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04 January 2021

URGENT FIELD SAFETY NOTICE (FSN)

DnaNudge CovidNudge: CT-0001

FSN – Identifier: 2020/001/004/601/002

Details of Affected Devices:

Product Code	Description	Batch/Lot No
CT-0001	DnaNudge CovidNudge	343590, 344038, 344570, 345227, 345787, 346411, 346928, 347432, 346411, 347432, 347984, 348679, 349103, 349529, 349923, 346435, 350381, 350995, 351662, 352545

Description of the Problem:

DnaNudge have been made aware of an issue with the CovidNudge cartridge through customer complaints:

- The identified batches of DNACartridges may report a negative result when a blank swab is inserted.

Field Safety Notice:

Required actions for users to follow:

- Confirm receipt of this FSN by completing the attached FSN Response Form and returning it to Dnanudge using the following email: andrew.rogers@dnanudge.com
- Follow best practice and medical guidance to ensure that a sufficient sample is obtained from the patient, to avoid an insufficient sample potentially leading to a false negative result
- Even in the presence of a negative result, a final diagnosis of the patient should consider all factors such as patient symptoms and context of admission, and not just the test result alone. No test is 100% accurate and a negative result does not rule out infection with SARS-CoV-2.

Distributors

Please provide this Field Safety Notice (FSN) to all your customers who have received products of the affected batch number(s), as stated above. Please send your customers the following documents:

- A copy of this FSN
- A copy of the FSN Response form

The FSN fax-back form should be completed by your customers and returned to you.

As a distributor you are required to confirm to DNANudge that you have received this FSN by completion and return of the attached fax back form.

As a distributor you are also required to confirm to DNANudge that you have completed the instructed activity for all your customers affected by this FSN. Please send all completed FSN fax back forms to the following email: andrew.rogers@dnanudge.com

Transmission of this Field Safety Notice

This notice needs to be passed on to all recipients/user of this product within your organisation the following:

All departments using this device
All Wards
Risk Managers
Health and Safety Managers
Purchasing Managers
Medical Directors
Nursing Directors
ITU Directors
A&E Directors
Maternity Units

Please maintain awareness of this FSN and resulting action for an appropriate period to ensure effectiveness of the corrective action.

For further information please contact our Technical Support Department by e-mail covid@dnanudge.com or by telephone 07566 778971

Contact Person

NAME OF CONTACT

Quality Assurance & Regulatory Affairs
DNANudge
Level 11, The Translation and Innovation Hub,
Imperial College White City Campus,
London,
W12 0BZ,
UK.

Telephone: 07566778966

Email: andrew.rogers@dnanudge.com

DNANudge apologies for any inconvenience this FSN may cause.

This FSN has been communicated to the MHRA.

Signature:



Name: Andrew Rogers

Title: Head of QA/RA

E-mail: andrew.rogers@dnanudge.com

FSN RESPONSE FORM

FIELD SAFETY NOTICE REF. NO: 2020/001/004/601/002

DATE: 05 Dec 2021

**CT-0001 - DnaNudge CovidNudge,
LOTs: 343590, 344038, 344570, 345227, 345787, 346411, 346928, 347432,
346411, 347432, 347984, 348679, 349103, 349529, 349923, 346435, 350381,
350995, 351662, 352545**

Please complete this form and return it to DNANudge, QA/RA
Department using email: andrew.rogers@dnanduge.com

I/we acknowledge receipt of the above FSN and that the information contained in this FSN
has been shared with all recipients/user of the above products within our organisation.

Name: _____ Mr/Mrs/Miss/Other: _____
Designation: _____
Organisation: _____
Department: _____
Address: _____

Post code: _____
Telephone No: _____ E-mail: _____
Signature: _____ Date: _____