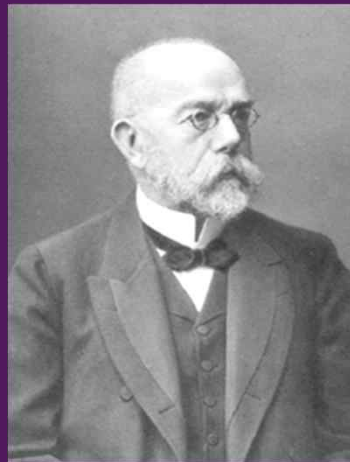


External QC for HAIN MTBDRs/



This training material is developed by ITRC as technical partner of LIFT-TB

Before
Start

Performing
QC

Example of
Reporting

Appendix:
DNA
Preparation

Appendix:
Genolyse

Appendix:
Reporting
Document

Before you start any kind of experiments, keep in mind

Validate equipment before start

- *If you do not validate equipment, you already failed.*

Don't worry for the new experiment

- *'There is nothing new under the sun'. If you understand background principle, there can be only unfamiliar to you, but nothing entirely new.*

Don't hurry up, but do accurately

- *If I have to take only one between speed and accuracy, I will take accuracy without any hesitation.*

Before Start
Performing QC
Example of Reporting
Appendix: DNA Preparation
Appendix: <u>Genolyse</u>
Appendix: Reporting Document

QC for Hain MTBDRs/ ver.2 & QC materials (Test panel DNA samples)

Purpose: To provide standardized and uniform QC procedures/QC materials for LPA to assure LIFT-TB participant laboratories in each country can perform LPA with qualified manner

Before start examinations on baseline samples, it is necessary to conduct quality control tests and assured full agreement on results: **This QC will be additional QC for LIFT-TB project (Optional issue to project participants; request to ITRC to support if necessary)**

***There are two verions of MTBDRs/ test kits available. In LIFT-TB project, use only the second version**

***LPA will be done on baseline sample (sputum) only**

Before Start
Performing QC
Example of Reporting
Appendix: DNA Preparation
Appendix: <u>Genolyse</u>
Appendix: Reporting Document

Performing QC

QC settings:

- **Test panel DNA will be provided by ITRC; *including positive control DNA***
- Positive control DNA (H37Rv) and negative control (without MTB DNA) should be included for each test batch (just in case of all the QC tests are not performed as one batch but separated into more than two batches)

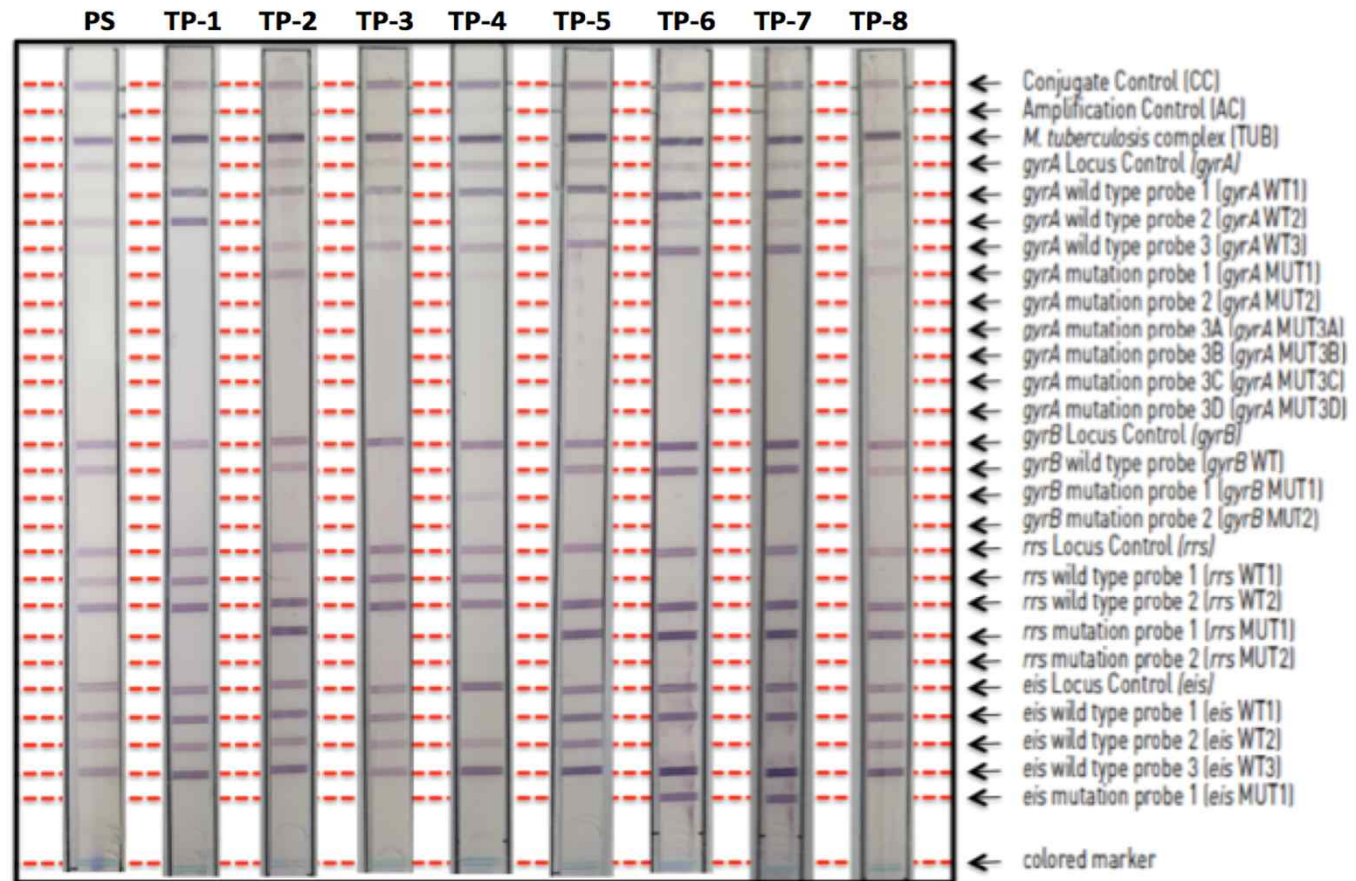
You can perform QC according to ‘User’s instruction’ from HAIN: procedure is the same as usual HAIN test except use test panel DNA

