



Training on Proficiency Testing Scheme (GeneXpert DTS)

Module 9: PT Pre-test and Stock Selection
for Panel

Venue

Facilitator's name

Date

Introduction

In order to select suitable isolates to compose a genexpert PT panel a pretest is essential. The selected isolates are pretested before the final dilution of the panel to ensure that the desired outcome is obtained.



Objectives

By the end of this module participants should be able

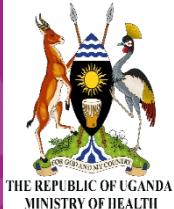
- To perform a pretest on selected isolates
- To understand the dilution factors used while carrying out a pretest
- Know the different factors that can consider a passed pretest or failed pretest
- To select suitable isolates to compose³ a



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Module outline

- What is A pretest
- Principle of pretesting
- Pretesting steps
- Pretest failure and passage
- Stock selection



What is a Pretest

- Pretest is the stage in genexpert PT preparation when inactivated selected isolates are tested, to evaluate the reliability and validity of the panel prior to final preparation and distribution.



Principle of pretesting (1)

Pre-testing should be

- conducted in circumstances that are as similar as possible to those that will be used in preparation of the final panel
 - selected dilution factor,
 - drying time
 - MTB RIF assay/Ultra
 - data analysis



Principle of pretesting (2)

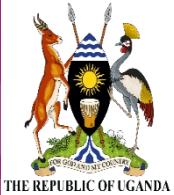
Problems encountered should be documented and possible solutions should be identified.



Pretesting Steps

1. Ensure the DTS prepared post inactivation are dry
2. Test the 5 DTS samples from each of the 8 isolates with Xpert MTB/RIF or Ultra
3. Enter Xpert MTB/RIF results and Ct data on digital DTS preparation worksheet
4. Analyze the standard deviation (SD) and mean of probe A for each stock prepared
5. Out of the 8 inactivated stock select 5 for panel preparation

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1. Ensuring DTS are Dry

DTS must be dried for a minimum of 7 days and maximum of 10 days

- Data demonstrate that when DTS are dried for 7-10 days instead of being capped when they appear dry at 4-5 days, the stability is improved

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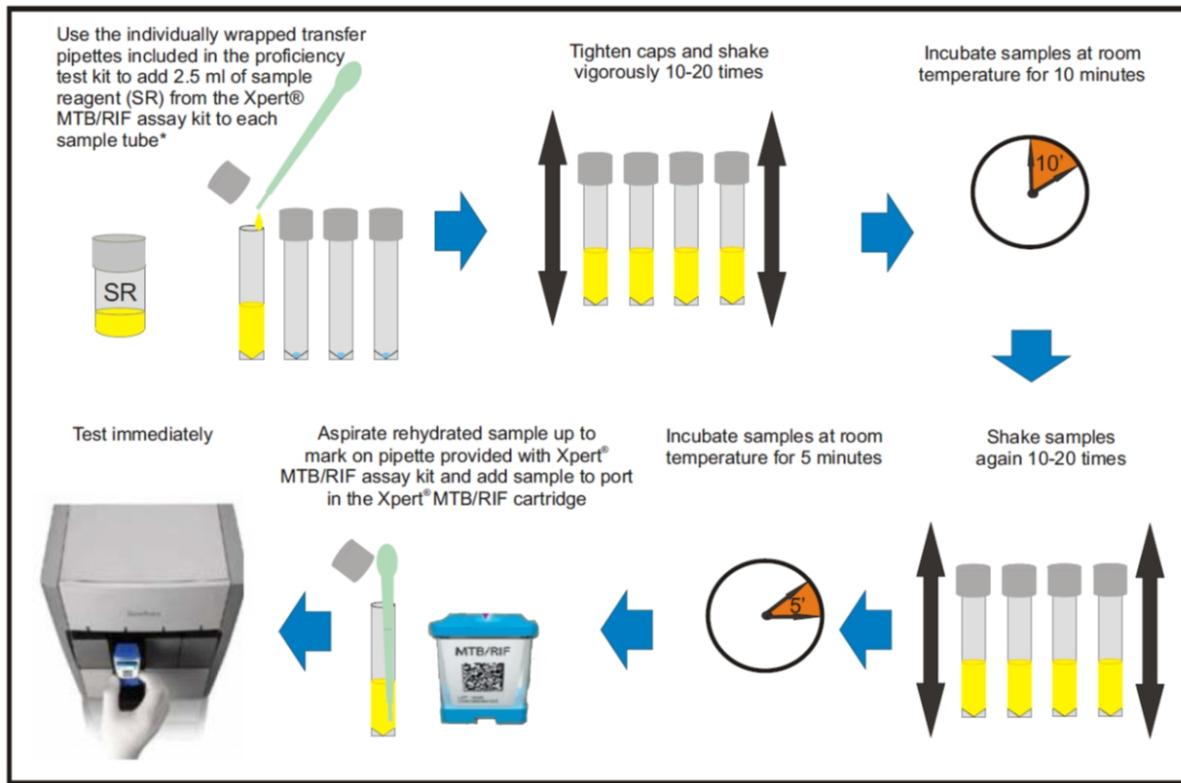
2. Test Pre-test Aliquots

- Following standard SOPs
- Test using MTB RIF/ Ultra cartridges

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2. Test Pre-test Aliquots with Xpert MTB/RIF or Ultra



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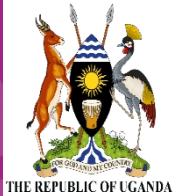


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3. Entry of results

- Enter Xpert MTB/RIF results and Ct data on digital/excel DTS preparation worksheet

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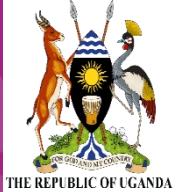


