Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

# Urgent Field Safety Notice
# Product Recall
**Immediate Action Required**

**Date Issued** June 02, 2016

**Product**

| Product Name | List Number | Serial/Lot Number | Expiration Date |
|---|---|---|---|
| Quantia Digitoxin Reagent | 6K40-01 | 03514I000 | 11 DEC 2015 |
| | | 02314G000 | 11 DEC 2015 |
| | | 01015B000 | 26 MAR 2016 |
| | | 01515D000 | 04 JUN 2016 |
| | | 01915I000 | 25 FEB 2017 |
| | | 03415I000 | 25 FEB 2017 |

**Explanation** Abbott received the attached letter from Biokit, the manufacturer of the Quantia Digitoxin Reagent. Internal studies performed by Biokit have determined that the antibody used in the manufacture of the lots listed above has higher cross-reactivity with Digoxin and other cardiac glycosides and reduced affinity to Digitoxin than previously manufactured lots.

**Patient Impact** Please refer to the attached letter from Biokit.

**Necessary Actions**

- Please review the attached Biokit letter carefully, follow the instructions, and retain a copy for your laboratory records.
- Complete and return the Customer Reply Form.
- Contact Abbott customer service for assistance if needed.
- If you have forwarded any of the lots above to another laboratory, please inform them of this Product Recall and provide to them a copy of this letter.

**Contact Information** We sincerely regret any inconvenience this issue may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

**FIELD SAFETY NOTICE**
QUANTIA DIGITOXIN
PART NUMBER: 6K40-01
Reduced antibody affinity for Digitoxin

Date: May 27, 2016

Dear Valued Customer:

Our records indicate that your laboratory may have used or currently has in inventory one or more kits of:

| Product | Code | Lot Number | Expiration Date |
|---|---|---|---|
| QUANTIA DIGITOXIN | 6K40-01 | 03514I000 | 2015-12-11 |
| | | 02314G000 | 2015-12-11 |
| | | 01015B000 | 2016-03-26 |
| | | 01515D000 | 2016-06-04 |
| | | 01915I000 | 2017-02-25 |
| | | 03415I000 | 2017-02-25 |

- **Issue Description and Patient Impact:**

With regard to the QUANTIA DIGITOXIN assay, Biokit has received notification from the digitoxin antibody supplier that the antibody used in the manufacture of the impacted lots listed above has higher cross-reactivity with digoxin and other cardiac glycosides and reduced affinity to digitoxin than previously manufactured lots.

The QUANTIA DIGITOXIN assay does not have any glycoside cross-reactivity claims and our investigation to-date has confirmed that all the impacted lots continue to meet Biokit Quality Control release specifications.

Studies performed by Biokit determined that the impacted lots of QUANTIA DIGITOXIN showed an under-recovery of 10 - 20% versus non-impacted lots. Biokit also assessed the risk of falsely depressed digitoxin results for patients with a serum concentration of digitoxin in the toxic range. Samples in the digitoxin toxic range (> 45 ng/ml) were under recovering by up to 40% but remaining above the digitoxin therapeutic range (10 - 25 ng/ml) indicated in the Instructions for Use. Although these patients would present values above the therapeutic range, the difficulty in detecting Digitoxin toxicity solely from a patient's symptoms could result in patients not receiving timely treatment for toxicity which could involve serious injury.

Two less likely scenarios have been identified where falsely elevated digitoxin results may occur:

(1) digoxin is present in serum from previous treatment

(2) digoxin-like immunoreactive substances are present in serum.

Biokit has performed an assessment of risk and has determined that the impacted lots cannot continue to be used.

- **Actions:**

Biokit has procured and tested a new digitoxin antibody lot which does not exhibit the increased cross-reactivity with digoxin or other cardiac glycosides neither the low affinity to digitoxin. Biokit expects that new QUANTIA DIGITOXIN reagent lots manufactured with this antibody will be available to market by end of June 2016.

Biokit is currently implementing procedures to prevent this situation from occurring in the future.

- **Mandatory Customer Action:**

Please stop using the affected lots and discard locally any remaining kits of the QUANTIA DIGITOXIN 6K40-01 from your inventory and analyzers.

Consult with your Medical Director to determine if a retrospective review of results generated with the impacted lots is required.

Please forward this notice to all organizations / individuals who are impacted by this action and retain this notice for your laboratory records.

We ask our customers to inform our local representatives of the current number of kits in their inventory in order to be able to provide you with the new material as soon as it becomes available.

In addition, Biokit would also like to advise you to take this information into account when using the future non-impacted lots of QUANTIA DIGITOXIN reagent.

We apologize for this temporary inconvenience and appreciate your prompt attention to this notification. Please contact your local representative with any questions.

Sincerely,

Joan Guixer
Quality Assurance & Regulatory Affairs Director
BIOKIT, S.A.