

LumiraDx Platform error messages overview

The LumiraDx Instrument performs internal checks to ensure the correct test procedure is followed and returns error codes for unexpected and unwanted conditions which may have arisen.

If an issue occurs, an error message will be displayed on the Instrument touch-screen. Error messages include useful information and are highlighted by an orange banner and a warning symbol. All messages will contain a description of the error, an instruction and an identifying code that may be used for further troubleshooting purposes.

Please always record the error code prior to calling LumiraDx Customer Services.

This document contains an overview of the common user error messages and on board control error messages which could be displayed by the Instrument as well as additional troubleshooting guidance where appropriate.

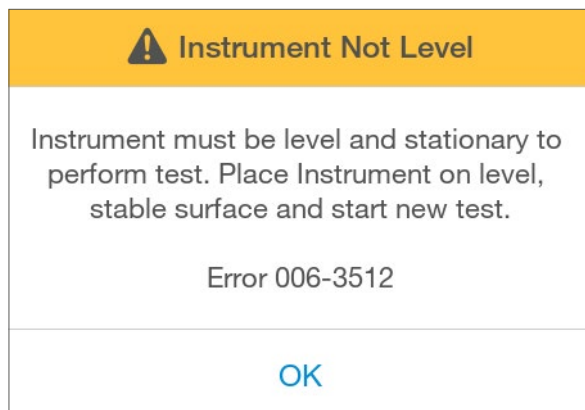
Error codes come in two formats:

Error XXX and Error XXX-YYYY

XXX => Error group number linked to the message shown on the screen

YYYY => Detailed technical message for LumiraDx

Example user error message with error code:



In case of a persistent problem please contact Customer Services:

Please email or call Customer Services if you have questions about this product.

Email: customerservices@lumiradx.com

Phone: for your local Customer Services phone number please visit the Contact Us page at lumiradx.com

Error messages and available troubleshooting guidance for the most frequently seen errors

Error Code	On-Screen Message	Additional Troubleshooting Guidance
002-3501 108-3502	Door Opened During Test Door Closed Unexpectedly	Never open or close the door unless instructed to do so by the Instructions on the screen.
003-3506 Error can occur and no error code returned.	Test Strip Not Detected	Verify that the Instrument screen changes from 'open door and insert Test Strip' to 'insert Test Strip' after the door is opened. Try the same Test Strip in a different Instrument if possible. Try a different Test Strip. Try power cycling the Instrument.
006-3510/3512	Instrument Not Level	The Instrument must be level, and stationary to perform the Test. Place the Instrument on a level, stable surface and start a new test. This error is more prevalent on portable worktops.
026-2201	Test Strip Past Expiry Date	Test Strip is past expiry date and cannot be used. Replace with valid Test Strip to continue, or cancel test.
038-3605	Insufficient Sample Volume	Repeat test with a new Test Strip. This could be caused by insufficient sample or be an issue with the Test Strip. You can re test using the same extracted swab sample but with a new Test Strip.
044	Barcode Error - Patient ID Barcode Not Recognized	Check with instrument manager or local LumiraDx contact that your barcode scanner has been data-formatted correctly. If not, please contact LumiraDx Customer Services.
046	Barcode Error – QC Solution Barcode Not Recognized	Check with Instrument Manager or local LumiraDx contact that your barcode scanner has been data-formatted correctly. If not, please contact LumiraDx Customer Services.
047	Barcode Error - User ID Barcode Not Recognized	Check with Instrument Manager or local LumiraDx contact that your barcode scanner has been data-formatted correctly. If not, please contact LumiraDx Customer Services.
048	Invalid Entry	QC solution Lot number is not recognized. Ensure the LumiraDx Instrument is on software version 1.28.1.9d56697 or above.
049-3521	Test Strip Invalid	Repeat Test with a Test Strip from a new carton. Contact customer services to notify them of this occurrence with the Test Strip lot number and Test Strip ID number.
051-2111	Sample Error	Sample concentration is out of range or the sample is not suitable for test. Please check the Product Insert for correct sample types and volumes.
053-2244	Strip Lot Expired	Strip Lot is past expiry date and cannot be used. Replace inserted Test Strip with valid Test Strip to continue, or cancel test.

Error Code	On-Screen Message	Additional Troubleshooting Guidance
054-2201	Strip Lot Expired	Strip Lot is past expiry date and cannot be used.
056-3514	Strip Lot Not Permitted	Strip Lot is not permitted in this region.
058-2219	Strip Lot Not Permitted	Strip Lot not supported by hardware.
060-2218	Strip Lot Not Permitted	Strip Lot not supported by software.
064	Unsealed Test Strip Detected	Unsealed Test Strip detected inside the Instrument. Possible risk of amplicon leakage. Follow product insert instructions for Test Strip disposal and Instrument cleaning.
068-1327	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been permanently disabled, contact Customer Services.
105-3302	Test Strip Reading Error	Test Strip has not been recognized. Replace with another valid test strip to continue or cancel test.
106	Invalid Lot Cal File	The Lot Calibration File has failed to load. Try again, making sure to hold the back of the Strip box steady against the Instrument while you click the install button and until a message appears on the screen that installation has been successful. Training videos are available in the Knowledge Centre found at www.LumiraDx.com titled "Chapter 3: Performing a Patient Test" for relevant guidance. Please contact LumiraDx Customer Services if the problem persists.
106-2240	Invalid Lot Cal File	Cannot install Lot Calibration File. Please try again.
108-1009	Test Operation Error	An onboard control check has failed. Try retesting with a new Test Strip. This is a time out error.
108-1813	Test Operation Error	An onboard control check has failed. Power cycle the Instrument. Repeat Test with a new Test Strip.
108-1713	Test Operation Error	An onboard control check has failed. Power cycle the Instrument.
108-2224	Test Operation Error	The Instrument has experienced a Lot Calibration File error. Try again after Installing the Lot Calibration File from a fresh carton and using Test Strips from the new carton.
108-2411	Test Operation Error	An onboard control check has failed. Try retesting with a new Test Strip.
108-2602	Test Operation Error	An onboard control check has failed for this test. Try re-testing with a new Test Strip.

Error Code	On-Screen Message	Additional Troubleshooting Guidance
115	Instrument Error During Start up	
115-1303	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
115-1304	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
115-1305	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
115-1307	Instrument Error	Contact Customer Services to report this issue.
115-1308	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
115-1309	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
115-1312	Instrument Error	An Instrument error has caused an onboard control mechanism to fail. Testing has been disabled. Try power cycling the Instrument.
116-1815	Test Operation Error	Instrument has experienced a problem and cannot complete test. Dispose of Test Strip and start new test. If problem persists, contact Customer Services.
124-1324/1325	Temperature Issue	Move Instrument to a warmer environment and wait for the Instrument to warm up. Allow the Instrument time to acclimatise to ambient temperatures. Power cycling may speed up this process.
127-4002	Internal Control Error	Dispose of Test Strip and start a new test. If repeated Internal Control Errors are obtained, repeat test with a new patient sample. If problem persists, contact Customer Services.

Manufactured by:

LumiraDx UK Ltd Dumyat Business Park Alloa FK10 2PB, UK

Registration Number: 09206123

Authorized representative in the European Union:

LumiraDx AB Västra Vägen 5A

16961 Solna, Sweden