Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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.. 85 ..... dated ..8/5/22.. Regarding NCMDR FSN of VIDAS® CMV IgG Avidity II from (mrf: BioMerieux Inc).

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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
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سلطنة عُمان
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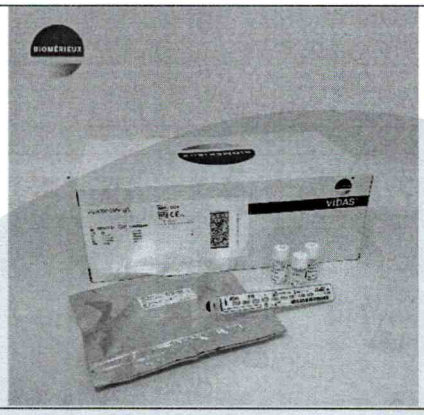
Circular No. 85 / 2022

07-10-1443 H

08-05-2022

Field Safety Notice of VIDAS® CMV IgG Avidity II from bioMerieux Inc

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16118
Product	VIDAS® CMV IgG Avidity II.
Description	IVD.
Manufacturer	BioMerieux Inc.
Local Agent	AL Hashar Pharmacy.
The affected products	Ref. 413557.
Reason	European regulation called REACH (Registration, Evaluation and Authorization of Chemicals) requires that bioMerieux add in the IFU of this assay, specific warning in waste section and an authorization number given to bioMérieux for use of specific raw material in the assay.
Action	1. Refer to the table in the attached FSN. 2. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Marcy L'Etoile, February 18, 2021

Subject: **Explanation letter for Change CR-00050/CR-00151**

To whom it may concern,

Please find below the summary of change reference CR-00050/CR-00151: Addition of REACH statement in the IFU.

Reference(s):

- VIDAS® CMV IgG Avidity II (Ref. 413557)

Reason for change:

This change is a result from an European regulation called REACH (Registration, Evaluation and Authorization of Chemicals).

Description of the change:

REACH regulation requires that we add in the IFU of this assay, specific warning in waste section and an authorization number given to bioMérieux for use of specific raw material in the assay.

It is why we have to update the IFU of this assay in order to:

- add a specific sentence in the Waste section recommending incineration of the waste for European countries
- an authorization number at the bottom of the IFU.

We took opportunity of the IFU revision, to harmonize wording, Section title, writing for all IFU (migration to CMS – Content Management System tools) + strip composition description to harmonized details with other IFU.

Refer to description in this table below.

Location	Current situation	Proposed change
IFU: - Waste section	WASTE DISPOSAL Dispose of used or unused reagents, as well as any other contaminated disposable materials, following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced, according to their nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.	WASTE DISPOSAL Dispose of used or unused reagents, as well as any other contaminated disposable materials, following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced, according to their nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations. For countries within the EU, It is recommended that all material associated with the test, including material used to clean up spills, contaminated packaging, and/or unused and expired IVD tests, is incinerated.
IFU: - End of document	N/A	Addition of the authorization number information simulation : "REACH: athorization# - pending EU Commission decision" *Note: This formulation* "REACH/XX/XX/X" or "REACH: athorization# - pending EU Commission decision" *will be replaced by the exact formulation given by ECHA to bioMérieux.* *"XXXX" will be replaced by the digits corresponding to the authorization number given by ECHA to bioMérieux from June 2021.*

IFU: Change of wording	Actual wording and section name.	Formatting, wording, section title, writing changes for use of CMS tools. Ex: Add of Intended use 1st section Add of "single use" word Add of reagent : The Reagent strip Add of wording: For professional use only, by qualified laboratory personnels in clinical laboratories Wording use of Samples instead of Specimens Writing of range of Temperature: +2°C/+8°C instead of 2-8°C; -31°C/-19°C instead of -25+6°C → no change of meaning.

The VIDAS Assays safety and performances are not changed. bioMérieux complies to REACH regulation requirements

Technical documentation:

In the Product Technical documentation, the following items are modified:

- Instruction for use (Package insert)

Detailed modifications are presented in appendix of this explanation letter.

Supportive documentation:

- VIDAS® CMV IgG Avidity II (Ref. 413557) IFU 049928 - -02

Claire Dumas
Regulatory Affairs Specialist
bioMérieux SA