08 February 2022

[redacted]

[Customer Address]

URGENT: Field Safety Notification – Customer Communication

LUMIRADX PLATFORM INSTRUMENT V5E REMOVAL NOTICE

Dear [Customer Name],

This notification letter is to inform you of a removal involving the LumiraDx Platform Instrument V5E (Catalogue number L001000303001) with **Serial Numbers:**

- **30874-21-15-32688**
- **30874-21-15-32636**

This removal has been identified due to observations of a manufacturing defect that may lead to reduced effectivity of the instrument control systems. Use of these instruments with D-Dimer or CRP assays may result in artificially reduced quantitative results.

Examine your inventory immediately per the guidance below and quarantine the instruments subject to this removal. We are instructing the affected instruments to be returned immediately to LumiraDx where they will be subject to investigation. Confirmation of any potential impact on test results will be provided following the return and evaluation of the instrument.

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

Your assistance is appreciated and necessary to prevent the risk of incorrect results.

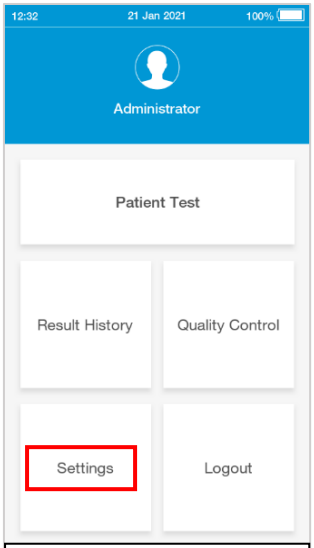
Please complete and return the enclosed customer response form as soon as possible. If you have any questions, contact LumiraDx Customer Services at customerservices@lumiradx.com or +44(0) 1172 842 535.

See the following guidance for identifying the Instrument Serial Number:

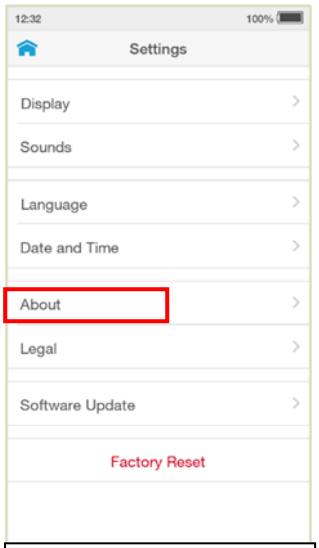
1) **Identifying instrument Serial Number from the instrument label**

The instrument Serial Number can be verified on the label on the underside of the instrument

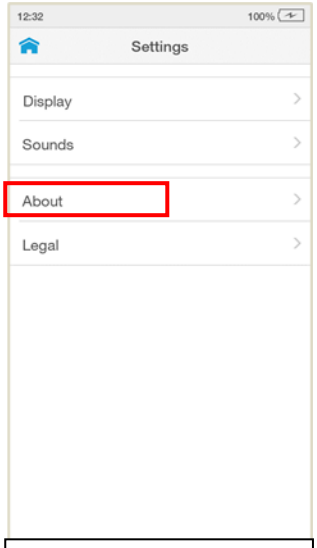
2) Identifying instrument Serial Number through the user interface:



Login to the Instrument then from the home-screen tap the **Settings** button



Tap the **About** button (Administrator Settings Menu)



Tap the **About** button (General User Settings Menu)

Confirm instrument serial number

URGENT: Field Safety Notification – Customer Response Form

LUMIRADX PLATFORM INSTRUMENT V5E REMOVAL RESPONSE FORM

LumiraDx Platform Instrument V5E (Catalogue number L001000303001), **Serial Numbers:**

- **30874-21-15-32688**
- **30874-21-15-32636**

Removal Notice Identifier: LMDX-FA-2022-01

Please check ALL appropriate boxes.

☐ I have read and understand the instructions provided in the letter dated 08 February 2022.
☐ I have checked my stock and have quarantined instrument with serial number **30874-21-15-32688**
☐ I have checked my stock and have quarantined instrument with serial number **30874-21-15-32636**

Indicated disposition of the identified instruments – contact Customer Services, customerservices@lumiradx.com, to arrange collection of the instruments.

☐Arranged the return of instrument with serial number **30874-21-15-32688**
☐Arranged the return of instrument with serial number **30874-21-15-32636**

Any adverse events associated with the identified instruments? ☐Yes ☐No

If yes, please explain:

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

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

Name/Title	
Telephone #	
Email Address	
Company Name	
Address	
Sign	
Date	

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

Or mail to: Attn: Field Corrective Action - QA, 39 Inchmuir Road, Whitehill Industrial Estate, Bathgate, EH48 2EP, United Kingdom