English (US)

Xpert® Xpress CoV-2/Flu/RSV *plus* (EUA) Documentation and ADF

For use under Emergency Use Authorization (EUA) only

Access to the Xpert Xpress CoV-2/Flu/RSV ***plus*** EUA documentation and ADF are available online at Cepheid.com/coronavirus-resources. Under the Xpert Xpress CoV-2/Flu/RSV ***plus*** Product Resources section on the webpage, select the Xpert Xpress CoV-2/Flu/RSV ***plus*** EUA item you wish to view. A new tab on your internet browser will open to allow access to the Xpert Xpress CoV-2/Flu/RSV ***plus*** EUA item selected.

Note: This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS CoV-2, influenza A virus, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens. The emergency use of this test 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 COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Please contact +1 (888) 838-3222 if you require a printed copy free of charge or need technical support to access the package insert.

Rx only. *In Vitro* Diagnostic Use Only.

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