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Trump Administration Deploys Abbott BinaxNOW Tests to States -

Rapid point-of-care tests will support Governors' reopening efforts

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The Trump Administration today detailed the national distribution plan for the Abbott BinaxNOW Ag Card rapid test to assist Governors' efforts to continue to safely reopen their states. BinaxNOW is a unique testing option to provide support to K-12 teachers and students, higher education, critical infrastructure, first responders, and other priorities as governors deem fit. The BinaxNOW rapid test – the only U.S. Food and Drug Administration-authorized antigen rapid point-of-care test that does not require an instrument – is easy to use, will produce COVID-19 test results in 15 minutes, and costs $5.

"This distribution of tens of millions of rapid tests is the fruit of President Trump's effective national testing strategy, which draws on the best of the public and private sectors," said HHS Secretary Alex Azar. "Coordination among FDA, private test developers, federal public health leaders, and state leadership has allowed us to build the world's largest and most effective testing system, supplying the right tests for the right circumstances."

The Federal government purchased these Abbott BinaxNOW diagnostic tests on August 27, 2020, to ensure equitable distribution of the first 150 million units – one day after an Emergency Use Authorization (EUA) was issued by the FDA to ensure they would be expeditiously distributed to vulnerable populations as quickly as possible. Significantly, the nation's governors will not have to compete for the initial BinaxNOW shipments, or take time to set up purchasing contracts.

"The Trump Administration has successfully prioritized scaling up point-of-care testing through deregulatory actions and strategic investments to facilitate the continued re-opening of our schools, businesses and overall national economy," said Assistant Secretary for Health Admiral Brett Giroir, M.D. "The fact that point-of-care rapid tests now account for over half of the available tests on the open market is a major achievement. The tests are simple to use and cost effective. Distributing BinaxNOW tests nationally will advance the testing needs of congregate living facilities, K-12 schools, critical infrastructure, and the other institutions critical to reopening America."

ADM Giroir pointed out that, in general, antigen tests are specific – but may not be as sensitive as laboratory-based nucleic acid tests. Results from an antigen test may need to be confirmed with a molecular test prior to making treatment decisions; this may be particularly true for negative results if there is a high clinical suspicion that the patient is infected.

"Negative results from an antigen test should be considered in the context of clinical observations, patient history, and epidemiological information. Negative antigen tests do not need to be repeated or confirmed with a high-sensitivity molecular test when they are employed for routine screening or surveillance," ADM Giroir continued. According to Abbott Diagnostics, it plans to make up to 48 million tests available monthly in the U.S. in the coming weeks.

As the U.S. has made demonstrable strides in expanding testing capacity and bringing testing innovations to market, it is critical to remember that testing does not replace personal responsibility. "Testing does not substitute for avoiding crowded indoor spaces, washing hands, or wearing a mask when you can't physically distance; further, a negative test today does not mean that you won't be positive tomorrow," ADM Giroir continued. "Combining personal responsibility with smart testing is a key component of the Administration's national strategy for combatting COVID-19 – and the strategy is working."

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