

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, a message will be displayed on the Instrument touch-screen.

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 trouble shooting guidance where appropriate.

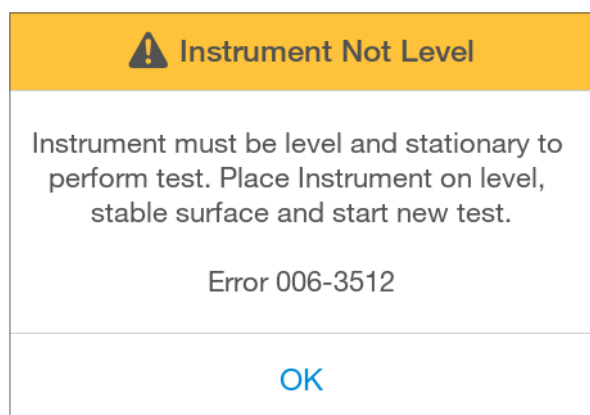
Error codes come in two formats:

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:

Mon - Fri 9am - 9pm EST

Sat - Sun 9am - 8pm EST

T: [888-586-4721](tel:888-586-4721) (option 1)

E-mail: technicalservices.us@lumiradx.com

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

Error Code	On-Screen Message	Additional trouble shooting guidance
002-3501	Door opened during test	
003-3506 Error can occur without error code displaying	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.
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.
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.
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 and contact customer services if the problem persists.
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	An onboard control check has failed. Try retesting with a new Test Strip.
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 trouble shooting 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.
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.

Manufactured by:

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

Registration Number: 09206123

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.