**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**

**OMB Form NO. \_\_0920-0600\_**

**Exp. Date \_05/31/2013**

**Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* and Nontuberculous Mycobacteria Drug Susceptibility Testing**

**WARNING: The panel provided in this survey consists of viable cultures of Mycobacterium tuberculosis complex, 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**](http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf)**.   
Biosafety Level 3 practices should be used when testing MTBC cultures.**

**GENERAL INSTRUCTIONS**

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

Check the contents of your package. It should contain:

1. Cover letter
2. Results Worksheet for recording testing results with instructions.

(3) 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 Lois Diemat404-639-2862 immediately.

**INSTRUCTIONS FOR ENTERING RESULTS**

Results must be entered in the on-line data entry system only no later than **June 6, 2011.** You will need your TPEP number and password. If you have forgotten or misplaced your password please contact Suzette Brown at 404 498-2283 or 888-465-6062.

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 in addition to sending updated information to [MTBNTMDST@CDC.GOV](mailto:MTBNTMDST@CDC.GOV).

3. If you can not use the on-line data entry system, please complete the Results Worksheet and contact the project coordinator at (888) 465-6062 or 404-498-2283.

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 check marks () or cross marks (X) within the circles**.

***MTBC* Results Worksheet**

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**Exp. Date \_05/31/2013**

**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 June 6, 2011**

***Please note:* Treat these cultures in the same manner that you routinely treat MTBC isolates. Please test each MTBC isolate against first line drugs and any second line drug tested in your laboratory. This will provide you with an opportunity to evaluate your performance for testing second-line drugs.**

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This manual can be accessed at** [**http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL\_5th\_Edition.pdf**](http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf)**.   
Biosafety Level 3 practices should be used when testing MTBC cultures.**

**If you do not have the capacity to enter your results online or if you need assistance contact**

**Suzette Brown at:**

* telephone (888) 465-6062 or (404) 498-2283
* email [MTBNTMDST@CDC.GOV](mailto:MTBNTMDST@CDC.GOV)

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 (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:

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

***MTBC* Worksheet**

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)

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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***MTBC* Woksheet**

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 – We do not use Middlebrook media

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

Yes

No

10b. 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.*

***MTBC Worksheet***

11. For each antimicrobial concentration tested: Select the antimicrobial, 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 | A B C O |  |  | 0 | . | 1 |  | R S O | R S O | R S O |
| Isoniazid | A B C O |  |  | 0 | . | 2 |  | R S O | R S O | R S O |
| Isoniazid | A B C O |  |  | 1 | . | 0 |  | R S O | R S O | R S O **NG** |

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Isoniazid | A B C O | 1 | 2 | - | . | - | 0 | R S O | R S O | R S O |
| Isoniazid | A B C O |  |  |  | . |  |  | R S O | R S O | R S O |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *MTBC Worksheet* \*\*Please provide the Test Method, the Concentration, and the Test Results for each line reported. | | | | | | | | | | | |
| **11.** Use the blank lines provided at the end of the form for other drugs or additional concentrations. Please provide the complete drug name when filling in additional spaces. | **A=Agar Proportion (7H10) B= Agar Proportion (7H10),**  C= **BACTEC**  **D= VERSA**  **E= MGIT**  **F= L-J Proportion**  **M= Molecular Method**  **O=Other** | | | | | | **Culture Identification Codes  (Fill in ONE letter for each culture)** **R=Resistant**  **S=Susceptible**  **B=Borderline**  **C=Contaminated**  **N=No Growth** | | | | |
| **Antimicrobial** | **Test Method** | **Conc. μg/mL** | | | | | **A** | **B** | **C** | **D** | **E** |
| 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.

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