FDA issues EUA for Yale’s SalivaDirect

written by CAP TODAY
October 19, 2020

October 2020—The FDA issued an emergency use authorization to Yale School of Public Health for its SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection, the agency says.

SalivaDirect does not require a special type of swab or collection device; a saliva sample can be collected in any sterile container. The test does not require a separate nucleic acid extraction step.

Yale intends to provide SalivaDirect to interested laboratories as an open source protocol, meaning that designated laboratories could follow the protocol to obtain the required components and perform the test in their labs according to Yale’s instructions for use. Because this test does not rely on proprietary equipment from Yale and can use a variety of commercially available testing components, it can be assembled and used in high-complexity laboratories, provided the labs comply with the conditions of authorization in the EUA.