

Analyses of June 2006 *M. tuberculosis* and Nontuberculous Mycobacteria Drug Susceptibility Test Results Reported by Participating Laboratories

This report analyzes the laboratory test results reported to the Centers for Disease Control and Prevention (CDC) by participant laboratories for the four *Mycobacterium tuberculosis* complex and one *M. simiae* strain shipped in June 2006. Participant laboratories received either four *M. tuberculosis* complex strains only or four *M. tuberculosis* complex strains and one nontuberculous mycobacteria (NTM) strain. Testing results were received and analyzed from 135 of 144 (93.8%) laboratories participating in this shipment. Of the laboratories submitting results, 92 (68.1%) reported via the online data entry system, a 20% increase over the January 2006 shipment.

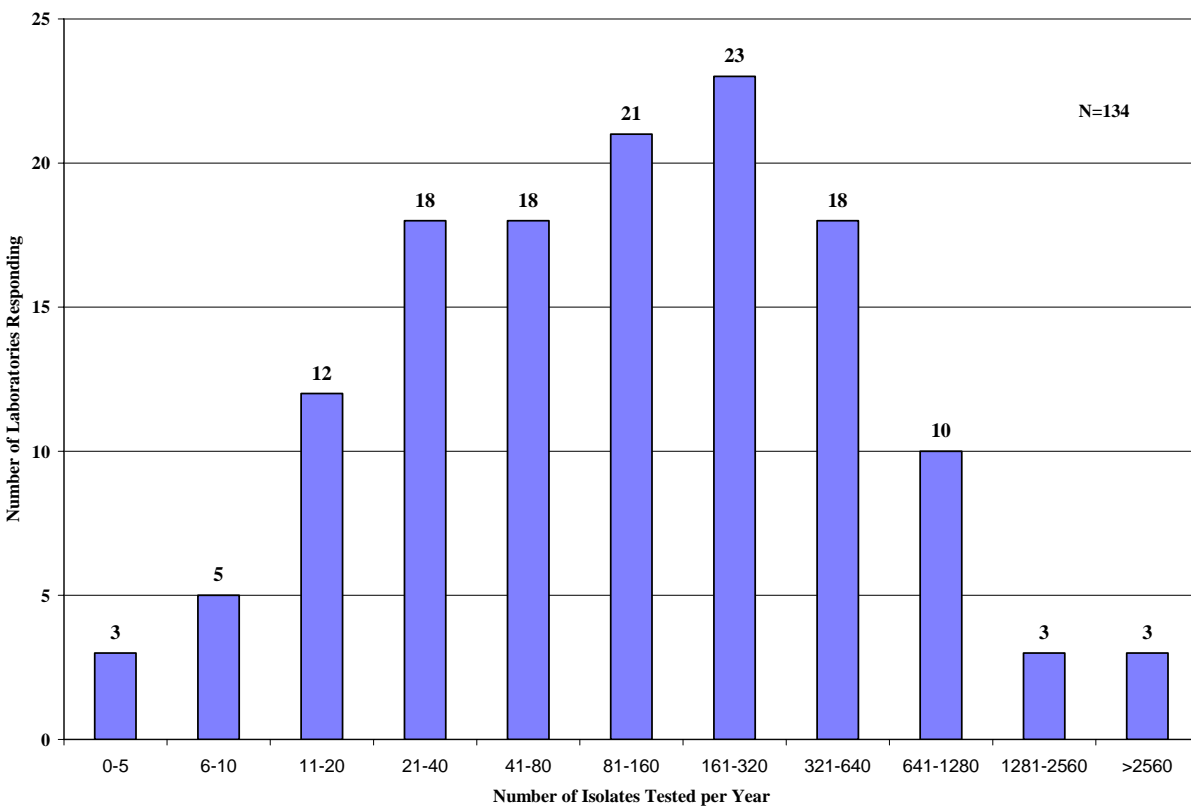
Descriptive Information on Participant Laboratories

Laboratory classifications reported by the 135 participants are:

- 79 (58.5%) health departments,
- 39 (28.9%) hospitals,
- 12 (8.9%) independent laboratories, and
- 5 (3.7%) other type of laboratories.

Figure 1 shows the distribution of the annual volume of *M. tuberculosis* susceptibility testing performed by participants. The numbers on top of the bars indicate the number of laboratories at the upper limit of that group.

Figure 1: Distribution of the Annual Volume of *M. tuberculosis* Isolates Tested for Drug Susceptibility by Participating Laboratories in Calendar Year 2005.



According to the annual volume of testing reported, some laboratories perform less than one drug susceptibility test per month. Laboratories performing these low testing volumes may want to consider referring drug susceptibility tests to other facilities.

Biosafety Levels of Participant Laboratories

The biosafety levels (BSL) reported by participant laboratories for handling *M. tuberculosis* are:

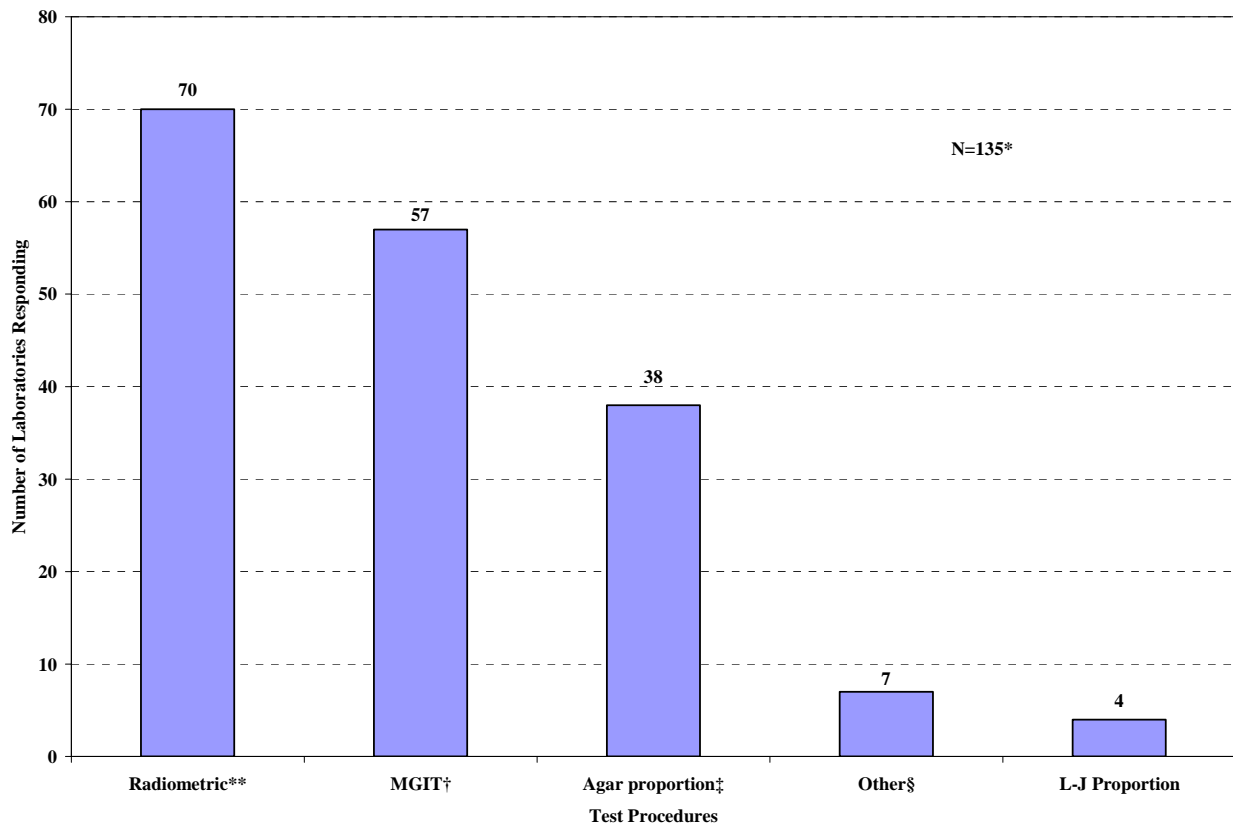
- BSL-3, 76 participants,
- BSL-2 with facilities with level 3 containment equipment, 45 participants,
- BSL-2, 14 participants.

