

REA 10 - Evaluation of IgM and IgG Chikungunya diagnostic assays: differences in sensitivity of serology assays in one outbreak in Brazil

Salvatore Giovanni De Simone¹; Patricia Fernandes^{1*}; Paloma Napoleão Pêgo¹; Isis C Prado¹; Michelle Pacheco¹; Viveca Giongo¹; David William Provance-Jr¹.

1 CDTS / Fiocruz.

Introduction:

Chikungunya is a mounting public health concern in many parts of the world. Definitive diagnosis is critical in differentiating the diseases, especially in Mayaro, Dengue and other endemic areas. There are some commercial chikungunya kits and published molecular protocols available, for serodiagnostic presumptive confirmation of viral infection, but no comprehensive comparative evaluation of them was performed. The current and recent outbreaks of several febrile diseases associated with recent outbreaks of CHYV and ZIKAV in Brazil has resulted in a massive effort to accelerate the development of new and specific diagnostic methods. Some are available in Europe or EUA using virus isolated from those countries or from Africa, but other need be developed. The introduction of these tests in other countries do not always work properly.

Objective:

Evaluate the performance of two commercially and one in house IgM and IgG Capture-ELISA assay for the detection of anti-Chikungunya virus (CHIKV).

Methodology:

We tested two commercial IgG test (CDC and NovaTec Immundiagnostica GmbH), one IgM test (NovaTec Immundiagnostica GmbH, Germany) alongside our two in-house IgM and IgG assays. The sensitivity and specificity of the five cap-ELISA assay were evaluated using a cohort comprised 100 sera obtained from one city of Brazil (Fortaleza, CE) affected by Chikungunya disease outbreak before the Olympics games in Brazil (2015) and 80 other sera from patients with dengue, Mayaro, yellow fever and healthy individuals. Sensitivities of the three immunological protocols were also evaluated based on ROC curve.

Results:

The commercial assays had different performances in detect IgM and IgG, with the IgM and IgG NovaTec cap-ELISA tests having the best performance, followed by our in-house test. A significant difference qualitative inter tests in detect acute and chronic disease (CDC x Novatec) was observed, in spite of all the tests being able to detect the febrile syndrome. All the tests presented an excellent sensitivity and specificity being the NovaTec the best ($\geq 98\%$).

Conclusion:

Use of the IgM and the IgG capture-ELISA tests assay improves a very good performance to detect Chikungunya. The evaluation carried out in this work demonstrates the importance of appraisal of commercial kit and published protocols before application of a diagnostic tool in the clinical and operational setting. Factors that may interfere with an immunological test are many and therefore a thorough evaluation of these tests is required before they are marketed and / or used on a large scale. Concluding, we report differences in IgG and IgM detection efficacy of different assays between the three assay analysed.

Keywords: Chikungunya; Serological assays; ELISA