



Hello:

February 2020

As the new coronavirus threatens to reach pandemic level, InBios leaders joined other industry representatives in a meeting convened by the U.S. Food and Drug Administration to [discuss how diagnostics are evaluated during and even after emergencies](#).

While the meeting was planned well before the coronavirus outbreak, it addressed the relatively few diagnostics that make the transition from emergency use authorization to full marketing status. [InBios' ZIKV Detect 2.0 IgM Capture ELISA](#) made that leap - moving from [FDA Emergency Use Authorization](#) (EUA) in 2016 to [FDA Marketing Authorization](#) in 2019.



As for the new coronavirus, InBios has had preliminary communications with the FDA with respect to regulatory guidance regarding the best pathway for quick diagnostic development.

Chagas Test Performs Well in Endemic Region Study

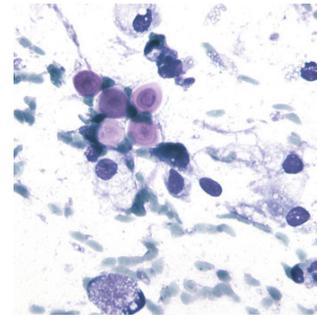


In a study published in [PLOS Neglected Tropical Diseases](#), researchers comparing commercial rapid diagnostic tests - including InBios' FDA cleared [Chagas Detect™ Plus \(CDP\) Rapid Test](#) - found they **worked well under very rugged field-testing conditions** and might someday be useful as diagnostic tools, in addition to their use for rapid infection screening. [Read more](#)

Leishmaniasis Diagnostics Could Be Key in Outbreak

InBios leaders will take part in the [World Health Organization's Global Leishmaniasis Programme Review](#) March 10-12 to discuss

diagnostics for this disease. The meeting comes on the heels of a recent [warning by WHO of a possible outbreak of cutaneous leishmaniasis in Pakistan](#). InBios offers [CL Detect™ Rapid Test](#), an FDA-cleared test for the rapid detection of *Leishmania* species antigen in ulcerative skin lesions.



InBios products have been used for diagnostic purposes in past leishmaniasis outbreaks. After [Bosaso General Hospital in Somalia reported the first cases in 2014](#), InBios' [Kalazar Detect™ Rapid Test for Visceral Leishmaniasis \(VL\)](#) was used in accordance with Somalia's national leishmaniasis guidelines.

WHO Calls for Investment in R&D for New Diagnostics

With 2020 well underway, WHO released a list of [13 urgent health care challenges](#) for the coming decade. Stopping infectious diseases is one of those challenges, with WHO outlining the **"need to invest in research and development of new diagnostics, medicines and vaccines."** The WHO report also acknowledges that vector-borne diseases such as chikungunya, malaria, Zika and dengue are on the rise and moving into new areas, which could lead to epidemics.

For more than 20 years, InBios has specialized in the development of *in vitro* diagnostics with a particular focus on infectious diseases. We offer diagnostic products for the vector-borne diseases WHO highlights in its report, as well as other diseases of global importance.

[Learn more](#)

Visit InBios at Upcoming Conferences to Learn about New Products

**Vector-Borne Infectious Disease
Conference**
March 23-25, 2020
Galveston, TX

APHL Annual Conference
June 8-11, 2020
Portland, OR
Booth Number 502

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