Urgent Field Safety Notice EN (UK)

NycoCard™ D-Dimer

FSCA-identifier: CAPA-00002815 Date: 10 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.

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.

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.

PLEASE COMPLETE AND RETURN THIS REPLY FORM AS SOON AS POSSIBLE

Confirmation form for the receipt of Field Safety Notice EN (UK)

NycoCard™ D-Dimer

FSCA-identifier: CAPA-00002815

This response form is to confirm the receipt of the Field Safety Notice.

If you have any questions or need additional information, please contact your local technical support provider or distributor.

1. Customer Details

Account/Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

2. Customer action undertaken on behalf of Healthcare Organisation

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	Customer to complete or enter N/A	
☐	The information and required actions have been brought to the attention of all relevant users and executed.*	Customer to complete or enter N/A	
☐	I have destroyed affected lots – enter number destroyed and date complete.*	Unopened lots:	
		Number of kits:	Lot(s):
		Opened lots:	
		Number of test devices:	Lot(s):

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☐	Or, there are not affected lots available for destruction.*	Customer to complete or enter N/A
☐	I have informed the medical doctors responsible for clinical interpretation of the NycoCard D-Dimer test results.*	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

3. Return acknowledgement to sender

Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Please complete and return this form within **10 business days** of receipt

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence Abbott needs to monitor the progress of the corrective actions.