

Urgent Field Safety Notice

regarding

NADAL® COVID-19 Ag + Influenza A/B plus Test

Product code: 243204N-20

LOT. SE2012064; SE2012065; SE2012066

Important customer information

Moers, 08.06.2022

To all users and distributors of the in-vitro diagnostic device listed below:

Name: **NADAL® COVID-19 Ag + Influenza A/B plus Test**
Product code: 243204N-20
LOT / Batch: SE2012064; SE2012065; SE2012066

Dear customer,

A number of NADAL® COVID-19 Ag + Influenza A/B plus Test kits from the batch listed above have been affected by a labelling error on the buffer ampoules provided with the kits.

Case description:

A portion of the buffer ampoules provided with the batch of test kits outlined above have another brand name listed on the product label. Instead of the buffer ampoules being correctly labelled as "NADAL® COVID-19 Ag + Influenza A/B plus Test", the label instead reads "VivaDiag™ SARS-COV-2/Flu A/Flu B Ag".

Risk:

With regard to the performance, use and interpretation of the tests, this incorrect labelling poses no risk – this is the correct buffer intended for use with these tests. We only foresee a risk in the potential for a delayed analysis, if a diligent user notices the discrepancy and postpones testing until clarification has been obtained.

Cause:

The reason for this discrepancy lies in an allocation error in the production of several product brands within one batch.

We help you care!

Rectifying measures:

Despite the incorrect labelling on the buffer ampoules, the tests can be carried out as normal.

The only error is the product name listed on the buffer ampoule labels.
The batch number and expiry date listed on the buffers are correct.

For safeguarding purposes, we recommend comparing the batch number of the buffer with that of the test. Both batch numbers must be identical.

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 products, 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 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,

A handwritten signature in blue ink, appearing to read 'G. Hagendorff', written over a light blue grid background.

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



We help you care!

Customer confirmation of receipt

By signing this document you are confirming that you have received the 'urgent field safety notice' dated 08.06.2022 concerning the following product

Name: **NADAL® COVID-19 Ag + Influenza A/B plus Test**
Product code: 243204N-20
LOT / Batch: SE2012064; SE2012065; SE2012066

and have taken note of the information contained therein.

Date: _____

Signature: _____

Name: _____

Customer name and full address (stamp): _____

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 contact person at nal von minden GmbH

We help you care!