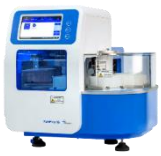
ABL received CE-IVD Mark for its single multiplex PCR test “DeepChek® Assay 13-Plex KB Drug Susceptibility Testing”

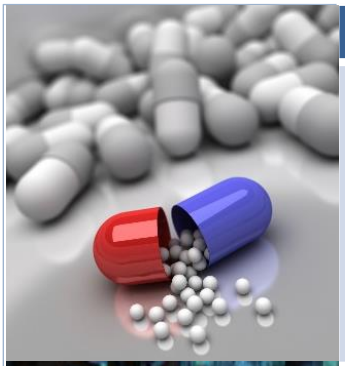
A validated End-to-End Solution for the determination of tuberculosis (TB) bacteria resistance with the detection of resistance associated mutations in MTB targeted genes by Sequencing

We are pleased to announce that our **DeepChek® Assay 13-Plex KB Drug Susceptibility Testing**, intended to be used for Tuberculosis Drug Resistance assessment through NGS sequencing, is now CE-IVD marked !

Sample preparation ▶ DNA extraction ▶ Multiplex PCR ▶ NGS sequencing ▶ Data analysis


List of targeted anti-TB drugs & MTB regions



1st Line	2nd Line	New antibiotics
▪ rifampicin (RMP) ▪ isoniazid (INH) ▪ pyrazinamide (PZA) ▪ ethambutol (EMB)	▪ Fluoroquinolones (moxifloxacin (MOX), levofloxacin (LFX)) ▪ amikacin (AMK) ▪ kanamycin (KAN) ▪ capreomycin (CAP) ▪ streptomycin (STR) ▪ ethionamide (ETH)	▪ bedaquiline (BDQ) ▪ clofazimine (CFZ)

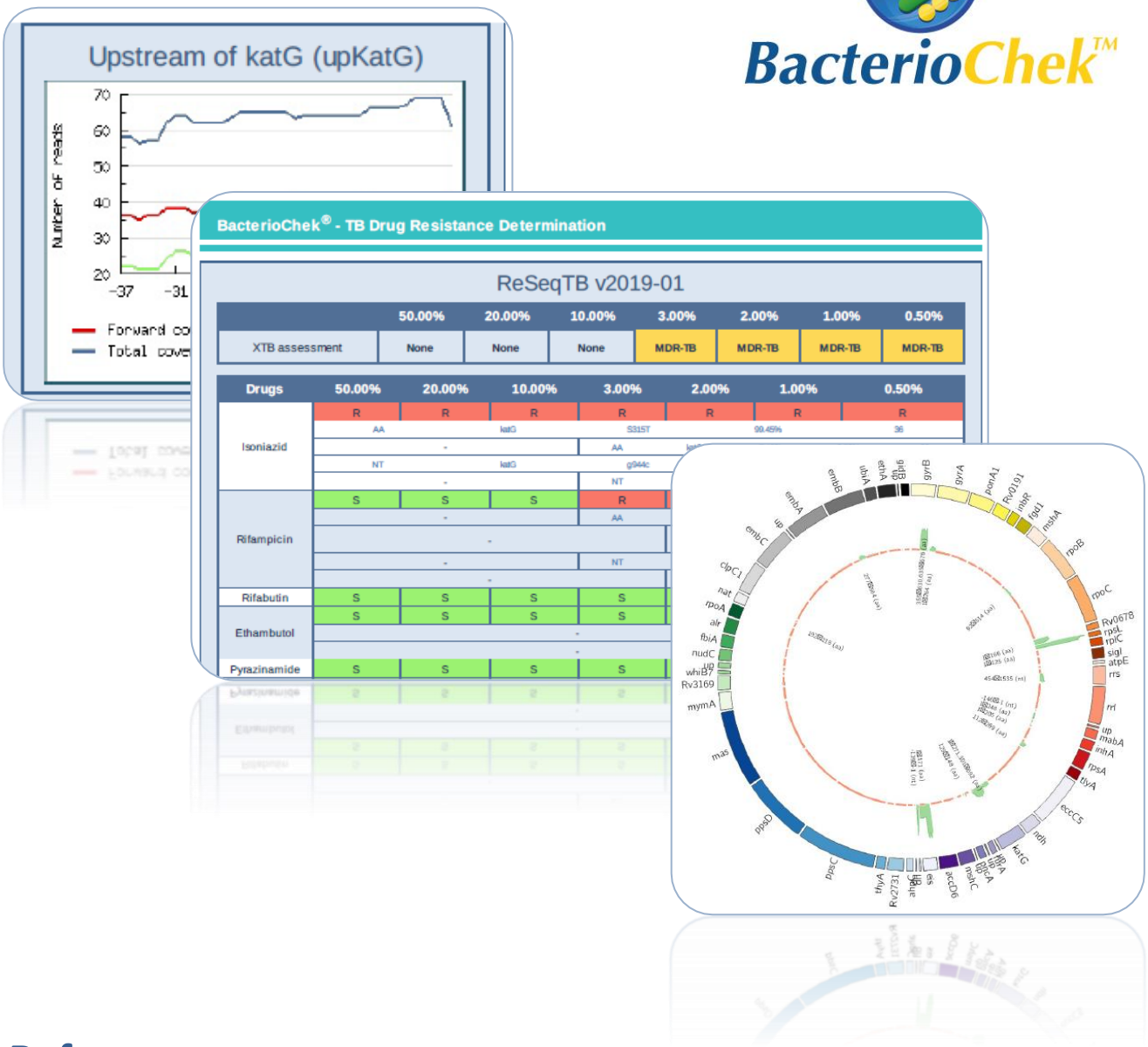
▪ mabA-inhA promoter ▪ inhA structral region	▪ rrs central region ▪ rrs 3'terminal region
▪ furA-katG intergenic region ▪ katG structural region	▪ rpoB
▪ rpsL	▪ rv0678
▪ embB	▪ tlyA
▪ eis promoter	▪ pncA
▪ gyrA	
▪ gyrB	▪ Hsp65 (complementary RUO assay)