Compile Pre-test Data on DTS Preparation Worksheet

CGH/DGHA - International Laboratory Branch - Atlanta, GA

Isolate name _TB35810		Stock # _1602	MTB/RIF Assay Kit Lot #: 09002	Expiry Date: 4/30/2017	Technologist: KD	Cycle Threshold					
Aliquot	Date Tested	MTB Detected	Rif Resistance	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
				SD	Mean						
A	1/13/2016	Medium	Not Detected	20.5	20.3	21.7	20.3	26.9	19.7		
B	1/13/2016	Medium	Not Detected	19.5	18.3	20.3	18.9	24.2	18.9		
C	1/14/2016	Medium	Not Detected	21.5	21.5	22.6	21.4	24.7	20.8		
D	1/14/2016	Low	Not Detected	23.7	23.5	24.6	23.5	27.1	22.8		
E	1/14/2016	Medium	Not Detected	21.1	20.7	21.9	20.9	25.5	20.2		
F											
G											
H											
I											
J											
K											
L											
M											
N											
O											
SD				1.558204094	1.888915032	1.570868647	1.682260384	1.2930584	1.472073368		
Mean				21.26	20.86	22.22	21	25.68	20.48		
%CV				7.329276079	9.055201496	7.068715785	8.010765154	5.0552741	7.187856241		
Isolate name _HS26D		Stock # _1603	MTB/RIF Assay Kit Lot #: 09002	Expiry Date: 4/30/2017	Technologist: KD	Cycle Threshold					
Aliquot	Date Tested	MTB Detected	Rif Resistance	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
				SD	Mean						
A	1/14/2016	Low	Detected	0	23.5	24.6	24	25.8	23.1		
B	1/14/2016	Low	Detected	0	23.3	24.2	23.4	25.6	22.8		
C	1/14/2016	Low	Detected	0	25.2	26.1	25.5	27.1	24.6		
D	1/14/2016	Low	Detected	0	24.6	25.7	25.1	26.6	24.3		
E	1/14/2016	Low	Detected	0	24.5	25.5	24.8	26.1	23.9		
F											
G											
H											
I											
K											
L											
M											
N											
O											
SD				0	0.798122798	0.791833516	0.84085292	0.6107573	0.770064932		
Mean				0	24.22	25.22	24.52	26.24	23.74		
%CV				#DIV/0!	3.295304697	3.139703869	3.42917178	3.2275048	3.24374445		

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4. Analysis of pre test data

Analyze

1. the standard deviation (SD)
2. mean of probe A for MTB RIF and mean of rpoB1 for Ultra



Analysis of pre test data (SD)

SD <3 Indicates

- Sample is homogeneous
- Stable
- high consistency in preparation

SD≥ 3 Indicates

- Sample not homogenously prepared due
 - Inadequate vertexing,
 - clumping,



Analysis of pre test data (CT Values)

By measuring the threshold-cycle (Ct) of multiple probes targeting the *rpoB* gene the mycobacterial load of a sample is determined. ie
High ,medium, Low ,Very low

- Mean CT of probe A (MTB/RIF) considered - bind to the first region of the Rif resistance determining region (RRDR)
- Mean CT of *rpoB1* (Ultra) considered-because there are less mutations in *rpoB1* region. Thus the CT Values is consistent



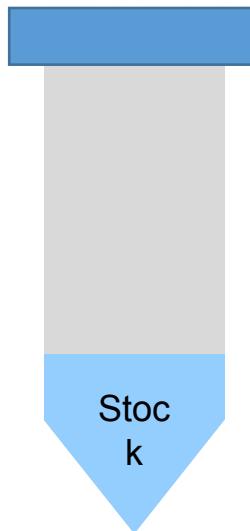
5. Stock /Panel selection

- Out of the 8 inactivated stock select 5 for panel preparation with desired:



Options for Diluting the Final Panel

1) Use neat stock, depending on how many panels you need (110 panels or less)



2) Use whole volume of stock diluted only enough to aliquot needed panel plus 2 ml for pipette error, (Example: 13:29 dilution = 42 ml = 400 aliquots)



3) Make a 1:10 dilution, good option if Ct is near 15-16 on pre-test, (Example: 4.2:37.8 = 42 ml = 400 aliquots)



Exercise: Let's Look at Some Pre-test Data from Previous Panels.....

Individually Analyze the pre-test results

- Determine the composition of your panel
 - Must have at least one of the following:
 - MTB Not Detected
 - MTB Detected, RIF Susceptible
 - MTB Detected, RIF resistant
 - Can have two or more of any of the above to achieve total of 5 samples
 - Try to ensure the validation mean Ct of probe A will be less than or equal to 23.0
 - Consider if/how you will dilute: use 1:10 or whole volume of stock diluted only enough to aliquot needed panel plus 2 ml for pipette error

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Panel 1 Exercise



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Panel 1 – Preparation and Pre-test Results

ILB-500-F23A: DTS Preparation for Xpert MTB/RIF Worksheet

DTS Preparation date: 1/6/2016

Tech: KD/PM

Turbidity and Pre-inactivation Viable Organism Quantification

Date 7H10/7H11 Agar Inoculated: 1/6/2016 KD		Date Read: 2/23/2016
Isolate Name	DTS Stock Number	Turbidity Reading
1 M. kansasii	1600	0.04
2 M. kansasii		Confluent growth
3 TB35811	1601	0.03
4 TB35811		11 cols
5 TB35810		12 cols
6 TB35810	1602	0.03
7 H526D	1603	0.03
8 H526D		14 cols
9 H526Y	1604	0.03
10 H526Y		7 cols
11 SS22L	1605	0.02
12 SS22L		133 cols
13 2011487164	1606	0.02
14 2011487164		20 cols
15 SS31L	1607	0.03
16 SS31L		6 cols
		32 cols
		8 cols
		13 cols

Reagent	Lot Number	Expiration Date
Sample Reagent (SR)	8395C301	6/19/2017
Phosphate Buffer pH 6.8	1600	1/5/2017
Saline 0.8%	1509	11/19/2016

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Xpert MTB/RIF Pretest Results

Isolate name _M. kansasii_ Stock # _1600_		Expiry Date:	4/30/2017		Technologist: KD		Cycle threshold		
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/13/2016	Not Detected	N/A	0	0	0	0	27.6	0
B	1/13/2016	Not Detected	N/A	0	0	0	0	26.2	0
C	1/13/2016	Not Detected	N/A	0	0	0	0	25.7	0
D	1/13/2016	Not Detected	N/A	0	0	0	0	25.6	0
E	1/13/2016	Not Detected	N/A	0	0	0	0	26.8	0
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	0	0	0	0.8318654	0
Mean				0	0	0	0	26.38	0
%CV				#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	3.1533941	#DIV/0!
Isolate name _TB35811_ Stock # _1601_		Expiry Date:	4/30/2017		Technologist: KD		Cycle threshold		
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/13/2016	Medium	Not Detected	21.9	21.5	22.9	21.7	25.9	21
B	1/14/2016	Medium	Not Detected	22.3	22.3	23.5	22.3	26.2	21.7
C	1/15/2016	Medium	Not Detected	20.3	20.2	21.6	20.1	24.5	19.6
D	1/16/2016	Medium	Not Detected	21.1	20.9	22.4	21.1	26	20.5
E	1/17/2016	Medium	Not Detected	21.6	21.4	22.7	21.6	27.4	20.9
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0.773304597	0.776530746	0.697853853	0.823407554	1.0319884	0.770064932
Mean				21.44	21.26	22.62	21.36	26	20.74
%CV				3.606831144	3.652543492	3.085118713	3.854904279	3.969186	3.712945672

