



Pennsylvania Department of Health Bureau of Laboratories Updates

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Quality Reminder!

There have been reports recently of incorrect blood glucose values that resulted when users of glucose meters used a reagent strip that was not meant for their meter. The Food and Drug Administration has issued a **Reminder that users of blood glucose meters must use only the test strip recommended for use with their meter.**

The FDA recommends: "Users of blood glucose meters should carefully read the Owner's Manual and only use the test strips that are specified for that meter. As an additional check, the test strip inserts identify the blood glucose meters with which they should be used. Healthcare providers and pharmacists should advise their patients to use only test strips that are compatible with their meter."

The full text of the Reminder is here:

<http://www.fda.gov/cdrh/oivd/test-strips.html>.

Genotyping

Pennsylvania's TB Control Program has been approved to participate in the CDC Tuberculosis Genotyping Program. Currently, the Michigan Department of Public Health Lab has been contracted by the CDC to perform genetic analysis on *M. tuberculosis* complex isolates. The BOL began submitting specimens for Genotyping in 2004. Genotyping results are available for epidemiologic investigations and surveillance activities for state and local TB control programs. There are many advantages to genotyping in identifying, tracking, and controlling tuberculosis:

- TB genotyping results, when combined with epidemiologic data, help to distinguish TB patients who are involved in the same chain of recent transmission.
- Help in early detection of sources of outbreaks by confirming linkages between cases when people share a genotype cluster. This allows for earlier treatment.
- Tracking unexpected or unusual transmissions when people who would not normally be connected are both part of a genotypic cluster.
- Identification of false positives due to cross-contamination in labs between patient specimens and control strains.
- It also helps to identify TB patients whose disease is the result of reactivation of a TB infection that was acquired in the past, as compared to re-infection, based on genotypic similarity of isolates.
- Spoligotyping (a genotyping method) is more rapid and less expensive than either REA or RFLP.
- Monitoring mycobacterium transmission, especially when a highly infectious strain is present.

- Possible correlation of genotypes with multi-drug resistance and tracking the prevalence and types of antibiotic resistance.
- Public health planning, evaluation, education.

If a person with active tuberculosis disease is culture-positive, the BOL submits an isolate to the Michigan Public Health laboratory (one isolate from each culture-positive patient with TB). Only the PA Department of Health Laboratory has the authorization to submit cultures to the genotyping reference laboratory.

The Michigan Public Health laboratory uses three genotyping methods to identify strains:

- Spoligotyping
- Mycobacterial interspersed repetitive unit (MIRU) analysis
- IS6110-based restriction fragment length polymorphism (RFLP) analysis can be requested under certain circumstances, and upon the request of the TB Program, on isolates that have matching genotypes by both spoligotyping and MIRU analysis.

Genotyping results will be reported to the TB Control Program and the PA Department of Health Laboratory. The results will be available in PA-NEDSS, PA Lab database and hard copies are being sent to submitters.

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