



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
Coordinating Center for Infectious Diseases, Mail Stop G-25  
Atlanta, Georgia 30333**



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**GENERAL INSTRUCTIONS and WORKSHEET**

**DRUG SUSCEPTIBILITY TESTING PROGRAM FOR  
*MYCOBACTERIUM TUBERCULOSIS* and NON-TUBERCULOUS  
MYCOBACTERIA**

**WARNING**

The culture panel provided in this survey consists of viable strains of *Mycobacterium tuberculosis* (*M. tb*) only, some of which are drug-resistant. The cultures in the panel should be considered hazardous and capable of transmitting infection. Testing should only be done if the recommended safety procedures are followed as described in the *Centers for Disease Control and Prevention's Biosafety in Microbiological and Biomedical Laboratories, 2007, 5th Edition*. This manual can be accessed at [http://www.cdc.gov/od/ohs/biosfty/bmb15/BMBL\\_5th\\_Edition.pdf](http://www.cdc.gov/od/ohs/biosfty/bmb15/BMBL_5th_Edition.pdf). This manual recommends use of Biosafety Level 3 practices when testing *M. tb* cultures.

**PLEASE READ ALL INSTRUCTION SHEETS COMPLETELY BEFORE  
PROCEEDING WITH ANY CULTURE EVALUATION.**

The results must be entered on-line or postmarked not later than MM/dd/yyyy

Check the contents of your package. It should contain:

1. Cover letter.
2. Envelope containing:
  - (a) Results Worksheet for recording testing results with instructions.
  - (b) Laboratory Information Change Form for recording any changes to laboratory information.

***Please note: All results must be entered online at***  
<http://wwwn.cdc.gov/mpep/mtbds/login.aspx>

3. Shipping container with a panel of four (4) labeled "TB Test Cultures." The culture tubes are labeled with individual identification codes.

**NOTE: Shipping containers with a panel of only four (4) cultures are provided to the laboratories that perform TB drug Susceptibility testing.**

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-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0600)

If the contents of your package are not complete, or if additional cultures are required, please call **Dr. Angela Ragin, Project Coordinator** at CDC at 404-498-2241 immediately.

**Treat these cultures in the same manner that you routinely treat *Mycobacterium tuberculosis* isolates.**

### **INSTRUCTIONS FOR ENTERING RESULTS**

**Please enter your results on-line data ONLY;** you will need

- your TPEP number \_\_\_\_\_
- password \_\_\_\_\_.

If you have forgotten or misplaced your password, contact **Dr. Angela Ragin, Project Coordinator** at **CDC toll free** at 1-888-465-6062 or 404-498-2241. Results must be entered in the on-line data entry system no later than **Month/day/year**.

1. After testing your samples, enter your results at the CDC Tuberculosis Drug Susceptibility Website using the password assigned to your laboratory. The Website is located at the following HTML address:

<http://wwwn.cdc.gov/mpep/mtbds/login.aspx>

2. Please **verify** laboratory information and make any changes on the Website or on the enclosed Laboratory Information Change Form then fax it to 404 498 2372.
3. **Only** on-line results entry will be accepted.
4. For multiple choice questions beginning on page 5 of the Results Worksheet worksheet, **fully blacken the circle** to the left of the appropriate answer. **Please do not use checks marks (✓) or cross marks (X) within the circles.**

**Do not mail the Results Worksheets. They are for your laboratory use only.**

Results must be entered online on or before the specified deadline.

If you require assistance entering your data, please contact Ms. Yolanda Castillo or Dr. Angela Ragin at 1-888-465-6062 (toll-free) or 404-498-2241

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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OMB Form NO. \_\_\_\_\_  
Exp. Date \_\_\_\_\_

**CDC DRUG SUSCEPTIBILITY TESTING PROGRAM FOR *MYCOBACTERIUM*  
*TUBERCULOSIS* AND NON-TUBERCULOUS MYCOBACTERIA RESULTS**

**WORKSHEET**  
Month Year

Completed Results Can Be Entered at the CDC Tuberculosis  
Susceptibility Website:

<http://wwwn.cdc.gov/mpep/mtbds/login.aspx>

FAX: (404) 498 2372

Or

Mail: Angela Ragin, Ph.D.  
Centers for Disease Control and Prevention  
Division of Laboratory Systems  
1600 Clifton Road, NE,  
Mail Stop G-23  
Atlanta, GA-30333

Please indicate changes to your laboratory information on the  
**Laboratory information Change Form** and return by email or fax to **project officer**.

The Project Officer can be contacted at:

[MTBNTMDST@CDC.GOV](mailto:MTBNTMDST@CDC.GOV) or  
[aragin@cdc.gov](mailto:aragin@cdc.gov) or 404 498-2241

FAX: 404 498-2372

Person Completing Form:

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

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

**M. tuberculosis Results Worksheet**

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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  
[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, YYYY), 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?

		/			/				
Month			Day			Year			

***M. tuberculosis* Results Worksheet**

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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 the level of biosafety practices followed in your mycobacteriological laboratory when working with ***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 460)
  - Lowenstein Jensen (LJ) proportion method
  - Automated MGIT 960
  - 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 460 12B (with or without PZA media)
  - Middlebrook 7H10
  - Middlebrook 7H11
  - Versa-Trek Myco
  - Automated MGIT 960
  - Other (please specify): \_\_\_\_\_

**M. tuberculosis Results Worksheet**

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9b. If you use a **rapid test method** for susceptibility testing of the anti-tuberculosis drugs, do 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

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
- Automated MGIT 960
- Other (please specify): \_\_\_\_\_

## *M. tuberculosis* Results Form Worksheet

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13. For each antimicrobial that you use routinely to determine the susceptibility of *M. tb*, 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. tb* results.

Isoniazid	A ● C ○			0	.	1		R ● O	● S ○	R ● O
Isoniazid	● B C ○			0	.	2		R ● O	● S ○	R ● O
Isoniazid	● B C ○			1	.	0		R ● O	● S ○	R S ● NG

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

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

## M. tuberculosis Results Worksheet

**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.**

<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 C=L-J Proportion D=MGIT O=Other: (Choose only one)	Please list <u>each</u> concentration	<b>Culture Identification Codes</b> (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,			
<b>Antimicrobial</b>	<b>Test Method</b>	<b>Conc. µg/mL</b>	<b>K</b>	<b>L</b>	<b>M</b>	<b>N</b>
<b>Isoniazid</b>	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
<b>Rifampin</b>	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
<b>Pyrazinamide</b>	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
<b>Ethambutol</b>	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
<b>Streptomycin</b>	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
<b>Ethionamide</b>	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
<b>Kanamycin</b>	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
<b>Capreomycin</b>	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
<b>Cycloserine</b>	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
<b>p-Aminosalicylic acid</b>	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
<b>Amikacin</b>	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
<b>Ofloxacin</b>	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
<b>Ciprofloxacin</b>	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.