Inactivation Verification
FAILED

ILB-500-F23A

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Effective Date: May



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Panel 1--Pre-test Results continued

Isolate name TB35810 Stock # 1602		MTB/RIF Assay Kit Lot #: 09002		Expiry Date: 4/30/2017		Technologist: KD		Cycle Threshold	
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/13/2016	Medium	Not Detected	20.5	20.3	21.7	20.3	26.9	19.7
B	1/13/2016	Medium	Not Detected	19.5	18.3	20.3	18.9	24.2	18.9
C	1/14/2016	Medium	Not Detected	21.5	21.5	22.6	21.4	24.7	20.8
D	1/14/2016	Low	Not Detected	23.7	23.5	24.6	23.5	27.1	22.8
E	1/14/2016	Medium	Not Detected	21.1	20.7	21.9	20.9	25.5	20.2
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				1.558204094	1.888915032	1.570668647	1.682260384	1.2930584	1.472073368
Mean				21.26	20.86	22.22	21	25.68	20.48
%CV				7.329276079	9.05201498	7.068715785	8.010763734	5.0352741	7.187858241
Isolate name H5260 Stock # 1603									
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/14/2016	Low	Detected	0	23.5	24.6	24	25.8	23.1
B	1/14/2016	Low	Detected	0	23.3	24.2	23.4	25.6	22.8
C	1/14/2016	Low	Detected	0	25.2	26.1	25.5	27.1	24.6
D	1/14/2016	Low	Detected	0	24.6	25.7	25.1	26.6	24.3
E	1/14/2016	Low	Detected	0	24.5	25.5	24.6	26.1	23.9
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	0.79812798	0.79183316	0.84083292	0.6107373	0.770064932
Mean				0	24.22	25.22	24.52	26.24	23.74
%CV				#DIV/0!	3.295304697	3.139703869	3.42917178	3.2375048	3.2437445

Isolate name H526Y Stock # 1604		MTB/RIF Assay Kit Lot #: 09002		Expiry Date: 4/30/2017		Technologist: KD		Cycle Threshold	
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/14/2016	Low	Detected	0	24.2	25.2	24.1	25.7	23.5
B	1/14/2016	Medium	Detected	0	23.3	22.2	21.3	24.4	20.5
C	1/14/2016	Low	Detected	0	23.5	24.1	23.2	25	22.4
D	1/14/2016	Low	Detected	0	23.8	24.4	23.7	25.6	23.2
E	1/14/2016	Low	Detected	0	24.2	24.8	24	25.6	23.3
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	1.189537725	1.161034022	1.150217571	0.5549775	1.235718415
Mean				0	23.3	24.14	23.26	25.26	22.58
%CV				#DIV/0!	5.105312126	4.80958584	4.945044586	2.1970605	5.47263625
Isolate name S522L Stock # 1605									
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/14/2016	Low	Detected	23.6	0	24.6	22.8	25.1	22.7
B	1/14/2016	Low	Detected	23.9	0	25	23.2	24.9	23.2
C	1/14/2016	Low	Detected	23.8	0	24.8	23.2	28	22.8
D	1/14/2016	Medium	Detected	21.5	0	22.6	20.9	24.5	20.5
E	1/14/2016	Medium	Detected	22.4	0	23.5	21.8	25.1	21.5
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				1.050238068	0	1.019803803	1.005982107	1.4078352	1.114899099
Mean				23.04	0	24.1	22.38	25.52	22.14
%CV				4.558324949	#DIV/0!	4.231551464	4.495004947	5.5165957	5.035677952

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Panel 1-- Pre-test Results Continued

Isolate name <u>2011487164</u> Stock # <u>1606</u>		Expiry Date: <u>4/30/2017</u>		Technologist: <u>KD</u> Cycle Threshold					
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/14/2016	Low	Detected	0	23.9	24.9	24.1	24.6	23.7
B	1/14/2016	Low	Detected	0	25.9	27.2	26.1	25.8	25.4
C	1/14/2016	Low	Detected	0	23.5	24.8	23.8	26.1	23.2
D	1/14/2016	Low	Detected	0	26.3	27.7	26.4	25.2	26.1
E	1/14/2016	Low	Detected	0	22.6	23.8	22.8	23.6	22.3
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	1.593110166	1.68136849	1.550161282	0.9989995	1.572577502
Mean				0	24.44	25.68	24.64	25.06	24.14
%CV				#DIV/0!	6.518454033	6.547385087	6.291238969	3.9864306	6.51440556
Isolate name <u>5531L</u> Stock # <u>1607</u>		Expiry Date: <u>4/30/2017</u>		Technologist: <u>KD</u> Cycle Threshold					
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
A	1/14/2016	Low	Detected	24	23.2	0	23.6	25.7	23.6
B	1/20/2016	Low	Detected	24.3	24.4	0	24.1	24.6	23.8
C	1/20/2016	Low	Detected	25.8	25.6	0	25.5	27.5	25.1
D	1/20/2016	Medium	Detected	21.4	21.5	0	21.3	22.8	20.7
E	1/20/2016	Low	Detected	23.5	23.4	0	23.1	24	22.7
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				1.592168333	1.520526225	0	1.530359435	1.7824141	1.630030675
Mean				23.8	23.62	0	23.52	24.92	23.18
%CV				6.689782911	6.437452264	#DIV/0!	6.50663025	7.1525445	7.032056404

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Panel 1 – Inactivation Verification

