JOURNAL OF CLINICAL MICROBIOLOGY, Apr. 1997, p. 1041–1042 Vol. 35, No. 4
0095-1137/97/$04.00+0

# Turnaround Times for Mycobacterial Cultures

In a recent Guest Commentary (5), Dr. Doern discusses some potential costs and benefits of nucleic acid amplification tests, such as the Gen-Probe Amplified Mycobacterium Tuberculosis Direct Test, for direct detection of *Mycobacterium tuberculosis* in clinical specimens. Discussion of these tests is useful because their place in laboratory practice is not yet clear. Centers for Disease Control and Prevention (CDC) recommendations regarding their use are being developed, and interim guidelines have appeared (4); a performance evaluation program for laboratories is also under development. Because much of Dr. Doern's cost-benefit analysis rests on difficulties in satisfying a "standard of 10 to 14 days for the isolation and definitive species identification of *M. tuberculosis*" attributed to "current CDC recommendations," we would like to clarify CDC positions regarding turnaround times for mycobacterial cultures.

The 10- to 14-day turnaround time for isolation and identification of *M. tuberculosis* cited by Dr. Doern is taken from an article (6) which discusses rapid mycobacteriology practices. However, the focus of the article is on recommendations for specific processes and techniques, and specific culture turnaround times are not included in the list of recommendations, despite discussion of the usual times for growth by rapid techniques. In some settings, the routine use of recommended methods can result in turnaround times as short as 10 to 14 days. However, because of limited resources in other mycobacteriology laboratories and variability in the growth of *M. tuberculosis* strains as well as in test performance, recent CDC-related publications recommend (or refer to recommendations for) turnaround times extending up to 21 days for isolation and identification (1–3). For example, the statement "Reporting of *M. tuberculosis* complex should average 14–21 days from receipt of specimen" appears on page 76 of *Mycobacterium tuberculosis*: *Assessing Your Laboratory* (1), a 1995 cooperative effort between CDC and the Association of State and Territorial Public Health Laboratory Directors. The CDC-recommended target turnaround times are based on use of liquid culture media and rapid identification tests. Most laboratories listed by Dr. Doern reported times of 22 days or less even during 1993, and increasing proportions of laboratories in both hospital and public health settings report achieving 21-day turnaround times in surveys published last year (2, 7, 8), suggesting continued performance improvement with established methods.

Analyses of feasibility, utility, and cost-effectiveness of new and established diagnostic methods for tuberculosis from different viewpoints are important. The balance of benefits and costs may change with the development of new tests and experience with their clinical applications and may vary with local disease prevalence and transmission risks. Existing CDC recommendations for mycobacteriology laboratory performance are goals to aim toward; they are not mandates or regulations. The recommendations reflect capabilities with available technology and evolve as new techniques are integrated into routine practice. Ultimately, the development of cost-effective methods for reducing the time to isolation, species identification, and drug susceptibility testing will serve to significantly improve decisions about the clinical care of affected persons.

## REFERENCES

1. **Association of State and Territorial Public Health Laboratory Directors and U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention.** 1995. *Mycobacterium tuberculosis*: assessing your laboratory. Association of State and Territorial Public Health Laboratory Directors and Centers for Disease Control and Prevention, Atlanta, Ga.
2. **Bird, B. R., M. M. Denniston, R. E. Huebner, and R. C. Good.** 1996. Changing practices in mycobacteriology: a follow-up survey of state and territorial public health laboratories. J. Clin. Microbiol. **34:**554–559.
3. **Centers for Disease Control and Prevention.** 1996. Prevention and control of tuberculosis in correctional facilities: recommendations of the Advisory Council for the Elimination of Tuberculosis. Morbid. Mortal. Weekly Rep. **45**(RR-8)**:**1–28.
4. **Centers for Disease Control and Prevention.** 1996. Nucleic acid amplification tests for tuberculosis. Morbid. Mortal. Weekly Rep. **45:**950–952.
5. **Doern, G. V.** 1996. Diagnostic mycobacteriology: where are we today? J. Clin. Microbiol. **34:**1873–1876.
6. **Tenover, F. C., J. T. Crawford, R. E. Huebner, L. J. Geiter, C. R. Horsburgh, Jr., and R. C. Good.** 1993. The resurgence of tuberculosis: is your laboratory ready? J. Clin. Microbiol. **31:**767–770.
7. **Tokars, J. I., J. R. Rudnick, K. Kroc, L. Manangan, G. Pugliese, R. E. Huebner, J. Chan, and W. R. Jarvis.** 1996. U.S. hospital mycobacteriology laboratories: status and comparison with state public health department laboratories. J. Clin. Microbiol. **34:**680–685.
8. **Woods, G. L., T. A. Long, and F. G. Witebsky.** 1996. Mycobacterial testing in clinical laboratories that participate in the College of American Pathologists mycobacteriology surveys. Changes in practices based on responses to 1992, 1993, and 1995 questionnaires. Arch. Pathol. Lab. Med. **120:**429–435.

