

Press Release

Lille - 25th October 2018

A major advance in the fight against multidrug-resistant tuberculosis

The new Deeplex®-MycTB mycobacterial antibiotic resistance test¹, developed by GenoScreen, has been used by an international research team in a molecular epidemiology study published in The Lancet Infectious Diseases. This study highlights the spread of tuberculosis strains resistant to first-line antibiotics, not detected by actual international tests.

With 10 million new cases per year and 1.6 million deceases in 2017, tuberculosis is the most deadly infectious disease in the world². The number of new cases of multidrug-resistant tuberculosis emerging each year (estimated at 450,000 new cases in 2017³) is a global public health problem.

On October 18th 2018, a study conducted in southern Africa, co-directed by Dr P. SUPPLY (CNRS/CHU/INSERM/ The University of Lille /Institut Pasteur de Lille), Dr B. de JONG (Institute of Tropical Medecine of Antwerp) and Dr E. ANDRÉ (Université Catholique de Louvain), has been published in *The Lancet Infectious Diseases*⁴. It reveals that multidrug-resistant strains of tuberculosis are not detected by current diagnostic tests which cause ineffective treatment for patients, increased mortality and contagion, as well as an accumulation of additional resistance in the bacterial strains involved.

These results were achieved, mainly, credits to the innovative molecular test for predicting antibiotic resistance to this disease: the Deeplex®-MycTB test, developed by GenoScreen.

This test is based on the latest DNA sequencing technologies (NGS) and the bioinformatic detection of mutations responsible for antibiotic resistance. A secure web application allows users to access analyse and interpret results using an interactive graphical interface wherever they are. Unlike the culture-specific testing which takes several weeks, the complete sample analysis can be finalised in just one to three days. After certification (CE-IVD marking) for medical use, Deeplex®-MycTB will be able to help clinicians to define more precisely and more quickly the appropriate treatment for patients.

On the basis of a single molecular test, this test allows to:

- identify more than 140 species of mycobacteria, including *Mycobacterium tuberculosis*, the agent responsible for tuberculosis,
- predict resistance to more than a dozen antibiotic molecules⁵ used in the antituberculosis treatment of this infectious-agent,
- identify the genetic type of the strain involved for epidemiological tracing purposes,
- visualise the results on an interactive graphical interface giving access to the detail of the results.

« Contrairement à d'autres tests de détection des résistances, Deeplex®-MycTB présente le triple-avantage d'être rapide, de détecter une large variété de mutations avec une grande sensibilité et de réaliser un typage facile des mycobactéries, pour suivre l'émergence de nouvelles souches résistantes. »

[trad : Unlike other resistance detection tests, Deeplex®-MycTB offers the triple advantage of being fast, detecting a wide variety of mutations with high sensitivity and easily typing mycobacteria, to monitor the emergence of new resistant strains.]

Dr. Gaëlle BISCH – « isolated microorganism » R&D Team Manager, GenoScreen

¹ Mycobacteria are a broad genus of bacteria, including several pathogens such as tuberculosis and leprosy...

² <http://www.who.int/fr/news-room/detail/26-09-2018-world-leaders-commit-to-bold-targets--and-urgent-action-to-end-tb>

³ **Global tuberculosis report 2018**, Organisation Mondiale de la Santé (OMS)

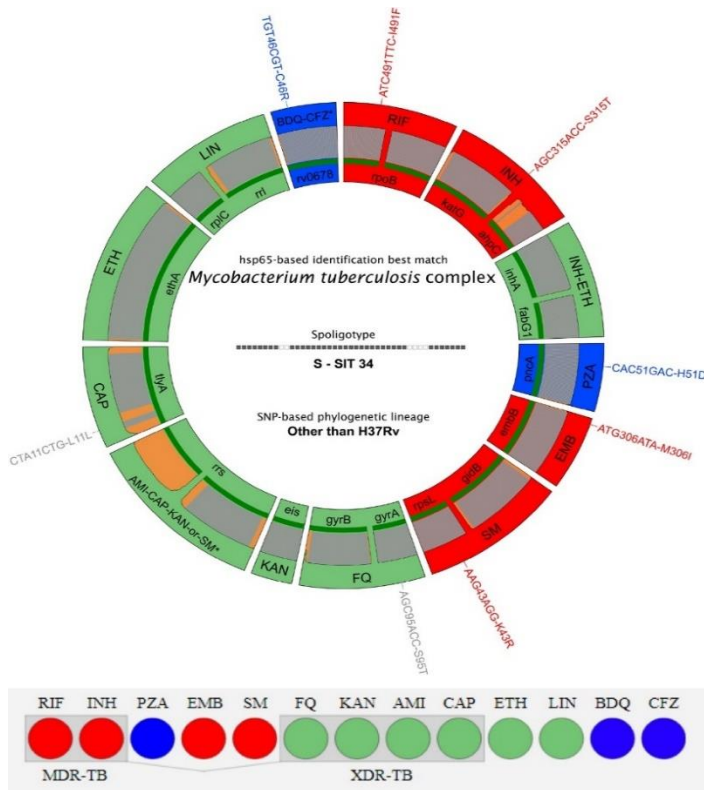
⁴ N. A Makhado, E. Matabane, M. Faccin, C. Pinçon, A. Jouet, F. Boutachkourt, L. Goeminne, C. Gaudin, G. Maphalala, P. Beckert, S. Niemann, J-C. Delvenne, M. Delmée, L. Razwiedani, M. Nchabeleng, P. Supply, B. C. de Jong et E. André. **Outbreak of multidrug-resistant tuberculosis in South Africa undetected by WHO-endorsed commercial tests: an observational study**, *The Lancet Infectious Diseases*, le 13 octobre 2018

