

**PERFORMANCE EVALUATION PROGRAM  
DRUG SUSCEPTIBILITY TESTING OF STRAINS OF *MYCOBACTERIUM  
TUBERCULOSIS (MTUBERCULOSIS)* and NON-TUBERCULOUS  
MYCOBACTERIA (NTM)**

**INSTRUCTIONS**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
Public Health Practice Program Office  
Atlanta, Georgia 30333**

**WARNING**

The culture panel provided in this survey consists of viable strains of *Mycobacterium tuberculosis* (*M. tuberculosis*) and Non-tuberculous Mycobacteria (NTM); some strains are drug-resistant. The cultures in the panel should be considered hazardous and capable of transmitting infection. Testing should only be done if recommended safety procedures are followed as described in the Centers for Disease Control and Prevention Biosafety Manual, 1999 4th Edition, Publication No. CDC-93-8395. This manual recommends use of Biosafety Level 3 practices when testing *M. tuberculosis* cultures.

*Please read all instruction sheets completely before proceeding with any culture evaluation.*

**Check** the contents of your package. It should contain:

1. A cover letter.
2. An envelope containing:
  - a. A Results Form for recording test results and instructions for completing the Results Form Booklet.
  - b. A Laboratory Information Change Form for recording any changes to your laboratory information from previous forms.
  - c. A pre-addressed envelope for mailing the completed Results Form Booklet and Laboratory Information Change Form (if applicable) to the Program Coordinator at **Contractor to be determined (CTD)**.
3. A shipping container with a panel of four (4) labeled "TB Test Cultures" and one (1) labeled "NTM Test Culture". Only four (4) cultures are provided to laboratories that do not perform NTM testing. The culture tubes are labeled with individual alphabetical identification codes.

**NOTE: Perform all susceptibility testing in the same manner as you routinely test *M. tuberculosis* or NTM isolates in your laboratory.**

If the contents of your package are not complete, or if additional cultures are required, please call **Coordinator (Name)** at **CTD** at xxx-xxx-xxxx or xxx-xxx-xxxx, immediately. Using your laboratory password, you may enter your result on-line at

<https://www.phppo.cdc.gov/mpep/mtbds/login.aspx>

Or, use the enclosed Result Form Booklet. The completed Results Form Booklet must be postmarked and mailed to Contractor to be decided (CTD) no later than **Month date, year**. Use **one** method, **do not** do enter your results on-line **and** mail. To ensure that your data will be included in the tabulations you may (at your expense) return your Results Form Booklet by overnight courier or fax it to **xxx-xxx-xxxx**. Please send your Results Form to:

**CTD**  
**Attention: Program Coordinator**  
**Address**  
**City, State Zip Code**

**INSTRUCTIONS FOR COMPLETING THE RESULTS FORM AND THE  
LABORATORY INFORMATION CHANGE FORM**

1. Please verify your laboratory information and make any changes on the enclosed Laboratory Information Change Form.
2. For multiple choice questions beginning on page 4 of the Results Form Booklet, **fully blacken the circle** to the left of the appropriate answer. **Please do not use checks marks (✓) or cross marks (X) within the circles.**
3. A colored sheet is included providing a case history on the NTM which the participants may want to use in determining the selection of drugs to be tested. **Please refer to the NCCLS Guidelines on Susceptibility Testing of Mycobacteria for further testing methods, drugs and concentrations recommended for NTM.**

If you need assistance in completing the forms, please call **Program Coordinator** of **CTD** at **xxx-xxx-xxxx** or **xxx-xxx-xxxx**.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention  
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SUSCEPTIBILITY TESTING OF *MYCOBACTERIUM TUBERCULOSIS* AND  
NON-TUBERCULOUS MYCOBACTERIA  
RESULTS FORM  
Month 2004

The following terms and abbreviations will be used in this survey:

*M. tuberculosis* = *Mycobacterium tuberculosis*

NTM = Non-tuberculous mycobacteria

Conc = Concentration

µg = Microgram

Prepared For:

Laboratory Name:  
Shipping Address of Laboratory (address to which samples should be sent):  
Street:  
City:  
State/Province:  
Zip/Postal Code:  
Country:  
Telephone Number:

Please indicate changes to your laboratory information on the enclosed **Laboratory Information Change Form** and return to:

**Program Coordinator**

**CTD**

**Address**

**City, State Zipcode**

**OR**

**Fax changes to: (xxx) xxx-xxxx**

**OR**

**E-Mail changes to: [programcoordinator@ctd.com](mailto:programcoordinator@ctd.com)**

Person Completing Form:

1. Name: \_\_\_\_\_

Public reporting of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-XXX)

