FDA issues EUA for saline oral rinse COVID-19 test

December 2020—OralDNA Labs announced that the FDA issued an amended emergency use authorization for the OraRisk COVID-19 RT-PCR test, allowing testing from a saline oral rinse collection. Samples are viable for up to 72 hours and do not require cold pack transportation.

“Oral rinse collection will be a game-changer for COVID testing,” George Hoedeman, CEO of OralDNA Labs, said in a press release. “A 30-second convenient collection without a nasal swab will improve patient comfort, minimize exposure risk to frontline health care professionals, shorten collection time, and avoid supply chain bottlenecks. These improvements, along with our exceptional turnaround times generally being shorter than our advertised 24 to 48 hours from sample receipt, will allow for an overall enhanced testing experience.”

The test is for the qualitative detection of nucleic acid from SARS-CoV-2 in oral saline rinse specimens, nasopharyngeal swabs, and nasal swab specimens collected in universal transport media, and nasal swabs collected in oral saline rinse, from individuals suspected of having COVID-19 by their health care provider.

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