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FDA issues EUA to first oral fluid rapid test for SARS-CoV-2 antibodies

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The CovAb™ test only requires an oral fluid sample obtained with a simple swab of the gumline, making it easy and painless

Diabetomics, Inc., with operations in US & India, has announced the granting of an Emergency Use Authorization (EUA) by the US Food and Drug Administration for the Company's CovAb™ SARS-CoV-2 Ab point-of-care test. The product had also received a CE mark for marketing in the EU earlier.

CovAb™ is the first and only rapid, oral fluid-based, point-of-care antibody test authorized by the FDA for use under an EUA. Unlike other COVID-19 antibody tests that require a blood draw, the CovAb™ test only requires an oral fluid sample obtained with a simple swab of the gumline, making it easy and painless. The test is CLIA-waived, is all-inclusive, does not require any additional components or instrumentation, and test results are available within 15 minutes.

In addition to being rapid and noninvasive, the CovAb™ test has sensitivity of 97.6% and specificity of 98.8%.

The CovAb™ test was developed and is manufactured in the US.

"We are excited to bring this revolutionary new COVID-19 antibody test to market, which offers an easy and quick testing option to determine antibody status," said Srinivasa Nagalla, M.D., Diabetomics CEO. "The CovAb™ test can be easily administered to adults and children with no discomfort and provides quick results."