, Clinical / Regulatory Affairs and Quality Assurance

Attachment 1

FIELD SAFETY NOTICE

Certificate of Destruction

Customer instructions: Please confirm that the product shown below has been properly **DESTROYED**, sign and date below, then return the completed form to CustomerNotifications@quidel.com. Please note how many Control kits you have on hand

Product Description: Quidel Triage TOX Drug Screen Control 1 Lot C3470AN

Confirmation: Receipt of product destruction

Number of Quidel Triage TOX Drug Screen Control 1 Lot C3470AN on hand _____
(prior to destruction).

Check here to acknowledge that the affected lots have been destroyed:

Check here if you do not have any inventory of the affected lots:

Customer Information:

Print Name: _____ Title: _____

Facility Name: _____

Phone #: _____

Facility Shipping Address: _____

E-mail: _____

The information in this document is accurate to the best of my knowledge.

Customer Signature: _____ Date: _____

quidel.com