All laboratories are strongly encouraged to consult the CDC/NIH manual, Biosafety in Microbiological and Biomedical Laboratories (4th Edition), which can be accessed on the web at <http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>, for recommendations and to determine their correct biosafety level.

Laboratory Test Procedures

Figure 2 shows the number of laboratories by the type of procedure used for drug susceptibility testing.

Figure 2: Procedures Used by the Participating Laboratories for *M. tuberculosis* Drug Susceptibility Testing



* Some participants reported more than one test method.

** Radiometric is BACTEC 460TB

† MGIT, Mycobacteria Growth Indicator Tube (BACTEC MGIT 960)

‡ Agar proportion using Middlebrook 7H10 or 7H11 medium.

§ Other methods listed were microtiter, BacT/ALERT, VersaTREK ESP and Colorimetric method for determining MICs with Alamar Blue, Pyrazinamidase test, and resistance ratio method (RRM) on LJ genotype MTBDR HAIN Lifescience.

Some methods, such as the RRM and BacT/ALERT, reflect procedures used by international participants.

M. tuberculosis Complex Strains Test Results:

To facilitate comparison among laboratories, the aggregate test results are provided in Tables 1.0 through 1.3 at the end of this document, representing strains F, G, H and I. The tables for the *M. tuberculosis* complex strains F, G, H, and I include the results for the radiometric (BACTEC), agar proportion (AP), Lowenstein-Jensen (L-J) proportion, MGIT and other methods at each concentration of drug.

In the tables, the concentrations recommended by CDC and the Clinical and Laboratory Standards Institute (CLSI) for the primary [isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB)] and secondary [streptomycin (SM), ethionamide (THA), kanamycin (KM), capreomycin (CM), and p-amino-salicylic acid (PAS)] antituberculosis drugs are highlighted for the conventional and radiometric methods.

Strain F and **strain I** are duplicate strains of *Mycobacterium tuberculosis*, resistant to ethambutol at 5.0 µg/ml by agar proportion and MGIT methods, and at 2.5 µg/ml of ethambutol by BACTEC 460TB. See Tables 1.0 and 1.3, respectively.

The table below shows the side-by-side comparison of the results reported to CDC by participant laboratories.

Table: Ethambutol Resistance reported by participant laboratories for Strains F and I.*

Method (drug concentration)	Strain F % resistant (#of laboratories)	Strain I % resistant (# of laboratories)
AP (5.0 µg/ml)	66.7% (20/30)	69.0% (20/29)
MGIT (5.0 µg/ml)	54.7% (29/53)	55.8% (29/52)
BACTEC 460TB (2.5 µg/ml)	98.2% (55/56)	98.2% (54/55)

* One laboratory reported both strains as sensitive to EMB at 5.0 µg/ml using ESPII.

Ethambutol is a first-line antituberculous drug used for treating all forms of tuberculosis. It is included in the initial treatment regimens primarily to prevent emergence of RIF resistance when primary resistance to INH may be present.¹ Exposure of EMB sensitive mycobacteria results in the accumulation of mycolic acid leading to cell death.²

The presence of microcolonies may represent true resistance, partial resistance, or may be a result of drug degradation followed by an overgrowth of susceptible organisms. It has been reported that most strains that had microcolonies with EMB in the agar proportion method had EMB-susceptible results with BACTEC 460TB.^{3,4}

The significance of microcolonies is unknown. Since the frequency of microcolonies may vary from one laboratory to another, each laboratory should determine how to best report results.⁵

Strain G, *M. tuberculosis*- INH resistant at 0.2 µg/ml by the agar proportion method. See Table 1.1.

This strain is a recently isolated clinical culture which demonstrated mono-resistance to low concentrations (0.1-0.2 µg/ml of INH).

Isoniazid has two recommended concentrations for the AP method (0.2 µg/ml and 1.0 µg/ml) and equivalent concentrations for BACTEC 460TB and MGIT (0.1 µg/ml and 0.4 µg/ml, respectively).

For participants using agar proportion,

- 75.9% (22/29) reported resistance at 0.2 µg/ml,
- 100% (31/31) of the laboratories reported the isolate as susceptible at 1.0 µg/ml.

For participants using BACTEC 460,

- 98.4% (61/62) reported resistance at 0.1 µg/ml,
- 100% (17/17) of the laboratories reported the isolate as susceptible at 0.4 µg/ml.

For participants using MGIT,

- 96.3% (52/54) detected resistance at 0.1 µg/ml and
- 96.1% (25/26) detected susceptibility at 0.4 µg/ml.

Strain H, *M. tuberculosis*, was resistant to rifampin at 2.0 µg/ml by the BACTEC method and to ciprofloxacin (a fluoroquinolone) at 2.0 µg/ml by the agar proportion and BACTEC 460TB methods. See Table 1.2.

One hundred thirty-five participants reported results for **strain H**:

- 58.6% (34/58) using BACTEC 460TB reported resistance to RIF at 2.0 µg/ml, and
- 69.7% (23/33) of the participant laboratories using the agar proportion method reported resistance to rifampin at the equivalent concentration of 1.0 µg/ml, and
- 28.3% (15/53) using MGIT reported resistance at 1.0 µg/ml.

Nineteen laboratories tested ciprofloxacin. Of the 12 laboratories that tested ciprofloxacin at 2.0 µg/ml:

- 66.7% (6/9) using the agar proportion method detected resistance, and
- 75.0% (3/4) using BACTEC 460TB method detected resistance.

