

To:

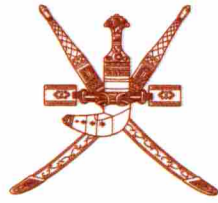
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 149 dated 18/7/23 Regarding NCMDR FSCA of Thyroglobulin Calibrator from (mfr: Beckman Coulter).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 149/20223

30-12-1444 H

18 -07-2023

نتقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Vision

### Field Safety Corrective Action of Thyroglobulin Calibrator from Beckman Coulter

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19609">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19609</a>
Product	Thyroglobulin Calibrator.
Description	IVD.
Manufacturer	Beckman Coulter.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Ref: PN 33865 Lot numbers and expiration dates: see the attachment
Reason	The calibrator card will cause a decrease of approximately 11% in patient results (distributed by Beckman Coulter communication in the April 2023 that provided alternate Access Thyroglobulin calibrator cards for use with the Thyg reagent packs).
Action	1. 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. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al-Rubaie  
Director General





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.

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>A false low Thyroglobulin result may delay the diagnosis and treatment of recurring thyroid cancer.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Only use Access Thyroglobulin calibrator lots 338013 or higher to calibrate Access Thyg reagent packs.</li> <li>Do not use the calibrator cards provided in the April 2023 communication.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter has resolved this issue with all future lots of Access Thyroglobulin calibrators.</li> </ul>

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  
109D1D39B30B415BBEC3779EBF0205D5

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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