

Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Test

The FDA has made the Molecular LDT COVID-19 Authorized Test from CirrusDx available under an Emergency Use Authorization (EUA). This EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 pandemic justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

The Molecular LDT COVID-19 Authorized Test from CirrusDx is available to licenced healthcare professionals and institutions for \$150.00.

For more information, please send an e-mail to info@cirrusdx.com.