

LumiraDx Platform Returns

Guidance on Returns

If you have any inquiries with your LumiraDx Platform, contact LumiraDx Technical Services at 1-888-586-4721 option 1, or email Technicalservices.us@Lumiradx.com in the first instance.

When there is a need to return the LumiraDx Platform, the LumiraDx Representative will issue you a case number, shipping return label and a Return Authorization Form.

Complete the following steps to ensure the LumiraDx Platform is processed correctly before returning:

1. **Personal Identifiable Data**

Technical Services will discuss and agree the decision made on Personal Identifiable Data, this could be either:

Data Deletion – LumiraDx requests the customer to remove any personal identifiable information prior to returning the LumiraDx Instrument. LumiraDx shall have no liability for any remaining data and shall, upon return of the LumiraDx Instrument remove or delete all remaining data.

Data Retention – for quality control and investigation purposes, LumiraDx requests that the customer does not remove any personal identifiable information prior to return of the LumiraDx Instrument. Upon completion of the investigation the data will be securely deleted and not available to the customer.

2. **Disinfection**

LumiraDx request that the customer cleans and disinfects the appropriate items being returned according to the instructions provided in the Platform User Manual, section 5.

3. **Packaging**

Please follow the instructions below when returning the LumiraDx Platform:

Unused strips and unused controls – should remain in their primary packaging and returned in suitable packaging.

Used Test strips – should only be returned in appropriate sealed packaging for the shipment of Hazardous Goods and appropriately labelled and identified.

Instruments and other hardware – this shall include the power supply unit. The Instrument or other hardware should be returned in their original packaging. If this is not available, then the replacement Instrument packaging can be used. If these materials are not available, please see instructions below for packaging the LumiraDx Instrument.

IMPORTANT: If the Instrument is not protected properly through transportation and shipping then the Instrument can be impacted by further damage which will hinder its investigation.

- a. Ensure the instrument is switched off.



- b. Place in the foam tray in the packaging.
The power cord sits in the enclosed box adjacent to the Instrument.



- c. Close the packaging.



- d. Slide the foam end caps on and place in the larger shipper box.

Lay the signed Customer Returns Declaration form on top.



Secure the shipping box with packing tape and affix the provided shipping returns label.

IMPORTANT: If you need to use your own packaging, please follow the guidance below:

- a. Instruments are encased in bubble wrap and/or similar available packaging material prior to placing in the shipping box.
- b. Utilize properly sized shipping boxes to limit movement of contents and help mitigate damage during transit.



4. **Arrange for package pickup** with respective courier or LumiraDx Representative for the returns items as soon as possible.

The LumiraDx SARS-CoV-2 Ag Test and the LumiraDx SARS-CoV-2 Ab Test have not been cleared or approved by FDA, but have been authorized for emergency use by FDA under an EUA for use by authorized laboratories. The LumiraDx SARS-CoV-2 Ag Test has been authorized only for the detection of proteins from SARS-CoV-2. The LumiraDx SARS-CoV-2 Ab Test has been authorized only for detecting the presence of total antibodies to SARS-CoV-2. They have not been authorized for use to detect any other viruses or pathogens. The Tests are authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic Tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Manufactured by:

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