Ofloxacin, the class representative for the fluoroquinolones, was tested by 24 laboratories. Eighteen of those laboratories tested ofloxacin at the recommended concentration of 2.0 µg/ml.

Of those 18 laboratories:

- 77.8% (7/9) using the agar proportion method detected resistance,
- 75.0% (6/8) using BACTEC 460TB detected resistance, and
- One laboratory using MGIT reported this isolate susceptible.

Several laboratories tested both ofloxacin and ciprofloxacin. There were no discrepant results reported by laboratories that tested both drugs at 2.0 µg/ml.

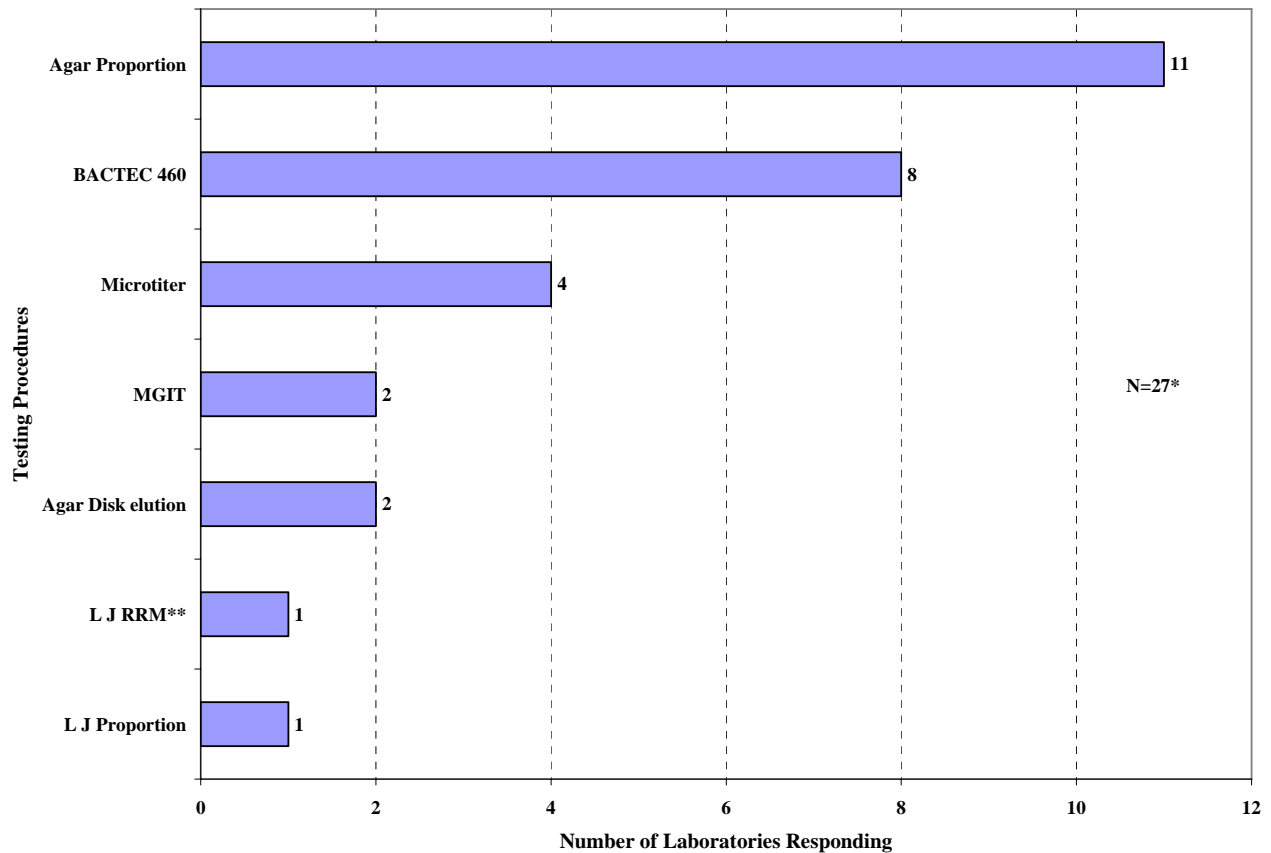
Note: This strain proved problematic for many of the participating laboratories. One laboratory reported a mutation in the 81bp core region of *rpoB* gene at codon His526. Several mutations in the *rpoB* gene have been shown to confer rifampin resistance.^{6,7}

Note: Our providing test results for all drugs that are reported to CDC by participant laboratories should not be construed as a recommendation or endorsement for testing particular drug concentrations with patient isolates of the *M. tuberculosis* complex. It is assumed that some of the drugs are being tested for research purposes or potential use in the few referral institutions that may treat patients with *M. tuberculosis* isolates resistant to almost all standard drugs. Laboratories should not add drugs to their testing regimen without consulting physicians having expertise in treating multi-drug resistant tuberculosis. Laboratories may contact their local TB control program for referrals of physicians with experience and expertise in treating multi-drug resistant tuberculosis.

Nontuberculous Mycobacteria-Strain J, *M. simiae*

Twenty-seven laboratories performed susceptibility testing on *M. simiae*. Figure 3 shows the procedures used.

Figure 3: Procedures Used by Participating Laboratories Testing Strain J, *M. simiae*



*Some participants reported more than one test method. Therefore, the total is greater than the number of laboratories reporting results.

** L J RRM, resistance ratio method

***M. simiae* case history:**

Patient: The patient was an 87 year old woman who had been in good health until 85 years of age when she noticed increasing dyspnea. After an acute episode of shortness of breath and cough, her chest x-ray was found to be abnormal, and her sputum was positive for acid fast bacilli (AFB). She was admitted to the hospital, where admission radiographs showed extensive infiltrates in both left and right lower lobes with generalized fibrosis.

Laboratory Findings: Sputum cultures were positive for *Mycobacterium simiae*. Cultures remained positive for this organism over a period of two years (13 isolates) despite treatment with isoniazid, streptomycin, ethambutol, and cycloserine; she was lost to follow-up.

M. simiae is an uncommon cause of pulmonary and disseminated infection. For patients with proven disease, initial therapy may be started with the regimen recommended for *M. avium* complex (clarithromycin, ethambutol, rifabutin and streptomycin). According to the Clinical and Laboratory Standards Institute (CLSI), susceptibility testing should include the same primary and secondary drugs used for *M. kansasii*, with the use of the same interpretive criteria. No specific susceptibility test method has been recommended for *M. simiae*. Antimicrobial agents recommended for testing *M. simiae* are found on pages 20, 23-24, and Table 6 on page 38 in the CLSI Guidelines.⁵ The drugs recommended for testing are rifampin (primary) and the secondary drugs, rifabutin, ethambutol, isoniazid, streptomycin, clarithromycin, amakacin, ciprofloxacin, moxifloxacin, and trimethoprim-sulfamethoxazole or sulfamethoxazole.⁸ Treatment for *M. simiae* is difficult and optimal pharmacological management has not been determined. However, a regimen of a macrolide (such as clarithromycin or azithromycin), TMP-SMX and moxifloxacin is recommended by most experts.