Interpret results

Observed by eye, or using a specialized scanner (GenoScan, or cellular phone application; *under developing*)

Before Start
Performing QC
Example of Reporting
Appendix: DNA Preparation
Appendix: <u>Genolyse</u>
Appendix: Reporting Document

Example of the reporting results: strips



Test panel samples will be shuffled before shipping

Before
Start

Performing
QC

Example of
Reporting

Appendix:
DNA
Preparation

Appendix:
Genolyse

Appendix:
Reporting
Document

Example of the reporting results: Interpret results

Probe	Positive control	Negative control	TP-1	TP-2	TP-3	TP-4	TP-5	TP-6	TP-7	TP-8
TUB	+	ND	+	+	+	+	+	+	+	+
<i>gyrA</i> -WT	+	ND	-	-	+	+	+	+	+	-
<i>gyrA</i> -MUT	-	ND	-	+	-	+	-	-	-	+
<i>gyrB</i> -WT	+	ND	-	+	-	-	+	+	+	+
<i>gyrB</i> -MUT	-	ND	-	-	-	+	-	-	-	-
<i>rrs</i> -WT	+	ND	+	-	+	+	-	-	-	-
<i>rrs</i> -MUT	-	ND	-	+	-	-	+	+	+	+
<i>eis</i> -WT	+	ND	+	+	+	-	+	-	-	+
<i>eis</i> -MUT	-	ND	-	-	-	-	-	+	+	-
FLQ resistant		ND	+	+	+	+				+
KAN/AMK/CAP		ND		+			+	+	+	+
KAN/CAP/VIO		ND								
KAN/AMK/CAP/ VIO		ND								
low-level KAN		ND						+	+	

Test panel samples will be shuffled before shipping

Before
Start

Performing
QC

Example of
Reporting

Appendix:
DNA
Preparation

Appendix:
Genolyse

Appendix:
Reporting
Document

Reporting document for QC results to LIFT-TB

QC Laboratory	Country:									
	Laboratory:									
Date of Testing	Date-Month-Year:									
Date of Reporting	Date-Month-Year:									
Reported by										
Confirmed by										
Probe	Positive control	Negative control	TP-1	TP-2	TP-3	TP-4	TP-5	TP-6	TP-7	TP-8
TUB										
<i>gyrA</i> -WT										
<i>gyrA</i> -MUT										
<i>gyrB</i> -WT										
<i>gyrB</i> -MUT										
<i>rrs</i> -WT										
<i>rrs</i> -MUT										
FLQ sensitive										
FLQ resistant										
KAN/AMK/CAP										
KAN/CAP/VIO										
KAN/AMK/CAP/VIO										
low-level KAN										

*Make separate report per test batch

Before Start
Performing QC
Example of Reporting
Appendix: DNA Preparation
Appendix: <u>Genolyse</u>
Appendix: Reporting Document

DNA preparation from sputum samples

HAIN MTBDRs/ kit has been intensively evaluated and used in many countries for years.

