U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Coordinating Center for Infectious Diseases, Mail Stop G-23
Atlanta, Georgia 30333

OMB Form NO. __0920-0600_
Exp. Date _05/13/2013_

DRUG SUSCEPTIBILITY TESTING PROGRAM FOR *MYCOBACTERIUM TUBERCULOSIS*

WARNING: The culture panel provided in this survey consists of viable strains of *Mycobacterium tuberculosis Complex (MTBC)* 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 *MTBC* cultures.

Check the contents of your package. It should contain:

(1) Cover letter
(2) Results Worksheet for recording testing results with instructions.
(3) Laboratory Information Change Form for recording any changes to laboratory information.
(4) Shipping container with five (5) cultures labeled "TB Cultures." The culture tubes are labeled with individual identification codes.

If the contents of your package are not complete, or if additional cultures are required, please call **XXXXX, Project Officer** at **CDC** at 404-498-XXXX immediately.

INSTRUCTIONS FOR ENTERING RESULTS

Results must be entered in the on-line data entry system only no later than **XX/XX/XXXX.** You will need your TPEP number and password. If you have forgotten or misplaced your password please contact Ms Sandra Neal at 404 498-2238.

1. After testing your samples, enter your results at the CDC Tuberculosis Drug Susceptibility Website: 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.
3. If you can not use the on-line data entry system, please complete the Results Worksheet and contact the project officer at (888) 465-6062 or 404-498-2238.
4. For multiple choice questions beginning on page 4 of the Results 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**.

***MTBC* Results Worksheet**

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CDC DRUG SUSCEPTIBILITY TESTING PROGRAM FOR *MYCOBACTERIUM TUBERCULOSIS* RESULTS FORM

Report your results Online (password required) at:

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

TPEP number: _____ (you will need this to enter your results online)

DEADLINE for submission XXXX, 2010

Please note: **Treat these cultures in the same manner that you routinely treat MTBC isolates, with the following exception:**
If you test second-line drugs in your laboratory, test these isolates (regardless of results from testing first-line drugs) using those second-line drugs normally used to test patient isolates. This will provide you with an opportunity to evaluate your performance for testing second-line drugs.

WARNING: The culture panel provided in this survey consists of viable strains of *Mycobacterium tuberculosis* Complex *(MTBC)* 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.

If you do not have the capacity to enter your results online or if you need assistance contact: XXX-XXX-XXXX
The Project Officer can be contacted at:
Sneal@cdc.gov or 404 498-2238

Please indicate changes to your laboratory information on the enclosed **Laboratory information Change Form** and return to **project officer.**

Person(s) Completing Form:

1. Name: _____

2. Title: _____

MTBC Worksheet

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, XXXX), how many *Mycobacterium tuberculosis complex* (MTBC) 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.**)

***MTBC* 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. What method(s) was used in your laboratory to perform drug susceptibility testing on the MTBC isolates **in this shipment**? **(Please blacken all that apply.)**

   ◯ Agar Proportion (Middlebrook 7H10)

   ◯ Agar Proportion (Middlebrook 7H11)

   ◯ Radiometric (BACTEC)

   ◯ VersaTREK Myco

   ◯ MGIT System

   ◯ Lowenstein Jensen (LJ) proportion method

   O Molecular Method (please specify): _____

   O Other (please specify): _____

8. If your laboratory uses more than one method for testing this shipment's isolates for first-line drugs for MTBC susceptibility, please indicate **the primary method (NOT confirmatory method)** that is used. **(Please blacken only one circle.)**

   ◯ Agar Proportion (Middlebrook 7H10)

   ◯ Agar Proportion (Middlebrook 7H11)

   ◯ Radiometric (BACTEC)

   ◯ VersaTREK Myco

   ◯ MGIT System

   ◯ Lowenstein Jensen (LJ) proportion method

   O Molecular Method (please specify): _____

   O Other (please specify): _____

9. If you use Middlebrook 7H10 or 7H11 media as either a primary or secondary method of *MTBC* 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

Note: Question 10 is a new question, to be asked one time only for informational purposes.

10 a. In your opinion, is there a need for offering performance evaluation of NTM strains?

- ◯ Yes
- ◯ No

10 b. If yes - For your laboratory, would it be more advantageous to offer evaluation of:

- ◯ Rapidly growing NTM
- ◯ Slowly growing NTM

Continue to the next page.

11. 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). 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	● Ⓑ Ⓒ●				·			Ⓡ● ●	● Ⓢ ●	● ● Ⓞ

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

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

12. (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**	**O**	**P**	**Q**	**R**	**S**
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.

Public reporting burden of this collection of information is estimated to average 6 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, Attn: PRA 0920-0600