Susceptibility results:

Of the 27 laboratories reporting susceptibility testing for *M. simiae*,

- 100% (15/15) reported resistance to RIF at 1.0 µg/ml and 2.0 µg/ml,
- 100% (12/12) reported resistance to EMB at 5.0 µg/ml, and
- 2 laboratories reported *M. simiae* as susceptible to clarithromycin at 16.0 µg/ml by AP and MGIT methods.

See Tables 2 and 3 for complete susceptibility testing results reported for *M. simiae*.

The addition of NTM strains to this performance evaluation program should not be interpreted as a recommendation for laboratories to adopt NTM drug susceptibility testing, especially if the laboratory has limited experience with these tests and methods. We encourage laboratories that perform NTM drug susceptibility testing to consult recommendations, references, and physicians with expertise in infectious diseases when selecting test methods, drugs, and test interpretations.

Tables

The test results are listed in the appropriate (susceptible or resistant) columns with a corresponding total number of tests (Sum) column provided as a denominator for determining the level of consensus. This report contains all results reported by participating laboratories, including many drug concentrations with only one result.

The CDC and CLSI recommendations reflect the critical concentrations of anti-tuberculosis drugs in 7H10 agar and those concentrations for the BACTEC 460TB method that directly correlate with the critical concentrations in the conventional method.^{9, 10, 11, 12} These critical values are highlighted. When two concentrations are highlighted, such as for isoniazid and ethambutol, the lower value is the critical concentration which should always be included for determining whether the *M. tuberculosis* isolate is resistant.

Participants should note that the Clinical and Laboratory Standards Institute approved standard “Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes,” M24-A (ISBN 1-56238-500-3) CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 2003 recommends testing streptomycin as a secondary drug and also adds ofloxacin and rifabutin to the list of recommended secondary drugs.

Concentrations are listed in micrograms per milliliter, µg/ml.

Acknowledgments

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Table 1.0: Participant Results for culture F, *M. tuberculosis* resistant to ethambutol at 5.0 µg/ml.

DRUG	Conc	Test Method																
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results				
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum		
Isoniazid	0.03															1		1
Isoniazid	0.05															1		1
Isoniazid	0.06															1		1
Isoniazid	0.10				60	1	61				54	1	55	2	1	3		
Isoniazid	0.12	1		1														
Isoniazid	0.20	29		29	3		3	4		4				1		1		
Isoniazid	0.40				15		15				15	1	16	1		1		
Isoniazid	0.50							1		1				1		1		
Isoniazid	1.00	31		31	4		4	2		2				1		1		
Isoniazid	5.00	5		5														
Isoniazid	10.00							2		2								
Isoniazid	100.00							1		1								
Rifampin	0.08															1		1
Rifampin	0.12															1		1
Rifampin	0.25															1		1
Rifampin	0.50				2		2									1		1
Rifampin	1.00	33		33	6		6		1	1	53		53	2		2		2
Rifampin	2.00	1		1	61		61				2		2	2		2		2
Rifampin	5.00	4		4				1		1								
Rifampin	8.00				1		1									1		1
Rifampin	16.00															1		1
Rifampin	32.00															1		1
Rifampin	40.00							3		3								
Rifampin	50.00							1		1								
Pyrazinamide	64.00															1		1
Pyrazinamide	99.00				1		1											
Pyrazinamide	100.00				52	1	53	1		1	45	1	46	2		2		2
Pyrazinamide	300.00				1		1											
Pyrazinamide	400.00							1		1								
Ethambutol	1.0								1	1							1	1
Ethambutol	1.6															1		1
Ethambutol	2.0							2	2	4							1	1
Ethambutol	2.5				1	55	56				2		2					
Ethambutol	3.2															1		1
Ethambutol	4.0					2	2										1	1
Ethambutol	5.0	10	20	30	3	4	7	1		1	24	29	53	1		1		1
Ethambutol	6.40															1		1
Ethambutol	7.50	1		1	11	3	14				4		4				1	1
Ethambutol	8.00															1	1	2
Ethambutol	10.00	10		10														
Ethambutol	16.00															1		1
Ethambutol	32.00															1		1
Streptomycin	0.25															1		1
Streptomycin	0.50															1		1
Streptomycin	1.00				1		1	1		1	39		39	1		1		1
Streptomycin	2.00	30		30	52		52				2		2	1		1		1
Streptomycin	4.00	1		1	2		2	3		3	6		6	1		1		1
Streptomycin	5.00							1		1								
Streptomycin	6.00				11		11										1	1
Streptomycin	7.50															1		1
Streptomycin	8.00															1		1
Streptomycin	10.00	22		22				1		1								
Streptomycin	15.00															1		1
Streptomycin	30.00															1		1

Table 1.0: Participant Results for culture F, *M. tuberculosis* resistant to ethambutol at 5.0 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ethionamide	1.00					1	1									
Ethionamide	1.25					2	2									
Ethionamide	2.00					1	1									
Ethionamide	2.50					3	3									
Ethionamide	4.00					1	1									
Ethionamide	5.00	21		21	1	1	2									
Ethionamide	10.00	4		4										1		1
Ethionamide	20.00							1		1				1		1
Ethionamide	40.00							1		1				1		1
Kanamycin	5.00	11		11	4		4									
Kanamycin	6.00	12		12												
Kanamycin	10.00							1		1						
Kanamycin	20.00							1		1						
Kanamycin	40.00							1		1						
Capreomycin	0.50													1		1
Capreomycin	1.00													1		1
Capreomycin	1.25					1	1									
Capreomycin	5.00					2	2									
Capreomycin	6.00	1		1												
Capreomycin	10.00	16		16												
Capreomycin	12.50													1		1
Capreomycin	25.00													1		1
Capreomycin	40.0							1		1						
Capreomycin	50.0													1		1
Cycloserine	10.0	1		1												
Cycloserine	12.0													1		1
Cycloserine	20.0								1	1						
Cycloserine	24.0													1		1
Cycloserine	25.0	1		1												
Cycloserine	30.0	9		9				1		1						
Cycloserine	40.0							1		1						
Cycloserine	48.0													1		1
Cycloserine	60.0	1		1												
p-Aminosalicylic acid	0.50								1	1						
p-Aminosalicylic acid	1.00							2		2						
p-Aminosalicylic acid	2.00	16		16												
p-Aminosalicylic acid	4.00				2		2									
p-Aminosalicylic acid	8.00	2		2												
p-Aminosalicylic acid	10.00	4		4												
Amikacin	0.50													1		1
Amikacin	1.00	1		1	2		2							1		1
Amikacin	2.00	1		1	2		2									
Amikacin	2.50				1		1									
Amikacin	4.00	3		3	1		1									
Amikacin	5.00				1		1									
Amikacin	6.00	7		7												
Amikacin	7.50													1		1
Amikacin	8.00				1		1									
Amikacin	12.00	2		2												
Amikacin	15.00													1		1
Amikacin	30.00													1		1

