

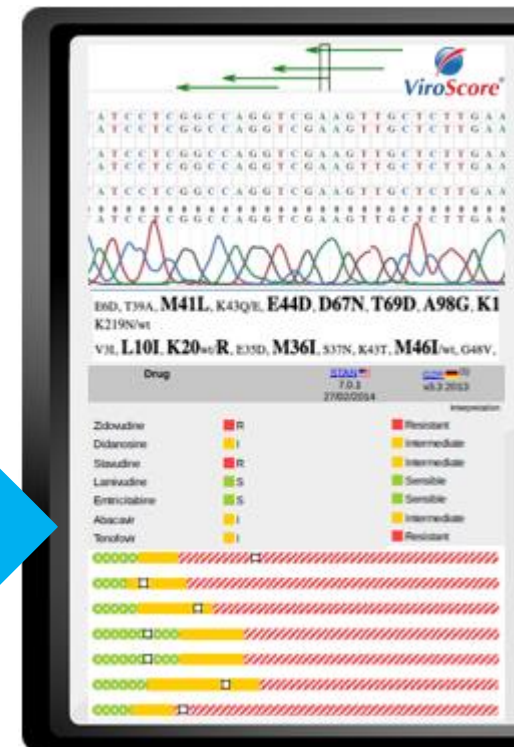
# ABL

Advanced  
Biological  
Laboratories

*Improving Disease Management*

## DeepChek® Assay 13-Plex KB Drug Susceptibility Testing V1

### End-to-End Solutions for Genotyping and Detection OF INFECTIOUS DISEASES



**Confidential & Proprietary ABL**  
**Do Not Distribute – Strictly Private and Confidential**



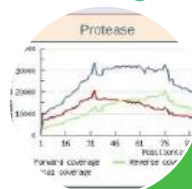
## END-TO-END

MOLECULAR  
DETECTION



Automation

- Lab workflow/Robot
- IT
- Lab Integration



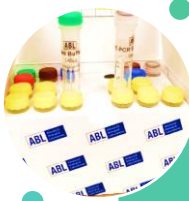
Software

- qPCR interpretation
