Urgent field safety notice

regarding

NADAL® TPHA Haemagglutination Test

Product code: 795027

LOT 618

Recall

Moers, 28.02.2024

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

Product:	**NADAL® TPHA Haemagglutination Test**
Product code:	795027
LOT / batch:	618

Dear customer,

Some of the NADAL® TPHA Haemagglutination Tests from the batch named above are affected by a labelling error on the test cells (TC) included with the kit.

Case description:
Isolated customer complaints have reported that the test cells (TC) in test kits are missing, whereas the control cells (CC) are duplicated. Following a stock check, it has been established that the vials containing test cells (TC; LOT 290623C) are present in kits from the named batch, but some are falsely labelled as control cells (CC; LOT 290623C).

Risk:
Incorrect labelling suggests that test cells (TC) are missing from the kit, meaning the test cannot be carried out and a diagnosis could potentially be delayed. Through accidental use of incorrectly labelled test cells as control cells, results for patient samples may be classed as reactive. Consequently, the risk of an incorrect diagnosis or treatment is unlikely, as any agglutination formed by a sample with control cells should not be interpreted (see instructions for use, section on result interpretation).

nal von minden GmbH
Carl-Zeiss-Strasse 12 · 47445 Moers · Germany
CEO: Lukas Eder
Commercial reg. Kleve · HRB 5679
Phone: +49 941 290 10-0 · Fax: +49 941 290 10-50

Cause:
The reason lies in incorrect labelling during the final assembling of the kits.

Measures:
- Batch 618 is **not to be used anymore**. The remainder of the faulty batch is to be destroyed and disposed of in accordance with applicable regulations.
- We ask that you confirm the destruction of the tests on the form enclosed.
- As we are obliged by the authorities to follow up on this recall, we ask that you confirm receipt of this safety notice.

If you have any questions, please get in touch with your nal von minden GmbH 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 supervisory authority has received a copy of this urgent field safety notice

We apologise for any inconvenience this situation may have caused.

Kind regards,

Dr. Gerd Hagendorff
PRRC
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers, Deutschland

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Customer confirmation of receipt

By signing this document, the customer confirms that they have received the urgent field safety notice dated 28.02.2024 concerning the following product:

Product:	**NADAL® TPHA Haemagglutination Test**
Product code:	795027
LOT / batch:	618

and have taken note of the information contained therein.

We ask you to further 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 an full address (stamp):

Date: _____

Signature: _____

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.

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