DTS Inactivation Verification Form									
Date of DTS Inactivation : <u>1/6/2016</u>	Initials: <u>kd</u>	Panel Name: <u>2016-A</u>							
Critical Step Checklist									
1. In the BSL3 laboratory in a BSC, transfer each MGIT culture into labeled conical tube. 2. Add sample reagent (SR) to each conical tube, in a 1:2 ratio of MGIT culture to SR. Tighten cap and vortex each tube for 30 seconds. 3. Incubate at room temperature for 2 hours, vortexing for 10 seconds every 15 minutes during incubation.									
			Start Time: <u>10:42 AM</u>	End Time: <u>12:46:00 PM</u>					
Isolate Name	DTS Stock Number	Date Inoculated/Tech	42 Day Incubation Result (Positive/Negative and Date)*	84 Day Incubation Result (Positive/Negative and Date)*	Final Result	Date/Tech	Comments**		
M. kansasii	1600	1/6/2016 kd	Positive 1/21/2016 KD		Positive	4/15/2016 KD	Stock discarded/autoclaved 2/29/16 KD		
TB35811	1601	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
TB35810	1602	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
H526D	1603	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
H526Y	1604	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
S522L	1605	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
2011487164	1606	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
S531L	1607	1/6/2016 kd	Negative 2/18/2016 KD	Negative 2/18/2016 KD	Negative	4/15/2016 KD			
*File copies of all unloaded positive and negative MGIT 960 Reports directly behind this report in the DTS Preparation Binder for the current year. **If culture is positive, indicate date all related cultures and DTS samples discarded									
Supervisor Signature _____			Date _____						

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Panel 2 Exercise

Enter section subtitle



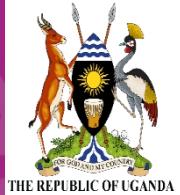
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Panel 2 -- Preparation and Pre-test Results

ILB-500-F23A: DTS Preparation for Xpert MTB/RIF Worksheet		
DTS Preparation date: 3/11/2016		Tech: KD
Turbidity and Pre-inactivation Viable Organism Quantification		
Date 7H10/7H11 Agar Inoculated:	3/11/2016	Date Read:
Isolate Name	DTS Stock Number	Turbidity Reading
1 S522L	1608	51, 35, 42
2 S522L		0.03 28, 26, 21
3 2011487164	1609	21, 22, 16
4 2011487164		0.03 25, 12, 13
5 2011487162	1610	13, 15, 16
6 2011487162		0.01 8, 14, 11
7 M. intracellularae	1611	CF
8 M. intracellularae		0.06 CF
9 M. kansasii	1612	CF
10 M. kansasii		0.03 CF
11 H37Rv	1613	65, 32, 39
12 H37Rv		0.03 15, 18, 28
13 TB35811	1614	60, 65, 68
14 TB35811		0.03 108, 120, 143
15 H526Y	1615	46, 78, 71
16 H526Y		0.02 55, 44, 26
Reagent		
Sample Reagent (SR)	1085C076	Expiration Date 2/16/2018
Phosphate Buffer pH 6.8	1602	3/10/2017
Saline 0.8%	1509	11/19/2016

Xpert MTB/RIF Pretest Results											
Isolate name: S522L		Stock #:	1608	Expiry Date:	4/30/2017	Technolo	KD	Cycle Threshold			
	MTB/RIF Assay Kit	9002				Probe D	Probe C	Probe E	Probe B	SPC	Probe A
Aliquot	Date Tested	MTB Detected	Rif Resistance								
A	3/18/2016	Low	Detected		23.1	0	24.4	22.5	27.2	22.3	
B	3/18/2016	Low	Detected		23.1	0	24.4	22.5	26.9	22.5	
C	3/18/2016	Medium	Detected		21.4	0	22.7	20.7	26.2	20.6	
D	3/18/2016	Low	Detected		23.6	0	24.7	22.9	26	22.8	
E	3/18/2016	Medium	Detected		21.5	0	22.9	21.2	25.3	20.9	
F											
G											
H											
I											
J											
K											
L											
M											
N											
O											
SD				1.016366076	0	0.94180677	0.9528903	0.752394	0.9984989		
Mean				22.54	0	23.82	21.96	26.32	21.82		
%CV				4.503165263	#DIV/0!	3.95384876	4.3392092	2.86032	4.5760718		
Isolate name: 7164		Stock #:	1609	Expiry Date:	4/30/2017	Technolo	Kyle	Cycle Threshold			
	MTB/RIF Assay Kit	03002				Probe D	Probe C	Probe E	Probe B	SPC	Probe A
Aliquot	Date Tested	MTB Detected	Rif Resistance								
A	3/18/2016	Low	Detected		0	23.2	24.1	23.2	25.3	22.7	
B	3/18/2016	Low	Detected		0	23.8	24.9	23.9	25.5	23.3	
C	3/18/2016	Low	Detected		0	24.6	25.5	24.6	25.6	24.1	
D	3/18/2016	Medium	Detected		0	22.1	23.4	22.3	24	21.7	
E	3/18/2016	Low	Detected		0	23.7	25.3	24.3	25.2	24	
F											
G											
H											
I											
J											
K											
L											
M											
N											
O											
SD				0	0.92032603	0.87635609	0.93214715	0.645755	0.9939819		
Mean				0	23.48	24.64	25.46	25.12	23.16		
%CV				#DIV/0!	3.919516582	3.556633938	142.3995	2.570582	4.2916044		

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Panel 2 -- Pre-test Results Continued

Isolate name 7162 Stock # 1610		MTB/RIF Assay Kit 09002 Expiry Date: 4/30/2016 Technolo kyle								
Aliquot	Date Tested	Results		Cycle Threshold						
		MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/19/2016	Low	Detected	25	25	26.1	0	26.7	24.4	
B	3/19/2016	Low	Detected	25	25	27.1	0	23.7	25.6	
C	3/19/2016	Low	Undetected	24	25.9	24.5	0	24.3	23.3	
D	3/19/2016	Low	Detected	24.9	24.8	26	0	24	24.4	
E	3/19/2016	Low	Detected	27.9	27.4	29	0	26.1	27.1	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				1430734077	132476413	155016128	0	1348332	1446/204	
Mean				25.48	25.4	26.64	0	24.96	24.96	
%CV				5.615125892	5.21560681	5.81892373	BDIV0!	5.401972	5.7961566	