- Genotyping interpretation



Sequencing

- Library Prep assays
- Sanger sequencing assays
- Sequencers



PCR

- qPCR instruments
- qPCR detection assays
- PCR assay



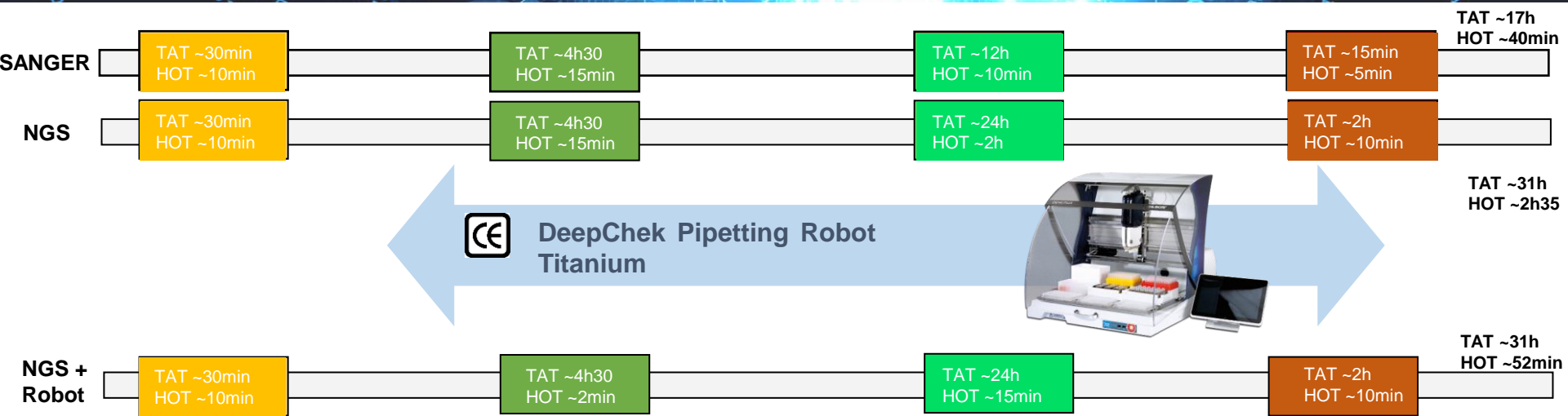
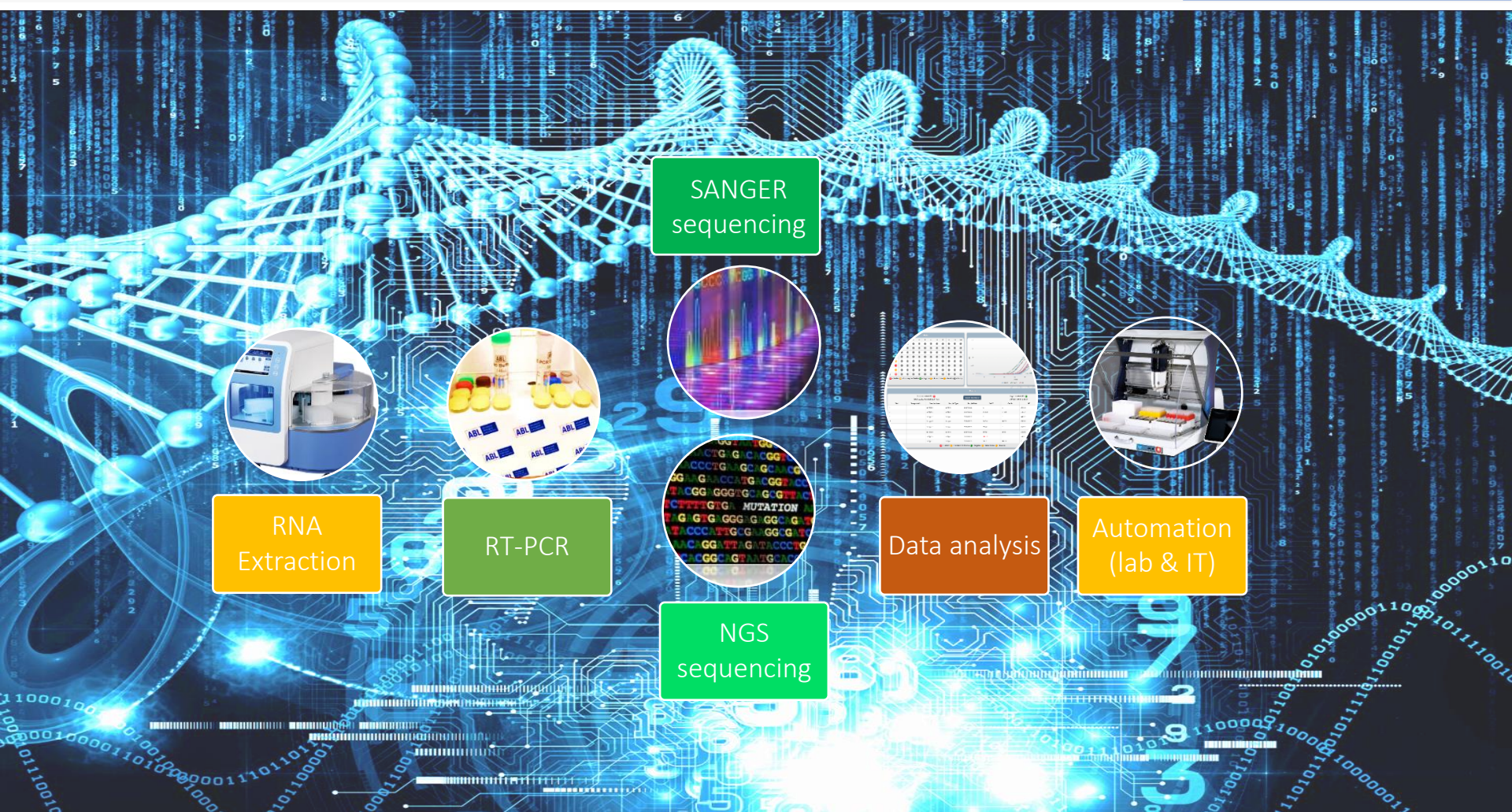
RNA/DNA Extraction

- Manual extraction
- Automatic extraction: kit + instrument



Sample collection

- Saliva collection kits
- Oro and Naso pharyngeal swabs



- **EXTRACTION**

- Validated on DNA extracted from
  - Sputum
  - Liquid cultures
  - Solid cultures
- Validated on MagNapure (ROCHE)