Table 1.0: Participant Results for culture F, *M. tuberculosis* resistant to ethambutol at 5.0 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ofloxacin	0.50														1	1
Ofloxacin	1.00	3		3	2		2								1	1
Ofloxacin	1.25														1	1
Ofloxacin	2.00	9		9	7	1	8	1		1	1		1			
Ofloxacin	2.50														1	1
Ofloxacin	4.00	1		1	3		3									
Ofloxacin	5.00														1	1
Ofloxacin	8.00				2		2									
Ciprofloxacin	0.5														1	1
Ciprofloxacin	1.0	2		2	4		4								1	1
Ciprofloxacin	1.6														1	1
Ciprofloxacin	2.0	9		9	4		4									
Ciprofloxacin	3.2														1	1
Ciprofloxacin	4.0				2		2									
Ciprofloxacin	6.4														1	1
Clarithromycin	6.00														1	1
Clarithromycin	12.00														1	1
Clarithromycin	24.00														1	1
Clofazimine	0.06				1	1	2									
Clofazimine	0.12				2		2									
Clofazimine	0.25				1		1									
Clofazimine	0.50				1		1								1	1
Clofazimine	1.00	1		1											1	1
Clofazimine	17.50														1	1
Clofazimine	35.00														1	1
Clofazimine	70.00														1	1
Rifabutin	0.50	4		4	1		1								1	1
Rifabutin	1.00	1		1											1	1
Rifabutin	2.00	5		5												
Levofloxacin	1.00										1		1			
Levofloxacin	2.00				2		2									
Levofloxacin	4.00				1		1									
Moxifloxacin	0.50	1		1												
Gatifloxacin	2.00	1		1												

Table 1.1: Participant Results for Culture G, *M. tuberculosis*, resistant to isoniazid at 0.2 µg/ml

DRUG	Conc	Test Method															
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results			
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	
Isoniazid	0.03															1	1
Isoniazid	0.05															1	1
Isoniazid	0.06															1	1
Isoniazid	0.10				1	61	62				2	52	54			3	3
Isoniazid	0.12		1	1													
Isoniazid	0.20	7	22	29	1	2	3	2	2	4					1		1
Isoniazid	0.40				17		17				25	1	26		1		1
Isoniazid	0.50							1		1					1		1
Isoniazid	1.00	31		31	4		4	2		2				1			1
Isoniazid	2.00				1		1										
Isoniazid	5.00	4		4													
Isoniazid	10.00							2		2							
Isoniazid	100.00							1		1							
Rifampin	0.08															1	1
Rifampin	0.12														1		1
Rifampin	0.25														1		1
Rifampin	0.50				2		2								1		1
Rifampin	1.00	32		32	6		6		1	1	53		53		2		2
Rifampin	2.00	1		1	61		61				2		2		2		2
Rifampin	5.00	5		5				1		1							
Rifampin	8.00				1		1								1		1
Rifampin	16.00														1		1
Rifampin	32.00														1		1
Rifampin	40.00							3		3							
Rifampin	50.00							1		1							
Pyrazinamide	64.00														1		1
Pyrazinamide	99.00				1		1										
Pyrazinamide	100.00				53		53	1		1	41	3	44	1	1	2	
Pyrazinamide	300.00				1		1										
Pyrazinamide	400.00							1		1							
Ethambutol	1.0							1		1						1	1
Ethambutol	1.6														1		1
Ethambutol	2.0							4		4					1		1
Ethambutol	2.5				54		54				2		2				
Ethambutol	3.2														1		1
Ethambutol	4.0				2		2								1		1
Ethambutol	5.0	30		30	6		6	1		1	53		53		1		1
Ethambutol	6.4														1		1
Ethambutol	7.50	1		1	12		12				3		3			1	1
Ethambutol	8.00														2		2
Ethambutol	10.00	11		11													
Ethambutol	16.00														1		1
Ethambutol	32.00														1		1
Streptomycin	0.25															1	1
Streptomycin	0.50														1		1
Streptomycin	1.00				1		1		1	1	37	2	39	1			1
Streptomycin	2.00	28	1	29	51		51				2		2	1			1
Streptomycin	4.00	1		1	2		2	3		3	6		6	1			1
Streptomycin	5.00							1		1							
Streptomycin	6.00				11		11								1		1
Streptomycin	7.50														1		1
Streptomycin	8.00														1		1
Streptomycin	10.00	23		23				1		1							
Streptomycin	15.00														1		1

Table 1.1: Participant Results for Culture G, *M. tuberculosis*, resistant to isoniazid at 0.2 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ethionamide	1.00					1	1									
Ethionamide	1.25					1	1									
Ethionamide	2.00					1	1									
Ethionamide	2.50				1	2	3									
Ethionamide	4.00					1	1									
Ethionamide	5.00	15	7	22		2	2									
Ethionamide	10.00	2	1	3											1	1
Ethionamide	20.00								1	1					1	1
Ethionamide	40.00								1	1					1	1
Kanamycin	5.00	10		10	3		3									
Kanamycin	6.00	12		12												
Kanamycin	10.00								1	1						
Kanamycin	20.00								1	1						
Kanamycin	40.00								1	1						
Capreomycin	0.50														1	1
Capreomycin	1.00														1	1
Capreomycin	1.25				1		1									
Capreomycin	5.00				2		2									
Capreomycin	6.00	1		1												
Capreomycin	10.00	15		15												
Capreomycin	12.50														1	1
Capreomycin	25.00														1	1
Capreomycin	40.0								1	1						
Capreomycin	50.0														1	1
Cycloserine	10.0	1		1												
Cycloserine	12.0														1	1
Cycloserine	20.0								1	1						
Cycloserine	24.0														1	1
Cycloserine	25.0	1		1												
Cycloserine	30.0	9		9					1	1						
Cycloserine	40.0								1	1						
Cycloserine	48.0														1	1
Cycloserine	60.0	1		1												
p-Aminosalicylic acid	0.50								1	1						
p-Aminosalicylic acid	1.00								1	1	2					
p-Aminosalicylic acid	2.00	17		17												
p-Aminosalicylic acid	4.00				2		2									
p-Aminosalicylic acid	8.00	2		2												
p-Aminosalicylic acid	10.00	4		4												
Amikacin	0.50														1	1
Amikacin	1.00	1		1	2		2								2	2
Amikacin	2.00	1		1	2		2									
Amikacin	2.50	1		1	1		1									
Amikacin	4.00	3		3	1		1									
Amikacin	5.00				1		1									
Amikacin	6.00	6		6												
Amikacin	7.50														1	1
Amikacin	8.00				1		1									
Amikacin	12.00	2		2												
Amikacin	15.00														1	1
Amikacin	30.00														1	1

