FDA Warnings about More COVID-19 Tests

After previously warning testing site personnel, healthcare providers and patients not to use COVID-19 tests from LuSys (also sold as EagleDx, Luscient Diagnostics or Vivera Pharmaceuticals) and Empowered Diagnostics, the FDA has added more companies to the list of unacceptable tests. E25Bio COVID-19 Direct Antigen Rapid Tests (also called E25Bio SARS-CoV-2 Antigen Test Kits), which were sold directly to individuals, are not approved for use in the U.S. SD Biosensor's STANDARD Q COVID-19 Ag Home Tests, which are not believed to have reached patients, were imported into the country illegally and they are being recalled. Neither should be used. Providers or patients who suspect results from one of the unapproved COVID-19 tests are false should consider retesting with an FDA-approved product if the test was within about two weeks. Tests administered more than two weeks previously probably do not need to be repeated.