- **MULTIPLEX AMPLIFICATION DESIGN**

- Multiplex in one single tube
- 13 genes

- **LIBRARY PREPARATION**

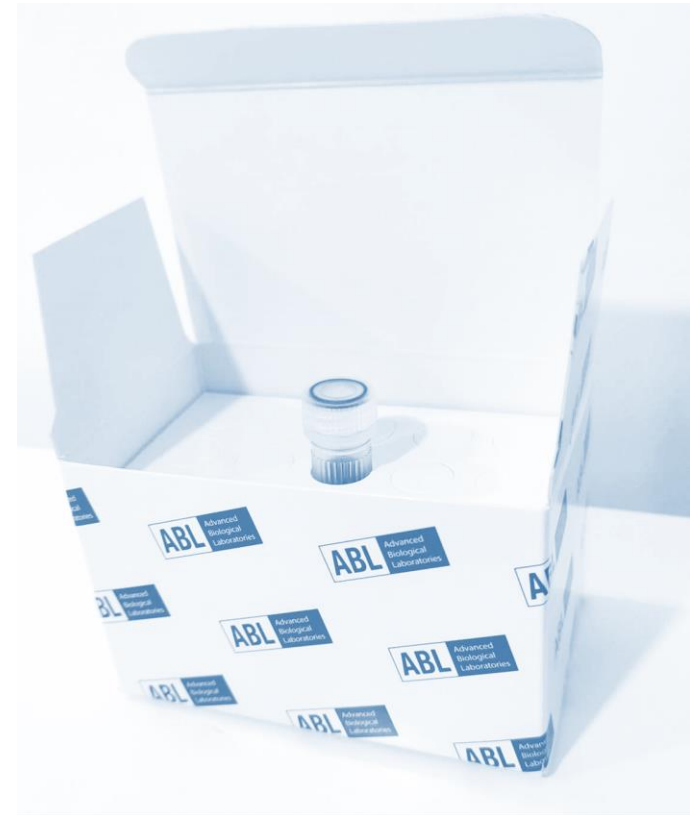
- DeepChek® NGS library preparation assay
- Available for 24, 48, 96 samples

- **SEQUENCING**

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

- **PERFORMANCES**


- Heteroresistance: Down to 0.1%
- Validated in QCMD panel
- Validated against GenXpert
- Sensitivity <1000 genomes (optimization ongoing)



## • DESIGN

<b>1st line</b>	Rifampicin	<ul style="list-style-type: none"> <li>rpoB 92-514 (Mtb)</li> </ul>
	Isoniazid	<ul style="list-style-type: none"> <li>up/mabA + inhA -140 to 1 (nt) / 1-248 (aa) +1-205 (aa)</li> <li>katG 1-271/301-692 (aa)</li> <li>furA-katG intergenic region 129-148 (aa)</li> </ul>
	Pyrazinamide	<ul style="list-style-type: none"> <li>pncA – to 190</li> </ul>
	Ethambutol	<ul style="list-style-type: none"> <li>embB 277-564 (aa)</li> </ul>
<b>2nd line</b>	Fluoroquinolones (moxifloxacin, levofloxacin)	<ul style="list-style-type: none"> <li>gyrB codons 355-630/635-676</li> <li>gyrA codons 1-264</li> </ul>
	Amikacin	<ul style="list-style-type: none"> <li>Rrs 454-1535 (nt)</li> </ul>
	Kanamycin	<ul style="list-style-type: none"> <li>Eis 1-171 (aa)</li> <li>up eis -139 to 1 (nt)</li> <li>rrs 454-1535 (nt)</li> </ul>
		Capreomycin
	Streptomycin	<ul style="list-style-type: none"> <li>Rrs 454-1535 (nt)</li> <li>rpsL 1-125 (aa)</li> </ul>
	Ethionamine	<ul style="list-style-type: none"> <li>inhA 1-205 (aa)</li> </ul>
<b>New drugs</b>	Bedaquiline Clofazimine	<ul style="list-style-type: none"> <li>Rv0678 1-166 (aa)</li> </ul>
	Linezolid	<ul style="list-style-type: none"> <li>Planned in version 2</li> </ul>

• EXAMPLE OF REPORT (ONE PAGE)



Patient / Sample Information		Sample		Physician / Project Information	
Patient ID		Alternative ID		Name	
Name		Date Collected	24/02/2020	Institution	
DOB		Date Reported	24/02/2020	Address	
Gender		Sequencing platform	Missing data		
Sample ID	QCMD8	Software version	2.0		
		Expert system	2.3		