Table 1.1: Participant Results for Culture G, *M. tuberculosis*, resistant to isoniazid at 0.2 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ofloxacin	1.00	4		4		2	2									
Ofloxacin	1.20	1		1												
Ofloxacin	1.25												1		1	
Ofloxacin	2.00	8		8	6	1	7	1		1		1		1		1
Ofloxacin	2.50												1		1	
Ofloxacin	4.00	1		1	3		3						1		1	
Ofloxacin	5.00												1		1	
Ofloxacin	8.00				2		2									
Ciprofloxacin	0.5													1		1
Ciprofloxacin	1.0	3		3	4		4						1		1	
Ciprofloxacin	1.6												1		1	
Ciprofloxacin	2.0	7		7	4		4									
Ciprofloxacin	3.2												1		1	
Ciprofloxacin	4.0				2		2									
Ciprofloxacin	6.4												1		1	
Clarithromycin	6.00													1		1
Clarithromycin	12.00													1		1
Clarithromycin	24.00													1		1
Clofazimine	0.06				2		2									
Clofazimine	0.12				2		2									
Clofazimine	0.25				1		1									
Clofazimine	0.50				1		1									
Clofazimine	1.00	1		1										1		1
Clofazimine	2.00												1		1	
Clofazimine	17.50												1		1	
Clofazimine	35.00												1		1	
Clofazimine	70.00												1		1	
Rifabutin	0.50	4		4										1		1
Rifabutin	1.00	1		1										1		1
Rifabutin	2.00	4		4												
Levofloxacin	1.00											1		1		
Levofloxacin	1.20	1		1												
Levofloxacin	2.00				2		2									
Levofloxacin	4.00				1		1									
Moxifloxacin	0.50	1		1												
Moxifloxacin	1.00	1		1												
Gatifloxacin	2.00	1		1												

Table 1.2: Participant Results for Culture H, *M. tuberculosis*, resistant to rifampin and ciprofloxacin at 2.0µg/ml

DRUG	Conc	Test Method																
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results				
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum		
Isoniazid	0.03															1		1
Isoniazid	0.05															1		1
Isoniazid	0.06															1		1
Isoniazid	0.10				60		60					52	3	55		2	1	3
Isoniazid	0.12	1		1														
Isoniazid	0.20	30		30	3		3	4		4					1		1	
Isoniazid	0.40				15		15					15	1	16	1		1	
Isoniazid	0.50							1		1					1		1	
Isoniazid	1.00	32		32	4		4	2		2					1		1	
Isoniazid	5.00	5		5														
Isoniazid	10.00							2		2								
Isoniazid	100.00							1		1								
Rifampin	0.08																1	1
Rifampin	0.12																1	1
Rifampin	0.25																1	1
Rifampin	0.50					2	2								1		1	
Rifampin	1.00	10	23	33	3	3	6	1	1		38	15	53	2		2	2	
Rifampin	2.00	1		1	24	34	58				2		2	2		2	2	
Rifampin	5.00	5		5		1	1	1	1									
Rifampin	8.00				1		1										1	1
Rifampin	16.00																1	1
Rifampin	32.00																1	1
Rifampin	40.00							3	3									
Rifampin	50.00							1	1									
Pyrazinamide	64.00														1		1	
Pyrazinamide	99.00				1		1											
Pyrazinamide	100.00				52	1	53	1	1		46		46	2		2	2	
Pyrazinamide	300.00				1		1											
Pyrazinamide	400.00							1	1									
Ethambutol	1.00							1	1								1	1
Ethambutol	1.60																1	1
Ethambutol	2.00							4	4						1		1	
Ethambutol	2.50				54		54				2		2					
Ethambutol	3.20															1	1	
Ethambutol	4.00				2		2								1		1	
Ethambutol	5.00	31	2	33	5	1	6	1	1		52	1	53	1		1	1	
Ethambutol	6.40														1		1	
Ethambutol	7.50	1		1	11		11				3		3			1	1	
Ethambutol	8.00														2		2	
Ethambutol	10.00	10		10														
Ethambutol	16.00														1		1	
Ethambutol	32.00														1		1	
Streptomycin	0.25														1		1	
Streptomycin	0.50														1		1	
Streptomycin	1.00				1		1	1	1		39		39	1		1	1	
Streptomycin	2.00	31		31	52		52				2		2	1		1	1	
Streptomycin	4.00	1		1	2		2	3	3		6		6	1		1	1	
Streptomycin	5.00							1	1									
Streptomycin	6.00				11		11									1	1	
Streptomycin	7.50														1		1	
Streptomycin	8.00														1		1	
Streptomycin	10.00	23		23				1	1									
Streptomycin	15.00														1		1	
Streptomycin	30.00														1		1	

Table 1.2: Participant Results for Culture H, *M. tuberculosis*, resistant to rifampin and ciprofloxacin at 2.0µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ofloxacin	1.00		4	4		2	2									
Ofloxacin	1.25													1	1	
Ofloxacin	2.00	2	7	9	2	6	8	1		1	1		1			
Ofloxacin	2.50													1	1	
Ofloxacin	4.00		1	1		3	3								1	1
Ofloxacin	5.00														1	1
Ofloxacin	8.00					2	2									
Ofloxacin	16.00													1	1	1
Ofloxacin	32.00													1		1
Ciprofloxacin	1.00		3	3	1	3	4									
Ciprofloxacin	1.60														1	1
Ciprofloxacin	2.00	3	6	9	1	3	4									
Ciprofloxacin	3.20														1	1
Ciprofloxacin	4.00					2	2								1	1
Ciprofloxacin	6.40															
Ciprofloxacin	8.00													1		1
Clarithromycin	6.00														1	1
Clarithromycin	12.00													1		1
Clarithromycin	24.00													1		1
Clofazimine	0.06				2		2									
Clofazimine	0.12				2		2									
Clofazimine	0.25				1		1									
Clofazimine	0.50				1		1							1		1
Clofazimine	1.00	1		1										1		1
Clofazimine	17.50														1	1
Clofazimine	35.00														1	1
Clofazimine	70.00														1	1
Rifabutin	0.50	3	1	4	1		1									
Rifabutin	1.00	1		1												
Rifabutin	2.00	5		5												
Rifabutin	8.00														1	1
Rifabutin	16.00													1		1
Levofloxacin	1.00										1		1			
Levofloxacin	2.00					2	2									
Levofloxacin	4.00				1		1									
Moxifloxacin	0.50		1	1												
Gatifloxacin	2.00	1		1												