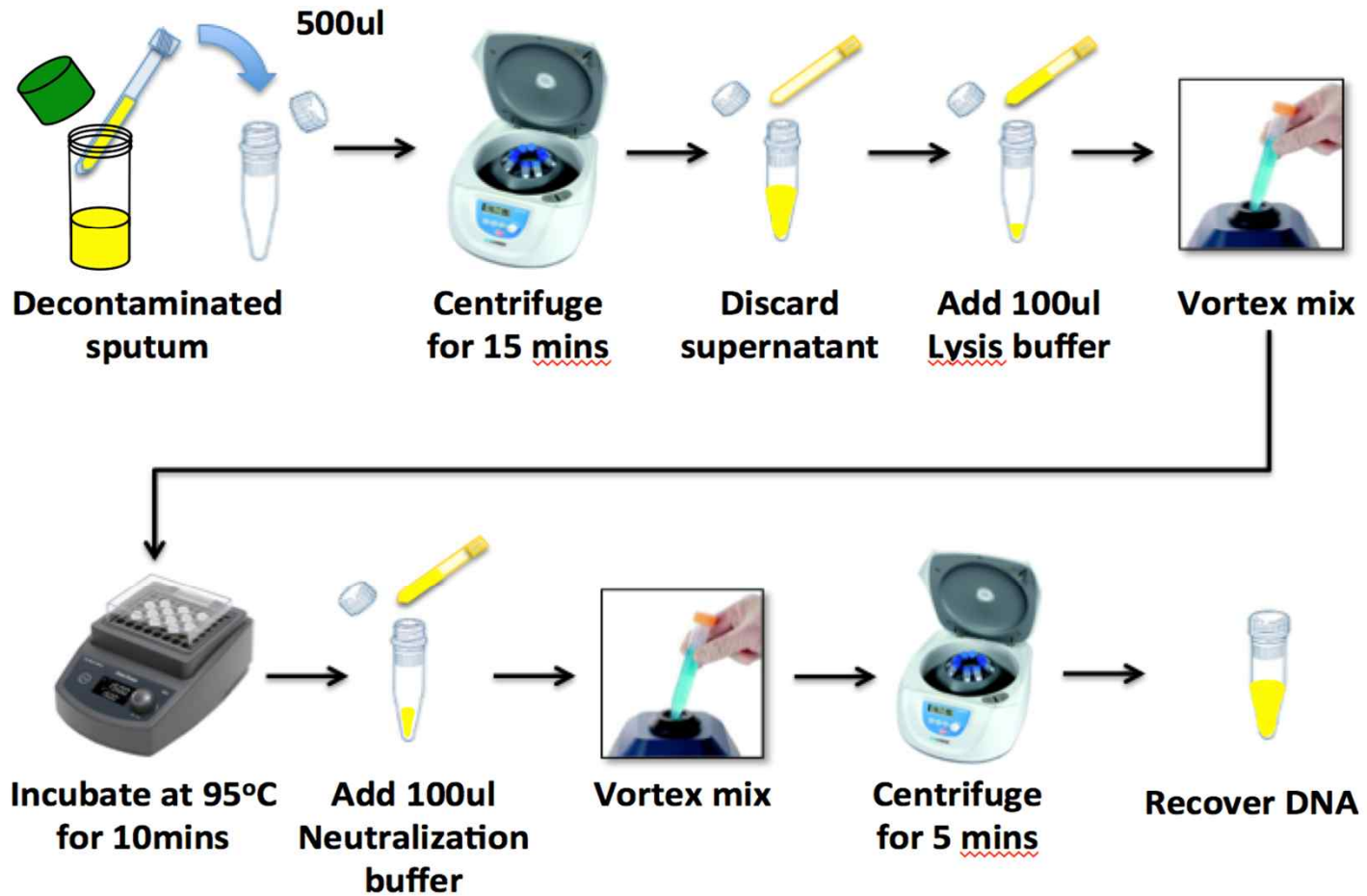
It shows very good sensitivity and specificity when Mtb isolates are tested, however there can be some invalid or failure cases when sputum samples are tested.

Most of invalids or failures come from either inappropriate DNA preparation or technical mistake. Another possibility might be sample contamination by NTM or other microbes.

To minimize the risk of invalid or failure, and also to make certain the test quality throughout project participant countries, ITRC strongly recommend to use the Genolyse to achieve such a necessary.

Before Start
Performing QC
Example of Reporting
Appendix: DNA Preparation
Appendix: Genolyse
Appendix: Reporting Document

Procedures of Genolyse



THANK YOU

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FOR QUESTIONS AND INQUIRIES

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