

# ZIKA VIRUS (ZIKV) POINT OF CARE (POC) DIAGNOSTICS



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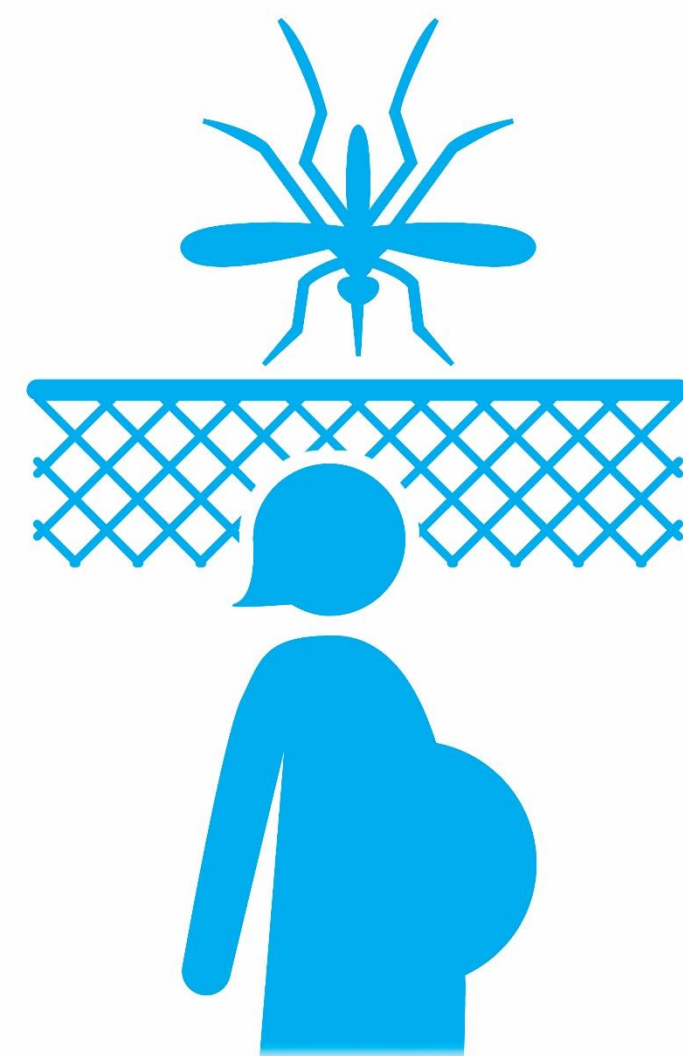
In February 2016, WHO declared the Zika virus (ZIKV) and its suspected link to birth defects be a Public Health Emergency of International Concern.

Drawing from lessons of the recent Ebola health crisis, the international health community mobilized quickly to respond to the ZIKV outbreak, including launching steps to make available, life-saving products that were not yet commercially available.

Within UNICEF Supply Division, a cross-disciplinary team of technical experts began working with partners and industry to address the lack of a ZIKV POC diagnostic test.

The three main stages in this endeavor are:

- Identifying need
- Incentivizing R&D
- Scaling the product



- Analysis of field-level need found out that >95% of ZIKV diagnoses are clinical, and when a lab is available lead-time for lab diagnosis is 4-8 weeks.
- In April 2016, a ZIKV diagnostics Target Product Profile (TPP) was launched jointly by WHO, PAHO and UNICEF. The TPP described a test for ZIKV that could give rapid and reliable diagnosis at community level.
- Consultations took place among UNICEF colleagues (including from the Regional Office for Latin American and Caribbean Regional Office), diagnostics experts from London School of Tropical Hygiene and Medicine, FIND and other stakeholders.
- Partners and experts modeled demand and procurement forecasts for ZIKV POC diagnostics.
- Communication and dialogue with industry included sharing of Q&A documents and webinars on demand forecasts.
- In May 2016, UNICEF-hosted industry consultations included participation of a range of stakeholders including: regulatory-setting agencies (e.g., WHO, FDA), academia and product developers from vaccine and diagnostics companies.
- Collaboration with WHO, PAHO and Biomedical Advanced Research and Development Authority (BARDA) focused on R&D, funding, regulatory approvals, demand forecasting, etc.
- A ZIKV POC diagnostic procurement strategy covering 2017-2019 was developed with a view to ensuring a healthy market for affordable, quality-assured supply.
- A \$10 million grant from USAID backing UNICEF's advance purchase commitment (APC) incentivized industry investment into appropriate R&D.
- A Request for Proposal (RFP) for procurement of ZIKV POC diagnostic tests was issued 28th of February. This including for access to an APC for delivery during 2017-2019- for ensuring perceived value that supports appropriate adoption/implementation of product for end-users and governments.