Can we trust coronavirus antibody tests never reviewed by the FDA?

The Food and Drug Administration, criticized for slowness in authorizing tests to detect coronavirus infections, has taken a strikingly different approach to antibody tests, allowing more than 90 on the market without prior review, including some marketed fraudulently and of dubious quality, according to testing experts and the agency itself.

Antibody, or serological, tests are designed to identify people who may have overcome covid-19, including those who had no symptoms, and developed an immune response. They are not designed to detect active infections. Some officials tout the blood tests as a way to reopen the economy by identifying individuals who have developed immunity and can safely return to work. But many scientists, as well as the World Health Organization, say evidence is lacking that even high-quality antibody tests can prove someone has immunity from the novel coronavirus and is not at risk of being reinfected.

The emergence of dozens of tests never reviewed by the FDA … could confuse doctors, hospitals, employers and consumers clamoring for the products, according to critics who say the agency's oversight of the tests has been lax. The questions are taking on special importance as federal and state officials debate strategies, including using serological testing, to help determine when they can end state and local lockdowns.

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