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

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/bmbl5/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.

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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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-303333

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 or**
> **aragin@cdc.gov or 404 498-2241**
> **FAX: 404 498-2372**

Person Completing Form:

1.	Name: _____

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]
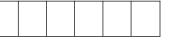
◯ Health Department
   [e.g., city, county, state, regional, district, national reference laboratory]

◯ Independent
   [e.g., commercial, commercial manufacturer of reagents, HMO satellite clinic, reference laboratory (non-government affiliated)]
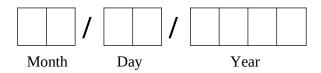
◯ Other
   [e.g., university-associated research, Federal government research (nonmilitary), privately-funded research]

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: ☐☐☐☐☐☐

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

_____

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): _____

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): _____

_____

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

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

Isoniazid	Ⓐ Ⓑ Ⓒ Ⓞ	1	2	-	.	-	0	☒ ● Ⓞ	Ⓡ ✓Ⓞ	✓Ⓢ Ⓞ
Isoniazid	● Ⓑ Ⓒ ●				.			Ⓡ ● ●	● Ⓢ ●	● ● Ⓞ

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.

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,			
Antimicrobial	**Test Method**	**Conc. µg/mL**	**K**	**L**	**M**	**N**
Isoniazid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Isoniazid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Isoniazid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Isoniazid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Rifampin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Rifampin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Rifampin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Pyrazinamide	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Pyrazinamide	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Pyrazinamide	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ethambutol	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ethambutol	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ethambutol	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Streptomycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Streptomycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Streptomycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ethionamide	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ethionamide	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Kanamycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Kanamycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Capreomycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Capreomycin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Cycloserine	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Cycloserine	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
p-Aminosalicylic acid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
p-Aminosalicylic acid	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Amikacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Amikacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ofloxacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ofloxacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ciprofloxacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
Ciprofloxacin	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ
	Ⓐ Ⓑ Ⓒ Ⓓ Ⓞ	.	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ	Ⓡ Ⓢ Ⓞ

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