FDA issues first EUA for sample pooling in dx testing

July 20, 2020—The FDA reissued on July 18 an emergency use authorization to Quest Diagnostics to authorize its Quest SARS-CoV-2 rRT-PCR test for use with pooled samples containing up to four individual swab specimens collected under observation. The Quest test is the first COVID-19 diagnostic test to be authorized for use with pooled samples.

“This EUA for sample pooling is an important step forward in getting more COVID-19 tests to more Americans more quickly while preserving testing supplies,” FDA commissioner Stephen M. Hahn, MD, said in a press statement. “Sample pooling becomes especially important as infection rates decline and we begin testing larger portions of the population.”

The Quest test, initially authorized on March 17, remains authorized to test individual samples from people with suspected COVID-19 infection. The test is authorized for use with individual nasal swab specimens that are self-collected at home or in a health care setting using an authorized home-collection kit when determined to be appropriate by a health care provider.