Urgent Field Safety Notice

Medical Device Recall D-DIMK20 D-Dimer Rapid Test from the market

Diagnostik Nord GmbH, Mecklenburgstr. 97, 19053 Schwerin

Recipient:
Users, operators, distributors of the
Diagnostik Nord GmbH
D-Dimer rapid test (D-DIMK20)

Schwerin, October 21. 2016

Dear valued customer,

This Urgent Field Safety Notice of the Diagnostik Nord GmbH concerns the D-Dimer Rapid Test D-DIMK20.

Details on affected devices

This notification relates only to the subsequent batches:

Produkt-ID	Produktname	Lot-Nummer	Verfall
D-DIMK20	D-Dimer Schnelltest	DIM16070008	2018-04
D-DIMK20	D-Dimer Schnelltest	DIM16070007	2018-04
D-DIMK20	D-Dimer Schnelltest	DIM16050004	2018-04
D-DIMK20	D-Dimer Schnelltest	DIM16050005	2018-04
D-DIMK20	D-Dimer Schnelltest	DIM16030006	2018-03
D-DIMK20	D-Dimer Schnelltest	DIM16030001	2018-02
D-DIMK20	D-Dimer Schnelltest	DIM16020004	2017-12
D-DIMK20	D-Dimer Schnelltest	DIM16010006	2017-12
D-DIMK20	D-Dimer Schnelltest	DIM16010003	2017-11
D-DIMK20	D-Dimer Schnelltest	DIM16010002	2017-12
D-DIMK20	D-Dimer Schnelltest	DIM15120003	2017-11
D-DIMK20	D-Dimer Schnelltest	DIM15100003	2017-10
D-DIMK20	D-Dimer Schnelltest	DIM15060002	2017-05
D-DIMK20	D-Dimer Schnelltest	DIM15060001	2017-05
D-DIMK20	D-Dimer Schnelltest	DIM15050008	2017-05
D-DIMK20	D-Dimer Schnelltest	DIM15050007	2017-05
D-DIMK20	D-Dimer Schnelltest	DIM15050006	2017-05
D-DIMK20	D-Dimer Schnelltest	DDI150303	2017-03
D-DIMK20	D-Dimer Schnelltest	DDI150302	2017-03
D-DIMK20	D-Dimer Schnelltest	DDI141202	2016-12
D-DIMK20	D-Dimer Schnelltest	DIM15110008	2017-11
D-DIMK20	D-Dimer Schnelltest	DIM15110007	2017-10
D-DIMK20	D-Dimer Schnelltest	DIM15100002	2017-10
D-DIMK20	D-Dimer Schnelltest	DIM15070002	2017-07
D-DIMK20	D-Dimer Schnelltest	DDI150102	2017-01

Description oft he problem

Due to weakly visible test lines in the said batches it came to an increased amount of false-negative results.

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Kto.-Nr. 305 451 700 BLZ 130 700 24
BIC/Swift-Code DEUTDEDBROS
IBAN DE26130700240305451700
Geschäftsführer Jan Müller
HRB 11319
St-Nr. 090/107/06286
USt.IdNr. DE284448057

Although the potential risk is considered to be minor with a test considered to be a pre diagnostic test, the product is being recalled from the European market by the Diagnostik Nord GmbH to prevent false negative results. As the test is used as an aid in diagnosis, there is residual risk that additional tests such as an ultrasound are not performed, particularly for patients considered to be at low risk. If you have performed this test recently consider the need to recall and retest patients with a laboratory based test. Production of new batches has been halted until further notice. **Please immediately discontinue use of the above-mentioned product, fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.**

Action to be taken by the user/distributor:

REQUIRED MEASURES End Customer/Users

- Please immediately discontinue use of all packages of the concerned batches, fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.
- Fill out the enclosed fax confirmation form and fax it to within 10 days to your invoice issuer/supplier in order to confirm receipt of this notice and communicate the number of destroyed single tests from your stocks/warehouse.
- If you acquired the product through a dealer, you should be sure to return the fax confirmation form to the invoice issuer/supplier. Only by doing so can proper processing and credit be ensured. If you purchased the product from Diagnostik Nord GmbH directly, please return the fax confirmation form to us.

