

News From the Food and Drug Administration

Pathway Eased for Serial COVID-19 Screening Tests

The FDA has created an [expedited pathway](#) for manufacturers seeking to obtain Emergency Use Authorization for products used in serial testing to detect SARS-CoV-2 in asymptomatic individuals. Currently, most tests are authorized for diagnosing people with a suspected infection.

Serial testing involves testing the same person more than once over a few days to increase the chances of detecting asymptomatic infection that a single test might not detect. The simplified recommendations apply to molecular and antigen tests used serially in any location, from point-of-care settings to homes, schools, airports, or sports venues.

A supplement to existing policy allows manufacturers whose tests for symptomatic individuals have achieved a positive percent agreement of at least 80% to request authorization for serial testing in asymptomatic people before they have validation data for that group.

The agency suggested that manufacturers specify that an asymptomatic person would be screened with their test twice over 2 to 3 days with 24 to 36 hours in between tests. Alternative intervals might apply for tests with higher sensitivity.

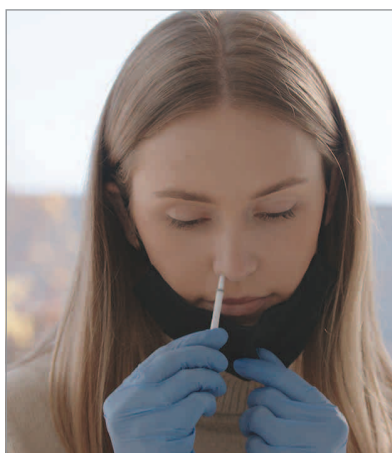
FDA officials said in a statement that the agency "believes that evidence of a test's strong performance in symptomatic patients combined with serial testing can mitigate the risk of false results when testing asymptomatic individuals."

The agency also issued a [fact sheet](#) to help schools, employers, and other organizations choose tests for screening programs to detect individual infections in groups not suspected to have SARS-CoV-2. Programs that use tests that aren't authorized for screening should consider using highly sensitive authorized tests, others authorized for pooled sample testing, or more frequent testing.

Molecular COVID-19 Test Gains First EAU for At-home Use

The first at-home molecular test for detecting COVID-19 has received an [Emergency](#)

[Use Authorization](#) (EAU). The Cue COVID-19 Test for Home and Over The Counter Use is intended for use in adults and children aged 2 years or older, with or without symptoms.



The product is a nucleic acid amplification test that detects SARS-CoV-2 RNA in the nostrils. It includes a wand for collecting a single-use anterior nasal swab specimen. Adults should swab children for samples.

To obtain a result, the user inserts the wand into a single-use test cartridge, where heating, mixing, amplification, and detection occur. In about 20 minutes, a battery-operated reader communicates the result to a mobile smartphone app. According to the FDA, the app will be able to report results to public health authorities for disease surveillance.

When studied for at-home use, the test correctly identified 96% of positive samples from symptomatic individuals and 100% of positive samples from asymptomatic individuals, FDA officials noted in a [statement](#). Cue Health expects to produce more than 100 000 tests daily by summer.

The test received an EUA in June 2020 for use in clinical and point-of care settings and is being used in schools, essential businesses, hospitals, physicians' offices, dental clinics, and nursing homes, according to a manufacturer's [statement](#).

Breaks in Ankle Implant Are a Cause for Concern

A plastic component in the Scandinavian Total Ankle Replacement (STAR) device has

a higher-than-expected fracture rate, with breaks occurring as soon as 3 to 4 years after implantation, the FDA advised in a [safety communication](#).

The component in question is a polyethylene mobile-bearing piece that allows parts of the implant to move and glide against each other. STAR implants are used in patients with osteoarthritis, post-traumatic arthritis, and rheumatoid arthritis. Risk of the component breaking appears highest in patients younger than 55 years, those with active lifestyles, and those with osteoarthritis. Thinner, 6-mm components appear more prone to fractures, which require surgery to repair or replace the implant.

FDA officials said fractures described in at least 300 adverse event reports since 2009 involve STAR devices manufactured before and after a 2014 packaging change was intended to keep plastic parts from degrading. Although the FDA couldn't determine a long-term fracture rate, a manufacturer's postapproval study showed that the plastic component fractured in 13.8% of devices at 8 years.

"When compared with other total ankle replacement devices, the higher fracture rate and earlier than expected occurrence of fracture are concerning," Raquel Peat, PhD, MPH, director of the FDA's Office of Orthopedic Devices, said in a [statement](#).

FDA officials didn't recommend removal of the devices, noting that they're still appropriate for older individuals with lower activity levels. However, surgeons should closely monitor patients who have the device and consider taking x-rays if pain or noise occurs. A computed tomographic scan, or in rare cases surgery, may be needed to detect a fracture, according to the FDA.

Patients with the implant should attend recommended follow-up visits and contact their surgeon if new or worsening pain or instability develops. Device problems should be reported through the FDA's [MedWatch](#) program. — Mary Chris Jaklevic, MSJ

Note: Source references are available through embedded hyperlinks in the article text online.