BioSpeedia

IMPORTANT /URGENT: SAFETY NOTICE

RECALL OF PRODUCT BATCHEES

Immediate action required

To:

- **The Directors of Health Institutions**
- **Local Reactoviglance correspondents**
- **Laboratory Managers**

Saint-Etienne , on March 18, 2021

COVID19Speed-Antigen Test
Reference: BSD_0503-25

Lot number:	Exoiration date:
20210218	01/08/2022
20210220	01/08/2022
20210233	01/08/2022

Dear Customer,

We hereby inform you of the voluntary recall by BioSpeedia International SARL of the aforementioned batches of COVID19Speed-Antigen Test.

Description of the anomaly

Customer complaints have reported false positive results on a small number of tests performed with batch 20210220 of product COVID19Speed-Antigen Test BSD_0503-25.

The internal investigations conducted on the product COVID19Speed-Antigen Test following the first claim have identified 3 batches potentially generating false positive s whereas the product normally has a specificity of 100%.

Only th e following lots are concerned:

1. Lot# 20210218
2. Lot# 20210220
3. Lot# 20210233

An initial analysis identified a component of the membrane as likely responsible for this defect (common denominator to the 3 batches produced). The supplier of this component is working on identifying the cause of this defect to remove any new deliveries of defective raw materi al.

Enh anced testing of all other BioSpeedia batches confirmed product compliance and reliability.

Health risk

There were no reported adver se event s related to the use of COVID19Speed - Antigen Test.

Under normal conditions of use, the test is used to aid in the diagnosis of the Covid-19 pandemic and any positive results must be confirmed by a PCR met hod .

There is th erefore no direct risk to the patient' s he alth , only erroneous and abusive precautionary measures can be taken against the patient pending the result by the reference method.

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Customer/User Action Items

Stop using COVID19Speed - Antigen Batch Test 20210218, 20210220 and 20210233

Quarantine, under retention not usable, stocks of COVID19Speed-Antigen Test batches 20210218, 20210220 and 20210233.

The boxes of the aforem enti oned lots will be re placed free of charge

Ensure that any positive results obtained with COVID19Speed-Antigen Test batches 20210218, 20210220 and 20210233 have been confirmed by PCR method and correlated results.

Make sure, that in case of result mismatch, the patient has been informed and perform a new quick check-up test

Communicate this information to any user of the COVID19Speed-Antigen Test product and keep a copy in the documentation of your Quality Management System.

Complete the acknowledgement of receipt attached to this document and return it by e-mail to: contact@biospeedia.com.

Action taken by the manufacturer

Corrective and preventive measures have been taken to prevent this from happening again.

In order to ensure that this will have an impact on your business, we will ship the BSD_0503-25 COVID19Speed Antigentest kits immediately upon receipt of your acknowledgement to replace the defective kits.

The remaining kitsfrom the COVID19Speed-Antigen Test, 850_0503 -25 batches 20210218, 20210220 and 20210233 will be taken over by Bio Speedia.

This safety information has been transmitted to the competent authorities, the Swiss Agency for Therapeutic Products Institute for Therapeutic Products (Swissmed_ic) and the National Agency for the Safety of Medicinal Products and Health Products (ANSM).

Aware of the disruptions this situation may cause, our Customer Relations Service is at your disposal for any further information:

Phone number: +33 (0)6 30 93 77 51
E-mail : **contact@biospeedia.com**

We ask you to accept our apologies for the inconvenience encountered, we thank you for your confidence in our brand.

Please receive , the assurance of our sincere consideration .

Evelyne Begaud
President
Head of Reacto vigilance

Atta ched : COV/D19Speed-Ant igen Test Batch Removal

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ACKNOWLEDGEMENT OF RECEIPT

Please complete this form to confirm receipt of product recall information

Please send by e-mail to: contact@biospeediacom

COVID19Speed-Antigen Test
Reference: 8S0_0503-25

RECALL OF BATCHES **20210218, 20210220** ET **20210233**

Client/Institution :.....

Name of Institution Representative: .....

Adress :.....

City:.....

Postal code :.....

Phone number: .....Email : .....

Delivery Adress (if different) :.....

Batch number	Number of kits received	Number of kits used	Number of remaining kits to return and exchange*
20210218			
20210220			
20210233			

* *Any Kit started is to be considered os complete Kit still to be exchanged*

Your sales representative will contact you to arrange the exchange and return of defective products.

☐ 1 certify that I have received the information referenced above and that I have implemented the actions requested

☐ 1 do not have (anymore) lots of product incriminated.

Comments / Additional information

Date :

Signature & Stamp :

In accordonce with the regulotory troceobility requirements, pleose complete the trocking ond verificotion form, even if you no langer hove the product.
Pleose return the form by e-mail.

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