

LumiraDx

February 03, 2021

**Field Safety Notice.**

**Mandatory Software Update LumiraDx SARS-CoV-2 Ag Test**

Dear Valued Customer,

The purpose of this letter is to advise you of a **mandatory** software update for the LumiraDx SARS-CoV-2 Antigen (Ag) Test.

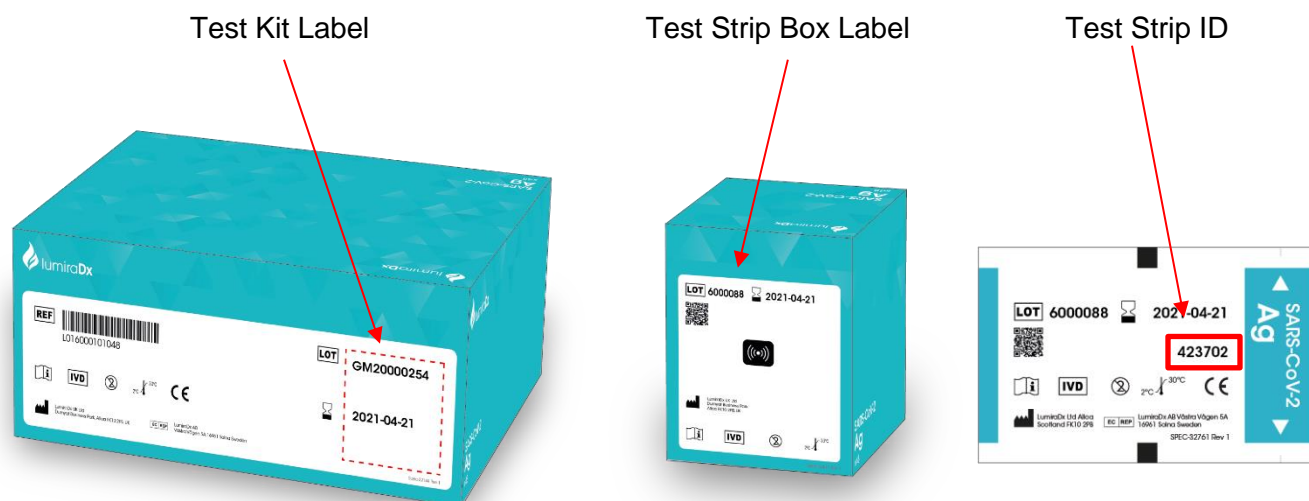
On 29th December 2020, a customer complaint was received regarding suspected false positive results with the SARS-CoV-2 Antigen (Ag) Test. A false positive may be suspected when a positive test result is obtained and does not agree with a patient's symptoms and medical history or follow up confirmatory testing produces a negative result. A false positive result may result in potential exposure to unnecessary treatment or quarantine. We have not received any reports of patient harm related to this issue.

The results of our investigation into the complaints identified a manufacturing issue that resulted in a small number of sequential Test Strips in certain batches having a potential for false positive results. We identified that approximately 1% of Test Strips are affected within 24 lots that are currently distributed in Europe, as detailed in the product and distribution information table below. Please forward this notice if these products were further distributed to additional customers. If you believe you have experienced any suspected false positive results due to use of these affected Test Strip serial numbers, please contact LumiraDx technical services to discuss your results.

Product and Distribution Information Table						
LumiraDx SARS-CoV-2 Antigen (Ag) Test Strips	Catalog Numbers L01600010 1048	Kit Lot Number	Strip Lot Number	Expiration Date (DD-MMM-YYYY)	First Digit of Affected Test	Last 5 Digits of Affected Test Strip Serial Number Range*
		GM2000254	6000088	25-Apr-21	4	23702 and higher
		GM2000255	6000089	26-Apr-21	1, 2 or 3	26126 and higher
		GM2000280	6000093	27-Apr-21	1 or 4	23384 and higher
		GM2000298	6000137	18-May-21	2 or 4	24535 and higher
		GM2000308	6000119	7-May-21	1, 2 or 4	24587 and higher
		GM2000113	5000187	2-Feb-21	2 or 4	18680 and higher
		GM2000131	5000223	12-Feb-21	2 or 4	20201 and higher
		GM2000133	5000222	11-Feb-21	1, 2, 3, 4	19027 and higher
		GM2000135	5000226	14-Feb-21	2 or 4	24429 and higher
		GM2000155	5000229	16-Feb-21	1 or 3	20946 and higher
		GM2000165	5000239	24-Feb-21	1 or 3	14959 and higher
		GM2000166	6000024	25-Feb-21	4	22636 and higher
		GM2000168	6000025	25-Feb-21	4	23213 and higher
		GM2000170	6000021	21-Feb-21	1	1796 and higher
		GM2000194	5000242	28-Feb-21	2 or 4	27631 and higher
		GM2000196	6000037	2-Mar-21	1	7047 and higher
		GM2000198	5000238	23-Feb-21	1 or 3	16668 and higher
		GM2000206	5000258	3-Mar-21	1 or 3	28465 and higher
		GM2000213	5000264	11-Mar-21	2 or 4	22727 and higher
		GM2000248	6000064	20-Apr-21	1, 3 or 4	25903 and higher
		GM2000252	6000065	20-Apr-21	1	21797 and higher
		GM2000231	6000066	23-Apr-21	1 or 3	27522 and higher
		GM2000256	6000091	27-Apr-21	1, 2, 3, 4	26833 and higher
		GM2000295	6000141	20-May-21	4	24008 and higher

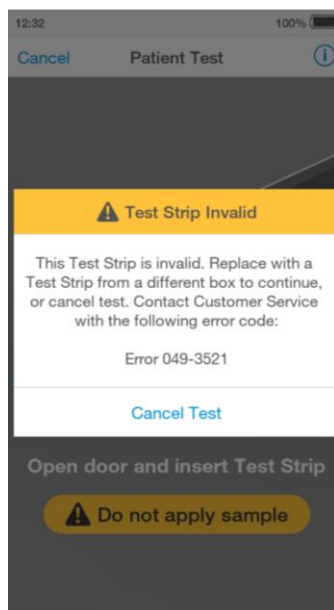
\*Test strip serial numbers are 6 digits and the first digit can be 1, 2, 3, or 4.

