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## ***For immediate release***

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## **First Commercial Serological Tests Available for Zika Virus Detection**

### **New Tests Overcome Problems of Flavivirus Cross Reactivity**

EUROIMMUN AG, a manufacturer of test systems and instrumentation for medical diagnostics headquartered in Luebeck, Germany, has developed the first system of comprehensive tests available for the serological detection and differentiation of Zika virus infections.

The EUROIMMUN Anti-Zika Virus ELISA and indirect immunofluorescence test (IFA) formats allow for detection of specific antibodies (IgM and IgG) in the blood of those who may be infected. These tests provide a longer window for detection than the currently available qPCR-based assay alone, making them particularly useful for disease surveillance. They can be used to diagnose patients with acute symptoms and to manage asymptomatic cases that fit a risk profile, particularly pregnant women. The highly specific viral antigen used in the EUROIMMUN ELISA assay eliminates cross reactivity with other flavivirus antibodies, ensuring reliable differentiation from diseases such as Dengue fever. These fully automated antibody detection test kits are suitable for rapid screening of large patient volumes and therefore provide efficient and effective monitoring of the virus spread.

“We have responded immediately to the growing concern of travelers and especially pregnant women around the world who have visited regions where the virus poses a potential risk,” said Katja Steinhagen, Head of the ELISA Infectious Serology Department at EUROIMMUN AG. “The ELISA and indirect immunofluorescence (IFA) tests have been evaluated in cooperation with the Bernhard-Nocht Institute for Tropical Medicine in Hamburg, Germany. Positive test results are a clear indicator of a Zika virus infection; our unique immunofluorescence mosaics enable laboratories to effectively evaluate samples for other viral fever diseases in parallel.”

The CE-marked EUROIMMUN kits are now available under RUO label and the company is prepared to address customer demand for these assays. “As this outbreak continues to spread, EUROIMMUN is fully committed to supporting the medical community and the public at large with innovative and accurate diagnostic solutions for optimal patient outcomes,” stated Hamid Erfanian, CEO of EUROIMMUN US.

### **The Importance of Serological Detection of Zika**

Serological analysis can aid in the differentiation of infections with Zika, Dengue and Chikungunya viruses. Key advantages of EUROIMMUN's Anti-Zika Virus tests include:

- A longer window for diagnosis than direct detection methods alone - Identification of the virus by RT-PCR is only effective within the first week after onset of symptoms, and may already be negative by the time a doctor is consulted.
- Effective diagnosis by detection of IgM and/or IgG antibodies - Zika antibodies appear around 4 to 7 days after the onset of symptoms. IgM antibodies reach their peak after two to three weeks and remain detectable for several months, while IgG antibodies are believed to persist life-long. The detection of specific IgM antibodies or a significant rise in the specific IgG titer in a pair of samples taken 7 to 10 days apart is evidence of an acute infection.

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Serological analyses are also important for establishing whether long-term consequences, such as microcephaly and Guillain-Barré syndrome, are a result of a previous Zika virus infection. If the link to congenital malformations is confirmed, Zika virus serology could play an important future role in prenatal diagnostics. Pregnant women with serological evidence of an infection could be offered advanced prenatal monitoring. Serology may also be useful for screening sample donations at blood centers and blood banks in hospital settings. Travelers returning from affected regions to Zika-free countries are advised not to donate blood for 26 days. After this time, serological testing can verify the safety of donated blood products.

A further, critical role for serological studies is to monitor the growing epidemiological reach of the Zika virus. As the virus is expected to continue to spread around the globe, knowledge about the regions it has reached is valuable for providing effective healthcare planning.

#### ELISA Test Format

Anti-Zika Virus ELISA (IgM or IgG) assays are based on a highly specific recombinant protein, which eliminates the cross reactivity typically associated with serological tests based on whole virus antigens. Data from panels of well-characterized sera have confirmed that there is no cross reactivity with flaviviruses including Dengue, Chikungunya, West Nile and Japanese Encephalitis Viruses. In studies on clinically and serologically characterized samples, the IgM and IgG ELISA showed 100% sensitivity and 100% specificity. Thus, these innovative ELISA assays overcome the major serological obstacle of flavivirus cross reactivity, which has hindered serological Zika virus diagnostics until now.

#### IFA Test Format

Anti-Zika Virus IFA (IgM or IgG) utilize Zika virus-infected cells as the antigenic substrate. Positive and negative results are evaluated by fluorescence microscopy. The Arboviral Fever Mosaic 2 contains a proprietary multiplex IFA technology incorporating a Zika Virus substrate that is incubated in parallel with substrates for Chikungunya Virus and Dengue Virus serotypes 1 to 4. This BIOCHIP combination can help in differentiating Zika, Dengue and Chikungunya Virus infections. Due to the use of whole virus particles, cross reactivity between flavivirus antibodies originating from either infections or vaccinations such as yellow fever can occur, especially in IgG detection. Investigating serial dilutions of the patient sample may enable determination of a dominant end-point titer.

#### About Zika

Zika virus is the pathogenic agent of Zika fever, an infectious tropical disease that manifests with fever, exanthema and arthritis. Zika virus infection has been linked to congenital malformations, in particular microcephaly, and also neurological complications such as Guillain-Barré syndrome. Until 2015, Zika virus was considered an obscure tropical disease, with sporadic outbreaks occurring in African and Asian countries and more recently on Pacific Islands. In March 2015, the first infections were reported in Brazil, and the virus has since spread exponentially throughout South America, Central America and the Caribbean, with confirmed cases now in the United States. It is anticipated that the virus will continue to spread to other currently unaffected regions. The virus is transmitted by mosquitos of the Aedes family, which are ubiquitous in many tropical and non-tropical countries.

#### About the Company

EUROIMMUN AG is an international manufacturer of medical laboratory reagents and instrument systems for autoimmune diseases, infectious diseases, allergy diagnostics and gene analytics. The company was founded in 1987 from the University of Luebeck (Germany). The company now has five sites in Germany and twelve international subsidiaries.

EUROIMMUN US is a wholly owned subsidiary of EUROIMMUN AG, and serves the needs of the U.S. laboratory diagnostics market with respect to autoimmunity, infectious diseases, and instrumentation solutions.

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