Highlights

Input sample type	▪ unprocessed sputum specimens ▪ concentrated sediments prepared from sputums or from MTB-positive culture
Library Preparation	▪ DeepChek® Library Prep Assay (24 / 48 /96 /384 indexes), …
Sequencing technologies	▪ Illumina® iSeq 100, MiniSeq*, MiSeq*, NextSeq*, Thermofisher® S5*, PGM*, Oxford Nanopore® MinIon*, Gridion*… ▪ Capacity to pool TB libraries with other DeepChek® libraries (Ex.: HIV, SARS-CoV-2, HCV, HBV, 16s RNA…)
Turnaround time	▪ From sample to analysis and interpretation report, the total time for 24 samples is about 29 hours
Kit content	▪ Multiplex PCR master mix, Multiplex Primer Mix
Drug Resistance Assessment	▪ Guidelines: PhyResSE, ReSeqTB, TB-Profiler, WHO Catalogue ▪ MDR-TB & XDR-TB
LOD	▪ 2.30 * 10^3 TCID50/mL for MTB
Data analysis	▪ BacterioChek®-TB software : Push-button system available through Cloud (HDS) or local installation

** instruments & related reagents shall be validated by the laboratory*

Example of report



References

DeepChek® Assay 13-Plex KB DRUG SUSCEPTIBILITY TESTING V1 (CE-IVD)	128A24
DeepChek® TB Sample Preparation (150 mL) (CE-IVD)	127B-240862
BacterioChek® - TB Software (CE-IVD)	S-12-023 (TL)
DeepChek® NGS Clean-up beads (60mL) (RUO)	N411-02
DeepChek® NGS LIBRARY PREPARATION V1 (24 indexes) (RUO)	116B24 + 124B24
DeepChek® NGS LIBRARY PREPARATION V1 (48 indexes) (RUO)	116B48 + 124B48
DeepChek® NGS LIBRARY PREPARATION V1 (96 indexes) (RUO)	116B96 + 124B96
DeepChek® NGS LIBRARY PREPARATION V1 (384 indexes) (RUO)	116B384 + 124B384