Table 1.3: Participant Results for Culture I, *M. tuberculosis*, resistant to ethambutol at 5.0 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Isoniazid	0.03													1		1
Isoniazid	0.05													1		1
Isoniazid	0.06													1		1
Isoniazid	0.10				59	1	60				54	1	55	2	1	3
Isoniazid	0.12	1		1												
Isoniazid	0.20	28		28	2		2	4		4				1		1
Isoniazid	0.40				14		14				16		16	1		1
Isoniazid	0.50							1		1				1		1
Isoniazid	1.00	30		30	4		4	2		2				1		1
Isoniazid	5.00	4		4												
Isoniazid	10.00							2		2						
Isoniazid	100.00							1		1						
Rifampin	0.12													1		1
Rifampin	0.25													1		1
Rifampin	0.50				2		2							1		1
Rifampin	1.00	32		32	6		6		1	1	53		53	2		2
Rifampin	2.00	1		1	60		60				2		2	2		2
Rifampin	5.00	4		4				1		1						
Rifampin	8.00				1		1							1		1
Rifampin	16.00													1		1
Rifampin	32.00													1		1
Rifampin	40.00							3		3						
Rifampin	50.00							1		1						
Pyrazinamide	64.00													1		1
Pyrazinamide	99.00				1		1									
Pyrazinamide	100.00				52		52	1		1	45	1	46	2		2
Pyrazinamide	300.00				1		1									
Pyrazinamide	400.00							1		1						
Ethambutol	1.00								1	1					1	1
Ethambutol	1.60														1	1
Ethambutol	2.00							2	2	4					1	1
Ethambutol	2.50				1	54	55				1	1	2			
Ethambutol	3.20													1		1
Ethambutol	4.00				1	1	2								1	1
Ethambutol	5.00	9	20	29	2	5	7	1		1	23	29	52	1		1
Ethambutol	6.40													1		1
Ethambutol	7.50	1		1	10	3	13				3		3		1	1
Ethambutol	8.00													1	1	2
Ethambutol	10.00	10		10												
Ethambutol	16.00													1		1
Ethambutol	32.00													1		1
Streptomycin	0.25													1		1
Streptomycin	0.50													1		1
Streptomycin	1.00				1		1	1		1	39		39	1		1
Streptomycin	2.00	29		29	51		51				2		2	1		1
Streptomycin	4.00	1		1	2		2	3		3	6		6	1		1
Streptomycin	5.00							1		1						
Streptomycin	6.00				10		10							1		1
Streptomycin	7.50													1		1
Streptomycin	8.00													1		1
Streptomycin	10.00	21		21				1		1						
Streptomycin	15.00													1		1
Streptomycin	30.00													1		1

Table 1.3: Participant Results for Culture I, *M. tuberculosis*, resistant to ethambutol at 5.0 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ethionamide	1.00				1		1									
Ethionamide	1.25				2		2									
Ethionamide	2.00				1		1									
Ethionamide	2.50				3		3									
Ethionamide	4.00				1		1									
Ethionamide	5.00	21		21	2		2									
Ethionamide	10.00	3		3										1		1
Ethionamide	20.00							1		1				1		1
Ethionamide	40.00							1		1				1		1
Kanamycin	5.00	11		11	4		4									
Kanamycin	6.00	12		12												
Kanamycin	10.00							1		1						
Kanamycin	20.00							1		1						
Kanamycin	40.00							1		1						
Capreomycin	0.50													1		1
Capreomycin	1.00													1		1
Capreomycin	1.25				1		1									
Capreomycin	5.00				2		2									
Capreomycin	6.00	1		1												
Capreomycin	10.00	16		16												
Capreomycin	12.50													1		1
Capreomycin	25.00													1		1
Capreomycin	40.00							1		1						
Capreomycin	50.00													1		1
Cycloserine	10.00	1		1												
Cycloserine	12.00													1		1
Cycloserine	20.00								1	1						
Cycloserine	24.00													1		1
Cycloserine	25.00	1		1												
Cycloserine	30.00	9		9				1		1						
Cycloserine	40.00							1		1						
Cycloserine	48.00													1		1
Cycloserine	60.00	1		1												
p-Aminosalicylic acid	0.50								1	1						
p-Aminosalicylic acid	1.00							2		2						
p-Aminosalicylic acid	2.00	15		15												
p-Aminosalicylic acid	4.00				2		2									
p-Aminosalicylic acid	8.00	2		2												
p-Aminosalicylic acid	10.00	4		4												
Amikacin	0.50													1		1
Amikacin	1.00	1		1	2		2							1		1
Amikacin	2.00	1		1	2		2									
Amikacin	2.50				1		1									
Amikacin	4.00	3		3	1		1									
Amikacin	5.00				1		1									
Amikacin	6.00	6		6												
Amikacin	7.50													1		1
Amikacin	8.00				1		1									
Amikacin	12.00	2		2												
Amikacin	15.00													1		1
Amikacin	30.00													1		1

Table 1.3: Participant Results for Culture I, *M. tuberculosis*, resistant to ethambutol at 5.0 µg/ml

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Ofloxacin	0.50														1	1
Ofloxacin	1.00	3		3	2		2							1		1
Ofloxacin	1.25													1		1
Ofloxacin	2.00	9		9	8		8	1		1	1		1			
Ofloxacin	2.50													1		1
Ofloxacin	4.00	1		1	3		3							1		1
Ofloxacin	5.00													1		1
Ofloxacin	8.00				2		2									
Ciprofloxacin	0.50													1		1
Ciprofloxacin	1.00	2		2	4		4							1		1
Ciprofloxacin	1.60													1		1
Ciprofloxacin	2.00	8		8	4		4									
Ciprofloxacin	4.00				2		2									
Ciprofloxacin	6.40													1		1
Clarithromycin	6.00													1		1
Clarithromycin	12.00													1		1
Clarithromycin	24.00													1		1
Clofazimine	0.06				2		2									
Clofazimine	0.12				2		2									
Clofazimine	0.25				1		1									
Clofazimine	0.50				1		1									
Clofazimine	1.00	1		1											1	1
Clofazimine	2.00													1		1
Clofazimine	17.50														1	1
Clofazimine	35.00													1		1
Clofazimine	70.00													1		1
Rifabutin	0.50	4		4	1		1							1		1
Rifabutin	1.00	1		1										1		1
Rifabutin	2.00	5		5												
Levofloxacin	1.00										1		1			
Levofloxacin	2.00				2		2									
Levofloxacin	4.00				1		1									
Moxifloxacin	0.50	1		1												
Moxifloxacin	1.00	1		1												
Gatifloxacin	2.00	1		1												