2. Title: \_\_\_\_\_

3. Please indicate the primary classification of your laboratory. **(Please blacken only one circle.)**

- Hospital  
[e.g., city, county, district, community, state, regional, military, Veterans Administration, Federal government (other than military), privately-owned, university, HMO/PPO-owned and operated, religious-associated]
- Health Department  
[e.g., city, county, state, regional, district, national reference laboratory]
- Independent (non-hospital-based)  
[e.g., commercial, commercial manufacturer of reagents, HMO satellite clinic, reference laboratory (non-government affiliated)]
- Other  
[e.g., university-associated research, Federal government research (nonmilitary), privately-funded research]

4. In the last **calendar year** (January 1 - December 31), how many *Mycobacterium tuberculosis* isolates (excluding quality control isolates) did your laboratory test for drug susceptibilities? **(Please write the number of *Mycobacterium tuberculosis* isolates your laboratory tested for susceptibility in the boxes below.)**

*Mycobacterium tuberculosis* isolates:

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The following questions pertain to the receiving and testing of the culture panel. In most cases, blacken the circle corresponding to your response in the circle provided to the left of the answer. Some questions may require more than one response; please blacken all that apply. In some cases, you will be asked to fill in the boxes to the right of the answer with an appropriate comment or number.

5. On what date was the culture panel received in your laboratory?

		/			/				
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Month

Day

Year

6. What was the condition of the cultures in the panel when they arrived? **(Please blacken only one circle.)**
- Satisfactory
  - Broken
  - Other (please explain): \_\_\_\_\_
7. Please indicate what level of biosafety practices your mycobacteriological laboratory follows for *M. tb* cultures. **(Please blacken only one circle.)**
- Biosafety Level 1
  - Biosafety Level 2
  - Biosafety Level 3
  - Biosafety Level 2 for facilities with Level 3 containment equipment
  - Do not know
8. What procedure(s) was used in your laboratory to perform drug susceptibility testing on these *M. tb* cultures **in this shipment?** **(Please blacken all that apply.)**
- Agar Proportion (Middlebrook medium)
  - Radiometric (BACTEC)
  - Lowenstein Jensen (LJ) proportion method
  - MGIT
  - Other (please specify): \_\_\_\_\_
- 9a. Indicate **the primary** *M. tb* susceptibility **test medium** used by your laboratory for the cultures in this shipment. **(Please blacken only one circle.)**
- BACTEC 12B (with or without PZA media)
  - Middlebrook 7H10
  - Middlebrook 7H11
  - ESP-Myco
  - MGIT
  - Other (please specify): \_\_\_\_\_

- 9b. If you use a **rapid test method** for susceptibility testing of the ant TPEP: «lngTPEPNum» you purchase the drugs from the manufacturer? **(Please blacken only one circle.)**
- Yes
  - No
  - Not Applicable
- 9c. If you use Middlebrook 7H10 or 7H11 media for any anti-tuberculosis drug susceptibility testing, your media is: **(Please blacken all that apply.)**
- purchased “commercially-prepared” containing anti-tuberculosis drugs
  - prepared in-house with disks containing anti-tuberculosis drugs
  - prepared in-house by reconstituting and adding anti-tuberculosis drugs
  - Not Applicable

**Non-tuberculous mycobacteria**

10. Does your laboratory perform **on-site** susceptibility testing of non-tuberculous mycobacteria? **(Please blacken only one circle.)**
- Yes
  - No
  - Not applicable
11. For the species of NTM that you **do not test in-house**, do you **refer (send out)** these to another laboratory for drug susceptibility testing? **(Please blacken only one circle.)**
- Yes
  - No
  - Not applicable
12. What procedure(s) was used in your laboratory to perform drug susceptibility testing on the **NTM culture in this shipment?** **(Please blacken all that apply.)**
- Do Not Perform
  - Agar Proportion
  - BACTEC 460
  - E-Test
  - Microtiter
  - Agar Disk Elution
  - Kirby Bauer
  - Lowenstein-Jensen
  - MGIT
  - Other (please specify): \_\_\_\_\_

**M. tuberculosis/NTM Results Form**

13. For each antimicrobial that you use routinely to determine the susceptibility of *M. tb* and NTM isolates, record a test method, the concentration of the antimicrobial and a result (R=Resistant, S=Susceptible, O=Other). (Please see example 1.) If the isolates in the panel were tested using more than one concentration of an antimicrobial, record those results on lines that correspond to the antimicrobial you are testing (example 1). If you need more lines than are provided for that antimicrobial, please record results in the blank lines provided at the bottom of the result page. Do not cross out an existing antimicrobial and write another drug name over it (example 2).

If you are testing an antimicrobial not listed on the result page, record the entire drug name (no abbreviations), a concentration and a result in the blank lines provided at the bottom of the result page. Please make sure that each result is recorded on a provided line and not written in the margins outside the form. Make a copy of the result page if you do not have enough room on the provided page to record all results.

Other responses related to susceptibility results such as Borderline, Contaminated, No Growth, etc. can be abbreviated and recorded to the right of the "O" selection in the result columns (examples 1 and 3).

