



ABL

Advanced
Biological
Laboratories

Diagnostics

Solution for Tuberculosis Drug Resistance

End-to-end RUO Solution for Mycobacterium Tuberculosis Drug
Susceptibility Testing by Sequencing

Suited to **Small, Medium & High** Throughput Laboratories

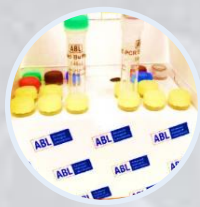


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Sample
Preparation



PCR



NGS
Sequencing



Data
Analysis

Lab & Data Analysis automation



1st Line

Rifampicin

Isoniazid

Pyrazinamid

Ethambutol

2nd Line

Moxifloxacin
Levofloxacin

Amikacin

Kanamycin

Capreomycin

Streptomycin

Ethionamin

New Drugs

Bedaquilin

Clofazimin



Sample Preparation



PCR



NGS sequencing



NGS data analysis

Sample collection	DNA extraction
Lab self-validate	

DeepChek® 13-Plex (RUO)

Library preparation reagents	Indexes (24/48/96/384)
DeepChek® NGS Library Preparation (RUO)	

Analysis	Reporting
BacterioChek® - TB Software (CE-IVD)	

NGS	
Turnaround time	~3-4 days
Hands-on-time	~1-3 h

MULTIPLEX AMPLIFICATION DESIGN

- Multiplex in one single tube
- 13 genes



PERFORMANCES

- Heteroresistance: Down to 0.1%
- Sensitivity < 1000 cp/mL (optimization ongoing)
- Validated on various Liquid & Solid Cultures

SEQUENCING

- Validated on iSeq100, MiniSeq, MiSeq (Illumina)
- Validated on S5 + Ion Chef (ThermoFisher)
- Validation on NanoPore MinIon ongoing

EXAMPLE OF REPORT (MULTIPLE PAGES)

- Complete or "One Page" report
- Large analysis panel

BacterioChek® - TB Drug Resistance Determination

03-2018 literature review 03-2018

XTB assessment	15.00%		10.00%		3.00%	
	MDR-TB		MDR-TB		MDR-TB	
Drugs	15.00%		10.00%		3.00%	
Isoniazid	R	R	R	R	R	R
	NT	upMabA	g-17i	99.44%	37	
	AA	katG	S315T	99.44%	37	
Rifampicin	R	R	R	R	R	R
	AA	rpoB	D489C (all 510)V	99.08%	37	
Rifabutin	NA	NA	NA	NA	NA	NA
Ethambutol	R	R	R	R	R	R
	AA	embB	M309	98.61%	37	
Pyrazinamide	S	S	S	S	S	S
Streptomycin	S	S	S	S	S	S
Fluoroquinolone	S	S	S	S	S	S
Levofloxacin	NA	NA	NA	NA	NA	NA
Moxifloxacin	NA	NA	NA	NA	NA	NA
Ofloxacin	NA	NA	NA	NA	NA	NA
Amikacin	R	R	R	R	R	R
	NT	rfs	a340tg	99.58%	37	
Kanamycin	R	R	R	R	R	R
	NT	rfs	a340tg	99.58%	37	
Capreomycin	R	R	R	R	R	R
	NT	rfs	a340tg	99.58%	37	
Linezolid	S	S	S	S	S	S
Bedaquiline	S	S	S	S	S	S
Ethionamide	NA	NA	NA	NA	NA	NA
Para-aminosalicylic acid	NA	NA	NA	NA	NA	NA
Cycloserine	NA	NA	NA	NA	NA	NA

Legend

XTB assessment	MDR-TB	Multidrug resistant TB	XDR-TB	Extensively drug resistant TB
Interpretations	S	Susceptible	R	Resistant
-	For the selected drug, at least one region impacting drug resistance according to the indicated guideline is not covered, therefore the derived drug resistance assessment cannot be determined			
Mutations	Type	Region	Mutation	Prevalence

BacterioChek® - TB Genotyping Report

BacterioChek® - TB analysis summary

Patient/Sample information

Patient data: QCMD2
 Past treatments: Missing data
 Last treatment: 21/02/2020
 Report id: 02-20731bcd-54b4-11ea-8216-0800278dc04d
 Reason for genotyping analysis: Missing data

Sample ID: QCMD2
Alternative ID: Missing data
Sample date: 21/02/2020
Input: accc6, atpE, eis, embA, embB, embC, ethA, fbaA, fgd1, h gyrB, inhA, katG, mabA, ndh, pncA, rpoC, rpoA, rpoB, rpoD, rps, rnt, ms, rv0678, thyA, thyA, ubiA, upd15, upkaiG, upM upWhiB7, whiB7, ponA1, Rv0191, inbR1, mshA, sigI, eccC upPncA, mshC, upAhpC, ahpC, Rv2731, ppsC, ppsD, mas Rv2169, nusC, sdc, nat, ctpC1, upImbA, upEhA, gidB : QCMD2_56_L001_R1_001.fastq
 QCMD2_56_L001_R2_001.fastq
 => 94.83% of the 95064 initial reads mapped to TB organum

Comments:

BacterioChek®-Sanger information

Not available

Coverage

Classification of mutations of interest ReSeqTB - 01

03-2018 literature review / 03-2018 03-2018 | Biontel university | v29 | ReSeqTB | v2019-01-01-2019 |

Sample ID: QCMD2
Sample date: 21/02/2020



DeepChek® Assay 13-Plex KB DRUG SUSCEPTIBILITY TESTING V1 (RUO)	128A24
DeepChek Sample Prep KB V1	127A24
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)	116A24+124A24
DeepChek® NGS LIBRARY PREPARATION V1 (48 indexes) (RUO)	116A48+124A48
DeepChek® NGS LIBRARY PREPARATION V1 (96 indexes) (RUO)	116A96+124A96
DeepChek® NGS LIBRARY PREPARATION V1 (384 indexes) (RUO)	116A384+124A384



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