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Pentagon Forks Over Another \$109M To Make OraSure's COVID-19 Antigen Test

by Ferdous Al-Faruque

The latest funding would upgrade OraSure's Pennsylvania plant, build a new factory and increase production of its antigen test by 100 million units by 2024.

InteliSwab test maker OraSure is getting another \$109m from the US Department of Defense to make and distribute the company's COVID-19 rapid over-the-counter antigen tests. The latest chunk of change comes after the firm had already received a one-year contract worth \$209m from the DOD to distribute tests nationwide.

The DOD said on 4 October that it awarded a firm-fixed-price contract through the Air Force to Pennsylvania-based OraSure to ramp up domestic production of its InteliSwab test.

"This contract provides for the retrofit of a production facility and a new additional facility with machinery to increase domestic COVID-19 rapid test production capacity," the defense department said. "Work will be performed in Bethlehem, Pennsylvania, and is expected to be completed by March 31, 2024."

OraSure hasn't decided yet where it will locate its new plant.

In addition to the new contract, the company says it's also funding its own expansion plans to produce 120 million tests annually by the second quarter of 2022. The DOD funding is aimed at expanding production of the tests even further by an additional 100 million annually by March 2024.

Testing has continued to be a critical part of the US government's efforts to curtail the ongoing coronavirus pandemic by trying to quarantine those infected with SARS-CoV-2. The latest funding, however, seems to be not just about addressing COVID-19, but future potential pandemics as well.

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"Home testing options prevent the risk of further spread of the virus, and minimize the burden on the individual, making them an ideal cornerstone of any national pandemic preparedness strategy," OraSure CEO Stephen Tang said. "Beyond that, this funding will allow OraSure to respond to future public health crises."

The new funding from the DOD comes on the heels of OraSure already receiving \$209m a few weeks ago to distribute tests to 25,000 sites around the country. (Also see "<u>DOD Contracts</u> <u>OraSure Rapid COVID-19 Tests For \$205M</u>" - Medtech Insight, 20 Sep, 2021.)

The company says its test is designed to be one of the simplest rapid antigen diagnostics on the market, and its intuitiveness makes it ideal for use in underserved communities and consumer testing settings. It also notes a study by the National Institutes of Health that shows rapid antigen tests perform on par with lab polymerase chain reaction tests, considered the gold standard for accuracy, when antigen tests are administered at least twice a week.

InteliSwab was developed in whole or in part with federal funds from the Department of Health and Human Services, the Office of the Assistant Secretary for Preparedness and Response, and the Biomedical Advanced Research and Development Authority.

The so-called "swab, swirl, see" test, which allows users to self-collect samples from the lower nostrils, has so far received three emergency use authorizations from the Food and Drug Administration. The most recent EUA allows the test to be used to collect saliva for COVID-19 diagnosis as part of another EUA-authorized diagnostic's home collection kit. And because it does not require the supervision of a health care professional, it can be used outside of clinical settings. (Also see "COVID-19: Newly Authorized Device From OraSure Subsidiary Allows At-Home Collection Of Saliva Samples" - Medtech Insight, 22 Oct, 2020.)