Beat: Health

U.S. FDA issues emergency use authorization for Zika test: Roche

Zika

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Zika virus, detected in Brazil and elsewhere last year before spreading to the Americas, is associated with microcephaly, a birth defect characterized by an unusually small head and potential developmental problems.
Through last week, the United States reported 2,517 Zika cases, 29 of which were likely acquired locally in Florida through mosquito bites and the rest brought in by travelers, the U.S. Centers for Disease Control and Prevention (CDC) said.
Some 9,000 additional cases have been reported in U.S. territories, including Puerto Rico.
With FDA approval, Roche's test now can be used to screen patients exhibiting Zika symptoms that meet CDC criteria, including fever, rash, joint pain and red eyes. Samples will be sent for analysis to specially-certified U.S. laboratories with the appropriate equipment, a Roche spokesman said.

"The LightMix Zika test is an easy-to-use molecular diagnostic test that enables healthcare professionals to quickly detect the virus," said Uwe Oberlaender, the head of molecular diagnostics at Basel-based Roche.
The FDA issues such Emergency Use Authorization during public health emergencies, to quickly deploy unapproved medical products for as long as they are needed.
As Zika cases caused by local Aedes aegypti mosquitoes in Florida mount and travelers from elsewhere continue to arrive with the disease, the FDA last week recommend universal testing of donated blood across the United States.
In March, Roche won separate investigational approval from the FDA for its Cobas 6800/8800 testing system to be used to test blood at U.S. blood centers including in Puerto Rico, where about 1 percent of donated blood has so far tested positive for the virus.
In Brazil, Zika virus has been linked to more than 1,800 cases of microcephaly, and U.S. officials expect as many as 270 cases in Puerto Rico.
(Reporting by Joshua Franklin and John Miller; Editing by Subhranshu Sahu and Susan Thomas)

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UPA United Press Agency LTD

483 Green Lanes
UK, London N13NV 4BS
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