



## "Demonstration of NOPERSIST results leading to novel, validated Diagnostic tests for active human and bovine tuberculosis"

Two European companies and two research institutes led by the coordinator LIONEX will team up in the EU-funded demonstration project "DEMO-NOPERSIST" for developing novel validated diagnostic tests which are able to specifically detect active TB in human and cattle.

### Partners:

**LIONEX GmbH** ([www.lionex.de](http://www.lionex.de)), Germany

**PRIONICS AG** (<http://www.prionics.com>), Switzerland

**ANIMAL HEALTH and VETERINARY LABORATORY AGENCY** ([www.ahvla.gov.uk](http://www.ahvla.gov.uk)), U.K.

**UNIVERSITY OF FLORENCE** ([www.unifi.it](http://www.unifi.it)), Italy

Tuberculosis (TB) in humans and bovine TB in farm animals are global health problems of immense social and economic importance. *Mycobacterium tuberculosis* (M.tb) is a slowly replicating bacillus that resides intracellularly within phagosomes of macrophages and commonly causes latent infections of the lung and in about 5% of the infected individuals it leads to active disease. Co-infection with *M. tuberculosis* is estimated in about one-third of HIV-1 infected subjects. Indeed, the risk of developing tuberculosis is increased several fold in HIV-1+ patients. Globally, there are more than 14 million individuals dually infected with TB and HIV. Drug resistance to HIV-treatment and appearance of multiple-drug resistance (MDR) and off late of Extra-Drug Resistance (XDR) strains of *M. tuberculosis*, the causative agent of human TB is steadily leading to a hopeless situation as far as the therapy is concerned. To make things worse, there is no effective vaccine available against HIV. *M. bovis* BCG, the only vaccine available against TB, has shown highly variable efficiency and has been very often ineffective. Its use has been discontinued in several countries.

**Bovine TB:** Bovine tuberculosis is caused by the bacterium *Mycobacterium bovis*, which is closely related to *Mycobacterium tuberculosis*. *M. bovis* can be transmitted to humans through the ingestion of unpasteurised milk and milk products as well as aerosols, from infected cows. The introduction of pasteurisation eliminated transmission through contaminated milk and greatly reduced the human health problem. The principal hosts for bovine tuberculosis are cattle and buffalo, however many other domestic and wild animals can become infected e.g. goats, cervids, pigs, wild boars, dogs, cats, camels, badgers, primates, hares, amongst others. Bovine tuberculosis is found worldwide. All developed countries currently have a TB eradication program in place for many years. These programs have been largely successful; however, incidences are increasing in many countries (e.g. UK, Ireland, France, Austria, Germany).

Diagnosis of human and bovine TB is extremely difficult, time-consuming and in-efficient. No efficient, cost effective tests are available for an early diagnosis of these infections. Furthermore, there is no test on the market which can differentiate the more than 500 million infected people (LTBI) from the active TB patients. A test which can differentiate between healthy infected and the TB patient shall, without doubt, have an immense positive impact on human health and prevention of tuberculosis.

The two SME members of this consortium with complimentary areas of research and business activities, LIONEX (SME) (in TB) and Prionics (in bovine TB) in cooperation with UNIFI and AHVLA are dedicated to solving the problems of the TB infections and disease mentioned above by using the excellent and highly promising results of the previous NOPERSIST project.

**The human TB tests shall be the World's first blood test for discriminating latent from active TB. Furthermore the goal is to develop and evaluate prototype test kits for active bovine TB. The project shall result in marketable, improved diagnostic products for human and bovine TB within a period of 2-3 years.**



LIONEX is a highly research intensive company dedicated to tuberculosis and has a prominent position in Europe in this field. LIONEX is ISO13458 certified and is fully capable of producing an In-Vitro Diagnostic Device (IVD) for humans. Similarly, Prionics is one of the largest veterinary diagnostic companies focussing on cattle diseases and offers a unique portfolio of bovine TB diagnostic tests and is the only source for all official OIE prescribed bovine TB tests. UNIFI and AHVLA have such exceptional expertise in infectious diseases. Both have already collaborated with the two SMEs (LIONEX and PRIONICS) in the NOPERSIST.

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