

Leprosy – A Curable Disease!

GenoType LepraeDR: Your Molecular Genetic Test System for the Detection of *Mycobacterium leprae* and its Resistance to Rifampicin, Ofloxacin and Dapsone from Smear-Positive Skin Biopsies based on **DNA•STRIP** technology.



Facts about Leprosy

Leprosy, also known as Hansen's disease, is a chronic infectious disease, caused by *Mycobacterium leprae*, an acid-fast, rod-shaped bacillus. The bacilli affect skin, mucous membranes, peripheral nerves, eyes and internal organs, in some cases the lymph nodes. The incubation time of the disease can take up to 20 years and more. On average it takes 2 – 4 years for the symptoms to appear.

Leprosy occurs in several clinical manifestations. In general it is classified in tuberculoid leprosy ("paucibacillary") and lepromatous leprosy ("multibacillary"). There is a wide spectrum of intermediate forms, also referred to as borderline leprosy.

Even if leprosy is thought to be eradicated in most of the countries, according to the WHO, we still had to face about 213.000 new cases worldwide at the beginning of 2009. An estimated 3 million people are suffering from long-term consequences. Until now preventative measures in form of immunization are not available.

The bacilli have never been cultured *in vitro*. The common diagnostic method is the detection of *Mycobacterium leprae* in skin smears. The microscopy allows the differentiation between paucibacillary (PB) leprosy (= smear-negative) and multibacillary (MB) leprosy (= smear-positive), which is an important information with regard to therapy.

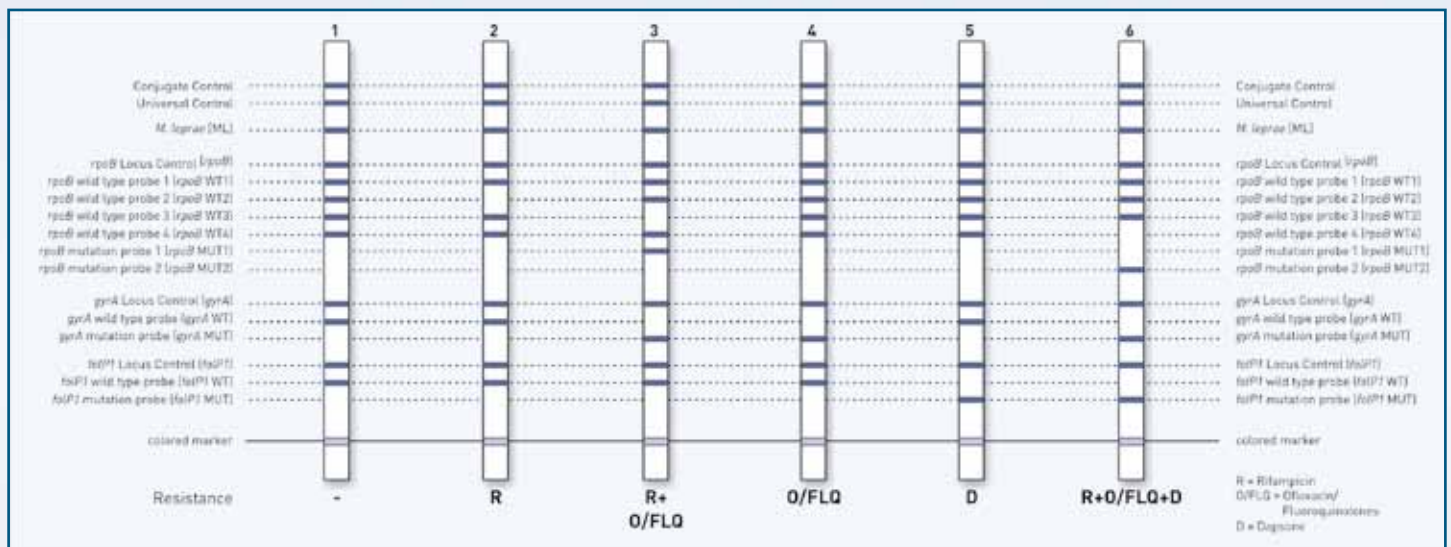
Because experience in practical application of histology and/or molecular biology is required, these sensitive detection methods are mainly performed in reference laboratories. The same also applies for the drug susceptibility testing in mouse foot pads which is very labour- and time-consuming. On the basis of these facts, it is difficult to get reliable data about primary and secondary antibiotic resistance rates; thereby resistances to rifampicin and dapsone are described.

Now, a fast and reliable test system for the molecular genetic identification of *M. leprae* and its antibiotic resistances is available: The **GenoType LepraeDR** permits the simultaneous detection of *M. leprae* and its resistance to rifampicin, ofloxacin and dapsone within a few hours.

GenoType LepraeDR

M. leprae and its Resistance to Rifampicin, Ofloxacin and Dapsone

Example Results with the GenoType LepraeDR



Characteristics of the GenoType LepraeDR

The **GenoType LepraeDR** is based on PCR and the **DNA•STRIP** technology. It permits the simultaneous molecular genetic identification of

- *M. leprae*
- its resistance to rifampicin by the detection of the most significant mutations of the *rpoB* gene (coding for the β -subunit of the RNA polymerase)
- its resistance to ofloxacin and other fluoroquinolones by the detection of the most significant mutations of the *gyrA* gene (coding for the A subunit of the DNA gyrase)
- its resistance to dapsone by the detection of the relevant region of the *folP1* gene (coding for the dihydropteroate synthase) from acid fast bacilli (AFB)-positive skin biopsies.

Indications for the Use of the GenoType LepraeDR

Diagnosing patients

- with suspicious anamnesis and AFB-positive biopsy
- after treatment failure and relapse
- for screening purposes to develop country-specific leprosy action plans.

Benefits and Advantages of Using the GenoType LepraeDR

- First commercial test system for the molecular detection of *Mycobacterium leprae*.
- Results are obtained in 5 hours compared to several months with conventional methods.
- Detection of resistance to first- and second-line drugs in one step.
- Safe and reliable due to internal controls and the combination of specific amplification and hybridization.
- Allows early, appropriate treatment which reduces long-term consequences.