Isolate name Intracellularae Stock # 1611		MTB/RIF Assay Kit 09002 Expiry Date: 4/30/2016 Technolo kyle								
Aliquot	Date Tested	Results		Cycle Threshold						
		MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/23/2016	Not Detected	NA	0	0	0	0	25.9	38.5	
B	3/23/2016	Not Detected	NA	0	0	0	0	23.7	0	
C	3/23/2016	Not Detected	NA	0	0	0	0	25.2	0	
D	3/23/2016	Not Detected	NA	0	0	0	0	23	37.2	
E	3/23/2016	Not Detected	NA	0	0	0	0	25	0	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0	0	0	0	0.415933	20.736393	
Mean				0	0	0	0	25.36	15.14	
%CV				#DIV/0!	#DIV/0!	#DIV/0!	BDIV0!	1640113	136.96429	

Isolate name Kansasii Stock # 1612		MTB/RIF Assay Kit 09002 Expiry Date: 4/30/2017 Technolo kyle								
Aliquot	Date Tested	Results		Cycle Threshold						
		MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/23/2016	Not Detected	NA	0	0	0	0	0	0	25.8
B	3/23/2016	Not Detected	NA	0	0	0	0	0	0	25.5
C	3/23/2016	Not Detected	NA	0	0	0	0	0	0	25
D	3/23/2016	Not Detected	NA	0	0	0	0	0	0	24.2
E	3/23/2016	Not Detected	NA	0	0	0	0	0	0	23.2
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0	0	0	0	0	0	0.642651
Mean				0	0	0	0	0	0	25.16
%CV				#DIV/0!	#DIV/0!	#DIV/0!	BDIV0!	2554256	#DIV/0!	

Isolate name H37Rv Stock # 1613		MTB/RIF Assay Kit 09002 Expiry Date: 4/30/2017 Technolo kyle								
Aliquot	Date Tested	Results		Cycle Threshold						
		MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/24/2016	Low	Not Detected	24	24.1	25.4	24.1	25.7	23.8	
B	3/25/2016	Low	Not Detected	24.1	24.1	25.3	24.1	25.9	23.5	
C	3/26/2016	Low	Not Detected	24.6	23.3	24.5	23.7	25.9	23	
D	3/27/2016	Low	Not Detected	24.6	24.5	25.6	24.5	25.3	24.1	
E	3/28/2016	Low	Not Detected	23.8	23.6	24.8	23.7	26.1	22.9	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0.363318042	0.4716876	0.45497253	0.334664	0.303315	0.512353	
Mean				24.22	23.92	25.12	24.02	25.78	23.46	
%CV				15000.74494	19897.6905	1811196.35	13932723	1176552	2.1859985	

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Panel 2 -- Pre-test Results Continued

	Isolate name 35811 Stock # 1614		Results		Expiry Date: 4/30/2017		Technolo Kyle		Cycle Threshold	
Aliquot	MTB/RIF Assay Kit 09002									
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/24/2016	Low	Not Detected	23.7	23.5	24.7	23.6	26.4	22.9	
B	3/25/2016	Medium	Not Detected	21.9	20.3	21.9	21.2	27	20.2	
C	3/26/2016	Low	Not Detected	25.8	25.5	26.8	25.4	26.6	25	
D	3/27/2016	Low	Not Detected	25.8	25.2	26.6	25.5	27.3	24.7	
E	3/28/2016	Medium	Not Detected	22.5	22.5	23.7	22.4	24.6	21.9	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				1.817415748	2.12602916	2.05255938	1.8740331	1.054514	1.9957455	
Mean				23.94	23.4	24.74	23.62	26.38	22.94	
%CV				7.591544477	9.08559471	8.29652133	7.9340943	3.9974	8.6938495	
<hr/>										
	Isolate name H526Y Stock # 1615		Results		Expiry Date: 4/30/2017		Technolo Kyle		Cycle Threshold	
Aliquot	MTB/RIF Assay Kit 09002									
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
A	3/24/2016	Low	Detected	0	19.1	20.7	20.3	22	19.3	
B	3/25/2016	Low	Detected	0	25.1	26	24.9	25	24.4	
C	3/26/2016	Low	Detected	0	25.2	27	25.2	23.8	25.9	
D	3/27/2016	Low	Detected	0	24.9	26.1	24.6	24.4	24.4	
E	3/28/2016	Low	Detected	0	24.4	25.4	24.2	25.9	23.7	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0	2.61208729	2.49258902	2.0132064	1.463557	2.5025986	
Mean				0	23.74	25.04	23.84	24.22	23.54	
%CV				#DIV/0!	11.0028951	9.95442898	8.4446577	6.042763	10.63126	

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Panel 2– Inactivation Verification

DTS Inactivation Verification Form							
Date of DTS Inactivation : <u>3/11/2016</u>	Initials: <u>kd</u>	Panel Name: <u>2016-B</u>					
Critical Step Checklist							
1. In the BSL3 laboratory in a BSC, transfer each MGIT culture into labeled conical tube.							
2. Add sample reagent (SR) to each conical tube, in a 1:2 ratio of MGIT culture to SR. Tighten cap and vortex each tube for 30 seconds.							
3. Incubate at room temperature for 2 hours, vortexing for 10 seconds every 15 minutes during incubation.							
				Start Time: <u>10:42 AM</u>	End Time: <u>12:40 PM</u>		
Isolate Name	DTS Stock Number	Date Inoculated/Tech	42 Day Incubation Result (Positive/Negative and Date)*	84 Day Incubation Result (Positive/Negative and Date)*	Final Result	Date/Tech	
SS22L	1608	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
2011487164	1609	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
2011487162	1610	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
M. intracellulare	1611	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
M. kansasii	1612	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
H37Rv	1613	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
TB35811	1614	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	
H526Y	1615	03/11/2016 kd	Negative 4/26/16	Negative 6/13/16	N	7/12/16 KD	

*File copies of all unloaded positive and negative MGIT 960 Reports directly behind this report in the DTS Preparation Binder for the current year.
**If culture is positive, indicate date all related cultures and DTS samples discarded

