Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Specialist

Contact person of this notification	…Stephanie Lim……
Department	…Marketing……
Telephone	…+60129826560……
Fax	…603 7772 0551..……
E-mail	… swlim@beckman.com……

Beckman Coulter Malaysia Sdn. Bhd. (861038-K)
No. 18, Jalan Tandang 51/205A,
Seksyen 51, 46050 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

Tel : (603) 7772 8256
Fax : (603) 7772 0551
Website : www.beckmancoulter.com

Docusign Envelope ID: FD8FA7A8-9B03-4D70-B2D6-563A9C62C482

July 2, 2025

URGENT MEDICAL DEVICE RECALL

Access Thyroglobulin

REF	LOT	
33860	439163	30-APR-2026

Attention Beckman Coulter Customer,

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

ISSUE: Access Thyroglobulin reagent lot 439163 may generate erroneously high patient results.

IMPACT:

- Internal studies indicate that approximately 27% of patient samples tested with Access Thyroglobulin reagent lot 439163 may be affected by this issue.
- The extent of the increase may vary based on the patient sample.
- Based on internal studies and customer data, affected patient samples that were ≤1 ng/mL on an alternate reagent lot illustrated recovery on average 1.9 ng/mL and up to 6.2 ng/mL higher when tested using Access Thyroglobulin reagent lot 439163.
  - Examples of specific patient sample shifts are shown below:

Tg (ng/mL)		Tg Concentration Difference (ng/mL)
Alternate Reagent Lot	Reagent Lot 439163	
0.2	0.8	0.6
0.1	1.8	1.7
0.8	7	6.2

- Based on internal studies and customer data, affected patient samples that were >1 ng/mL on an alternate reagent lot illustrated recovery on average 82% and up to 207% higher when tested using Access Thyroglobulin reagent lot 439163.
  - Examples of specific patient sample shifts are shown below:

Tg (ng/mL)		Tg Percent Difference
Alternate Reagent Lot	Reagent Lot 439163	
1.1	1.6	47%
3	4.5	50%
1.4	4.3	207%

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

phone: 952.448.4848
www.beckmancoulter.com

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	• Falsely increased Access Thyroglobulin results may lead a physician to pursue unnecessary diagnostic imaging studies and/or inappropriate therapy adjustments in patients being monitored for residual or recurrent thyroid cancer.
ACTION:	• Discontinue using Access Thyroglobulin reagent lot 439163 and discard all remaining reagent packs from this lot. • At the discretion of the medical director, a retrospective review of patient results generated with Access Thyroglobulin reagent lot 439163 should be performed, which includes reviewing patient history, to assess the need for retesting. • Please contact your local Beckman Coulter representative for replacement product requests and to receive updates on availability and delivery.
RESOLUTION:	Beckman Coulter is investigating the root cause of this issue to prevent similar occurrences.

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 listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center:

- From our website: http://www.beckmancoulter.com
- Contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:
Jennifer Chau
Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 03-Jul-2025 | 7:45:31 AM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, US Quality Operations

Enclosure: Response Form, Product Replacement Form

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