

Implementing Zika virus (ZIKV) laboratory diagnostics in Brazil: past challenges, current difficulties and the promising future

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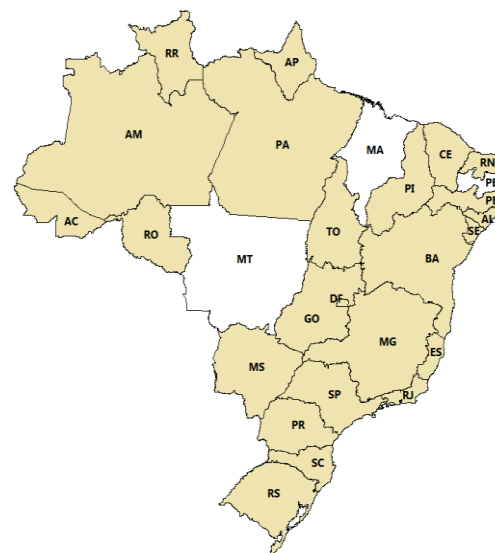
Past Challenges – Current Difficulties

- With the Zika Virus outbreak, the rise of microcephaly cases and consequent declaration of Public Health Emergency of International Concern (PHEIC), the Ministry of Health of Brazil gathered efforts to improve and to bolster the Public Health Laboratories Network as part of the National Emergency Plan to face the situation.
- Convergence of key sectors:
 - Federal Government;
 - State Government;
 - Local Government;
 - WHO/Pan-American Health Organization;
 - CDC;
 - Researchers;
 - IVD industry.
- Although the WHO declared the end of PHEIC, in Brazil, ZIKV remains a Public Health Emergency of National Concern and is faced as a long term threat;

Past Challenges – Current Difficulties

- As part of this improvement process, the General Coordination of Public Health Laboratories in partnership with Pan American Health Organization, CDC and the Reference Laboratories - Instituto Evandro Chagas and Fiocruz - provided assessment, training and supplies for the implementation of molecular methods and MAC ELISA technique in those facilities with the required infrastructure.
 - 85% of the public health laboratories network with the capacity to run RT qPCR tests (in-house protocol);
 - 200.000 reactions delivered by MoH;
 - 80.000 RT qPCR exams carried out by laboratories;
 - PRNT only at Reference Labs
 - State Laboratories without RT qPCR implemented, sent the samples to Regional or National reference lab assuring 100% coverage.

The amount of samples sent to the laboratories had increased up to 5 fold.



Zika virus diagnosis

- Need to provide timely and accurate response;
- Need to increase the throughput of testing;
- Sustainability and quality;
- Support the development and technology transfer for new diagnostic tests;

Technological improvements

- Implementation of a triplex for Zika, Dengue and Chikungunya RT qPCR developed by Biomanguinhos/FIOCRUZ
- Recent adoption of rapid diagnostic tests (RDTs) IgM/IgG and IgM/IgG ELISA.
- Adaptation of the lab-testing algorithm.

Zika virus diagnosis

Status of the RDT implementation

- December 2016 - Acquisition of 3,5 millions of tests IgG/IgM;
- February 2017- First delivery to all states;
- March 2017 – beginning of use and assessment.

Status of the ELISA IgM/IgG implementation

- February 2017 – Acquisition of 750.000 IgM and 500.000 IgG;
- Ongoing acquisition.
- April 2017