Supervisor Signature _____ Date _____

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Panel 2 Validation Summary

DTS for Xpert MTB/RIF Panel Validation Worksheet									
Panel/sample ID	Isolate Name		Stock Number	Date Diluted and Aliquoted		Tech			
2016-B-1	H37Rv		1613	6/15/2016		KD			
2016-B-2	S522L		1608	6/20/2016		KD			
2016-B-3	M. intracellulareae		1611	6/17/2016		KD			
2016-B-4	TB35811		1614	6/14/2016		KD			
2016-B-5	M. kansasii		1612	7/12/2016		KD			
Validation Summary									
	Panel/Sample ID	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
SD	H37Rv_1613	Low	Not Detected	1.86763	2.02323	1.95442	2.03911	1.9414	2.01869
Mean				23.3237	22.339	23.5915	22.9881	25.651	22.0203
%CV				8.00743	9.05694	8.28441	8.87026	7.5686	9.16737
SD	S522L_1608	Medium	Detected	2.11868	10.6253	1.96952	2.03996	2.288	1.99227
Mean				23.0172	3.57241	23.3448	22.1224	25.909	21.6707
%CV				9.20477	297.425	8.43664	9.22122	8.8309	9.19337
SD	M. intracell. 1611	Not Detected	N/A	0	0	0	0	2.319	14.1053
Mean				0	0	0	0	26.724	32.6966
%CV				0	0	0	0	8.6776	43.14
SD	TB35811_1614	Medium	Not Detected	2.56828	2.77253	2.66988	2.74594	3.0609	2.71745
Mean				22.1035	20.886	22.2509	21.4982	25.33	20.6211
%CV				11.6193	13.2746	11.999	12.7728	12.084	13.1781
SD	M. kansasii_1612	Not Detected	N/A	0	4.62176	4.81541	0	1.518	0
Mean				0	0.59667	0.62167	0	26.737	0
%CV				0	774.597	774.597	0	5.6777	0

Page 1

Tough panel

- H526Y_1615
 - Mean Ct for Probe A = 24.8
- 7164_1609
 - Mean Ct for Probe A = 25.9

Panel 3 Exercise

Enter section subtitle



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Panel 3 – Preparation and Pre-test Results

ILB-500-F23A: DTS Preparation for Xpert MTB/RIF Worksheet		
DTS Preparation date: 6/13/2018		
Pre-inactivation Purity Check		Tech: kd
Date 7H11 Agar Inoculated:		Date Read: 7/3/18 kd
Isolate Name	DTS Stock Number	Morphology at 3 weeks
1 MTB H526D 3005010458		R, B, I
2 MTB H526D 3005010458	1816	R, B, I
3 MTB H526D 3005010458		R, B, I
4 MTB H526D 3005010458		R, B, I
5 MTB s522L 3005010448		R, B, I
6 MTB s522L 3005010448	1817	R, B, I
7 MTB s522L 3005010448		R, B, I
8 MTB s522L 3005010448		R, B, I
9 MTB s531L 3005010457		R, B, I
10 MTB s531L 3005010457	1818	R, B, I
11 MTB s531L 3005010457		R, B, I
12 MTB s531L 3005010457		R, B, I
13 MTB H526Y 3005010449		R, B, I
14 MTB H526Y 3005010449	1819	R, B, I
15 MTB H526Y 3005010449		R, B, I
16 MTB H526Y 3005010449		R, B, I
17 MTB 35810 3005010452		R, B, I
18 MTB 35810 3005010452	1820	R, B, I
19 MTB 35810 3005010452		R, B, I
20 MTB 35810 3005010452		R, B, I
21 MTB H37Rv 3005010		R, B, I
22 MTB H37Rv 3005010	1821	R, B, I
23 MTB H37Rv 3005010		R, B, I
24 MTB H37Rv 3005010		R, B, I
25 M. gordonae 3005010	1822	Y, W
26 M. gordonae 3005010		Y, W
27 M. intracellulare 3005010456	1823	B, W
28 M. intracellulare 3005010456		B, W

* Morphology Abbreviations: B=Buff, R=Rough, I=Irregular, W=Wet, Y=Yellow, M=Mucoid, S=Spreading

Reagent	Lot Number	Expiration Date
Saline 0.8%	1710	8/3/2018

Xpert MTB/RIF Pretest Results									
Isolate name_H526D_Stock #_1816		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo[KD]Cycle Threshold			
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
1816_H526d_A	7/27/2018 10:17	MTB DETECTED	Rif Resistance DETECTED	0	24.9	26.2	25.5	26.1	24.4
1816_H526d_B	7/27/2018 10:17	MTB DETECTED	Rif Resistance DETECTED	0	23.4	24.7	23.9	27.8	22.9
1816_H526d_C	7/27/2018 10:17	MTB DETECTED	Rif Resistance DETECTED	0	25.2	26.3	25.8	28.2	24.6
1816_H526d_D	7/27/2018 10:18	MTB DETECTED	Rif Resistance DETECTED	0	22.6	23.7	22.9	28.3	21.9
1816_H526d_E	7/27/2018 10:31	MTB DETECTED	Rif Resistance DETECTED	0	22.6	24.1	23.3	25.9	22.2
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	124418648	1.19582607	1.3046072	1.167476	1.2429803
Mean				0	23.74	25	24.28	27.26	23.2
%CV				#DIV/0!	5.24088661	4.7833043	5.3731764	4.282744	5.3576737
Isolate name_s522L_Stock #_1817		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo[KD]Cycle Threshold			
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A
s522l_1817_A	7/27/2018 10:32	MTB DETECTED	Rif Resistance DETECTED	21.9	0	23.3	21.3	26.1	21.1
s522l_1817_B	7/27/2018 10:32	MTB DETECTED	Rif Resistance DETECTED	24.6	0	26	24.1	29.9	24
s522l_1817_C	7/27/2018 10:33	MTB DETECTED	Rif Resistance DETECTED	21.9	0	23.2	21.1	31.9	20.7
1817_s522L_D	8/7/2018 9:28	MTB DETECTED	Rif Resistance DETECTED	22.2	0	23.6	21.7	34.3	21.2
1817_s522L_E	8/7/2018 9:28	MTB DETECTED	Rif Resistance DETECTED	21.1	0	22.2	20.3	25.2	19.9
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				1.3277801	0	1.40996454	1.43527	3.840833	1.5514509
Mean				22.34	0	23.66	21.7	29.48	21.38
%CV				#DIV/0!	5.94350986	5.95927531	6.6141475	13.02861	7.2565525

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Panel 3-- Pre-test Results Continued

