

# Letter to the Editor

## Gen-Probe Test Should Not Be Considered Final in *Mycobacterium tuberculosis* Identification

The package insert for the Gen-Probe Mycobacterium TB complex (Gen-Probe, Inc., San Diego, Calif.) states very clearly:

"The Gen-Probe rapid diagnostic system for Mycobacterium TB complex is a test to confirm the identity of members of the *Mycobacterium tuberculosis* complex isolated in culture. The test uses a specific <sup>125</sup>I-DNA probe complementary to the ribosomal RNAs of members of the *M. tuberculosis* complex: *M. tuberculosis*, *M. bovis*, *M. bovis* BCG, *M. africanum*, and *M. microti*."

The advantage of this rapid technique (as well as the BACTEC NAP [*p*-nitro- $\alpha$ -acetyl-amino- $\beta$ -hydroxy-propionophenone] test) is obvious: to alert the physician in the short term that the patient's isolate belongs to the *M. tuberculosis* complex and very likely is *M. tuberculosis*. This message can be used as a basis for immediate public health measures, as well as for starting appropriate chemotherapy. But the Gen-Probe technique cannot provide final identification of *M. tuberculosis*, whose identification can be confirmed only by a battery of tests that differentiates *M. tuberculosis* from other members of the complex: niacin, nitrate reduction, pyrazinamidase, and 2-thiophene carboxylic acid susceptibility.

This fact was overlooked in the recent paper by Paul D. Ellner, Timothy E. Kiehn, Robert Cammarata, and Marion Hosmer (J. Clin. Microbiol. 26:1349-1352, 1988). The authors said nothing about the limitations of the Gen-Probe TB complex techniques. They said, "Biochemical tests for identification can add 2 to 4 weeks to the completion time of the final report. The probe procedure can be performed in approximately 2 h, and the specificity of the probes permits the elimination of biochemical testing on those isolates giving positive probe reactions."

The Gen-Probe technique is an excellent development, but the above-quoted statement is misleading in regard to the advantages of the Gen-Probe technology. In fact, the Gen-Probe method must not eliminate the biochemical testing of those isolates identified as *M. tuberculosis* complex, especially of those isolates from extrapulmonary specimens.

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### Author's Reply

Dr. Heifets is correct in stating that the *Mycobacterium tuberculosis* complex probe identifies the *M. tuberculosis* complex and that further biochemical testing is necessary to specifically identify *M. tuberculosis*.

The probability that an isolate is *M. bovis* is quite low in the United States, and this organism is readily identified in probe-positive isolates by negative niacin and nitrate tests. In actuality, both of our laboratories provide a preliminary report of "*M. tuberculosis* complex" on probe-positive specimens, permitting physicians to initiate appropriate therapy. A final report of "*M. tuberculosis* confirmed," accompanied by susceptibilities to antituberculous drugs, is made when the results of niacin and nitrate tests become available.

The other members of the *M. tuberculosis* complex would be extremely rare: *M. africanum*, found in tropical Africa, is probably not a distinct species (3); and *M. microti*, occurring in voles and other animals, may be regarded as a biovar of *M. tuberculosis* (1, 2).

Some laboratories may well elect to limit the identification of respiratory isolates to the probe procedure, based upon the probability that in their patient populations all such isolates are *M. tuberculosis*. In these situations, reports should indicate presumptive *M. tuberculosis* or *M. tuberculosis* complex.

### LITERATURE CITED

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