⁵ Deeplex®-MycTB predicts resistance to 1st-line antibiotics (rifampicin, isoniazid, pyrazinamide, ethambutol), as well as 2nd-line molecules, including aminoglycosides (kanamycin, amikacin, capreomycin, streptomycin), fluoroquinolones (such as levofloxacin, moxifloxacin and ciprofloxacin), ethionamide and clofazimine; as well as new antibiotic molecules (bedaquiline, linezolid).



Deeplex®-MycTB differs from current tests in other ways:

- The wide range of targeted genetic regions: 20 mycobacterial DNA regions are simultaneously analysed to detect resistance mutations to more than 12 antibiotics.
- The automation of the analysis and the ease of use of the visualisation and interpretation tools: with an intuitive design, these tools allow a quick and synthetic understanding of the results. Interactive, they also permit a detailed analysis of the detection data for each mutation and direct access to bibliographic sources associated with the prediction results.



1: Visualisation and interpretation of Deeplex®-MycTB results.

The circle, or "Deeplex map", represents the genes studied with their names on the inside and the antibiotic(s) concerned on the outside.

Color refers to the results of antibiotic susceptibility prediction (red for resistant, green for sensitive and blue for "not characterised until now in the scientific literature").

Mutations are indicated on the outside of the circle, using the same colour code (grey for mutations without effect on resistance).

The resistance results are synthesised by a "resistotype" shown below, using the same color codes associated with the resistance prediction for each antibiotic (RIF, INH, PZA...).

Currently in commercial **launching** phase for the researchers (RUO⁶), Deeplex®-MycTB is already deployed in several National and Supra National Reference Centres in Europe (OMS Collaborating Centre at the San Raffaele Institute in Milan, Institute of Tropical Medicine in Antwerp) and in Africa (in Benin and Rwanda). This test is expected to be homologated as a diagnostic test in 2019.

« Deeplex®-MycTB est né de la collaboration de scientifiques de différentes spécialités : bioinformaticiens, chercheurs spécialistes de la tuberculose, de la génomique bactérienne ou de l'évolution moléculaire. Le défi a été de rendre simple et facile d'utilisation une technique sophistiquée, aussi bien au niveau moléculaire qu'analytique. Les premiers retours que nous avons lors des formations sont très positifs et nous confirment que notre test répond réellement aux attentes de nos utilisateurs. »

[trad : "Deeplex®-MycTB was born from the collaboration of scientists with different specialties: bioinformaticians, researchers specialising in tuberculosis, bacterial genomics or molecular evolution. The challenge was to make a sophisticated technique, simple and easy to use, both at the molecular and analytical level. The first feedback during the training sessions is very positive and confirms that our test really fulfills our users' expectations. »

Dr. Agathe JOUET – Deeplex Development Officer, GenoScreen

« At first, I was very skeptical, but today I am very excited about the Deeplex test. It's truly an amazing test that simplifies complex tests for tuberculosis susceptibility and reduces them from months to days! »

Jean-Claude SEMUTO (Tuberculosis National Control Program, Kigali, RWANDA).

⁶ RUO : Research Use Only



About GenoScreen :

GenoScreen is a French biotechnology company founded in 2001, specialised in genomics and bioinformatics.

Our innovation strategy through research allows us to provide innovative services and solutions to academic and industrial research teams to analyse and exploit the DNA characteristics of all kinds of genomes and metagenomes.

Our activities are organised into 3 divisions:

- **A Services division** that provides standardised and customised analysis services, under ISO quality, of all types of genomes (human, animal, plant, microbial).
- **An Expertise division** that meets the research and consulting needs of companies developing projects related to genomics. GenoScreen is especially recognised for its expertise in the analysis of microbial genomes and metagenomes,
- **An Innovations division which** produces and commercialises analysis, but also control solutions and tools that meet the needs of various sectors of activity (health, cosmetics, agri-food, agronomy, environment, etc.).

In response to the accelerated evolution of technologies and uses, our research teams are pursuing their mission, **which is to manage genomic information in the benefit of human health and environment.**

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