

26 February 2021



[Client Name]  
[Client Address Line 1]  
[Client Address Line 2]  
[Client Address Line 3]

**FIELD SAFETY NOTICE**  
**URGENT: CUSTOMER COMMUNICATION**  
**LUMIRADX SARS-COV-2 ANTIGEN (AG) TEST STRIP KITS CE MARK REMOVAL NOTICE**

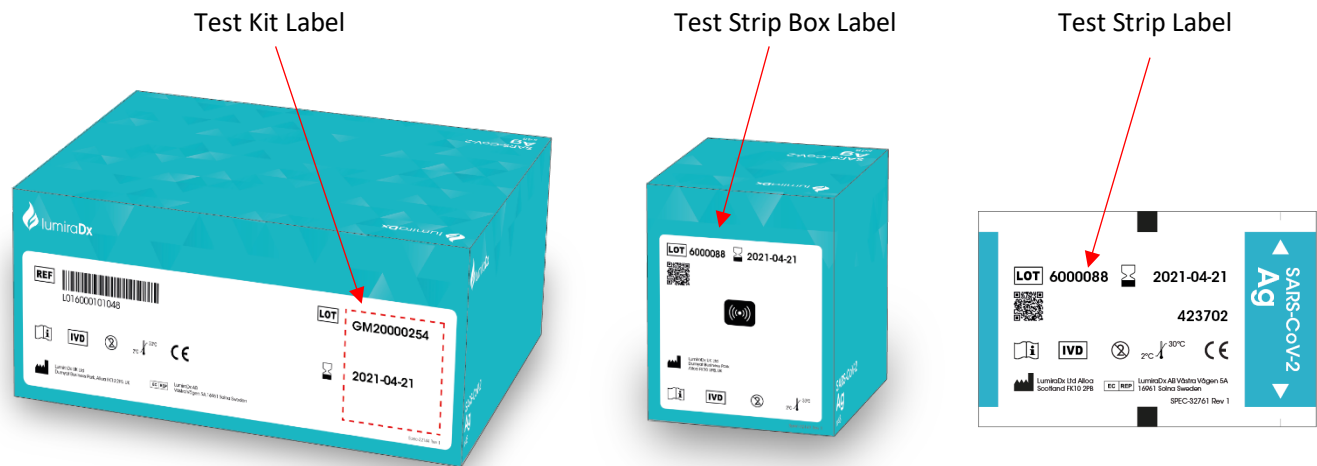
Dear [Client Name],

This notification letter is to inform you of a voluntary removal involving the following LumiraDx SARS-CoV-2 Antigen (Ag) Test Strip Kits CE Mark (Catalogue number L016000101048):

- **6000100 (GM2000322)**
- **6000142 (GM2000296)**
- **5000323 (GM2000354)**

These lots are subject to recent feedback from a small number of customers regarding a small to moderate elevation in numbers of reported false positive patient test results. We continue to investigate the root cause of these suspected false results. We have made a pro-active decision to help minimise disruption to your established testing program, we therefore advise that you remove this specific lot from use with immediate effect. These lots will be replaced free of charge.

See the following Test Strip kit labels for ease in identifying the Lot number:



Please examine your inventory immediately and quarantine the Test Strip Lot(s) subject to this withdrawal. We are instructing the affected Lots to be returned immediately to LumiraDx.

Please forward this notice to additional testing sites if these products were further distributed.

Your assistance is appreciated and necessary to prevent potential false positive results which could result in potential exposure of patients to unnecessary treatment or quarantine.



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Please complete and return the enclosed response form as soon as possible. If you have any questions, contact LumiraDx Customer Services

**Contact Information:**

[customerservices@lumiradx.com](mailto:customerservices@lumiradx.com)

00800 5864 7239 available 9:00 to 17:00 Monday through Friday

Lumiradx.com

26 February 2021



**URGENT: CUSTOMER COMMUNICATION**

**LUMIRADX SARS-COV-2 ANTIGEN (AG) TEST STRIP KITS CE MARK REMOVAL RESPONSE FORM**

LumiraDx SARS-CoV-2 Antigen (Ag) Test Strip Kits CE Mark (catalogue number L016000101048),:

- **6000100 (GM2000322)**
- **6000142 (GM2000296)**
- **5000323 (GM2000354)**

Please check ALL boxes.

- I have read and understand the instructions provided in the 26 February 2021 letter
- I have checked my stock and have quarantined inventory consisting of

\_\_\_\_\_ **Test Strip kits from Lot# 6000100 (GM2000322)**

\_\_\_\_\_ **Test Strip kits from Lot# 6000142 (GM2000296)**

\_\_\_\_\_ **Test Strip kits from Lot# 5000323 (GM2000354)**

Any adverse events associated with the identified test strip Lots? Yes No

If yes, please explain:

Please check the appropriate box(es) to describe the nature of your business:

- Wholesaler/distributor  Other:
- Independent Health Care Professional
- Group Practice Health Care Professional
- Hospital/Hospital Chain
- Chain Store Health Care Center

<b>Name/Title</b>	
<b>Telephone #</b>	
<b>Email Address</b>	
<b>Firm Name</b>	
<b>Address</b>	

**Please Email completed response form to customerservices@lumiradx.com within two (2) business days of receipt of the notice.**

**Or mail to: attn: Field Corrective Action, LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK**

**Please contact LumiraDx Customer Services at customerservices@lumiradx.com to arrange return and replacement of affected lots.**