

Justification for Change Request

Purpose

CDC is requesting OMB approval for a non-substantial change request to OMB 0920-0600 Model Performance Evaluation Program for Mycobacterium tuberculosis/non-tuberculosis Mycobacteria Drug Susceptibility Testing Program. These are minor changes that include:

(1) additional choices that a participant can select from in answering 2 of the questions (Question #7 and Question #8) on the MTBC Results Worksheet that accompanies the *M. tuberculosis* (TB) isolates. Two (2) of the additional choices list specific molecular methods, so with these additions, we can delete the current choice for a generic molecular method with instructions to write-in the specific molecular method. Modifying these choices should minimize the events in which a participant must write in a testing methodology, and also simplify analysis.

(2) revising text in Question #8 from “If your laboratory uses more than one method for testing **this shipment’s isolate...**” to “If your laboratory uses more than one method for testing **routine samples...**”; and to change the wording from “**primary method (not confirmatory).**” to “**initial method.**” These revisions would clarify the intent of the question and provide more accurate information.

(3) clarifying in Question #9 that the selection for ‘not applicable’ means that the laboratory does not use the method in question. Previously, a few participants made a selection for how they obtained their media, as well as selecting ‘not applicable.’

(4) correcting our address to account for a new Mailstop as a result of CDC’s reorganization.

Previously Approved Questions

Below are Questions #7 and #8 that were approved in October 2010, showing the way they are worded, and the options from which a participant can select in answering the questions:

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
- Molecular Method (please specify): _____
- 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
- Molecular Method (please specify): _____
- Other (please specify): _____

9. If you use Middlebrook 7H10 or 7H11 media as either an initial 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

Modified Questions

We are requesting to modify the questions to read (revisions highlighted):

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)
- Genotype MTBDRplus (Hain Lifescience)
- Genotype MTBDRsl (Hain Lifescience)
- Lowenstein Jensen (LJ) proportion method
- MGIT System
- Radiometric (BACTEC 460)
- VersaTREK Myco
- XPERT MTB/RIF (Cepheid)
- Laboratory Developed Test (LDT) (please specify): _____
- Other (please specify): _____

8. If your laboratory uses more than one method for testing routine samples for first-line drugs for MTBC susceptibility, please indicate the initial method that is used. (Please blacken only one circle.)

- Agar Proportion (Middlebrook 7H10)
- Agar Proportion (Middlebrook 7H11)
- Genotype MTBDRplus (Hain Lifescience)
- Genotype MTBDRsl (Hain Lifescience)
- Lowenstein Jensen (LJ) proportion method
- MGIT System
- Radiometric (BACTEC 460)
- VersaTREK Myco
- XPERT MTB/RIF (Cepheid)
- Laboratory Developed Test (LDT) (please specify): _____
- Other (please specify): _____

9. If you use Middlebrook 7H10 or 7H11 media as either an initial 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

- o prepared in-house by reconstituting and adding anti-tuberculosis drugs
- o Not Applicable – We do not use Middlebrook media