Press release

Lille - November 2nd, 2020

Publication of the first comprehensive performance evaluation of the "Deeplex® Myc-TB" test for the prediction of tuberculosis antibiotic resistance.

The innovative Deeplex® Myc-TB antibiotic resistance prediction test has been evaluated by an international research team. By analyzing data from more than 5,600 strains and samples of various origins and types, this study measures for the first time the sensitivity, specificity and detection limit of this test.

With 10 million new cases per year and 1.4 million deaths in 2018[1], tuberculosis remains the world's deadliest infectious bacterial disease. The emergence and spread of multidrug-resistant mycobacterial strains (causing nearly 400,000 new cases in 2018) is a global public health problem that complicates the combat against tuberculosis.

The Deeplex® Myc-TB test, thanks to its innovative engineering by deep sequencing, allows the simultaneous detection of susceptibility or resistance to 13 classes of antibiotic molecules[2], including first and second line antituberculosis drugs, and new molecules. This test is based on the targeted amplification and sequencing of more than 20 genetic regions. The major benefit of this test is the ability to obtain an extensive antibiotic resistance profile and genotype of the bacterium from a clinical sample, without any prior culture step.

The study published in the high-impact medical-scientific journal "*The European respiratory journal*"[3], is the first to exhaustively assess the specificity, sensitivity and detection limit of this test, based on data from a large panel of more than 4,000 strains and 1,600 clinical samples. To conduct this evaluation, the GenoScreen team analysed the antimicrobial resistance data obtained with Deeplex® Myc-TB, and compared them to the data from reference tests currently in use (phenotypic tests and/or whole genome analyses (WGS), carried out after culture), obtained by Belgian (Institute of Tropical Medicine - Antwerp, Sciensano, - Brussels) and Italian (San Raffaelle Institute - Milan) teams.

On this analysis, the researchers could determine the performance of the Deeplex® Myc-TB test for predicting resistance or sensitivity to tuberculosis drugs.

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[1] OMS. Global tuberculosis report 2019. https://www.who.int/tb/publications/global_report/en/

[2] 1st intention molecules (rifampicin, isoniazid, pyrazinamide, ethambutol); 2nd intention molecules: - fluoroquinolones (such as levofloxacin, moxifloxacin and ciprofloxacin), aminoglycosides (kanamycin, amikacin, capreomycin, streptomycin), - ethionamide, - clofazimine, and new antibiotic molecules (bedaquiline, linezolid).

[3] Jouet A, Gaudin C, Badalato N, et al. Deep amplicon sequencing for culture-free prediction of susceptibility or resistance to 13 anti-tuberculous drugs. *Eur Respir J* 2020; in press (https://doi.org/10.1183/13993003.02338-2020)

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- Compared to phenotypic tests on reference strains, the overall sensitivity of Deeplex® Myc-TB is 95.3% and its specificity is 97.4%.
- Compared to WGS analyses (with the MTBseq tool) carried out after clinical sample culture, the sensitivity of Deeplex® Myc-TB is 93.5%, and its specificity 98.5%.

These data show the high degree of accuracy of Deeplex® Myc-TB for extended prediction of resistance or susceptibility to anti-tuberculosis drugs, compared to reference tests, with the major advantage of being directly applicable on clinical specimens. The results indicate that the residual differences between the reference tests and Deeplex® Myc-TB are explained, in the majority of cases, by the limitations of these reference tests (undetected minority sub-populations, mutations conferring low levels of resistance, etc.).

This study reinforces and amplifies the results of preliminary work carried out by another international team with GenoScreen, on a smaller set of strains and clinical samples. This study, carried out with the Research Centre Borstel (Germany), published in August 2020 in "*The European respiratory journal*"[4], showed that:

- The matching rate between Deeplex® Myc-TB and the WGS results obtained on these strains was around 98%.
- The matching rate between Deeplex® Myc-TB results and those of the phenotypic tests was over 95–97% for 1st line antibiotics and 70–100% for 2nd line drugs (the 70% matching rate being due to mutations conferring low resistance to an antibiotic, which are difficult to detect by phenotypic tests).

These results demonstrate the potential of Deeplex® Myc-TB for the rapid diagnosis of multi-drug resistant tuberculosis.

Publication

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About GenoScreen

GenoScreen is a French biotech company founded in 2001, specialized in genomics and bioinformatics.

Its strategy of innovation through research leads it to offer innovative services and solutions to academic and industrial research teams for analyzing and exploiting the genetic information of all types of genomes and metagenomes.

Its business portfolio is organized into 3 divisions:

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

Its mission: Mastering genomic information to the benefit of human health and the environment.

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[4] Feuerriegel, Silke *et al*. "Rapid genomic first- and second-line drug resistance prediction from clinical *Mycobacterium tuberculosis* specimens using Deeplex®-MycTB." *The European respiratory journal*, 2001796. 6 Aug. 2020, doi:10.1183/13993003.01796-2020