Table 2: Participant Results for Culture J, *M. simiae*

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Amikacin	1.00					1	1									
Amikacin	4.00		1	1												
Amikacin	6.00		1	1												
Amikacin	10.00		1	1												
Amikacin	32.00	1		1												
Amikacin	50.00				1		1									
Clofazimine	1.00	1		1												
Clarithromycin	3.00		1	1												
Clarithromycin	4.00				1	1	2				1		1			
Clarithromycin	6.00													1	1	
Clarithromycin	10.00		1	1											1	1
Clarithromycin	12.00														1	1
Clarithromycin	15.00	1		1												
Clarithromycin	16.00	1		1							1		1			
Clarithromycin	24.00														1	1
Clarithromycin	32.00				1		1									
Clarithromycin	64.00				1		1									
Capreomycin	10.00		2	2												
Capreomycin	12.50														1	1
Capreomycin	25.00														1	1
Capreomycin	50.00														1	1
Ciprofloxacin	1.60														1	1
Ciprofloxacin	2.00	3	1	4												
Ciprofloxacin	3.20														1	1
Ciprofloxacin	4.00	1		1												
Ciprofloxacin	6.40													1		1
Cycloserine	12.00														1	1
Cycloserine	24.00														1	1
Cycloserine	30.00	2		2												
Cycloserine	40.00								1	1						
Cycloserine	48.00													1		1
Doxycycline	5.00		1	1												
Ethambutol	1.60														1	1
Ethambutol	2.50					3	3									
Ethambutol	3.20														1	1
Ethambutol	5.00	9	9			1	1		1	1		1	1			
Ethambutol	6.40														1	1
Ethambutol	7.50				1		1									
Ethambutol	10.00		3	3												
Ethambutol	50.00				1		1									
Isoniazid	0.05														1	1
Isoniazid	0.10					3	3					1	1		1	1
Isoniazid	0.20		5	5											1	1
Isoniazid	1.00		8	8		1	1									
Isoniazid	5.00	1	2	3		1	1									
Isoniazid	10.00					1	1		1	1						

Table 2: Participant Results for Culture J, *M. simiae*

DRUG	Conc	Test Method														
		AP Results			BACTEC Results			LJ Prop Results			MGIT Results			Other Tests Results		
		S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum	S	R	Sum
Kanamycin	5.00	1		1												
Kanamycin	6.00	3		3												
Kanamycin	20.00							1	1							
Levofloxacin	2.00				1		1									
Levofloxacin	5.00	1		1												
Moxifloxacin	0.50		1	1												
Ofloxacin	1.00		1	1												
Ofloxacin	1.25													1	1	
Ofloxacin	2.00		2	2										1	1	
Ofloxacin	2.50													1	1	
Ofloxacin	5.00													1	1	
Ofloxacin	20.00				1		1									
p-Aminosalicylic acid	1.00								1	1						
p-Aminosalicylic acid	2.00		3	3												
Pyrazinamide	400.00								1	1						
Rifabutin	0.10					1	1									
Rifabutin	0.50		1	1												
Rifabutin	1.00		1	1		1	1									
Rifabutin	2.00		4	4												
Rifampin	1.00		9	9		1	1					1	1			
Rifampin	2.00					4	4									
Rifampin	5.00		2	2												
Rifampin	8.00													1	1	
Rifampin	10.00					1	1									
Rifampin	16.00													1	1	
Rifampin	32.00													1	1	
Rifampin	50.00								1	1						
Streptomycin	1.00					1	1					1	1			
Streptomycin	2.00		7	7	1	2	3									
Streptomycin	7.50													1	1	
Streptomycin	10.00	9	1	10	1		1		1	1						
Streptomycin	15.00													1	1	
Streptomycin	30.00													1	1	
Streptomycin	50.00				1		1									
StreptomycinX	32.00	1		1												
StreptomycinX	38.00	1		1												
Ethionamide	5.00	3		3												
Ethionamide	10.00	2		2											1	1
Ethionamide	20.00														1	1
Ethionamide	40.00								1	1				1		1
Trimethoprim-Sulfamethoxazole	2.50	1		1												
Trimethoprim-Sulfamethoxazole	30.00	1		1												

Table 3: Minimum Inhibitory Concentrations for Culture J, *M. simiae*

DRUG	Test Method	MIC	Susceptible	Resistant	Intermediate	Sum
Amikacin*	BACTEC 460	≥8.00		1	1	2
Amikacin	Microtiter	≤0.50		1		1
Amikacin	Microtiter	≥1.00	1			1
Amikacin	Microtiter	4.00	2			2
Amikacin	Microtiter	16.00	1			1
Amikacin	MGIT	≥1.00		1		1
Azithromycin	Microtiter	>32.00		1		1
Clofazimine	BACTEC 460	0.12	1			1
Clarithromycin	BACTEC 460	≤8.00	1			1
Clarithromycin	BACTEC 460	16.00		1		1
Clarithromycin	BACTEC 460	≥32.00		1		1
Clarithromycin	Microtiter	≤0.50	2			2
Clarithromycin	Microtiter	2.00	1			1
Clarithromycin	Microtiter	≤4.00		1		1
Clarithromycin	Microtiter	≥8.00	1			1
Clarithromycin	MGIT	≤16.00	1			1
Ciprofloxacin	BACTEC 460	≤1.00	1			1
Ciprofloxacin*	BACTEC 460	≤2.00	1			1
Ciprofloxacin	Microtiter	≥0.50	1			1
Ciprofloxacin	Microtiter	1.00	1			1
Ciprofloxacin	Microtiter	2.00		1		1
Ciprofloxacin	Microtiter	4.00		1		1
Ciprofloxacin	MGIT	≤1.00	1			1
Cycloserine	BACTEC 460	>16.00		1		1
Ethambutol	BACTEC 460	4.00	1			1
Ethambutol	BACTEC 460	≥8.00	1	1		2
Ethambutol	Microtiter	4.00	1			1
Ethambutol	Microtiter	8.00		1		1
Ethambutol	Microtiter	≥32.00		1		1
Linezolid	BACTEC 460	≥16.00		1		1
Moxifloxacin	BACTEC 460	1.00			1	1
Ofloxacin	Microtiter	≤4.00		1		1
Ofloxacin	Microtiter	≥8.00	1			1
Rifabutin	BACTEC 460	≥0.5		1		1
Rifabutin	BACTEC 460	≥1.0		1		1
Rifabutin	Microtiter	1.00	1			1
Rifabutin	Microtiter	8.00		1		1
Rifabutin	Microtiter	≥32.0		1		1
Rifabutin	MGIT	1.00	1			1
Rifampin	BACTEC 460	4.00		1		1
Rifampin	BACTEC 460	≥8.00		1		1
Rifampin	Microtiter	≥8.00		2		2
Rifampin	Microtiter	≥16.00		1		1
Streptomycin	BACTEC 460	4.00			1	1
Streptomycin	BACTEC 460	4.00	1			1
Streptomycin	Microtiter	2.00	2			2
Streptomycin	Microtiter	8.00	1			1
Streptomycin	Microtiter	≥32.00		2		2
Ethionamide	BACTEC 460	≥4.00		1		1
Trimethoprim-Sulfamethoxazole	Microtiter	8.00		1		1

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