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FDA Authorizes Marketing for First Combination Flu and COVID-19 At-Home Test Outside of Emergency Use

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On October 7, 2024, FDA granted marketing authorization for the over-the-counter combination flu and COVID-19 combination test, Healgen Rapid Check COVID-19/Flu A&B Antigen Test. Although other at-home combination tests detecting the flu and COVID-19 exist, they are authorized only for emergency use. The Healgen test is the first combination test authorized to be marketed outside of emergency use. This authorization is consistent with FDA's continued commitment to supporting the development and availability of at-home tests.

The Healgen test does not require a prescription and is authorized for self-use by individuals 14 years and older experiencing respiratory symptoms. The test is authorized for use by individuals 2 years through 13 years of age with a sample taken and tested by an adult. The test uses a nasal swab sample to detect proteins from SARS-CoV-2 and influenza A and B, the viruses that cause COVID-19 and the flu, respectively. Results are delivered in approximately 15 minutes. According to data from a study of individuals exhibiting COVID-19 and flu symptoms, the test correctly identified 99% of negative and 92% of positive SARS-CoV-2 samples, 99.9% of negative flu A and B samples, 92.5% of positive flu A samples and 90.5% of flu B samples.

"As with all rapid antigen tests, which generally have lower sensitivity than molecular tests, there is a risk of false negative test results," said FDA in its news release. FDA also added that those who tested negative but continue to experience symptoms or tested positive should follow up with their health care provider.

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