REQUIRED MEASURES Distributors/ Drug stores

- Please immediately discontinue use of all packages of gabControl® Strep A test cards, fill out the attached fax confirmation form and dispose of any remaining stocks in accordance with local regulations.
- Fill out the enclosed fax confirmation form and fax it to within 10 days to your invoice issuer/supplier in order to confirm receipt of this notice and communicate the number of destroyed single tests from your stocks/warehouse. **ONLY completely filled out fax confirmation forms are essential for problem-free processing and credit.**
- If you acquired the product through a dealer, you should be sure to return the fax confirmation form to the invoice issuer/supplier. Only by doing so can proper processing and credit be ensured. If you purchased the product from Diagnostik Nord GmbH directly, please return the fax confirmation form to us.
- Please return the fax confirmation form along with the single tests destroyed by your customers to the invoice issuer/supplier with 30 days of receipt of this notice. You will then receive an appropriate credit.
- For purposes of providing absolutely necessary information to your customers, you can also request this letter in Word format e.g. so that you can modify it as needed. Simply send a brief e-mail to info@diagnostik-nord.de. We will then send you the document without delay.

Transmission of this Field Safety Notice:

Diagnostik Nord GmbH
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This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please send this notice to any other organisations or customers on which this action has an impact.

Please maintain awareness of this notice and resulting action to ensure effectiveness of the corrective action.

Contact reference:
All relevant National Competent Authorities have been advised of this field safety corrective action. If you have any further questions about the content of this Notice, please contact:

Diagnostik Nord GmbH
Mecklenburgstr. 97
19053 Schwerin
Tel. 0385-208 409 0
E-Mail: info@diagnostik-nord.de

We sincerely regret any inconvenience which may have been caused by the problem with the product quality. Please note that the competent authorities have received a copy of this Field Safety Notice and the recall measure.

We invite you to review the attached confirmation fax as soon as possible and to send it as soon as possible to the invoice issuer/supplier. We may be required to notify competent authorities of all customers who do not respond to this FSN.

Yours sincerely
Diagnostik Nord GmbH

[redacted]

Please fill out this form even if you no longer have any of the aforementioned products and fax it to the invoice issuer/supplier.

Confirmation fax
Urgent Field Safety Notice

D-DIMK20 D-Dimer Rapid Test

1. I have read and understood the Urgent Field Safety Notice from the Diagnostik Nord GmbH regarding the D-DIMK20 D-Dimer Rapid
2. We confirm that all areas where the product could be located have been checked..
3. **PLEASE SELECT ALL STATEMENTS THAT APPLY, SIGN THIS FORM** and **FAX** to your distribution partner.

☐	We do not have any affected product. If so, indicate zero on the form below.
☐	The notice was redistributed to other organization(s). We forwarded a copy of this field safety notice to this/these organization(s). We will ensure that the collected data of this/these organization(s) will be forwarded to our invoicing party/supplier.
☐	We have the affected product. We have read and understood the Urgent Field Safety Notice information.
☐	We discarded the products as mentioned in “Annex I” and expect a credit note:

Date*

Authorized signature*

Please complete in block capitals

Name*

Company/Institution*

Address*

Phone*

Field for institution stamp

Please fill out this form **AND ADDITIONALLY ANNEX I** and fax it within 10 working days after receipt to the invoicing party/your supplier to fulfill the global reporting obligation.

***) Mandatory field**

ANNEX I

INSTITUTION NAME:_____

Please give LOT-Number, Expiry, amount of used and discarded single tests as well as discard date

Product - ID	Lot - Number	Purchase Quantity (single tests)	Used Quantity (single tests)	Discard Quantity (single tests)	Date Discarded
D-DIMK20					
D-DIMK20					
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