Isolate name _s531L Stock # _1818		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo KD		Cycle Threshold	
Aliquot	Date Tested	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
		MTB Detected	Rif Resistance						
1818_S531_L_A	9/7/2018 9:29	MTB DETECTED	Rif Resistance DETECTED	23.5	23.2	0	23.6	30.7	22.5
1818_S531_L_B	9/7/2018 9:30	MTB DETECTED	Rif Resistance DETECTED	24.2	23.9	0	24.1	29.6	23.3
1818_S531_L_C	9/7/2018 9:30	MTB DETECTED	Rif Resistance DETECTED	25.4	25.4	0	25.4	31	24.6
1818_S531_L_D	9/7/2018 9:31	MTB DETECTED	Rif Resistance DETECTED	22.8	22.3	0	22.8	29.8	21.7
1818_S531_L_E	9/7/2018 9:31	MTB DETECTED	Rif Resistance DETECTED	21.2	20.7	0	21	24.4	20.2
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				156907616	175641681	0	16315637	2.692582	18562005
Mean				23.42	23.1	0	23.38	29.1	22.46
%CV				6.69972742	7.60353956	#DIV/0!	6.9784588	9.25286	7.3740003

Isolate name _1819 Stock # _H526Y		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo KD		Cycle Threshold	
Aliquot	Date Tested	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
		MTB Detected	Rif Resistance						
1819_H526_Y_A	9/7/2018 9:32	MTB DETECTED	Rif Resistance DETECTED	0	25.2	26.3	25.4	29.7	24.6
1819_H526_Y_B	9/7/2018 9:32	MTB DETECTED	Rif Resistance DETECTED	0	24.3	25.3	24.5	26.1	23.4
1819_H526_Y_C	9/7/2018 9:33	MTB DETECTED	Rif Resistance DETECTED	0	25.4	26.6	25.5	34.7	24.5
1819_H526_Y_D	9/7/2018 9:33	MTB DETECTED	Rif Resistance DETECTED	0	28.2	29	28.2	30.1	27.3
1819_H526_Y_E	9/7/2018 9:34	MTB DETECTED	Rif Resistance DETECTED	0	29.7	30.7	30.5	39.4	28.9
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0	2.28319951	2.21065601	2.4793144	5.141984	2.2766203
Mean				0	26.56	27.58	26.82	32	25.74
%CV				#DIV/0!	8.5953837	8.01543151	9.2442745	16.0687	8.8446787

Isolate name _TB35810 Stock # _1820		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo KD		Cycle Threshold	
Aliquot	Date Tested	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
		MTB Detected	Rif Resistance						
1820_35810_A	9/7/2018 9:34	MTB DETECTED	Rif Resistance NOT DETECTED	219	213	22.3	21.7	28.2	20.7
1820_35810_B	9/7/2018 9:36	MTB DETECTED	Rif Resistance NOT DETECTED	25.5	25.2	26.5	25.6	27.7	24.6
1820_35810_C	9/7/2018 9:36	MTB DETECTED	Rif Resistance NOT DETECTED	23.3	22.8	24.3	23.1	25.3	22.2
1820_35810_D	9/7/2018 9:37	MTB DETECTED	Rif Resistance NOT DETECTED	216	211	22.6	21.3	26.3	20.4
1820_35810_E	9/7/2018 9:50	MTB DETECTED	Rif Resistance NOT DETECTED	22.3	21.6	23.4	22.2	24.3	21.9
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				15786098	169852878	15633947	1.737678	1546509	1.707337
Mean				22.92	22.4	23.94	22.78	26.48	21.9
%CV				6.88745501	7.58271775	6.55553378	7.5231246	5.840563	7.8312616

Isolate name _H37Rv Stock # _1821		MTB/RIF Assay Kit Lot #: 22801		Expiry Date: 6/30/2019		Technolo KD		Cycle Threshold	
Aliquot	Date Tested	Results		Probe D	Probe C	Probe E	Probe B	SPC	Probe A
		MTB Detected	Rif Resistance						
1821_H37Rv_A	9/7/2018 9:51	MTB DETECTED	Rif Resistance NOT DETECTED	215	20.9	22.6	21.4	31	20.6
1821_H37Rv_B	9/7/2018 9:51	MTB DETECTED	Rif Resistance NOT DETECTED	218	21.2	22.8	21.6	26	20.7
1821_H37Rv_C	9/7/2018 9:52	MTB DETECTED	Rif Resistance NOT DETECTED	22.9	22.4	24	22.7	27.4	21.9
1821_H37Rv_D	8/9/2018 13:34	Error 501: Signal loss detected in the amplification curve for analyte [Probe C]. 19.8 decrease in signal with 20.1% decrease		23.6	23.6	25	23.8	30.8	23.2
1821_H37Rv_E	8/9/2018 13:35	MTB DETECTED	Rif Resistance NOT DETECTED						
F									
G									
H									
I									
J									
K									
L									
M									
N									
O									
SD				0.97467943	1.23389527	1.11952371	1.1006779	2.492656	1.2192894
Mean				22.45	22.025	23.6	22.375	28.8	21.6
%CV				4.3415565	5.6022532	4.74374453	4.954985	8.655055	5.6448564

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Panel 3 --Pre-test Results Continued

Isolate name <u>M. gordonae</u>		Stock # <u>1822</u>			Technolo		Cycle Threshold			
MTB/RIF Assay Kit Lot #: <u>22801</u>		Expiry Date:	<u>6/30/2019</u>							
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
1822_GORD_1	8/9/2018 13:36	MTB NOT DETECTED		0	40.2	0	0	29.4	0	
1822_GORD_2	8/9/2018 13:36	MTB NOT DETECTED		0	37.8	0	0	25.6	0	
1822_GORD_3	8/9/2018 13:26	MTB NOT DETECTED		0	40.1	0	0	31.8	0	
1822_GORD_4	8/9/2018 13:26	MTB NOT DETECTED		0	39.2	0	0	34	0	
1822_GORD_5	8/9/2018 13:27	MTB NOT DETECTED		0	38	0	0	33.1	0	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0	113049662	0	0	3.373722	0	
Mean				0	39.05	0	0	30.78	0	
%CV				#DIV/0!	2.89423098	#DIV/0!	#DIV/0!	10.95076	#DIV/0!	
Isolate name <u>M. intracellulare</u>		Stock # <u>1823</u>			Technolo		Cycle Threshold			
MTB/RIF Assay Kit Lot #: <u>22801</u>		Expiry Date:	<u>6/30/2019</u>							
Aliquot	Date Tested	MTB Detected	Rif Resistance	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
1823_INTRCL_1	8/9/2018 13:28	MTB NOT DETECTED		0	0	0	0	28.2	39.1	
1823_INTRCL_2	8/9/2018 13:28	MTB NOT DETECTED		0	0	0	0	23.4	39	
1823_INTRCL_3	8/9/2018 13:28	MTB NOT DETECTED		0	0	0	0	31.4	39.2	
1823_INTRCL_4	8/9/2018 13:29	MTB NOT DETECTED		0	0	0	0	32.1	36.5	
1823_INTRCL_5	8/9/2018 13:29	MTB NOT DETECTED		0	0	0	0	27.4	37	
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
SD				0	0	0	0	2.017424	1.3011533	
Mean				0	0	0	0	23.7	38.16	
%CV				#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	6.792674	3.409731	

