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

سلطنة عمان
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.21**..... dated .**23/01/12**. Regarding NCMDR Recall Nyco-Card D-Dimer-In vitro diagnostic test (Mfr: Abbott)**

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**

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

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Circular No. 21 / 2020

27-05-1441 H

23-01-2020

Recall Nyco-Card D-Dimer-In vitro diagnostic test of from Abbott

Source of Recall	**NCMDR** National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15002
Product	NycoCard D-Dimer In vitro diagnostic test
Manufacturer	Abbott
Local agent	Waleed Pharmacy
The affected products	Multiple Lot numbers of the affected device are provided in the attached
Reason for Recall	A review of data for NycoCard D-Dimer results indicates discrepant low giving results below the clinical cut-off level for NycoCard D-Dimer (0.3 mg/L), as compared to other laboratory methods that detected D-dimer results above their clinical cut-off.
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Discard all unused kits from the listed lots.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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

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Fax: +47 24 05 6010
www.abbott.com/poct

Urgent Field Safety Notice

en (SA)

NycoCard™ D-Dimer

FSCA-identifier: CAPA-00002815 Date: 13 December 2019

For the attention of USER OF NYCOCARD D-DIMER

Dear customer,

Our records indicate that you have received deliveries of the following affected product:

Product name: **NycoCard™ D-Dimer**

Catalogue numbers: **1116081, 1116082**

Manufacturer: On label: Alere Technologies AS
Alere Technologies AS changed name to Abbott Diagnostics Technologies AS on 10 January 2019

Lot numbers:

Lot number (LOT)	Expiry date	Lot number (LOT)	Expiry date
10202867	14.12.2019	10204136	18.03.2020
10202890	14.12.2019	10204137	18.03.2020
10202900	14.12.2019	10204139	18.03.2020
10202908	14.12.2019	10204140	18.03.2020
10202932	14.12.2019	10204185	18.03.2020
10203193	27.12.2019	10204334	26.03.2020
10203194	27.12.2019	10204485	03.04.2020
10203210	27.12.2019	10204486	03.04.2020
10203214	27.12.2019		

Product description: *In vitro* diagnostic test for the rapid determination of the fibrin degradation product D-dimer in human plasma.
For professional near-patient testing and laboratory use.
For use with the NycoCard™ READER II.

Expected plasma values when using NycoCard D-Dimer:
- The clinical cut-off level is 0.3 mg/L.
- Healthy subjects are expected to have a D-dimer concentration below 0.3 mg/L.

Abbott

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Description of the problem

A review of data for NycoCard D-Dimer results indicates discrepant low results may be observed in comparison to other laboratory methods. The affected lots of NycoCard D-Dimer have been investigated and show results may be discrepant low, giving results below the clinical cut-off level for NycoCard D-Dimer (0.3 mg/L), as compared to other laboratory methods that detected D-dimer results above their clinical cut-off.

The user may not recognize discrepant results unless the result is compared with another method, or if the test result is inconsistent with the clinical assessment and patient history.

Risk to Health

The analysis of available data for NycoCard D-Dimer has concluded that use of the affected lots may lead to a missed or delayed diagnosis in identifying patients potentially at risk for adverse health consequences.

If the NycoCard D-Dimer is used to rule out venous thromboembolism (VTE) in patients with low or moderate risk, without a comparative or confirmatory test, it could lead to a missed or delayed diagnosis in identifying patients with deep venous thrombosis (DVT) or pulmonary embolism (PE).

Abbott is not aware of any reports of adverse health events on affected lots in relation to this issue.

Actions to be taken:

1. If the affected NycoCard D-Dimer kits have been further distributed within or beyond your organization, please ensure that this information is forwarded to the user(s) of the device.
2. Review your inventory of NycoCard D-Dimer and identify the remaining packages of the affected lots and immediately discontinue use. Discard all unused kits from the listed lots according to your local requirements.
3. Ensure that treating physicians are aware of this issue and follow the advice below.
4. Complete and return the Confirmation Form attached to this letter as soon as possible.
   Your supplier will credit you for the discarded kits upon receipt of the Confirmation Form. Please be informed that there are no available lots for replacement at this time.
5. Please retain this letter within your records.

Abbott

Advice on actions to be taken by the MEDICAL DOCTORS:

1. Discontinue the use of the affected lots of NycoCard D-Dimer.
2. Abbott recommends that the treating physicians review the patients who presented in the last ninety (90) days with clinical signs of VTE as they may have been categorized into low or moderate risk using PTPs and have undergone NycoCard D-Dimer tests.
3. If additional testing is determined to be needed, please be advised that testing will need to be performed with another commercially available test.