

Strasbourg, 27/01/2023

SAFETY NOTICE – Toda® Autotest nasal COVID-19

INFORMATION TO USERS

Dear customer,

You have received the product Toda® Autotest nasal COVID-19.

Device name	Commercial reference	Batch number	Expiry date
Toda® Autotest nasal COVID-19	2276-AT-NS-5	I2011110C	2022-10

Purpose of the device : Nasal self-test for the detection of infection with the Covid-19 virus.

Description of the detected anomaly:

An error was detected in the expiry date written on some boxes of the Toda® Autotest nasal COVID-19 from lot I2011110C.

These boxes have an expiry date of 2023-10 when the product has an expiration date of 2022-10.

The expiry date on the test pouch inside the box is correct: 2022-10.

The batch of this test was released during 2021.

Risk for the patient:

The test is expired at this time.

Tests with negative and positive controls have been performed on this batch, in January 2023, and the results are compliant. The risk of an erroneous result is therefore low.

However, the result obtained with the test is not guaranteed beyond the expiry date.

Note: Investigations are ongoing. We are proactively sending this communication to all customers who have received this product.

Action to be taken:


- Identify the product and the batch concerned, if you still have them
- If necessary, destroy the products according to the safety standards in force
- If you are interested, Toda Pharma will arrange for a replacement product if necessary, while stocks last
- Pass on this safety notice to all customers who have received this product.

Please report any potential incidents to the manufacturer or distributor as your feedback is important.

If you have any other questions, please contact our quality department at 03 88 24 28 99 or qualite@todapharma.com

Please complete the return receipt attached to this safety notice and return it within five days to: qualite@todapharma.com

This safety notice has been forwarded to the French Competent Authority, ANSM, for information.



Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns, please contact Toda Pharma's technical services.

Quality Department
Toda Pharma

RETURN RECEIPT

Please complete this form to confirm receipt of the FSN01-23 information

Please send by e-mail to Daniel Berros, qualite@todapharma.com

Device name	Commercial reference	Batch number	Expiry date
Toda® Autotest nasal COVID-19	2276-AT-NS-5	I2011110C	2022-10

CUSTOMER INFORMATION	
Customer/Institution	
Name of the representative	
Adress / zipcode / city / country	
Telephone number	
Email adress	
Delivery adress if different	

☐ I have read and understood the instructions provided in the Important Information Letter dated 27/01/2023 on the product concerned.

Actions to be taken by the customer (check and complete)		Add a comment or non applicable
<input type="checkbox"/>	I have initiated the requested actions	
<input type="checkbox"/>	I have quarantined the products where applicable	Quantity :
<input type="checkbox"/>	I have destroyed the products concerned, if applicable	Quantity :
<input type="checkbox"/>	I request the replacement of the products by Toda Pharma within the limits of available stocks if necessary (send the request to commandes@todapharma.com)	Quantity :

Date :	Name and signature :
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