Statement to ProPublica from the Food and Drug Administration
December 21, 2021

Americans need tests that work. When the data is sound, the FDA has moved quickly to authorize tests, with at-home tests being a top priority for the agency since early in the pandemic. By balancing speed with safety, we have taken numerous actions to speed public access to accurate and reliable at-home tests.

To be clear, the recommendations the FDA provides in templates are just that, and we are extremely willing to speak with test developers about their tests and how we can ensure that Americans have a test they can trust, whether that is through showing a certain level of sensitivity with a single test, or potentially lower sensitivity with an alternative testing method, such as serial testing.

Unfortunately, many submissions the FDA has received for home tests include incomplete or poor data, and it is the FDA's responsibility to protect the public health by declining to authorize poorly performing tests or those without complete data. When the submissions include complete data demonstrating appropriate performance, the FDA is able to authorize tests very quickly. We have also worked interactively with many developers to resolve concerns when data was incomplete or unclear, or to find solutions to issues that arose during review. If the FDA received a home test that the data and science supported in early-to-mid 2020, we would have quickly authorized it.