

Urgent field safety notice

26. August 2026
Reference FSNA-2026-01

Dear customer,

Our records show that you have purchased or are using the product listed below. For this reason, we are sending you this safety notice containing important information.

Product identification:

Name: NADAL® Rota-Adenovirus Test

Product code: 481915N-10

Lot number: E2602053

Expiry date: 2028-02-26

Manufacturer: nal von minden GmbH, Carl-Zeiss-Str. 12, 47445 Moers, Germany (SRN DE-MF-000013321)

Problem description:

Following a customer complaint, it was discovered that the buffer-filled specimen collection tubes included in the kit had been mistakenly labelled with an expiry date of 26 February 2026. The correct expiry date for the specimen collection tubes is 26 February 2028.

Cause:

The cause of the incorrect information is a labelling error during production.

Risk:

As the expiry date stated is too early, the user might mistakenly consider the kit to have expired and refrain from using it, which could delay necessary diagnostic testing. If the specimen collection tube is used anyway, there is no additional risk to patients, as the product's performance and safety are not compromised.



info@nal-vonminden.com | nal-vonminden.com

nal von minden GmbH | Carl-Zeiss-Straße 12 | 47445 Moers | Germany
Chief Executive Officer: Lukas Eder | Commercial reg. Klevé | HRB 5679
Tel.: +49 941 290 10-0 | Fax: +49 941 290 10-50



Actions to be taken by the user::

- Provided the kit is stored correctly, the **user** may use it up to the **specified expiry date of 26 February 2028**, as the product's performance and safety remain unaffected. Section 6 of the instructions for use ('Storage and stability') must be observed in this regard.
- Please **confirm receipt** of this safety notice. To do so, please return the **acknowledgement of receipt** (page 3) to nal von minden GmbH at your **earliest convenience**.
- If you purchased the product from a **distributor**, please return the acknowledgement of receipt (page 3) to your **distributor as soon as possible**.

Actions to be taken by the distributor:

- Provided it is stored correctly, the product in question may continue to be used and distributed until the **expiry date of 26 February 2028**, as stated on the kit's outer label, as the product's performance and safety are not compromised.
- Please forward this **safety notice** immediately to **all** users and any other relevant parties to whom you have supplied the product in question. Ask your customers to complete the **acknowledgement of receipt** and return it to **you**. Please retain the completed acknowledgement of receipt.
- Please also return the **completed acknowledgement of receipt** (page 3) to us at your **earliest convenience**. In doing so, you confirm that you have received the notification and have passed on the safety notice to all users and other relevant parties.

Please ensure that everyone within your organisation who needs to be informed is made aware of this Urgent Field Safety Notice. Please retain a copy of this safety notice as part of your quality records. The relevant regulatory authority has received a copy of this Urgent Safety Notice.

If you have any further questions, please contact your nal von minden representative or use the contact details provided below. We apologise for any inconvenience this may cause.

Kind regards,

i.A.
Dr. Sebastian Brenning
Complaint Specialist

Miriam Lang
PRRC

nal von minden GmbH
SRN DE-MF-000013321



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Confirmation of receipt

By signing, you confirm that you have read the 'Urgent Field Safety Notice' dated 26 August 2026 (reference FSNA-2026-01) regarding the

NADAL® Rota-Adenovirus Test

Product code: 481915N-10

Lot number: E2602053

Expiry: 2028-02-26

and that you have read and understood the information contained therein. If you have supplied the product to third parties, you also confirm that you have forwarded the Urgent Field Safety Notice to all users and any other persons who need to be informed.

Date	
Name	
Signed	
Customer name / Name of the institution and full address (Stamp):	

Please return this confirmation as soon as possible to your contact person or using the contact details provided below.



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