<b>XDR-TB</b>	Extensively drug resistant TB
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DRUGS	INTERPRETATION	BacterioChek®TB (ReSeqTB v2019-01)						
Drugs	Predicted drug susceptibility	Resistance-conferring mutations > 5.00%						
		Type	Region	Name	Prevalence	Q-Score	Confidence	
TB inhibitor	Isoniazid	AA	katG	R463L	97.67%	36	LOW	
		AA	katG	S315T	99.12%	36	LOW	
		NT	katG	g944c	99.53%	36	LOW	
		NT	katG	g1388t	99.2%	36	LOW	
	Rifampicin	AA	rpoB	S450(E.coli 531)L	91.87%	36	HIGH	
		NT	rpoB	c1349t	92.95%	36	HIGH	
	Rifabutin	AA	rpoB	S450(E.coli 531)L	91.87%	36	HIGH	
		NT	rpoB	c1349t	92.95%	36	HIGH	
	Ethambutol	⊘						
	Pyrazinamide	⊘						
	Streptomycin	R	AA	rpsL	K43R	96.06%	36	HIGH
			NT	rpsL	a128g	97.06%	36	HIGH
	Fluoroquinolone	NA						
	Amikacin	S						
	Kanamycin	R	NT	upEis	g-10a	99.08%	36	MEDIUM
	Capreomycin	S						
	Linezolid	NA						
	Bedaquiline	NA						
Ethionamide	⊘							
Para-aminosalicylic acid	NA							
Cycloserine	⊘							
		AA	gyrA	D94G	41.58%	36	HIGH	
		AA	gyrA	D94N	55.92%	36	HIGH	
		NT	gyrA	a281g	42.02%	36	HIGH	
		NT	gyrA	g280a	55.03%	36	HIGH	
		AA	gyrA	D94G	41.58%	36	HIGH	
		AA	gyrA	D94N	55.92%	36	HIGH	
		NT	gyrA	a281g	42.02%	36	HIGH	
		NT	gyrA	g280a	55.03%	36	HIGH	
		AA	gyrA	D94G	41.58%	36	HIGH	
		AA	gyrA	D94N	55.92%	36	HIGH	
		NT	gyrA	a281g	42.02%	36	HIGH	
		NT	gyrA	g280a	55.03%	36	HIGH	
Levofloxacin	R							
Moxifloxacin	R							
Ofloxacin	R							

S	Susceptible	R	Resistant
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- 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

• EXAMPLE OF REPORT (MULTIPLE PAGES)

**BacterioChek® - TB Drug Resistance Determination**

ReSeqTB v2019-01

XTB assessment	20.00%	3.00%
XTB assessment	None	None

Drugs	20.00%	3.00%
Isoniazid	S	S
Rifampicin	R	R
Rifabutin	S	S
Ethambutol	S	S
Pyrazinamide	S	S
Streptomycin	S	S
Fluoroquinolone		
Levofloxacin		
Moxifloxacin		
Ofloxacin		
Amikacin		
Kanamycin		
Capreomycin		
Linezolid		
Bedaquiline		
Ethionamide		
Para-aminosalicylic acid		
Cycloserine		

XTB assessment	<b>MDR-TB</b>	Multidrug res
Interpretations	<b>S</b>	Suscept
Mutations	Type	Regio

**BacterioChek®-TB - Clinical Genotyping report**

TB analysis summary

Sample ID: QCMD2  
 Alternative ID: Missing data  
 Sample type: 21/02/2020  
 Sample date: Missing data  
 Reason for genotyping analysis: Missing data  
 Input: accD6, atpE, eis, embA, embB, embC, ethA, fbiA, fgd1, furA, gyrA, gyrB, inhA, katG, mabA, ndh, pncA, rplC, rpoA, rpoB, rpoC, rpsA, rpsL, rrs, Rv0678, thyA, ubiA, upEis, upKatG, upMabA, upWhiB7, whiB7, ponA1, Rv0191, inhR, mshA, sigI, eccC5, upFurA, upPncA, mshC, upAhpC, ahpC, Rv2731, ppsC, ppsD, mas, mymA, Rv3169, nudC, alk, nat, clpC1, upEmbA, upEthA, gidB : QCMD2\_S6\_L001\_R1\_001.fastq QCMD2\_S6\_L001\_R2\_001.fastq -> 94.83% of the 950564 initial reads mapped to TB organism

Comments

**BacterioChek®-Sanger Information**

Not available

BacterioChek®-TB software version 2.0  
 BacterioChek®-TB expert system 2.3  
 BacterioChek®-TB algorithms version 2.0

03-2018 literature review ( 03-2018 03-2018 )  
 Bonstel university ( v29 )  
 ReSeqTB ( v2019-01 01-2019 )

Classification of mutations of interest ReSeqTB-01

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





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