

02 March 2021



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

Dear Customer,

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):

- **5000275 (GM2000220)**
- **5000243 (GM2000195)**
- **5000263 (GM2000212)**
- **5000265 (GM2000218)**

These lots were subject to 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. To help minimise disruption to our customers established testing programs, we made a pro-active decision to remove each of the listed lots from use and replace them free of charge.

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



All customers were instructed to examine their inventory immediately and quarantine the Test Strip Lot(s) subject to this withdrawal. We are arranging for all 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.

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