See the Test Strip Kit label and Test Strip pictures below for ease in identifying affected Test Strips. The affected Test Strips in each lot can be identified by their serial number. The Serial number is a 6-digit number and the first digit can be either 1, 2, 3, or 4. Only the Test Strips in the serial number range listed in the table above are affected by this issue. **Following this mandatory software update, affected Test Strips will automatically be recognized by the Instrument as invalid and will not need to be manually identified. Test Strips outside the affected serial number ranges for each lot will run normally when inserted into the Instrument.**



LumiraDx has identified the root cause and immediately implemented changes to our manufacturing process as well as updated our QC release and test procedures to rectify this manufacturing issue going forward.

To continue testing with LumiraDx SARS-CoV-2 Ag Test, software version 1.21 must be installed immediately. This is a mandatory software update to ensure only valid Test Strips are used. The software identifies the specific Test Strip ID numbers that have a potential to indicate false positive results and prevents the tests from being used. When a user inserts such a Test Strip, the Instrument will instruct the user to discard the Test Strip and the remaining Test Strips from its opened box – see invalid Test Strip screen image below. Please note, LumiraDx will replace all affected Test Strips free of charge.



This software update includes lot calibration files introducing additional error-checking measures to minimize any potential for false results.

Depending on the current software version for your LumiraDx Instrument, this update will also include following features:

- Software Version 1.7
  - LumiraDx Barcode Scanner compatibility
- Software Version 1.20
  - LumiraDx Printer compatibility
  - Expanded Quality Control policy management
  - Quality Control reporting
  - Operator training compliance
  - User management – disable/enable accounts
  - EHR Connect – Middleware integration enhancements
- Software Version 1.21
  - Instrument alert to inform operators upon startup when the Instrument is outside of the acceptable operating temperature range
  - Addition of a second sample type option for the LumiraDx SARS-CoV-2 Antigen test allowing nasal or nasopharyngeal samples to be used

**LumiraDx is committed to providing the highest quality and performance of its Platform in our Customers' hands along with effective and responsive customer service. Please provide any feedback for this action to XXXX@LumiraDx.com.**

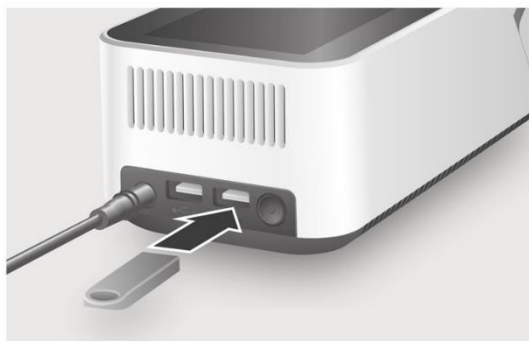
## Installation Instructions

Please ensure that the Instrument is connected to a power supply before performing the software update:

1. Power OFF the Instrument
2. Insert USB Memory Stick whilst the Instrument is switched OFF

Remove the USB Memory Stick from its packaging.

Looking at the rear of the Instrument, insert into the right-side USB port, nearest the power button.

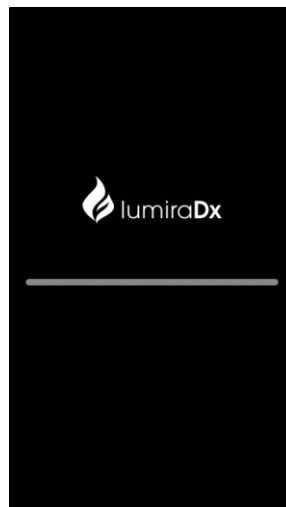


3. Power ON the Instrument

Power on the Instrument by pressing the power button at the rear of the Instrument.

A progress bar on the Instrument display will indicate installation.

Once installation is completed the Instrument will power on as usual.



4. Allow the Instrument to start up and complete the self-test



5. Once you reach the login screen, remove the USB stick.  
**IMPORTANT:** do not remove the USB stick before the login screen is shown.



*(Stand alone)*



*(Connected)*

6. After completing the software update, complete the Medical Device Response Form at the end of this notice and return to LumiraDx by email at [XXXX@lumiradx.com](mailto:XXXX@lumiradx.com) within two (2) days of receipt.

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.

Contact Information:

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

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

Lumiradx.com



## Mandatory Software Update

### LUMIRADX SARS-COV-2 ANTIGEN (AG) TEST STRIP SOFTWARE UPDATE RESPONSE FORM

LumiraDx Platform Instrument (catalog number L001000201001) and SARS-CoV-2 Antigen (Ag) Test Strips (catalog number L016000101048)

Please complete both steps below and indicate the completion by checking both boxes:

- ☐ I have read and understand the instructions provided in the XX February 2021 letter  
☐ I have performed the software update as instructed in the communication

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

Name/Title	
Telephone #	
Email Address	
Firm Name	
Address	

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