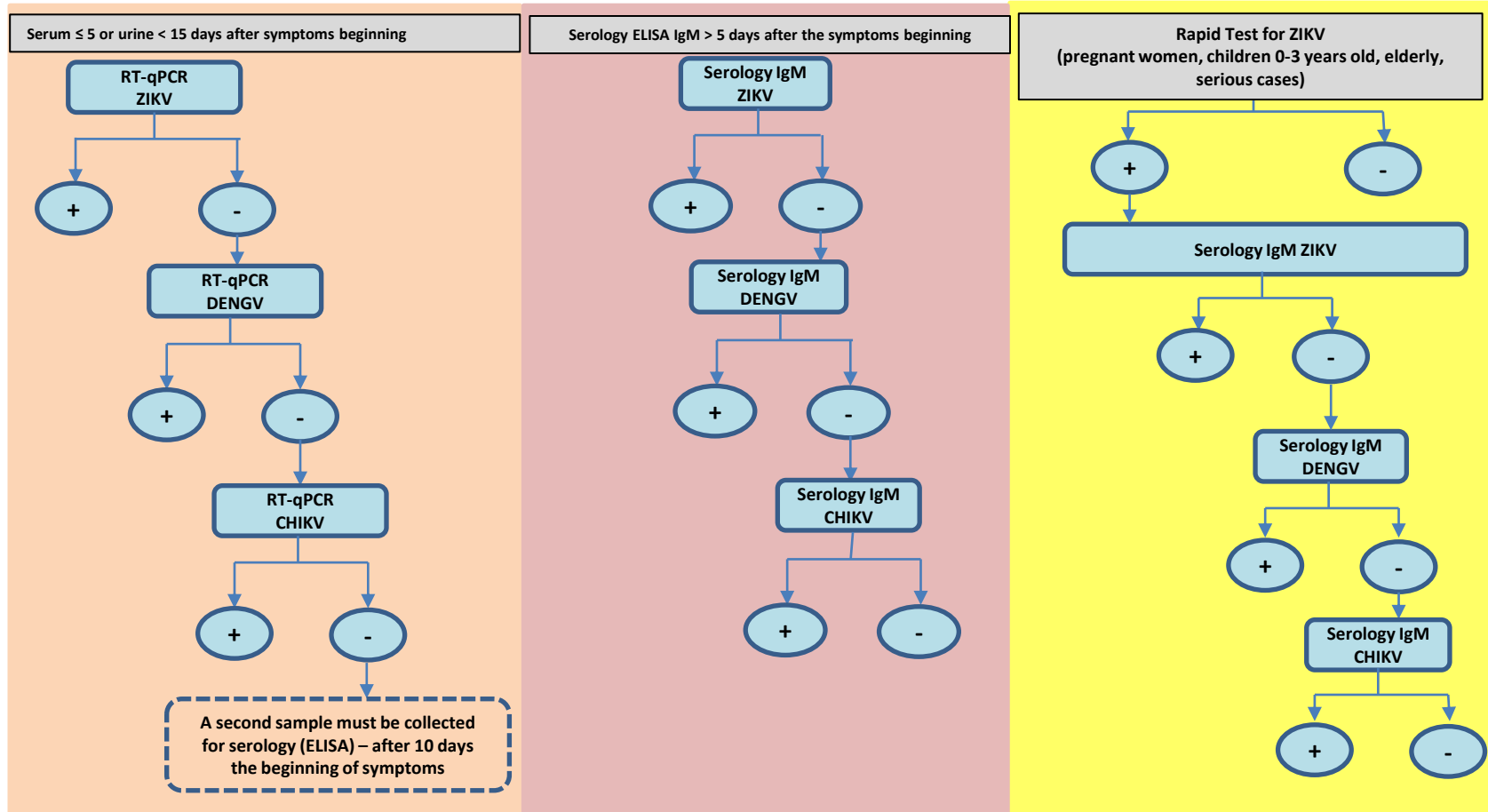
Status of Triplex RT qPCR implementation

- March validation for the RL;
- May 2017 - beginning of use and assessment.

Zika virus diagnosis - The Brazilian Lab Algorithm

Suspect case of Zika infection

Suspect case definition: patient presenting exanthema accompanied by two or more signs and symptoms: fever, red eyes, joint pain, edema, asthenia.



Zika virus diagnosis

- The IgM/IgG Rapid test is expected to be the first algorithm adopted by the MOH for the public health services – screening and providing access.
 - Product manufacturer – Bahiafarma/Genbody Inc.
 - Parameters (INCQS):
 - Sensibility IgM = 97%
 - Specificity IgM = 96%
 - Sensibility IgG = 100%
 - Specificity IgG = 98%
- In the case of a reactive result, the patient sample will be confirmed for possible ZIKV infection, through IgM/IgG ELISA, by the lab.
- If the patient additionally displays symptoms compatible with a ZIKV infection, a sample will be tested using RT-qPCR (gold standard).

Zika virus diagnosis

- A technical assistance partnership between the CDC/Brazil office and the Brazilian MOH was launched in November 2016, aiming to build diagnostics capacity in the areas of immunohistochemistry and immunopathology, improving the accurate *post-mortem* diagnostics in human tissues, preventing cross-reactive results from other arboviruses.

Challenges of Zika virus diagnosis

New Methodologies

- Luminex technology
- **Simultaneous serological detection of antibodies for several diseases in a single test**
- Multiplex viremia assessment

Changes the dynamic of surveillance

- From traditional surveillance of disease based on detection of cases or deaths, **to innovative surveillance based on the population's susceptibility and immune response** (no need to wait for 1st case)

Assessment and QC

- Standardization of Immunohistochemistry (IHC) in the Zika Diagnostic Routine post-mortem;
- Assessment and monitoring the RDT and ELISA implementation;
- Development and distribution of quality controls panels
- Continuous support for the improvement of the public health laboratories network.

Thank you



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