

InVictus



INNOVATIVE
DIAGNOSTICS FOR
INFECTIOUS
DISEASES

562 1st Ave. South,
Suite 600
Seattle, WA 98104
USA

Telephone:
206.344.5821

Website:
www.inbios.com

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Emerging Diseases: Little Known About the Deadly Reduviid Bug

Despite remarkable scientific advances in modern medicine today infectious diseases still remain one of the leading causes of death worldwide. Amongst the variety of infectious diseases popularly known in the medical media, there are still countless others that are rarely talked about. Chagas is one such disease that is rarely talked about today, and because its lack of popularity in the medical media, little is known about the disease that kills more people in South America than malaria. An estimated 10 million are infected with *Trypanosoma cruzi* (the parasite that causes Chagas). The parasite spreads by a bite from the reduviid bug or triatomines, also known as the kissing bug. When the insect sucks the blood of a carrier, it eats the parasite which spreads to other victims through feces that the bug deposits in the open wound it leaves on the skin. The bug then feeds on the face of a sleeping victim—thus, called the “kissing bug”. Victims rub the feces in their open wound, mouth or eyes, which allows the bug to enter the blood stream. Chagas is considered a disease of poverty because the bugs live in cracks in the walls and roofs of mud, adobe and straw houses, typically found in the slums of Latin America. Although, the disease is most prevalent in Latin America, but due to migration, it is slowly spreading to other parts of the world. Evidence of the Chagas disease has been seen in Europe, Japan and U.S.

The disease can remain dormant in the bloodstream for years, emerging much later. Millions of people who contracted the disease don't even know it because diagnosis is complicated, and often no symptoms are present in the early stages. Sadly, once a chronic form of the disease has progressed, current drugs and treatments are no longer effective. There is no vaccine against Chagas, and a person can become infected again after treatment. According to *Medical News Today*, about 20 - 30% of those infected develop the chronic form of the disease, up to 20 years afterwards. By this time, they could have irreversible damage to the heart, esophagus and colon; hence, their condition becomes terminal and they die. InBios has developed rapid and ELISA diagnostic kits for Chagas. Our rapid test is field friendly and can be used in remote area in a point of care setting. It is highly sensitive and specific. To learn about our diagnostic kits please visit our website: www.inbios.com, and to learn more about the disease please visit: <http://www.medicalnewstoday.com/articles/233097.php>. Thank you!



Snap Shots

To have a quality product, the underlying technology must be outstanding. This is where Namratha Ram, Research Assistant at InBios plays a critical role. Namratha is part of the Molecular Biology team at InBios. Her work involves cloning and large scale production of antigens for all our ELISAs and rapid test kits. She is also involved in the development of gold nano particles for that may prove to be useful in rapid diagnostic detection systems. Namratha earned a BS in Biotechnology and MS in Biochemistry from the University of Bangalore, India. Prior to her employment at InBios, she worked at the Indian Institute of Science in the Microbiology and Cell Biology department, where she deciphered the role of SUB I protein and its influence on transcription machinery using *Saccharomyces cerevisiae* as the model organism. She also worked at the University of Agricultural Sciences, Bangalore, India. Besides her passion for molecular biology, she loves to travel, ski and do outdoor adventure sports. Her most exciting travel experience thus far, was to Galapagos Islands. She felt that traveling to the islands was a biologist's dream come true because she was able to traverse the same paths that led to the great theory of evolution. When Namratha is not adventuring out to some exotic place, she loves to hike the numerous trails and mountains of the Northwest.



Namratha Ram,
Research Assistant

The Regulatory Corner

Many companies wonder whether they can legally export their medical devices that lack FDA clearance or approval. The answer in most cases fortunately is yes. The FDA allows manufacturers to export product pursuant to Section 801(e) or Section 802 of the Act. To export under 801(e) the manufacturer must first certify the following: 1) Each product for export accords to the specification of the foreign purchaser; 2) The product is not in conflict with the laws of the country to which it is intended for export, 3) the product shipping package is labeled on the outside that is intended for export only 4) product is not sold or offered for sale in the US 5) No HIV or Class III products can be included. Form FDA 3613a must be completed and the statement certifying the above signed. Of course, companies must be careful not to export to countries where the U.S. State Department has banned exports. Having an export certificate from the FDA is very useful when marketing products internationally. The FDA does charge a nominal fee for the certificates. A future article will be written about how to export under Section 802. For up to date information about how to export medical device, visit the FDA website at www.fda.gov.



UPCOMING EVENTS:

- **Medica 2011**
November 16-19,
2011
Düsseldorf,
Germany. Visit us
in the US Pavilion:
Hall 3, D-29-3.

Come see us!