Press release

EMBARGOED:
until march 23, 2020 17 :00 Paris time

GenoScreen launches a rapid, effective diagnostic kit, to combat tuberculosis antibiotic resistance

Key points:

- ***The Deeplex® Myc-TB test is now available for medical use.***
- ***This rapid test is based on the genetic analysis of the microbial strains responsible for TB. It offers a new solution to identify the antibiotic susceptibility or resistance of these pathogens and, ultimately, effectively combat drug and multidrug-resistant forms of TB.***
- ***It can predict the resistance of strains to 15 antibiotic drugs.***
- ***The test uses mass sequencing technologies and automated bioinformatics analysis via a secure cloud.***
- ***It can accurately identify the strain(s) infecting a patient, contributing to better epidemiological monitoring of the disease.***

Lille, March 24, 2020 — GenoScreen announces the CE-IVD marking of its Deeplex® Myc-TB kit, in accordance with the requirements of the European directive for in vitro diagnostic medical devices. The kit is the first molecular diagnostic kit that uses -Next Generation Sequencing (NGS) to combat the scourge of drug-resistant and multidrug resistant tuberculosis.

Tuberculosis (TB) is a bacterial infection caused by a pathogen called *Mycobacterium tuberculosis*, sometimes also known as “Koch’s bacillus”. This infectious disease is one of the top 10 causes of mortality worldwide. With 1.2 million deaths in 2018, TB is the most lethal infectious disease in the world (ranking above AIDS), affecting around 10 million people each year[1].

The disease is primarily treated by the simultaneous administration of several antibiotics. However, these treatments are becoming less and less effective as a result of the emergence and growing spread of strains that are resistant to one or more of these drugs. This drug-resistance, which is not specific to TB, is an increasingly significant threat to global public health.

GenoScreen
1 rue du Pr. Calmette
59 000 Lille
Tel.: +33 (0) 320 877 153
contact@genoscreen.com - www.genoscreen.com

One of the main causes of resistance is antibiotic misuse. In particular, this is due to inadequate and/or delayed characterisation of antibiotic susceptibility or resistance. A lack of rapid, precise and exhaustive methods to diagnose the drug resistance of TB bacteria has played a major role in the worsening of this pandemic. According to WHO estimates, in 2018 only a third of new cases of multidrug-resistant TB cases were detected[1].

Current tools used to diagnose the antibiotic resistance of TB are based on two methods:

- Bacterial culture tests: In these tests, the highly pathogenic agents are first cultured then incubated in media containing antibiotics. By observing the growth or decline of these cultures, the susceptibility of the bacteria to anti-TB drugs can be assessed. Applied to TB pathogens, this method takes around 1 month to provide results.
- Genetic tests: These involve detecting the presence of any genetic markers known to cause resistance to one or two antibiotics. A result can be obtained much more quickly with these tests than with bacterial culture tests.

The Deeplex® Myc-TB kit is a new rapid, effective and exhaustive test[2], based on in-depth analysis of the DNA of mycobacteria[3]. It predicts susceptibility and resistance to 15 antibiotics in order to guide the treatment of patients. It can be used directly on clinical samples (with no prior culture step), providing results in less than 48 hours. The kit also precisely identifies the strain(s) infecting a patient (genetic typing or spoligotyping), contributing to better epidemiological monitoring of the disease.

The Deeplex® Myc-TB test also has a number of other characteristics that set it apart from current genetic diagnostic tests:

- The number of genetic regions covered by the molecular analysis: 23 regions of the mycobacterial DNA are studied simultaneously in order to detect mutations causing resistance to 15 antibiotics, at the same time identifying the bacterium.
- Its sensitivity: it is capable of detecting the presence of mutations causing resistance to antibiotics, even when these still show low levels of emergence within the bacterial population present in a sample (detection of minority populations, from a presence of 3% of the said strain in the sample).
- The automation of the analysis and its ease of use: due to an intuitive secure Web Application, it enables rapid, concise interpretation of the diagnostic test results. The interactive Web interface also allows users to examine the analytical data for each mutation in detail and to directly consult the associated bibliographic sources.
- The upgradability of the test: This test will be regularly updated in line with research advances, with the integration of new mutations following their validation by scientific communities.

Deeplex® Myc-TB is already used for research purposes and epidemiological studies in a number of national and supranational reference laboratories in various countries in Europe, Africa and Asia for the monitoring of drug-resistant TB.

Having obtained CE-IVD marking, this test is now available for medical diagnostic purposes and will help us more effectively fight this global scourge.

---

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

[2] 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 and E. André. **Outbreak of multidrug-resistant tuberculosis in South Africa undetected by WHO-endorsed commercial tests: an observational study**, *The Lancet Infectious Diseases*, 13 October 2018

[3] Bacterial genus to which the infectious agents causing TB, leprosy, etc. belong.

