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Yale School receives FDA nod for COVID-19 saliva test

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The U.S. Food and Drug Administration has issued an emergency use authorization (EUA) 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 SalivaDirect test for rapid detection of SARS-CoV-2 is yet another testing innovation game changer that will reduce the demand for scarce testing resources,” said Assistant Secretary for Health and COVID-19 Testing Coordinator Admiral Brett P. Giroir, M.D. “Our current national expansion of COVID-19 testing is only possible because of FDA’s technical expertise and reduction of regulatory barriers, coupled with the private sector’s ability to innovate and their high motivation to answer complex challenges posed by this pandemic.”

SalivaDirect does not require any special type of swab or collection device; a saliva sample can be collected in any sterile container. This test is also unique because it does not require a separate nucleic acid extraction step. This is significant because the extraction kits used for this step in other tests have been prone to shortages in the past. Being able to perform a test without these kits enhances the capacity for increased testing, while reducing the strain on available resources.

Additionally, the SalivaDirect methodology has been validated and authorized for use with different combinations of commonly used reagents and instruments, meaning the test could be used broadly in most high-complexity labs.