

FDA provides new tools for tests to detect Zika virus infection

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Singapore- As an additional measure in the fight against Zika virus, today the U.S. Food and Drug Administration announced that it has made available a panel of human plasma samples to aid in the regulatory evaluation of serological tests to detect recent Zika virus infection.

"At the onset of the Zika virus outbreak, when little was known about the disease or how to diagnose it, the FDA worked quickly with manufacturers to encourage the development of diagnostic tests and ensure they were available using its Emergency Use Authorization authorities," said FDA Commissioner Scott Gottlieb, M.D. "By providing manufacturers of these tests with standardized patient samples to use in properly validating these diagnostics, we will be able to better assess how well their tests perform. This is part of our effort to ultimately bring these tests through the FDA's formal review process to better ensure their reliability, and to enable broader access to Zika diagnostic testing."

There are two primary blood diagnostic tests: nucleic acid tests that identify infection by confirming the presence of a virus' genetic material (RNA) and serological tests that identify proteins (antibodies) produced by the body's immune system when it detects harmful organisms, such as Zika virus, in the blood. Serological tests are especially important because there is often a small window when the virus' genetic material is detectable. However, development of these types of tests has been particularly challenging because antibodies produced by the body to fight Zika virus are difficult to differentiate from antibodies produced to fight related viruses, such as dengue and West Nile viruses.