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FDA approves Roche's Zika screening test

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Roche has secured approval from the US Food and Drug Administration (FDA) for its cobas Zika test to detect RNA of the Zika virus in human plasma samples.

Intended for the screening of blood and plasma donations in the country, the test is approved for use on the firm's cobas 6800 / 8800 systems.

The cobas Zika test has been designed as a qualitative in-vitro nucleic acid screening indication to directly detect the virus' RNA in plasma samples of individual blood donors.

Initially deployed under the IND protocol in April last year for the screening of blood donations in Puerto Rico, the test was expanded by the end of the year to support donor screening efforts in the US.

With the cobas 6800 / 8800 systems, which carry out automated sample preparation and PCR amplification and detection, the cobas Zika test is intended to ensure that potentially infected units are not used for blood transfusion.

The cobas 6800 / 8800 software performs automated data management and assigns a result as non-reactive, reactive or invalid.