




March 08, 2023

URGENT FIELD SAFETY NOTICE

Access Free T3 Triiodothyronine, Free Reagent

REF	LOT	
A13422	233968	30 Jun 2023

Dear Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<ul style="list-style-type: none"> Beckman Coulter has determined that Access Free T3 reagent lot 233968 included an insufficient concentration of blocking reagent.
IMPACT:	<ul style="list-style-type: none"> Patient samples tested with Access Free T3 reagent lot 233968 may demonstrate repeatable falsely elevated results, which are caused by insufficiently blocked interferents. Internal studies indicate that approximately 15-20% of patient samples tested with Access Free T3 reagent lot 233968 are affected by this issue. Internal studies show the results of affected samples tested with Access Free T3 reagent lot 233968 are approximately 30-80% higher than expected. The extent of this increase may vary based upon the amount of interferent that is present in the sample.
ACTION:	<ul style="list-style-type: none"> Discontinue using Access Free T3 reagent lot 233968. Discard all remaining reagent packs from this lot. Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results. Contact your local Beckman Coulter representative for replacement product requests.
RESOLUTION:	<ul style="list-style-type: none"> Beckman Coulter is no longer distributing Access Free T3 reagent lot 233968. Beckman Coulter is investigating the root cause of this issue.

250 S Kraemer Blvd, Brea, CA 92821. • 714.993.5321. • www.beckmancoulter.com

FA-23006 | Page 1



The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Center.

- From our website: <http://www.beckmancoulter.com>
- By telephone: 714-993-5321
- You may request replacement product by contacting your local Beckman Coulter Representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Courtney Walton
Signer Name: Courtney Walton
Signing Reason: I approve this document
Signing Time: 08-Mar-2023 | 2:48:23 PM PST
A78060F7687943039615B491616B80F6

Courtney Walton
Senior Director, Quality & Regulatory Affairs
Beckman Coulter Inc.
250 S. Kraemer Blvd. Brea,
CA 92821-6232
Telephone: 714-993-5321
Email: BECFA@beckman.com

Enclosure: Response Form

2023 Beckman Coulter. All rights reserved. Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries. All other trademarks are the property of their respective owners.