1. Following are examples of **CORRECTLY** reported *M. tuberculosis* results.

Antimicrobial	Test Method	Concentration			Strain K	Strain L	Strain M
Isoniazid	A ● C ○		0	.	1	R ● O	● S ○ R ● O <b>NG</b>
Isoniazid	● B C ○		0	.	2	R ● O	● S ○ R ● O <b>NG</b>
Isoniazid	● B C ○		1	.	0	R ● O	● S ○ R S ● <b>NG</b>

2. Following are examples of **INCORRECTLY** reported *M. tuberculosis* results.

Isoniazid	A B C ○	1	2	-	.	-	0	<del>R ● O</del>	R S ○	R S ○
Rifampin <b>Isoniazid</b>	● B C ●				.			R ● ●	● S ●	● ● ○

3. Following are examples of **CORRECTLY** reported NTM results.

Rifampin	● B C D E F ○		1	.	0	R ● O	⊖ ⊗ ⊖		.	R S ○
Rifampin	A ● C D E F ○		2	.	0	R S ● <b>B</b>	⊖ ⊗ ⊖		.	R S ○
Rifampin	A B ● D E F ○			.		R S ○	⊖ ● ⊖	1	.	5 ● S ○

**These are the results for *M. tuberculosis* complex testing.**

The NTM results (if applicable) will go on the next page.

**\*\*Please provide the Test Method, the Concentration, and the Test Results for each line reported.**

13. (Continued) Use the blank lines provided at the end of the form for other drugs or additional concentrations.	A=Agar Proportion B=BACTEC C=L-J Proportion D=MGIT O=Other: (Choose only one)	Please list each concentration	Culture Identification Codes (Fill in ONE letter for each culture) R=Resistant S=Susceptible O=Other Please indicate any other responses in the space provided For example: B=Borderline, C=Contaminated, NG=No growth			
Antimicrobia I	Test Method	Conc. µg/mL	P	Q	R	S
Isoniazid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Isoniazid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Isoniazid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Isoniazid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Rifampin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Rifampin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Rifampin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Pyrazinamide	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Pyrazinamide	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Pyrazinamide	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ethambutol	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ethambutol	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ethambutol	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Streptomycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Streptomycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Streptomycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ethionamide	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ethionamide	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Kanamycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Kanamycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Capreomycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Capreomycin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Cycloserine	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Cycloserine	A B C D O	. . . . .	R S O	R S O	R S O	R S O
p-Aminosalicylic acid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
p-Aminosalicylic acid	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Amikacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Amikacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ofloxacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ofloxacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ciprofloxacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
Ciprofloxacin	A B C D O	. . . . .	R S O	R S O	R S O	R S O
	A B C D O	. . . . .	R S O	R S O	R S O	R S O
	A B C D O	. . . . .	R S O	R S O	R S O	R S O
	A B C D O	. . . . .	R S O	R S O	R S O	R S O
	A B C D O	. . . . .	R S O	R S O	R S O	R S O
	A B C D O	. . . . .	R S O	R S O	R S O	R S O

Note: Please provide the complete drug name when filling in additional spaces.



**M. tuberculosis/NTM Results Form**

TPEP:

**STRAIN T RESULTS – M. fortuitum**

**These are the results for NTM testing.**

**\*\*Please provide the Test Method, the Concentration, and the Test Results for each line reported.**

	METHOD	CONC.	RESULT	FOR MIC TEST RESULTS ONLY					
<b>13.(Continued)</b> Use the blank lines provided at the end of the form for other drugs or additional concentrations.	A=Agar Proportion B=BACTEC 460 C=L-J Proportion D=E-Test E=Microtiter F=Disk Elution (macro broth) G=Kirby Bauer H=MGIT O=Other: _____ (Choose only one)	Please list <u>each</u> Concentration (µg/mL)	<b>R=Resistant</b> <b>S=Susceptible</b> <b>O=Other</b> Please indicate any other responses in the space provided.	These spaces are for the MIC test results. Blacken the appropriate sign.		Please list <u>each</u> Concentration (µg/mL)		<b>R=Resistant</b> <b>S=Susceptible</b> <b>O=Other</b> Please indicate any other responses in the space provided.	
<b>Clarithromycin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Clarithromycin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Azithromycin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Azithromycin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Rifampin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Rifampin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Rifabutin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Rifabutin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Amikacin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Amikacin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Cefoxitin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Cefoxitin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Imipenem</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Imipenem	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Sulfamethoxazole</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Sulfamethoxazole	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>TMP/SMX(TMP)*</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
TMP/SMX(TMP)*	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Ofloxacin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Ofloxacin	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Doxycycline</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Doxycycline	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Minocycline</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
Minocycline	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Tobramycin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Ciprofloxacin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Isoniazid</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Ethambutol</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
<b>Streptomycin</b>	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	
	A B C D E F G H C	.	R S O	≤	≥	=	.	R S O	

\* If you are using TMP/SMX, please provide only the concentration for TMP on the appropriate line.

NOTE: Please provide the complete drug name when filling in additional spaces.