



Circular No. 120 / 2024

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24 -02-1446 H
29 -08-2024

Field Safety Corrective Action of IMMAGE Immunoglobulin M (IgM) from Beckman Coulter Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/54
Product	IMMAGE Immunoglobulin M (IgM).
Manufacturer	Beckman Coulter Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Ref: 447610 UDI: 15099590221195 Lot (Expiry Date): M307362 (31May2025), M309410 (31Jul2025).
Reason	The IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots listed above are not meeting the sensitivity statement in the IFU: “Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for IGM determination is 4.2 mg/dL.”
Action	1. Discontinue use of affected IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots and please follow product replacement instructions in the attachment. 2. It has been recommended by Beckman Coulter sharing the content of the attachment with your laboratory and/or medical director regarding the need to perform a retrospective review of the patient results generated from the affected IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots to determine if retesting is necessary. 3. 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: vigilance-md@moh.gov.om

Ph. Ahmed Al Harbi
Acting Director General





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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 120 dated 29.8.2024 Regarding SFDA Field Safety Corrective Action of IMAGE Immunoglobulin M (IgM) from (mfr: Beckman Coulter Inc).

Copy to:


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



August 02, 2024

URGENT FIELD SAFETY NOTICE

IMMAGE Immunochemistry Systems IGM Immunoglobulin M Reagent
IGM reagent cartridge: 1 x 15.2 mL
IGM compartment A: 7.6 mL
IGM compartment B: 7.6 mL
Number of tests: 300

REF	UDI	LOT	
447610	15099590221195	M307362 M309410	31May2025 31Jul2025

Single Registration Number (SRN): US-MF-000010288

Attention 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">As a result of internal investigations, Beckman Coulter has discovered that IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots listed above are not meeting the sensitivity statement in the IFU: <i>"Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for IGM determination is 4.2 mg/dL."</i>
IMPACT:	<ul style="list-style-type: none">This issue has no impact on patient results that recover within the initial analytical range of 25 – 400 mg/dL.The use of affected IMMAGE Immunochemistry Systems IGM Immunoglobulin reagent lots may lead to false low results in the extended low range (below 25 mg/dL). This may lead to inappropriate diagnosis of IgM deficiency.
ACTION:	<ul style="list-style-type: none">Discontinue use of affected IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots and please follow product replacement instructions below.Review the Safety Data Sheet (SDS) and discard according to your laboratory's Standard Operating Procedures and/or your local regulations. The SDS is available on www.beckmancoulter.com.Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to perform a retrospective review of the patient results generated from the



	affected IMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots to determine if retesting is necessary.
RESOLUTION:	<ul style="list-style-type: none"> Beckman Coulter is no longer distributing the affected lots.

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 our Customer Support Center:

- From our website: <http://www.beckmancoulter.com>
- By phone: call 1-800-854-3633 in the United States.
 - Outside the United States, contact your local Beckman Coulter representative.
- For customers in the United States, if you need replacement product:
 - Complete the attached "Replacement Order Form" and email to askbeckman@beckman.com or fax to (866) 294-7850 OR
 - Call Client Services at (800) 526-3821
- For customers in other geographies, contact your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:
Rachel Davison
 Signer Name: Rachel Davison
 Signing Reason: I approve this document
 Signing Time: 02-Aug-2024 | 8:37:35 AM PDT
 109D1D39B30B415BBEC3779EBF0205D5

Rachel Davison
 Vice President Quality and Regulatory Affairs

Enclosure: Response Form
 Replacement Order Form

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.

SA-04-08-24-541

Details

Reference Number

SA-04-08-24-541

Manufacturer Company

Beckman Coulter Inc.

Medical Device Name

IMMAGE Immunoglobulin M (IgM)

Affected Devices

Ref: 447610
UDI: 15099590221195
Lot (Expiry Date): M307362 (31May2025), M309410 (31Jul2025)

Authorized Representative

Beckman Coulter Saudi Arabia Co Ltd

Reason of Problem

The IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots listed above are not meeting the sensitivity statement in the IFU: "Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for IGM determination is 4.2 mg/dL."

Action

- Discontinue use of affected IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots and please follow product replacement instructions in the attachment.
- It has been recommended by Beckman Coulter sharing the content of the attachment with your laboratory and/or medical director regarding the need to perform a retrospective review of the patient results generated from the affected IMMAGE Immunochemistry Systems IGM Immunoglobulin M reagent lots to determine if retesting is necessary.

Attach Files

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