

Urgent field safety notice

concerning

NADAL® Troponin I Test

Product code: 282041N-10/ 282041N-20

LOT 180941

Recall

Moers, 20.06.2024

To all users and distributors of the following *in-vitro* diagnostic device

Product: **NADAL® Troponin I Test**
Product code: 282041N-10/ 282041N-20
LOT / Batch: **180941**

Dear customer,

This letter contains important safety information regarding the following product: NADAL® Troponin I Test (batch number 180941).

Case description:

A number of customer complaints have reported problems when using blood samples with this test. It has been reported that migration of the sample is hindered or does not occur at all, and that the test has produced invalid results. There are also isolated cases in which positive results could not be confirmed using follow-up tests. Internal investigations using blood samples have not yet established migration problems or invalid test results, though some false-positive results were observed.

Cause:

False-positive results, insufficient sample migration and therefore invalid results are caused by the faulty production of this batch.

Risks:

False positive results when using blood samples have occurred with the aforementioned batch of NADAL® Troponin I Tests. As a result, unnecessary examinations could be carried out, as positive results require further diagnostics using additional clinical methods. The possibility that sample migration does not occur, and thus leads to invalid results, cannot be ruled out. This could lead to a delayed diagnosis.

We help you care!

Measures to be taken:

- As a result of customer reports and the results of internal investigations, batch **180941 is no longer to be used.**
- The remaining tests from this batch is to be destroyed and disposed of in accordance with current regulations. We ask that you confirm the destruction of the tests using the form provided.
- As we are required by the authorities to follow up on this recall, **we ask that you confirm that you have received this safety notice.** Please send us the provided confirmation of receipt (page 3) as soon as possible.

Should you have any questions, please get in touch with your nal von minden contact person, or use the contact data provided below.

Please ensure within your organisation that all those who use the product, or to whom this information is relevant, receive a copy of this **urgent field safety notice**. If the product has been passed on to third parties, please also forward a copy of this information or get in touch with the contact person listed below. Please retain a copy of this information, at least until all measures have been carried out. The relevant competent authority has received a copy of this urgent field safety notice

We apologise for any inconvenience this situation may have caused.

Kind regards,
nal von minden GmbH

i.V.

██████████
Complaint Specialist

██████████
PRRC

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers, Deutschland
SRN DE-MF-000013321



We help you care!

Customer confirmation of receipt

By signing this document, you confirm that you have received this Urgent Field Safety Notice dated 20.06.2024 regarding

Product: **NADAL® Troponin I Test**
Product code: 282041N-10/ 282041N-20
LOT / Batch: 180941

and that you have taken note of the information contained therein. If you have passed the product on to a third party, please confirm that you have passed on a copy of this Urgent Field Safety Notice to all users and relevant individuals.

We ask you further to confirm that:

the remainder of tests from this batch has been destroyed. Number of tests destroyed: _____ tests

No further tests remain from this batch.
Please cross

Customer name and full address (stamp):

Date: _____

Signed: _____

Name: _____

Please return this confirmation as soon as possible to:

nal von minden GmbH
Fax: +49 2841 99 820 – 1
E-Mail: info@nal-vonminden.com

Or to your nal von minden GmbH contact person.

We help you care!