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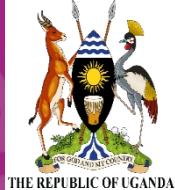


Panel 3 Inactivation Verification

CGH/DGHT - International Laboratory Branch - Atlanta, GA

DTS Inactivation Verification Form								
Date of DTS Inactivation : <u>06/13/2018</u>	Initials: <u>KD</u>	Panel Name: <u>2018-B</u>						
Critical Step Checklist								
1. Remove MGIT tubes from biotransport container and place in pre-heated racks inside oven.								
2. Close oven door tightly and wait for temperature to stabilize between 30 and 85°C. Start the timer for 30 minutes, record the time and temperature.								
3. After 30 minutes has elapsed verify oven temperature is 80-85°C, record the temperature and time on the inactivation verification worksheet. Start timer for additional 30 minutes.				Start Time: <u>9:45 AM</u>	Time at 30 min.: <u>10:15</u>	End Time: <u>10:45</u>		
4. Once a total of 1 hour has elapsed verify temperature is 80-85°C. Remove MGIT tubes from the oven and record the temperature and time removed.				Start Temp: <u>80.0</u>	Temp at 30 min.: <u>82.9</u>	End Temp: <u>83.0</u>		
Isolate Name	DTS Stock Number	Date Inoculated/Tech	42 Day Incubation Result (Positive/Negative and Date)*	84 Day Incubation Result (Positive/Negative and Date)*	Final Result	Date/Tech	Comments**	
MTB H526D 3005010458	1816	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
MTB s522L 3005010448	1817	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
MTB s531L 3005010457	1818	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
MTB H526Y 3005010449	1819	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
MTB 35810 3005010452	1820	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
MTB H37Rv 3005010	1821	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
M. gordonae 3005010	1822	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
M. intracellulare 3005010456	1823	<u>6/13/18 KD</u>	<u>Neg 7/26/18 100</u>	<u>Neg 9/10/18 100</u>	<u>Neg</u>	<u>9/10/18 100</u>		
*File copies of all unloaded positive and negative MGIT 960 Reports directly behind this report in the DTS Preparation Binder for the current year.								
**If culture is positive, indicate date all related inactivated stock and DTS samples discarded								
Supervisor Signature _____			Date _____					

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Panel 3 Validation Summary

DTS for Xpert MTB/RIF Panel Validation Worksheet									
Panel/sample ID	Isolate Name	Stock Number	Date Diluted and Aliquoted	m aliquoted	Specimen				
2018-B-1	s531L M. tuberculosis	1818	9/5/2018	4084	KD				
2018-B-2	M. gordonae	1822	8/10/2018	4084	KD				
2018-B-3	s522L M. tuberculosis	1817	8/17/2018	4084	KD				
2018-B-4	H37Rv M. tuberculosis	1821	8/10/2018	4083	KD				
2018-B-5	H525D M. tuberculosis	1816	8/17/2018	4083	KD				
Validation Summary									
	Panel/Sample ID	MTB / RIF Result	Probe D	Probe C	Probe E	Probe B	SPC	Probe A	
SD	2018-B-1_s531L_1818	MTB DETECTED;Rif Resistance DETECTED	1.9	2.1	0.0	2.1	1.4	2.0	
Mean			21.9	21.2	0.0	21.9	26.1	20.8	
%CV			8.9	9.9	#DIV/0!	9.6	5.3	9.7	
SD	2018-B-2_gord_1822	MTB NOT DETECTED	0.0	20.0	0.0	0.0	2.4	0.0	
Mean			0.0	23.2	0.0	0.0	28.1	0.0	
%CV			#DIV/0!	86.3	#DIV/0!	#DIV/0!	8.5	#DIV/0!	
SD	2018-B-3_s522L_1817	MTB DETECTED;Rif Resistance DETECTED	2.4	0.0	2.4	2.5	1.2	2.5	
Mean			20.2	0.0	20.9	19.6	26.2	19.0	
%CV			11.8	#DIV/0!	11.3	12.9	4.6	13.0	
SD	2018-B-4_H37Rv_1821	MTB DETECTED;Rif Resistance NOT DETECTED	2.6	2.7	2.6	2.9	1.8	2.7	
Mean			20.7	19.8	21.3	20.7	26.4	19.6	
%CV			12.8	13.9	12.3	13.8	6.6	13.8	
SD	2018-B-5_H526D_1816	MTB DETECTED;Rif Resistance DETECTED	0.0	1.7	1.6	1.7	1.1	1.6	
Mean			0.0	20.5	21.8	21.4	25.8	20.2	
%CV			#DIV/0!	8.3	7.1	8.1	4.4	7.9	
Validation Performed by Signature: _____ Date: _____									
Team Lead Signature: _____ Date: _____									

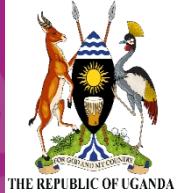
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Assessment

1. How do we ensure that the DTS prepared post inactivation are dry? Is this essential? If yes or no, WHY?
2. What are the steps taken in the choice of a stock for use in DTS preparation?

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Summary

- Ensure the DTS prepared post inactivation are dry to ensure quality Ct values
- Test the 5 DTS samples from each of the 8 isolates with Xpert MTB/RIF or Ultra
- Enter Xpert MTB/RIF results and Ct data on digital DTS preparation worksheet for proper data management
- Analyze the standard deviation (SD) and mean of probe A and rpoB1 for each stock prepared
- Out of the 8 inactivated stock select 5 for panel preparation

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References

- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials – General and statistical principles for certification*
- Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)
- ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)
- ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*



ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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Acknowledgments