About Deeplex® Myc-TB:

Technical information:

- Antibiotics taken into account:
    - First-line antibiotics: Rifampicin, Isoniazid, Pyrazinamide, Ethambutol,
    - Second-line antibiotics:
        - Aminoglycosides: Kanamycin, Amikacin, Capreomycin, Streptomycin,
        - Fluoroquinolones: Levofloxacin, Moxifloxacin and Ciprofloxacin,
        - Ethionamide,
        - Bedaquiline,
        - Linezolid,
        - Clofazimine.
- Gene regions studied for antibiotic resistance: rpoB, inhA, fabG1, katG, ahpC, pncA, embB, gidB, rpsL, rrs, eis, tlyA, gyrA, gyrB, ethA, rrl, rplC, rv0678

- List of identified bacteria: *M. abscessus (subsp abscessus, bolletii), M. africanum, M. agri, M. aichiense, M. algericum, M. alvei, M. aromaticivorans, M. arosiense, M. arupense, M. asiaticum, M. aubagnense, M. aurum, M. austroafricanum, M. avium (subsp avium, paratuberculosis, silvaticum), M. boenickei, M. bohemicum, M. botniense, M. bouchedurhonense, M. bourgelatii, M. bovis, M. bovis BCG, M. branderi, M. brisbanense, M. brumae, M. canariasense, M. canettii (CIPT 140010059, STB-D, E, G, H, I, J, K, L), M. caprae, M. celatum, M. chelonae, M. chimaera, M. chitae, M. chlorophenolicum, M. chubuense, M. colombiense, M. conceptionense, M. confluentis, M. conspicuum, M. cookii, M. cosmeticum, M. crocinum, M. diernhoferi, M. doricum, M. duvalii, M. elephantis, M. europaeum, M. fallax, M. farcinogenes, M. flavescens, M. florentinum, M. fluoranthenivorans, M. fortuitum (subsp acetamidolyticum, fortuitum), M. fragae, M. frederiksbergense, M. gadium, M. gastri, M. genavense, M. gilvum, M. goodii, M. gordonae, M. haemophilum, M. hassiacum, M. heckeshornense, M. heidelbergense, M. hiberniae, M. hodleri, M. holsaticum, M. houstonense, M. immunogenum, M. insubricum, M. interjectum, M. intermedium, M. intracellulare, M. kansasii, M. komossense, M. kubicae, M. kumamotonense, M. kyorinense, M. lacus, M. lentiflavum, M. lepraemurium, M. leprae, M. llatzerense, M. madagascariense, M. mageritense, M. malmoense, M. mantenii, M. marinum, M. marinum M, M. marseillense, M. massiliense, M. microti, M. monacense, M. montefiorense, M. moriokaense, M. mucogenicum, M. murale, M. nebraskense, M. neoaurum, M. neworleansense, M. onchromogenicum, M. noviomagense, M. novocastrense, M. obuense, M. pallens, M. palustre, M. paraffinicum, M. parafortuitum, M. parascrofulaceum, M. paraseoulense, M. parmense, M. peregrinum, M. phlei, M. phocaicum, M. porcinum, M. poriferae, M. pseudoshottsii, M. psychrotolerans, M. pulveris, M. pyrenivorans, M. rhodesiae, M. riyadhense, M. rufum, M. rutilum, M. salmoniphilum, M. saskatchewanense, M. scrofulaceum, M. sediminis, M. senegalense, M. senuense, M. seoulense, M. septicum, M. setense, M. sherrisii, M. shimoidei, M. shinjukuense, M. shottsii, M. simiae, M. smegmatis, M. sphagni, M. stomatepiae, M. szulgai, M. terrae, M. thermoresistibile, M. timonense, M. tokaiense, M. triplex, M. triviale, M. tuberculosis complex, M. tusciae, M. ulcerans, M. vaccae, M. vanbaalenii, M. vulneris, M. wolinskyi, M. xenopi, M. yongonense.*

About GenoScreen

We are a French biotech company specialising in genomics and bioinformatics.

Our strategy of innovation through research enables us to develop innovative services and tools to analyse and exploit the genetic information carried in the DNA of all types of genomes and metagenomes. There is a strong focus on microbiological research and its medical and industrial applications.

Our activity portfolio is organised into 3 divisions:

- **An Innovation division**, which develops, produces and markets testing and monitoring solutions, kits and tools addressing the needs of a variety of sectors (health, cosmetics, agrifoods, agronomics, environment, etc.) in compliance with ISO:13485.
- **A Service division**, which provides ISO:9001-compliant standardised and custom analysis services for all types of genome.
- **An Expertise division**, which serves the study and consultancy needs of companies developing R&D projects related to genomics and metagenomics.

With these activities, we pursue our objective of harnessing genomic information for the benefit of humankind and the environment.