**Barbara A. Styrt**
*Division of TB Elimination*
*National Center for HIV, STD, and TB Prevention*

**Thomas M. Shinnick**
*Division of AIDS, STD, and TB Laboratory Research*
*National Center for Infectious Diseases*

**John C. Ridderhof**
*Division of Laboratory Systems*
*Public Health Practice Program Office*

**Jack T. Crawford**
*Division of AIDS, STD, and TB Laboratory Research*
*National Center for Infectious Diseases*

**Fred C. Tenover**
*Hospital Infections Program*
*National Center for Infectious Diseases*
*Centers for Disease Control and Prevention*
*1600 Clifton Rd. N.E.*
*Atlanta, Georgia 30333*

## Author's Reply

I express my appreciation to B. A. Styrt and colleagues for their helpful comments. They have clarified what has been a source of considerable confusion for clinical microbiologists, at least those working in hospital-based and private independent laboratories. To wit, what really is the CDC's position on requisite turnaround time for recovery and identification of *Mycobacterium tuberculosis*? In a definitive 1992 statement describing a national initiative to combat multidrug-resistant tuberculosis (2), Hinman et al. of the CDC wrote that "positive cultures should be identified as to species within 17–21 days of receipt of specimen." This article was followed 1 year later by a Guest Commentary in this journal in which Tenover and colleagues of the CDC state, in concluding remarks, the following: "Studies carried out on the basis of these recommen-

dations should ensure. . . .identification of *M. tuberculosis* within 10 to 14 days. . . .of specimen collection. Is your laboratory ready?" (4). As Styrt et al. indicate in their letter, more-recent CDC publications, including a national survey of mycobacteriology laboratory practices (1), return to the original turnaround time recommendation of ≤21 days.

Turnaround may be the operative word here. The Guest Commentary I authored was written subsequent to the commentary of Tenover et al. As part of our laboratory's quality assurance program, we had, 3 years previously, established length of time to recovery and definitive species identification of *M. tuberculosis* as a process indicator to be tracked continuously in our mycobacteriology section. I knew from this quality assurance monitor that on the average, our laboratory required 20 days to isolate and identify *M. tuberculosis*, even though we routinely employed a broth-based radiometric detection system with probe-based identification directly on growth in primary positive cultures. To wit, we seemed to be meeting an initial CDC guideline (2) but fell conspicuously short of the recommendation published by Tenover and colleagues in 1993 (4).

I performed the survey described in my commentary expressly for purposes of determining whether other laboratories using comparable techniques were doing better than we were and, if that were the case, how we could improve on our performance. In general, as communicated in my commentary, I found that our laboratory was pretty typical. That was reassuring. I was, however, bothered by the fact that 8 of 10 large, academic medical center laboratories appeared to fall conspicuously short of what I thought was a CDC guideline defining ≤14 days as the turnaround time target for isolating and identifying *M. tuberculosis* (4). This recommendation had been widely embraced by the clinical microbiology community; it had been the topic for discussion at both national microbiology and infectious disease meetings, as well as in the peer-reviewed literature (5). That the real goal of the CDC is a turnaround time of ≤21 days will be welcome information to all practicing clinical microbiologists. This objective is reasonable and can be achieved by laboratories employing currently available, state-of-the-art methods for recovery and identification of *M. tuberculosis* (1, 3).

Parenthetically, I would like to comment on one of the statements made by Styrt et al. in their letter. They write, "Existing CDC recommendations for mycobacteriology laboratory performance are goals to aim toward; they are not mandates or regulations." In this, I am reminded of a comment made to me by a baseball coach more years ago than I care to admit, when I was a college freshman. We were about to play Indiana. It went something like this: "Gary, unless you move closer to the plate, you'll never be able to reach this guy's fastball on the corner. I recommend you move in at least 6 or 8 inches." I did not, and I proceeded to strike out three times, all on outside fastballs. I sat on the bench for the next four games.

The point is this: recommendations or guidelines or objectives, or whatever else we choose to call them, take on added weight when they come from an agency as authoritative and entrenched as the CDC. Rightly or wrongly, CDC recommendations are often, if not usually, perceived as mandates or directives. In this respect, extraordinary care should be exercised when developing "recommendations" regarding laboratory practices, especially those that will potentially have an impact on hospital-based or private, independent laboratories. The process whereby such recommendations are developed should be a consensus one, with extensive input from people who actually work in the laboratories that will be affected. Furthermore, the promulgation of such recommendations must be clear and consistent.

## REFERENCES

1. **Bird, B. R., M. M. Denniston, R. E. Huebner, and R. C. Good.** 1996. Changing practices in mycobacteriology: a follow-up survey of state and territorial public health laboratories. J. Clin. Microbiol. **34:**554–559.
2. **Centers for Disease Control and Prevention.** 1992. National action plan to combat multidrug-resistant tuberculosis. Morbid. Mortal. Weekly Rep. **41**(RR-11)**:**1–71.
3. **Doern, G. V.** 1996. Diagnostic mycobacteriology: where are we today? J. Clin. Microbiol. **34:**1873–1876.
4. **Tenover, F. C., J. T. Crawford, R. E. Huebner, L. J. Geiter, C. R. Horsburgh, and R. C. Good.** 1993. The resurgence of tuberculosis: is your laboratory ready? J. Clin. Microbiol. **31:**767–770.
5. **Wood, G. L., and F. G. Witebsky.** 1995. Mycobacterial testing in clinical laboratories that participate in the College of American Pathologists' mycobacteriology E survey: results of a 1993 questionnaire. J. Clin. Microbiol. **33:**407–412.

**Gary V. Doern, Ph.D.**
*Clinical Microbiology Laboratories*
*University of Massachusetts Medical Center*
*55 Lake Avenue North*
*Worcester, Massachusetts 01655*