Chembio rapid Zika IgM test gets FDA EUA, 12/17

December 2017—Chembio Diagnostics received FDA emergency use authorization for its DPP Zika System. The system, for use in high- and moderate-complexity CLIA-certified laboratories, provides results in 15–20 minutes from 10 µL of blood and includes the DPP Zika IgM Assay and DPP Micro Reader.

The test is authorized for the presumptive detection of Zika virus IgM antibodies in fingerstick whole blood, EDTA venous whole blood, EDTA plasma (each collected alongside a patient-matched serum specimen) or serum (plain or separation gel) specimens collected from individuals meeting CDC Zika virus clinical and/or epidemiological criteria, from eight days of onset and up to 12 weeks.

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