

Leprosy: Vaccine & Diagnostic Test Update

IDRI's Advances Toward Improved Leprosy Diagnosis and Vaccine Development

In partnership with American Leprosy Missions, IDRI has embarked on an aggressive program to develop an effective vaccine and better diagnostic test for leprosy. IDRI is developing an accurate and inexpensive diagnostic test that provides much greater diagnostic power than those currently in use; additionally, IDRI is developing a vaccine against leprosy. This focus on both vaccines and diagnostics means that, for the first time, eradication of this disease may be achievable.

Leprosy

Leprosy, or Hansen's Disease, is a chronic infectious disease caused by *Mycobacterium leprae*, a bacterium related to the organism that causes tuberculosis (TB). Leprosy bacteria are most likely transmitted through droplets from the nose and mouth of infected people. The bacteria primarily grow on cooler areas of the body, such as the skin, limbs, eyes, and nasal cavity. Damage to the nerves in leprosy lesions leads to muscle weakness and atrophy, and numbness or loss of sensitivity to touch. It is this nerve damage that leads to the injuries and deformities often associated with the disease. The stigma attached to leprosy has often caused those who contract the disease to be shunned by family, friends, and society.



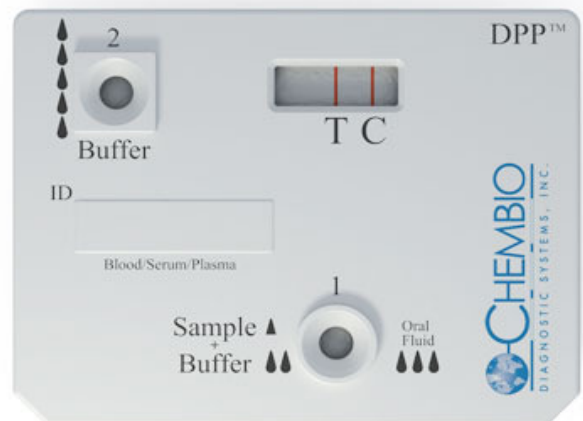
A diagnostic capable of detecting leprosy will greatly reduce the burden of this disease.

Historically, leprosy has afflicted people in nearly every part of the world. Today, it is still a public health problem in 24 countries in Africa, Asia, and Latin America, due in large part to poverty. Although it is possible to treat leprosy with multi-drug therapy (MDT) and the World Health Organization (WHO) has declared leprosy to be "under control" in many countries where it was previously endemic, most experts agree that current measures alone are not sufficient to fully eradicate the disease. Drug therapy is successful only if started during the early stages of the disease when the drug can reduce both disease progression and bacterial spread. While the total number of registered cases has declined since the introduction of MDT, the reported number of new cases registered each year has stayed steady (at 500,000 to 700,000) over the same period. Slow and insensitive diagnostic tests, as well as a lack of access to regular health care, means that many who develop leprosy are treated too late, after disfigurement and transmission to others have already occurred. Development of safe, precise, and low-cost diagnostic tests to detect infection with the leprosy bacterium before signs and symptoms appear, combined with an effective vaccine, would bolster any leprosy eradication program.

IDRI's Successes in Leprosy Diagnosis

IDRI is currently working with an industrial partner, ChemBio Diagnostics, to develop an advanced platform for use as a leprosy diagnostic kit. This advanced platform uses a fusion of multiple proteins — thus increasing the chance of successful diagnosis — to detect antibodies in a tiny amount of leprosy patient's blood. Testing shows that the ChemBio platform is much more sensitive at detecting leprosy antibodies, and can be used on samples under a wider variety of conditions, than the commercially available test. Any guesswork in reading the result of the ChemBio test can be eliminated by using a small, cheap, field-friendly digital reader.

IDRI continues to expand its serum bank for developing and validating the diagnostic test and has conducted further testing with blood samples from Nepal (in collaboration with Dr. Murdo Macdonald) and Venezuela (with Dr. Olga Zerpa), and is in the process of extending testing to China (with Dr. Vara Vissa). IDRI is currently in conversation with Dr. Om Parkash (JALMA, Agra-India) and Dr. Gift Norman (SLRTC, Karigiri-India) to extend testing to India. This is important, because the test must function well despite regional differences in patient antibody responses.



Example of a positive test result using the IDRI-ChemBio rapid leprosy diagnostic.

IDRI's Future Strategy for its Leprosy Diagnostic

Over this next year, IDRI will optimize the leprosy diagnostic platform with the goal of producing a broadly applicable field-friendly test for the rapid diagnosis of leprosy patients. IDRI anticipates that a cost-effective, field-appropriate diagnostic should be available for use in the next several years. Furthermore, ALM and IDRI will use this innovative diagnostic platform to seek funding for a broad-based eradication program.