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Co-Diagnostics receives CE mark for Zika Test

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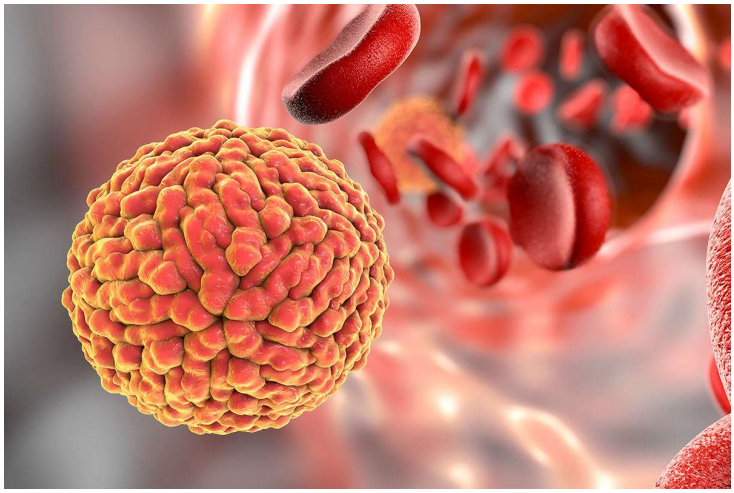
The Logix Smart Zika Test uses polymerase chain reaction (PCR) technology to detect the presence or absence of the Zika virus.



US based Co-Diagnostics, Inc., a molecular diagnostics company with a unique, proprietary platform for the development of molecular diagnostic tests, has announced that its Logix Smart Zika Test technical file has obtained CE mark approval, the principle regulatory clearance allowing the test to be sold as an in vitro diagnostic (IVD) for the diagnosis of Zika virus in European Union states and other markets that accept a CE-IVD mark as valid regulatory approval.

The CE mark confirms that the test meets the Essential Requirements of the European Community's In-Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC), allowing sales of the product to commence as an IVD with the CE marking included.

The Logix Smart Zika Test uses polymerase chain reaction (PCR) technology to detect the presence or absence of the Zika virus in serum, plasma, collected alongside with urine, from patients suspected to be infected. While not lethal itself, studies have directly linked Zika with cases of microcephaly, a neurological disease that affects the brain development of fetuses. The WHO has raised the priority for R&D investments for Zika in their 2018 annual review of diseases.