



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 Affairs Specialist

Contact person of this notification	... Alice Wong.....
Department	... Marketing.....
Telephone	... 6012-296 0320.....
Fax	... 603 7772 0551.....
E-mail	... awong02@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) 77728256
Fax : (603) 77720551
Website : www.beckmancoulter.com



June 28, 2023

URGENT MEDICAL DEVICE RECALL

Thyroglobulin Calibrator (PN 33865)

REF	LOT	
PN 33865	233806	2023-04-30
	234171	2023-06-30
	234355	2023-08-31
	234443	2023-09-30
	234444	2023-10-31
	234617	2023-11-30
	337940	2024-01-31

Dear Beckman Coulter Customer,
 Beckman Coulter is sending this letter to notify your laboratory of an issue associated with the Access Thyroglobulin calibrators that are for use with the Access Thyroglobulin (Thyg) assay (REF C71762). Patient results may be affected.

ISSUE:	<ul style="list-style-type: none"> In April 2023, Beckman Coulter distributed a letter that provided alternate Access Thyroglobulin calibrator cards for use with the Thyg reagent packs. It has been determined through an internal investigation that the calibrator card will cause a decrease of approximately 11% in patient results.
IMPACT:	<ul style="list-style-type: none"> A false low Thyroglobulin result may delay the diagnosis and treatment of recurring thyroid cancer.
ACTION:	<ul style="list-style-type: none"> Only use Access Thyroglobulin calibrator lots 338013 or higher to calibrate Access Thyg reagent packs. Do not use the calibrator cards provided in the April 2023 communication.
RESOLUTION:	<ul style="list-style-type: none"> Beckman Coulter has resolved this issue with all future lots of Access Thyroglobulin calibrators.

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 products 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>

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:
Rachel Davison

 Signer Name: Rachel Davison
Signing Reason: I approve this document
Signing Time: 29-Jun-2023 | 6:45:38 AM PDT
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Rachel Davison
Vice President Quality & Regulatory Affairs
Beckman Coulter Inc.
250 S. Kraemer Blvd. Brea,
CA 92821-6232
Telephone: 714-993-5321

Enclosure: Response Form

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